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Health Policy Series

Everything you always wanted to know about European Union health policies but were afraid to ask

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FOURTH, REVISED EDITION

European Observatory on Health Systems and Policies
a partnership hosted by WHO

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Fourth, revised edition

The European Observatory on Health Systems and Policies is a partnership, hosted by WHO Regional Office for Europe, which includes other international organizations (the European Commission); national and regional governments (Austria, Belgium, Finland, Ireland, Netherlands, Norway, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the Veneto Region of Italy (with Agenas)); other health system organizations (the French National Union of Health Insurance Funds (UNCAM), the Health Foundation); and academia (the London School of Economics and Political Science (LSE) and the London School of Hygiene & Tropical Medicine (LSHTM)). The Observatory has a secretariat in Brussels and it has hubs in London (at LSE and LSHTM) and at the Berlin University of Technology.

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List of acronyms and abbreviations

ACTA	Anti-Counterfeiting Trade Agreement
AI	Artificial Intelligence
AMR	Antimicrobial Resistance
ASGS	Annual Sustainable Growth Survey
ATMP	Advanced-Therapy Medicinal Products
AU	African Union
BARDA	Biomedical Advanced Research and Development Authority
BEPG	Broad Economic Policy Guidelines
BSE	Bovine Spongiform Encephalopathy
CAP	Corrective Action Plan
CE mark	Conformité Européenne Mark
CF	Cohesion Fund
CFREU	Charter of Fundamental Rights of the European Union
CHAFEA	Consumers, Food and Health Executive Agency
CJEU	Court of Justice of the European Union
CRII	Coronavirus Response Investment Initiative
CRII+	Coronavirus Response Investment Initiative Plus
CSR	Country Specific Recommendations
CTR	Clinical Trials Regulation
DBP	Draft Budgetary Plans
DG	Directorate-General
DG AGRI	Directorate-General for Agriculture and Rural Development
DG CLIMA	Directorate-General for Climate Action
DG CNECT	Directorate-General for Communications Networks, Content and Technology
DG ECFIN	Directorate-General for Economic and Financial Affairs

DG ECHO	Directorate-General for European Civil Protection and Humanitarian Aid Operations
DG EMPL	Directorate-General for Employment, Social Affairs and Inclusion
DG ENV	Directorate-General for Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG INTPA	Directorate-General for International Partnerships
DG NEAR	Directorate-General for Neighbourhood and Enlargement Negotiations
DG REGIO	Directorate-General for Regional and Urban Policy
DG REFORM	Directorate-General for Structural Reform Support
DG RTD	Directorate-General for Research and Innovation
DG SANCO	Directorate-General for Health and Consumer Protection
DG SANTE	Directorate-General for Health and Food Safety
DG TAXUD	Directorate-General for Taxation and Customers Union
DG TRADE	Directorate-General for Trade
ECB	European Central Bank
ECDC	European Centre for Disease Prevention and Control
ECHR	European Convention on Human Rights
ECI	European Citizens' Initiative
ECJ	European Court of Justice
ECOFIN	Economic and Financial Affairs Council
ECtHR	European Court of Human Rights
EDP	Excessive Deficit Procedure
EEA	European Economic Area
EEAS	European External Action Service
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHDS	European Health Data Space
EHF	European Health Forum
EHIC	European Health Insurance Card
EIB	European Investment Bank
EIP	Excessive Imbalance Procedure
EMA	European Medicines Agency
EMC	European Medical Corps
EMCO	Employment Committee
EPP	European People's Party

EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EPSR	European Pillar of Social Rights
ERDF	European Regional Development Fund
ERN	European Reference Network
ESF	European Social Fund
ESIF	European Structural and Investment Funds
EU	European Union
EU-27	All 27 Member States of the European Union
EU-OSHA	European Agency for Safety and Health at Work
EUHPP	EU Health Policy Platform
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
HaDEA	Health and Digital Executive Agency
HERA	Health Emergency Preparedness and Response Authority
HSPA	Health Systems Performance Assessment
HTA	Health Technology Assessment
HTAR	Health Technology Assessment Regulation
ICT	Information and Communication Technology
IDR	In-Depth Reviews
JPA	Joint Procurement Agreement
MDR	Medical Device Regulation
MEP	Member of European Parliament
MFF	Multiannual Financial Framework
MIP	Macroeconomic Imbalance Procedure
Mpox	Monkeypox (former name)
MSSG	Medicine Shortages Steering Group
MTO	Medium-Term Objective
NB	Notified Body
NGEU	Next Generation EU
NGO	Non-Governmental Organization
NRP	National Reform Programme

NRRP	National Recovery and Resilience Programmes
ODA	Overseas Development Assistance
OECD	Organisation for Economic Co-operation and Development
OMC	Open Method of Coordination
OPC	Open Public Consultation
PPE	Personal Protective Equipment
PPP	Public and Private Partnership
QMV	Qualified Majority Voting
REACT-EU	Recovery Assistance for Cohesion and the Territories of Europe
RRF	Recovery and Resilience Facility
RRP	Recovery and Resilience Plans
S&D	Socialists and Democrats
SARS	Severe Acute Respiratory Syndrome
SCP	Stability Programmes and Convergence Programmes
SDG	Sustainable Development Goal
SEPEN	Support for the Health Workforce Planning and Forecasting Expert Network
SGEI, SGI	Services of General (Economic) Interest
SGP	Stability and Growth Pact
SME	Small and Medium-Sized Enterprise
SoHO	Substances of Human Origin
SPC	Social Protection Committee
SPC	Supplementary Protection Certificate
SPOC	Single Point of Contact
SRSS	Structural Reform Support Service
SURE	Support to Mitigate Unemployment Risks in an Emergency
TEU	Treaty on the European Union (Maastricht Treaty)
TFEU	Treaty on the Functioning of the European Union
TPD	Tobacco Products Directive
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TSCG	Treaty on Stability, Coordination and Governance
VHT	Virtual Human Twins
WHO	World Health Organization

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Chapter 1

European Union health policy: context, history, politics, and mechanisms

1.1 What is European Union health policy?

There is no European Union (EU) health system but there is an EU health policy. The EU affects the health of its citizens, the health of people around the world, and the operation and finance of its Member States' healthcare systems in myriad ways. Many of them are poorly understood. The history of EU health politics and law has in large part been a process in which health policy-makers and various kinds of advocates came to understand the impact of EU policies on health systems and health outcomes, and engage in those policy debates.

This chapter first presents the context of EU health policy, which exists in an extremely diverse union of 27 countries with very different health and economic trajectories. The differences between countries and their health systems, and the amount of money it would take to establish common social rights, shape what the EU can do in health and other areas. The next section presents the history of EU health policy, showing how Member States and EU policy-makers managed the tensions between increasingly important shared interests in health and their continuing diversity. The solution, in health as in many other areas, was powerful EU law and a large regulatory framework, but little financial resources. The following section discusses the dynamics and politics of European integration. The asymmetry between market-making regulation and social policy marks EU policy in health as in other areas. The EU cannot guarantee a common standard of healthcare, but it can regulate health systems in various ways and enact regulations in areas as diverse as clinical trials standards and pesticide regulation that affect health outcomes. The EU's most powerful tools might be law and regulation, but in health as in many other areas there are other policy mechanisms at work, and since COVID-19 they are more important in health. The chapter concludes by presenting these mechanisms and outlining the organization of the book.

1.2 Context

European Union health policy operates in the context of great inequalities among its Member States. Figure 1.1 shows the considerable differences in GDP per capita between the Member States.

In comparison with federal countries within or outside of the European Union, this is a very large gap. Central and Eastern Europe, the poorest region, has a GDP per capita that is consistently lower than Western Europe. This is partly because of the sheer size and recent development of the EU. It is also the source of a core EU problem. Federal countries reduce inequalities between their units with big transfers to individuals, such as pensions and healthcare, and in most cases direct fiscal equalization between units of government. The EU largely does not, although it has taken some steps in that direction since the COVID-19 pandemic (see Chapter 6). The vast economic and political differences between Member States hinder any effort to redistribute funds between them and contribute to the EU's strong focus on regulatory rather than fiscal or social policy tools.

These inequalities filter through into health policy. For example, a European basket of health services, agreed and provided by all Member States, would be difficult to establish because some Member States can simply afford to pay for more elaborate health services. For example, the *Elchinov* case, discussed in 2.1.4 below, was in part about whether the Bulgarian health system had an obligation under EU law to fund a better and more expensive treatment available in Germany.

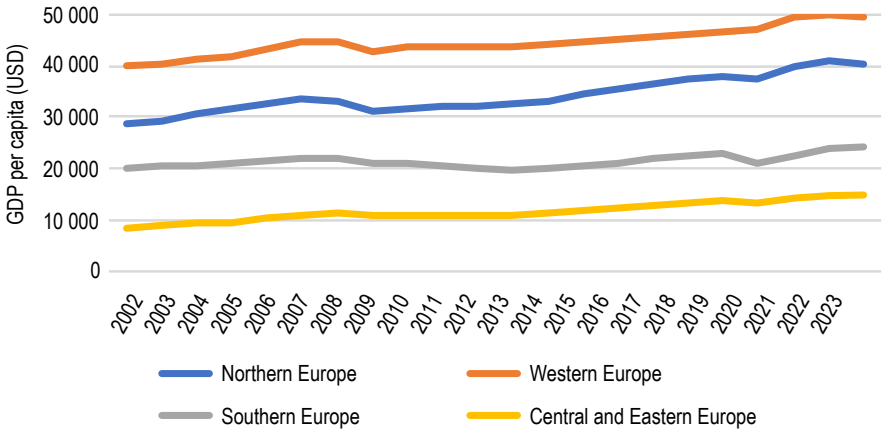
Figure 1.1 also shows that, contrary to the hopes of many, membership in the European Union does not necessarily produce economic convergence. It is difficult to look at the lines representing GDP per capita and envisage the Member States converging. In particular, it is noteworthy that the 2008 financial crisis and its aftermath set Southern Europe back at least seven years in absolute terms, and far more as regards the gap between their present situation and their pre-2008 growth trajectories.

This lack of convergence in economic models or results is an obstacle to policies based on European solidarity.[1] Not only are the problems and opportunities of European Union Member States quite different; the scale of redistribution between countries that would be required to start harmonizing social rights would be immense. The development of shared fiscal measures (see Chapter 6) is impressive but still far less than it would take.

Inequalities between Member States extend to health, although not in quite the same patterns. Figure 1.2 shows life expectancies and Figure 1.3 shows gaps in

1 Moschella, Manuela, Lucia Quaglia, and Aneta Spendzharova (2023). *European Political Economy: Theoretical Approaches and Policy Issues*. Oxford University Press.

Fig. 1.1 *Average GDP per capita by region in Europe (2000–2023)*



Northern Europe: Denmark, Estonia, Finland, Latvia, Lithuania, Sweden.
Western Europe: Austria, Belgium, France, Germany, Ireland, Netherlands, Luxembourg.
Southern Europe: Croatia, Cyprus, Greece, Italy, Malta, Portugal, Spain.
Central and Eastern Europe: Bulgaria, Czechia, Hungary, Poland, Romania, Slovakia, Slovenia.

Source: Eurostat 2023a.

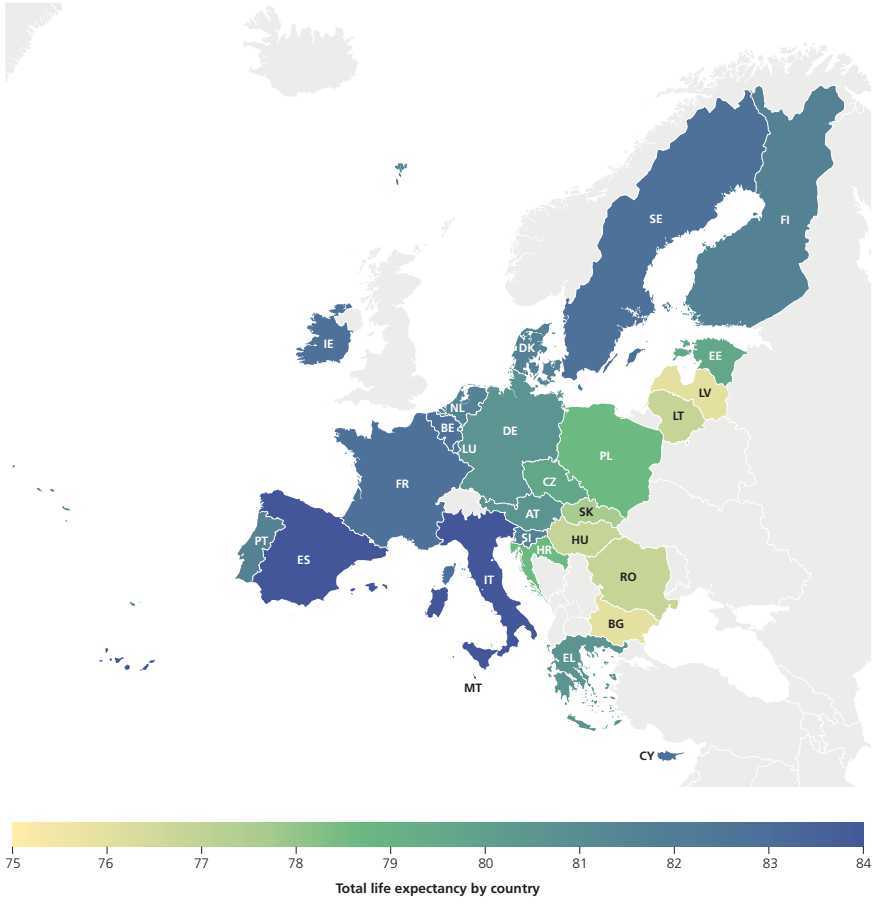
healthy life expectancies. The gaps are large and longstanding. Unlike in the GDP statistics, there is slightly more evidence of convergence until 2019. The impact of the COVID-19 pandemic on mortality and life expectancy was dramatic but highly variable. Central and Eastern Europe (CEE) faced bigger drops in life expectancy due to the pandemic, reflecting in part their different health, social and ageing policies as well as a higher level of vaccine hesitancy and resistance, discussed further in Chapter 7.

Finally, life expectancy is but one indicator of population health. Figure 1.3 shows healthy life years and life expectancy in a scatterplot. In a perfect world, the two numbers would be very close, which would mean that people were healthy until their deaths, with a minimal time of illness and impairment. A larger gap means that people will spend more of their lives in a state of ill health. The plot shows that while people in some countries do enjoy healthy lives until close to their deaths, citizens of some other countries might face a long period of illness. As with life expectancy, wealth alone does not explain all of this variation. Broader social, economic and policy determinants of health are at play.

1.3 History

The EU has affected health for as long as it or its ancestors, such as the European Coal and Steel Community, have existed. Creating and regulating markets for

Fig. 1.2 *Total life expectancy in EU countries*

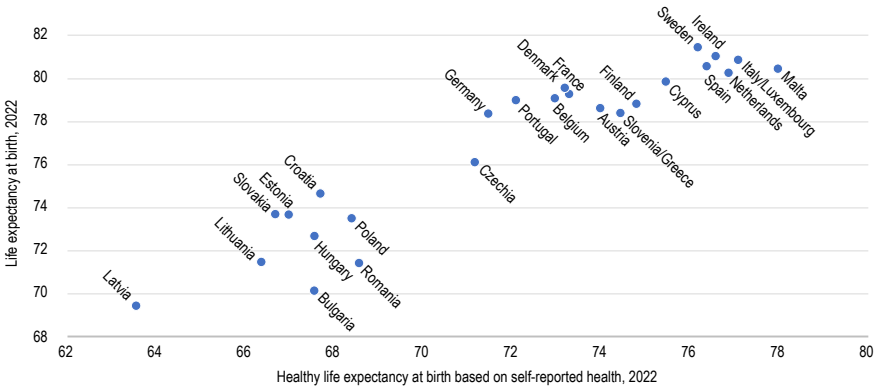


Source: Eurostat (2023b).

goods, services and labour necessarily involves decisions with implications for the health of workers, consumers and people in the broader environment. As might be expected, health has been part of social security coordination since the EU was established (see Chapter 5). That reflected the postwar assumption that health meant healthcare and that healthcare was simply part of social insurance.[2] In most EU Member States until the 1980s, regardless of their system, healthcare finance and policy were under the ministry of labour or social security rather than a separate health ministry. Correspondingly, at the EU level the main health issues for many years were the coordination of social security benefits that might include health, occupational safety legislation applied to healthcare workers, and pharmaceutical legislation. Otherwise, "public health"

2 Mätzke, Margitta (2010). The organization of health policy functions in the German Federal Government. *Social Policy & Administration* 44, no. 2: 120–141. Greer, Scott L (2010). Editorial Introduction: Health Departments in Health Policy. *Social Policy & Administration* 44, no. 2: 113–119.

Fig. 1.3 *Life expectancy vs healthy life expectancy in European countries*



Source: Healthy life years source: Eurostat, Healthy Life Years by Sex, DOI: 10.2908/hlth_hlye; Life expectancy source: Eurostat, Life Expectancy at Birth by Sex, DOI: 10.2908/tps00208. Available at: https://ec.europa.eu/eurostat/en/

meant the same thing that it meant in international trade law: a possible reason for a Member State to make a policy that impeded the free movement of goods, people and services, and one that the European Court of Justice (ECJ) regarded with some suspicion. Understanding the history of how this changed allows us to understand both the peculiarities of contemporary EU health policy and the prospects for change.[3]

1.3.1 From Europe Against Cancer to COVID-19

EU health policy as such, with health as its declared objective, began in the 1980s for fairly clear political reasons. Individual heads of government, notably French President François Mitterrand, took an interest in particular health issues such as cancer. If nothing else, heads of government who saw political opportunities in health topics would naturally see them as a suitable way to justify spending several days at a summit. In the context of European Council meetings, Mitterrand and like-minded leaders put through commitments such as the Europe Against Cancer programme or action against HIV in the aftermath of tainted blood scandals.[4] But given the rising profile of healthcare in many national polities and the rising profile of the EU in those years, the idea that

3 Greer SL & Jarman H (2021). What Is EU Public Health and Why? Explaining the Scope and Organization of Public Health in the European Union. *Journal of Health Politics, Policy and Law*, 46(1):23–47. Hervey T K (2017). Telling stories about European Union Health Law: The emergence of a new field of law. *Comparative European Politics*, 15(3), 352–369.

4 Steffen M (1999). The nation's blood: Medicine, justice, and the State in France, in Feldman EA & Bayer R (eds). *Blood feuds: AIDS, blood, and the politics of medical disaster*. New York: Oxford University Press, pp. 95–126. Steffen M (2012). The Europeanization of public health: how does it work? The seminal role of the AIDS case. *Journal of Health Politics, Policy and Law*, 37(6):1057–89.

effective European public health action was possible became normalized.[5] That rising profile, meanwhile, was part of how the European institutions began to establish more policies affecting health. The 1986 Single European Act created the 1992 programme of market integration. It involved a long list of harmonizing measures that meant Member States would mutually recognize one another's regulations once they had hit an EU-wide regulatory minimum. In these measures were some of the first European policies affecting healthcare, including the start of European regulation of pharmaceuticals and medical devices.[6]

The 1992 Maastricht Treaty was a major step in institutionalizing public health as a distinctive European power and activity. For the first time it created a legal basis for public health and explicitly enabled the EU to take (limited) actions to support Member State action and cooperation on health. The concrete issues discussed in this new article in the Treaty (then numbered 129)[7] were limited and reflected the politics of the day, with action against harmful drugs underlined as a scourge to be addressed. The language made it clear that there would be no major initiatives or institutional protagonism for the institutions of the EU. From that time on we see amendments to the text and the place of the health legal basis in the EC Treaty and subsequent Treaties (see Annex for the evolution of the Treaty public health article since 1992).

Against the background of optimism in 1992 – with the end of the Cold War, German reunification, the completion of the Single Europe Act's project, agreement on the creation of a monetary union, and talk of an ambitious Social Europe to match the single market – the inclusion of this weak authorization for European health action should not be too surprising. It was an opportunity to do something creditworthy, it might reap benefits from coordination, and it had no legal language that suggested it would create a European health policy that might infringe on Member States. Its restrictive language and list of topics also put a clear limit on European integration that had been developing apace in the form of individual disease programmes such as Europe Against Cancer, so it is not necessarily the step forward for health policy that it is often made out to be.

In the later 1990s more governments of the left came to power and sought to complement the preparations for monetary union with a more social dimension, creating a series of discussion forums known as the Open Method of Coordination

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5 De Ruijter A (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. Oxford University Press.

6 Hauray B (2006). *L'Europe Du Médicament: Politique – Expertise — Intérêts Privés* [The Europe of Medicines: Policy – Expertise – Private Interests]. Paris: Presses de Sciences Po. Hauray B (2013). The European Regulation of Medicines, in Greer SL & Kurzer P (eds). *European Union Public Health Policy: Regional and Global Trends*. Abingdon: Routledge. Permanand G (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester University Press.

7 Treaty articles are identified by their article number and the Treaty in which they are found, such as "Article 129 EC Treaty" or "Article 129 TFEU".

(OMC), with the aim of pushing social policy goals such as quality services and equity onto a European policy agenda dominated by efforts to hit the fiscal goals for monetary union laid out in the Maastricht Treaty. The OMC came to include health, and while its impact on Member States' policies was indirect at best, it did start to shape shared European understandings of social policy, including health, and helped to create shared European social policy debates and concepts.[8] It also heralded a second pattern, in which more social policy advocates and governments of the left try to use soft law and other policy mechanisms to redress the basic asymmetry in European politics that puts more legal and political power on the side of market-making and regulation than on management of markets' effects (discussed below in 1.4).

This background activity was overshadowed by what might be thought of as the EU's foundational health crisis, the BSE episode. Bovine spongiform encephalopathy (BSE), nicknamed "mad cow disease" by the media, was caused by prions that, if ingested by humans, could give them the alarming and fatal neurodegenerative variant Creutzfeldt-Jakob disease (vCJD). Apart from the shocking images of dying cows and the terrifying implications for human victims, BSE had such an impact because it revealed ways in which an established area of EU internal market activity, agriculture, was failing to regulate a rapidly changing food system. BSE was related to the sheep disease scrapie. It was being spread by agricultural techniques that rendered remains of dead animals into animal feed, thereby turning herbivorous food animals into not just carnivores but occasional cannibals. Tracing infection proved extremely difficult due to limited and antiquated procedures for tracking animals or products. Member State relations deteriorated, with France putting an embargo on British meat in March 1996, other countries restricting blood donations by people who had eaten meat in the United Kingdom, and the British press and government responding robustly to the insults being aimed at the national icon of British beef.[9] It seemed like a textbook example of an area in which European integration had outpaced the capacity, or political willingness, of the Member States to undertake coordinating activities at an intergovernmental level. Some sort of EU action would be necessary if the existing level of integration was to be preserved safely.

BSE struck in the midst of the preparations for what became known as the Treaty of Amsterdam, in which the health article was substantially expanded. This article (later renamed Article 152 EC Treaty through the amendments to

8 Greer S & Vanhercke B (2010). Governing health care through EU soft law, in *Health System Governance in Europe: The Role of EU Law and Policy*. Cambridge: Cambridge University Press, 186–230. de la Porte C & Pochet P (2012). Why and how (still) study the Open Method of Coordination (OMC)? *Journal of European Social Policy*, 22(3):336–49. Heidenreich M & Zeitlin J (eds) (2009). *Changing European employment and welfare regimes: the influence of the open method of coordination on national reforms*. Routledge.

9 Ansell C & Vogel D (eds) (2006). *What's the Beef? The Contested Governance of European Food Safety*. Cambridge, MA: MIT Press. Rogers B (2004). *Beef and Liberty*. Vintage.

the 1997 Treaty of Amsterdam, effective in 1999) became longer, wordier, and more ambitious (see Annex), but it added only one concrete new EU power: a responsibility to regulate substances of human origin such as blood and blood products. Nonetheless, almost every key word remained noncoercive in EU law, from verbs such as "complement", "encourage" and "coordinate", to modifying clauses clarifying that the Member States' decision to coordinate is crucial and EU institutions may support them, and finally to the last sentences, which make it clear that the public health article "shall fully respect" Member States' "organization and delivery of health services and medical care". At the same time as the development of the legislative basis for health in the Treaty, European integration was proceeding apace in the area of food safety, on agricultural and other Treaty bases (see Chapter 3). Scandals involving dioxane-contaminated chicken in Belgium and the ongoing BSE problem kept the issue on the agenda, and the General Food Law was passed in 2002, harmonizing much practice and creating the European Food Safety Authority.

If the new public health power in the Treaty authorized more public health legislative ambitions, there was still no dedicated Directorate-General (DG) for public health (DG V, which evolved into DG EMPL, had most of the existing health policy responsibilities). The Prodi Commission took that next step and created the Directorate-General for Health and Consumer Protection, known as DG SANCO, under the Irish Commissioner David Byrne (1999–2004). There were three main reasons for this new DG. The first was that the Prodi Commission took office in the wake of the resignation of the Santer Commission due to a corruption scandal, and the new College of Commissioners had an interest in showing a valuable face of the EU. The second was that there had to be one commissioner per Member State, so there was good reason to divide portfolios and a search for divisions that created meaningful jobs for commissioners. The third, and most important, was that the BSE episode had not reinforced confidence in the old model of uniting regulatory and promotional functions in one organization, in this case the Directorate-General for Agriculture. Moving health regulation away from its previous home in industry-promoting directorates was a way to strengthen public health and reduce bureaucratic and political incentives to downplay public health issues.

Once a policy arena exists in the EU, and once there is authorization to act for health, then the EU political system begins to reward policy entrepreneurs. The Health Strategy and Health Programme and the new DG SANCO anchored the new EU health policy arena, with a set of programmes, priorities, experts and advocates intersecting with the DG, the commissioner and health ministers to define and act in the new EU policy arena.

As the EU's public health apparatus and ambition expanded, additional impetus came in the way the EU's regulatory and legal nature would lead us to expect: via a court case. The 1998 *Kohll* and *Decker* decisions by the European Court of Justice (ECJ, later renamed the Court of Justice of the European Union, CJEU) established the principle that the provision of health goods and services had to comply with internal market law, even when they were being financed through publicly funded healthcare systems, in this case Luxembourg's social insurance system (see Section 4.6.1 for more details). The cases immediately captured the attention of health interest groups, scholars, and Member State representatives. They started a long string of cases on patient mobility that made it clear that EU internal market law applied to healthcare activities in the eyes of the Court of Justice, and that the only way to constrain judicial application of internal market law was to start developing a European approach to healthcare services that would bring health objectives and expertise into the European system. It took some time for health advocates, ministers, and ministries to recognize the paradoxical logic that the way to respond to an uninvited EU move into healthcare – the application of EU internal market law by courts – was to legislate at the EU level.

Patient mobility, a case of the EU legal system acting autonomously to expand the internal market, was a key reason for the birth of an EU policy sphere. It also gave rise to easily the largest literature on EU health policy, detailing the law and politics of this policy area.[10] However inconsequential actual patient mobility in this particular legal framework may be, it was the policy area that made clear the Europeanization of healthcare policy and politics. At the end was the directive on the application of patients' rights in cross-border healthcare, discussed in Section 4.6.1. While formally it was an internal market policy, its passage at least established that healthcare services are not like other services and

10 Including: Brooks E (2025). *European Union Health Policy: What is it, how does it work and why does it matter?* Manchester University Press. Brooks E (2012). Crossing Borders: A Critical Review of the Role of the European Court of Justice in EU Health Policy. *Health Policy*, 105:33–7. Obermaier AJ (2009). *The End of Territoriality? The Impact of ECJ Rulings on British, German and French Social Policy*. Aldershot: Ashgate. McKee M, Mossialos E & Baeten R (eds) (2002). *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang. McKee M, Mossialos E & Baeten R (eds) (2002). *EU Law and the Social Character of Health Care*. Brussels: Peter Lang. Busse R, Wismar M & Berman PC (eds) (2002). *The European Union and Health Services: The Impact of the Single European Market on Member States*. Amsterdam: IOS/ European Health Management Association. Wasserfallen F (2010). The Judiciary as Legislator? How the European Court of Justice Shapes Policy-Making in the European Union. *Journal of European Public Policy*, 17:1128–46. Martinsen DS (2005). Towards an Internal Health Market With the European Court. *West European Politics*, 28:1035–56. Greer SL (2006). Uninvited Europeanization: Neofunctionalism and the EU in Health Policy. *Journal of European Public Policy*, 13:134–52. Lamping W & Steffen M (2009). European Union and Health Policy: The "chaordic" Dynamics of Integration. *Social Science Quarterly*, 90:1361–79. Martinsen DS (2015). *An ever more powerful court?: The political constraints of legal integration in the European Union*. Oxford: Oxford University Press. de Ruijter A (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. Oxford University Press.

health stakeholders were politically strong enough to defend such an assertion of separateness against those who would treat healthcare like any other service.[11]

More consensually, European authorities established the European Medicines Agency (EMA) in London in 1995, although it did not fall under DG SANCO's jurisdiction at the time since its Treaty bases and motivation were to be found in the internal market. The justification for EMA was in large part the completion of the 1992 single internal market project, creating a single market for pharmaceuticals and devices by coordinating Member State regulators and regulatory regimes.

EU public health policy, meanwhile, took its next steps forward with strong tobacco control legislation (see Section 3.2.1) and the institutionalization of its role in communicable disease control. Severe acute respiratory syndrome (SARS) in 2002–2004 had essentially no impact on European health but it shook policy-makers worldwide and created a new interest in communicable disease control. Bioterrorism in the United States in 2001 using weaponized anthrax was also a worrisome precedent, and new pandemic influenzas were looming as an increasingly important threat. Given that for various reasons public health was becoming increasingly visible and important as a political agenda item in its own right around Europe, including in France, Germany and the United Kingdom, the result was support for a strong EU role in communicable disease control. Using Article 152 EC Treaty, the EU institutions created the European Centre for Disease Prevention and Control (ECDC) in 2004, an EU agency tasked with rationalizing, strengthening and coordinating EU and Member State activities for health, with a special initial focus on surveillance, science, and preparing for and assisting Member States with responses to new health threats. The agency was just being set up when the 2009 H1N1 influenza pandemic happened. While the pandemic turned out to be a much less serious health threat than imagined, it saw the development of what amounted to prototypes for EU action against future respiratory pandemics in the form of the ECDC and possible medicines authorization and purchasing.

European Union health policy was not a priority of the 2014–2019 Juncker Commission, which promised to be "big on the big things and small on the small things",[12] and gave a strong impression that health was a "small thing". In the aftermath of the 2016 Brexit vote in the United Kingdom, the Commission

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11 Greer SL (2008). Choosing Paths in European Union Health Policy: A Political Analysis of a Critical Juncture. *Journal of European Social Policy*, 18:219–31. Greer SL (2009). The Changing World of European Health Lobbies, in Coen D & Richardson JJ (eds). *Lobbying in the European Union*. Oxford: Oxford University Press. Greer SL (2013). Avoiding Another Directive: The Unstable Politics of European Union Cross-Border Health Care Law. *Health Economics, Policy and Law*, 8(4):415–21.

12 A statement that Jean-Claude Juncker made a number of times in key speeches, e.g. his 2018 State of the Union speech. Available at: http://europa.eu/rapid/press-release_SPEECH-18-5808_en.htm (accessed 19 February 2022).

produced a strategy paper on possible EU futures with one of the five options being an EU that did nothing on or for health.[13] Despite this hostility to health policy from the top of the Commission, EU health policy did not go away. DG SANCO, having developed into DG SANTE in 2014, spearheaded several important policies for health and over the five years before the COVID-19 pandemic the Commission steadily incorporated health goals into key policy areas including the internal market (see Chapter 4) and fiscal governance (see Chapter 6). Commissioner Andriukaitis, responsible for health and food safety, was able to advance work in these areas, notably on tobacco control, and insert health and food safety priorities in other policy areas despite a lack of support from the top leadership of the Commission and a very limited mission letter.[14]

The 2019–2024 von der Leyen Commission, led by a German Christian Democrat with public health training, entered office alongside new Council leaders and a new and more fragmented European Parliament that had stronger voices on the left and for health. By the end of the Juncker Commission, EU health advocates feared that DG SANTE would cease to exist entirely. They were therefore pleasantly surprised that it was not just retained, but that its new commissioner, psychologist and cancer advocate Stella Kyriakides of Cyprus, was given a broader and more ambitious mandate than Commissioner Andriukaitis had. The implementation of that mandate was just starting when the COVID-19 pandemic began.

1.3.2 From COVID-19 to the European Health Union

COVID-19 was first identified in Europe in January 2020 and quickly became the dominant political issue across the EU. The pandemic and the responses to it have dramatically changed the nature and importance of EU health policy. The changes made in response to the pandemic are discussed throughout the book.[15]

The first reaction of governments at all levels and across the world was often nationalistic and even local – border closures, aggressive efforts to secure personal protective equipment (PPE), and general failures of solidarity. These were also seen in the EU, which took a long time to even activate its RescEU civil protection mechanism (see Section 3.3). The voices in the media which predict a terminal crisis whenever the EU faces a problem predicted a terminal crisis. But instead,

13 European Commission (2017). *White Paper on the Future of Europe: Five Scenarios*.

14 Reproduced in the second edition of this book (2019).

15 Brooks E, de Ruijter A & Greer SL (2021). Another European Rescue of the Nation-State? In Greer SL, King EJ, Massard da Fonseca E & Peralta-Santos A (eds). *Coronavirus Politics: The Comparative Politics and Policy of COVID-19*. University of Michigan Press Open Access. Greer SL, de Ruijter A & Brooks E (2021). The COVID-19 pandemic: Failing forward in public health, in Riddervold M, Trondal, J, Newsome, A (eds). *The Palgrave Handbook of EU Crises*, Palgrave Macmillan, pp. 747–64. Brooks E, Rozenblum S, Greer SL & de Ruijter A (2022). COVID-19 and the European Union, in Cini M & Pérez-Solórzano Borragán N (eds). E*uropean Union Politics*. 7th ed. Oxford University press.

what happened was that the EU and its Member States realized with remarkable speed that their integration was too deep to avoid collaborating in their response.

In terms of public health policy, discussed in more detail in Chapter 3, the Member States agreed in March 2021 on a far larger budget for health: the restoration of the Health Programme as EU4Health, with a budget that grew from around €46 million a year to €5.1 billion; an expansion of the remit and budget of ECDC; a Vaccines Strategy for procurement of COVID-19 vaccines; a Pharmaceutical Strategy to ensure a supply of relevant medicines in the future; and a new pandemic preparedness and response service called HERA (Health Emergency Preparedness and Response Authority). HERA supports pandemic preparedness in the area of medical countermeasures. For civil protection, Member States agreed on the expansion of RescEU, with a budget that leapt from €766.5 million (for 2014–2020) to €772.7 million (for 2021 alone).[16] Legally and organizationally, civil protection is not part of public health, but that should not obscure the role of civil protection, e.g. PPE stockpiling, in EU pandemic responses now and in the future. This is an impressively expanded commitment to EU health policy. The decision to procure vaccines collectively through the Vaccines Strategy was particularly important, for it meant EU governments pooling their resources on the single most important issue they faced.

In terms of the internal market, the initial challenge in spring 2020 was simply to keep it functioning. In this, the EU institutions were aided by the rapid collective discovery that EU Member States were so integrated as to make restrictions on movement of goods self-defeating. Not only did supply chains for crucial medical equipment turn out to almost always cross Member State borders, but so did supply chains for almost everything, making autarchy impossible. The EU helped facilitate the resumption of travel with the Green Lanes scheme for transport in 2020 and then with its vaccine passport. The application of EU law on issues such as state aids and competition also became far less stringent as the Commission deferred to Member States on issues in the middle of the crisis. The maintenance of the internal market was an achievement and a testament to the depth of EU integration.

In terms of fiscal governance, the crisis came when the existing system had already lost its coherence and its focus on austerity. In the face of the pandemic, the Commission lost no time in invoking the "general escape clause" which suspended the application of the fiscal governance process. Facing what appeared to be an economic disaster in 2020, Member States instead agreed to the Recovery and

16 Available at: https://ec.europa.eu/info/strategy/eu-budget/performance-and-reporting/programmes-performance/union-civil-protection-mechanism-resceu-performance_en#predecessor-programmes-2014-2020 and https://ec.europa.eu/info/sites/default/files/about_the_european_commission/eu_budget/programme_and_performance_-_civil_protection.pdf (accessed 16 August 2021).

Resilience Facility (RRF), which directs funds to Member States for general budgetary support (see Section 6.5.1). This is in contrast to existing EU funding models, which support specific projects or goals such as agricultural policy. It was a striking step forward for the EU: issuing common debt to support the broad needs of its Member States. The RRF comes with conditionality which means that Member States must specify the use they will make of it, but it nonetheless set a very important precedent and made the EU start to approximate its structure to the world's other federations, all of which have some level of intergovernmental risk pooling.[17] The European Semester and its legal underpinnings (see Section 6.4) have not gone away; RRF conditionality has been joined by a resumption of eurozone rules. But the commitment to budgetary austerity that EU Member States adopted in the aftermath of the 2008 financial crisis was weakened, and the future politics of fiscal governance in the EU may be quite different.

In much of the world, the striking thing about the COVID-19 pandemic was how little it immediately and directly changed politics. In country after country, despite the immensity of the shock, by 2022 we were already discussing its more indirect effects because political institutions and party politics had changed so little.[18] The EU is an exception. Its leaders quickly and comprehensively changed the scale and scope of its work in health policy, civil protection and fiscal governance, expanding older systems such as RescEU and the ECDC and expanding with new forms such as the Vaccines Strategy.[19] The question now is whether, heading into the next budget cycle starting in 2027, this newly ambitious and protective EU health policy will convince Member States and others of its utility and value.

In November 2020, the European Commission produced a set of proposals that together jumpstarted the building of a European Health Union (EHU) focusing on preparedness and resilience.[20] The European Health Union was a set of proposals to expand the mandate of the EMA and the ECDC, and to adopt a new regulation about the way the EU generally can respond to and coordinate

17 Greer SL (2021). Health, federalism and the European Union: lessons from comparative federalism about the European Union. *Health Economics, Policy and Law*, 16(1):90–103.

18 Predictions of political breakdown and major change due to infectious disease are common and often wrong. States and political systems are very resilient. Pandemics will often speed up existing trends, but otherwise are often better viewed as an opportunity to learn new things about existing political systems rather than as a force for change. De Waal A (2013). *AIDS and Power: Why there is no political crisis yet*. Zed Books. Greer SL, King E, Massard da Fonseca E & Peralta-Santos A (2021). *Coronavirus politics: The comparative politics and policy of COVID-19.* University of Michigan Press.

19 Deruelle T (2022). Covid-19 as a catalyst for a European Health Union: recent developments in health threats management, in Vanhercke B & Spasova S (eds). *Social Policy in the European Union: State of Play 2021*. Brussels: ETUI/OSE, pp. 127–44.

20 European Commission (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats*. COM/2020/724 final. eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724

serious disease outbreaks. These three proposals formed the first step in the building of the European Health Union, which then expanded to include the new Pharmaceuticals Strategy, HERA, action against antimicrobial resistance, and the Europe's Beating Cancer plan among other measures.[21]

The European Health Union has seen several developments since its inception, notably with the introduction of the European Health Data Space initiative (EHDS). The EHDS aims to create a unified framework for data sharing across the EU and foster innovation within the healthcare sector. The European Health Data Space Regulation was adopted by the European Parliament in April 2024 and is expected to be formally adopted by the Council later in the year. The early-stage institutionalisation of the European Health Union also involved the implementation of the Recovery and Resilience Facility (RRF). The RRF was designed as a critical component of the EU's broader response to the COVID-19 pandemic, aiming to boost the economic recovery of Member States. A focus of the RRF has been on facilitating green and digital transitions across countries, with substantial funding allocated to these areas. Initial studies show that the RRF effectively supports Member States in implementing essential health reforms and making strategic investments that would have been difficult to achieve without the financial assistance provided by the facility. These investments are not only helping immediate recovery efforts but are also laying the groundwork for long-term resilience of healthcare systems across the EU.[22]

As with most EU responses, the European Health Union is a much more vigorous use of existing policy tools rather than a novel form of integration. Most of the plans were basically piloted under ad hoc legislation during the pandemic and had already been recognized as weak spots in the existing legislation.

However, in parallel to this focus on crisis response, the European Health Union is also intended to address longer-term challenges such as antimicrobial resistance, the health impacts of climate change, ageing populations and pressures on health systems, and evolving disease patterns. As such, it incorporates elements of the EU4Health programme and related initiatives. In specific areas of concern – namely the development and procurement of medical countermeasures (vaccines) and wider pharmaceutical supply chains – additional initiatives have been launched. The Vaccines Strategy aims to accelerate the development, manufacture and distribution of COVID-19 vaccines, including via joint procurement by the European Commission, while the Pharmaceutical Strategy seeks to address

21 European Commission (2024). COM(2024) *The European Health Union: acting together for people's health*.

22 Fischer, T., Mauer, N., & Tille, F. (2024). A Framework for Studying EU Health Policy through a Political Determinants of Health Lens: The Case of the European Health Union. *Journal of Health Politics, Policy and Law*, 11257056.

structural issues within the pharmaceutical sector, primarily by revising the regulatory framework.

Using established policy mechanisms can disguise the scale of change. A big enough change in quantity, such as budget allocation, can become a change in quality. EU4Health is so much larger than the Health Programme as to be a different programme, just as the Vaccines Strategy is much more than the earlier tentative joint purchasing schemes. EU public health and health security matter much more now. The question is where they go next and whether Member States will continue to agree on their usefulness and importance.

1.4 Politics

European integration has been extensively theorized but at its core is a simple repeated calculation: a group of relatively small, trade-exposed countries realized that they had a range of collective interests in common that could be served through integration. Over time, more states made the same calculation and achieved the requirements for entry, expanding the union from its original six members to its current 27. Integration, meanwhile, begat more integration, because it created spillovers between sectors (as when integrated livestock markets created a need for integrated food safety) and because an increasingly large and sophisticated European political arena created legal and political venues for people to make claims (as in the *Kohll* and *Decker* cases, when some Luxembourg citizens' desire for cross-border healthcare triggered the process that led to an EU patient mobility directive).

It is common to say that crises catalyse European integration. As early European leader Jean Monnet wrote in his *Memoires*, "Europe will be forged in crises and will be the sum of the solutions adopted for those crises".[23] Recent history can seem to confirm Monnet: the 2008 financial crisis, the 2015 refugee movements, the COVID-19 pandemic and the Russian Federation's invasion of Ukraine all led first to media claims that the EU would break up – and then to deeper European integration as Member State governments realized that the costs of disintegration, or even an uncoordinated response, exceeded those of cooperation through EU institutions. Not all crises lead to further European integration, not all integration leads to good policies, and the integration born of crisis can contain the seeds of a future crisis, but a crisis nonetheless is an opportunity

23 Monnet, J. (1978). *Memoirs* (R. Mayne, Trans.). Doubleday and Company, page 417.

for policy entrepreneurs to bring Member States and others in the EU to agree that action must be taken.[24]

A political system in which Member States accept the shared benefits of integration is not one with a determined shape or endpoint, but it is one that will be full of compromises. The overall design of policy will often follow the least common denominator approach, one that solves the problem that faces Member State governments with minimum impact on their sovereignty. Influential scholars have called this dynamic "failing forward": the EU response to a shared crisis can be both integrative and a failure by the standards of what policy analysts might suggest is necessary to address the problem.[25]

Thus, for example, the BSE crisis led to new but very tightly constrained EU health powers, and most of the actual policy impact came through changes in agricultural policy that improved regulation and surveillance of animal and food movements. Likewise, the sequence of SARS (2003), H1N1 influenza (2009) and then COVID-19 led to the slow development of shared surveillance and vaccination procurement capacity that at each step fell short of a complete policy but was still a major advance.[26]

European Union policies also work differently in different Member States. This is partly a point of principle, due to subsidiarity: the EU should not make policy when Member States could do it better. It is partly in the design of EU law: the modality of a directive is designed to give Member States autonomy over implementation by having them transpose the law. It is partly in the design of policy, relying on Member States and networks of Member State agencies (such as medicines regulators) to do most of the actual work,[27] and on litigants, rather

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24 Jones E, Kelemen RD, Meunier S (2021). Failing forward? Crises and patterns of European integration. *Journal of European Public Policy* 28, no. 10: 1519–1536. Riddervold M, Trondal J, Newsome A, eds (2021). *The Palgrave handbook of EU crises*. Houndmills: Palgrave Macmillan. Rhinard M, Nugent N, Paterson WE, eds (2023). *Crises and challenges for the European union*. Bloomsbury Publishing.

25 Jones E, Kelemen RD, Meunier S (2021). Failing forward? Crises and patterns of European integration. *Journal of European Public Policy* 28, no. 10: 1519-1536.

26 de Ruijter A. (2019). *EU health law & policy: the expansion of EU power in public health and health care*. Oxford University Press. Cox RH, Kurzer P (2024). For want of a champion: why the EU won't be ready for the next public health crisis. *Journal of European Public Policy* 31, no. 2: 610–631.

27 Page, E.C. (2003). The European Union and the Bureaucratic Mode of Production, in Anand Menon, and Vincent Wright (eds), *From the Nation State to Europe: Essays in Honour of Jack Hayward* (Oxford 2001; online edn, Oxford Academic, 1 Nov. 2003), https://doi.org/10.1093/0199244030.003.0009,(accessed 17 June 2024). Page, E.C. (2012). The European Commission Bureaucracy: Handling Sovereignty through the Back and Front Doors. In: Hayward, J., Wurzel, R. (eds) *European Disunion*. Palgrave Studies in European Union Politics. Palgrave Macmillan, London. https://doi.org/10.1057/9781137271358_7, 82–98. Bickerton, C. J., Hodson, D., & Puetter, U. (Eds.). (2015). *The new intergovernmentalism: states and supranational actors in the post-Maastricht era*. Oxford University Press. Schimmelfennig, F. (2015). What's the News in New Intergovernmentalism: A Critique of Bickerton, Hodson and Puetter. *Journal of Common Market Studies* 53 (2015): 723.

than the Commission, to bring cases when EU law is violated.[28] Finally, it is also often in legislation itself, with delays to implementation for particular sectors or Member States, or other special treatment for cases in which a government faces serious consequences from the policy.[29] The Working Time Directive's application in health, discussed in chapter 5, is an example. It was deliberately implemented slowly in order to allow systems dependent on long hours to adapt. The result is that EU policy can seem to be a bit of a moving target. The gap between general principles and pragmatic reality can be large, and the politics explaining the gap hard to understand.

Member State governments also frequently blame "Europe" for problems that they created or failed to solve for themselves. This is to be expected, since it is basic politics everywhere to take credit for good things and cast blame on others for bad outcomes. Member State governments take credit for the benefits of EU policies such as healthcare workforce mobility, infrastructure spending and the Vaccines Strategy, but can equally blame the EU for anything that goes wrong with vaccination campaigns or migration. Voters generally disagree, focusing attention and accountability on their Member State governments, although they vary widely between states in their esteem for the EU.

That said, there is a high degree of confidence in the EU, relative to Member State governments and others. Figure 1.4 shows Eurobarometer data on citizens' trust in institutions, asking whether they tend to trust their national government and the EU or not. Eurobarometer surveys also show considerable popular support for EU action on health and policies related to health such as climate change. For example, Eurobarometer 101 in spring 2024 asked where the EU could act over the next five years to improve citizens' lives. In response 34% of the respondents said security and defence, 30% said climate and the environment, and 26% said health. Bearing in mind that Eurobarometer offers its respondents many other options, such as migration control and jobs, third place for health is noteworthy.[30]

The fact that EU policies often operate in the background, as with the cross-border social security regime, makes it more difficult to connect them to their benefits, while the many gaps and inconsistencies that can be expected in anything as complex as a 27-country social security or regulatory regime look like European failures. The result is that it is possible to politicize the EU, often

28 Kelemen, R. Daniel (2011). *Eurolegalism: The transformation of law and regulation in the European Union*. Harvard University Press.

29 Kleine, Mareike (2013). *Informal governance in the European Union: How governments make international organizations work*. Cornell University Press.

30 Standard Eurobarometer 101, April/May 2024. Questions QA 6.8 and 6.10. https://europa.eu/eurobarometer/surveys/detail/3216 and final report https://europa.eu/eurobarometer/api/deliverable/download/file?deliverableId=92175 (accessed 26 August 2024). This finding has been echoed by other surveys, e.g. Gubbala, S. (2023). *People broadly view the EU favorably, both in member states and elsewhere*. Pew Research Center, 24 October 2023.

in quite a negative way, while also reaping the benefits of membership. The United Kingdom's post-2016 search for the advantages of Brexit has shown this harshly. Over and over again it emerges that putative Brexit freedoms could have been achieved without exiting the EU.[31] Seeking credit and casting blame, behaviour that is ubiquitous in politics,[32] often deprives the EU of credit and saddles it with blame that it does not deserve.

1.5 Mechanisms

Different EU Treaty bases, and political compromises built on them, shape policies. They authorize different kinds of action and exercise greater or lesser power at the EU level. The result is what scholars call the EU's "constitutional asymmetry".[33] The EU operates on the basis of what constitutional lawyers call conferred powers: it has the powers that its founding Treaties allocate to it, and no more. If the legislative powers based on the internal market are capacious and allow more extensive regulatory and harmonizing measures, then this legal basis for EU law and policy will be a more likely route to regulate a wider range of issues. If the public health article, by contrast, emphasizes limited EU actions, then not much policy will be made on that basis. This is quite different from many federal states where the federal government will typically enjoy, or have created, a more general mandate to legislate.

The result of this structure is that the EU, compared to Member States, is enormously strong in areas that address regulatory issues, such as health and safety conditions of goods, but strikingly weak in other functions of government involving the redistribution of wealth, guarantee of social rights, or ensuring equal access to public services. It is the paragon of what we call a regulatory state, meaning a political system that acts through regulation instead of other tools such as taxation, spending or direct deployment of its own resources.[34] It regulates the actions of others, achieving public policy ends by shaping the actions

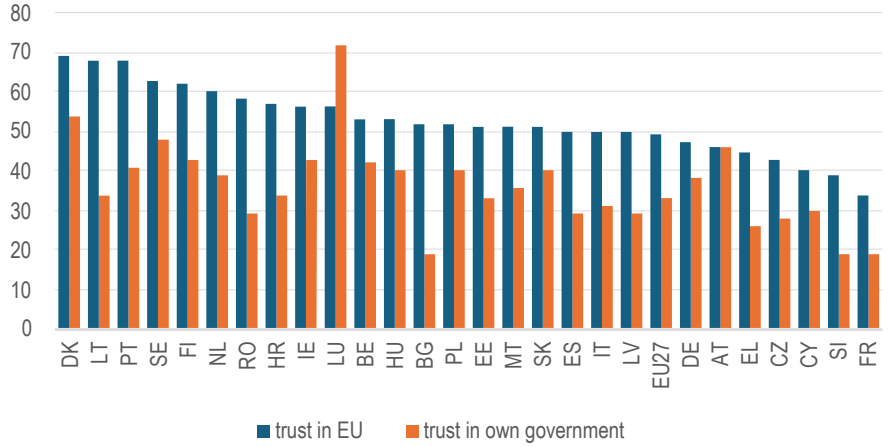
31 Hervey T, Antova I, Flear ML, Wood M (2023). *Not What the Bus Promised: Health Governance After Brexit*. Bloomsbury Publishing.

32 Hinterleitner M (2017). Reconciling perspectives on blame avoidance behaviour. *Political Studies Review* 15, no. 2: 243-254. Greer SL, Rozenblum S, Falkenbach M, Löblová O, Jarman H, Williams N, Wismar M (2022). Centralizing and decentralizing governance in the COVID-19 pandemic: The politics of credit and blame. *Health Policy* 126, no. 5: 408–417.

33 Scharpf FW (2002). The European social model. *JCMS: Journal of Common Market Studies*, 40(4):645–70. Scharpf FW (2010). The asymmetry of European integration, or why the EU cannot be a "social market economy". *Socio-economic Review*, 8(2):211–50. Kelemen RD & McNamara KR (2021). State-building and the European Union: Markets, War, and Europe's Uneven Political Development. *Comparative Political Studies*. October 2021.

34 Majone G (1994). The Rise of the Regulatory State in Europe. *West European Politics*, 17:77–102.

Fig. 1.4 *Citizens' trust in European institutions and their member state governments*



Source: Standard Eurobarometer 101, Spring 2024. https://europa.eu/eurobarometer/surveys/detail/3216 (accessed 18 September 2024).

and rules made by its Member States. The EU's regulatory nature explains how it can be so consequential yet in staff terms so small.[35]

The EU regulates Member States above all, with its legislation focused on regulating their actions, and their court systems primarily responsible for ensuring that they cannot disobey EU law. At times the constitutional asymmetry of the EU's regulatory power to promote market efficiencies, while lacking the ability to also ensure social welfare aims, has actively threatened health objectives, such as in challenges brought under EU law to alcohol minimum pricing (see Section 3.2.3), or in the string of patient mobility cases where the Court of Justice determined that health systems are a service in the single market and only later showed an appreciation of healthcare's redistributive and distinctive complexity, risk pooling, and social and welfare roles. The core of EU power is in law, EU legal supremacy, the direct effect of Union law, and the rule of law itself, which is why authoritarian backsliding and calls for "legal pluralism" that undermine EU law are such existential challenges to the EU.[36] See Box 1.1 for the rather limited formal tools identified as being useful in enforcing the rule of law in a Member State.

35 Page EC (2001). The European Union and the Bureaucratic Mode of Production, in Menon A (ed.). *From the Nation State to Europe: Essays in Honour of Jack Hayward*. Oxford: Oxford University Press.

36 Pavone T & Kelemen RD (2019). The evolving judicial politics of European Integration: The European Court of Justice and national courts revisited. *European Law Journal*, 25(4):352–73. Kelemen RD (2019). Is differentiation possible in rule of law? *Comparative European Politics*, 17(2):246–60. Kelemen RD (2020). The European Union's authoritarian equilibrium. *Journal of European Public Policy*, 27(3):481–99. Kelemen RD & Pech L (2018). *Why autocrats love constitutional identity and constitutional pluralism* (No. 2). RECONNECT Working Paper. Available at: https://reconnect-europe.eu/wp-content/uploads/2018/10/RECONNECT-WorkingPaper2-Kelemen-Pech-LP-KO.pdf (accessed 19 February 2022).

In principle, positive rights (e.g. a right to housing or healthcare) could be instituted in the same way and enforced by courts. Indeed, there are a number of positive normative declarations, notably the European Pillar of Social Rights (EPSR – see Annex for details). The EPSR was jointly proclaimed by the Commission and Council in 2017 at a summit in Gothenburg, Sweden and reaffirmed in a series of Council actions affirming conclusions of a Social Summit organized by the Portuguese Presidency in 2021.[37] The Pillar combines commitments to EU action and Member State actions (e.g. that within its competencies, the EU shall support those principles) with the kinds of targets for Member States that are long familiar in EU social policy. It is still not the kind of powerful and finely honed regulatory device that we see in market-building areas such as competition, trade, internal market or even labour and environmental law.

Likewise, the EU is signed up to the United Nations Sustainable Development Goals (SDG), a set of objectives for 2030 agreed by governments and reproduced in the Annex. The SDGs are even currently targets for the EU's fiscal governance architecture (see Chapter 6). But, again, they are goals for EU and Member State action, not rules that can be enforced by regulators or litigated in court. If a political majority in favour of any given SDG, such as environmental sustainability or equality, is weak, then there is no automatic mechanism maintaining current policy or ensuring future gains.

The EU budget receives considerable, perhaps disproportionate attention. In order to avoid annual rows over funding, the EU prefers to have one big argument every seven years and agree on an overall allocation of funding for that whole seven-year period. This is called the Multiannual Financial Framework (MFF). The MFF for 2021–2027 is for a total of around €2 trillion. Although the detailed EU budget is still negotiated and agreed annually, this takes place within the overall MFF, and thus these total amounts are unlikely to shift substantially over a given period.

European Union spending is focused on agriculture, where the health effects are still not clearly beneficial overall, and on structural and investment funds, its aid to infrastructure, and development in poorer regions. These are large areas of spending, especially given their focus on a few particular countries. They are not, however, the core of EU power. The EU budget's maximum has only recently been allowed to go up to 2% of EU GDP in order to underpin the borrowing that is part of the Next Generation EU (see Figure 1.6). Within that, as can be seen in Figure 1.5, the amounts spent on health are much increased but still small.

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37 European Commission (2022). *European Pillar of Social Rights - Building a fairer and more inclusive European Union*. https://ec.europa.eu/social/main.jsp?catId=1226&langId=en

Box 1.1 *Enforcing the rule of law: Article 7 TEU, EU budget, Rule of Law Framework*

The rule of law is a core principle of the European Union. It holds that all public authority is bound by EU law and needs to be exercised in accordance with the law. In recent years, as some very visible democratic backsliding has occurred in Member States, pressure has grown to uphold the rule of law and to use the EU's powers to do so.

An increasing volume of research has found that the rule of law is good for health outcomes,[a] but it also has clear and direct relevance to health management and policy. European Commission research has found that healthcare is one of the sectors of the whole EU most plagued by corruption,[b] which is what the research on corruption and informal payments in health care would lead us to expect.[c] Expanding the effectiveness of the rule of law could have important benefits for health budgets.[d]

There is a Treaty procedure to enforce the rule of law in Member States. Article 7 TEU allows the EU to suspend any rights of a Member State that violates the rule of law (there is no expulsion mechanism). The procedure starts with the Commission, Parliament or one third of Member States claiming a "clear risk of breach" of rule of law obligations. If endorsed by a two-thirds majority of the Parliament, the issue is referred to the Council, which can identify a breach with a four-fifths majority vote and issue guidance to the Member State. If the Commission or one third of Member States claim that the Member State did not rectify the breach and the Parliament agrees with a two-thirds majority that there is a "serious and persistent breach", the Council can decide to agree, by unanimous vote of all Member States except the one being discussed. If the Council does agree, then it can determine by qualified majority vote what rights of the Member State are suspended. The full Article 7 process has never been used, with efforts to start proceedings ending at the first stage. The unanimity requirement makes Article 7 difficult to use since it only requires that one Member State object to the identification of serious and persistent breaches. (However, as with any other part of the Treaty, the unanimity requirement could be turned into qualified majority voting if Member States were to use the *passerelle* clause.)

In the absence of unanimity among Member States or even supermajorities in the Council and Parliament, one of the most legally solid and politically promising ways to promote the rule of law is by viewing it as a threat to the budget. The logic is that good budgetary governance cannot happen without the rule of law. This is the basis of a 2020 regulation on the protection of the EU budget, known as the Rule of Law Conditionality Regulation.[e] This can cause suspension of some or all EU payments to a Member State in the event that it is found to have "generalised deficiencies". As eventually passed by the Council, the regulation is focused on fraud against the EU budget although it is informed by the Rule of Law Framework (see below),the EU's fraud investigation service OLAF,[f] the Court of Auditors (see Chapter 2) and public complaints. Hungary and Poland challenged the regulation before the Court of Justice, which upheld it in 2022.[g] There has been one

>> continues

case to date under the regulation, a procedure raised by the Commission against Hungary in 2022.[h]

In addition, the Commission has developed a set of frameworks for promoting the rule of law through characteristic EU "soft law" tools such as we will see in other areas including social rights. It adopted a Rule of Law Framework[i] that it updated in 2019,[j] much of which was focused on identifying legal bases for support of the rule of law in Treaty bases. The Rule of Law Mechanism provides annual reports on the state of the rule of law in the EU in order to identify potential breaches and be able to remedy them before or without formal proceedings. These reports are based on work between November and January, which includes visits to Member States and opportunities for public comment, and are published in the summer.[k] They can lead to Commission Recommendations. Resolutions of the Parliament can also highlight rule of law breaches in Member States. None of these have immediate legal effect on Member State actions, but they are highly visible and could inform more stringent mechanisms such as budgetary procedures or action under Article 7 TEU.

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a Montez, J. K., Cheng, K. J., & Grumbach, J. M. (2023). Electoral Democracy and Working-Age Mortality. *The Milbank Quarterly*, 101(3), 700–730. Willison, C. E., Falkenbach, M., Greer, S. L., & Singer, P. M. (2023). Backsliding among indicators of democratic stability relevant to public health: Risks in OECD nations. *World Medical & Health Policy*, 15(4), 455–475. Batinti, A., & Costa-Font, J. (2023). Do democratic regimes exhibit 'better' health outcomes?. In *Handbook on the Political Economy of Health Systems* (pp. 27–41). Edward Elgar Publishing.

b European Commission (2017). *Updated Study on Corruption in the Healthcare Sector – Final Report*.

c Hutchinson E, Balabanova D, McKee M. (2019). We Need to Talk About Corruption in Health Systems. *International Journal of Health Policy and Management*, Apr 1;8(4):191–194. Gaal, P., Belli, P. C., McKee, M., & Szocska, M. (2006). Informal payments for health care: definitions, distinctions, and dilemmas. *Journal of Health Politics, Policy and Law*, 31(2), 251–293.

d Radin D (2016). Why health care corruption needs a new approach. *Journal of Health Services Research and Policy*, 21(3):212–14.

e European Parliament and Council (2020). Regulation (EU, Euratom) 2020/2092 of the European Parliament and of the Council of 16 December 2020 on a general regime of conditionality for the protection of the Union budget. *Official Journal of the European Union*. OJ L 433I, 22.12.2020.

f French acronym for Office for the Fight against Fraud.

g Court of Justice of the European Union (2022). *Judgment of the Court (Full Court) of 16 February 2022, Hungary v European Parliament and Council of the European Union, C-156/21; Judgment of the Court (Full Court) of 16 February 2022, Republic of Poland v European Parliament and Council of the European Union, C-157/21*.

h Discussed in the Commission's review of the implementation of the Directive: Brussels, COM(2024) 17 final: *Communication on the application of Regulation (EU, Euratom) 2020/2092 of the European Parliament and of the Council of 16 December 2020 on a general regime of conditionality for the protection of the Union budget*.

i European Commission. *Communication from the Commission to the European Parliament and the Council. "A new EU Framework to strengthen the Rule of Law"*. COM/2014/0158 final.

j European Commission (2019). *Communication from the Commission to the European Parliament, the European Council and the Council "Further strengthening the Rule of Law within the Union. State of play and possible next steps"*. COM(2019)163 final. Brussels, 3.4.2019.

k European Commission (2024). *Communication: 2024 Rule of Law Report: The rule of law situation in the European Union*. COM(2024)800 final. 7 July, 2024.

The real power in the EU lies in the development of regulatory policies that harmonize standards (e.g. with food safety) as a way to create an internal market and in a way that both Member State bureaucracies and Member State courts will implement and enforce.[38] Visible policies with supporters who will pressure Member States to comply with EU regulations become entrenched and powerful, and can shape the economy and society for health. The EU's COVID-19 response noticeably changed the spending priorities of the EU, with large commitments to a renewed health programme (EU4Health), civil protection via the RescEU programme, and support for old and new agencies and services such as HERA (see Chapter 3).

The resulting EU policy system has a set of characteristic policy mechanisms, which we present in detail in Section 2.2. They are, first, regulation, the most important and powerful mechanism but one which has rarely been deployed as an explicit health policy due to constraints in Article 168 of the Treaty on the Functioning of the European Union (TFEU), even if it is powerful in other areas. Second, there are resources: the EU's budget but also its ability to guarantee loans or otherwise mobilize funding through mechanisms such as the European Investment Bank. Third, there is information, which takes advantage of the ability of the EU to produce cross-nationally comparable data and advice, and to sustain professional networks that can produce and validate it, in cases such as health technology assessment. Finally, there is governance, meaning the ability of the EU to alter the way decisions are made and implemented in a sector, such as we see in the process of forging Member State agencies (e.g. pharmaceutical regulators) into tight networks.

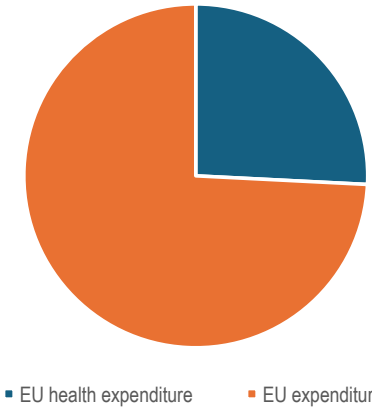
1.6 Organization of the book

Chapter 2 presents the EU health policy-making process in the context of broader EU politics and institutions.

Chapter 3 then explores European Union public health policy, one of the oldest areas of explicit EU health policy and one that became much more visible and important during and after the COVID-19 pandemic. It addresses the EU's communicable disease and public health protection measures as well as the EU's work on acknowledged determinants of health such as diet, nutrition, workforce safety and pollution.

38 Greer SL & de Almagro Iniesta MM (2013). How Bureaucracies Listen to Courts: Bureaucratized Calculations and European Law. *Law and Social Inquiry*, 39:361–8.

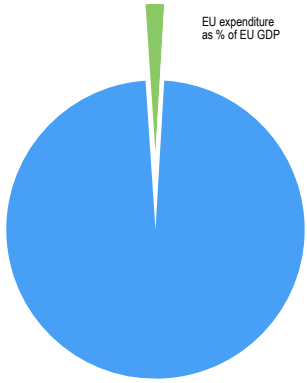
Fig. 1.5 *EU health expenditure as share of total EU expenditure, 2024*



Source: European Commission (n.d.). *European Health Union: EU4Health Work Programme 2024*. https://health.ec.europa.eu/document/download/74b61d90-329e-4973-bb46-7006b4f300fc_en?filename=funding_eu4Health_wp2024-factsheet_en_0.pdf (accessed 26 August 2024).

Notes: Programmes included are: Europe's Beating Cancer Plan; resilience to cross-border threats to health; European Health Data Space; health promotion and disease prevention; Pharmaceutical Strategy; global health and international initiatives; and ongoing activities of DG SANTE.

Fig. 1.6 *Maximum EU budget as a share of EU GDP*



Source: European Commission (n.d.). NextGenerationEU. https://commission.europa.eu/strategy-and-policy/eu-budget/eu-borrower-investor-relations/nextgenerationeu_en (accessed 26 August 2024)

Chapter 4 moves to healthcare, an area in which the EU's impact was long veiled, legally and politically derived from internal market and market regulation rules. But if we look at how EU law and policy shapes the governance, resource generation, financing and delivery of healthcare, we can see how profoundly the EU shapes healthcare systems and how acknowledging the health impact of these policies is increasingly common and increasingly useful.

Chapter 5 then addresses the three major transitions identified by the EU: the green, digital and social transitions. The green transition involves the goal of a carbon-neutral and environmentally sustainable continent in which economic

growth is decoupled from pollution, and the digital transition covers the host of data-intensive knowledge industries and technologies that policy-makers have identified as crucial to the future. These two transitions both shape health policies and outcomes, and EU health policies are part of conversations about topics such as carbon neutral hospitals or new ways to balance data protection and research. The goal of the European social transition, particularly through the implementation of the European Pillar of Social Rights (EPSR), is to promote social fairness, improve living and working conditions, and ensure that the benefits of economic growth and development are broadly shared across all segments of society within the EU.

Chapter 6 turns to the ever-evolving EU fiscal agenda, once born as a way to constrain Member State expenditure and now increasingly a complex combination of constraining fiscal oversight and extensive EU investment in Member States that provides new opportunities for health and health systems.

Chapter 7 addresses the EU's global health policies, which include its first explicit Global Health Strategy but stretch beyond it. The EU is one of the world's largest economies, donors and regulators, shapes the law and political economy of major health industries such as pharmaceuticals and medical devices, and its trade, regulatory, intellectual property, research and other policies are global health policies whether they are part of its strategy or not.

In conclusion, Chapter 8 reflects on the trajectory of EU health policies before, during and after the COVID-19 pandemic, and shares insights from a structured Europe-wide debate about health priorities for EU action .

1.7 Conclusion

In the EU a legal basis such as Article 168 TFEU can create a starting point for policy entrepreneurship,[39] but the public health legal basis was not written to permit much of this. That manifestly does not mean that the EU lacks health policy. Instead, it historically has meant that the EU's health policies are made under other headings, as part of efforts to promote and regulate the internal market, to ensure the protection of workers, consumers and the environment, to invest in poorer regions, or to monitor the fiscal decisions of its Member States. There are powerful tools there, but in each case they legally, politically and practically belong to another sector. There can be and is an EU policy on

39 Page EC (2012). The European Commission Bureaucracy: Handling Sovereignty Through the Back and Front Doors, in Hayward J & Wurzel R (eds). *European Disunion: Between Sovereignty and Solidarity*. Basingstoke: Palgrave Macmillan.

acceptable rules for developing baskets of covered healthcare services, but it cannot be made with health as its declared primary goal, just as there are EU recommendations, some very specific and backed by the threat of fines, to Member States about how to operate their health systems, but they cannot primarily be made with health as their goal, as against fiscal sustainability.

If Article 9 TFEU's commitment that the EU shall always take into account "protection of human health" is to carry any weight, the solution will be in understanding and finding ways to gain leverage over multiple powerful and promising elements of EU policy, from the European Semester to medical devices regulation.

That has, in a sense, been happening. Previous editions of this book were organized in terms of the "three faces" of European Union health policy: explicit health policy, internal market policy and fiscal governance.[40] But we found that as EU health policy becomes broader and more complex, and as health is accepted as a justification for action in more and more areas, that has broken down. European Union global health policy, for example, is a new face of the EU, while more and more fiscal governance[41] and internal market policies such as pharmaceuticals regulation are acquiring an acknowledged and explicit health dimension. European Union health policy is starting to encompass more and more areas of EU action that always had a health dimension. The health dimension is becoming recognized, and policies made accountable for health in more areas. The growth and consolidation of European Union health law and policy is a process of articulating what a health policy is, often in the face of political opposition from those who prefer to see a policy area such as pharmaceuticals, climate change, insurance or artificial intelligence viewed as an economic issue.[42]

The twenty-first century, and in particular the EU's COVID-19 response, has shown what can be done within the limits of Article 168 TFEU. Health policies we discuss range from the State of Health in the EU reports to tobacco control and European Reference Networks, and the Commission, particularly DG SANTE, has taken action in crucial areas such as healthy lifestyles, vaccination and antimicrobial resistance. Combined with action across the EU's many other policies, where health has gained prominence as a goal and policy area, the

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40 Greer, SL (2014). The three faces of European Union health policy: policy, markets, and austerity. *Policy and Society* 33, no. 1 : 13–24.

41 Greer, SL, Brooks, E (2021). Termites of solidarity in the house of austerity: undermining fiscal governance in the European Union. *Journal of health politics, policy and law* 46, no. 1: 71–92. Vanhercke, B, Verdun, A. The European semester as goldilocks: Macroeconomic policy coordination and the recovery and resilience facility. *JCMS: Journal of Common Market Studies* 60, no. 1 (2022): 204–223.

42 Hervey TK (2017). Telling stories about European Union Health Law: The emergence of a new field of law. *Comparative European Politics* 15: 352–369. Brooks E (2025). *European Union Health Policy: What is it, how does it work and why does it matter?* Manchester University Press.

result has shaped health outcomes and shows how powerful, and inescapable, EU health policy can be.

Chapter 2

European Union health policy-making

This chapter introduces the EU institutions in the field of health and a few key points for the analysis and interpretation of EU health policy. EU institutions are complex – there is an official web page to help people understand the different roles and functions of the various EU Presidents[1] – but there are two particularly important threads or facts about institutions and understandings of institutional procedures that underlie health law and policy in the EU.

The first thread to follow is the importance of the Treaties and Treaty bases. Treaty bases (or legal competence) create the power for EU institutions to make laws and policies. The legal article in the Treaty on the Functioning of the EU (TFEU) that makes it possible to make laws in the field of health is in principle Article 168. But other areas where the EU has lawmaking powers are also often used to create laws that have important bearing on health, such as Article 114 for the functioning of the internal market.

The Treaties and associated jurisprudence therefore shape what is possible. The EU, like many international organizations and federal governments, operates on the principle of attributed powers. Member States might have a general lawmaking power, but the EU can only make policies within the specifically attributed powers listed in the Treaties where the Member States of the EU have given the EU the power to make laws. This EU power to act is known as competence. As a result, an EU policy proposal without a legal competence, also known as a Treaty base, is but a vague hope. Any legislative proposal by the European Commission needs a legal competence, and all delegated or implementing decisions by EU institutions need a legal basis in a Union law. This can also mean that the Treaty base cited in legislation is fundamental to the impact of the legislation, the mechanisms it uses, and the priorities in it.

All EU laws must furthermore stand the test of subsidiarity, which means that the objective for which a particular law is adopted needs to be better served by EU action rather than the Member States going it alone. Subsidiarity limits the extent to which policy advocates can undertake so-called competence shopping.

1 European Union (n.d.). *EU Presidents – who does what?* Available at: https://europa.eu/european-union/about-eu/presidents_en (accessed 20 June 2024).

While EU legislative competence is relatively limited in health, this has not deterred lawmakers from adopting legal instruments with an important health implication or policy advocates from thinking of new ways to use existing competencies. Instead, when a winning coalition in the European Commission, Member States in the Council of the EU and the European Parliament see a need for legislation, a competence is usually found that could underpin their preferred policy in what has been called the treaty base game.[2] The Member States have for instance attributed strong lawmaking powers to the EU in the development and extension of the single internal market. Adopting laws regarding the functioning of the single internal market is easier than making policy on the basis of improving health, and so policies whose explicit objective is health have a harder time finding a competence or effective sponsors in the Commission and Council than policies whose objective is explicitly market-making or fiscal governance.

European Union lawmaking based on Article 168 TFEU is limited by paragraphs 5 and 7 which specify that the EU cannot harmonize national laws and exert authority over health systems (see the Annex for the full text). At the same time, the fiscal governance system created after the 2008 financial crisis almost immediately led to the Council issuing recommendations on health policy issues as detailed as the role of primary care in Austria or the appropriate medical school admissions policies of France (see Chapter 6). It was a striking demonstration of how one competence could be carefully limited to keep the EU out of health policy while a different one could be used to make health policy decisions of striking ambition and detail.

The following Sections present each EU institution and their place in the legislative and other political processes. But it is important to remember the second thread in political analysis. These institutions exist in a broad European political system. In the EU legislative and policy process, there are constant formal and informal dialogues, and signals exchanged, between institutions, Member States and even agencies. The Commission, for example, has a near-monopoly on legislative initiative, but it generally will use that to introduce proposed legislation that has a chance to pass. The other EU institutions, notably the Council and Parliament, therefore have an opportunity to signal to the Commission that they would like to see a particular action, for instance through adopting Resolutions or Conclusions which provide reassurance that a proposal along those lines would have a chance to pass.

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2 Rhodes, M. (1995). A Regulatory Conundrum: Industrial Relations and the Social Dimension. In S. Leibfried & P. Pierson (Eds.), *European Social Policy: Between Fragmentation and Integration* (pp. 78–128). Washington, DC: Brookings.

Likewise, Council formations do not directly comment on each other's work (it is up to Member States to coordinate their positions or not). As a result, when one group of ministers wishes to express a view on policies outside their formal remit, they might use Conclusions to express broad views that an informed reader would recognize as a statement (as with the 2013 Council Conclusions on the reflection process on modern, responsive and sustainable health systems, which were in large part health ministers commenting on the objectives of the growing fiscal governance architecture; see Chapter 6). Coordination of the complex EU legislative process in the trilogues (see Box 2.2) has enhanced coordination between the Commission, Council and Parliament, although at the price of centralization within the relevant institutions. Informally, of course, there is even more communication; institutions, Member States and lobbies of all kinds are constantly making their preferences known to each other.

2.1 European political institutions

The EU has four core institutions: an executive (the European Commission), two legislative bodies (the European Parliament, with members (MEPs) directly elected in each Member State, and the Council of the European Union, comprising national ministers from each Member State and meeting in ten different configurations), and a Court of Justice. There is a separate structure for foreign policy that is a hybrid of the Council and the Commission; it is discussed separately in Chapter 7 (see Section 7.1.3)

2.1.1 The European Commission

The executive body of the EU is the European Commission, whose College is made up of individual commissioners, one from each Member State and appointed by agreement between the Parliament and the Council; the President of the Commission is Ursula von der Leyen, appointed in 2019 and renewed for another term in 2024. In addition to their personal office (or cabinet), these commissioners are supported by directorates-general (DGs), akin to ministries; each has a name and a shorthand name usually presented in capital letters.[3] Commission Vice-Presidents chosen from among the commissioners oversee groups of individual commissioners on broad topics.

3 For a complete list, see European Commission (2024). *Departments (Directorates-General) and Executive Agencies*. Brussels: European Commission. Available at: https://ec.europa.eu/info/departments_en (accessed 20 June 2024).

The lead DG for health is the DG for Health and Animal Welfare, known as SANTE. Before 2014, when it was separated from consumer protection, it was called DG SANCO. From 2014 to 2024 it was titled as the DG for Health and Food Safety. Led from 2019 to 2024 by Cypriot Commissioner Stella Kyriakides, its Commissioner-designate for 2024-2029 is Hungarian Olivér Várhelyi, formerly Commissioner for relations with accession states (DG NEAR). DG SANTE is responsible for EU actions in public health and food safety, including many of the policy areas discussed in this book. Other DGs have more specialized but consequential roles to play for health systems, and there are DGs with indirect responsibility for health, e.g. reducing carbon emissions or promoting sustainable agriculture (these are discussed in Chapter 5). Each of the policy areas that lead to their involvement are discussed in this book:

DG Communications Networks, Content and Technology (CNECT) is a major funder and policy-maker in health information technology and e-health;

DG Competition (COMP) is responsible for the development and application of competition law and state aid, which has touched on the organization of healthcare in a variety of cases;

DG Civil Protection and Humanitarian Aid Operations (ECHO) oversees the EU's significant international humanitarian aid programmes (see Chapter 7) as well as the Civil Protection Mechanism, including the stockpiling system RescEU (see Chapter 3);

DG Employment, Social Affairs and Inclusion (EMPL) has a major role in EU social policy; in addition to its responsibility for health and safety, it touches on health via its broad social policy proposals, its administration of the European Social Fund and its administration of social security coordination, which includes much cross-border healthcare;

DG Eurostat (EUROSTAT) is the statistical office of the EU, responsible for publishing Europe-wide statistics and indicators that enable comparisons between countries and regions, including a limited number of health-related statistics;

DG Internal Market, Industry, Entrepreneurship and Small and Medium-sized Enterprises (GROW) is the guardian of the internal market law and its enforcement, which made it a major part of the story on cross-border patient and health professional mobility (on account of its competency for recognizing health professionals' qualifications);

DG Structural Reform Support (REFORM) "coordinates and provides tailor-made technical support to EU Member States" and its views

carry weight in discussions of Member State policies and adherence to EU objectives.[4]

DG Regional and Urban Policy (REGIO) is responsible for managing the cohesion funds (the EU's regional development aid system), which is important for the finances of recipient regions and pays for substantial health infrastructure;

DG Research and Innovation (RTD) is in charge of the substantial EU research budget, which includes financing for biomedical and health-related research;

DG Trade (TRADE) negotiates for the EU in its international trade dealings, including with the World Trade Organization (WTO) and in other trade relationships.

Each commissioner receives their mandate in the form of a "mission letter" from the Commission President.[5]

Health systems, of course, are not the whole of health policy, and a number of DGs that are not widely seen as part of the health sector play an important role in shaping the health of Europeans. A few that are particularly powerful within the EU and affect health in Europe are DG Agriculture and Rural Development (AGRI), which administers and helps to shape EU food and agriculture policy; and DG Environment (ENV), which works on environmental protection, where the EU has extensive powers that have afforded Europeans a comparatively high level of protection from myriad environmental threats to health. For those outside the EU, development, crisis response and, in some cases, neighbourhood policies, all of which influence global health, are the responsibility of DG International Cooperation and Development (INTPA), DG Climate Action (CLIMA) and DG European Neighbourhood Policy and Enlargement Negotiations (NEAR), depending on the country and issue concerned.

The Commission acts highly collectively in its decision-making and has strong internal mechanisms supporting the College of Commissioners to ensure that collective approach, with any decision by the Commission subject to multiple levels of internal consultation – between DGs (referred to as interservice consultation), among the cabinets of the commissioners, and through collective consideration by the College of Commissioners themselves.

The powerful Secretariat-General, part of the Commission, is responsible for coordinating the work across the entire Commission to make sure that all initiatives are aligned with the political priorities of the President, and for steering

4 Greer, Scott L., et al. (2019). *Everything you always wanted to know about European Union health policies but were afraid to ask*. Copenhagen: WHO Regional Office for Europe (Second, revised edition), p.35.

5 See the Annex for Commissioner-designate Várhelyi's mission letter.

these new policies through the other EU institutions. Over time Vice-Presidents, whose portfolios span several DGs (and commissioners), have become increasingly important figures, occupying a level between the Commission President and other commissioners. The portfolios of Vice-Presidents and the choice of Vice-Presidents are an important statement of priorities and the political coalitions involved. Over time, the Commission has seen a political centralization, with more power in the hands of the President and the Vice-Presidents, and less autonomy for commissioners and particular DGs. This centralization explains, for example, the difficulties that SANTE faced in promoting health under the Juncker Commission.

By the standards of the national government of a medium or large EU country such as Spain or France, the Commission is a relatively small body (32 484 staff[6] as of 1 January 2024, many of them translators). That small size is misleading, since the Commission is almost entirely dedicated to policy-making. It can influence most aspects of life in Europe with fewer employees than many regional governments because its employees do not sweep streets or inspect abattoirs or drive buses or even work out the detailed application of much of the legislation. The Member States do the implementation and much of the actual detailed policy formulation, in a system of outsourcing that makes the EU a remarkably efficient policy-making mechanism.[7] Member States, interested in understanding and shaping EU policy, will often also second their own officials to the EU for a time.

The Commission has what is termed the "right of initiative". EU legislation, although decided by the Council and Parliament, normally only begins with a Commission proposal, which gives the Commission enormous influence in shaping the detailed content (although given that both the Council and the Parliament can and do request the Commission to bring forward particular proposals, this is less of a restriction than it might seem) (see Box 2.1).

The Commission does not just act through legislative proposals; it typically announces its priorities and approaches to its responsibilities in Communications (a formal statement of policy), as well as using tools such as financing. Even old Communications from previous Commission leaderships will often still be taken as the authorization for policies or ways of thinking until they are explicitly overruled or replaced. Communications that are later supported by Council Conclusions tend to have particular force and staying power (as with the Global Health Strategy, discussed in Chapter 7). The Commission has the power to take

6 European Commission (2024). *Human resources key figures card: staff members*. Brussels: Publications of the European Commission. The "HR Key Figures Dashboard" for the Commission is linked from: https://commission.europa.eu/about-european-commission/organisation-european-commission/commission-staff_en (accessed 24 July 2024).

7 Page EC (2001). The European Union and the bureaucratic mode of production, in Menon A (ed.). *From the nation state to Europe: essays in honour of Jack Hayward*. Oxford: Oxford University Press.

Box 2.1 *Commission proposal development*

The European Commission is responsible for planning, preparing and proposing new European legislation. In an attempt to increase transparency and policy coherence, the Barroso Commission (2004–2014) introduced a requirement in policy-making that includes publishing the intention to present a proposal at the earliest stage on a publicly accessible roadmap. Roadmaps seek to describe the problem to be tackled and the objectives to be met by the new legislation. They also explain why EU legislation is needed and describe the main features of the consultation strategy. Legislative and other important proposals are introduced by a consultative document, followed by a public consultation and a Commission impact assessment focusing on economic, environmental and social aspects (including impact on public health and health systems under the social Pillar). Any important proposal needs to have its impact assessment pass the Regulatory Scrutiny Board, composed of directors from the coordinating DGs and outside experts, before it can be agreed internally. In this case, the roadmap is replaced by an inception impact assessment, which goes into greater detail.

The Commission's presentation of this process can be found on their Planning and Proposing Law web page.[a]

a European Commission (n.d.). *Planning and Proposing Law*. Available at: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law_en (accessed 9 August 2024).

its own binding Decisions in some areas, in particular for competition rulings or where it has powers delegated by primary legislation.

Although the key role of the Commission remains policy-making, there has been an increasing shift of the Commission towards executive action such as interventions in markets and services that are directly relevant to citizens. Historically, this kind of executive action has been the preserve of agriculture, anti-fraud or humanitarian action. In health we have seen only very narrow examples such as the European Health Insurance Card (EHIC). However, the pandemic saw the Commission taking on an executive role more like a national administration, such as in the joint procurement of vaccines and personal protective equipment, and work through the European Medicines Agency to more actively intervene in the development and supply of medicines. In some ways, this is a logical consequence of the steady accretion of powers at the European level, and the potential added value of leveraging the EU's collective weight in markets as it already does in trade negotiations, for example. The Vaccines Strategy in response to COVID-19 was a major step forward in this regard.

Since April 2012, by means of the European Citizens' Initiative (ECI) introduced by the Lisbon Treaty, EU citizens may call on the Commission to make proposals.

Two out of the ten initiatives[8] that have successfully reached the required number of statements of support since 2012 deal explicitly with health issues, although a few others deal with issues touching on health and animal welfare such as bee-friendly agriculture. In the first ECI from 2012,[9] EU citizens asked the Commission to propose legislation implementing a human right to water and sanitation, as recognized by the United Nations. The Commission committed in 2013[10] to take a series of actions reinforcing implementation of EU water quality legislation.

In January 2017, EU citizens also called on the Commission to propose to Member States a ban on glyphosate and to reform the EU pesticide approval procedure and set EU-wide mandatory reduction targets for pesticide use.[11] Although the Commission concluded in December 2017[12] that there were "neither scientific nor legal grounds to justify a ban of glyphosate", DG SANTE responded with changes to procedures intended to shore up the credibility of Commission decision-making on the issue. A proposal on transparency and sustainability of the EU risk assessment in the food chain was adopted by the Commission in April 2018[13] in response to the second aim of the initiative (to "ensure that the scientific evaluation of pesticides for EU approval is based only on published studies that are not commissioned by the pesticides industry"), which was approved by the European Parliament and the Council in June 2019.[14]

The Commission also has a role as the so-called guardian of the Treaties. This means that it is authorized to file cases against Member States that are not in compliance with EU law. The associated procedures involve tracking the transposition of EU legislation into Member State law and warning the Member State that the Commission considers it to be failing in the transposition or implementation of EU law. Ultimately, the Commission has standing to take

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8 See the list of current and past initiatives at https://europa.eu/citizens-initiative/_en (accessed 20 June 2024).

9 European Commission (2012). The European Citizens' Initiative – Official Register. "Water and sanitation are a human right! Water is a public good, not a commodity!", registered 10 May 2012.

10 European Commission (2014). Communication from the Commission on the European Citizens' Initiative "Water and sanitation are a human right! Water is a public good, not a commodity!" Brussels, released on 19 March 2014.

11 European Commission (2017). The European Citizens' Initiative – Official Register. "Ban glyphosate and protect people and the environment from toxic pesticides", registered 25 January 2017.

12 European Commission (2017). Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides". Brussels, released on 12 December 2017.

13 European Commission (2018). *Proposal for a regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain*. Brussels, 11 April 2018.

14 European Commission (2019). Press release: "Boosting trust in scientific studies on food safety: Commission welcomes the provisional agreement reached today". Brussels, released 11 February 2019.

Member States to the Court of Justice of the European Union over failure to transpose or correctly implement EU law.[15]

The Health Emergency Preparedness and Response Authority (HERA), was established in 2021 as a Commission Service.[16] As such, it operates much like a DG, but without a commissioner. Its head has the equivalent rank to a Director-General. The head of HERA reports to a Coordination Committee made up of the Commission Vice-President in charge of health and the commissioners responsible for health, innovation and research, and crisis management. The HERA board has a representative from each Member State and observers from the Parliament and relevant EU agencies. It is a mechanism for Member States to observe and hold HERA accountable. According to its founding Decision, its governance is to be reviewed by the Commission by 2025.

2.1.2 European Parliament

The first EU legislative chamber is the European Parliament, which has been gaining power since its establishment in the 1970s. Although initially very much the junior partner, the Parliament now acts as co-legislator with the Council of Ministers in nearly all areas. The Parliament is directly elected across Europe for a five-year term and organized into party groups that largely resemble the party groupings of most Member States. No single political group has a majority within the Parliament, and so decision-making in practice requires considerable collaboration across political groups.

Over time, the Parliament has been gaining power, with more and more areas subject to ordinary legislative procedure (also known as co-decisions – see Box 2.2), with increased powers over the budget, the power to hold hearings on a variety of issues and question commissioners, and the ability to veto candidates for Commission President as put forth by the Council.

Not surprisingly, following negotiations between EU institutions can be complex and challenging – see Box 2.3 for information about a helpful tool.

In practical terms, the Parliament works principally through standing committees for the different policy areas, with the committee responsible for the subject of a proposal taking the lead in the Parliament's consideration of it. The lead committee for health issues has been the Environment, Public Health and Food Safety Committee (ENVI), although other committees also play a significant

15 The searchable infringements database is at https://commission.europa.eu/law/application-eu-law_en (accessed 24 July 2024). The bulk of DG SANTE infringements are to do with food law and safety.

16 Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (2021/C 393 I/02). For a useful discussion, see Clement Thierry Evroux (2022). European Parliament Briefing: "HERA, the EU's new Health Emergency Preparedness and Response Authority".

Box 2.2 *EU legislative processes*

The "ordinary legislative procedure", based on co-decision of the European Parliament and the Council, is the general procedure that is used for adopting legislation at the EU level (Article 294 TFEU). It applies in 85 defined policy areas, which cover most of the EU's areas of competence. This procedure is essentially similar to that in most national parliaments, with a proposal going through two readings alternating between two chambers (in this case, the European Parliament and the Council of Ministers), which must reach agreement for the proposal to be adopted.

The Commission holds the right of initiative. The ordinary legislative procedure starts therefore with a Commission legislative proposal. The proposal is sent to the Parliament, which may amend it in a "first reading". The Commission's proposal is simultaneously sent to national parliaments, which may issue a "reasoned opinion" stating why they think the draft legislative act does not comply with the principle of subsidiarity (in accordance with Protocol No. 1 on the role of national parliaments[a] and Protocol No. 2 on the principles of subsidiarity and proportionality).

The amended proposal then goes to the Council, which may amend the Parliament's proposal in its own first reading. If they agree, then they can both pass it and it becomes law. If they do not agree, the legislation will pass through a second reading in both, which is quite common. The co-legislators can agree on a compromise text, and then complete the legislative procedure, at any reading. These agreements are reached through inter-institutional negotiations known as tripartite meetings or trilogues between the EU Parliament, the Council and the Commission.[b] Trilogues consist mostly of political negotiations, although they may be preceded by technical meetings. Any agreement reached in a trilogue is provisional. It must then be approved through the formal procedures applicable within each institution. The number of trilogues depends on the draft proposal debated and specific political circumstances. The institutionalized use of trilogues seems to have strengthened transparency and accountability within the Parliament.[c]

Trilogues have also changed the actual operation of the political process. By coordinating the institutions early in the process, they smooth the path to legislation and reduce the number of initiatives proposed that do not pass. Whether trilogues will continue to work that way as the political factions in the Council and Parliament continue to fragment remains to be seen.

If the Council's second reading does not approve the amendments from the Parliament's second reading, a "conciliation committee" of MEPs and Council representatives tries to formulate a compromise. If they formulate a proposal and both the Parliament and the Council pass it unamended, then it becomes law; if they fail to agree on a proposal or it is not passed by Council or Parliament, then the legislative proposal has failed. This process is used for most legislation relevant to health.

The Parliament has a majority voting rule: a majority of MEPs wins a vote. The Council has more complex voting rules that depend on the issue. Simple majority is a simple majority of Member

States (14 being a majority at the moment). The qualified majority voting rules (QMV) require votes from at least 15 Member States, and the proposal must be supported by Member States representing at least 65% of the total EU population. Some issues, such as regulation of social security (which includes the European Health Insurance Card), require unanimity in the Council. Fiscal governance issues sometimes require the newest voting rule, reverse qualified majority voting, in which a qualified majority is required to reject the Commission proposal; this is a rule designed to strengthen the Commission. The Treaties spell out the voting rules for each issue. The Treaties include a *passerelle* clause allowing voting rules to be changed from special to the ordinary legislative procedure, or to replace unanimity rules with QMV.

These formal procedures shape what is often an informal negotiation process, in which institutions signal their preferences to each other (e.g. calling upon the Commission to introduce particular legislation) and then directly negotiate in the trilogue. While all actors are very aware of the processes and power balances, a preference for negotiation and Council unanimity mean that conflicts are often avoided or smoothed out in private.

a In European law, protocols are legal instruments that are attached to the main EU treaties. They have the same legal force as the treaties themselves and are used to address specific issues, clarify certain provisions, outline specific actions to be adopted later, or grant exceptions to certain Member States.

b European Parliament (2020). *Handbook on the Ordinary Legislative Procedure. A guide to how the European Parliament co-legislates*. Available at: https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/handbook-on-the-ordinary-legislative-procedure (accessed 15 July 2024).

c Idem, p. 29.

role in relation to health, such as the Employment and Social Affairs Committee (which deals with social security coordination, for example), or the Industry, Research and Energy Committee (which deals with research on health). In terms of process for a given proposal, an individual MEP within the committee concerned is nominated to prepare a report on behalf of the Parliament; this member is termed the rapporteur for the proposal. This report is then considered and revised by the committee as a whole, and then by Parliament as a whole in one of the monthly plenary sessions.

Box 2.3 *How to follow negotiations between the EU institutions*

The European Parliament provides a railway-themed "legislative train schedule" on its website. It enables the process of a particular legislative proposal to be followed in detail. It is at https://www.europarl.europa.eu/legislative-train/. The process can be followed in all the institutions from the Commission's initial proposal, and the current position can be seen. With some knowledge of the decision-making processes of the institutions, this provides an excellent overview and access to the individual documents and positions along the way.

The 2019 elections were a landmark. For the first time since direct elections to the European Parliament began in 1979, the two largest groups – the Group of the European People's Party (EPP) and the Group of the Progressive Alliance of Socialists and Democrats (S&D) – lost their combined majority in the Parliament, which in practice increased the power of Green and liberal parties. In 2024, while the EPP and S&D made up the majority of the parties, the number of parties increased, with a greater number of MEPs being members of groups to the right, such as the European Conservatives and Reformists Group and the Renew Europe Group (see Box 2.4).[17] This more fragmented European Parliament, which mirrors the more fragmented political systems of most Member States, creates new political and coalitional possibilities, might change the way trilogues operate (see Box 2.2), and makes the EU agenda less predictable.

Box 2.4 *Political groups in the 2024–2029 European Parliament and percentage of members*[a]

Group of the European People's Party (Christian Democrats): 26.11%

Group of the Progressive Alliance of Socialists and Democrats: 18.89%

Patriots for Europe: 11.67%

European Conservatives and Reformists Group: 10.83%

Renew Europe: 10.69%

Groups of the Greens/European Free Alliance: 7.36%

The Left group in the European Parliament: 6.39%

Europe of Sovereign Nations: 3.47%

Non-Attached Members 4.58%

a European Union (2024, July 23). 2024 European Election Results: European parliament. https://results.elections.europa.eu/en/tools/widget-europe/2024-2029/ (accessed 9 August 2024).

2.1.3 Council of the European Union and the European Council

The second EU legislative body is the Council of the EU. This is made up of the relevant ministers from each Member State meeting in one of ten topic-specific

17 European Union (2024, July 23). *2024 European Election Results: European parliament*. https://results.elections.europa.eu/en/tools/widget-europe/2024-2029/ (accessed 9 August 2024).

configurations (e.g. the Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO) is composed of the ministers responsible for health when discussing health issues).[18] Indeed, a Member State may be represented by several different ministers during the course of a single Council meeting, depending on the subjects being discussed. This structure is unlike any national government, where there is usually a single body for multiple policies. Although technically the Council is one body, in practice the Council for e.g., Agriculture and Fisheries, is not made up of the same national representatives as the Council for Employment, Social Policy, Health and Consumer Affairs. This system relies on effective coordination at national level to ensure that the positions expressed in one Council take account of the full range of views domestically (e.g. if health-related expenditure is being discussed in the Economic and Financial Affairs Council). Given that the Member States (and indeed the Commission) face the usual coordination problems of big bureaucracies and handle them with varying success,[19] the result is that a level of fragmentation exists in the heart of the EU legislative process. Some Member States care much more than others about coherence between Council formations, and there have been tensions when a minister votes in the Council in a way members of their government do not support.

In the Council, coordination is in the hands of the Council Presidency, which holds the pivotal role of chairing Council meetings, setting their agenda and brokering compromises. The responsibility for doing this is shared among all the EU countries, with each country taking a six-month stint to hold the Presidency of the Council (see Table 2.1).[20] The Council has an intricate but broadly majority-type voting system, although in practice the Council aims to seek consensus wherever possible. Most European legislation, including health legislation, requires the agreement of both the Parliament and the Council (see Box 2.2). Both the Council and the Parliament can also agree on political statements, which are not legally enforceable but which clearly state priorities and policies (as with the European Declaration on Digital Rights and Principles, discussed in 5.1.2 below). The Council can also adopt recommendations; these are legal acts but without

18 See Council of the European Union (2019). *Council configurations*. Brussels, Council of the European Union. Available at: https://www.consilium.europa.eu/en/council-eu/configurations/ (accessed 2 May 2019).

19 The classic articulation of the problem is seen in Wright V (1996). The national co-ordination of European policy-making: negotiating the quagmire, in Richardson JJ (ed.). *European Union: power and policy-making*. London: Routledge; also Greer SL (2010). Standing up for health? Health departments in the making of EU policy. *Social Policy and Administration*, 44(2):208–24.

20 Council of the European Union (2021). Council Decision (EU) 2021/689 of 29 April 2021 determining the order in which the office of President of the Council shall be held until 2030. *Official Journal of the European Union*, L 183/1, 30 April 2021.

any legal mechanism of enforcement. Nevertheless, the political weight of such a commitment is substantial.[21]

Table 2.1 *Order of presidencies of the Council of Ministers, 2024–2030*

Period	Country
2024 (first half)	Belgium
2024 (second half)	Hungary
2025 (first half)	Poland
2025 (second half)	Denmark
2026 (first half)	Cyprus
2026 (second half)	Ireland
2027 (first half)	Lithuania
2027 (second half)	Greece
2028 (first half)	Italy
2028 (second half)	Latvia
2029 (first half)	Luxembourg
2029 (second half)	Netherlands
2030 (first half)	Slovakia
2030 (second half)	Malta

The European Council is made up of the heads of state and government of the Member States. It is formally a separate body from the Council of the EU (and cannot adopt legislation, for example), but as it is made up of the most powerful political figures in Europe, it has a leadership role in setting the overall direction of the EU and brokering solutions to its most intractable problems. Unlike the rotating Presidency of the Council of Ministers, the European Council has an elected President chosen by the Member States (typically as part of a larger negotiation about the allocation of multiple top jobs). The first elected President of the Council was Belgian Christian Democrat and former prime minister Herman van Rompuy. Donald Tusk, former Prime Minister of Poland from the European People's Party member Civil Coalition, replaced him on 1 December 2014. Belgian liberal and former prime minister Charles Michel replaced Tusk in 2019. Portuguese socialist and former prime minister António Costa was elected president in 2024, replacing Michel.

Various types of EU legal instruments are specified in the Treaties, and the differences between them are legally and politically significant (see Box 2.5).

2.1.4 Court of Justice of the European Union

Finally, the EU has the Court of Justice of the European Union (CJEU). Formerly known as the European Court of Justice, it is the most powerful supranational court in history.[22] It is made up of judges nominated by the Member States, sitting in Luxembourg. It is the final arbiter of EU law. In principle, if Member States disagree with the CJEU on legal interpretation, they must change the law, and if they disagree with its interpretation of Treaties, they must change the Treaties.

21 Council of the European Union (2003). Recommendation of 2 December 2003 on cancer screening. Official Journal, L 327/34.

22 Stone Sweet A (2005). Judicial authority and market integration in Europe, in Ginsburg T & Kagan RA (eds). *Institutions and public law: comparative approaches*. Frankfurt: Peter Lang.

Box 2.5 *Commonly used legal instruments in European Union law*

Regulations and directives

Regulations and directives are the EU's principal legal instruments. A regulation, once passed, is directly applicable: it becomes Member State law, without the need for a legal transposition into national law. For social security and health, the Regulation on the coordination of social security systems is important, as it provides for people receiving healthcare in other Member States. Regulations are also used to establish agencies, such as the European Medicines Agency. A directive, such as Directive 2011/24/EU on patients' rights in cross-border healthcare, is EU legislation that Member States must transpose into their own domestic law. It sets out the objectives to be achieved but leaves it up to Member States as to how they achieve those objectives in their national context.

Decisions

A decision is binding on its addressees within specific legislative areas and can do a variety of things, such as ratify Commission reports (as in the European Semester – see Section 6.4).

Recommendations and declarative documents

Council recommendations are legal acts but have no binding force. The institutions also adopt various types of declarative documents (principally communications from the Commission, conclusions from the Council and opinions from the Parliament); these also have no binding force but shape the agenda. Council recommendations and resolutions have more force than conclusions. The Commission, in particular, strongly prefers to have authorization from such a document for its proposals and activities, even if Member States and outsiders might complain that what the Commission is doing is not what they intended.[a]

Delegation

Detailed primary legislation is not always appropriate (e.g. in areas where there are frequent technical changes) and so EU legislation adopted by the Council and Parliament frequently delegates powers to the Commission to adopt subsidiary measures under the main legislation. This is subject to scrutiny by the Member States (typically through the Commission consulting a committee of Member State representatives before adopting a subsidiary measure) and the European Parliament. Before the Lisbon Treaty amendments, the system of delegated powers for the Commission and the controls over them was generally set out in a "comitology" decision of the Council.[b] This provided for a range of different procedures with differing degrees of oversight from the Council (and the Parliament, although less so). The Lisbon Treaty amendments aimed to simplify these procedures, reducing what had become quite a wide range of ways in which powers could be delegated.

The Lisbon Treaty replaced the previous systems of delegated powers with two types of delegated power. These are described in the Treaty itself:[c]

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Delegated acts: where the Commission is given

> the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power (Article 290 of the Treaty on the Functioning of the European Union).

Unlike previous procedures, no formal committee of Member State representatives is required, although the Commission is committed to consulting "experts from the national authorities of all the Member States, which will be responsible for implementing the delegated acts once they have been adopted".[d]

Implementing acts:

> Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council (Article 291 TFEU).

Two specific procedures for how the Commission consults a committee of Member States' representatives for implementing acts have been set out in Regulation (EU) 182/2011,[e] a lighter advisory procedure and a stricter examination procedure; any implementing act affecting the health or safety of humans must follow the stricter examination procedure.[f]

In practice, what this means is that in addition to the formal and high-profile processes of law-making that take place through the Council and the Parliament, there is also a much less visible process of adopting secondary acts. Even though these are only secondary legislation, they can involve decisions that can be highly significant for those affected by the relevant primary legislation.

An alternative legislative method allows the social partners (sectoral representatives of employers and labour) to negotiate legislation with one another and have it become law for their sector. In health, this has produced one piece of legislation: a directive on sharps (e.g. safe handling of needles and other products that can pose a hazard to workers).[g]

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a Page EC (2012). The European Commission bureaucracy: handling sovereignty through the back and front doors, in Hayward J & Wurzel R (eds). *European disunion: between sovereignty and solidarity*. Basingstoke: Palgrave Macmillan. b See Council Decision 1999/468/EC, *Official Journal*, L 184, 17 July 1999.

c For a more detailed guide see Hardacre A & Kaeding M (2013). *Delegated & implementing acts: The new comitology*. 5th ed. Maastricht, Netherlands: European Institute of Public Administration (EIPA).

d See COM(2009)673. e *Official Journal*, L 55, 28 February 2011.

f See Article 2(b)(iii).

g Council of the European Union (2010). Directive 2010/32/EU: Prevention from sharp injuries in the hospital and healthcare sector of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU. Brussels: Council of the European Union.

European Union law is an impressive edifice, built by both the CJEU and the courts of the Member States interpreting EU law in the course of deciding cases on the correct interpretation of EU law (see Box 2.6). European Union law in most cases has both direct effect, meaning that it can create rights and obligations for citizens directly in Member States, even if the Member State has not transposed it into domestic legislation, and supremacy, meaning that it overrides Member State law (with only a few qualifications, every EU Member State court has accepted both of these doctrines). European Union institutions can bring cases directly to the CJEU, such as when the Commission sues Member States for failure to correctly implement legislation, but many CJEU cases come about because of litigation in a Member State that raises a question of EU law. The Member States' courts may interpret EU law as well as their domestic laws, and they may use the preliminary reference procedure to refer the question to the CJEU for clarification (Article 267 TFEU). The CJEU ruling is then case law, binding until overridden by legislation, a Treaty change or new CJEU case law. Much of the history of healthcare law in the EU has involved the CJEU making rulings under the preliminary reference procedure when courts in Member States have faced cases brought by people who wished to use healthcare outside their home country.[23] As with most courts, the CJEU has also learned about the sector through the cases it sees, and it is possible to read its jurisprudence as a process in which the Court learned how to adapt internal market principles to the specific politics and issues in healthcare.[24]

The considerable differences between the EU's Member States has led to cases that address the responsibilities of health systems.[25] National courts have used the preliminary reference procedure to seek answers through the CJEU. In *Georgi Ivanov Elchinov v. Natsionalna zdravnoosiguritelna kasa*,[26] for example, a Bulgarian court asked the CJEU about the payment of costs incurred in a hospital located in another EU Member State (in this case Germany), because the patient could not receive his preferred treatment in his home country, Bulgaria, where there was an alternative treatment, which was both less effective and more radical than the treatment available in Germany.[27] The CJEU ruled that prior authorization may be refused if the medical benefits provided abroad are not covered under

23 Obermaier AJ (2008). The national judiciary: sword of European Court of Justice rulings – the example of the Kohll/Decker jurisprudence. *European Law Journal*, 14(6):735–52.

24 Martinsen DS (2015). *An ever more powerful court? The political constraints of legal integration in the European Union*. Oxford: Oxford University Press.

25 Stanislas A, Cheynel B, Rolin F (2015). La Cour de justice, acteur multifonctionnel du développement du droit économique de l'Union, *Revue internationale de droit économique*, 2015:4.

26 CJEU (2010). Judgment of the Court (Grand Chamber) of 5 October 2010, *Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa*.

27 Court of Justice of the European Union (2018). *The Court of Justice and healthcare*. Available at: https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-11/qd-04-18-747-en-n.pdf (accessed 10 June 2019).

Box 2.6 *Key concepts in European integration*

Creating an integrated Europe through implementing free movement of goods, services, capital and people is an awesome legal and policy-making task. The EU has developed a series of legal principles and techniques that it uses to carry out this task. Viewed together, they are a toolkit for creating both a powerful legal system and an increasingly integrated market and society. There are several key legal tools and concepts.

Harmonization. This refers to setting EU standards for something in place of diverging national standards (e.g. basic requirements for the number of hours that constitute medical education).

Mutual recognition. EU Member States, even if their regulations differ, agree to recognize the quality of the regulations in other EU Member States and not discriminate against goods, services, capital or people regulated by another Member State. It is often used with a measure of harmonization that sets the floor.[a] For example, the EU has mutual recognition of medical qualifications combined with limited harmonization of the requirements for achieving those qualifications. The virtue of mutual recognition is that it spares the EU from having to legislate detailed standards for everything in the EU (e.g. the full set of requirements to be a doctor in Europe), which would be time-consuming if not impossible. The potential drawback is that it depends on very different Member States having equally good regulation and gives Member States very few responses if the floor is set too low in EU law or another Member State has less stringent standards or enforcement. Since most legislation is adopted under QMV, Member States will have had chances to influence it but might not have been in agreement with it.

Country of origin principle. This is similar to the mutual recognition scheme. It states that a service or product acceptable in one country must be accepted in another. While the country of origin principle has no explicit legal basis in the Treaties, it forms part of the foundations of the internal market. The country of origin principle was exemplified in a legal dispute between France and Germany on the alcoholic beverage Cassis de Dijon.[b]

Direct effect. Individuals may rely on rights provided by EU law directly (under certain circumstances), even when the rights in question were in principle intended to only bind the Member State, and regardless of whether the Member State in question has taken measures to incorporate that EU law into their domestic legislation. A legal doctrine developed by the CJEU, it means that even if a Member State fails to transpose a directive into law or enforce it, citizens can use the EU law as a basis for litigation, provided that certain conditions are met (in particular that the rights concerned are clear, unconditional and do not require additional measures).

Supremacy. The CJEU has also developed the doctrine of supremacy, meaning that EU law trumps Member States' law, and if a Member State law contradicts EU law, then the EU law shall be applied.

Subsidiarity. Balancing all of this integrative apparatus is the concept of subsidiarity, which is that tasks should be performed at the smallest unit possible. Usually, this is taken to mean that

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the EU can only legislate when the issue can be regulated better when the Member States act together.

Decentralized enforcement of EU law. Finally, the EU relies principally on the Member States for decentralized enforcement of its law. Direct effect and supremacy mean that individual citizens or companies can bring challenges under EU law in their national courts. So, even if the Commission does not start a court case against a Member State for some form of non-compliance, those affected by the law can often bring cases themselves. If their Member State courts see an issue of lack of clarity in applicable EU law, the national court can use the preliminary reference procedure to ask the CJEU's opinion. This is how a single case of a citizen or a company with a problem can go via Member State courts to the CJEU and influence or use EU law even if no elected official supports the citizen or company's case. Rulings by the CJEU have precedence, which means that even though they are directed towards individual cases, the Court, through its case law, can establish principles that must be respected throughout the EU in the interpretation and application of EU law.

a Nicolaidis K (2005). Globalization with a human face: managed mutual recognition and the free movement of professionals, in Kostoris F & Schioppa P (eds). *The principle of mutual recognition in the European integration process*. Basingstoke: Palgrave Macmillan.

b European Court of Justice (1979). Case C-120/78 Cassis de Dijon.

the patient's social security system. However, if the treatment method applied abroad corresponds to benefits covered in the patient's Member State, it is not permissible to refuse prior authorization on the ground that such a method is not practised in that Member State.[28] While *Elchinov*'s practical effects are being managed, the questions it raised illustrate the difficulties of making health law in an EU with Member States whose fiscal capacities differ greatly.

2.1.5 Other Treaty bodies

The **European Central Bank** (ECB), although not part of the EU legislative process, is particularly important as the central bank of the eurozone. Its high level of autonomy entrenched in Treaties gives it specific obligations, notably to keep inflation low, and constraints, including a prohibition on making loans to EU institutions or Member States. Its leadership is made up of an executive board, whose six members are appointed by the Council under QMV; a governing council, made up of the executive board and the Member States' central bank heads of the eurozone; and a general council, made up of the executive board and the heads of all the EU central banks. All have security of tenure and may not be reappointed; by law, they must be politically independent. In July 2019

28 Greer SL, Sokol T (2014). Rules for Rights: European Law, Health Care and Social Citizenship. *European Law Journal*, 20(1):66–87. Sokol T (2010). Rindal and Elchinov: A(n) (Impending) Revolution in EU Law on Patient Mobility? *Croatian Yearbook of European Law and Policy*, 6(6):167–208.

Christine Lagarde, former finance minister of France and managing director of the IMF, was appointed President of the ECB for an eight-year non-renewable term.

On paper, the ECB has a narrowly limited remit that has little to do with health. In practice, the ECB is powerful and can shape health policy. The logic of increasing the predictability of central banks by decreasing their accountability to others has the obvious flaw that the unaccountable can be unpredictable, and the activity of the ECB since its inception was probably not anticipated by anybody.[29] The ECB demonstrated this over the decade since the financial crisis began, with unconventional monetary policy whose relationship to its mission could be unclear.[30] Its participation in the so-called Troika (European Commission, European Central Bank and International Monetary Fund) using conditional lending to reform Cyprus, Greece, Ireland and Portugal, and to a lesser extent Spain and Italy, was quite novel in the history of central banking.[31] Likewise, interventions by the ECB and its member banks in the domestic politics of Italy and Greece were not clearly justified in the Treaties. Regardless of the legitimacy and effect of these interventions, they were certainly consequential for health. During the COVID-19 pandemic, the ECB, like most central banks, pursued a very accommodative monetary strategy in order to keep the broad economy functioning through the various shocks associated with the pandemic.

The **European Investment Bank** (EIB) (see Chapter 6) provides funding for projects that seek to achieve EU goals, within or outside the European Union. Over the last decade it has increased its exposure to health and sought to improve the sophistication of its lending, in particular to health systems.

The **European Court of Auditors** (ECA) was established in 1977 to audit the EU's finances. As the EU's independent external auditor, the ECA is responsible for checking if the EU budget has been implemented correctly and if EU funds have been spent legally and in accordance with EU public finance regulations. The Court of Auditors has been making an increasing number of interventions into the health arena, focusing on misjudged policies and misspent money. Most

29 Adolph C (2013). *Bankers, bureaucrats and central bank politics: the myth of neutrality*. Cambridge: Cambridge University Press.

30 Ban C (2020). The Economic and Monetary Union: How Did the Euro Area Get a Lender of Last Resort?, in Coman R, Crespy A & Schmidt V (eds). *Governance and Politics in the Post-Crisis European Union*. Cambridge: Cambridge University Press, pp. 179–95.

31 Greer SL, Jarman H (2016). Reinforcing Europe's failed fiscal regulatory state, in Dallago B, Guri G & McGowan J (eds). *A Global Perspective on the European Economic Crisis*. London: Routledge, pp. 122–43. Fahy N (2012). Who is shaping the future of European health systems? *BMJ*, 13;344:e1712. Greer SL, Jarman H (2018). European citizenship rights and European fiscal politics after the crisis. *Government and Opposition*, 53(1):76–103.

recently, it evaluated the impact of the Directive on cross-border patient mobility and the performance of EU agencies in the COVID-19 pandemic.[32]

The **European Ombudsman** is a person elected by the European Parliament under Article 228 TFEU with a mission to

> receive complaints from any citizen of the Union or any natural or legal person residing or having its registered office in a Member State concerning instances of maladministration in the activities of the Union institutions, bodies, offices or agencies, with the exception of the Court of Justice of the European Union acting in its judicial role. He or she shall examine such complaints and report on them.[33]

The Ombudsman's term coincides with that of the European Parliament. The Ombudsman since 2014, Emily O'Reilly, whose term is set to expire in December 2024, has proved adept at using the position to raise inconvenient questions about decision-making processes.[34] This has recently led to, among other things, two inquiries into corporate sponsorship of EU Presidencies,[35] the transparency of the Medical Device Coordination Group, which advises the Commission on the topic,[36] and, perhaps of particular interest, the composition of the Commission's Regulatory Scrutiny Board and its interaction with interest groups, an inquiry that was underway in mid-2024.[37]

Finally, the EU legislative process also includes the **Economic and Social Committee**, which represents social partners (employers and workers), and the **Committee of the Regions**, which agglomerates the opinions of subnational governments. Both are strictly advisory, although consultation with them is mandatory in some areas of policy specified in the Treaties. Their practical influence can vary. For example, the Commission can use them to get a sense

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32 European Court of Auditors (2019). *Special report 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required*. European Court of Auditors. Available at: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=49945 (accessed 25 February 2022). European Court of Auditors (2024). *Preparing for the Next Pandemic: The EU Medical Agencies Need a Booster*. European Court of Auditors. Available at: https://www.eca.europa.eu/en/news/NEWS-SR-2024-12 (accessed 16 September 2024).

33 European Union (2012). Consolidated version of the Treaty on the Functioning of the European Union. *Official Journal of the European Union*, C 326, 26.10.2012, p. 141.

34 Lee M (2015). Accountability and Co-Production Beyond Courts: The Role of the European Ombudsman, in Weimer M & de Ruijter A (eds). *Regulating Risks in the European Union: The co-production of Expert and Executive Power*. Hart Publishing, pp. 217–40.

35 European Ombudsman. Decision of the European Ombudsman in case 1069/2019/MIG on sponsorship of the Presidency of the Council of the European Union; see also the initiation of a follow up inquiry in March 2024, Corporate sponsorship of the Presidency of the Council of the European Union, case SI/3/2024/MIG.

36 European Ombudsman. Decision on how the European Commission ensures the transparency of the Medical Device Coordination Group (case 2132/2022/KR).

37 European Ombudsman. The composition of the European Commission's Regulatory Scrutiny Board and how it interacts with interest representatives (Case 439/2023/KR).

of the coalitions for and against an idea, and the two bodies can choose as rapporteurs champions who are effective at influencing the agenda on a specific point. They are not, however, inherently powerful actors.

2.1.6 Agencies

Beyond the central institutions of the EU, there is also a constellation of specialist EU agencies created to carry out specific tasks. There are many of relevance to health policy, including the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA),[38] the European Environment Agency (EEA), the European Chemicals Agency (ECHA), the Community Plant Variety Office (CVPO) and the European Agency for Safety & Health at Work (EU-OSHA). Their common denominator is that they are established by EU regulations, and their power is limited to the specific activities delegated to them in the legal act establishing them. Agencies are not the same thing as executive agencies (see Section 2.1.7), which are specialist parts of the Commission without their own legislative bases, or Commission Services, such as HERA.

The case for agencies in the EU is in large part the same as the case for agencies elsewhere. Agencies are partially freed from the changing priorities of the central civil service (in this case, the Commission) and can more easily hire and retain technical experts. Their focus and physical distance from Brussels make them more technocratic and, if not less political, at least less embroiled in the day-to-day politics of the EU. The governing regulations of the agencies give them clear and circumscribed missions which limit the possibility of so-called mission creep. Member States are represented on the boards of the agencies, so as to ensure the existence of an accountability forum and a limit on their political engagement. Member States often express the concern that the Commission will use any resources or mandates to expand its power.[39]

As a result of their attributes – predictability, technical focus and autonomy within limits – agencies have been a popular tool of EU action (although more so with national governments than with the European Parliament, which has raised doubts about its lack of oversight of agencies). Agencies are particularly densely concentrated in technical areas such as the safety of chemicals or aviation, where details are complex, intricate, not particularly visible in daily life, and prone to cause crises when they are not handled well.

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38 Urrestarazu A et al. (2019). Brexit threatens the United Kingdom's ability to tackle illicit drugs and organised crime: What needs to happen now? *Health Policy*, 123(6):521–5.

39 Pollack MA (2003). *The engines of European integration: delegation, agency, and agenda setting in the EU*. Oxford: Oxford University Press.

In political terms, a key limitation of these agencies is that they have no ability to propose changes to any of the legislation that they help to implement. Any such proposals still have to be made by the Commission. This means that such agencies may well be seen as technically authoritative, but they are not direct actors in the EU decision-making processes.

Another part of the appeal of EU agencies to national governments has been that they are distributed around the Union, rather than being based in Brussels. As well as distributing the benefits of jobs and economic activity more widely, countries have argued that they can provide particularly appropriate homes for certain agencies, such as through synergies with particular domestic facilities. How much difference the specific geographical location of an EU agency really makes to either the agency or its host country has been unclear but is undergoing some empirical tests with the post-Brexit moves of the European Medicines Agency from London to Amsterdam, and of the European Banking Authority to Paris.

In analysing EU agencies, it is important to remember that their powers and structures can vary significantly. Each has a governing regulation which specifies its scope of action, the composition of its board, the structure of its governance and the form and meaning of its actions. Agencies' governing boards in this regard form an extra level of control for Member States, and the composition of the boards matters and varies a great deal. Agencies with large boards (e.g. with representatives from every Member State) might have informed stakeholders but such unwieldy boards will often allow great autonomy to executives. Most agencies have to work closely with Member State agencies and organizations and the legal basis of that relationship will also be spelled out in the regulation. These legal bases can determine the power, autonomy, resources and practical impact of agencies and merit attention; it is not advisable to assume that lessons about agencies from one agency will transfer in a simple way to another.

2.1.7 Executive agencies

Not all EU agencies are specialist agencies with a statutory base such as EMA or ECDC. There is also a kind of agency, known as an executive agency, which lacks a statutory base of its own and is legally a component of the Commission, constituted under a 2003 Council decision creating the basis for delegation to executive agencies.[40] In health, this long meant CHAFEA (the Consumers, Food and Health Executive Agency), which was wound up in April 2021 with its roles mostly assumed by other grant management executive agencies within the

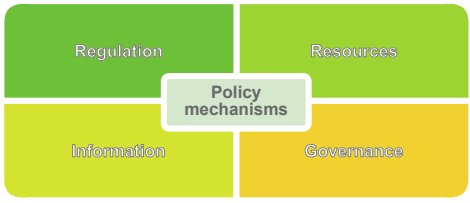
40 Council of the European Union (2002). Regulation (EC) 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes. *Official Journal*, L 011, 16/01/2003 P. 0001–0008.

Commission. Now it means a new 2021 agency related to pandemic preparedness and response: the European Health and Digital Executive Agency (HaDEA).

The new agency takes on the work of CHAFEA in administering health and safer food programmes, including the EU4Health programme, and became active in April 2021. As with its predecessor CHAFEA, HaDEA is part of a shifting ecology of EU executive agencies whose purpose is to support grant-making and contracting work in different areas. The basic logic of these executive agencies is that they concentrate intricate and routine specialist activity (e.g. managing the paperwork associated with bids and grant administration) in specific areas separate from other Commission work such as policy formulation and enforcement. The recurrent frustration is that delinking executive agencies focused on management of grants and programmes from the policy units can lead to poor communication about goals and performance. The lead DG for HaDEA is SANTE and HaDEA administers HERA tenders, but it is also responsible for work on behalf of the DGs for digital technology (DG CNECT, DG RTD and DG SANTE). Over the current MFF (see Section 2.2) it will administer around €20 billion of grants and programmes, about half of which will be health-focused (notably EU4Health, €4.7 billion of which is administered by HaDEA and the €4.1 billion Horizon Europe health cluster).

2.2 Mechanisms

Fig. 2.1 *Types of policy mechanisms*



As discussed in chapter 1, the EU has a particular set of available policy mechanisms that are not like those of the Member States. Compared to a Member State, it has a tiny bureaucracy, directly delivers almost nothing, has an enormously elaborated and powerful legal system and a very small budget, and sits amidst endless networks that it collaborates with to set practices and gather or diffuse information. Law and information are prominent in EU action, governance changes a common effect, and resources both much smaller than those of a Member State and deployed in quite different ways (loans and support for cross-border networks instead of, for example, paying for healthcare). This section describes policy mechanisms under four broad types: regulation, resources, information and governance (see Figure 2.1).

2.2.1 Regulation

The primary policy mechanism used by the European Union is law. This reflects the overall aims and history of the European Union, founded in order to bring its Member States closer together, in particular through reducing barriers to trade between them. The central mechanism through which the EU has reduced barriers and differences between EU countries has been laws at the European level in place of different national laws.

The EU's law-making powers are set out in the EU's Treaties. The different articles of each Treaty address different areas of potential action, setting out what the EU's aims are in that area and what mechanisms the EU can use to achieve them. While the EU can only legislate within those powers that the Treaties specifically provide, there is enough flexibility that in practice the scope for EU legislation is very wide, provided that there is sufficient political agreement.

The way that the Treaties provide the EU with powers to act on health is fragmented, which makes it hard to grasp the scope of the EU's potential role on health. The specific Treaty provisions enabling action on health are narrow in scope, as described in chapter 1 and presented in the Annex. In particular, the ability to use regulation directly for health is limited, and focused on specific areas such as blood, tissues and human organs, and quality and safety of medicinal products and devices for medical use.[41] The EU does have much wider powers to use regulation for health and has done so, but these derive from other Treaty provisions whose primary objective is not health.

This creates two challenges. The first is one of visibility. It is much harder to understand the full breadth of how regulation is used by the EU to affect health than in Member States, where regulation for health is typically concentrated in health-specific legislation. The second is one of tensions between policy objectives. Because the primary objective of most EU regulation on health is not health itself, there are tensions between those other objectives and health objectives which can create limits on EU action for health which sometimes appear illogical from a health perspective.

The need to accommodate the differences between countries means that there are two basic types of European law. Regulations are those which, like typical national laws, apply directly and universally throughout the EU. The EU also legislates through directives, which require Member States to adopt measures that achieve a certain effect, but leave it up to them how to do so, with the aim of achieving an EU-wide result while allowing for different approaches within different EU countries. In addition to these two basic types of EU law, there are also decisions (which only apply to those to whom they are addressed), as well

41 See Article 168.4 TFEU.

as secondary acts which the Commission is empowered to adopt by the Council and Parliament, typically in technical or fast-changing areas where it would be impractical to keep updating the underpinning legislation.

Another mechanism of indirect EU regulation is through standards. These are technical specifications developed and agreed by stakeholders for products or services which can act as a means of regulation for the areas they cover, and be used to show compatibility with regulatory requirements. They are largely developed at the initiative of stakeholders, although the European Commission can also push for specific standards.[42] They are particularly relevant for health-related products such as medical devices.

2.2.2 Resources

The second major policy mechanism in most areas of government is resources – principally funding through public expenditure, although in the case of health the health workforce is also a vital resource. However, in this respect the EU's powers are particularly weak, with relatively limited public expenditure through the EU. General government expenditure averages around 50% of gross domestic product (GDP) across the EU, but this is overwhelmingly spent within the Member States themselves. The EU's own resources are capped at just under 1.5% of the EU's gross national income (although this was temporarily raised to 2% to cover additional expenditure related to the COVID-19 pandemic recovery). In other words, the overwhelming majority of public expenditure within the EU is decided within the EU countries themselves rather than through the EU institutions, making allocation of resources an usually weak policy mechanism for the EU.

The EU has an annual budget cycle but its key budget cycle runs for seven years and is known as the Multiannual Financial Framework (MFF). The MFF concentrates the biggest arguments about funding instruments and priorities into one septennial argument. The EU is currently in the 2020–2027 MFF, which means key decisions about the fate of programmes, including the COVID-19 pandemic response programmes in health, will be negotiated in 2026 and 2027.

The COVID-19 pandemic has led to a novel addition to the EU's funding: an additional recovery fund (Next Generation EU or NGEU) of €750 billion to help finance the EU's recovery from the pandemic, including by providing additional funding to existing instruments. Unusually, this is being financed by borrowing, to be supported in the future by new revenue streams for the EU. The NGEU funding was initially crafted with a broad focus on economic

42 For more information about harmonized standards see https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en (accessed 16 July 2024).

recovery and resilience.[43] Although health was not its primary focus, the pandemic highlighted the need for more robust health systems, which led several Member States, including Spain,[44] to incorporate health-related investments into their recovery plans. Consequently, the NGEU supported significant investments in healthcare infrastructure, digital solutions, and public health capacities. Additionally, a portion of the funding was also directed toward improving the EU's capacity to respond to health emergencies, including vaccine distribution and the development of new medical treatments.

Even within this limited amount of EU expenditure, health has a much smaller allocation at EU level than is the case at country level, where it is typically the second-largest area of public expenditure. The only EU financing programme dedicated to health is EU4Health, established with a budget of €5.3 billion over the period 2021–2027. Even though this is over ten times larger than the previous EU health programmes, it remains less than one-half of one percent of the total EU budget. Moreover, at time of writing, the EU institutions had decided to cut this by €1 billion as part of measures to redirect EU funds to support Ukraine. With or without that cut, the size of the health programme within an already very small overall EU budget means that the EU's health programme can only ever be a small and supplementary mechanism for health policy, although it has been effective in supporting European collaboration and building capacity.

However, as with regulation, there are many more areas of EU resources that can support health policy objectives than just the dedicated health programme, even though health is not their primary aim. This includes some of the largest EU funds, among them the Recovery and Resilience Facility, the Cohesion Policy Funds, the Horizon Europe research programme, InvestEU and support from the European Investment Bank.[45] These can provide support in different ways, according to their primary objectives. For example, the Cohesion Policy Funds can support infrastructure and capital investment in improved health and care facilities, and have become an important source of support for less well-off Member States in particular. The funds have also invested in education and training programmes for health workers.

Health is one of the foremost priorities of the Horizon Europe research programme, and the EU also helps to coordinate European funding of research more generally

43 Bisciari, P., Butzen, P., Gelade, W., Melyn, W., & Van Parys, S. (2021). The EU budget and the Next Generation EU Recovery Plan: a game changer. *NBB Economic Review*, 2, 29–67.

44 Council of the European Union (2021). Council Implementing Decision (EU) 2021/1087 of 28 June 2021 on the approval of the assessment of the recovery and resilience plan for Spain. *Official Journal of the European Union*, L 234/14. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D1087

45 Fahy, N, Mauer, N., & Panteli, D. (2021). *European support for improving health and care systems* (Policy Brief 43). European Observatory on Health Systems and Policies. Available at: https://eurohealthobservatory.who.int/publications/i/european-support-for-improving-health-and-care-systems.

to maximize effectiveness and avoid duplication, such as through partnerships which provide a basis for collaboration between the Commission and other public or private sector actors.

2.2.3 Information

The third type of policy mechanism is information: the use of instruments aiming to change behaviour without the compulsion of regulation or the incentives of resources. This type of tool is widely used by the EU. Indeed, there are specific categories of official documents from EU institutions which make formal statements, most frequently communications from the European Commission and conclusions from the Council of Ministers, and these can have substantial impact.

There are also formal recommendations, which may be adopted by the Commission or the Council, and which explicitly aim to direct behaviour but which have no binding power. For example, the Council Recommendation on cancer screening which recommended screening for breast, cervical and colorectal cancer,[46] and which was supported by detailed technical guidelines,[47] became a reference point for cancer screening programmes across the EU.

A particularly effective form of EU information has been comparable data about health across EU countries. Again, cancer has been an area of where comparable data have had a particularly powerful effect on policy.[48] More widespread use of comparable data for health policy has been limited, however, by the relative lack of comparable data for health at a European level. The scope of health data in official European statistics has been limited in part linked to concerns about subsidiarity in the sensitive area of health. European Union agencies in particular areas have had the capability to develop more detailed comparable data, notably the European Centre for Disease Prevention and Control on communicable diseases and the European Union Drugs Agency (formerly the European Monitoring Centre on Drugs and Drug Addiction). But the EU lacks any such agency for health overall, leaving a relative lack of data for key policy areas such as non-communicable diseases.

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46 Council of the European Union (2003). Council Recommendation on cancer screening (2003/878/EC). *Official Journal*, L327/34.

47 Perry, N., Broeders, M., de Wolf, C., Törnberg, S., Holland, R., von Karsa, L., & Puthaar, E. (Eds.) (2006). *European guidelines for quality assurance in breast cancer screening and diagnosis* (4th ed.). Office for Official Publications of the European Communities.

48 Coleman, M. P., Alexe, D.-M., Albreht, T., & McKee, M. (Eds.) (2008). *Responding to the challenge of cancer in Europe*. Institute of Public Health of the Republic of Slovenia.

2.2.4 Governance

The fourth policy mechanism we describe is governance: the institutions and structures of a system, and the processes through which they interact. As with the other policy mechanisms, the governance of health at the EU level is highly fragmented. Most of the EU's action on health arises as a dimension of other policies, rather than as a specific objective in its own right. The result is a very wide range of European tools with an impact on health, but operating according to a bewildering range of different objectives, structures and processes. These tools do not align well with typical governance structures for health in Member States, where ministries of health are the principal actors on policy mechanisms for health. This lack of alignment between governance structures for health at Member State and European levels has created persistent frictions and dislocations between national and European action for health.

2.3 Influencing factors

Brussels is commonly referred to as the European capital of lobbying,[49] and the second global capital of lobbying after Washington DC.[50] The early literature on EU lobbying and interest groups describes "the extreme openness of [EU] decision-making to lobbyists" as part of a distinct EU public policy style that differs greatly from traditional forms of interest representation in Member States.[51] The drivers of this receptiveness to influence are threefold. Firstly, throughput legitimacy – the result of a robust policy process emphasizing extensive consultation and participation – is crucial to the EU's wider democratic credentials, particularly in the absence of a clear demos and high policy visibility.[52] Secondly, and linked to this, it has historically been in the Commission's interest to nurture constituencies of interests, by directly networking and resourcing them, so as to garner support for its specific initiatives.[53] Finally, the Commission is a small bureaucracy managing a large and complex portfolio of policies, and

49 Laurens, S. (2017). *Lobbyists and bureaucrats in Brussels: Capitalism's brokers*. Routledge.

50 The Economist (2021). *The power of lobbyists is growing in Brussels and Berlin*. https://www.economist.com/business/2021/05/15/the-power-of-lobbyists-is-growing-in-brussels-and-berlin (accessed 19 August 2024).

51 Coen, D. (2009). Business lobbying in the European Union. *Lobbying the European Union: institutions, actors and issues*, 145–168. Richardson, J. (2006). *European Union: Power and policy-making* (3rd ed.). Routledge.

52 Schmidt, V. A. (2013). Democracy and legitimacy in the European Union revisited: Input, output and 'throughput'. *Political Studies*, 61(1), 2–22. https://doi.org/10.1111/j.1467-9248.2012.00962.x

53 Mazey, S., & Richardson, J. (2006). Interest groups and EU policy-making: Organizational logic and venue shopping. In J. Richardson (Ed.), *European Union: Power and policy-making* (3rd ed., pp. 247–268). Routledge.

thus relies on outside expertise to support policy-making.[54] As such, where competences are transferred to the EU level, we should expect a proliferation of interest groups to shortly follow.

Health is an exception that proves the rule. While the legal mandate in health is comparatively narrow, suggesting that the pool of stakeholders will be small, there are more interest groups in the health field than in most other policy domains.[55] This is explained by the economic significance of the sectors that market-related health policies address – pharmaceuticals, medical devices, food safety – and by the scope and impact of EU activity that affects health. The explicit legal competence is narrow but, as this book demonstrates, the range of health-shaping activities that the EU engages in reaches far beyond it, and the community of interest groups seeking to understand and influence this activity has grown accordingly.

This section maps the landscape of EU health interest groups, the sites via which they access and influence health policy, and the role that the Commission plays in nurturing them.

2.3.1 Interest groups in EU health policy

Identifying health stakeholders is difficult. Practically speaking, the various registers, lists and databases that might be used for such a task are fragmented, come and go over time, and are more or less helpful in recording and presenting information about the actors that they register. At best, they present a snapshot in time. Given the speed at which temporary lobbying operations can be established and dismantled, such a list is quickly outdated. Using them to identify the community of health stakeholders also assumes that everyone in that community wishes to be identified; in reality, not all like to be publicly visible and some have incentives to operate through other organizations that conceal their underlying interest. Institutionally, what the field of health policy encompasses changes over time; for instance, the addition of food safety to the DG SANTE and ENVI Committee portfolios, and the relocation of responsibility for pharmaceuticals shifted the boundaries of what is considered health policy during particular political mandates.[56] On a case by case basis, there will be disagreement about what these boundaries mean for specific actors: are multinational agricultural

54 Bouwen, P. (2002). Corporate lobbying in the European Union: The logic of access. *Journal of European Public Policy*, 9(3), 365–390. https://doi.org/10.1080/13501760210138796. Broscheid, A., & Coen, D. (2007). Lobbying activity and fora creation in the EU: Empirically exploring the nature of the policy good. *Journal of European Public Policy*, 14(3), 346–365. https://doi.org/10.1080/13501760701243749

55 Coen, D., Katsaitis, A., & Vannoni, M. (2021). Business lobbying in the European Union. *Oxford Research Encyclopedia of Politics*. https://doi.org/10.1093/acrefore/9780190228637.013.2038

56 de Ruijter, A. (2019). *EU health law & policy: The expansion of EU power in public health and health care*. Oxford University Press.

companies legitimate health policy interests, either in their own view or the view of others? Across issues, health advocates also need to engage outside of the health policy field, to promote health within initiatives on trade, transport, agriculture, research and numerous other non-health topics, meaning that the lobbying of most significance to health may not be happening within the health policy field at all.

There are two primary platforms via which an organization might declare their interest in EU health policy, and from which we might thus identify a community of health stakeholders. The first is the Transparency Register, a database of "interest representatives" whose activities are designed to influence EU policy-making. Since the 2021 interinstitutional agreement was adopted, the register operates across all three legislative institutions on a principle of conditionality. Registration is not legally required but is a precondition for interest representatives to be able to carry out certain activities, including participating in meetings with institutional staff, Parliament intergroups and Commission expert groups.[57] The EU Health Policy Platform (EUHPP) is an online community of health stakeholders, managed and moderated by DG SANTE. It replaces and is different from the European Health Forum (EHF), which was a consultative body used to solicit feedback on health policy files and initiatives. The EUHPP, by contrast, is a "multilateral communication channel" structured around various thematic networks and discussion spaces.[58] Members should appear in the Transparency Register (with some exceptions), commit to health promotion, protection and improvement, and may not use the platform for commercial purposes.

In May 2024, the Transparency Register contained 12 604 entries, of which 3594 organizations listed public health as a field of interest, while the EUHPP listed 9128 platform users, of which 6518 are users of the EUHPP's networks. Comparable historical data are not available but, using an earlier database[59] identified 70 health-related groups (from a pool of 700 listed groups) in 2008, illustrating the transformation of the EU interest group landscape over this period. So who are these stakeholders and how do they (seek to) influence EU health policy-making?

Some qualifications should first be made. Among those listing public health as an interest in the Transparency Register are organizations whose entries indicate,

57 European Union (2021). Interinstitutional agreement between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register. *Official Journal of the European Union*, L 207, 12–26. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.207.01.0012.01.ENG&toc=OJ%3AL%3A2021%3A207%3ATOC

58 European Commission (2023a). *EU Health Policy Platform*. Available at: https://health.ec.europa.eu/eu-health-policy-platform_en (accessed 19 August 2024).

59 Greer, S. L., Da Fonseca, E. M., & Adolph, C. (2008). Mobilizing bias in Europe: Lobbies, democracy and EU health policy-making. European Union Politics, 9(3), 403–433. https://doi.org/10.1177/1465116508093491

for instance, that they are not active at the European level, and that they are interested in up to 40 policy areas, of which public health is just one. Similarly, membership of the EUHPP is relatively easy to acquire, and is granted on an individual basis, meaning that multiple individuals from the same organization commonly register (for instance, 68 of the 6158 EUHPP network users list DG SANTE as their organization). Moreover, there are likely numerous registrants on both platforms that are largely inactive through choice, and a handful of others that, as theories of interest groups politics anticipate, can be considered insiders. Insider forums are created in policy fields that have large numbers of interest groups and therefore an unavoidable level of so-called babbling, from which policy-makers need to identify technical and policy-relevant information.[60] The EHF was a good example of this kind of forum, set up with an open forum for mass participation and a smaller, permanent forum for chosen interest groups.[61] In the less consultation-driven EUHPP, an equivalent gauge of activity might be membership of a thematic network. In May 2024, the platform's three exchange networks – run by DG SANTE on the themes of climate and health education in Europe, digital skills for doctors, and training on migration and health – had 131, 120 and 59 members respectively. As a crude indicator, this would suggest that a higher number of declared health interest groups does not necessarily correlate with more active and engaged stakeholders.

Combining the most active members of the EUHPP (via its directory function), participation in recent key health consultations, and membership of the EU4Health Civil Society Alliance, there are some clear repeat players in the EU health stakeholder community, most of which are Eurogroups (EU-level associations). Within civil society, they include the Association of European Cancer Leagues (ECL), the European Association of Hospital Pharmacists (EAHP), the European Cancer Organisation (ECCO), the European Consumers Organisation (BEUC), the European Public Health Alliance (EPHA), EuroHealthNet, the European Association of Public Health (EUPHA), the European Patients Forum (EPH), and the Standing Committee of European Doctors (CPME). Key industry groups are the European Federation of Pharmaceutical Industries and Associations (EFPIA), Medicines for Europe, MedTech Europe and EuropaBio, but repeat engagement by specific companies (MSD, Novartis and Sanofi are particularly active) and national associations (the German Medical Association, the Irish Cancer Society and the Norwegian Institute of Public Health, for instance) can also be observed.

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60 Broscheid, A., & Coen, D. (2007). Lobbying activity and fora creation in the EU: Empirically exploring the nature of the policy good. *Journal of European Public Policy*, 14(3), 346–365. https://doi.org/10.1080/13501760701243749

61 Greer, S. L., Da Fonseca, E. M., & Adolph, C. (2008). Mobilizing bias in Europe: Lobbies, democracy and EU health policy-making. *European Union Politics*, 9(3), 403–433. https://doi.org/10.1177/1465116508093491

2.3.2 Sites of access, influence and coalition-building

Interest groups engage in, influence and seek to influence EU health policy via short-term advocacy targeting a specific legislative file or development, and longer-term, sustained involvement within relevant networks.

2.3.2.1 Consultation and EU health policy-making

The Commission is required to conduct a 12-week open public consultation (OPC) for all initiatives that will have an impact assessment, as well as for evaluations conducted alongside impact assessments, and Green Papers; it is recommended to conduct them for fitness checks and evaluations of broad public interest.[62] Since 2021 the OPC is included in a call for evidence, which also encompasses previously separate steps where stakeholders can offer feedback on the inception impact assessment or roadmap. Such open formats are complemented by closed instruments, including targeted consultation meetings, interviews or surveys with groups of invited stakeholders, as well as bilateral interviews and meetings with the Commission officials working on the file (see Table 2.2). In addition to the call for evidence document, the Commission also solicits feedback on draft delegated and implementing acts, and adopted legislative proposals. At any time, an interested party can make a submission to the *Have Your Say: Simplify!* portal,[63] which collects citizens' views on EU laws and considers them for simplification and/or modernization.

Table 2.2 *EU consultation instruments*

Instrument	Openness
Open public consultation	Open
Feedback	Open
Conferences and public hearings	Generally open
Workshops and seminars	Generally closed
Interviews, focus groups and surveys	Closed
Bilateral and small group meetings	Closed
Dialogue with and within existing bodies/formal structures	Closed

2.3.2.2 Networks, forums and platforms

A number of networks, forums and platforms have been established by the Commission over the years, to acquire information, foster ownership of policy objectives and strengthen the legitimacy of its health policy. Key among these were the EU platform for Diet, Physical Activity and Health, the High-Level Group on Nutrition and Physical Activity, and the EU Alcohol and Health Forum.

62 European Commission (2021). *Better regulation: Guidelines and toolbox*. Available at: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en (accessed 19 August 2024).

63 European Commission (n.d.). *Have your say: Simplify!* Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say-simplify_en (accessed 19 August 2024).

Each ceased operation in the 2010s and their work is now subsumed under the Beating Cancer stakeholder contact group (hosted on the EUHPP) and the Steering Group on health promotion, disease prevention and management of non-communicable diseases, as part of the Commission's commitment to addressing the United Nations Sustainable Development Goals (SDGs). Events such as the annual European Health Forum Gastein and the annual in-person conference of the EUHPP offer additional opportunities for networking, coalition-building and influence.

2.3.3 Nurturing influencing factors: civil society, legitimacy and democracy

The EU's distinctive politics, in which much of its work is done by and through Member States, courts and others, means that interacting with Europe's enormously diverse societies and maintaining its credibility as a democratic, responsive polity and responsible policy-maker takes work. This work is made harder by the problems discussed above of identifying influences. How does the EU manage influences on its health policies?

2.3.3.1 The European Commission and health civil society

Keen to foster legitimacy in its policy processes, and as part of its wider priority "A new push for European democracy", the Commission has spearheaded initiatives such as the Conference on the Future of Europe, and the European citizens' panels, to enhance participation in EU decision-making. Pressure to better recognize and support the role of civil society has been growing, particularly since the COVID-19 pandemic. In June 2022, Civil Society Europe and the European Civic Forum submitted a letter signed by over 300 civil society organizations, calling for the development of a European civil society strategy.[64] Referencing the World Health Organization's (WHO) Framework for engagement with non-state actors, the EU4Health Civil Society Alliance has specifically called for more meaningful engagement of public health civil society in EU policy-making, going beyond the EUHPP.[65] It argues that health civil society provides expertise on health issues to inform policy development, supporting the application of the health in all policies principle, and contributes to implementing programmes such as the European Green Deal and the SDGs. Civil society organizations are

64 Civil Society Europe. (2022). *Letter to the European Commission: Call for a European civil society strategy*. Available at: https://civilsocietyeurope.eu/wp-content/uploads/2023/08/Civil-Society-Strategy-letter-3.pdf (accessed 26 August 2024).

65 EU4Health Civil Society Alliance. (2022). *Statement: Call for a stronger engagement of public health civil society in EU policy-making*. Available at: https://eu4health.eu/content/uploads/2022/12/221215-meaningful-engagement-of-health-csos-joint-position-paper-final-version.pdf (accessed 26 August 2024).

also partners in the delivery of EU health programmes, including the EU4Health programme, and in raising broad awareness of health issues and EU actions.

2.3.3.2 Regulating lobbying activities while preserving the EU civic space

Although the EU is known as an open and participatory decision-making system, the civic space in Brussels is under increasing pressure. In January 2024 the European Parliament adopted a report on the transparency and accountability of non-governmental organizations (NGOs) funded from the EU budget. An odd amalgamation of praise for the work done by NGOs and warnings about "the danger of EU funds […] being subject to fraud and irregularities, foreign interference or entryism", the report is nevertheless of concern to civil society activists.[66] For health NGOs, it follows a period of funding uncertainty. In 2021 plans to remove operating grants from the EU4Health programme were abandoned but a one-year funding cycle was introduced in their place, hampering long-term planning. A Framework Partnership Agreement was published in March 2024, inviting NGOs to apply for a two-year operating grant in the 2025–2026 period.[67] But in light of the €1 billion cut from the EU4Health programme in January 2024, the extent and sustainability of this funding, and how activity during the end of the current funding period will be affected, is again uncertain.[68]

Beyond the health field, the EU institutions have taken a number of steps in response to various scandals and a perceived threat that foreign agents are able to influence EU policy and law-making. The EU institutions have responded with measures aimed at safeguarding the decision-making process and increasing transparency, although these have not all been met favourably by civil society campaigners. In December 2023 the Commission published a proposal for a directive on the transparency of interest representation on behalf of third countries[69] as part of its Defence of Democracy package. The proposed text requires interest groups to keep records of any activity in which they represent third countries. It has raised concerns that, while seeking to

66 Civil Society Europe (2024). *Report on the transparency and accountability of non-governmental organizations (NGOs) funded from the EU budget*. Available at: https://www.europarl.europa.eu/doceo/document/A-9-2023-0446_EN.html (accessed 19 August 2024).

67 European Commission (2024). *Framework Partnership Agreement: Operating grants for NGOs under the EU4Health programme 2025–2026*. Available at: https://hadea.ec.europa.eu/calls-proposals/eu4health-call-proposals-framework-partnership-agreement-operating-grants-2025-2026-non-governmental_en (accessed 19 August 2024).

68 EU4Health Civil Society Alliance (2024). *Statement on the €1 billion cut from the EU4Health programme and its implications*. Available at: https://eurohealthnet.eu/publication/the-eu4health-civil-society-alliances-statement-for-a-strong-and-stable-eu4health-programme/ (accessed 19 August 2024).

69 European Commission (2023). *Proposal for a directive on the transparency of interest representation on behalf of third countries* (COM(2023) 900 final).

protect EU policy-making from undue interference from foreign and malicious interests, it imposes unfeasible obligations on legitimate civil society organizations, risks stigmatization and mistrust, and infringes on freedom of association.[70] Meanwhile, eight EU institutions reached agreement in April 2024 to create a joint Body for Ethical Standards. The ethics body will develop and report on minimum standards for ethical conduct across the Parliament, the Council of Ministers, the Commission, the Court of Justice, the European Central Bank, the European Court of Auditors, the European Economic and Social Committee and the European Committee of the Regions. The European Council is not a signatory, and the body has been criticized as "toothless", given the absence of effective independent monitoring, oversight and sanctioning.[71]

2.4 Conclusion

The particular institutional structure and history of the EU has given it a distinctive and often powerful set of policies for health. The institutional structures described here help to explain how it has been created and how it might change and help to identify some of the levers and options within the system.

The next chapters show how these institutions and political processes work: in public health, in healthcare, in the green, social and digital transitions, in fiscal governance and in global health policy. Tensions between centralization and fragmentation, formality and informality in governance, and asymmetry between market-making and social policy mark all these areas. The challenge for the increasingly centralized European institutions is to manage and respond to increasing political fragmentation in an effective way that promotes health.

70 Evroux, C (2024). *Making representation of third countries' interests more transparent*. European Parliament Research Service. Available at: https://www.europarl.europa.eu/RegData/etudes/BRIE/2024/762312/EPRS_BRI(2024)762312_EN.pdf (accessed 26 August 2024).

71 Nielsen, R. P. (2023). Ethical Engagement: Observer Obstacles. In *Encyclopedia of Business and Professional Ethics* (pp. 730–737). Cham: Springer International Publishing.

Chapter 3

Public health

3.1 What is European Union public health policy?

It might seem natural, if you want to know about the content of EU public health policy, to start with the Treaty article on public health, Article 168 TFEU. Comparing that article with the actual contributions to health and health policy of the EU over time will, however, show just how poor a guide to health policy that Treaty article can be.

Health appears in multiple places throughout the Treaties. It is an explicit goal of the EU as a whole (Article 9 TFEU) and an explicit goal of social policy, environmental and consumer protection policy (see Annex). In fact, the largest impacts of the EU on public health have historically not been through health. Those social (occupational health and safety), environmental and consumer protection policies have made the lives of millions of people healthier and safer. On the other hand, policies such as the austerity programme of the so-called Troika (European Commission, European Central Bank and International Monetary Fund) after 2010 have had demonstrable, large, negative effects on health.[1] The application of internal market rules has also created substantial friction and legal or compliance issues with unclear net benefits, particularly with regards to healthcare topics discussed in chapter 4 such as patient mobility rules, professional regulation, and the application of state aids and competition law.

Meanwhile, Article 168 TFEU, the obvious place to look for public health, was written to enable just as much public health action as the Member States wanted. The Treaty language authorizing public health action was careful and constraining, enabling the EU institutions to take actions that complemented and supported the Member States, rather than led or constrained them. We likened it in the second edition of this book to a gate with no fence: in Article 168 TFEU, the Member States built a solid gate, one they could open and shut as they wished,

1 The justification for austerity measures is generally not their effect on health; it is that they are unavoidable and good for long-term welfare, which would in the future improve health among other social indicators. Thomson S, Figueras J, Evetovits T, Jowett M, Mladovsky P, Maresso A, et al. (2015). *Economic crisis, health systems and health in Europe: impact and implications for policy*. Copenhagen: WHO Regional Office for Europe. For a summary of the health effects, see Kentikelenis A, Stubbs T (2023). *A thousand cuts: social protection in the age of austerity*. Oxford University Press.

but the absence of a fence meant that health policy could be made by simply going around it using Treaty bases in areas such as the internal market. The result was that much EU health policy was historically made outside the sphere of Article 168 TFEU, DG SANTE or the health politics world in general.

In 2020 the EU's leaders opened the gate. All the tentative language authorizing EU health action turned out to be useful as well as constraining, constituting a Treaty base for a dramatic expansion in the activity and resources of the EU in public health policy and even aspects of healthcare. This chapter discusses the EU public health world in the aftermath of 2020's decisions, reviewing both older areas of EU engagement such as tobacco control, and the old but dramatically expanded work in public health protection and health emergency response.

Besides a number of references to the protection of public health throughout its constitutional legal instruments, Treaty Article 168 TFEU creates the legal basis to adopt public health law and policies. There is a Directorate-General for Health (DG SANTE) and a set of health forums, strategies and policies. Right from the introduction of a specific article on health in the Maastricht Treaty (formally the Treaty on the European Union [TEU]) in 1992,[2] the challenge of EU public health policy has been to strike a balance between potential common interests in working on health and the high degree of national sensitivity and specificity about health matters. This is reflected in the complex language of that article, in particular the requirement that the Union "respect the responsibilities of the Member States" for their health systems.[3] Although legally this provision does not really add much to the formal division of powers between the EU and the Member States (Article 5 TEU), it highlights the concerns of national governments in drafting the Treaty provisions on health.

The nature of competences is summarized at the start of the TFEU, which came into force in 2009. The only area of shared competence between the EU and the Member States in health is "common safety concerns in public health matters"[4] for the wider objective of the "protection and improvement of human health",[5] and even then the EU may only "support, coordinate or supplement" Member States' actions.[6]

Article 168 TFEU (see Annex) attributes legislative and policy-making powers to the EU in the area of public health. This is a deliberate attempt by the drafters of the Treaties to orient EU action towards population-level measures and away from action on health services and individual access to medical care,

2 European Communities (1992). *Treaty on the European Union*. Luxembourg: European Communities. Available at: http://www.eurotreaties.com/maastrichtec.pdf (accessed 1 May 2019).
3 TFEU, Article 168, paragraph 7.
4 TFEU, Article 4, paragraph 2(k) j; Article 114 TFEU.
5 TFEU, Article 6, subparagraph (a).
6 TFEU, Article 6.

which involves significant public finances. Indeed, the objective of restricting EU action in healthcare is reflected in the objectives of the article, which are focused towards public health activities and health determinants (tobacco and alcohol being specifically mentioned).

Furthermore, the powers given to the EU to achieve public health objectives are limited. The only area in which Article 168 TFEU calls for binding legislation covers concerns of quality and safety standards for substances of human origin, blood and blood derivatives.[7] Article 168 TFEU does also provide for the EU to give financial support for actions more broadly in support of public health,[8] but this of course depends on the budgetary means available, which have in practice also been very limited. The article does include a "mainstreaming clause" requiring health protection to be ensured in all EU policies and activities,[9] but this does not in itself provide a basis for additional measures.

There are also some additional mechanisms provided in Article 168 TFEU, mostly information and guidance as defined in Chapter 2. One is the power for the Council of the European Union to adopt recommendations in support of the objectives of the article. These recommendations are non-binding acts. While these are not exactly the most powerful of instruments, they have been used to good effect in the health area, such as establishing a European commitment to cancer screening or global health.[10]

Another form of policy-making power is the provision in the Treaty for Member States to coordinate their own policies in areas too sensitive for legislation or outside their scope, working through "the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation".[11]

The EU's considerable powers and activities that affect the determinants of health go far beyond the constraints of Article 168 TFEU. This chapter begins with those determinants, showing key EU policies that affect the social and commercial determinants of health. Looking at determinants of health (see Figure 3.1) reframes individual problems and behaviours such as smoking or drinking by showing how they are affected by broader social and economic structures such as exposure to pollution or stressful work schedules. The first half of this chapter discusses a range of key EU policies that affect these determinants and therefore health, from tobacco use to occupational health and safety. In most cases the Treaty bases for these policies lie outside health, but we have seen more

7 TFEU, Article 168, paragraph 4.
8 TFEU, Article 168, paragraph 5: "incentive measures" refers to financing tools, not binding legislation.
9 TFEU, Article 168, paragraph 1; see also Article 9.
10 Council of the European Union (2003). Council recommendation 2003/878/EC on cancer screening. *Official Journal*, L 327/34.
11 TFEU, Article 168, paragraph 2.

explicit attention to health over the decades. In some cases, such as environmental protection and workplace health and safety, we might see the most effective health policies the EU has made in its history.

The second half of the chapter focuses on public health policy – the policies that could come through the sturdy gate called Article 168 TFEU. These are primarily focused on communicable disease control and health emergencies, are justified primarily by Article 168 TFEU, and are led or implemented by DG SANTE within the Commission. They include the bulk of public health policy responses to the COVID-19 pandemic, including both immediate responses and new initiatives designed to prepare for future health emergencies. We also include the civil protection system here. While civil protection is authorized under Article 196 TFEU rather than Article 168, its role in health since 2020 has become so important as to merit discussion here. This is despite its distinctive politics and organizational as well as legal footing.

3.2 Determinants of health

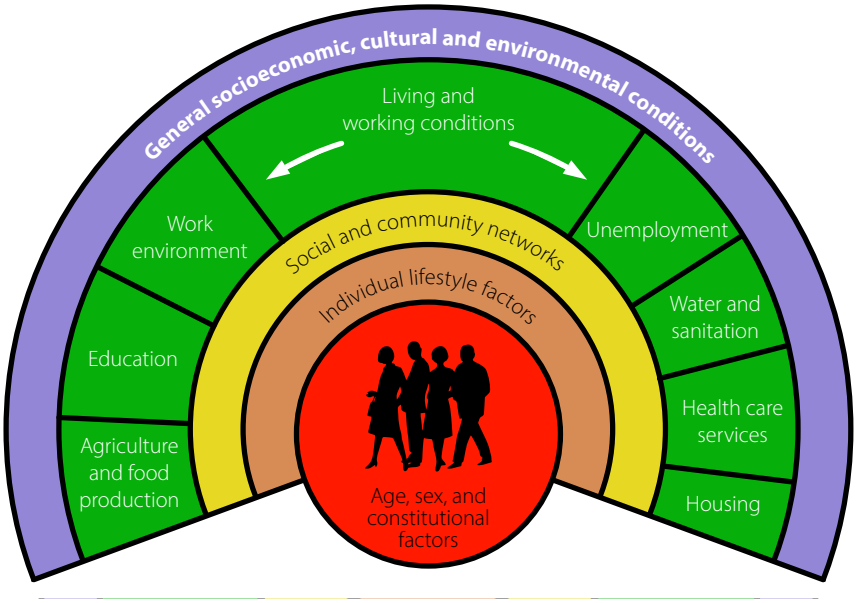
Many of the EU's policies address the social determinants of health. These are "the non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live and age, and the wider set of forces and systems shaping the conditions of daily life."[12] Understanding how social determinants affect health outcomes is a vital part of identifying policies that can both improve those outcomes overall and improve societal equity.

Public health actors around the world frequently use rainbow models to map determinants of health and raise awareness of the connections between them. Figure 3.1 shows a commonly used rainbow model of social determinants of health, the Dahlgren-Whitehead model, to show areas where policy-makers such as those of the EU can act.

As represented in the rainbow model, determinants of health are social rather than personal, and amenable to such policies as the EU can make. Truncating the analysis of individual or population health to individual lifestyle factors (e.g. smoking or eating habits) ignores powerful policy determinants identified in the rainbow. To ignore the whole rainbow is both analytically wrong, given that social, economic and political factors influence health behaviours, and a very constricting view of what policy is and can do. Focusing on individual behaviours and persuasion is notoriously ineffective in public health because people are social

12 This is the WHO definition, at https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1 (accessed 16 July 2024).

Fig. 3.1 *Rainbow model of determinants of health*



Source: Patient Safety Learning (n.d.). *The Dahlgren-Whitehead rainbow (1991)*. Available at: https://www.pslhub.org/learn/improving-patient-safety/health-inequalities/the-dahlgren-whitehead-rainbow-1991-r5870/ (accessed 28 August 2024).

animals who live in economies and environments they did not create.[13] Simply advocating individual lifestyle changes such as more sleep or exercise for people working long hours or in areas with unsafe street infrastructure is ineffective and can be borderline insulting.

Policies across the rainbow often have an important policy dimension that the EU can affect. In this chapter we emphasize a series of determinants of health in which the EU is particularly important, including commercial determinants of health (e.g. regulation of the tobacco and alcohol industries), environmental policy, social policy, consumer protection, and food safety. We exclude healthcare services, which are an important policy-responsive determinant of health, simply because they are discussed in chapter 4. The Europe's Beating Cancer plan currently touches on many of these areas of policy and provides some focus to a diverse range of determinants and policies that are not always regarded as health policies.

The following sections discuss some of the EU's most important policies that explicitly address social determinants of health, including tobacco use, alcohol use, diet, nutrition and physical activity, environmental pollution and climate change, health and safety at work, consumer protection, and cancer. We discuss

13 Lynch, J. (2020). *Regimes of inequality: The political economy of health and wealth*. Cambridge University Press.

food safety in Chapter 5 (see Section 5.3.2). Chapter 5 also discusses EU environmental policy, which is enormous and complex. We cannot do it justice here beyond highlighting its large current and potential benefits for public health.

3.2.1 Tobacco control

Tobacco is one of the largest causes of sickness and death in the world and remains a significant avoidable health risk for people living in the EU. Although smoking prevalence has decreased in many Member States in the past decade, prevalence in others is static, and the disparity among states in levels of smoking remains large.

Best practice tobacco control policies are defined internationally by the acronym MPOWER. States should:

- Monitor tobacco use via integrated surveillance policies;
- Protect people from second-hand smoke;
- Offer cessation support;
- Warn the public about the dangers of smoking (e.g. via warning labels and advertising);
- Enforce bans on tobacco advertising, promotion and sponsorship; and
- Raise taxes on tobacco.[14]

Historically, the EU and its Member States have been successful in some of these areas but less so in others. As of 2023, however, policies in Member States had improved or remained stable across the vast majority of the MPOWER categories as evaluated by WHO (see Table 3.1). One of the biggest successes is an overall decline in smoking prevalence among people in the EU aged 15+, falling from 26% in 2014 to 23% in 2020.[15] Another success is labelling and packaging, with several Member States adopting plain packaging policies. The price of tobacco products has increased in many Member States since 2012. This is also good news, as research suggests that rising prices deter consumption.[16] Implementation

14 World Health Organization (2008). *WHO report on the global tobacco epidemic, 2008: The MPOWER package*. Geneva: World Health Organization.

15 European Commission (2021). *Report on the Application of Directive 2014/40/EU*. COM(2021)249 final.

16 WHO (2021). *WHO technical manual on tobacco tax policy and administration*. Geneva: World Health Organization. Available at: https://iris.who.int/handle/10665/340659 (accessed 19 February 2022).

Table 3.1 *EU Member States' performance against WHO tobacco control targets*

Member State	Adult Daily Smoking Prevalence (2021) %	Monitoring	Smoke-Free Policies	Cessation	Health Warings	Mass Media	Advertising Bans	Taxation	Cigarettes Less Affordable Since 2010?
Austria	20%	4	3	5	5	2	4	74.0%	Same
Belgium	21%	4	2	4	5	2	4	79.9%	Yes
Bulgaria	32%	4	5	4	5	2	4	85.3%	No
Croatia	31%	4	4	4	5	2	4	86.0%	Same
Cyprus	29%	4	4	4	5	4	4	74.4%	Same
Czechia	23%	4	3	5	5	3	4	75.6%	Yes
Denmark	14%	4	2	5	5	2	4	81.5%	Same
Estonia	20%	4	2	4	5	5	4	88.2%	No
Finland	14%	4	2	4	5	3	5	89.4%	Yes
France	28%	4	3	4	5	5	4	83.8%	Yes
Germany	17%	4	2	4	5	4	4	64.4%	Yes
Greece	26%	4	5	4	5	2	4	81.2%	Same
Hungary	28%	4	4	4	5	4	4	72.0%	Same
Ireland	16%	4	5	5	5	5	4	78.9%	No
Italy	21%	4	2	4	5	2	4	76.7%	Same
Latvia	26%	4	4	4	5	2	4	81.4%	No
Lithuania	23%	4	3	4	5	3	4	76.1%	Same
Luxembourg	18%	4	3	5	5	2	4	68.5%	Same
Malta	20%	4	5	4	5	2	4	77.6%	No
Netherlands	17%	4	5	5	5	5	5	76.9%	Same
Poland	21%	4	3	4	5	3	4	78.4%	No
Portugal	19%	4	4	4	5	2	4	78.0%	No
Romania	26%	4	5	5	5	2	4	69.1%	No
Slovakia	24%	4	3	5	5	2	4	76.7%	Yes
Slovenia	18%	4	3	4	5	2	5	79.0%	Same
Spain	26%	4	5	4	5	4	5	77.6%	Same
Sweden	8%	4	2	5	5	2	4	67.9%	Same

Worst performance against WHO standards > ■2 ■3 ■4 ■5 < Best performance against WHO standards

■ = performance improved; ■ = performance stable; ■ = performance declined

Source: WHO (2023). *WHO Report on the Global Tobacco Epidemic, 2023*. Geneva: World Health Organization

More comprehensive analysis is available here: World Health Organization (2023). Global tobacco report 2023. Available at: https://www.who.int/teams/health-promotion/tobacco-control/global-tobacco-report-2023 (accessed 12 May 2024)..

of restrictions on exposure to second-hand smoke and regulation of tobacco depictions in mass media remain relatively patchy, however.[17]

From the 1980s onwards, EU policy-makers adopted a wide variety of tobacco control measures (summarized in Table 3.2) despite strong opposition from the tobacco industry. EU subsidies to tobacco farmers were phased out entirely by 2010.

The EU has also played a significant role in supporting international efforts to coordinate tobacco control policies across borders, primarily through the only international agreement against tobacco, the Framework Convention on Tobacco Control (FCTC). Internationally, countries are now focusing on fully implementing the FCTC as part of the United Nations Sustainable Development Agenda.

The core of current tobacco regulation in the EU is the Tobacco Products Directive (TPD).[18] The TPD broadened the scope of EU tobacco regulation in some significant ways, including setting maximum permissible levels of tar, nicotine and carbon monoxide for cigarettes and establishing a framework to allow monitoring of further ingredients and emissions. The TPD requires Member States to ban tobacco products with certain additives, including those with a characterizing flavour (e.g. fruit, vanilla or menthol), those that ease inhalation (e.g. menthol or clove), or those with additives that have been proven to increase addiction (e.g. menthol; a requirement to ban menthol products came into effect in 2020). Articles 15 and 16 of the TPD also provide for the creation of EU-wide traceability and security systems to tackle illicit trade in tobacco products. These have been operating in the EU since 2019.

In terms of warning the public about the dangers of tobacco products, the TPD requires that combined health warnings consisting of text plus a colour image must cover 65% of the front and back of tobacco packages (for smoking products only). Slim packages, which are often designed to resemble designer perfume packaging in order to appeal to women, are banned, as are misleading elements that make health claims about tobacco products, such as "free from additives". Cigarette packages must contain at least 20 cigarettes. The TPD stops short of mandating plain packaging, which is recognized internationally as the best practice standard, but it does not preclude Member States from adopting more

17 WHO (2021). *WHO report on the global tobacco epidemic, 2021: addressing new and emerging products*. Geneva: World Health Organization. Available at: https://www.who.int/publications/i/item/9789240032095 (accessed 19 February 2022).

18 European Parliament and Council (2014). *Consolidated text: Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.*

Table 3.2 *Summary of EU tobacco control legislation*

Name (year) of measure	Number	Key requirements
Labelling directives (1989, 1992)	89/622/EEC	Requires rotating health warnings on tobacco products
	92/41/EEC	Ban on the marketing of certain tobacco products for oral use
Advertising directives (1989, 1997, 1998, 2003)	89/552/EEC 97/36/EC	Ban all forms of TV advertising for tobacco products
	98/43/EC	Ban on tobacco advertising in the press, radio and on the Internet
	2003/33/EC	Ban on tobacco sponsorship of events with cross-border effects
Tar Yield Directive (1990)	90/239/EEC	Sets a maximum tar yield of 15mg per cigarette by 31 December 1992 and of 12mg per cigarette from 31 December 1997
Tax directives (1992, 1995, 2002, 2011)	92/78/EEC 92/79/EEC 92/80/EEC 95/59/EC 2002/10/EC 2011/64/EU	Set minimum levels of excise duties on cigarettes and tobacco
Tobacco Product Regulation Directive (2001)	2001/37/EC	Larger warning labels are required on all tobacco products; descriptors suggesting that one tobacco product is less harmful than another are banned; manufacturers and importers must submit a list of all ingredients used in the manufacture of tobacco products; maximum levels of tar, nicotine and carbon monoxide established for cigarettes (10mg tar, 1mg nicotine and 10mg carbon monoxide per cigarette)
Workplace Air Quality directives (1989, 1992)	89/654/EEC 92/57/EEC 92/91/EEC 92/104/EEC	Require employers to ensure that workers have access to fresh air and ventilation
Framework Directive on Health and Safety in the Workplace (1989)	89/391/EEC	Requires a health assessment to be carried out by employers, which should include exposure to second-hand smoke in the workplace
Asbestos Directive (1983)	83/477/EEC	Prohibits smoking in areas where asbestos is handled
Resolution on Smoking in Public Places (1989), Smoke-free Environments Recommendation (2009)		Invites Member States to adopt measures protecting people from exposure to smoke in indoor workplaces, public places and public transport
Pregnant Women Directive (1992)	92/85/EEC	Requires employers to take action to protect pregnant and breastfeeding women from exposure to an extensive list of substances, including carbon monoxide
Carcinogens Directive (1990)	90/394/EEC	Restricts smoking in workplace areas where carcinogenic substances are handled
Council Resolutions and Proposals to Member States and the Commission (1993, 1996, 1999) on measures to combat smoking (non-binding)		Various measures to combat smoking

>> continues

Name (year) of measure	Number	Key requirements
Council recommendation (2003)	2003/54/EC	Concerns aspects of tobacco control that are the responsibility of the Member States, including tobacco sales to children and adolescents; tobacco advertising and promotion that has no cross-border effects; provision of information on advertising expenditure; environmental effects of tobacco smoke
WHO Framework Convention on Tobacco Control (2004)	2004/513/EC (Council adoption decision)	Wide-ranging global treaty on tobacco control
WHO FCTC, Protocol to Eliminate Illicit Trade in Tobacco Products (ratified 2016)	2016/1749/EU and 2016/1750/EU (Council adoption decisions)	Addition to the FCTC focusing on control of illicit trade in tobacco products
Tobacco Products Directive (2014)	2014/40/EU	Major legislation on tobacco products (see text)
Commission Delegated Directive (EU) 2022/2100 on the Withdrawal of Certain Exemptions Regarding Heated Tobacco Products (2022)	2022/2100	Extends TPD to cover heated tobacco products

Sources: Authors; ASPECT (Analysis of the Science and Policy for European Control of Tobacco) Consortium (2004). *Tobacco or health in the European Union: past, present and future* (Luxembourg: Publications Office of the European Union); European Commission, 'Tobacco > Product regulation', available at: https://ec.europa.eu/health/tobacco/products_en (accessed 15 May 2024).

stringent packaging requirements. Subsequently, several EU Member States have adopted plain packaging laws.

EU tobacco control policies have been the subject of multiple legal challenges. The limitations of using the internal market Treaty provisions as a basis for public health laws were clearly shown by the annulment of the first Tobacco Advertising Directive by the European Court of Justice. This directive was also based on internal market provisions of the Treaty but, following legal action brought by Germany, the Court annulled the directive on the grounds that the total ban on tobacco advertising introduced by the directive went beyond what could be justified in order to enable functioning of the internal market, in particular for local products such as parasols and other articles used in hotels. In this legal argument, the reference to parasols and hotel-related items served as an example of local products that, according to the Court, did not warrant the same level of advertising restriction as that aimed at transnational or cross-border goods.

This decision has proved to be an outlier, however. The Court did explicitly recognize the legitimacy of mainstreaming health objectives into internal market objectives in principle. And the Court later upheld the second, narrower, directive on tobacco advertising when that was also contested by Germany on the grounds that its internal market legal base was not sufficient for its health effects.

In more recent legal disputes relating to the TPD addressing traceability systems, product standardization, e-cigarettes, plain packaging, menthol and snus, the Court has emphasized health and the internal market as parallel functions of the EU, as well as emphasizing the EU's binding international commitments to adopt tobacco control policies under the FCTC. Despite the TPD surviving each of these disputes, policy-makers should expect new tobacco control policies to be subject to challenges in the EU court system. Legislating and regulating in a way that makes it easier to defend against such suits, and then defending against them, will require extensive preparation and resources, strong adherence to governance procedures and accurate synthesis of large bodies of scientific evidence.

Since its passage, focus has shifted towards implementation of the TPD. In addition to its role adopting implementing acts on subjects including traceability, flavours, additives and labelling, the Commission regularly reviews the directive's implementation and impact. Implementation of such a complex piece of law has been tricky, with challenges arising around timely and accurate transposition, inconsistent enforcement activity across Member States, and difficulties in encouraging Member States to share and use data on ingredients and emissions.[19] A further revision of the directive could potentially address some of these issues, although the previous revision took over five years and was highly contested by the tobacco industry.

A significant challenge for the EU lies in the increasing diversity of tobacco and nicotine products on the market. While a large body of scientific evidence shows that traditional tobacco products such as cigarettes and cigars are extremely harmful for health, we know somewhat less about the long-term health risks of non-traditional tobacco products such as e-cigarettes, and much less about the potential risks of non-tobacco containing nicotine products. There are several main challenges for the EU in this regard: first, it can be challenging for policy-makers to reconcile different levels of scientific knowledge about different types of tobacco products with consistent public health messages. Second, novel tobacco products can present different risks for different populations, e.g. e-cigarette use increases health risks for a young person who has never smoked but could reduce health risks for a lifelong heavy smoker who switches entirely to e-cigarettes. Third, differences between national approaches to newer tobacco products may have a deleterious effect on policy-making at the EU level. And fourth, keeping up with the diversity of the market requires considerable governance capacity.

The EU has already confronted this dilemma in seeking to regulate oral tobacco (defined as snus and moist snuff), where an exclusionary solution was reached: the sale of snus is banned in all EU countries except Sweden. Similar flexibilities are built into the TPD regarding the ban on characterizing flavours, which

19 European Commission (2021). *Report on the Application of Directive 2014/40/EU*. COM(2021)249 final.

does not apply at all to oral tobacco products. Member States can also decide to exempt other products from the directive (e.g. cigarillos, pipe tobacco). The TPD regulates electronic cigarettes, categorizing them as consumer goods, and stipulates various product characteristics such as the maximum permissible concentration of nicotine.

Nicotine-containing products (e.g. oral nicotine pouches, which are distinct from snus in that they do not contain tobacco) represent an emerging challenge for the EU. As with e-cigarettes, some experts are concerned about the potential health risks of nicotine intake or intake of unknown chemicals from these products, particularly for young people who have never used tobacco products, while others view the products as potentially safer than e-cigarettes and part of a potential harm reduction approach. A few Member States have banned pouches, while others are regulating their sale. Review of the TPD is ongoing and EU institutions may decide to take a position on these new products in the future. Commissioner-designate Várhelyi's mission letter asks him to advance tobacco control measures, notably novel nicotine products aimed at youth. Given the quickly shifting range of nicotine products on the market, this could be an important agenda.

Despite these challenges, the EU has shown that it is willing to act to assess and address the risks of new tobacco products. The Commission can act through delegated legislation to change the scope of application for the TPD under certain conditions. If there is a "substantial change in circumstances", defined as at least 10% increase in sales volume for a category of products in at least five Member States, with the sales volume of those products exceeding 2.5% within the single market as a whole, the Commission can withdraw exemption from the TPD for those products. As of 2022, the TPD's exemption for heated tobacco products, a type of tobacco product that uses a heating element to warm up tobacco-containing sticks, pods or plugs, was removed.

The Commission's ambitious Europe's Beating Cancer plan (see Section 3.2.7), published in 2021, proposes a tobacco free-generation where less than 5% of the population uses tobacco products by 2040, with an interim goal of 20% by 2025.[20] The EU institutions have come under fire from interest groups who have criticized the lack of progress towards these benchmarks, but recent plans announced in Member States including France and Spain offer hope that policy actions remain feasible in some settings. Achieving the 2040 target is likely to require stronger regulation, better implementation and enforcement at national level, and higher taxation.

20 European Commission (2021). *Europe's Beating Cancer Plan*. COM(2021)44 final.

3.2.2 Diet, nutrition and physical activity

Non-communicable diseases are a major health threat in the EU, and many argue that the root of them is some combination of poor diet (poor nutrition, sometimes food poverty), obesity and a lack of exercise.[21] The EU's contribution to the prevention of non-communicable diseases is multiple and ambiguous: food safety, infrastructure investment, protected designation of origin law,[22] fiscal governance, infrastructure support (cohesion funds and EIB loans), climate change policy, trade policy and agricultural policy all affect diet, nutrition and physical activity for better or for worse. There is scope for a great deal of policy coherence – or policy incoherence.[23]

"Diet, nutrition and physical activity" came onto the EU agenda as such under the Barroso Commission, with a flurry of initiatives: a 2005 Green Paper, a 2005 Nutrition Strategy White Paper,[24] and Health Programme initiatives as well as the innovative Platform on Diet, Nutrition and Physical Activity in which a variety of participants would report data on their contributions to better outcomes (e.g. companies could pledge to reduce salt), in an initiative similar to what some Member States tried around the same time.[25] The topic may continue to loom large in Europe's public health challenges, in informed public health thinking, and in the minds of the many who are trying to eat and live better, but it has been sliding off the EU agenda since 2014.

New policies have started to emerge, however. Europe's Beating Cancer plan (see Section 3.2.7) represents an important political commitment in that it acknowledges the joint effects of unhealthy diets and physical inactivity on cancer risks. But significant measures to address these problems, such as proposals for

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21 As many have noted, if exercise were a pill, it would be hailed as a miracle drug and widely prescribed. That raises the question of why so many aspects of our lives seem designed to prevent it, from buildings without visible and accessible stairs to roads that make it difficult to walk or ride a bicycle. Some of these problematic infrastructures are financed by the EU. For a particularly well-presented discussion of the medical benefits of exercise, see Academy of Medical Royal Colleges (2015). *Exercise – The Miracle Cure*. London: Academy of Medical Royal Colleges. Available at: https://www.aomrc.org.uk/reports-guidance/exercise-the-miracle-cure-0215/ (accessed 19 February 2022).

22 The European legal framework for the protection of certain foods from particular places, produced in certain ways, e.g. the French *Appellation d'origine contrôlée* designation.

23 For example, Parsons K & Hawkes C (2018). *Connecting food systems for co-benefits: How can food systems combine diet-related health with environmental and economic policy goals?* Policy Brief. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies.

24 European Commission (2007). *White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity-related health issues*. COM(2007)279 final.

25 Bekker, M. P., Mays, N., Kees Helderman, J., Petticrew, M., Jansen, M. W., Knai, C., & Ruwaard, D. (2018). Comparative institutional analysis for public health: governing voluntary collaborative agreements for public health in England and the Netherlands. *European Journal of Public Health*, 28(suppl_3), 19–25. Bekker, M., Helderman, J. K., Jansen, M., & Ruwaard, D. (2017). The conditions and contributions of 'Whole of Society' governance in the Dutch 'All about Health…'programme. In Greer, SL, Wismar, M., Kosinskao, M., and Pastorino, G. (eds.) *Civil society and health: Contributions and potential* (pp. 159–183). Copenhagen: WHO Regional Office for Europe, European Observatory on Health Systems and Policies.

mandatory, harmonized front of pack nutrition labelling, have stalled amid disagreements among Member States over which system to use.

3.2.3 Alcohol

Alcohol is a particularly European determinant of health; Europe has the highest consumption of alcohol per head in the world (almost double the global average),[26] although there has been an overall but uneven decline in recorded alcohol consumption since the early 1990s.[27] Alcohol is classified by WHO's International Agency for Research on Cancer (IARC) as a group 1 carcinogen. The agency considers there to be no level of alcohol use that is safe for health.

Although alcohol is considered to be the third largest risk factor for ill-health in the EU,[28] it is also a major part of European society. Quite apart from its economic contribution (e.g. the EU produces more than half of the world's wine),[29] alcohol in its various forms is a central part of European culture and politics.[30] The EU's strategy regarding alcohol and health (officially started in 2006 and actively implemented around 2012) was, therefore, much more nuanced and limited than that for tobacco, focusing on education and discouraging drinking among particular groups, notably children, pregnant women and people driving cars – the populations and actions on which the industry already said it agreed.[31] The means used were also much softer than for tobacco, with the EU pursuing this strategy through supporting guidelines, exchanges of good practice, research and monitoring, rather than with legislation (although of course there is also relevant legislation, in particular the EU requirement that all alcoholic drinks show the strength of alcohol on their label).[32] On the face of it, this might seem a little weak; if alcohol is such a major determinant, why is the action to address it so limited, particularly in comparison to tobacco?

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26 World Health Organization (2013). *Status report on alcohol and health in 35 European countries 2013*. Copenhagen: WHO Regional Office for Europe.

27 Recorded alcohol consumption tends to be very sensitive to methods, e.g. questionnaires that are sensitive to a variety of biases, and under-report actual consumption.

28 European Commission (2009). *First progress report on the implementation of the EU alcohol strategy*. Brussels: DG Health and Consumer Protection, European Commission.

29 European Commission (2014). *What is the current situation of the European Union's wine sector?* Brussels: European Commission. Available at: http://ec.europa.eu/agriculture/markets/wine/index_en.htm (accessed 4 July 2014). Nordlund, S. (2016). Alcohol policy, norms and drinking habits in different European countries. *Journal of Alcoholism & Drug Dependence* 4, no. 250: 2.

30 Colman T (2008). *Wine politics: How governments, environmentalists, mobsters, and critics influence the wines we drink*. University of California Press.

31 European Commission (2006). *An EU strategy to support Member States in reducing alcohol-related harm*. (COM(2006)625). Brussels: European Commission.

32 European Commission (1987). Directive 87/250/EEC on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer. *Official Journal*, L 113/57.

One obvious answer is that there is a broad social consensus on combating tobacco across Europe that does not exist for alcohol, which clearly affects the feasibility of Europe-wide measures. The well-established and well-known differences in national traditions regarding alcohol have made it difficult to establish the basics of a policy discussion about alcohol as a social determinant of health. This is changing, however, in part because of European integration and the growth of very large international companies that have worked out how to homogenize products such as alcopops in Europe. Policy-makers who defend traditional alcohol use patterns sometimes rethink in the face of such homogenizing new products.[33] Moreover, the relationship between public policy and alcohol consumption is not straightforward. While overall there is an impact from restrictive measures, these interact with wider social changes (such as urbanization or changes in working patterns) and informal social norms (which tend to be the opposite to formal policies, meaning that where social norms are restrictive, such as in southern Europe, formal policies are relatively liberal, and vice versa),[34] as well as the history of different countries.

Nevertheless, although the relationship is complex, the evidence shows more restrictive alcohol policies do have an impact in reducing harm from alcohol.[35] So could the EU do more to address this, using stronger tools than deployed so far? This can be considered for three key aspects of alcohol policies, ones that resemble the toolkit already see in tobacco control: physical availability, economic availability, and advertising and labelling.

Regarding physical availability, a key example is the restrictive retail monopolies on alcohol sales in Sweden and Finland, which constitute a strong limitation on the physical availability of alcohol. These were challenged before the European Court of Justice on the basis that such a monopoly was contrary to the EU's internal market.[36] However, the Court did not agree, accepting the argument that the monopoly was an appropriate tool to protect public health. So while it has not been easy to extend alcohol regulation, the EU internal market has not prevented Member States from having such controls on physical availability at national level.[37]

For economic availability, the central tool is taxation: increasing the cost of the product reduces consumption. Conversely, the main impact of the internal market

33 Cisneros Ornberg J (2013). Alcohol policy in the European Union, in Greer SL & Kurzer P (eds). *European Union public health policies: regional and global perspectives.* Abingdon: Routledge, pp. 168–80.

34 Anderson B & Reynolds G (eds) (2012). *Making and implementing European alcohol policy*. The AMPHORA (Alcohol Measures for Public Health Research Alliance) project.

35 Anderson P, Braddick F, Reynolds J & Gual A (eds) (2012). *Alcohol Policy in Europe: Evidence from AMPHORA*. The AMPHORA project.

36 European Court of Justice. Case C-189/95 *Franzén*.

37 See the classic book, Kurzer P (2001). *Markets and moral regulation: cultural change in the European Union*. Cambridge: Cambridge University Press.

on increased alcohol consumption in Sweden and Finland has not come from any increases in physical availability at home but rather from the increased availability of lower-priced alcohol because of lower rates of excise duty in neighbouring countries to the south.[38] This is not a consequence of a lack of powers for the EU to act, as there is already legislation on excise duties for alcohol.[39] However, unlike for tobacco, that legislation has not been used to set a high minimum level of excise duty and thus price for alcohol throughout Europe. One does not have to look far to understand why. Unlike tobacco (production of which has been relatively limited in the EU and concentrated in a few countries), alcohol production is spread much more widely throughout the EU, and for taxation legislation such as this, the unanimous agreement of EU Member States in the Council is required. Even a Commission proposal[40] to at least upgrade the current minimum levels of excise duty on alcohol failed to make progress in the Council and was rejected outright by the European Parliament. So while the legal capacity is there, the democratic agreement in the legislative bodies of the EU to price alcohol more highly seems to be lacking. The first von der Leyen Commission reviewed EU legislation on the taxation of alcohol.[41] Since 2022, however, the EU has not introduced new overarching legislation specifically addressing this.

Globally, WHO's European Framework for Action on Alcohol 2022–2025 and Global Alcohol Action Plan 2022–2030 both recommend the use of health warning labels as a public education tool. Given the existing restrictions on advertising and labelling of tobacco products, there is clearly legal scope for the EU to do much more in restricting advertising of alcoholic products and to label them more clearly. Culturally, however, the acceptance of risks from tobacco is entirely different from the perceived risks of alcohol – and while that might be considered in itself an argument for EU action, it also underlines the likely difficulties on reaching agreement on increasingly restrictive advertising or labelling rules.

In 2021, in order to reduce harmful alcohol consumption in line with the SDGs, EU's Beating Cancer plan promised the introduction of a mandatory indication of ingredients on alcoholic beverage labels before the end of 2022 and of health warnings on labels before the end of 2023.[42] These policies had not materialized

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38 Tigerstedt C et al. (2006). Health in alcohol policies: the European Union and its Nordic Member States, in Ståhl T et al. (eds). *Health in all policies: prospects and potentials*. Helsinki: Ministry of Social Affairs and Health, pp. 111–28.

39 Council of the European Union (1992). *Directive 92/83/EEC on the harmonization of the structures of excise duties on alcohol and alcoholic beverages*; *Directive 92/84/EEC on the approximation of the rates of excise duty on alcohol and alcoholic beverages*. Luxembourg: Publications Office of the European Union.

40 European Commission (2006). *Proposal for a Council Directive amending Directive 92/84/EEC on the approximation of the rates of excise duty on alcohol and alcoholic beverages* (COM(2006)486). Brussels: European Commission.

41 European Commission (2021). *Europe's Beating Cancer Plan* (COM(2021)44). European Commission.

42 European Commission (2021). *Europe's Beating Cancer Plan* (COM(2021)44). European Commission.

as of mid-2024. The plan nevertheless contains a significant target of a "relative reduction of at least 10% in the harmful use of alcohol by 2025".[43]

Labelling of alcohol products varies greatly among EU Member States, with wide divergences regarding the presence, type and form of health-related messages.[44] Most notably, in 2023, Ireland became the first country in Europe to mandate labelling of alcohol products after the proposed regulations passed through the EU notification process without objections being raised. Labels must include a warning that alcohol causes liver disease, acknowledge that there is a direct link between alcohol and cancers, and display a pictogram relating to the dangers of consuming alcohol while pregnant. Alcohol content and calories must also be labelled. Other countries have adopted more voluntarist measures on alcohol labelling, including France and Lithuania, where labels are required to warn consumers about the potential health consequences of drinking while being pregnant, either with a pictogram or with text.

The same effort that we see in diet, nutrition and physical activity policy to build consensus and seek positive-sum solutions, or at least keep an issue on the agenda when there would be no real regulation, explained the creation of the Alcohol and Health Forum. This was another stakeholder forum including industry as well as civil society. It started operation in 2009. In 2015 representatives of 20 public health civil society organizations walked out in protest against the failure of the Commission to produce a new strategy after the 2013 expiry of the previous one. The new commitments on tackling alcohol under Europe's Beating Cancer plan are ambitious, but have yet to lead to sustained action. It remains to be seen whether this strategy of situating commitments on alcohol under the specific umbrella of cancer will change the scope of what proves achievable.

3.2.4 Environment

The Treaty sets out broad objectives for the EU in the area of the environment, which includes health:[45]

> European Union policy on the environment shall contribute to pursuit of the following objectives:

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43 World Health Organization (2023). Joint statement by WHO/Europe and IARC to the European Parliament - raising awareness of the link between alcohol and cancer. 6 November 2023. Available at: https://www.who.int/europe/news/item/06-11-2023-joint-statement-by-who-europe-and-iarc-to-the-european-parliament---raising-awareness-of-the-link-between-alcohol-and-cancer#:~:text=WHO%2FEurope's%20European%20Framework%20for,health%20consequences%20of%20alcohol%20use (accessed 16 July 2024).

44 European Commission (2014). *State of play in the use of alcoholic beverage labels to inform consumers about health aspects. Action to prevent and reduce harm from alcohol*. Brussels: European Commission.

45 TFEU, Article 191, paragraph 1.

- preserving, protecting and improving the quality of the environment,
- *protecting human health*,
- prudent and rational utilization of natural resources, and
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change [emphasis added].

The powers to achieve this objective are wide ranging, although they require unanimity in the Council for some topics such as town and county planning and measures affecting the general structure of energy supply for a country.[46] Like health, environment also has a mainstreaming clause, requiring environmental protection requirements to be integrated throughout the EU's policies and activities.[47]

Reflecting the broad powers in the Treaties for environmental objectives, the EU has a formidable body of legislation and action on the environment, much of which also directly helps to improve human health. European Union measures include legislation covering air and water quality, noise, chemicals and waste, as well as a wide range of other topics, with well over a hundred different directives, regulations and decisions.[48] The central importance of such environmental protection is illustrated by some of the links between health and environmental factors shown in Table 3.3; indeed, WHO estimates that environmental causes account for 18–20% of the overall burden of disease throughout the WHO European Region (although more of that burden is in the eastern part of the WHO Region than in the EU).[49]

Despite the progress made in many areas, challenges remain for environmental impact on health.[50] For example, for air pollutants there has been progress with some factors (such as sulphur dioxide and lead), but exposure to particulate matter and ground-level ozone is still causing significant ill health. Box 3.1 gives an example of EU action on fine particle pollution.

Another example concerns chemicals. Although the EU's REACH legislation puts in place a detailed system of oversight for individual chemicals, there has been increasing concern about the real-world impact of cumulative exposure to many different chemicals over time. In 2020, DG Environment adopted a

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46 TFEU, Article 192.

47 TFEU, Article 11.

48 European Commission (2003). *Handbook on the implementation of EC environmental legislation*. Luxembourg: Publications Office of the European Union. Available at: http://ec.europa.eu/environment/enlarg/pdf/handbook_impl_ec_envi_legisl.pdf (accessed 4 July 2014).

49 European Environment Agency (2010). *The European environment: state and outlook 2010 – synthesis*. Luxembourg: Publications Office of the European Union.

50 Ibid.

Table 3.3 *Some health impacts and associations with environmental and lifestyle factors: a list of examples*

Health impact	Association with some environmental exposures and lifestyle factors	
Infectious diseases	Water Air and food contamination	Changes in pathogen lifecycles related to climate change
Cancer	Air pollution (PMs, mainly ≤PM2.5) Smoking and ETS Some pesticides Asbestos Natural toxins (aflatoxin) Polycyclic aromatic hydrocarbons (e.g. in diesel fumes)	Some metals (e.g. arsenic, cadmium, chromium) Radiation (including sunlight) Radon Dioxins Alcohol Some foods
Cardiovascular diseases	Air pollution (carbon monoxide, ground-level ozone, PMs) Smoking and ETS Lead Noise	Inhalable particles Food (e.g. high cholesterol) Stress Poor exercise levels Salt
Respiratory diseases including asthma	Smoking and ETS Air pollution (sulphur dioxide, nitrogen dioxide, ground-level ozone, PM2.5 and PM10) Fungal spores	Dust mites Pollen Pet hairs Skin and excreta Damp
Skin diseases	Ultraviolet radiation Some metals (e.g. nickel)	Pentachlorophenol Dioxins
Diabetes, obesity	Foods (e.g. high fat)	Poor exercise levels
Reproductive dysfunctions	PCBs DDT Cadmium	Phthalates Endocrine disruptors Pharmaceuticals
Developmental (fetal and childhood) disorders	Metals (cadmium, lead, mercury) Smoking and ETS Some pesticides	Endocrine disruptors Infectious diseases Alcohol
Nervous system disorders	Metals (lead, manganese) Methyl mercury	Some solvents Organophosphates
Immune dysfunction	Ultraviolet-B radiation	Some pesticides
Increased chemical sensitivity	Multiple chemical exposures at low doses	

Source: EPHA (2008). Report on the status of health in the European Union: towards a healthier Europe (EUGLOREH Project). Brussels: DG Health and Consumers. Available at: http://ec.europa.eu/health/reports/publications/index_en.htm (accessed 28 July 2014).

Notes: ETS: environmental tobacco smoke; PCBs: polychlorinated biphenyls; PM: particulate matter.

new Chemicals Strategy for Sustainability as part of the European Green Deal, including a proposed ban on harmful chemicals in a range of consumer products to be achieved via a revision of REACH. These revisions have been serially delayed, however, and progress towards better chemicals regulation has remained slow for quite some time.[51] More recently, the Commission introduced new criteria to define what constitutes an essential use of harmful chemicals, ensuring that such chemicals can only be used when necessary for health, safety or critical society functions, or when no viable alternatives exist.[52] Several other initiatives have been launched under the Chemicals Strategy for Sustainability, including efforts to address endocrine disruptors, phasing out per- and polyfluoroalkyl substances (PFAS), and promoting "safe and sustainable by design" chemicals.[53] Additionally, the strategy includes a "one substance, one assessment" approach to streamline and harmonize chemical safety evaluations across EU legislation.

Finally, there is possibly the single biggest threat to public health anywhere: climate change. Climate change results in crop failures, which impact nutrition. Climate change is also related to many human diseases that have been linked to climate fluctuations, including cardiovascular disease, respiratory illness exacerbated by heatwaves, and changes in the transmission of infectious, especially vector-borne, diseases such as malaria.[54] The EU, over the 2010s, increasingly came to treat climate change as a separate policy area, albeit one linked tightly to environmental law, policy and legal bases. Under the 2019–2024 von der Leyen Commission, the relevant policy package came to be known as the Green Deal as part of a green transition. These policies are treated in Chapter 5. In 2009 the Commission published a working paper on the health impacts of climate change,[55] which identified heat-related morbidity and mortality as the primary concern when assessing the impact of climate change on health. Changes in the transmission of food- and vector-borne diseases will also emerge as health threats and will interact with other public health issues, such as migration, movement of staff and cross-border healthcare. This underlines the relevance of the EU's work on climate change more generally for health.

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51 Greer SL, Trump B (2019). Regulation and regime: the comparative politics of adaptive regulation in synthetic biology. *Policy Sciences* 52, no. 4: 505–524.

52 Bridges, J. W., Greim, H., van Leeuwen, K., Stegmann, R., Vermeire, T., & den Haan, K. (2023). Is the EU chemicals strategy for sustainability a green deal? *Regulatory Toxicology and Pharmacology*, 139, 105356. https://doi.org/10.1016/j.yrtph.2023.105356

53 Sonne, C., Jenssen, B. M., Rinklebe, J., Lam, S. S., Hansen, M., Bossi, R., et al. (2023). EU need to protect its environment from toxic per-and polyfluoroalkyl substances. *Science of The Total Environment*, 876, 162770. https://doi.org/10.1016/j.scitotenv.2023.162770

54 Patz JA & Thomson MC (2018). Climate change and health: Moving from theory to practice. *PLoS Medicine*, 15(7):e1002628. Hotez PJ (2016). Neglected Tropical Diseases in the Anthropocene: The Cases of Zika, Ebola, and Other Infections. *PLoS Neglected Tropical Diseases*, 10(4):e0004648.

55 European Commission (2009). *Staff Working Document: human, animal and plant health impacts of climate change* (COM(2009)147 final). Brussels: European Commission. Available at: http://ec.europa.eu/health/ archive/ph_threats/climate/docs/com_2009-147_en.pdf (accessed 4 July 2014).

Given the importance of EU environmental protection for health, therefore, the relative lack of attention to this contribution to public health in Europe (e.g. in research) is surprising. This is perhaps because of the organizational factors discussed in Chapter 2: the EU's environmental action is not led by the health part of the European Commission but rather, since 2010, by a specific DG for action on climate change.[56] This organizational issue perhaps leads its vital contribution to improving human health to be overlooked by health stakeholders, both in terms of research and in terms of engagement by the wider health community.

The healthcare sector is itself a meaningful contributor to climate change, as discussed in Chapter 5, and other forms of pollution such as plastic waste. A range of decisions can influence carbon consumption, from the choice of technique in anaesthetic to the location and design of healthcare facilities. Hospitals, for example, can drive traffic if they are located outside cities and surrounded by parking, and reduce it if they have good public transportation; their buildings can be more or less green in design and in reuse of older construction (construction being a major source of greenhouse emissions), and their waste management and purchasing can be more or less mindful of carbon budgets.

The corollary of health *in* all policies might be more interest in the effect of health and healthcare on other policies – health *for* all policies.[57] Given that much of the EU's expenditure on health is in healthcare infrastructure, especially if we consider EIB loans, there is ample scope to help the EU be greener through healthcare infrastructure approaches (see Figure 3.2 for an example).

The COVID-19 pandemic created extraordinary challenges, and the EU put in place the largest financial stimulus package in its history in order to support its recovery[58] (see also Chapter 6). Although this does include some support for under-pressure health systems, the EU's strategy is to use this investment to help the green and digital transitions – specifically, aiming to achieve climate neutrality by 2050 (as well as maximizing the potential of digital technologies). This places the environment at the heart of Europe's post-COVID recovery. As described above, action on the environment also often has positive impacts for health. This investment in action on climate change may therefore also represent an important dimension of the EU's impact on health in the years after the COVID-19 pandemic.

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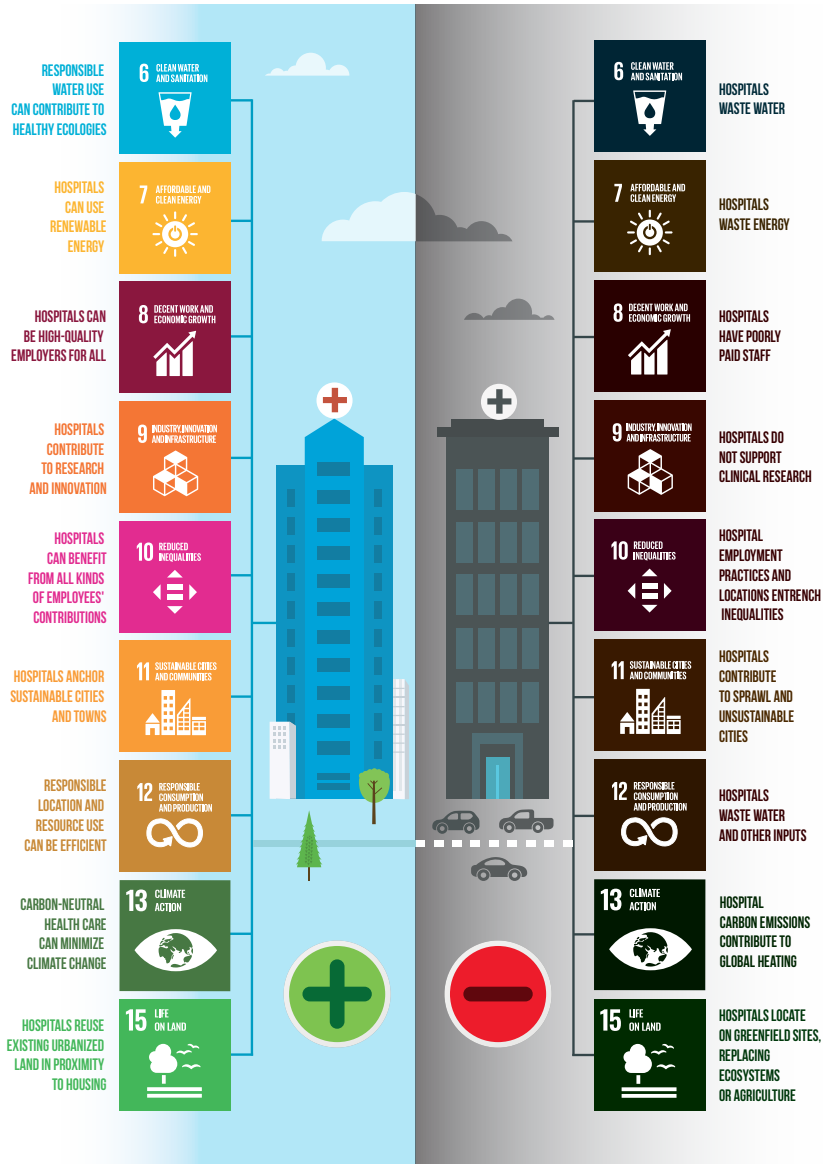
56 Although the European Commission sets out an integrated approach (European Commission [2003]. *European environment and health strategy* (COM(2003)338). Brussels: European Commission), the Treaty base for action on climate change is in large part the environmental Treaty Article 191 TFEU.

57 Greer, S. L., Falkenbach, M., Siciliani, L., McKee, M., Wismar, M., & Figueras, J. (2022). From health in all policies to health for all policies. *The Lancet Public Health*, 7(8), e718-e720. Greer, S. L., Falkenbach, M., Figueras, J., & Wismar, M. (2024). *Health for All Policies*. Cambridge University Press.

58 Available at: https://ec.europa.eu/info/strategy/recovery-plan-europe_en (accessed 19 February 2022).

The green transition and European Green Deal are the core of the EU's response to climate change as of 2024, although political shifts underway might change the salience and commitment to those policies. They are discussed in more detail in Chapter 5.

Fig. 3.2 *A hospital can have positive and negative spillovers on many sustainable development goals*



Source: Greer, Scott L., Michelle Falkenbach, Luigi Siciliani, Martin McKee, Matthias Wismar, Praneetha Vissapragada, et al. (2023). *Making Health for All Policies: Harnessing the co-benefits of health*. European Observatory on Health Systems and Policies.

Box 3.1 *An example of environmental regulation: fine particle pollution*

The scope and breadth of EU environmental policy is far beyond what we can discuss in this book. This box provides merely one timely example of EU environmental policy action with health benefits: fine particle pollution. Although air quality has improved in the EU over the last decades, the quality of life of many EU citizens remains restricted due to poor air quality, especially in urban areas.[a] The EU's action to improve air quality was previously based on three main pillars:[b] the ambient air quality standards set out in the Ambient Air Quality Directives (EU 2004, 2008) that required countries to adopt and implement air quality plans; the national emission reduction targets established in the National Emission Ceilings Directive (EU, 2016) that required Member States to develop national air pollution control programmes by 2019 to comply with their emission reduction commitments; and emission standards that were set out in 2015 in EU legislation targeting industrial emissions, vehicles, transport fuels, etc.[c] In addition to these directives, the Clean Air Programme for Europe (CAPE), adopted in 2013, sought to ensure full compliance with existing legislation by 2020.

In 2018 the European Commission published its first clean air outlook in which it recognized that action must be taken urgently in order to achieve the objectives set out in the Ambient Air Quality Directives at all governance levels.[d] Since publication the EU has made several advances in reducing fine particle pollution through various initiatives. In its second clean air outlook published in 2021, the European Commission projected a potential 55% reduction in premature deaths from air pollution by 2030 if existing measures were fully implemented.[e] While progress was projected for most pollutants, the report identified challenges in meeting the reduction targets for ammonia emissions, particularly from the agricultural sector.

In May 2021, the EU introduced the Zero Pollution Action Plan as part of the broader European Green Deal, aiming for stricter air quality standards and alignment with WHO guidelines by 2050.[f] The plan sets out specific targets to achieve a toxin-free environment by 2050, with intermediate targets for 2030, including a reduction of more than 55% in air pollution.

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a European Commission (2018). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Europe that protects: Clean Air for all* (released 17 May 2018).

b Ibid.

c European Environment Agency (2018). *Air quality in Europe – 2018 report*. Luxembourg: Publications Office of the European Union, p. 15.

d European Commission (2018). The first Clean Air Outlook report: An analysis of the prospects for reducing air pollution in the European Union up to 2030. Luxembourg: Publications Office of the European Union. https://ec.europa.eu/environment/air/pdf/clean_air_outlook_overview_report.pdf

e European Commission (2021, January 8). Second Clean Air Outlook report: Full implementation of clean air measures could reduce premature deaths due to air pollution by 55% in 2030. https://environment.ec.europa.eu/news/second-clean-air-outlook-report-full-implementation-clean-air-measures-could-reduce-premature-deaths-2021-01-08_en

In 2022 the Commission proposed new rules and legislation for cleaner air and water to achieve health and environmental goals.[g] These initiatives include the revised Ambient Air Quality Directives,[h] which aim to set stricter limits on pollutants to better protect public health; and the revised Industrial Emissions Directive,[i] which introduces more stringent controls on emissions from large industrial facilities. Also, the Methane Strategy[j] (2020) targets the reduction of methane emissions across multiple sectors including energy, agriculture and waste management.

f European Commission (n.d.). *Zero Pollution Action Plan*. Available at: https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en (accessed 10 August 2024).

g European Commission (2022). *Press release: European Green Deal—Commission adopts new proposals to reduce air pollution from large combustion plants*. https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_22_6278/IP_22_6278_EN.pdf

h European Commission (2022). *Proposal for a directive of the European Parliament and of the Council on ambient air quality and cleaner air for Europe* [COM/2022/542 final]. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2022:542:FIN (accessed 20 August 2024).

i European Commission (2022). *Proposal for a directive of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control)* [COM/2022/156 final]. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2022:156:FIN (accessed 20 August 2024).

j European Commission (2020). *EU Methane Strategy*. Available at: https://energy.ec.europa.eu/topics/carbon-management-and-fossil-fuels/methane-emissions_en?prefLang=pt#eu-methane-strategy (accessed 20 August 2024).

3.2.5 Social policy

Within the TFEU Title on social policy are some key areas of action for health in the form of occupational health and safety, and equalities protection including for people with disabilities. Although both are directly concerned with health, they are often oddly sidelined in health policy discussions, perhaps because they are typically the responsibility of employment or social ministries, as they are in the Commission, rather than health ministries.

3.2.5.1 Occupational health and safety

The health and safety at work powers of the Treaties have given rise to an extensive set of requirements to protect health at work. As well as the overall framework directive on safety and health at work,[59] there is a wide range of detailed and sectoral provisions. An overall strategy for action on health and safety at work

59 Council of the European Union (1989). Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. *Official Journal* L 183, 29.6.1989.

was set out by the European Commission in 2021,[60] which has three overall objectives:

1. Anticipating and managing change in the new world of work, in particular addressing the challenges posed by the green and digital transitions, demographic changes, and mental health in the workplace (especially since the COVID-19 pandemic);

2. Improving the prevention of work-related diseases and accidents through a "vision zero" approach aiming to eliminate work-related deaths and reduce accidents and illnesses, in particular relating to cancer, reproductive and respiratory diseases;

3. Increasing preparedness for possible future health threats, to enable processes for rapid deployment of measures in future health crises.

Three European agencies play a particular role in implementing EU action on safety and health at work:

- European Agency for Safety and Health at Work (EU-OSHA)
- European Chemicals Agency (ECHA)
- and the European Foundation for Living and Working Conditions (Eurofound).

The COVID-19 pandemic generated serious occupational health concerns, as millions of workers rapidly transitioned into work from home arrangements in the spring of 2020, and revealed many complexities and failures to communicate between public health and occupational safety and health (OSH) organizations and experts. Workers previously viewed as lower status (such as grocery employees) were recognized to be essential, and healthcare professionals took significant health risks to treat COVID-19 patients. In 2019 only 5.4% of EU employees worked from home occasionally. Many of them were high-skilled professionals holding managerial positions.[61] Close to 40% of European workers began full-time teleworking as a direct result of the pandemic. More than half of them had no prior experience with teleworking, which made the transition particularly challenging for those with limited equipment or digital literacy. Other workers were constrained to go to work and were disproportionately impacted by the virus.

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60 European Commission (2021). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU strategic framework on health and safety at work 2021-2027. Occupational safety and health in a changing world of work* (COM(2021)323).

61 European Commission (2020). *Telework in the EU before and after the COVID-19: where we are, where we head to*. Science for policy brief.

In Italy, for instance, COVID-19 infections occurred at the workplace more often than at home and represented a substantial portion of the total cases in 2020 (19.4%).[62] In 2022, COVID-19 was recognized by the European Commission as an occupational disease as part of a recommendation[63] to Member States to do likewise and take appropriate measures in response.

3.2.5.2 Working Time Directive

One particularly high-profile area where EU action on health and safety at work had an impact on health systems was legislation on working time, in particular for doctors in training. As part of the drive towards the integrated market launched by the Single European Act, there was concern that this should not be a race to the bottom for workers, with countries competing to become more competitive by lowering employment standards. Reflecting this, in 1990 the Commission proposed setting minimum standards for certain aspects of working time, in particular a minimum of 11 hours of rest per 24 hour period and specific protection for night workers and shift workers.[64] Health ministries typically had mixed feelings about the proposal. On the one hand, protecting health professionals against long hours and patients from errors made by tired doctors would help to ensure good health. On the other hand, some health systems were themselves dependent on historical practices of long hours being worked by junior doctors. The directive as agreed in 1993 reflected this,[65] excluding doctors in training from these protections and allowing more general exceptions to be made for hospitals (as well as for some other sectors such as transport and sea fishing).

This exemption was intended to give time to find solutions to protect excluded categories of workers. The situation of doctors in training was given particular attention, with work undertaken for the Commission identifying a range of options that the Member States could take,[66] including reorganizing work patterns, having some routine clinical work and administrative work undertaken by other staff such as senior nurses, improving retention of doctors in training

62 Marinaccio A et al. (2020). Occupational factors in the COVID-19 pandemic in Italy: compensation claims applications support establishing an occupational surveillance system. *Occupational and Environmental Medicine*, 77:818–21.

63 European Commission (2022). Recommendation (EU) 2022/2337 of 28 November 2022 concerning the European schedule of occupational diseases, *Official Journal* L 309/12 of 30.11.2022.

64 Commission of the European Communities (1990). *Proposal for a Council directive concerning certain aspects of the organization of working time* (COM(90)317 final). Luxembourg: Publications Office of the European Union.

65 Council of the European Union (1993). Council Directive 93/104/EC concerning certain aspects of the organization of working time. *Official Journal*, L 307:18–24.

66 Cambridge Policy Consultants (2003). *Business impact assessment – working time: excluded sectors: supplementary report: doctors in training*. Cambridge: Cambridge Policy Consultants. Available at: tinyurl.com/yckvekcw (accessed 19 February 2022).

who currently leave career grades, recruiting more junior doctors, and sharing the workload with other facilities, including in the private sector. Accordingly, EU legislation was progressively extended to cover doctors in training,[67] although it also allowed Member States to provide for exceptions allowing employees to choose to work longer hours if they wished, and for managers to be exempted from the cap.

The changes brought about by the directive are dramatic when we remember the historical practice of doctors working well over 100 hours a week in many countries. It is perhaps not surprising that some doctors and managers were critical of the provisions to reduce working hours, arguing that these would reduce the scope for clinical training, and discounting the benefits to patients from fewer fatigue-related errors and to the long-term health of doctors themselves.[68] Indeed, it has taken considerable time and debate to arrive at models of care organization that reconcile these different objectives, and the issue is still debated. The criticisms that the 2003 EU working time legislation had been developed without taking account of its impact on health systems were more difficult to understand, given that the issue had been a central part of the European debate since the original directive in 1993. The reason seems to lie in the general absence of engagement of health professionals and policy-makers in this debate until the implementation of the 2003 directive in the mid-2000s. This seems to be another example where the wider health community did not understand or engage with the impact of Europe on health – perhaps because the working time directives were part of health and safety at work, rather than coming under the article on public health, and discussion largely took place in employment-related forums rather than the Health Council, for example. The Working Time Directive, along with the Services Directive and the development of patient mobility law, were all key reasons why health policy-makers and healthcare interests began to take a real interest in EU policy-making.

3.2.5.3 Social partners in EU law

Social policy works in a distinctive way, with a central role for social partners (employer organizations and trade unions) in making European social policy through a process of social dialogue. This can be consultative, but there is also scope for social partners to reach their own agreements directly, and where these are within the scope of EU legislation, they may be implemented into EU law

67 European Parliament and Council (2000). Directive 2000/34/EC amending Council Directive 93/104/EC concerning certain aspects of the organization of working time to cover sectors and activities excluded from that Directive. *Official Journal*, L 195:41–4.

68 Mossialos E et al. (eds) (2010). *Health systems governance in Europe: the role of EU law and policy*. Cambridge: Cambridge University Press.

by a Commission proposal and Council decision.[69] As well as its general role in implementing the EU strategy for occupational safety and health, this procedure has been used to produce a directive on sharps,[70] such as used needles, which are a major health and safety issue in healthcare.

3.2.5.4 Equalities and non-discrimination

One key area of social policy where there are strong EU measures is that of non-discrimination. Here the EU has strong powers to prohibit discrimination on six grounds – gender, racial or ethnic origin, religion or belief, disability, age, and sexual orientation[71] – and it has put in place wide-ranging legislation to combat discrimination on these grounds. The most directly relevant for health policy is disability. The EU is a signatory to the United Nations Convention on the Rights of Persons with Disabilities,[72] which defines people with disabilities as those "who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others".[73] This therefore includes people with chronic conditions which meet that definition, and indeed the Commission refers to chronic conditions such as chronic pain, or impairments arising from cancer or rare diseases, as part of its action on disability.[74] In March 2021, the European Council adopted a new 2021–2030 Strategy for the rights of persons with disabilities,[75] which furthers the previous strategy by considering the long-term impacts of disabilities and accounting for them in the aid it provides to individuals with disabilities.[76]

In principle, therefore, the EU provides strong protection for people with chronic conditions. However, patient groups have been reluctant to claim the label of disability, despite the strong EU legal protections that it brings, and challenges of

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69 TFEU, Article 153. For more political background, see Johnson A (2005). *European Welfare States and Supranational Governance of Social Policy*. London: Palgrave Macmillan, pp. 1–27.

70 European Council (2010). Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU. *Official Journal* L 134/66 of 1.5.2010.

71 TFEU, Articles 10 and 19.

72 European Commission (2010). *European disability strategy 2010–2020: a renewed commitment to a barrier-free Europe* (COM(2010)636). Brussels: European Commission.

73 United Nations (2006). *Convention on the rights of persons with disabilities*. New York: United Nations.

74 European Commission. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Union of Equality: Strategy for the Rights of Persons with Disabilities 2021-2030*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021DC0101 (accessed 24 July 2024).

75 European Parliament (2021, December 5). *A new ambitious EU disability strategy for 2021-2030:*. European Parliament. Available at: https://www.europarl.europa.eu/topics/en/article/20200604STO80506/a-new-ambitious-eu-disability-strategy-for-2021-2030 (accessed 24 July 2024).

76 European Commission (2021). *Union of equality: Strategy for the rights of persons with disabilities 2021-2030*. European Commission Employment, Social Affairs & Inclusion -. Available at: https://ec.europa.eu/social/main.jsp?catId=1484 (accessed 24 July 2024).

discrimination remain for patients. Use of decentralized enforcement of disability law – which allows people to sue governments on the grounds that they violate EU protections– is nonetheless useful for a variety of people.

3.2.6 Consumer protection

Consumer protection in the European Union, like environmental protection and, to some extent, health, grew up in internal market law before becoming part of the Treaties in 1992 at Maastricht. In other words, the 1992 appearance of consumer protection as its own Treaty article (then Article 153 TEU, now Article 169 TFEU) does not mean that it only became a concern then, but rather that it added a useful Treaty base for complementing or redirecting concerns to do with regulation of the internal market. The objectives of the EU on consumer protection include contributing to "the health, safety and economic interests of consumers" (emphasis added).[77] These objectives are principally achieved through internal market legislation, but internal market measures protecting the health of consumers (consumers being understood in EU law as anyone acting outside their trade or profession) can also be justified on the basis of the consumer protection article with and using the ordinary legislative procedure on its Treaty base. Examples include food safety, labelling and nutritional health claims. Organizationally, consumer protection was linked with public health to create DG SANCO under the Prodi Commission (1999–2004), but it was delinked and moved to the DG for Justice and Consumers (DG JUST) under the Juncker Commission (2014–2019).

The keystone of EU consumer protection law is found in two old directives, updated in 2012 and 2019.[78] The Product Liability Directive of 1985 imposed strict liability on enterprises for harm to consumers from defective products, with the definition of a defect flowing from what consumers should be entitled to expect. The Unfair Terms in Consumer Contracts Directive of 1993 deems a contract unfair and not binding if it "causes a significant imbalance in the parties' rights and obligations arising under the contract, to the detriment of the consumer".[79] A network of European Consumer Centres (ECC-net) provides

77 TFEU, Article 169.

78 Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council Text with EEA relevance; Directive (EU) 2019/2161 of the European Parliament and of the Council of 27 November 2019 amending Council Directive 93/13/EEC and Directives 98/6/EC, 2005/29/EC and 2011/83/EU of the European Parliament and of the Council as regards the better enforcement and modernisation of Union consumer protection rules.

79 Council of the European Communities (1993). Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, 1993. *Official Journal of the European Communities*, (L 95) 29–34. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31993L0013

national contact points to explain consumer rights and assist with cross-border issues. Nowadays the rights of consumers include a minimum 14 day right to return a product and a two year guarantee against faulty goods, using standards that include the claims made by suppliers.

Overall, the law is established and has been interpreted by Member State and EU courts as giving consumers a right to redress for defective products and making unfair contracts non-binding, taking into account the weaker position of consumers vis-à-vis business, which means that they should get more protection than businesses in commercial contracts. The 2019 update responded to a series of problems found in very different Member States' implementation, and also responded to the rise of online markets, personalization of various sorts, and other new internet-enabled interactions between buyers and sellers.

Consumer protection law in its current form has probably done much to promote health and safety. Many of the key patient safety and consumer protection issues in health policy, such as professional, pharmaceuticals or devices regulation, are regulated by other frameworks (see Chapter 4), but there might be untapped potential to develop consumer protection law for health.

3.2.7 Cancer and determinants of health

The fight against cancer was one of the original driving forces behind EU health policies, and today, policies with this goal remain an important part of the EU's agenda. This is for good reason – as the European population ages, the burden of cancer is increasing. In 2020, health researchers estimated that one in 20 Europeans in the 29 countries studied had faced a cancer diagnosis in their lifetime.[80] The number of people living with cancer has increased significantly since 2010. By 2040, the number of new cancer diagnoses is expected to increase by 18%, with cancer deaths predicted to increase by 26%.

Many of the social determinants of health covered in this chapter, including tobacco use, alcohol use and exposure to toxic chemicals, have been shown to impact cancer risks. To address these and other factors contributing to cancer, the European Commission introduced Europe's Beating Cancer plan, an overarching strategy document intended to cover prevention, early detection, diagnosis and treatment, and the quality of life for cancer patients and survivors (Box 3.2).

In the areas of the cancer plan that relate to social determinants of health, the EU has funded a range of projects focussed on prevention via targeted health education, civil society development and policy coordination. However,

80 De Angelis et al. (2024). Complete cancer prevalence in Europe in 2020 by disease duration and country (EUROCARE-6): a population based study. *Lancet Oncology* 25(3). Available at: https://doi.org/10.1016/S1470-2045(23)00646-0.

Box 3.2 *Europe's Beating Cancer plan*

The European Commission's Beating Cancer plan[a] marks a step up in ambition for the EU's action on cancer. Tackling cancer was where the EU's action on health began, but the need to respect the primary role of Member States on health meant that the EU's action was originally limited in scope, focused on research, cooperation, and support to national action.[b] While the EU's Beating Cancer plan still complements national action, its scope is markedly more ambitious, including action on improving healthcare for cancer, and it mobilizes a wider range of EU tools than previous initiatives.

Key goals and objectives

The Beating Cancer plan's overarching ambition is to significantly reduce the mortality and morbidity of cancer in the EU by 2030. It addresses the whole disease pathway, organized around four key action areas.

1. **Prevention:** The EU aims to reduce preventable cancers by addressing risk factors such as tobacco and alcohol, promoting healthy diets and physical activity, doing more to address environmental pollution and exposure to carcinogens, and supporting vaccination for preventable cancers (on which the Commission has proposed a new recommendation[c]).
2. **Early detection:** The EU aims to provide more support to strengthen cancer screening programmes across the EU, ensuring quality and access for all. The plan also aims to expand targeted screening beyond breast, cervical and colorectal cancer to other cancers like prostate, lung and gastric cancer.
3. **Diagnosis and treatment:** The plan aims to ensure that everyone across the EU has access to high-quality cancer care. This involves sharing expertise, including through European Reference Networks, supporting training for health professionals, improving access to innovative diagnostics and treatments, and supporting personalized medicine.
4. **Quality of life of cancer patients and survivors:** The plan recognizes the importance of supporting cancer patients and survivors. This involves addressing the physical, psychological and social impacts of cancer, as well as providing rehabilitation and palliative care. The plan also emphasizes the need to integrate cancer survivors back into the workforce and society.

The Beating Cancer plan is being implemented through a wide range of policy areas, including health, research, environment, agriculture and education. The plan is financed through various EU funding instruments, with a total of €4 billion earmarked for actions addressing cancer, including funding from the EU4Health, Horizon Europe and Digital Europe programmes. This represents an enormous increase in funds compared to previous efforts, and the integration of a health objective across a wide range of EU policies.

The approach taken in Europe's Beating Cancer plan could also be used for other non-communicable diseases, indeed with potential synergies. The EU established a Healthier Together initiative on non-communicable diseases in 2021, with five strands of health determinants: cardiovascular diseases, diabetes, chronic respiratory diseases, and mental health and neurological disorders.[d]

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However, this initiative is not supported by the broad engagement of EU policy tools in the same way as action on cancer and, with less than 5% of the funds for all five areas, has a much lower degree of ambition.

a European Commission (2021). Communication from the Commission to the European Parliament and the Council - Europe's Beating Cancer Plan. COM(2021)44 of 3.2.2021.

b European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Action Against Cancer: European Partnership. COM(2009)291 of 24.6.2009.

c European Commission (2024). Proposal for a Council Recommendation on vaccine-preventable cancers. COM(2024)45 of 31.1.2024

d European Commission (2021). Healthier together- EU non-communicable diseases initiative. Brussels. Available at: https://health.ec.europa.eu/non-communicable-diseases/healthier-together-eu-non-communicable-diseases-initiative_en (accessed 20 June 2024).

EU-wide actions that explicitly focus on public health and prevention through market interventions, such as labelling schemes, have been less likely to come to fruition than those that focus on healthcare such as cancer screening or vaccine-preventable cancer. It remains to be seen to what extent the plan's specific goals regarding social determinants of health are implemented in the future.

3.3 Communicable diseases and threats to health

One of the most consistent areas of EU health action has been on communicable diseases and other cross-border threats to health.[81] The logic of an EU role in the area is difficult to ignore. Spillover from an increasingly integrated Europe creates incentives to coordinate knowledge and responses; integration means population movements and supply chains and, as a result, infectious diseases can cross borders. Coordination and integration in the area of communicable disease control is nonetheless very difficult. The starting points in different Member States varied greatly, with different organizations, resources and skills.[82]

Politically, communicable disease control policy is caught in the logic of crisis and collective action. Outside of crises, it is hard to find energy for collective action, whereas during crises, countries can sometimes overcome the barriers to

81 See: The Politics of Communicable Disease Control in Europe, a 2012 special issue of *Journal of Health Politics, Policy and Law*, 37(6). de Ruijter A (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. Oxford University Press.

82 Elliott H, Jones DK & Greer SL (2012). Mapping infectious disease control in the European Union. *Journal of Health Politics, Policy and Law*, 37(6):935–54. Reintjes R (2012). Variation matters: epidemiological surveillance in Europe. *Journal of Health Politics, Policy and Law*, 37(6):955–65. Reintjes R et al. (2007). Benchmarking national surveillance systems: a new tool for the comparison of communicable disease surveillance and control in Europe. *European Journal of Public Health*, 17(4):375–80. Greer SL & Mätzke M (2012). Bacteria without borders: communicable disease politics in Europe. *Journal of Health Politics, Policy and Law*, 37(6):815–914.

collective measures and take actions (in others, they merely fall into recriminations and local initiatives).

Protection against health threats accordingly creates a combination of pressure for and constraint on European integration. On the one hand, the subject matter of diseases and health threats including bioterrorism is an inherent cross-border issue where the EU has complementary legislative competence to coordinate Member States' responses.[83] Infectious disease outbreaks (including SARS, influenza H1N1 and COVID-19 in recent years) affect multiple European countries. This is a case for coordination, particularly given that Member States' capacity for risk assessment and management is variable. On the other hand, Member States have very different infrastructures, resources and politics, and are not always willing to cooperate, particularly as they retain competence with respect to national healthcare budgets.[84] The result is that the EU has taken some decisive steps into control of communicable diseases, but it has not been granted the full range of powers that are associated with a coherent communicable disease control and response system.

3.3.1 Monitoring and surveillance of communicable diseases

Beginning in the 1980s, the EU began to fund research, training and disease-specific monitoring networks, and this evolved into a network for monitoring and surveillance of communicable diseases, formalized in 1998.[85] However, this overarching network had evolved from a series of disease-specific networks and depended on ad hoc coordination between national authorities, coordinated by the Commission. The anthrax attacks of 2001 in the United States, the sudden global spread of the virus causing SARS in 2003, and then pandemic influenza threats, all focused attention on the weaknesses of these arrangements, and a specialist agency, the ECDC, was established in 2005 to coordinate surveillance and monitoring of communicable diseases.[86]

Reflecting the wider distribution of health powers between the EU and Member States, the ECDC has not become a single European centre in the same way

83 TFEU, Article 168(1).

84 TFEU, Article 168(7).

85 European Parliament and Council (1998). Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community. *Official Journal*, L 268/1. Greer SL (2017). Constituting Public Health Surveillance in Twenty-First Century Europe, in Weimer M & de Ruijter A (eds). *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power*. London: Bloomsbury. de Ruijter A (2013). *Uncovering European Health Law*. Amsterdam: University of Amsterdam.

86 European Parliament and Council (2004). Regulation (EC) 851/2004 establishing a European centre for disease prevention and control. *Official Journal*, L 142/1. Greer SL (2012). The European Centre for Disease Prevention and Control: hub or hollow core? *Journal of Health Politics, Policy and Law*, 37(6):1001–30.

as the Centers for Disease Control and Prevention (CDC) have in the United States. Rather, Europe adopted the already existing network approach that was developed under Commission auspices, with the ECDC acting as a focal point of surveillance undertaken by the Member States. While this means that the number of staff of the ECDC is small in comparison with the American CDC, it is an order of magnitude larger than the couple of dozen staff formerly responsible for communicable diseases in the European Commission, and indeed more than the entire public health directorate of the European Commission. It is not directly charged with risk management, which remains overwhelmingly the job of Member States. Its job is surveillance and risk assessment, plus to some extent developing public communication strategies. However, in recent years, in the context of particular regional crises, the ECDC has also developed some operational capabilities and from time to time sends its public health specialists to affected areas to report directly on the ground. Like so much of European policy, the ECDC relies on networks of scientists as well as international organizations, and its effectiveness rested on its own effectiveness at inspiring and using them. The ECDC played a very visible role in the COVID-19 response and has gained new roles, resources and powers (see Box 3.3). It can use them to bolster EU-level public health, along with its existing networks and stature.

3.3.2 Managing and responding to threats

The responsibilities of the ECDC, even after its expansion, are centred in monitoring and surveillance, and to some extent capacity building and research. The responsibility for response to threats to health has primarily been kept by the Member States and the core EU institutions and is, in the first instance, the responsibility of a Health Security Committee,[87] which addresses issues such as preparedness and response for public health emergencies, as well as coordinating responses in crisis situations. The Health Security Committee's evolution has been interesting. Many of its functions today accumulated informally as Member State officials found it was a useful venue to coordinate their activities.

Historically, crisis response and management has been the weak point of European action on health threats. Faced with urgent situations and domestic pressures, Member State governments have tended to revert to taking national measures, sometimes even against the interests of other Member States. The ECDC's visibility is not matched with legal powers or capabilities to intervene, and even the Commission has limited ability to coordinate what Member States do. This was demonstrated all too clearly during the A (H1N1) 2009 pandemic when

87 European Parliament and Council (2013). *Decision 1082/2013/EU on serious cross-border threats to health and repealing Decision 2119/98/EC*. Luxembourg: Publications Office of the European Union. de Ruijter A (2013). *Uncovering European health law* [thesis]. Faculty of Law, University of Amsterdam.

Box 3.3 *European Centre for Disease Prevention and Control (ECDC)*

Established in 2005, the ECDC is a decentralized health agency based in Stockholm tasked with identifying, assessing and communicating emerging health threats. Its powers and resources are rather limited. The ECDC has no binding authority outside its own staff and, due to its lack of executive and operational powers, it is weaker than other EU health agencies such as the European Medicines Agency (EMA). The ECDC's budget for 2023 was €92.8 million and it employed 161 contract and 225 permanent staff,[a] significantly increased from the 286 temporary and permanent staff and €60.4 million budget with which it started 2020 (and compared to the $9,683 million 2024–2025 budget and approximately 15 000 employees of the United States Centers for Disease Control and Prevention[b]). The ECDC model was always that of a hub and coordinator for networks of Member State agencies, not a giant European agency.

The COVID-19 pandemic both increased Member States' respect for ECDC's capabilities and highlighted some of ECDC's limitations, as was made clear in a number of reports including that of the Ombudsman,[c] which also noted transparency issues. Two limitations stood out in particular. First, its mandate was limited to risk assessment rather than risk management, which undermines its ability to prescribe appropriate responses to a disease outbreak. Second, implementation of its recommendations relied primarily on national public health capacities and resources, which vary considerably from one Member State to another. Responding to these limitations, a regulation (2022/237) addressed these issues, explicitly expanding its remit. The recitals to the regulation capture the objectives and ECDC's new role:[d]

> The Centre should be tasked with providing timely epidemiological information and analysis of that information, epidemiological modelling, anticipation and forecasting, and with providing timely relevant risk assessments and science-based recommendations, which set out options for the prevention and control of communicable diseases. Risk assessments should be carried out in as short a period as possible, while ensuring that sufficient necessary information is gathered. The Centre's actions should be consistent with the 'One Health' approach, recognising the interconnections between human and animal health and the environment, as many outbreaks of communicable diseases are of zoonotic origin. The Centre should, in close cooperation with Member States, monitor the capacity of Member States' health systems to detect, prevent, respond to and recover from outbreaks of communicable diseases, identify gaps and provide science-based recommendations for the strengthening of health systems. The monitoring of Member States' health system capacity should be based on agreed indicators. The Centre should organise visits to Member States to provide additional support for prevention, preparedness and response planning activities. The Centre should support the implementation of actions that are funded by the relevant

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> Union funding programmes and instruments, and are related to communicable diseases. It should also provide guidelines for case management and support for professional networks to improve guidelines for treatment based on a thorough assessment of the latest evidence. The Centre should support epidemic and outbreak responses in Member States and third countries, including field response and personnel training, and provide the public with timely, objective, reliable and easily accessible information on communicable diseases. The Centre should also establish clear procedures for cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health, such as the WHO, hence contributing to the Union's commitment to reinforcing partners' preparedness and response capacity.

Unsurprisingly, the recitals specify immediately that ECDC's views are "inherently nonbinding". The regulation expands ECDC's remit in a variety of ways to enable it to work towards these goals, including by giving it an expanded mission, a role in monitoring Member States' surveillance and providing technical assistance, a greater role in research and provision of guidelines on coordinated action, technological assessment, and a role in monitoring vaccine effectiveness and safety as well as vaccination programmes. Further, the Regulation addresses weakness in data transmission from Member States and enhances epidemiological surveillance through integrated systems that enable real-time monitoring.[e] Member States are obliged to communicate regularly with ECDC, both in data and in approaches to public health, in order to improve both preparedness (e.g. to set up effective surveillance) and effective data sharing during a crisis.

a European Centre for Disease Prevention and Control (2024). Statement of revenue and expenditure for the 2024 financial year.(ECDC)(C/2024/1323).

b Centers for Disease Control and Prevention (2024). FY 2025 CDC Budget Overview. Available at: https://www.cdc.gov/budget/documents/fy2025/FY-25-Budget-Overview-Factsheet.pdf (accessed 2 July 2024).

c European Ombudsman. Strategic Inquiry OE/3/2020/TE.

d European Parliament and Council (2022). Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control.

e European Parliament (2021, November 24). EU strengthens its disease prevention and control capacity. https://www.europarl.europa.eu/news/en/press-room/20211124IPR18011/eu-strengthens-its-disease-prevention-and-control-capacity

several Member States bought what influenza vaccines and antiviral medications they could and declined to share. This episode gave rise to joint procurement as an EU policy instrument (see Section 4.3.4).[88] It also contributed to the need for a revised regulation on cross-border threats (see Box 3.4).

88 European Commission (2019). *Framework contracts for pandemic influenza vaccines 28 March 2019*. Memo 28/03/2019. Available at: https://ec.europa.eu/health/system/files/2019-03/ev_20190328_memo_en_0.pdf (accessed 19 February 2022).

The initial step in addressing a public health emergency, as discussed in the previous section and in the crisis management literature, is the effective detection and assessment of rapidly evolving threats.[89] Over the past few years, the European Union has prioritized the early detection of these emerging threats. To achieve this, the EU has set up several alert systems, including the Early Warning and Response System (EWRS), which is used for notifying alerts at the EU level of serious cross-border threats to health such as chemical, environmental threats or threats of unknown origins, and the Animal Disease Information System (ADIS), which monitors emerging animal health issues. These systems are integrated under the Argus and Argus II frameworks, which are overseen by the Commission's Secretariat-General.[90]

Building on this foundation of threat detection, the next critical step involves mobilizing the necessary resources, institutions, and stakeholders to curb the spread of the health threat. To this end, the EU has developed various mechanisms for cooperation and resource mobilization. These include financial tools, such as the Instrument for Security and Stability, the EU Solidarity Fund, or DG ECHO's RescEU package, which is designed to financially assist Member States during disasters.

Additionally, institutional arrangements such as the Integrated Political Crisis Response (IPCR) or the EU's Civil Protection Mechanism have been implemented, outlining decision-making routines and practices that can prepare the EU for crisis situations within hours.

Despite these tools, public health warnings do not always lead to immediate political intervention. Various factors may contribute to this delay, including crowded agendas, uncertainty, collective action barriers, and a desire to avoid causing public alarm.[91] These challenges partially explain why, despite early recognition of COVID-19 as a threat and subsequent warnings from European authorities, national officials were slow to respond in the early stages of the COVID-19 pandemic. Consequently, the EU adjusted its focus to activities within its legal remit: controlling borders, restricting the movement of unvaccinated individuals, and coordinating the procurement of COVID-19 vaccines and therapeutics, alongside the distribution of medical supplies to southern countries. Improving these early warning and resource mobilization systems will be critical for effectively managing future pandemics by ensuring quicker and more coordinated responses across the EU.

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89 Boin, A., & Rhinard, M. (2023). Crisis management performance and the European Union: the case of COVID-19. *Journal of European Public Policy*, 30(4), 655–675.

90 Bengtsson, L., Borg, S., & Rhinard, M. (2018). European security and early warning systems: From risks to threats in the European Union's health security sector. *European Security*, 27(1), 20–40.

91 Boin, A., Ekengren, M., & Rhinard, M. (2020). Hiding in plain sight: Conceptualizing the creeping crisis. *Risk, Hazards & Crisis in Public Policy*, 11(2), 116–138. https://doi.org/10.1002/rhc3.12193

Box 3.4 *Revised regulation on cross-border threats*

The revised Regulation on Serious Cross-Border Threats to Health (Regulation (EU) 2022/2371)[a] was adopted by the European Parliament and the Council in November 2022 as a key element of the European Health Union. This regulation was developed in response to the COVID-19 pandemic and is designed to enhance the EU's ability to anticipate, prepare for, monitor, and respond to serious cross-border health threats.

The regulation covers a wide range of threats, including biological, chemical, environmental, health, and unknown threats. Among other things, the revised regulation strengthens the role of the EU Health Security Committee, allowing this body to issue guidance more frequently and effectively. The revised regulation also grants the European Commission the authority to declare an EU-wide public health emergency. Such a declaration activates a range of response mechanisms, including the fast tracking of medicine approvals and the deployment of necessary resources.

Additionally, the revised regulation mandates the establishment of a high-performing epidemiological surveillance system at the EU level. This system leverages artificial intelligence and digital tools to enhance the quality of surveillance data reported by Member States. Finally, the revised regulation provides a legal basis for creating European reference laboratories in public health. These laboratories are intended to play a critical role in aligning diagnostics, testing methods, and the use of specific tests for uniform surveillance and reporting of diseases by Member States.

a European Commission (2022). Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. https://health.ec.europa.eu/publications/regulation-eu-20222371-serious-cross-border-threats-health-and-repealing-decision-no-10822013eu_en.

3.3.3 Enhancing response capacity in medical countermeasures

After every health emergency it is important to learn lessons and take actions that will enable a faster and more effective response to the next emergency. In the case of COVID-19, European policy-makers, as with many policy-makers around the world, concluded that the EU needed greater ability to anticipate threats (since preparing for pandemic influenza did not equate to preparing for a SARS virus such as caused COVID-19), develop resilient supply chains (to avoid the problems with PPE and vaccines in 2020–2021) and strengthen the scientific research base responsible for treatments and vaccinations. Unlike many policy-makers around the world, they responded with substantial expenditure and changes including, specifically, the European Health Emergency Preparedness and Response Authority (HERA).

HERA is a Commission Service announced in a communication of September 2021 after discussions of the appropriate legal form for the agency.[92] It has an annual budget of around €1 billion. HERA was established to be a core part of the EU's response to COVID-19 and efforts to be more resistant to and resilient in similar health crises in the future. HERA's role focuses on enhancing capacity in the area of medical countermeasures. HERA's primary responsibilities include developing the necessary response capabilities in the EU, and facilitating the production and dissemination of medicines, vaccines and protective equipment across Europe.[93] HERA's specific task is to "strengthen Europe's ability to prevent, detect and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement and equitable distribution of key medical countermeasures". In doing so,

> HERA will have different modes of operation during preparedness and crisis times. In the 'preparedness phase', it will steer investments and actions in strengthening prevention, preparedness and readiness for new public health emergencies. In the 'crisis phase', HERA will be able to draw on stronger powers for swift decision-making and implementation of emergency measures. Its actions in both phases will be aimed at ensuring swift access to safe and effective medical countermeasures and at the scale needed.[94]

Its €6 billion budget over the six years of the current budget period (MFF, see Section 2.2) is in addition to other expenditure such as RescEU and EU4Health and the budgets of agencies such as ECDC. Its board and director have some autonomy within the Commission, and the board includes Member State representatives as well as Commission officials. The Commission communication introducing HERA takes care to point out that many other sources of EU funding, from cohesion funds to EIB loans, can be used to support its goals.[95]

The aim of HERA is to enable the EU to rapidly make available the necessary countermeasures for health emergencies by covering the whole innovation chain from conception to distribution and use. Initially, it was to be modelled on the United States' Biomedical Advanced Research and Development Authority

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92 European Commission (2021). *Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union*. COM/2021/576 final, 16 September 2021.

93 Steitz, C. (2023). The European Health Union and the protection of public health in the European Union: Is the European Union prepared for future cross-border health threats? *ERA Forum* 23, 543–566. https://doi.org/10.1007/s12027-023-00732-1

94 European Commission (2021). *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union*. Available at: https://health.ec.europa.eu/document/download/43aaa66d-3eee-4d91-8bff-c974bd5851a3_en (accessed 10 August 2024).

95 Ibid.

(BARDA), which plays a similar role for private sector investors in actively supporting the development of particular early-stage innovations towards their practical application, but does so in pursuit of the public policy objectives of preparedness for public health emergencies rather than in pursuit of market rewards. BARDA also plays an active role in making sure that relevant supplies are actually available through procurement and stockpiling. Again, this would represent a significant expansion of the EU's role in pharmaceuticals beyond the existing focus of licensing products for the EU's market. In practice, HERA is less involved in speculative research than BARDA, and has found a different niche in EU politics.

An example of early HERA activities is its role during the 2022 Mpox outbreak (see Box 3.5).

3.3.4 Vaccines and vaccination

Vaccination is one of the most cost-effective public health measures. Vaccines have contributed significantly to the control of communicable diseases worldwide,

Box 3.5 *HERA's role during the Mpox outbreak*[a]

HERA was activated in May 2022 in response to an outbreak of Mpox (formerly monkeypox) across the EU. As the situation unfolded, the agency engaged in extensive consultations with Member States on the production, acquisition and distributions of vaccines and therapeutics. In line with the 2022 work plan, which had been previously approved by HERA, the European Commission procured 333 000 doses of the JYNNEOS vaccine. These doses were distributed to Member States based on their specific needs and population sizes, facilitated by a donation agreement between HERA and the respective Member States. Notably, this initiative marked the first time the EU budget, specifically through the EU4Health Programme, was used to directly purchase vaccine doses and distribute them to Member States via the Civil Protection Mechanism. The ECDC reported that, between May 2022 and February 2023, approximately 333 000 vaccine doses manufactured by Bavarian Nordic were administered across 25 countries in the EU and European Economic Area (EEA).[b] This coordinated approach contributed to a sharp decline in Mpox cases across the region.[c]

a Toshev, A., Petkova-Gueorguieva, E., Mihaylova, A., Pavlova, G., Parahuleva, N., Balkanski, S., et al. (2024). Health Emergency Preparedness and Response Authority's (HERA) role in dealing with the monkeypox emergency in the European Union. Pharmacia, 71, 1-6.

b European Centre for Disease Prevention and Control (2023). Public health considerations for mpox in EU/EEA countries. Available at: https://www. ecdc.europa.eu/en/publications-data/public-health-considerationsmpox-eueea-countries (accessed 16 July 2024).

c Toshev, A., Petkova-Gueorguieva, E., Mihaylova, A., Pavlova, G., Parahuleva, N., Balkanski, S., et al. (2024). Health Emergency Preparedness and Response Authority's (HERA) role in dealing with the monkeypox emergency in the European Union. Pharmacia, 71, 1-6.

saving millions of lives.[96] Vaccines are responsible for the worldwide eradication of smallpox and Europe's polio-free status.[97] Successful, rapid vaccine development against SARS-CoV-2, the virus that causes COVID-19, was one bright spot during the pandemic, with multiple effective and safe vaccines against the virus developed in record time.

It is important to distinguish between vaccines and vaccinations. A vaccine is a dose of a proven safe and effective biological preparation; a vaccination is the actual administration of that vaccine.[98] Vaccines and vaccination present quite different policy challenges. Vaccine development is a problem of scientific research and clinical trials. Vaccine production and acquisition is a problem of political economy in which resources and power matter a great deal and rich countries will frequently adopt policies that reproduce global inequalities. Vaccination is a problem of public health and healthcare within countries, with challenges ranging from trust in the population to cold chain storage and the feasibility of vaccine passports. Broadly speaking, the EU has an important role in vaccines policy, and an especially important role in COVID-19 vaccines policy. It has a much less important role in vaccination policy, which subsidiarity largely reserves for Member States. This distinction is not always appreciated by the public, or by policy-makers who would like to avoid blame for problems in vaccination policy.

3.3.4.1 Routine EU vaccine and vaccination policies

Vaccination is certainly an important public health issue across Europe. Coverage rates for certain routine vaccinations (e.g. against measles) have fallen below the level required to maintain herd immunity in some EU Member States. The reasons for the fall in coverage include failure to reach vulnerable groups of people within the population, increased vaccine hesitancy (a "delay in acceptance or refusal of vaccines despite availability of vaccine services") and deficiencies in organization, financing and provision within Member States' health systems.[99] Suboptimal vaccination coverage is thus a symptom of larger political and social problems, including income inequality and social exclusion, poor access to healthcare, low trust in governments and/or scientific evidence, and inadequately resourced or

96 There are many estimates of the impact of vaccines on health, all showing enormous benefits. For one example, see Toor J et al. (2021). Lives saved with vaccination for 10 pathogens across 112 countries in a pre-COVID-19 world. eLife, 2021 Jul 13;10:e67635.

97 *European Commission (2018). Questions and Answers: EU Cooperation on Communicable Diseases*. Available at: http://europa.eu/rapid/press-release_MEMO-18-3458_en.htm (accessed 19 February 2021).

98 Jarman, H., da Fonseca, E. M., & King, E. J. (2024). The Political Economy of Vaccines during the COVID-19 Pandemic. *Journal of Health Politics, Policy and Law*, 49(1), 1-8. Greer, S. L., Jarman, H., King, E. J., & Massard da Fonseca, E. (Eds.) (2025). *Vaccination Politics: The comparative politics and policy of COVID-19 vaccination*. University of Michigan Press.

99 Rechel B, Richardson E & McKee M (2018). *The Organization and Delivery of Vaccination Services in the EU*. Copenhagen: WHO Regional Office for Europe on behalf of European Observatory on Health Systems and Policies.

managed health services. There is therefore considerable variation in vaccination rates across the EU.

Prior to the COVID-19 pandemic, concerns had already been raised about falling confidence in vaccination among members of the public and health professionals.[100] The reasons for this decline in confidence are complex and have been a long time in the making. In many cases, attitudes towards vaccination are influenced by the relationships of individuals and communities to governments, including both a lack of public trust in the policy-makers setting vaccine policy as well as distrust of the medical professionals or government agents administering vaccinations at ground level. Historic and current experiences of structural discrimination, marginalization and poor quality healthcare also play an important role, as do the spread of disinformation via social media and the politicization of vaccination. Pro-vaccination public health messages are often ineffective in the face of these factors.[101] A further complication is an increase in hesitancy to promote vaccines among health professionals, which points to a gap between stated national policies and the attitudes of health professionals responsible for implementing these policies, e.g. pharmacists, nurses and doctors.[102]

The regulation of vaccines as products for sale in the single market is the responsibility of both the EU and Member States. This means that the approval of vaccines, along with pharmacovigilance (the act of monitoring the effects of a medical product after it enters the market and the reporting of adverse effects), fall under areas of shared competency.[103] Influenza vaccines for use in the single market must be authorized through a centralized procedure governed by the European Medicines Agency and the European Commission. Most vaccine manufacturers choose to use this central route to obtain authorization for their vaccines. The ECDC has new powers to monitor vaccine effectiveness (see Box 3.3.).

The procurement and use of vaccines are not within the legal competence of the EU and remain Member State competencies. Hence, in terms of policies governing vaccine use, there is significant variation by country. In response to measles, for example, vaccination is mandatory in 14 Member States and

100 De Figueiredo et al. (2020). Mapping global trends in vaccine confidence and investigating barriers to vaccine uptake: a large-scale retrospective temporal modelling study. Lancet, 396(10255):898–908.

101 Larson J et al. (2018). The State of Vaccine Confidence in the EU. *The Lancet*, 392(10161):2244–6. European Commission (2020). *State of Vaccine Confidence in the EU and the UK*. Public Health (europa.eu).

102 Ibid.

103 De Ruijter A (2019). *EU Health Law and Policy: the Expansion of EU Power in Public Health and Health Care*. Oxford: Oxford University Press.

voluntary in the other 13 countries (as of February 2024).[104] Other measures such as vaccine requirements for children entering the school system complicate this picture.[105] Vaccination policies also vary considerably by disease. In the case of adult influenza vaccinations, the EU has a generally subpar coverage rate, even among older, vulnerable populations, with some national variation.[106]

The EU institutions play a vital role in promoting recommended vaccinations in order to protect public health. In response to concerns about low coverage rates and decreased vaccine confidence, the Council recommended a series of EU actions to strengthen cooperation among Member States.[107] These actions include:

- the collation and dissemination of data on vaccination rates and levels of confidence across the EU
- evaluation of the feasibility of creating an EU-wide vaccination card
- monitoring national policies and the creation of guidance that can inform them
- technological solutions that enable interoperable data exchange of national vaccination records
- the promotion of vaccination through a public awareness campaign
- convening key pro-vaccination stakeholders, and
- measures to facilitate the joint procurement of vaccines, e.g. by exploring stockpiling and engaging collectively with vaccine manufacturers.

It remains to be seen to what extent these policies will be effective in addressing the concerns of public health officials with regard to falling coverage. The Commission has developed an action plan to implement the Council recommendations by 2022.[108] However, to the extent that anti-vaccination remains a politically

104 European Centre for Disease Prevention and Control. (2024). Measles: EU threat assessment brief, February 2024. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/measles-eu-threat-assessment-brief-february-2024.pdf

105 Rechel B, Richardson E & McKee M (2018). *The Organization and Delivery of Vaccine Services in the EU*. Copenhagen: WHO Regional Office for Europe on behalf of European Observatory on Health Systems and Policies.

106 Ibid.

107 European Council (2018). *Recommendation of 7 December 2018 (2018/C 466/01) on strengthened cooperation against vaccine-preventable diseases*.

108 European Commission (2019). *Roadmap for the implementation of actions by the European Commission based on the Commission Communication and the Council Recommendation on strengthening cooperation against vaccine preventable diseases*. Available at: https://ec.europa.eu/health/system/ files/2019-09/2019-2022_ roadmap_en_0.pdf (accessed 25 February 2022).

popular position in Europe, we can expect some Member States to be themselves hesitant to act.

3.3.4.2 COVID-19 and the EU Vaccines Strategy

In the case of conditionally authorizing vaccines to enter the EU market as a response to disease outbreak, a centralized procedure is employed that allows vaccines to be pre-authorized in generic form and then more quickly authorized once a pandemic occurs (see also Section 3.3.3).[109]

The COVID-19 pandemic was a huge challenge for vaccine authorization, procurement and distribution within the EU and globally. The European Commission presented its Vaccines Strategy in June 2020, with the objective of speeding up the production of COVID-19 vaccines and ensuring equitable access for all Member States to an affordable vaccine.[110] The EU Vaccines Strategy provided for European authorities to forge agreements with individual vaccine manufacturers on behalf of interested Member States, using advance purchase agreements (APAs). By the end of 2020 the Commission had signed APAs with six pharmaceutical companies: Pfizer-BioNTech, Moderna, AstraZeneca and Johnson & Johnson, whose vaccines were authorized for use in the EU following positive scientific recommendation by the European Medicines Agency (see Box 3.6), as well as with Sanofi and CureVac, whose initial plans for vaccine development were eventually altered due to other companies' dominance in the market.

The European Vaccines Strategy has stronger central control than a joint procurement agreement under the Health Threats decisions. The Vaccines Strategy foresaw vaccine distribution on a per capita basis to ensure equitable access and support from a platform to monitor the effectiveness of national vaccination strategies. Its operation, however, was far from coordinated across Member States. Although in theory the advance purchase agreements prevented governments from engaging in parallel negotiations, several countries purchased more doses on their own, such as Germany, which bought 30 million additional doses in the autumn of 2020. In addition to coordination issues, the EU has limited capacity for producing vaccines on a large scale and at speed. There are also systematic weaknesses in the supply chains of pharmaceutical manufacturing that put the EU at a disadvantage compared to other governments. Aiming to address these supply chain issues, in 2020 the European Commission published its Pharmaceutical Strategy for Europe and in September 2021 the Commission established HERA.

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109 Hervey T & McHale J (2015). *European Union Health Law: Themes and Implications*. Cambridge: Cambridge University Press.

110 European Commission (2020). *Communication on the EU Strategy for COVID-19 vaccines*. COM(2020)245 final, 17.6.2020.

Box 3.6 *Role of European Medicines Agency (EMA) during COVID-19 pandemic*

During the COVID-19 pandemic, the European Medicines Agency (EMA) evaluated the safety, efficacy and quality of vaccines based on rigorous scientific data. This assessments was sent to the European Commission, which then made the final decision to grant marketing authorization for the vaccines across the EU.[a] The agency encountered minimal political resistance from Member States, largely because the EMA's processes were seen as straightforward by national governments and the agency operates with a significant degree of independence from political influence.[b] In addition, the EMA also bolstered its existing emergency regulations. A key part of this enhancement involved publishing comprehensive data related to COVID-19 vaccines, along with detailed scientific assessments.[c]

The EMA's pre-existing emergency regulatory framework enabled the agency to respond decisively and transparently to a fast-evolving crisis. This strategic adaptation proved crucial in securing broad public trust and governmental support for the EMA's decisions regarding the authorization of COVID-19 vaccines. The EMA's actions have set a precedent for managing future pandemics, highlighting the effectiveness of rapid and transparent responses grounded in pre-existing, robust, and adaptable emergency regulatory procedures.

The EMA has been given an expanded mandate, effective from March 2022, to enhance its role in crisis preparedness and management within the EU.[d] This new mandate strengthens the EMA's responsibilities in monitoring and mitigating shortages of critical medicines during health emergencies, provides greater authority in offering scientific advice on the development of products intended for use during a public health emergency, and increases its involvement with medical devices. Additionally, the EMA now collaborates more closely with HERA to ensure a coordinated response to public health crises.

a Nachlis, H., & Thomson, K. (2024). Emergency Regulatory Procedures, Pharmaceutical Regulatory Politics, and the Political Economy of Vaccine Regulation in the COVID-19 Pandemic. *Journal of Health Politics, Policy and Law*, 49(1), 73–98.

b Cavaleri, M., Enzmann, H., Straus, S., & Cooke, E. (2021). The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines. *The Lancet*, 397(10272), 355–357.

c Caplanusi, I., Szmigiel, A., van der Elst, M., Schougaard Christiansen, M. L., Thirstrup, S., Zaccaria, C., et al. (2024). The role of the European Medicines Agency in the safety monitoring of COVID-19 vaccines and future directions in enhancing vaccine safety globally. *Drug Safety*, 47(5), 405–418.

d European Union (2022). Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123

Vaccine hesitancy remained a significant barrier to vaccine uptake during the pandemic. In early 2021, before vaccines were widely available throughout the EU, opposition to taking a COVID-19 vaccine was very high in some Member States. In January 2021, 47% of respondents in France and 31% of respondents in Germany stated that they were "unvaccinated and not willing to get vaccinated". Over time, however, opposition in France decreased dramatically, falling to 20% in September 2021.[111] Although the determinants of vaccine hesitancy and opposition are complex, this decline suggests that the combination of policies implemented in France, including requirements to be vaccinated in order to enter certain public spaces, may have changed the risk calculus for many.

There remains a minority of people in each Member State who do not want to be vaccinated but, as the example of COVID-19 shows, Member State policies can increase vaccination uptake. Uneven rates of vaccination in an integrated market might continue to lead to localized surges and cross-border transmission of vaccine-preventable communicable diseases. It also remains to be seen how the politics and social dynamics of COVID-19 and vaccination campaigns against it change broader thinking about vaccination.

3.3.5 Civil protection: RescEU and the European Medical Corps

Global and European health challenges increasingly include hybrid threats, health or other emergencies such as new disease outbreaks, large forest fires and other natural disasters associated with human-induced climate change, as well as long-standing threats such as radiological accidents.[112] The increased tempo – and increased likelihood – of such disasters is the justification for the EU's increasingly developed civil protection mechanisms.

The EU's role in civil protection stems from three Treaty bases. Article 214 TFEU authorizes civil protection

> within the framework of the principles and objectives of the external action of the Union. Such operations shall be intended to provide ad hoc assistance, relief and protection for people in third countries who are victims of natural or man-made disasters, in order to meet the humanitarian needs resulting from these different

111 Imperial College London/YouGov. *COVID-19 Behavioural Tracker Data Hub*. Available at: www. coviddatahub.com (accessed 19 February 2022).

112 The EURATOM Treaty to this day is separate from the other EU Treaties and there is no interest in integrating it. This means that the legal structure for handling radiological threats to health is different from other kinds of emergencies, but in practice the formal and informal weight of the EU mechanisms means that EU preparation and practice guide planning for radiological as well as other threats.

> situations. The Union's measures and those of the Member States shall complement and reinforce each other.

Article 196 TFEU (see Annex) is another gate similar to Article 168. It creates a legal base for civil protection work at the EU level within the EU, but does not make it easy. Member States have to want the EU to support and complement their work and harmonization is excluded. It is not hard to see how it was that the civil protection system within the EU started small and only grew when COVID-19 made it clear that there was quite a lot of possible scope for EU coordination and support. Finally, the solidarity clause: Article 222 TFEU says that Member States

> shall act jointly in a spirit of solidarity if a Member State is the object of a terrorist attack or the victim of a natural or man-made disaster. The Union shall mobilise all the instruments at its disposal, including the military resources made available by the Member States, to ... assist a Member State in its territory, at the request of its political authorities, in the event of a natural or man-made disaster. (222.1 TFEU)

It is worth noting that Article 222 permits the use of Member State militaries under an EU umbrella for disaster response. There had obviously been pragmatic decisions by Member States to send troops for work such as search and rescue operations before the Lisbon Treaty, but they had no particular place in EU law.

The Civil Protection Mechanism, operative since 2001, gives flesh to these two articles. It is a mechanism for the coordination and strengthening of Member States' relief capacities in action as well as in disaster preparedness and training. Initially primarily used for disaster relief outside the EU, it has increasingly operated inside the EU for civil protection crises beyond the capabilities of individual Member States. It has been activated to respond to the refugees arriving in 2015, Mediterranean forest fires in 2017 and forest fires in Sweden in 2018.

In March 2019 the mechanism was upgraded and renamed RescEU.[113] It is based on Article 196 TFEU, which mandates that the EU shall help coordinate Member State civil protection, and Article 214 TFEU, which authorizes the EU to assist victims of natural or human-caused disasters worldwide. The Civil Protection Pool is the register of assets that Member States make available to RescEU activities.[114] These specialized assets are certified as suitable and engage in regular exercises in order to ensure that they can be deployed and work together. They are only deployed on EU activities by their Member States after a request from the Civil

113 European Parliament and Council (2019). *Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision 1313/2013/EU on a European Union Civil Protection Mechanism*.

114 And Iceland, Norway, Serbia, North Macedonia, Montenegro and Türkiye.

Protection Mechanism. The Emergency Response Coordination Centre acts as a hub for requests and coordination. In other words, it remains under Member State control, but with a slowly increasing degree of Europeanization coming through coordination, joint planning, joint preparation and exercises, and joint service in crises.

The Civil Protection Pool includes the European Medical Corps (EMC), which was set up in the aftermath of the 2014 Ebola outbreak in West Africa and began operating in February 2016.[115] It is the EU's principal contribution to WHO's Global Health Emergency Workforce initiative, which seeks to certify the competency and identify the types of medical resources needed in an emergency and thereby improve matching (ensuring that the right expertise and equipment arrives) and ensure quality among the diverse groups, including civil society and governments, that might have willingness to help and useful resources. The EMC initiative is closely coordinated with the WHO initiative.

As COVID-19 proved, RescEU and civil protection in general will be an issue to watch. On one hand, Member States jealously guard their autonomy and resources, in principle and in practice. On the other hand, in the face of natural and human-caused disasters in an increasingly integrated EU, and an increasingly threatening global climate, there is a case for coordination, joint work and even pooled resources. The creation of the civil protection machinery reflects the case for joint working even if its effectiveness and evolution remain to be established.

Member States saw in RescEU an important way to respond to the COVID-19 pandemic. The increase in its budget was every bit as dramatic as the increase in the Health Programme when it became EU4Health. The entire RescEU budget for 2014–2020 was €766.5 million (with a higher eventual total due to pandemic response in 2020). Its budget in 2021 alone was €772.7 million. It continued in this range for three years, peaking at €786.5 million in 2023, and then dropped by two-thirds to around €245 million per year through to the end of the current budget at the end of 2027.[116]

The steep drop in the budget can make sense given that RescEU is fundamentally a stockpile and secondarily a data management system (e.g. the management of the EMC). Both of these involve significant start-up costs such as the acquisition of aeroplanes for fire-fighting or PPE for healthcare and the development of a database and knowledge to go into it. Once the stockpile and data management are in place, the budget would logically be focused on replacing expired or consumed equipment and ongoing database operations as well as acquiring supplies to face new threats. As a number of countries found in the COVID-19

115 Pariat M (2016). Europe's medical emergency response. *Crisis Response Journal*, 11:3.

116 https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/resceu_en, accessed 16 July 2024.

pandemic, sustaining stockpiles is politically hard; masks acquired in response to the 2009 H1N1 virus turned out to have expired by 2019 and not been replaced, which can be understood if we think about the salience of PPE and the tenor of conversations around government budgeting in 2018–2019. The rigidity of EU programmes and budgets might make RescEU more predictable than Member State programmes which are not insulated from lack of political interest by anything like the EU's multi-year budget. The solidarity inherent in RescEU and shared civil protection might also create a durable political coalition for it among smaller and less wealthy Member States which cannot afford all possibly necessary equipment, and even larger ones which might appreciate access to emergency resources.

It is also worth noting that RescEU, historically and organizationally, works beyond the EU's borders. It is a rare case of an EU external policy that turned out to have useful internal possibilities. Despite its important new internal function, it continues to operate in its older role as an instrument of international disaster response. Its internal application, new in 2019, is now a large part of its budget. It remains to be seen how DG ECHO, which leads RescEU, and other relevant policy-makers will handle any gaps or tensions between its internal and external faces.

3.4 Substances of human origin (SoHO)

Many changes in public health systems and policies come about not through carefully considered development but rather in response to specific crises, as has already been discussed with communicable diseases. There are, however, certain issues where Member States see a clear advantage to organizing at the European level as well as pooling policy and technical resources. Substances of human origin is such an issue. The original health article introduced in the Maastricht Treaty in 1992 did not include powers for European legislation on this topic; the choice by Member States to add such powers through the Amsterdam Treaty in 1997 reflected national problems, in particular the HIV-contaminated blood scandal in France in the 1980s, as well as perceived gaps in the regulatory regime for substances of human origin, in comparison, for example, with the developing regulations for medicinal products.[117]

117 Tabuteau D (2007). La sécurité sanitaire, réforme institutionnelle ou résurgence des politiques de santé publique? [Health security, institutional reform or resurgence of public health?] *Les Tribunes de la santé*, 16(3):87–103. Brooks E (2025). *European Union Health Policy: What is it, how does it work and why does it matter?* Manchester University Press.

The development of legislation on blood also illustrated another dynamic of EU policy development: the manner in which discussions in other forums are used to develop and build consensus first, and only afterwards is actual legislation brought forward, coming at the end of a much longer process. In this case the Council of Europe acted as an antechamber for the legislation ultimately proposed by the Commission, drawing on a long history of developing European standards in this area.[118]

The actual legislation on blood, blood products, tissues and cells itself is relatively limited, reflecting the narrow Treaty mandate.[119] It is focused on setting minimum standards for quality and safety, such as oversight of providers, traceability and notification of adverse incidents, and a range of technical requirements. The legislation notably does not set requirements to ensure self-sufficiency in blood for the EU, despite this being part of the original set of objectives identified by the Member States.[120] This reflects the perennial concern of national administrations about granting powers to the EU relating to the organization of their health systems.[121] In 2017 and 2018 the European Commission carried out the first formal evaluation of the EU blood, tissues and cells legislation since the adoption of the basic acts in 2002 (on blood) and 2004 (on tissues and cells).[122]

In July 2024 a new Regulation on substances of human origin was passed. The regulation[123] drew on two decades of experience, a review and the experience of COVID-19 to update the law in light of scientific developments, failures to protect patients, donors and children born of in vitro fertilization, and very different Member State oversight regimes that limited exchange of substances. The new regulation expands the category of substances of human origin (SoHO) to include human microbiota and breast milk, and allows the designation of new future SoHO as technology changes. It develops the EU approach to SoHO in

118 Faber J-C (2004). The European Blood Directive: a new era of blood regulation has begun. *Transfusion Medicine*, 14(4):257–73. Farrell A-M (2005). The emergence of EU governance in public health: the case of blood policy and regulation, in Steffen M (ed.). *Health governance in Europe: issues, challenges and theories*. Abingdon: Routledge, pp. 134–51. Steffen M (2012). The Europeanization of public health: how does it work? The seminal role of the AIDS case. *Journal of Health Politics, Policy and Law*, 37(6):1057–89.

119 Article 168 (4): "The European Parliament and the Council... shall... adopt: (a) measures setting high standards of quality and safety of organs, and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member States from maintaining or introducing more stringent protective measures."

120 Council of the European Union (1996). *Council resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community* (96/C 374/01). Luxembourg: Publications Office of the European Communities.

121 Article 168 (7): "These measures (para 4(a)) shall not affect national provisions on the donation or medical use of organs and blood."

122 European Commission (2019). *Evaluation of the EU blood, tissues and cells legislation*. Available at: https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en (accessed 19 February 2022).

123 European Commission (2024). New EU rules on substances of human origin. Available at: https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/new-eu-rules-substances-human-origin_en (accessed 17 July 2024).

a way that resembles its approach to other areas, with stronger coordination and shared procedures for a network of designated Member State authorities. It sets up a new European SoHO board, creates EU-wide procedures for authorizing SoHO preparations, mandates Member States to create competent bodies for SoHO, and increases EU-level requirements for establishments that handle SoHO.

Separate legislation addresses the quality and safety of organs for transplantation.[124] Some financial mechanisms, e.g. EU4Health, also support the improvement of quality and safety standards and procedures for organ transplantation.[125]

3.5 Conclusion

For a long time EU public health policy was the gate with no fence. Article 168 TFEU was a sturdy gate that would keep out policy entrepreneurs when closed but which Member States could open as and when they chose to work together. The result until 2020 was that most of the consequential EU public health policy was made in some other way, notably through the internal market Treaty bases we discuss in Chapter 5. But over the last twenty years an infrastructure and political arena of EU public health policy has built up, sometimes hard to see (as in work on joint procurement) and sometimes relatively ineffective (as with alcohol policy) but nonetheless more consolidated and coherent than before. Even the Juncker Commission's studied lack of interest in stronger public health policy, seen in the weak mandate given to Commissioner Andriukaitis (responsible for health and food safety), did not prevent the normalization and development of public health policy as an issue and the slow incorporation of public health goals into other policies.

The COVID-19 pandemic struck when EU public health advocates were allowing themselves to feel optimistic. Not only had DG SANTE survived, but Commissioner Kyriakides had a more ambitious mandate letter from President von der Leyen. By the summer of 2020 those ambitions seemed small. An expanded ECDC and EMA, a new HERA entity, a vastly expanded and more flexible RescEU, a rebooted and much larger health programme (EU4Health),

124 European Parliament and Council (2010). *Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation*. European Commission (2012). Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. *Official Journal* L 275, 10.10.2012, pp. 27–32. European Commission (2015). *Report from the Commission to the European Parliament and the Council on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on the standards of quality and safety of human organs intended for transplantation* (COM(2015) 123 final of 10.3.2015).

125 https://health.ec.europa.eu/blood-tissues-cells-and-organs/organs_en (accessed 17 July 2024).

a Pharmaceuticals Strategy, support for COVAX (see Chapter 7) and, perhaps most dramatically, the Vaccines Strategy all pointed to a recognition by EU Member States that they were all in it together.

The story of many federal states in the pandemic was of state-level efforts to compensate for the failure of their federal governments in 2020, whether in Brazil, India or the United States.[126] The story of the EU is of individual Member States recognizing that they were so tightly interconnected as to make national egotism an impossible approach. They quickly established a much stronger "federal" public health power that could match the EU's integration with dedicated public health resources.

EU public health policy today is partly a legacy of efforts to address older and still serious problems such as obesity, partly the immediate responses to COVID-19 such as the Vaccines Strategy, and partly longer-term investments in public health capacity and resilience such as EU4Health, the Pharmaceuticals Strategy, the much larger RescEU, the increased ECDC budget, and HERA. Non-communicable diseases, inequalities and their causes are not going away, and both their persistence and the persistence of relevant public health advocates can keep them on the agenda. In this, they might be aided by the new prominence and resources of public health.

The future of post-COVID-19 EU public health policy will largely be decided in the negotiations leading up to the 2027 budget, when institutions and governments revisit the funding decisions that have shaped EU4Health and RescEU in particular. Will Member States decide that the vastly expanded or new programmes were worth it? Will the expenditures prove their worth? Even if they do, will political leaders, having forgotten the pandemic, have refocused on other topics? They have already sought to redirect public health funds into new priorities such as managing the impact of the Russian Federation's invasion of Ukraine. The challenge of the next few years is to show the added value of the large-scale new investments in EU public health, and be frankly critical of any problems so that they can be addressed as governments start to scrutinize the EU budget in preparation for 2027.

126 Greer SL, King E, Massard da Fonseca E & Peralta-Santos A (2021). *Coronavirus politics: The comparative politics and policy of COVID-19*. University of Michigan Press. Greer, S. L., Dubin, K. A., Falkenbach, M., Jarman, H., & Trump, B. D. (2023). Alignment and authority: Federalism, social policy, and COVID-19 response. *Health Policy*, 127, 12-18.

Chapter 4

Healthcare systems

4.1 The European Union's role in healthcare

Article 168 TFEU is quite clear about the EU's role in healthcare:

> Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

The rise of European Union healthcare policy, and its impact on almost every dimension of healthcare services, might therefore be something of a surprise. Indeed, EU healthcare policy is a patchwork of different competencies that influenced health,[1] some with explicit health goals that had unexpected effects on health (as with labour law) and some with explicit internal market goals and little interest in health effects.

Working out how different policy areas affect healthcare systems, and the scale and kind of impact they have, has been a policy challenge but in many areas policy has become relatively settled in the almost thirty years since the Kohll and Decker decisions alerted many in health to the potential impact of internal market and other EU policies on healthcare systems. This chapter presents EU policy mechanisms in four categories: governance, resource generation (in the case of the EU, this primarily means goods such as devices and medicines), people (workforce and patients), and finance. It does not discuss EU financial contributions to healthcare infrastructure, which are covered in Chapter 6.

1 Hervey, T. (2015). The past, present and future of EU health law. In *Pioneering Healthcare Law* (pp. 67–77). Routledge.

4.2 Governance

The first dimension of a health system is how its governance works: how decisions are made and implemented. Article 168 TFEU, of course, states that the EU must respect the Member States' primary responsibility for setting their health policy and managing their health services, including the allocation of resources for medical care.

The EU's direct impact on the governance of healthcare and health systems has accordingly been limited by competences and subsidiarity. It has nonetheless had some impact, notably through the governance structures of regulatory agencies, European Reference Networks (ERNs) and health technology assessment, all discussed below and all of which affect in some ways the decisions of healthcare systems and policy-makers.

However there are two additional dimensions of EU governance that shape EU healthcare. The first is hard to identify but significant: the necessity for the internal governance of national health systems to operate within the EU policy context. This understanding helps avoid conflicts with evolving EU laws affecting healthcare systems. It also allows national health systems, or at least their governments, to better grasp opportunities for information, resources or influence. Understanding, let alone accessing EU resources or shaping its policy debates, can be expensive and even well-resourced Member States might not deem it a priority (memorably, one official of a big Member State told researchers that health policy developments were not important to their government, unlike haddock quotas, which were).[2] Developing expertise in EU health policy, whether it is rules about public procurement or methods to tap financial resources, requires significant resources, while governance must often be adapted in many small ways to comply with EU law, by for example complying with the directive and law on cross-border patient mobility (see Section 4.6) or the Working Time Directive (see Chapter 3).

The second dimension of EU governance is the governance approach of the EU itself in health policy. Chapters 1 and 2 discussed the EU's political processes and the development of its health policies. This section reviews the governance approach that has developed through multiple statements of values, priorities and goals. It highlights efforts to ensure that key actors in the EU understand the impact of European actions on health and guide them accordingly. Not every political actor in the EU is interested in health or the effects of health policy, so this section documents not just efforts to structure EU health policy action but also to define the ways in which health policy ought to be an EU preoccupation.

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2 Greer SL, de Almagro Iniesta MM (2014). How bureaucracies listen to courts: Bureaucratized calculations and European law. *Law & social inquiry* 39, no. 2: 361–386.

4.2.1 How the EU policy process takes health into account

The Commission's approach has been discussed above. EU action stems from a high degree of internal coordination before policies are proposed. However, the effectiveness of this coordination is sometimes debated, and since these processes are not public, the trade-offs made remain opaque to outsiders.[3]

The Parliament has clear mechanisms to incorporate different perspectives into its processes. When multiple committees are interested in a particular issue, they can be consulted and propose amendments relevant to their responsibilities. Persistent disagreements are addressed and resolved in a full plenary session of Parliament. Additionally, since the legislative meetings, amendments and discussions are public, it is fairly easy to see which interests have been considered and how they have been balanced.[4]

The Council, however, takes a different approach and one that gives rise to particular tensions. Although the Council meets in various thematic formations (see Section 2.1.3), it does not allow a Council section with one thematic focus (such as health) to comment or otherwise engage with the decisions being taken by another (such as economic affairs). This means that a wide range of decisions are made in the Council by ministers other than health ministers. The logic behind this is that Member State governments should do their coordination at home and whoever represents the government in Brussels should be able to present an integrated opinion. However, this is not always effective, and for a subject such as health it can be very frustrating for national health ministers to find that they have no direct way to express their views in Brussels on most of the decisions that affect them (see Chapter 2). In an attempt to increase transparency and policy coherence, the concept of a roadmap has been established (see Box 2.1).[5]

Partly due to the limitations Article 168 TFEU places on legislation, health has been an area of significant experimentation with newer forms of governance that aim to coordinate and influence policy without relying on hard law. This section presents key documents that have shaped the direction of EU health policy by outlining the nature of healthcare policy in the EU context, shared values, and policy directions deemed acceptable by Member States and health policy communities. Together, these documents form a relatively clear set of values and

3 See chapters 1 and 2 of this book.

4 European Parliament. *Rules of procedure of the European Parliament*. Brussels: European Parliament. Available at: http://www.europarl.europa.eu/sides/getLastRules.do?language=EN&reference=TOC (accessed 4 July 2014).

5 Roadmaps are available at: https://ec.europa.eu/smart-regulation/roadmaps/index_en.htm (accessed 16 June 2024).

priorities for health policy, as well as a statement of what health ministers and stakeholders consider to be policies compatible with good healthcare practices.

4.2.1.1 State of Health in the EU cycle

Developed in cooperation with the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies, State of Health in the EU is a recurring two-year initiative by the European Commission. It aims to provide health policy-makers and other relevant actors with comparative data on health systems in EU countries.

First launched in 2016, the two-year State of Health in the EU cycle consists of four stages. The first stage entails the periodic publication of *Health at a Glance: Europe*, a comparative overview of EU health systems. The second stage in the cycle is the periodic publication of *Country Health Profile*s for all EU Member States. This joint publication by the European Commission, the OECD and the European Observatory on Health Systems and Policies provides a snapshot of each country's population health and key risk factors, along with an analysis of each health system's performance in terms of effectiveness, accessibility and resilience. The third stage is the publication of a Synthesis Report, formerly known as a Companion Report, which is released alongside the country health profiles and links common policy priorities across EU Member States. Finally, at the end of the two-year cycle, health authorities can solicit the experts behind the studies to discuss potential policy responses. This is not an academic exercise. The State of Health reports play a crucial role in informing the European Semester, a very consequential form of policy (see chapter 6).

4.2.1.2 Expert Group on Health Systems Performance Assessment

Given the increased interest in monitoring Member States' health systems and assessing their comparative performance, particularly within the context of the European Semester, the Commission set up an Expert Group on Health Systems Performance Assessment (HSPA) in 2014. This group consists of representatives from all EU Member States and Norway. The goal is to develop a common understanding of HSPA approaches, tools and methodologies by sharing relevant national experiences. Experts from WHO, OECD and the European Observatory on Health Systems and Policies provide additional support and guidance. The group's efforts have focused on assessing performance in specific domains such as disease prevention, care quality, efficiency, access, primary care, integrated care, and resilience. In 2022, the mandate of the Expert Group was broadened to encompass collaborative efforts aimed at developing more strategic approaches for innovative solutions and transforming health systems.

4.2.1.3 Expert Panel on Effective Ways of Investing in Health

To ensure timely, scientific, non-binding advice on strategically relevant health matters, the European Commission established a multidisciplinary independent Expert Panel on Effective Ways of Investing in Health in 2012. The panel's mandate expired in December 2022. Its overall aim was to make scientific contributions to the effectiveness, accessibility and resilience of European health systems.[6] The panel's work also acknowledged the role of public health and health systems in promoting health and wealth in the EU, contrasting with mere cost containment or austerity policies promoted by other directorates-general. The panel consisted of 14 members who served a three-year term and produced numerous opinions on topics such as digital transformation, cross-border care and vaccination.[7]

4.2.1.4 The EU Health Policy Platform

The EU Health Policy Platform is the largest and one of many institutionalized consultative mechanisms organized by DG SANTE (see Section 2.3.1 for its context and function). It is an open platform with over 5000 members at the time of writing, ranging from the Brewers of Europe and the European Association of Sugar Manufacturers to the Irish Cancer Society and the Caritas of the Diocese of Coimbra in Portugal (to select from the 70 organizations attending its March 2021 meeting). Membership and engagement reflect an interest in health policy rather than a specific stance, as evidenced by the presence of industry representatives. The platform hosts a variety of activities, including an annual meeting, an award, and thematic groups that can formulate agendas to develop over a year, with voluntary participation and a presentation at the annual meeting. Like most consultative groups, it provides a way for stakeholders, including poorly resourced ones, to maintain contact with the Commission and each other and to stay informed, and for the Commission to validate thinking and test support for different policy ideas. Its importance varies with the importance the Commission assigns to it, which participants can gauge by observing who from the Commission participates. The platform disseminates technical and political information, formally and informally, but its impact on policy or its members is variable.

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6 European Commission (2022). *Expert Panel on effective ways of investing in health*. Brussels. Available at: https://ec.europa.eu/health/expert-panel-effective-ways-investing-health/overview_en (accessed 22 June 2024).

7 All opinions are available online at: European Commission. *Expert Panel on effective ways of investing in health*. Brussels. Available at: https://ec.europa.eu/health/expert-panel-effective-ways-investing-health/overview_en (accessed 22 June 2024).

4.2.1.5 The Council Working Party on Public Health (High Level)

The Council Working Party on Public Health (High Level), formerly known as the Working Party on Public Health at the Senior Level, is a Council working group that provides input on behalf of ministers on a wide range of topics. It consists of senior officials from Member States who are responsible for public health. This working party plays a role in developing public health policies across the EU; strategic guidance and coordination on public health issues such as disease prevention, health promotion, and response to health crises; drafting Council conclusions and recommendations on public health matters; and assisting the rotating EU Council presidencies in managing the public health agenda and preparing for health ministers' meetings. As a Council formation, its importance varies with the presidency; for example, when it was still known as the Working Party on Public Health at the Senior Level, the 2018 Austrian Presidency primarily called meetings at the attaché level.

4.2.1.6 The Expert Group on Public Health

The Expert Group on Public Health replaced the Steering Group on Health Promotion, Disease Prevention and Management of Non-communicable Diseases – also known as "the Steering Group" – which was set up by the European Commission in 2018 to help Member States reach the health targets of the SDGs.[8]

Established in 2021, the Expert Group on Public Health provides advice and guidance to the Commission on matters related to public health and health systems.[9] It addresses both non-communicable diseases (such as cancer and mental health) and communicable diseases (such as HIV/AIDS, tuberculosis and hepatitis). In addition, the group offers recommendations on tackling key challenges concerning vaccination strategies, management of long COVID, and antimicrobial resistance.

Through coordinated efforts across various policy areas, the group aims to alleviate human suffering and achieve significant outcomes including decreasing the economic and social impact of diseases, strengthening national health and social welfare systems, and enhancing economic productivity and growth through a healthier workforce. These efforts also support Member States in achieving the SDGs and meeting the WHO's targets on non-communicable diseases.

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8 European Commission (2018). *Decision of 17.7.2018 setting up a Commission expert group "Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases" and repealing the Decision setting up a Commission expert group on rare diseases and the Decision establishing a Commission expert group on Cancer Control*. Brussels, 17.7.2018 C(2018) 4492 final.

9 European Commission (n.d.). Expert Group on Public Health. Available at: https://health.ec.europa.eu/non-communicable-diseases/expert-group-public-health_en (accessed 21 August 2024).

4.2.2 Health systems values

What has the EU done to shape health systems thinking, or at least what has been the impact of EU policies on health systems? The EU has produced a number of key statements that guide its policies and either enable or constrain new initiatives. In healthcare, the 2006 Council conclusion on health systems values has helped to shape the role of health systems as a distinctive policy concern with shared moral values that should influence policy. The European Pillar of Social Rights covers a wide range of policies, most with health relevance, and also explicitly focuses on health systems values. Both statements influence broader EU policy, such as the European Semester (see Chapter 6), by clarifying the values that Member States have agreed on, beyond fiscal sustainability.

It is important to note the different objectives and uses of these statements and their evolution over time. Earlier statements were often reactive, aimed at shaping debates framed in terms of markets or fiscal governance. Today, articulating health systems values means trying to reframe those debates and shape new ones. These statements also represent efforts to define a more comprehensive EU with broader goals, enhancing its legitimacy and impact on its citizens – compare the 2006 statement on health systems, which was a reaction to integrating health into the internal market, with the European Pillar of Social Rights, which was deliberately designed as an aspirational, and even constitutional, framework.

4.2.2.1 Charter of Fundamental Rights

With the amendments of the Treaty of Lisbon in 2009, the Charter of Fundamental Rights (CFREU) that had been adopted in 2000 as a non-binding instrument became part of EU primary law through its inclusion in Article 6 TEU. In its chapter on Solidarity, the Charter constitutionalized some of the understandings of Social Europe. Generally, the EU is to ensure that its institutions and the Member States, when implementing EU law, adhere to the rights laid out in the Charter (Article 51 CFREU). However, the articles under the Solidarity chapter are considered principles rather than rights, making them non-justiciable for individuals. In this context, some of the stronger proclamations on dignity, which specifically reference informed consent or equality, might prove to be more relevant for health than the specific article on healthcare (Article 35 CFREU).[10] The European Court of Human Rights of the Council of Europe has a long history of deciding legal cases in the field of health. Through the legal interpretation of the CFREU articles, this case law can also inspire EU case law that addresses the role of the EU institutions or Member States in applying EU health law, by referring to Article 52 CFREU. Article 52(1) CFREU can be used

10 See further Hervey T & McHale J (2014). Article 35 Health Care, *The EU Charter of Fundamental Rights* (Hart Publishing).

to assess the legality of restrictions on fundamental rights, particularly during public health emergencies. This article requires that any limitation on rights be legally grounded, proportionate, and necessary to achieve a legitimate aim, such as protecting public health during a pandemic.

4.2.2.2 2006 Statement on health systems values

The 2006 Council Conclusions on common values and principles in European Union health systems[11] is in part a creature of its time, reflecting a specific agreement by Member States under a United Kingdom Presidency that contemporary efforts to incorporate healthcare into the general internal market for services (e.g. with the first proposed Services Directive) were inappropriate and did not reflect the core values of their healthcare systems. The existence of the statement undercut any new efforts to assimilate healthcare with the principles regulating other sectors and also to shape broader discussions of health policy, including in the Semester.

4.2.2.3 Effective, accessible and resilient health systems

The next key statement of values and priorities came from the EPSCO Council in late 2013 through their conclusions, followed by the Commission's 2014 Communication on effective, accessible and resilient health systems.[12] The Council conclusions were a wide-ranging declaration of health values and priorities, emphasizing the importance of health as a general European priority. This was, among other things, a response from health ministers to the strengthened fiscal governance system's encroachments into health policy (see Chapter 6), reiterating the importance of health and health systems and encouraging the EU to play a supportive role. The Commission translated this request into the 2014 communication. These two documents superseded the 2006 Council conclusions. The communication set three goals in the area of health systems:

1. Strengthen the effectiveness of health systems;
2. Increase the accessibility of healthcare;
3. Improve the resilience of health systems.

While many actions necessary to achieve these goals are designed to be taken at the Member State level, the communication lists various EU actions from health

11 Council of the European Union (2006). *Conclusions on Common values and principles in European Union Health Systems* (2006/C 146/01).

12 Council of the European Union (2013). *Conclusions on the Reflection process on modern, responsive and sustainable health systems*. Brussels, 10 December 2013. European Commission (2014). *Communication on effective, accessible and resilient health systems*. April 2014, COM(2014)215.

systems performance assessment (HSPA) to health technology assessment (HTA) that contribute to Member States' policies and effectiveness.

The issue of resilience of course became central during the COVID-19 pandemic. In addition to defining in more detail what resilience might mean,[13] the Commission has placed resilience at the centre of its specific response to the pandemic through its Recovery and Resilience Facility, providing additional funding to help respond to the challenges of the pandemic (see Chapter 6).[14] Although this facility is not specific to health systems, several countries have chosen to prioritize health funding under the scheme. This represents a milestone in the EU's transition from merely stating the importance of strong and resilient health systems to actively providing substantial funding to help achieve this.

4.2.2.4 The European Pillar of Social Rights

The European Pillar of Social Rights (EPSR) was declared by the Council, Parliament, Member States and the European Commission in 2017.[15] It has 20 principles – 20 rights – in the categories of equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion (see Annex).

As ever with EU health policy, it is tempting to turn directly to the category of social protection and inclusion, and look for the healthcare principle, but almost all of these rights affect health and many can be affected by healthcare systems. Homelessness, for example, is both a major public health problem (a short period of homelessness can have lasting and diverse negative health effects) and is often caused by failures in healthcare, especially to do with mental health treatment. Work–life balance is categorized as being about fair working conditions, but evidence shows that supporting parents in their work reaps health benefits for everybody in the family. Fair working conditions also include an explicit right to a healthy workplace, for workplaces and work practices are indeed a key source of good or ill health and employers do not always provide appropriate conditions without regulation. Gender equality, under Equal opportunities and access to the labour market, is a key determinant of the well-being and health of all genders.

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13 EU Expert Group on Health System Performance Assessment (2020). *Assessing the resilience of health systems in Europe: An overview of the theory, current practice and strategies for improvement*. Publications Office of the European Union. Available at: https://ec.europa.eu/health/system/files/2021-10/2020_resilience_en_0.pdf (accessed 19 February 2022).

14 European Commission (2022). *The Recovery and Resilience Facility*. Available at: https://ec.europa.eu/info/business-economy-euro/recovery-coronavirus/recovery-and-resilience-facility_en (accessed 19 February 2022).

15 European Commission (2017). *Proclamation of the European Pillar of Social Rights*. 16 November. Brussels: European Commission.

That said, there is specific healthcare content, such as: "Everyone has the right to timely access to affordable, preventive, and curative health care of good quality". This is complemented by a commitment to long-term care: "Everyone has the right to affordable long-term care services of good quality, in particular home-care and community-based services". Notably, by the standards of most political systems, the ESPR is both ambitious and concrete. Even if its main effect is to limit contradictory policy initiatives within the EU and empower advocates within the Member States, that is significant.[16]

Implementation of the European Pillar of Social Rights is primarily led by DG EMPL, with a web of reports and policies on commitments and progress such as MISSOC (Mutual Information System on Social Protection), which has been linking the Commission with Member State agencies to provide standardized and coherent information on social protection since 1990, and the European Social Policy Analysis Network (ESPAN) reports which provide views from independent experts. The implementation of the Pillar has, for whatever reason, often been seen as distinct from health policy, but that distinction is more grounded in Treaty bases, Commission organization and policy communities than in an analysis of the determinants of health.

4.3 Goods

Health-related products are a major part of the internal market, with highly detailed European requirements governing them.[17] The EU has a strong role in ensuring the health and safety of products that are traded in the EU, whether they are specifically related to health or not, and this has been reflected in the wider rules for products within the EU.

4.3.1 Regulation of pharmaceuticals

In the wake of the thalidomide disaster, the EU has steadily harmonized the rules governing the requirements allowing the sale of medicinal products in

16 For the political background of the EPSR, as a case study in how the EU approach to social policy has changed over the years, see Sabato S & Vanhercke B (2017). Towards a European Pillar of Social Rights: from a preliminary outline to a Commission Recommendation, in Vanhercke B, Sabato S & Bourget D (eds). *Social policy in the European Union: state of play* (Brussels: ETUI/OSE), pp. 73–96.

17 "Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives" are covered by a specific provision of Article 168 TFEU and are therefore discussed in Section 3.4.

the EU since 1965,[18] to the extent that this is now one of the most regulated sectors of the European market.[19] One such regulation is the 2011 Falsified Medicines Directive, which regulates the medicine markets through methods like standardizing packaging, common EU logos and rules on pharmaceutical ingredients.[20] Initially focused on setting common standards for national licensing bodies, the EU now has different options for licensing (or "authorizing") pharmaceuticals at either the national or European level. The centralized authorization procedure works with one single application for a licence, which is then valid for the entire EU. This route is compulsory for some product types, in particular:

- those derived from biotechnology;
- those containing a new active substance and intended to treat the priority conditions of HIV/AIDS, cancer, neurodegenerative diseases or diabetes;
- advanced therapy medicinal products (ATMPs), such as gene therapy, somatic cell therapy or tissue-engineered medicines; and
- orphan medicines.

This means that the great majority of new, innovative medicines entering the market today need to pass through the centralized authorization procedure. The centralized procedure is run by the European Medicines Agency (EMA),[21] one of the major health-related European agencies, originally based in London and relocated to Amsterdam in 2019. The EMA also oversees the systems for monitoring any problems that may become apparent with medicines after they are licensed (the pharmacovigilance system). While the EMA is responsible for evaluating applications for authorization and making recommendations, it has no authority to actually permit marketing in the EU. It is the European Commission that is the final authorizing body for all centrally authorized products.

Otherwise, applications can be made to individual national authorities. This is the pathway used for the majority of generic and over the counter medicines (as well as for older medicines authorized before the creation of the EMA). Pharmaceutical manufacturers wishing to market their products in several EU

18 European Council (1995). *Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products*. Brussels: European Commission.

19 Principally governed by Directive 2001/83/EC and Regulation (EC) 726/2004; see also Hauray B (2006). *L'Europe Du Médicament: Politique – Expertise – Intérêts Privés* [The Europe of Medicines – policy – expertise – private interests]. Paris: Presses de Sciences Po. Permanand G (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester: Manchester University Press.

20 European Commission (2011). *Falsified Medicines Directive (Directive 2011/62/EU)*. Available at: https://health.ec.europa.eu/medicinal-products/falsified-medicines_en (accessed 17 July 2024).

21 European Medicines Agency [website]: http://www.ema.europa.eu/ema/ (accessed 20 February 2022).

countries can choose between the mutual recognition procedure, whereby an authorization granted by one national regulator can be recognized by others, or the decentralized procedure, which entails applying to several countries simultaneously.

The licensing process for pharmaceuticals is lengthy, with a sequence of ideally three phases of clinical trials required before licensing in order to progressively provide the data necessary about the quality, safety and efficacy of the product for the application to be evaluated.[22] For some types of medicines, or certain indications, phase III trials may not be required for authorization. While the EMA does not authorize clinical trials itself (medicine developers need to get approval from the competent authorities in the countries where the trials are conducted), the EU provides the regulatory framework for good clinical practice (GCP) and good manufacturing practice (GMP) that needs to be followed in all trials conducted in the EU and submitted as evidence to support market authorizations. The key legislation underpinning these principles is the Clinical Trials Regulation (CTR, Regulation 536/2014), which replaced the Clinical Trials Directive to strengthen safety for trial participants and transparency of trial information, and has been in effect as of January 2022.[23] The EMA also provides scientific advice to medicines developers to help them produce evidence that is in line with its expectations.

The regulation of clinical trials at the EU level[24] has been controversial, with debate about whether the requirements imposed are too onerous, in particular for non-commercial applicants. At the same time, the CTR enables trial sponsors to submit one application for approval to run a clinical trial in several European countries, substantially simplifying the process of conducting multinational trials. Following pressure from patient groups, the EU had already improved the provision of information about clinical trials, by making it available through a database at the European level, the EU clinical trials register.[25] The new CTR foresees a new platform with a searchable, public website to further enhance transparency and streamline application processes, the Clinical Trials Information System (CTIS). The real-world implications of the new provisions of the CTR

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22 World Health Organization (2014). *International clinical trials registry platform*. Geneva: World Health Organization. Available at: https://www.who.int/clinical-trials-registry-platform (accessed 13 January 2022).

23 The CTR will be the sole governing framework for clinical trials in the EU as of 1 January 2025. There are clear transition guidelines for clinical trials that were initiated under the Clinical Trials Directive and are foreseen to continue beyond that date.

24 European Parliament and Council (2001). Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal*, L 121:34.

25 European Medicines Agency (2014). *EU clinical trials register*. Brussels: European Medicines Agency. Available at: https://www.clinicaltrialsregister.eu/ctr-search/search (accessed 13 January 2022).

remain to be assessed moving forward. In any case, the lengthy process that is required between the development of a new medicine and its authorization creates a different challenge for industry regarding intellectual protection and recouping development costs through sales (see Box 4.1).

Box 4.1 *Intellectual property rights for medicines in the EU*

Companies developing new drugs have to wait several years between when they patent their potential products and when the products are actually licensed and can be sold, meaning that at the time of authorization, only a fraction of the period of patent protection (usually 20 years) remains. For this reason, the patent protection of pharmaceutical products in the EU can be extended for up to five years by means of a supplementary protection certificate (SPC).[a] Additionally, new medicinal products in the EU have an eight year period of data protection on market entry, during which marketing authorization holders have exclusive rights to the clinical and preclinical data used for marketing authorization. This period is followed by two years of marketing protection, during which generic manufacturers may use the data and prepare applications for competitor products, but these products cannot be marketed. This marketing protection can be extended by one additional year, if the marketing authorization holder has obtained an authorization for a new indication and the product combines substantial clinical benefit compared to alternatives. This is known as the 8+2+1 model.

The EU has attempted to promote the development of medicines for rare diseases ("orphan medicinal products") through similar mechanisms, providing orphan medicines with ten years of market exclusivity (i.e. protection from similar medicines in the same indication) after they are licensed[b] and medicines for children, by providing possibilities for additional SPCs and market exclusivity extensions.

Within the proposed revisions of the EU's pharmaceutical legislative framework proposed in April 2023, the Commission included changes in the protections described above, to foster needs-driven innovation and address inequities in access to medicines across Member States. Baseline data protection (for all new medicines) and market exclusivity (for orphan drugs) are generally shortened, but possible extensions can be awarded for launching and continuously supplying the new medicine to all EU Member States, addressing unmet needs, or meeting certain evidentiary requirements (comparative trials for new active pharmaceutical ingredients). With these additional extensions, the total protection periods can match and even extend beyond the current regime. These proposals have been heavily opposed, and their future remains unclear as the trilogue is underway.[c]

a European Parliament and Council (2009). Regulation (EC) 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products. *Official Journal*, L 152:1.

b European Parliament and Council (2000). Regulation (EC) 141/2000 of 16 December 1999 on orphan medicinal products. *Official Journal*, L 18:1.

c For the Commission website on the proposal: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en (accessed 17 July 2024).

So far, the regulatory regime for pharmaceuticals in the EU resembles that of the world's other giant pharmaceutical market, the United States. However, when it comes to pricing, marketing and availability of pharmaceuticals, the EU looks very different. This is because the provision of healthcare is a Member State competence in the EU and, unlike the United States, more than half of pharmaceuticals are paid for by public funds, not privately. The price of medicines and other healthcare products varies substantially between different EU countries, including as a result of specific national regulation. Therefore, although the EU has a reasonably unified market access regime, its reimbursement and pricing models and markets remain fragmented. Revisions to existing legislation, including on rare diseases and child health, as well as to the general pharmaceutical legislation, are likely to follow in future.

On 25 January 2022 the Council approved revisions to the EMA's founding regulation which, according to the Council, allow it to

> facilitate a coordinated EU-level response to health crises by:
>
> - monitoring and mitigating the **risk of shortages** of critical medicines and medical devices, including "warm" facilities available to immediately produce necessary goods;
> - providing **scientific advice on medicines** that may have the potential to treat, prevent or diagnose the diseases causing those crises;
> - coordinating studies to monitor the **effectiveness and safety of medicinal products** intended to treat, prevent or diagnose diseases related to the public health crisis;
> - coordinating clinical trials for medicinal products intended to treat, prevent or diagnose diseases related to the public health crisis;
> - transferring the expert panels of the Medical Device Regulation to the Agency [emphases added].[26]

The EU also has a role in regulating and purchasing healthcare goods internationally (see Box 4.2).

26 European Union (2022). Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123

Box 4.2 *International dimensions of healthcare goods*

Pharmaceutical supply chains are global, which necessitates detailed regulation of production and logistics to ensure quality and prevent fraud. The EU has signed mutual recognition pacts with regard to good manufacturing practice with Australia, Canada, Japan, New Zealand, Switzerland and the United States, as well as a similar agreement with Israel. The EMA and the Commission also participate in international networks of regulators who focus on developing standards and identifying problems in regulation. Challenges remain in agreeing standards and their enforcement with regulators in China and India, who have large industries, and there are cooperative instruments to that end. Pharmaceuticals are also covered by trade agreements (see Section 7.3.1) and enforcement of intellectual property law.[a] In all of these fields, the EU is one of the key forces shaping global standards and regulatory procedures within its trading partners.

Nevertheless, the COVID-19 pandemic has demonstrated that the source of the EU's soft power in this area – its ability to act as one large market – comes with trade-offs. Tensions arose among Member States over the acquisition of personal protective equipment as well as vaccine procurement. In each case, the strengths of collective bargaining power, including lower prices and potentially better quality products, were balanced by slower decision-making. Some Member States chose to take independent action to procure supplies and sign contracts for vaccines although, as discussed throughout this book, the EU and its Member States pivoted quickly to more unified action. While the EU ultimately was able to procure enough supplies and heal divisions among Member States, this experience demonstrates that EU decision-making cannot be separated from global markets and politics. In a global perspective (see Chapter 7), the problem becomes even clearer: the EU might have solved its problems and been more generous than other big powers, but its interests are still conflicted and its policies still a contributor to global vaccine inequity.

a Massard da Fonseca E (2013). Intellectual property enforcement in the European Union, in Greer SL & Kurzer P (eds). *European Union Public Health Policy*. Abingdon: Routledge, pp. 126–38.

4.3.2 Regulation of medical devices

Medical devices (that is, products or equipment intended for a medical purpose) must undergo a conformity assessment to demonstrate that they are safe and perform as intended in order to be marketed in the EU, and obtain the relevant certificate (Conformité Européenne, or CE mark). If regulation for the market entry of pharmaceuticals is at one end of a scale (with strict scrutiny of detailed trials before products can be marketed), and the general EU approach for consumer product safety is at the other end (with it being primarily up to manufacturers to ensure the safety of their own products), regulation of medical devices is somewhere in the middle.[27] While the relevant EU legislation has

27 A good account of the background can be found in Hancher L & Sauter W (2012). *EU competition and internal market law in the health care sector*. Oxford: Oxford University Press.

requirements for the initial scrutiny of new medical devices, these are lighter than for pharmaceutical products. Moreover, whereas licensing of pharmaceutical products is undertaken by public bodies (EMA and national agencies), the scrutiny of medical devices is undertaken by private companies that have been designated as Notified Bodies (NBs) by the competent authority of the Member State in question (however, the EU has a role in some of the regulatory processes, see Box 4.3). The number of NBs accredited to evaluate different types of medical devices varies (from 49 for devices under the Medical Device Regulation in general, to 10 for active implantable devices as of June 2024) and can be found on the NANDO platform. Requirements for marketing medical devices in the EU vary according to the level of risk that different medical products represent for patients. At the low-risk end (class I devices, such as thermometers and corrective vision aids), manufacturers themselves may simply declare that the products meet relevant standards following certain guidelines, and must collect data on post-marketing surveillance. At the high-risk end (class III devices, such as artificial heart valves and joint prostheses), NBs must also conduct a clinical evaluation during the conformity assessment, on top of post-marketing surveillance and the periodic safety update reports demanded from manufacturers.[28] However, the criteria for clinical evaluation are less strict compared to pharmaceuticals and the regulatory regime for medical devices in the United States. Most medical devices are not evaluated for their safety and effectiveness; rather, a narrower assessment is made of their safety and whether they function as intended.

Traditionally, higher-risk medical devices tended to be authorized more quickly in the EU than in the United States, where clinical trials are required – which has potentially meant quicker access to innovation, but also that patients in Europe may thereby be exposed to medical devices with greater potential for harm or an unfavourable benefit/risk ratio.[29] This was most famously demonstrated by the results of a global investigation known as the Implant Files, published in November 2018 (see Box 4.3).[30] Doubts have also been expressed about the role of NBs in the regulatory process; as private companies whose income derives from the fees that they charge manufacturers, NBs face a contradictory set of objectives, balancing the need to fulfil their obligations while maintaining approvals business from manufacturers. There is also a serious shortage of data about how effective the controls are in practice, with a lack of public access to data about product licensing or adverse events.[31] To address these issues, the

28 Chai JY (2000). Medical device regulation in the United States and the European Union: a comparative study. *Food and Drug Law Journal*, 55:57.

29 Kramer DB, Xu S & Kesselheim AS (2012). Regulation of medical devices in the United States and European Union. *New England Journal of Medicine*, 366(9):848–55.

30 International Consortium of Investigative Journalists (2018). *Implant Files*. Available at: https://www.icij.org/investigations/implant-files/ (accessed 13 January 2022).

31 Kramer DB, Xu S & Kesselheim AS (2012). How does medical device regulation perform in the United States and the European Union? A systematic review. *PLoS Medicine*, 9(7):e1001276.

Box 4.3 *Medical device safety scandals and their impact on EU regulation*

In November 2018, a global investigation known as the Implant Files revealed the harm caused by medical devices that had been poorly tested in Europe.[a] One significant scandal concerns defective breast implants, known as PIP implants. Manufactured by a French company and marketed in 65 countries around the world, they were available for over a decade with official authorization despite multiple warnings from physicians and despite the fact that the Food and Drug Administration (FDA) had banned these implants from the United States market as early as 2000. In total, more than 400 000 women in 65 countries received these implants. On 30 March 2010 the then French Health Products Security Agency (AFSSAPS) announced the recall of PIP implants due to their unusually high rupture rates, combined with the re-discovery that the manufacturers had been deliberately using unapproved industrial silicone since 2001 in order to save money. As ever, crises have a way of driving change, and the Commission proposed some strengthening of the oversight for medical devices, in particular following serious problems involving these faulty breast implants, vaginal mesh and some hip replacements, resulting in the passing of the MDR and IVDR in 2017.[b]

a International Consortium of Investigative Journalists (2018). *Implant Files*. Available at: https://www.icij.org/investigations/implant-files/ (accessed 13 January 2022).

b European Commission (2012). *Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals* (COM(2012)540 final). Luxembourg: Publications Office of the European Union.

Commission revised its regulatory framework for medical devices in 2017, passing two milestone pieces of legislation, Regulation 2017/745 (the Medical Devices Regulation, MDR) and Regulation 2017/746 (the In Vitro Diagnostic Medical Devices Regulation, IVDR).

The new regulations address some of the weaknesses of the EU regulatory system. First, they seek to increase the transparency of the system through the collation of key supply chain data. The 2017 regulations therefore expand the EU's existing centralized database (EUDAMED) to collect new data on vigilance and post-market surveillance in a form that is supposed to be interoperable with centrally held clinical trials data on pharmaceuticals.[32] Second, they institutionalized a central register of supply chain operators and NBs, as well as the centralization of serious incident reports. Patients will now get implant cards describing the type of implants they received. Third, the EU Commission can now investigate when an NB does not seem to be fulfilling its function properly. At the national level, health agencies can conduct unannounced visits and NBs must submit documentation upon request. Finally, national agencies can control an NB's

32 McHale JV (2018). Health law, Brexit and medical devices: a question of legal regulation and patient safety. *Medical Law International*, 18(2–3):195–215.

assessment of a manufacturer's documentation before the device is placed on the market.

Although these reforms represent significant improvements to the previous regulatory framework, some key issues are left unaddressed.[33] Industry representatives initially raised strong concerns that the timetable for adapting to the new regulations was too tight. In January 2022, of the 58 NBs in the EU, 24 had been approved for NB status under the EU MDR[34] and only five NBs had been designated under the EU IVDR.[35] The situation has improved in the meantime, despite persistent challenges.

As of mid-2024, there has been a significant increase in the number of notified bodies designated under both the EU MDR and the EU IVDR. The NANDO database shows that there are currently 41 NBs designated under the EU MDR and 13 under the EU IVDR, marking a clear improvement from the lower numbers recorded in early 2022.[36] However, despite the increase in designated NBs, concerns remain regarding their capacity to handle the large volume of certifications required under the new regulations.[37]

In response to these challenges, in late 2023 the European Commission proposed extending the transition periods for both MDR and IVDR compliance to 2027 or 2028, depending on the classification of the device. This is intended to alleviate some of the pressure on manufacturers and NBs by providing additional time for conformity assessments and certification processes. The proposal also seeks to prevent potential shortages of medical devices in the EU market by ensuring that products can remain on the market during the extended transition period.

The EMA[38] and the European Commission[39] issued updated guidance documents in 2024 to help stakeholders navigate the regulatory requirements. These include clarifications on the implementation of the regulations for medical devices used

33 Jarman H, Rozenblum S & Huang T (2020). Neither protective nor harmonized: The cross-border regulation of medical devices in the EU. *Health Economics, Policy and Law*, doi:10.1017/S1744133120000158, 1–13.

34 European Commission. *NANDO MDR database*. Available at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34 (accessed 10 January 2022).

35 European Commission. *NANDO IVDR database*. Available at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35 (accessed 10 January 2022).

36 European Commission (n.d.). NANDO (New Approach Notified and Designated Organisations) database. European Commission. Available at: https://ec.europa.eu/growth/tools-databases/nando/ (accessed 11 August 2024).

37 Carl, A. K., & Hochmann, D. (2024). Impact of the new European medical device regulation: a two-year comparison. *Biomedical Engineering/Biomedizinische Technik*, 69(3), 317–326.

38 European Medicines Agency (2024, May 21). *Medical devices: New guidance for industry and notified bodies*. European Medicines Agency. Available at: https://www.ema.europa.eu/en/news/medical-devices-new-guidance-industry-notified-bodies (accessed 21 August 2024).

39 European Commission (2024, July 26). Medical devices - New regulations. Available at: https://health.ec.europa.eu/medical-devices-new-regulations_en (accessed 21 August 2024).

in combination with medicinal products, as well as revisions informed by the experience gained since the regulations came into effect.

Vitally, under the new directives NBs and supply chain operators remain almost entirely responsible for pre-market control. The pre-2017 frameworks remain, in that respect, largely intact, despite the fact that Member States lack the capacity to effectively control the actions of NBs. Finally, although the EU Commission originally proposed a more centralized system analogous to that embodied by the EMA or the American FDA, private actors and NBs lobbied against it.[40] Taken together, both regulations only marginally improve a dangerous situation, which has resulted in poor health outcomes for patients in the past (see Box 4.3).[41]

Next to increasing the demand for vital medical devices, the COVID-19 pandemic disrupted the application of the new regulations for medical devices and in vitro diagnostic devices. The MDR was due to be applied from 26 May 2020, while the IVDR was to be fully effective in 2022. However, in April 2020 the Commission announced the postponement of the application of the MDR for one year and introduced a new derogation from existing conformity assessment procedures to expedite the production of PPE and containers for intravenous injections and to alter requirements for ventilators. These initiatives were intended to give manufacturers more time to conform to the new regulatory regime and address medical devices shortages during the pandemic.[42] The MDR became applicable in the EU on 26 May 2021, with exceptional transition periods for certain types of devices. The IVDR has been applicable since 26 May 2022, but the Commission has granted additional compliance extensions for different types of devices, with goals for December 2027 for high risk devices, December 2028 for medium risk and December 2029 for lower risk devices.[43]

4.3.3 Health technology assessment (HTA)

While the market entry of medical products is regulated extensively at the EU level, as described in the previous section, pricing and reimbursement decisions are a Member State competence. Health technology assessment (HTA) has emerged as an increasingly used tool to support evidence-based decisions in reimbursement

40 Hervey TK & McHale JV (2015). *European Union Law: Themes and Implications*. Cambridge: Cambridge University Press.

41 Jarman H, Rozenblum S & Huang T (2020). Neither protective nor harmonized: The cross-border regulation of medical devices in the EU. *Health Economics, Policy and Law*, doi:10.1017/S1744133120000158, 1–13.

42 O'Rourke B, Oortwijn W, Schuller T (2020). International Joint Task Group. The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care*. 2020 Jun;36(3):187–190.

43 Further information, including Factsheets and the proposal at: https://health.ec.europa.eu/latest-updates/commission-proposes-extend-transition-periods-certain-ivds-gradual-roll-out-eudamed-and-information-2024-01-23_en (accessed 17 July 2024).

and pricing.[44] HTA evaluates the implications of health technologies such as pharmaceuticals, medical devices, non-pharmacological interventions, etc., and considers clinical, economic, ethical, social, legal and organizational elements. It can be applied to new technologies entering the market, comparing them to existing alternatives, or to a group of technologies in use for a given indication to support optimal treatment and allocation of resources. In some countries, HTA is used to determine the cost-effectiveness of interventions based on the price suggested by manufacturers, with a famous example being the National Institute for Health and Care Excellence in the United Kingdom, while in others the results of HTA are used to shape the prices health systems are willing to pay. In the majority of cases, institutions carrying out HTA are not the final decision-makers, leaving it to some other part of the health system to decide whether the technology is included in the basket of covered services and at what price.[45] The processes and methodologies for HTA, as well as decision-making criteria famously vary across countries (and EU Member States), creating a fragmented environment for industry.

Because it entails a systematic evaluation of all available evidence on the different implications described above, robust HTA is resource-intensive and requires a range of diverse skills. Additionally, evidence on safety and effectiveness, derived from clinical trials, is largely the same regardless of the country where the HTA is conducted. Therefore, while there is no imperative to pursue European HTA action, there is a strong case for European coordination and resource pooling in the area of HTA. Given the high numbers of new technologies competing for health system resources, the EU can have added value by reducing duplication through better coordination of Member State initiatives and supporting countries with less established HTA systems to optimize their resource allocation. On the other hand, HTA is not an obvious political winner. It has upfront and concentrated costs, diffuse and uncertain benefits, and can incur instant opposition from industry, mobilized patients and providers, which explains why it has not been as rapidly or extensively adopted as its promise to rationalize the use of health technology, and optimize care and investments, might lead one to expect.[46]

The EU has been involved in HTA for almost as long as there has been such a field. EU-funded programmes to develop methodologies and collaboration have

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44 Löblová, O., Trayanov, T., Csanádi, M., & Ozierański, P. (2020). The emerging social science literature on health technology assessment: a narrative review. *Value in Health*, 23(1), 3–9.

45 Kristensen FB, Nielsen CP, Panteli D. (2019). Regulating the input – Health Technology Assessment. In: Busse R, Klazinga N, Panteli D, et al., eds. *Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies*. European Observatory on Health Systems and Policies.

46 Löblová, O. (2016). Three worlds of health technology assessment: explaining patterns of diffusion of HTA agencies in Europe. *Health Economics, Policy and Law*, 11(3), 253–273. Löblová, O. (2018). What has health technology assessment ever done for us? *Journal of Health Services Research & Policy*, 23(2), 134–136.

been running almost continuously since the 1990s, building up to EUnetHTA, a joint action funded by the Health Programme through 2020. Its activities ranged from building a common methodological foundation (culminating in the EUnetHTA core model for HTA), through capacity building, to facilitating its members to conduct joint assessments of specific technologies. EUnetHTA also worked with EMA to align the criteria for market authorization and HTA. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare formalized European collaboration in HTA, by creating a voluntary Health Technology Assessment Network (HTA Network) of Member States, which started meeting in 2013 and was supported for scientific purposes by EUnetHTA. Five years later, in 2018, the Commission proposed a regulation to create a formal structure of collaboration between Member States, overseen by an EU-level committee, to produce joint clinical assessments, provide joint scientific consultation for technology developers, carry out horizon scanning for emerging health technologies, and engage in additional voluntary collaboration activities. Effectively, this regulation replaced the voluntary network of national authorities (HTA Network) and EUnetHTA with a permanent framework for joint work.[47]

The motivation for the regulation was largely derived from the need to provide a uniform framework of parameters for technology developers across the EU in line with the principles of the internal market so as to improve EU-wide access to innovation. By the end of the Juncker Commission, the HTA Regulation proposal was the only health dossier of consequence still open, despite the support of the 2019 Romanian and Finnish presidencies of the Council. The key obstacle was a variety of Member States that objected on different grounds, including subsidiarity. COVID-19 pushed the issue off the agenda for much of 2020, but a final version was passed on 13 December 2021 following amendments as a result of the trilogue between the Commission, the Council and the Parliament (see Box 4.4). The formalization of HTA can be viewed as a classic case of how European integration develops: by gradually creating a European constituency that collectively and individually sees added value in pooling its efforts via EU-level mechanisms, in the same way that communicable disease control or medicines regulation was gradually Europeanized.

4.3.4 Joint procurement

As with reimbursement and pricing decisions, procurement is a clear Member State competence. However, following the experience of the H1N1 flu pandemic

47 European Parliament and Council (2021). *Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)*.

Box 4.4 *The Health Technology Assessment Regulation (HTAR)*

Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and will apply from 12 January 2025. The regulation created a coordination group of HTA national or regional authorities and a stakeholder network, and lays down rules on joint clinical assessments and joint scientific consultations with patients, clinical experts and other relevant experts.

The coordination group will lead five areas: joint clinical assessments; joint scientific consultations; methodologies; identification of emerging health technologies; and voluntary cooperation. Starting from January 2025, all new oncology drugs and advanced therapy medicinal products (ATMPs) (which include gene therapies, cell therapies and tissue-engineered products) that are seeking market authorization will be subject to the new requirements and evaluations outlined in the regulation. Joint clinical assessments will target successively new orphan medicines (as of January 2028) and all other medicines seeking centralized authorization by the EMA (as of January 2030), as well as a range of high-risk medical devices and in vitro diagnostics to be selected periodically by the Commission once the HTAR is in effect. Joint scientific consultations will allow developers of new technologies to consult with the HTA bodies about the kinds of evidence that may be required in future HTAs. Identification of emerging health technologies refers to horizon scanning work identifying new technologies or developments that will benefit from HTA. "Voluntary cooperation" means that the group will be able to develop or support further cooperation not foreseen in the regulation on a voluntary basis.

In the preparatory phase for the implementation of the HTAR (January 2022 – January 2025), the EU funded additional supporting work to strengthen methodological guidance and set out procedural details.[a] The Commission plans to adopt six implementing acts setting out rules for joint clinical assessments, joint scientific consultations, management of conflict of interest, and the exchange of information with the EMA. The first implementing act was adopted on 23 May 2024, detailing procedural rules for joint clinical assessments of medicinal products for human use and templates for these assessments.

a European Parliament and Council (2021). *Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)*.

b European Commission (2021). *Implementing Regulation (EU) of 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments.*

in 2009, when EU countries were competing to purchase and stockpile available flu vaccine supplies and antiviral medication, for which they paid relatively high amounts without using them,[48] both the Council and the European Parliament concluded that a joint procurement mechanism would help to improve the purchasing power of Member States and strengthen solidarity between them by ensuring equitable access.[49]

Thus, within the context of EU action against cross-border health threats (see Section 3.3), Decision 1082/2013/EU introduced the possibility for Member States to engage on a voluntary basis in a procedure to jointly procure medical countermeasures, particularly vaccines (Article 5). The EU Joint Procurement Agreement (JPA) was adopted and entered into force in 2014, signed by 14 Member States. By 2019, 25 Member States had joined. The European Commission acts as the Permanent Secretariat, and is also in charge of the preparation and organization of the joint procurement procedure. For each procurement procedure, the technical specifications and allocation criteria are determined by a separate committee, and countries are free to join calls for tenders.[50] The JPA is by nature confined to medical countermeasures to address serious cross-border threats to health. This includes medicines, medical devices, services and goods that could be used to mitigate or treat a life-threatening or otherwise serious hazard to health from a biological, chemical, environmental or unknown origin which spreads, or entails a significant risk of spreading, across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.[51] These could include communicable diseases, bio-toxins, and chemical and environmental events. The first joint procurement procedure was successfully concluded in 2016 for the botulinum anti-toxin. In March 2019 framework contracts were signed between the 15 Member States, the Commission and a pharmaceutical company for the production and supply of pandemic influenza vaccines.[52]

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48 Nicoll A & McKee M (2010). Moderate pandemic, not many dead: learning the right lessons in Europe from the 2009 pandemic. *European Journal of Public Health*, 20(5):486–8.

49 European Council (2010). *Conclusions on Lessons learned from the A/H1N1 pandemic – Health security in the European Union*. Brussels, 13 September 2010. European Parliament (2011). *Resolution of 8 March 2011 on Evaluation of the management of H1N1 influenza in 2009–2010 in the EU* (2010/2153(INI)).

50 Azzopardi-Muscat N, Schroder-Back P & Brand H (2016). The European Union Joint Procurement Agreement for cross-border health threats: What is the potential for this new mechanism of health system collaboration? *Health Economics, Policy and Law*, 12(1):43–59.

51 European Commission (2014). *Medical countermeasures that could be procured in common under the Joint Procurement Agreement*. December 2014.

52 European Commission (2019). *Framework contracts for pandemic influenza vaccines*. Memo 28 March 2019. Available at: https://ec.europa.eu/health/system/files/2019-03/ev_20190328_memo_en_0.pdf (accessed 19 February 2022).

The system of joint procurement for health emergencies faced significant pressure during the COVID-19 outbreak. The JPA system relies on contributions from participating Member States and allows for parallel purchases of the same technology being coordinated. While the JPA was used to procure PPE, ventilators and COVID-19 therapeutics, parallel efforts by Member States revealed inequities in power distribution and access.

Alongside the JPA, there is a centralized procurement system called RescEU, which operates under the Civil Protection Mechanism (see also Chapter 3). This system is broader, less health-specific, and designed to foster cooperation in preventing and responding to natural or man-made disasters. During the COVID-19 outbreak, initial discussions about purchasing medical supplies and vaccines saw these systems working in parallel. However, while RescEU offered a more centralized and coordinated approach at the EU level for purchasing emergency medical supplies, it faced challenges due to its relatively small budget, compared to other mechanisms like the health-specific procurement system under the JPA. This meant that RescEU had fewer resources to allocate quickly and efficiently during the pandemic. In other words, while RescEU had the structural capacity to take a lead role in emergency procurement, its financial constraints hindered its ability to respond as swiftly as the more specialized health procurement systems could.

Ultimately, a third approach was adopted for purchasing COVID-19 vaccines, driven by the urgent need for investment to finalize development and production, and to avoid issues with access and price negotiations. The Commission was given the authority to negotiate advance purchase agreements on behalf of the Member States. This built on the governance mechanisms of the JPA system while leveraging the Emergency Support Instrument for funding. Through this agreement, Member States were able to access a large portfolio of COVID-19 vaccines, and parallel negotiations were no longer allowed (Article 7 Annex to Decision C2020 4192), based on existing law related to the EU solidarity clause in Article 122 TFEU.[53]

In response to these lessons, the JPA process was amended (see Article 12 of Regulation 2022/2371) to include a potential exclusivity clause. This clause prevents participating countries from procuring the same medical countermeasures through other channels, thereby eliminating parallel negotiation processes.

The idea of using joint procurement beyond emergency situations has gained traction in recent years, particularly in response to the issue of high-priced medicines, which came to the forefront in 2014 with the hepatitis C drug

53 European Commission (2020). *Decision of 18 June 2020 on Approving the Agreement with Member States on Procuring Covid-19 Vaccines on Behalf of the Member States and Related Procedures* (COM(2020)4192 final) (2020).

sofosbuvir. In a resolution adopted in 2017, the European Parliament urged the Commission and the Council to develop new measures and tools to ensure patients had access to affordable medicines without placing undue strain on public healthcare budgets. These measures included voluntary joint procurements and cooperative price negotiation. This approach was further explored during the Maltese Presidency in 2017, which drew attention to the specific challenges of purchasing health technologies for smaller populations and advocated for enhanced voluntary cooperation between countries.[54]

Various European countries have since engaged in regional collaborations, such as the BeNeLuxA initiative[55] (launched in 2015) or the Valletta Declaration[56] (2017). These projects aim at improving transparency, sharing experiences and enhancing the bargaining power of procurement agencies. They focus on collaboration throughout the entire procurement process, from horizon scanning and health technology assessment to price negotiations. Meanwhile, long-standing collaborations like the Nordic Pharmaceutical Forum and the Baltic Procurement Initiative offer valuable lessons for the future.

Joint procurement is particularly relevant for certain medicines, such as orphan drugs, where individual countries may have small target populations and face significant access barriers. In the context of addressing antimicrobial resistance (AMR), joint efforts to incentivize continued access to both novel and existing medicines also deserve consideration.

See Box 4.5 for the impact of the COVID-19 pandemic on medicines regulation and supply.

4.4 People

A commitment to the mobility of people has been a preoccupation of the EU for as long as there has been an EU: at its inception, Italy was concerned with ensuring its citizens could work in the prosperous coalfields of Belgium and West Germany and fought for strong free movement provisions that would allow them to do so.[57] In health today, there are three major issues in the free movement of people. The first is the biggest: the movement and regulation of the healthcare workforce within Europe. The second is the movement of patients both under

54 Espin J et al. (2017). *How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?* Policy Brief 21, Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies.

55 Available at: http://www.beneluxa.org/collaboration (accessed 19 February 2022).

56 Available at: https://www.southeusummit.com/about/valletta-declaration/ (accessed 19 February 2022).

57 Maas, W. (2007). *Creating European Citizens*. Rowman & Littlefield.

Box 4.5 *The legacy of the COVID-19 pandemic for medicines regulation and supply*

The COVID-19 pandemic highlighted challenges of supply of medicines and the role of public authorities in actively supporting the development of new medicines where necessary to meet public needs. Challenges include ensuring adequate supply of medicines (especially given increasing demand), reliance on non-EU supply due to weaknesses in domestic manufacturing capacity, and data availability. As part of its European Health Union package of proposals, the Commission has proposed strengthening the role of EMA not only to license medicines, but also to help coordinate the development, assessment and supply of medicines particularly in relation to crises or shortages (see Section 4.3.1).[a] This would formalize the practical cooperation that was put in place as part of the response to the pandemic, and represents a significant broadening of the EU's role both earlier and later than the primary point of intervention in the process at the stage of licensing. On 25 January 2022 the Council approved revisions to the EMA's founding regulation which, according to the Council, allow it to

> facilitate a coordinated EU-level response to health crises by working towards monitoring critical medicines and medical devices shortages, providing scientific guidelines on medicines effective at diagnosing or treating diseases. Additionally, the EMA revisions proposed coordinating research on the effectiveness and safety of medicinal products and coordination of clinical trials for medical products that address public health crises. The revision includes a governance change of transferring the Medical Device Regulation expert panels under the EMA's supervision. The legislation also formally establishes the Medicines and Medical Devices Shortages Steering Group and the Emergency Task Force, working on the above tasks.[b]

Furthermore, in recognition of these challenges, the European Commission published a specific Pharmaceuticals Strategy, a Commission communication envisaging a wider range of actions to more actively shape the market for medicines and strengthen incentives to address key areas of need, including novel antimicrobials, medicines for children and rare diseases. The strategy encompasses four pillars of action: access to affordable medicines; support for sustainable, competitive and innovative markets; enhancing resilience mechanisms within supply chains; and promotion of effective and quality pharmaceuticals,[c,d]

As a communication, the Pharmaceutical Strategy did not change existing EU legislation but set the Commission's approach to policy in the area, elevating some priorities (crisis preparedness and response mechanism; antimicrobial resistance), adding some (notably the interest in a "diversified and secure supply chain") and reiterating others (e.g. competitiveness and safety). After many years of EU pharmaceutical regulation remaining relatively unchanged in its substance, the European Health Union proposals and the Strategy suggest a broader and more active role for the EU in this area in the coming years. Indeed, in 2023, the Commission published extensive proposals to

>> continues

revise the EU's pharmaceutical legislation, with discussions being expected to continue well into the mandate of the new institutions following the European elections in June 2024.

a European Commission (2020). Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020)725).

b European Commission (2022). Regulation 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. 25 February 2022. See also: https://ec.europa. eu/commission/presscorner/detail/en/ip_22_543 (accessed 23 February 2022).

c European Commission (2020). Communication: Pharmaceutical Strategy for Europe COM/2020/761 final.

d Summary of the Communication available at: https://ec.europa.eu/health/human-use/strategy_en (accessed 20 February 2022).

social security law (the long-established mechanism for patient mobility that includes the EHIC card) and under the cross-border healthcare directive. The third deals with migration in and out of the EU itself. In health and in general, the movements of the workforce, of consumers and of third country nationals (non-EU citizens) are very different issues.

4.4.1 Health workforce

According to the 2023 OECD *Health at a Glance* report, health and social care jobs accounted for 10.5% of all jobs in OECD countries as of 2021.[58] The 2022 WHO *Time to Act* report states that, overall, the workforce of medical doctors, nurses and midwives in the European region increased by 10% between 2010 and 2020.[59] Despite this growth, the health and social care sector in the EU continues to face two competing challenges. The COVID-19 pandemic exacerbated existing shortages in the healthcare workforce and strategies to increase surge capacity during the pandemic often relied on medical graduates entering the workforce early, retirees and others non-practicing medical professionals, private sector workers and foreign-trained healthcare workers. Other strategies emphasized mitigation using reskilling and retention to address existing shortages. In the short term, the sector must address acute shortages fuelled by factors such as difficulties in recruiting and retaining healthcare professionals, an increasing turnover in the health professions and a growing desire for a better work-life balance that can be difficult to achieve with a medical career.

In the long term, demographic changes driven by population ageing will impact the European healthcare workforce in three ways. First, demand for healthcare professionals in Europe will increase significantly in the next decades as the

58 OECD (2023). *Health at a Glance*. OECD.

59 World Health Organization (2022). *Health and Care Workforce in Europe: Time to Act*. Copenhagen: WHO Regional Office for Europe.

European population ages and as the number of patients with chronic conditions grows. The growing number of elderly patients with chronic pathologies will require new models of healthcare delivery, which involves expanding physician training. Second, shrinking cohorts of young people and competition with other sectors is already straining recruitment into the health professions. Smaller cohorts of new healthcare professionals, particularly in primary care, will require optimizing skill distributions, which involves accurate forecasting, training and workforce planning. Finally, population ageing will contribute to additional workforce reductions as older practising healthcare professionals retire. The 2022 WHO *Time to Act* report found that across workforces in the European region, the median percentage of medical doctors aged 55 or older was 30%. For nurses, the median percentage was 18%. Population ageing is likely to exacerbate the shortage of healthcare professionals that most EU Member States are already facing today. Replenishment of existing workforces and the need for sustained growth present a difficult challenge for the EU.

Free cross-border travel for health workers has historically been essential for many European health systems to ensure the functioning and delivery of services, particularly in times like the COVID-19 pandemic when the healthcare workforce was under enormous pressure. Since the 2011 EU research project on health professionals mobility and health systems (PROMeTHEUS), which illustrated a chronic undersupply of health professionals in rural and sparsely populated areas and an oversupply of medical doctors in urban areas, new reports have demonstrated the ongoing relevance of workforce distribution and cross-border workforce migration. An east-west and north-south asymmetry of doctors, nurses and dentists continues, and western and northern EU countries experience both inflows and outflows of healthcare professionals while other EU Member States mostly experience outflows.[60]

The European Directive on the recognition of professional qualifications helped support these workforce flows. Making professional qualification comparable has been a key issue for the European Union over the last twenty years.[61] The Bologna process was initiated in the early 2000s to harmonize European higher educational systems. European institutions funded various programmes to stimulate cross-national research and student exchange programmes. These initiatives, however, did not specifically target medical education. Healthcare qualifications may therefore still vary significantly between countries.

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60 Wismar, M., Maier, C. B., Glinos, I. A., Dussault, G., Figueras, J., & World Health Organization (2011). *Health professional mobility and health systems: evidence from 17 European countries*. Copenhagen: WHO Regional Office for Europe.

61 Greer, S.L., Kuhlmann, E. (2019). Health and Education Policy: Labour Markets, Qualifications, and the Struggle over Standards. In: St. John, S., Murphy, M. (eds) *Education and Public Policy in the European Union*. Palgrave Macmillan.

A few notable exceptions to this observation include the 2005 professional qualification directive, which established the rules for temporary mobility and a system of recognition of qualifications for "professions with harmonised minimum training conditions". The directive established a list of regulated professions including medical doctors, nurses, midwives, pharmacists and veterinarians who enjoy automatic recognition. It established minimum standards and minimum training requirements for these professions; for instance, medical doctors and nurses are required to complete a minimum number of training hours. There is widespread agreement that the directive is generally beneficial although some, including the Belgian Presidency, have questioned whether it fully reflects the rapidly changing landscape of healthcare and the healthcare workforce.[62]

Migration of healthcare workers from outside the EU has also historically contributed to the functioning of many European health systems. However, across the European Region most countries seem to comply with the 2010 WHO Global Code of Practice on the International Recruitment of Health Personnel. There is relatively little international recruitment from third countries and low and middle income countries (a phenomenon often referred to as brain drain).[63] Differences across EU Member States persist and, according to the 2023 OECD *Health at a Glance* report, the share of foreign-trained doctors in Switzerland, Ireland, Norway and New Zealand was around 40% in 2021 and in Israel nearly 60%.[64] Importantly, data on foreign-trained health professionals often reflect country of training rather than country of origin, which confuses medical doctors who emigrate for education and remain in the country of training after completion with those who train abroad and return to their country of origin following completion. Statistics on foreign-trained medical doctors may, therefore, better reflection the globalization of medical education rather than the international recruitment of health professionals.

Given the magnitude of the predicted increase in demand on EU health systems, recruitment of healthcare professionals either from within the EU or from non-EU countries is unlikely to be a sufficient solution. In response, forecasting and planning to optimize the distribution of professionals and skills has been prioritized. In 2012 the European Commission released an Action Plan for the EU Health Workforce, proposing concrete actions to improve forecasting, planning methodologies and sharing of good practice on effective recruitment and retention strategies. This was followed by a Joint Action on Workforce

62 Wismar, M., & Goffin, T. (2023). Tackling the health workforce crisis: Towards a European health workforce strategy. *Eurohealth*, 29(3).

63 Williams, G. A., Jacob, G., Rakovac, I., Scotter, C., & Wismar, M. (2020). Health professional mobility in the WHO European Region and the WHO Global Code of Practice: data from the joint OECD/EUROSTAT/WHO-Europe questionnaire. *European Journal of Public Health*, 30(Supplement_4), iv5-iv11.

64 OECD (2023). *Health at a Glance 2023*. OECD.

Planning and Forecasting (2013–2016) to advance the issue of intra-EU mobility. Building on this work, SEPEN – Support for the health workforce planning and forecasting expert network (2017–2018) – was established to develop expert networking, policy mapping and knowledge exchange, and to provide support to EU countries on national implementation of health workforce planning. Some other examples of EU initiatives are included in Box 4.6.

Box 4.6 *Some EU initiatives to improve workforce sustainability*

In the context of health workforce shortages, ongoing technological innovation and climate change, several projects have been launched to improve EU workforce resilience and sustainability and to facilitate Europe's transition to a green and digital economy. One such project, the EU Health Workforce Projects Cluster, was launched in 2021 and includes five EU projects co-funded with the Third Health Programme:

1. Action for Health and Equity – Addressing Medical Deserts (AHEAD)
2. Mental health: focus on retention of healthcare workers (METEOR)
3. Promoting evidence-based reforms (OASES)
4. Empowering EU health policies on task shifting (TASHI)
5. A roadmap out of medical deserts into supportive health workforce initiatives and policies (ROUTE-HWF).

Additionally, the BeWell project (2022–2026) was launched as part of the European Skills Agenda, as a partial response to a stated objective to "adopt processes and technologies to reinforce transformation into a greener and more digital economy". This was one of the objectives of the Skills Partnerships – 30 cross-sectoral, interdisciplinary and trans-European teams of workforce stakeholders launched in 2022 to support implementation of the European Commission's New Industrial Strategy for Europe.[a] The BeWell project was established through the European Skills Agenda 2020 and aims to upskill and reskill the healthcare workforce and improve skills intelligence. This involves developing the first Blueprint Alliance to create a skills strategy, large-scale partnership through the Pact for Skills initiative, and development of a pilot training program.[b]

The Joint Action (JA) on Health workforce to meet health challenges (HEROES) (2023–2026) follows the previous JA Health Workforce and SEPEN joint tender with involvement from 19 European countries and 51 partner organizations. Launched with the goal of improving national capacity for health workforce planning, the project focuses on data and analysis, forecasting and planning, skills and capacities for health workforce planning, and stakeholder engagement.[c]

a Joint Cluster Initiatives (EUROCLUSTERS) for Europe's recovery. Available at: https://eismea.ec.europa.eu/funding-opportunities/calls-proposals/joint-cluster-initiatives-euroclusters-europes-recovery_en#description (accessed 2 July 2024).

b https://bewell-project.eu/project/ (accessed 2 July 2024).

c https://healthworkforce.eu/the-project/ (accessed 2 July 2024).

4.4.2 Patients in cross-border care

Since the EU has always partly been about encouraging labour mobility within its borders, it should be no surprise that some of its oldest legislation is about social security coordination. This refers to the body of law implemented by Member States which ensures that people can cross borders to work and live, temporarily or permanently, without losing access to social security benefits. It does not mean that there is a European system of social security, any more than there is a European health system.

These provisions mean that if an individual moves to another country for a job, the social security rights that have been built up (including rights to healthcare) move with the person; similarly, if an individual temporarily travels to another EU country for a purpose such as work, study or holiday and there falls ill, they are covered and will be treated by that country's health system. However, if someone wishes to go abroad for the purpose of healthcare itself, then these provisions are highly restrictive. Prior authorization is required from the domestic authorities, which will vary and might often choose not to authorize care at the tariff of the destination state (some countries might benefit if their citizens seek care abroad, at lower prices, but is it in the interests of Bulgaria to finance much care in Germany, at German prices?). Reflecting these provisions, the volume of patients travelling to other countries in order to receive healthcare within the EU has historically been marginal.

Social security coordination has four principles overall, as stated by DG EMPL:

1. You are covered by the legislation of one country at a time so you only pay contributions in one country. The decision on which country's legislation applies to you will be made by the social security institutions. You cannot choose.

2. You have the same rights and obligations as the nationals of the country where you are covered. This is known as the principle of equal treatment or nondiscrimination.

3. When you claim a benefit, your previous periods of insurance, work or residence in other countries are taken into account if necessary.

4. If you are entitled to a cash benefit from one country, you may generally receive it even if you are living in a different country. This is known as the principle of exportability.[65]

65 European Commission (n.d.). EU Social Protection and Social Inclusion. Available at: https://ec.europa.eu/social/main.jsp?catId=849&langId=en (accessed 11 August 2024).

Because health was long considered as part of the social security system in many Member States, it was not surprising that the core mechanism for handling cross-border healthcare was located in social security coordination. It produces the core, visible, benefit of the European Health Insurance Card (EHIC). There is substantial legal and policy literature on the health policy dimensions of social security coordination. An EHIC is the tangible and portable manifestation of the two European rights that the limited data on it help to implement. The first right is to emergency care on the same terms as citizens when travelling abroad for a short term (around three months or less). Thus, if citizens of a Member State must pay a co-payment for treatment, so must people using an EHIC. The second right is to care in another Member State on the same terms as citizens if the home system has pre-authorized the care.

Member States then settle accounts with each other for EHIC treatment given to each other's citizens. In some cases, as with German citizens in Spain, this amounts to both a bargain for the home Member States, since Spanish healthcare costs less, and is an economic growth strategy for the sunny parts of Spain where they congregate. It is administered by DG EMPL. The internal politics of how Member States administer EHIC charges and reimbursement are not always straightforward, and the EU is sometimes unfairly blamed for distortions created within systems by Member State administrative decisions (e.g. slow reimbursement to providers or underpayments).

The law of social security coordination is made by unanimity in the Council – one of the few areas of EU internal law where a unanimity rule still governs. That shows how concerned Member States are to maintain their autonomy, and how easy it is to cause problems with these intricate systems. After a long period of legislative stability under Regulation 1408/71, the EU passed a new pair of regulations in 2010 that promised "modernized coordination". This coordination is more modern in both technical and social policy terms. In technical terms, it improved on the technology for data transfer that was available in 1971, launching an electronic system for the transfer of social security information between Member States. In social policy terms, it moved social security coordination and rights to social security away from the traditional labour market-based, male breadwinner model by expanding rights to include parental and other leave, and expanding the covered population to include people who were not working (e.g. young, retired or simply not working).

Some Member States and regions have developed bilateral agreements for cross-border collaboration. These types of agreements have a high level of variation, but are most common in regions with similar welfare state traditions or shared history, and within Central and Western Europe. For example, Germany, France and Switzerland make up TRISAN, a regional competence centre that conducts

Box 4.7 *The social security mechanism and the patient rights directive*

Cross-border healthcare is arranged within two mechanisms: social security and the free movement of goods and services, although the social security mechanism is much larger and more entrenched. One point worth underlining in the discussion of social security health mobility is that *it is far more important to patients and health systems than patient mobility under internal market or health law*. The integrating dynamics of the EU mean that while internal market law led to the integration of healthcare as a service subject to EU law, the actual provision of healthcare across borders was a problem that was largely solved in 1971. The 1971 solution of social security coordination, which had been developing since the first days of the Coal and Steel Community, solved the problem in a way that allowed national administrations to keep a tight grip on what rights individuals had and how they could be exercised. The legal and political drama that began with the *Kohll* and *Decker* decisions (see Section 4.6.1), and which provisionally ended with the Directive on patient rights in cross-border healthcare, was about the governance of European healthcare, not the extremely niche problem of people with insurance who wanted to be reimbursed at home state tariffs for care that was not pre-authorized.

The patient rights directive has two main parts, including a section on patient entitlements, and another non-binding section on European Reference Networks. These reference networks connect centres of expertise to support in the detection and treatment of rare diseases, a long-standing challenge for the EU.

studies and facilitates stakeholder collaboration with a particular emphasis on sharing best practices in support of improving cross-border collaboration in the Upper Rhine region.

Box 4.7 gives more detail about the link between the social security mechanism and the patient rights directive.

4.4.3 Migrants and health

In recent years a significant number of refugees and other migrants have sought asylum or the opportunity to live and work in the EU. The arrival of large numbers of people at EU borders in 2015–2016 triggered talk of a migration crisis.[66] Unsurprisingly (but not predictably), perceptions of crisis led to increasing Europeanization, new tensions and new actors in the migration policy area.[67] There were some very disparate political responses within different EU Member

66 It is worth noting that, compared to either the numbers of migrants in states in the European neighbourhood today, or the numbers of migrants at various times in 20th century European history, the numbers in the EU are not large.

67 Micinski NR (2022). *Delegating Responsibility: International Cooperation on Migration in the European Union*. University of Michigan Press.

States, ranging from Germany's welcome to the deployment of armed police by some other Member States. Efforts to allocate refugees across Member States proved politically contentious, as did support for border guards or humanitarian relief workers in states such as Italy and Greece where most migrants first arrived.

While most of these migrants were young and healthy, they had special health needs related to their specific situation, including physical exhaustion, mental stress or unhealthy living conditions that needed to be addressed. It was felt that their alleged risk of contracting or spreading communicable diseases required a response. Even if this in the first place was the responsibility of reception countries, the visibility and geographic location of the arrivals suggested EU action, especially to support those Member States receiving a high number of migrants. In 2016 around €7.5 million was provided to improve healthcare for migrants and training of health professionals. Together with the International Organization for Migration (IOM), the Commission also created a personal health record (with accompanying handbook) to ensure continuity of care for migrants moving around from one Member State to another. As discussed in Section 7.4.4, the EU also gave considerable aid to countries on its borders, especially Türkiye, to host migrants who would otherwise have been able to continue on to EU borders.

The COVID-19 pandemic significantly impacted migrant workers, especially extra-European migrants. Foreign-born workers accounted for 13% of the European "essential workforce" in 2020.[68] They were over-represented in the economic sectors most affected by the pandemic and were particularly concentrated in low-income professions, working as cleaners, helpers, personal care workers, drivers, and mobile plant and food processing operators.[69] A report published by the European Commission Joint Research Centre highlighted some of the difficulties encountered by migrant workers in the EU during the COVID-19 pandemic. Foreign-born workers were more likely to have fixed-term contracts, earn lower wages, hold jobs that were less amenable to teleworking, and to be laid-off with limited to no social benefits or compensation.[70] In Spain, for example, unemployment within the migrant population rose to almost 25% by early September 2020.[71]

Healthwise, migrants had limited access to healthcare services, sick pay, unemployment or social benefits, and linguistically relevant health information about

68 Fasani F & Mazza J (2020, April). *Immigrant Key Workers: Their Contribution to Europe's COVID-19 Response*. IZA Policy Papers 155, Institute of Labor Economics (IZA).

69 Fasani F & Mazza J (2020). *A Vulnerable Workforce: Migrant Workers in the COVID-19 Pandemic*. Joint Research Centre Technical Report. European Commission.

70 Ibid.

71 Instituto Nacional de Estadistica (2020). Encuesta de Poblacion Activa (EPA). E*fectos de la COVID-19 en la EPA de este trimestre* [Active Population Survey (EPA). Effects of COVID-19 on the EPA this quarter.]

infection prevention measures. As a result, migrant workers made up one of the groups most at risk of contracting COVID-19.[72] This was especially the case if their migration status was undocumented or they worked in the informal economy, but administrative burdens also prevented them from easily accessing benefits due to them.[73] They were also more likely to be exposed to the virus because they tended to live in more densely populated areas, work in crowded conditions or in more direct contact with potentially sick individuals in healthcare facilities or care homes. These occupations cannot be carried out remotely and hence exposed them to a higher risk of contagion than the rest of the population. Widespread contagion occurred, for instance, in meat processing plants in Germany which primarily employ migrant workers. COVID-19 related mortality and infection rates for immigrants ended up exceeding those of the native-born population in several EU Member States. In France, for example, a study reported that individuals born in Africa or Asia and living in the Paris metropolitan area were twice as likely to die from COVID-19 than their French-born counterparts during the first wave of the pandemic (spring 2020).[74]

EU Member States took action to address some of the challenges faced by documented and undocumented migrants. Some of them improved access to medical care through state medical assistance (e.g. France). Others sought to protect the status of their migrant workforce, in particular if it was necessary for agricultural production.

As EU Member States attempted to scale up their health workforce capacity during the COVID-19 pandemic, foreign-trained doctors were frequently solicited by governments and asked to join the workforce. Several EU Member States facing workforce shortages took targeted initiatives to enable foreign-trained healthcare professionals to support containment efforts. In Germany, for instance, about 14 000 foreign-trained physicians were waiting to get their medical credentials recognized when the pandemic broke out. Several German states, such as Bavaria and North Rhine-Westphalia, allowed foreign-trained doctors specializing in anaesthetics, ENT and general internal medicine to practise medicine under supervision, provided they passed a language exam and had a pre-existing employment contract with a healthcare facility. In Ireland asylum seekers and

72 Fernandez-Reino M & McNeil R (2020). *Migrants' labour market profile and the health and economic impacts of the COVID-19 pandemic*. Report. The Migration Observatory, University of Oxford.

73 Van Ginneken E & Gray BH (2015). European policies on healthcare for undocumented migrants, in Kuhlmannn E, Blank RH, Bourgeault IL & Wendt C (eds). *The Palgrave International Handbook of Healthcare Policy and Governance*. Palgrave Macmillan, London, pp. 631–48. Palm W, Webb E, Hernández-Quevedo C, Scarpetti G, Lessof S, Siciliani L & van Ginneken E (2021). Gaps in coverage and access in the European Union. *Health Policy*, 125(3):341–50.

74 Papon S & Robert-Bobée I (2021). *Décès en 2020: hausse plus forte pour les personnes nées à l'étranger que pour celles nées en France, surtout en mars-avril* [Deaths in 2020: Greater increase for people born abroad than for those born in France, above all in March-April]. Institut national de la statistique et des études économiques (INSEE). INSEE FOCUS No 231. Published 16 April 2021.

refugees with medical qualifications were authorized to work in support roles such as medical assistants.[75]

Finally, the European Union took a series of actions targeted at migrant workers and vulnerable migrant communities during the COVID-19 pandemic. On 23 September 2020 the European Commission released the New Pact on Migration and Asylum, proposing to overhaul the EU's long ailing policies in this area.[76]

The Russian Federation's invasion of Ukraine in February 2022 led many Ukrainians to flee, with as many as four million entering the EU by mid-April. European Union and Member State responses were mostly quite unlike their responses to refugees in 2015–2016. In March 2022, the EU institutions approved the Cohesion's Action for Refugees in Europe (CARE) plan which allowed redirection of various funds including those from the REACT-EU facility (which grouped European Structural and Investment Funds [ESIF] and funds discussed in Chapter 6 for quick disbursement). On 1 March the EU, for the first time, activated the Temporary Protection Directive, which extends EU social rights to refugees. There was no organized effort to send Ukrainian refugees to different Member States, in distinction to the politically contentious efforts to shift refugees from the Middle East and North Africa. A recent survey by the European Observatory on Health Systems and Policies found that most Member States were able to speak to the legal structures in place to for healthcare coverage, but data were less available on the realities of access to quality care and barriers to that care.[77]

4.5 Financing

The EU does not directly finance the provision of health services. Instead, its impact on healthcare financing comes through two routes. One is its various loan and grant programmes for infrastructure, which are discussed in Section 6.3 The other is through its various regulatory regimes governing the operation of health financing systems by the Member States. This section discusses the EU

75 Williams GA et al. (2020). What strategies are countries using to expand health workforce surge capacity during the COVID-19 pandemic? *Eurohealth*, 26(2).

76 European Commission (2020). *Migration and Asylum Package: New Pact on Migration and Asylum documents adopted on 23 September 2020*. First published on 23 September 2020. Available at: https://ec.europa.eu/info/publications/migration-and-asylum-package-new-pact-migration-and-asylum-documents-adopted-23-september-2020_en (accessed 20 February 2022).

77 Mauer, N., Eriksen, E., Hernandez-Quevedo, C., and van Ginneken, E. (2023). *Access to health care one year on: Implementation of Temporary Protection Directive (2001/55/EC) in EU Member States*. European Observatory on Health Systems and Policies/ European Commission. Available at: https://health.ec.europa.eu/document/download/18de10c0-9224-4850-9c79-9a4a0e3439ea_en?filename=security_2023_tpd_rep_en.pdf&prefLang=ga (accessed 2 July 2024).

policies which affect healthcare financing. As so often in EU health policy, these policies were developed in other sectors, were not justified by health concerns, and were applied without much regard to the specificities of healthcare. Even if the general goals are laudable, their application in health has caused difficulties. In many cases, there has been a process of adaptation, in which legislation, court cases and Member State implementation have come to a rough balance of general principles and health relevance. That does not mean any of these policies are necessarily stable or intrinsically supportive of equitable and sustainable healthcare financing; they all bear watching even if there is no obvious current problem.

4.5.1 Competition, state aid and services of general interest

The EU has long had strong competition (anti-trust) law, with a powerful enforcement role for the Commission. Seen as a complement to internal market regulation establishing free movement and fostering free competition across borders, competition law is justified by the goal of ensuring fair competition between enterprises. It is aimed at economic agents (undertakings), prohibiting them from behaving in a way that is likely to distort market competition. However, governments can also distort competition by granting exclusive rights to certain operators or by providing them with state aid. This is likely to be very relevant for the health sector, with its predominance of public funding and the presence of a variety of actors with varying degrees of scale, autonomy and business orientation.[78]

Whereas the rules on competition are specified directly in the TFEU,[79] the question as to whether and how competition rules apply to health systems remains a source of uncertainty.[80] First, it depends on the qualification of health services as "economic" and of the actors operating within health systems as "undertakings". Given the absence of clear definitions of these concepts, this needed to be clarified by the CJEU, in a similar way to that which happened for the free movement of health services.[81] From this case law, it appears that it is not the legal status but rather the nature of the activity that is determinant.[82] Even non-profit-making

78 Hancher L & Sauter W (2012). *EU competition and internal market law in the health care sector*. Oxford, Oxford University Press. Guy M (2019). *Competition Policy in Healthcare: Frontiers in Insurance-Based and Taxation-Funded Systems*. Intersentia.

79 TFEU, Chapter 1 of Title VII, Articles 101–9.

80 Mossialos E & Lear J (2012). Balancing economic freedom against social policy principles: EC competition law and national health systems, *Health Policy*, 106:127–37.

81 See also Gekiere W, Baeten R & Palm W (2010). Free movement of services in the EU and health care, in Mossialos E et al. (eds). *Health systems governance in Europe: the role of EU law and policy*. Cambridge: Cambridge University Press, pp. 461–508.

82 Prosser T (2010). EU competition law and public services, in Mossialos E et al. (eds). *Health systems governance in Europe: the role of EU law and policy*. Cambridge: Cambridge University Press, pp. 315–36.

institutions are considered undertakings if they are engaged in activities of an economic nature.[83] However, institutions entrusted with the administration of mandatory schemes of social security, which are based on solidarity and serve an exclusively social function, are excluded from the application of EU competition law as the activities they perform are considered non-economic.[84]

Even if competition rules apply in principle, which is likely for the actual provision of healthcare, the specificity and non-commercial motivations of many activities could justify exemptions or derogations. The legal concept that is used here to shield public, state and welfare services from competition and state aids law is "services of general (economic) interest" (SGEI or SGI).[85] The TFEU explicitly refers to this concept for allowing the setting aside of rules if they would obstruct the performance of SGEIs entrusted to an undertaking.[86]

As public service sectors increasingly became liberalized, the concept was used to define the scope of regulation to protect and preserve the general good principles of universality, continuity, affordability and quality within these new markets. This required a different approach. With the inclusion of a specific article on services of general interest in the Amsterdam Treaty in 1997, the focus shifted away from a mere derogation towards a positive duty for Member States and the EU to promote SGEIs.[87] While a derogation needs to be interpreted strictly and with due respect to proportionality, the new legal base of Article 14 TFEU allows for a more proactive and systematic approach, with the EU adopting regulations to further define operational principles and conditions for SGEIs to ensure they can achieve their mission. In a protocol attached to the TFEU the concept and role of SGEIs are further elaborated, as well as their underpinning principles and values, yet a broader and consistent regulatory framework is still lacking, probably partly because of the diversity of legal traditions that use variations on the concept.[88]

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83 European Court of Justice. Cases C-41/90 *Höfner and Elser*, C-475/99 *Ambulanz Glöckner*, C-67/96 *Albany*, C-180/98–C-184/98 *Pavlov*.

84 European Court of Justice. Cases C-159/91 and C-160/91 *Poucet-Pistre, Garcia, Cisal, FENIN, AOK*.

85 Services of General Interest is a problematic topic. Some EU Member State legal traditions have no such concept, or if they do have an equivalent, they formulate it quite differently. Others have a well developed legal or political concept of SGI, as in France and Germany, but in their legal traditions its meanings and impact vary considerably. The concept therefore generates misunderstandings and has trouble gaining political traction either in the abstract or in any specific formulation. See Schweitzer H (2011). Services of general economic interest: European law's impact on the role of markets and of Member States, in Cremona M (ed.). *Market Integration and Public Services in the European Union*. Oxford: Oxford University Press, pp. 11–62.

86 TFEU, Article 106(2).

87 Szyszcak E (2007). Competition law and services of general economic interest, in *ERA Conference on European integration and national social protection systems: towards a new form of internal market*. Brussels, 31 May–1 June 2007.

88 Schweitzer H (2011). Services of general economic interest: European law's impact on the role of markets and of Member States, in Cremona M (ed.). *Market Integration and Public Services in the European Union*. Oxford: Oxford University Press, pp. 11–62.

Instead, the European Commission has developed – also based on CJEU jurisprudence – a set of criteria to define SGEIs and the scope for derogation to be granted. In 2004, in its White Paper on Services of General Interest,[89] the Commission announced a specific Communication on Social and Health Services of General Interest, to identify and recognize these and to clarify the framework in which they operate and can be modernized. However, after health services were excluded from the Services Directive,[90] they were also excluded from the scope of this communication in 2006,[91] the claim being that they would be covered in the upcoming Directive on the Application of Patients' Rights in Cross-Border Healthcare. However, while this directive did address the reimbursement of cross-border health services, it did not cover the wider application of internal market rules on the health sector.

One area that has attracted attention in the health sector is state aid. This refer to assistance such as subsidies from public bodies to private undertakings. On the one hand, these can distort competition, which means that much EU law is hostile to them. On the other hand, subsidies to private or non-profit-making undertakings are often an ordinary part of health systems. The potential clash between state aid law and health system practice has caused some concern and led the EU to develop an elaborate framework to monitor and sanction financial discrimination of economic operators. As state aid is an exclusive EU competence, the Commission's decisions here are crucial. Since 2005 the European Commission has further specified the rules for state funding of SGEIs with the so-called Altmark package (referring to the European Court of Justice case concerning Altmark, a German bus company awarded state aid[92]), also known as the Monti–Kroes package,[93] updated in 2012 by the Almunia package. Essentially, if public funding merely compensates for the fulfilment of public service obligations, it is not regarded as state aid. Following the CJEU rulings,[94]

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89 European Commission (2004). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. White paper on services of general interest* (COM(2004)0374 final). Luxembourg: Publications Office of the European Union.

90 European Parliament and Council (2006). *Directive 2006/123 on services in the internal market*. Luxembourg: Publications Office of the European Union.

91 European Commission (2006). *Implementing the Lisbon programme: social services of general interest in the European Union* (COM(2006)177final). Luxembourg: Publications Office of the European Union. In 2019 DG COMP (Competition) consulted on an evaluation "to check if the rules on health and social services of general economic interest … meet their objectives under the 2012 services package". Available at: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-3777435_en (accessed 20 February 2022).

92 European Court of Justice. Case C-280/00 *Altmark*.

93 European Commission (2005). Commission *Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (2005/842/EC)*. Brussels: European Commission.

94 European Court of Justice. Cases C-280/00 *Altmark*, C-53/00 *Ferring*.

this is subject to strict criteria: there needs to be an explicit mandate as well as objective and transparent parameters for calculating the compensation, which cannot exceed actual costs.[95] Even if not all of these Altmark criteria are fulfilled, state aid can still be declared compatible (in advance) without the need for prior notification to the Commission. This applies to a range of mostly social services of a local nature, including hospitals and other care organizations.[96] In addition, a special de minimis rule applies, allowing local authorities to provide for smaller amounts of public support that does not affect intercountry trade.[97] In this way it might seem as if the effect of competition and state aid rules on the health sector is limited to, for example, competition in the pharmaceutical sector, although some would argue that the legal uncertainty would force them to adopt hiding and distraction strategies and other unusual organizational relationships that might not be efficient, transparent, solidaristic or flexible.[98]

The COVID-19 pandemic showed the limits of the perspective underlying this area of law. Conceptually, health systems resilience does not seem to be best served by this broad legal approach, which emphasizes competitive relations.[99] Practical evidence for this might be seen in the relaxed approach of the Commission and Member State competition authorities in 2020 and 2021, with many cases of state aid and coordination between competitors ignored because they were seen as necessary to respond to an unprecedented disaster. What lessons will be drawn in this area of law and policy remains to be seen.

4.5.2 Public and private partnerships

Public private partnerships as a phrase has many meanings, including research collaborations with industry, but one specific area, often known as PPPs, involves public authorities such as health systems that enter into long-term contracts with

95 European Commission (2012). Communication on the application of the European Union state aid rules to compensation granted for the provision of services of general economic interest. *Official Journal*, C 8:4.

96 European Commission (2012). Decision of 20 December on the application of Article 106(2) of the Treaty on the Functioning of the European Union to state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest. *Official Journal*, L 7:3.

97 European Commission (2014). Regulation (EC) 1407/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid. *Official Journal*, L 352:1–8. See also European Commission (2014). *Block exemption regulations*. Brussels: European Commission.

98 Hervey TK (2011). If only it were so simple: public health services and EU law, in Cremona M (ed.). *Market integration and public services in the European Union*. Oxford: Oxford University Press, pp. 179–250. For the situation regarding the work of competition authorities in the pharmaceutical sector, see European Commission (2019). *Competition Enforcement in the Pharmaceutical Sector (2009–2017): European competition authorities working together for affordable and innovative medicines*, COM(2019)17.

99 Sagan A, Webb E, Azzopardi-Muscat N, de la Mata I, McKee M & Figueras J (eds) (2021). *Health system resilience during COVID-19: Lessons for building back better*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies. Health Policy Series 56.

a private company for some combination of services including building, operating and transferring a facility such as a hospital. The EU position with regard to public and private partnerships emerges from the interaction of two legal facts. One is that the EU has very powerful legal instruments to enforce fair public procurement procedures. The other is that it has comparatively limited powers or responsibilities for commissioning services (most of what the Commission refers to as a public private partnership today is a research collaboration with industry). The result is that there are two faces of EU PPP policy: the smaller issue of using PPPs in EU-financed projects and the larger issue of determining whether EU legal frameworks are helpful for those who would use PPPs with any source of funding.

The first issue, concerning the use of PPPs in EU-financed projects (principally meaning projects financed by the structural and cohesion funds and research projects), was discussed in a wide-ranging 2009 Commission communication.[100] The communication simultaneously noted the potential usefulness of PPPs (in light of what it saw as vast future obligations for infrastructure investment) and committed the Commission to their use, but stressed the difficulty of untangling the potential legal issues involved. Most of the examples of PPPs that the communication discussed were in the co-financing of research programmes with private firms. It noted that:

> the Commission is aware of difficulties in combining different sets of EU and national rules, practices and timetables. The Commission therefore intends to review the rules and practices to ensure that PPPs are not put at a disadvantage and issue the necessary guidance to assist the public authorities in the preparation of projects.[101]

This puts the focus on the second and bigger issue with PPPs: not whether the EU is using them in its programmes but rather whether the EU is striking the right balance between its goal of free and equal access to public markets and the practicalities of bidding on PPPs. Use of PPPs was the subject of a Commission Green Paper in 2004,[102] followed by a consultation and a 2005 communication.[103] In the communication the Commission concluded that further legislation would probably introduce new complexity and that the

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100 European Commission (2008). *Interpretative communication on the application of Community law on Public Procurement and Concessions to institutionalised PPP* (IPPP)(2008/C 91/02).

101 European Commission (2008). *Interpretative communication on the application of Community law on Public Procurement and Concessions to institutionalised PPP* (IPPP)(2008/C 91/02).

102 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2004). *Green paper on public–private partnerships and community law on public contracts and concessions (COM(2004)327)*. Luxembourg: Publications Office of the European Union.

103 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2005). *Communication on public–private partnerships and community law on public procurement and concessions (COM(2005)569)*. Luxembourg, Publications Office of the European Union.

implementation of public procurement law need not present difficulties to public or private sector participants. In particular, the competitive dialogue procedure offered the possibility of letting potential commissioners and providers have in-depth discussions without violating public procurement law – a potential problem given that standard public procurement law dissuades close interaction between potential vendors and potential buyers. Another particular issue is that of concessions, where the private sector provides services together with public authorities (e.g. toll roads).[104]

In practice, making use of PPPs is risky and requires considerable expertise.[105] This is one of the key issues highlighted by national representatives themselves in the toolbox on the use of the structural funds for health (see Section 6.3).[106] It remains to be seen whether Member States (separately or working together) can build up greater expertise in using PPPs. Concern about the promotion of PPPs by the Commission and within EU funds has re-arisen in the aftermath of the COVID-19 pandemic. Civil society actors, worried that recovery funds and EU programmes like the ESIF will be used to support PPPs in healthcare and other sectors, have re-issued studies of the evidence on PPPs and their effectiveness, and warn against the potential for the crisis to be used as an opportunity by businesses keen to promote joint undertakings.[107]

4.6 Delivery

The delivery of healthcare services is not just shaped by broader EU legislation, policy and jurisprudence. It is also at the heart of EU healthcare law, for it is the

104 See European Parliament (2014). *Press release: new EU-procurement rules to ensure better quality and value for money*. Brussels: European Parliament. Available at: http://www.europarl.europa.eu/news/en/news-room/content/20140110IPR32386/html/New-EU-procurement-rules-to-ensure-better-quality-and-value-for-money (accessed 14 July 2014).

105 Lieberherr E, Maarse H & Jeurissen P (2015). The governance of public–private partnerships, in Greer SL, Wismar M & Figueras J (eds). *Strengthening health systems governance: Better policies, stronger performance*. Maidenhead: Open University Press. See also Expert Panel on Effective Ways of Investing in Health (2014). *Health and economic analysis for an evaluation of the public–private partnerships in health care delivery across Europe*. Brussels: European Commission DG Health and Consumer Protection. Available at: http://ec.europa.eu/ health/ expert_panel/experts/working_groups/index_en.htm (accessed 14 July 2014).

106 General Secretariat of the Council (2013). *Reflection process: towards modern, responsive and sustainable health systems (12981/13 ADD 2)*. Luxembourg: Publications Office of the European Union, see Section 5.

107 See, for instance, European Public Service Union (2020). *Why public-private partnerships are still not delivering*. Available at: https://www.epsu.org/sites/default/files/article/files/PPPs_EN.pdf (accessed 1 July 2021). Corporate Europe Observatory (2021). *When the market becomes deadly: How pressures towards privatisation of health and long-term care put Europe on a poor footing for a pandemic*. Available at: https:// corporateeurope.org/sites/default/files/2021-01/healthcare-privatisation-final.pdf (accessed 1 July 2021).

basis of the string of court cases starting with 1998's *Kohll* and *Decker* decisions that created the most important direct EU case law and legislation on healthcare.[108]

The freedom to provide services across borders in the EU is an important legal principle even if its actual importance in the lives of Europeans differs sharply from sector to sector. In the case of health, the amount of cross-border services that have been delivered is rarely important (with the partial exception of pharmacy, see Section 4.6.4), but it was as a service across borders that the Court of Justice first brought healthcare under EU law in the 1998 *Kohll* and *Decker* rulings, and it is on the freedom to provide services that the key (only) legislation on healthcare systems rests.

4.6.1 Cross-border healthcare and patient mobility

The central issue for health in terms of services is cross-border healthcare. This has been historically very limited within the EU. As discussed in Section 4.4.2, there are long-standing provisions on coordination of social security designed to ensure the free movement of workers (social security in EU terms is taken to include healthcare).

The EU law on cross-border care changed fundamentally in 1998, however. Two Luxembourg citizens, Kohll and Decker, argued that they should be able to exercise their right to healthcare in other EU countries and that preventing them from doing so was a barrier to the internal market.[109] The Luxembourg courts agreed that there was an issue of EU law meriting a preliminary reference procedure and the European Court of Justice agreed with Kohll and Decker that their cases showed a discriminatory restraint on trade in services. This was easier to argue in the case of an insurance-based system such as that in Luxembourg, in which citizens pay for their healthcare initially and are then reimbursed; why should they not be able to purchase their healthcare from a provider just across the border if it does not cost any more? It was less obvious in public provision systems such as the national health service systems of countries such as Spain, Italy and the United Kingdom, but the Court confirmed through a series of cases that the same legal principles applied.

However, the Court only established the basic principles. It remained up to legislators to decide how to implement them. Given the sensitivities in Member States over health systems, this might have been expected to be a lengthy and fraught process, and indeed it was, taking over a decade before the adoption of the Directive on the Application of Patients' Rights in Cross-Border Healthcare

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108 European Parliament and Council (2004). Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems. *Official Journal*, L 166:1.

109 European Court of Justice. Cases C-158/96 *Kohll*, C-120/95 *Decker*.

Table 4.1 *Comparison between cross-border healthcare rules under the social security regulation and the patients' rights in cross-border healthcare directive*

	Regulation on the Coordination of Social Security Systems	Directive on the Application of Patients' Rights in Cross-Border Healthcare
Prior authorization	Required for any planned healthcare in another EU Member State; not required for immediately necessary care while in another EU Member State for other reasons	May be required for hospital care (meaning inpatient care) and other cost-intensive treatments, and in order to prevent health hazards and use of unsuitable providers
Tariffs	The State of treatment; the State where the person is covered if this means more than the State of treatment (up to the level of actual cost)	The State where the person is covered (up to the level of actual cost)
Payment method	Publicly funded element settled between national ministries/insurers	Paid by the patient with subsequent reimbursement by the State where they are covered (unless the State makes direct arrangements to pay)
Provider	Only providers affiliated with the State of treatment's social security system	All providers who legally provide healthcare in the State of treatment
Travel and accommodation costs	State of coverage covers costs that are inseparable from the treatment if it would cover them domestically and the travel to the country of treatment	Covered to the same extent as they would be domestically – although by virtue of travelling abroad and thus different, what this means in practice is unclear

Source: Greer SL & Sokol T (2014). Rules for rights: European law, health care, and social citizenship. *European Law Journal*, 20(1):66–87.

in 2011.[110] However, like the Court's original rulings, this system coexists with the original regulations on coordination of social security systems, meaning that there are now two EU systems for cross-border healthcare running in parallel, as set out in Table 4.1.

In practice, and despite the controversy over the Court's rulings, the actual numbers of patients seeking care abroad under the directive remains very low,[111] at around 547 000 in 2022,[112] which is only around a tenth of the number using the regulation that provides for the European Health Insurance Card, and a vanishingly small proportion of total care provided domestically.

However, the directive has had larger impacts in other ways. One has been through domestic measures taken in response to the directive that have a potential

110 European Parliament and Council (2011). Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare. *Official Journal*, L 88:45.

111 European Commission (2018). *Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare*. COM(2018)651, 21 September 2018.

112 This number is imprecise. The report on patient mobility under the directive, which is produced annually, notes that there are "several data quality issues". For the most recent report: European Commission (2024). *Member State data on cross-border patient healthcare following Directive 2011/24/EU; Reference year 2022*. European Commission DG SANTE. https://health.ec.europa.eu/document/download/69e33702-c7cc-4f0e-afc0-f3cf13e127ab_en?filename=crossborder_2022_patient-healthcare_data_en.pdf

effect for all patients, whether travelling abroad or not. Elements of the directive aligned better with some national systems than others, and in some systems the requirements of the directive led to significant domestic change.[113] For example, the logic of the directive required some explicit statement of what was and what was not included as part of a patient's healthcare entitlement, which some systems did not have but introduced following the directive. Similarly, some systems did not have requirements for liability insurance for professionals in case of problems with care. The directive was also neutral about the public or private status of providers in other countries, which led to discussions in several countries about whether there should be some form of access enabled for private providers within the domestic system. One effect of the directive has been to show the diversity and extensive interactions with public systems of Europe's private providers. How far these provisions have concretely changed the experience of patients in regard to their health systems is not yet clear. However, it does suggest that the directive has had a wider impact on health systems than simply as regards patients seeking care abroad under its provisions.

The other major impact of the directive is through its ancillary provisions on practical cooperation between European health systems. The Commission took the opportunity of the directive to provide a legal mechanism for greater European cooperation between health systems, building on the issues that emerged from the discussions that led up to the directive, including cross-border recognition of prescriptions, health technology assessment and European Reference Networks (discussed in Section 4.6.2).

Understanding the impact of the directive requires assumptions about just what it was supposed to do. One of the most obvious objectives was to provide legal certainty: to replace case by case jurisprudence with stable legislation. The track record of this strategy as a way to slow judicial integration is imperfect, since legislation often raises the profile of the issue and makes both lawyers and judges more confident.[114] There is still a risk of that in healthcare[115] but it seems to have been avoided by Member States' general approach of simply granting most requests to the relatively small number of people who make them.[116] Another objective was to enhance patients' rights – which makes little sense given that we are still discussing people who choose to seek non-emergency treatment abroad,

113 Azzopardi-Muscat N et al. (2018). The role of the 2011 patients' rights in cross-border healthcare directive in shaping seven national health systems: looking beyond patient mobility. *Health Policy*, 122(3):279–83.

114 Kelemen RD (2011). Eurolegalism: *The transformation of law and regulation in the European Union*. Cambridge, MA: Harvard University Press.

115 Greer SL (2013). Avoiding another directive: the unstable politics of European Union cross-border health care law. *Health Economics, Policy and Law*, 8(4):415–21.

116 European Commission (2024): *Member State data on cross-border patient healthcare following Directive 2011/24/EU Reference year 2022*. Final version, January 2024. Available at: https://health.ec.europa.eu/document/download/69e33702-c7cc-4f0e-afc0-f3cf13e127ab_en?filename=crossborder_2022_patient-healthcare_data_en.pdf (accessed 2 July 2024).

pay out of pocket and then seek reimbursement. That is a very small and very specific segment of European society.

A third was to try to improve European healthcare policy by adding dimensions of healthcare improvement to the directive. That certainly happened.

The COVID-19 pandemic put Member States' healthcare systems under extreme pressure. Hospitals across the EU faced workforce and intensive care unit bed shortages as early as the spring of 2020. The European Commission published guidelines in April 2020 to encourage cross-border healthcare cooperation between national, regional and local authorities.[117] The guidelines outlined key elements of cross-border care, such as emergency transport of patients, reimbursement of patients' medical costs in the treating Member State, and healthcare personnel working across borders. These cooperation initiatives were, however, limited in scope and frequency. Luxembourg, Austria and several German states offered intensive care beds and hospital treatment to French and Italian patients in the spring of 2020, but these practices were not generalized.

4.6.2 European Reference Networks

In the directive on patients' rights in cross-border healthcare, under the chapter on cooperation in healthcare, a legal basis was established for the creation of European Reference Networks (ERNs). Article 12 lays out the fundamental principles and objectives for these ERNs. The idea is to link existing centres of expertise in various Member States that are specialized in the diagnosis and care of rare, low prevalence and complex diseases. This should help centralize knowledge and expertise, and strengthen medical research and training, as well as facilitate improvements in diagnosis and treatment for patients with a medical condition that requires a pooling of knowledge and concentration of expertise in medical domains where this expertise is rare.[118]

In a delegated decision the Commission further specified the legal criteria and conditions that ERNs and participating healthcare providers must fulfil.[119] Simultaneously, in an implementing decision, it detailed the criteria for establishing and evaluating ERNs and their members and for facilitating

117 European Commission (2020). *Communication from the Commission. Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis*. Brussels, 3 April 2020. Available at: https://ec.europa.eu/info/sites/default/files/guidelines_on_eu_emergency_assistance_in_cross-bordercooperationin_healthcare_related_to_the_covid-19_crisis.pdf (accessed 13 January 2022).

118 Palm, W., Glinos, I. A., Rechel, B., Garel, P., Busse, R., Figueras, J., & World Health Organization. (2013). *Building European reference networks in health care: exploring concepts and national practices in the European Union*. European Observatory on Health Systems and Policies.

119 European Commission (2014). Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil. *Official Journal*, L 147:71.

exchanges of information and expertise on establishing and evaluating such networks.[120] In this voluntary process, a strong role was attributed to the Member States. A Board of Member States is responsible for developing the overall ERN strategy, approving the networks as well as recognizing the participating centres at national level.

Each ERN is led by an ERN coordinator. The ERN coordinators group meets three times a year. While clinical services provided in the context of the ERNs are not funded, the various EU funding programmes (EU4Health, Connecting Europe Facility and Horizon Europe) financially support the coordination and management of the ERNs as well as specific functions or projects (e.g. grants for registries or clinical research). In addition, the Commission has provided in-kind support with the set-up of a web-based Collaborative Platform (ECP) to stimulate and facilitate collaboration between ERN members, and the establishment of a clinical patient management system (CPMS), which is an IT platform for ERN members to share clinical data on specific patients and organize virtual consultations.

As of 2024, the 24 operating ERNs include 1619 specialized centres in 382 hospitals across all 27 Member States (and Norway).[121] Among the challenges for the ERNs in the coming years are their integration into national health systems and alignment with national strategies on rare diseases, as well as their further enlargement to other providers, including affiliated partners and clinical areas. An opinion report by the Expert Panel on Effective Ways of Investing in Health (EXPH) advised against further expanding the ERNs to other areas of healthcare before fully evaluating their costs and benefits.[122] A continuous monitoring and quality improvement system was introduced accordingly.[123] Researchers have noted challenges ranging from Brexit (and the loss of British participants) to organizational issues, as well as achievements.[124] One challenge – or perhaps opportunity – is the development of virtual ERNs. Much needs to be done to map out practical ways in which digital technologies could enhance ERN effectiveness.

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120 European Commission (2014). Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks. *Official Journal*, L 147:79.

121 https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/european-reference-networks_en (accessed 2 July 2024).

122 Expert Panel on Effective Ways of Investing in Health (EXPH) (2018). *Opinion on the Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area*. European Union.

123 European Commission. *ERN Continuous Monitoring and Quality Improvement System*. https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/european-reference-networks/ern-continuous-monitoring-and-quality-improvement-system_en (accessed 18 July 2024).

124 Tumiene B et al. (2021). European Reference Networks: challenges and opportunities. *Journal of Community Genetics*, 12(2):217–29. doi.org/10.1007/s12687-021-00521-8.

4.6.3 Patient safety and healthcare quality

Patient safety is defined as the absence of preventable harm to a patient during the healthcare process. It might seem to be moving a long way from single internal market law and patient mobility, but it is within the framework of patient mobility that the EU has developed a role in patient safety. If there is to be any kind of European market in publicly financed health services, then, as with anything else, the logic of the European regulatory state demands that it have enough regulation and transparency to be safe even if the number of people using the market is tiny.

The result is that patient safety and healthcare quality, for all that it might naturally seem to belong somewhere else, grows out of the Treaty bases and policies developed for the internal market. It is an equivalent of product safety or environmental regulation, aimed at producing some basic level of safety (while providing an opportunity for various advocates to promote their agendas at the EU level).

Treaty base aside, there is certainly scope for work on the topic. It is estimated that 8–12% of patients admitted to a hospital in the European Union suffer from adverse effects while receiving healthcare, such as healthcare-associated infections, errors in diagnosis, and medication-related and surgical errors.[125]

Issues of patient safety do have a cross-border dimension, both for cross-border care and because healthcare-associated infections are one of the key potential threats to the safety of patients that can potentially cross borders with a patient. The EU's action is broader, although aiming to support improvements in best practice more generally, given the scope for mutual learning in this area, and best practices were distilled down into a Council Recommendation on Patient Safety, adopted in 2009.[126] While a variety of projects can and have been funded from the health and research programmes on the issue of patient safety, it is possible that the most impact will come from improved, transparent and comparable data if the projects are able to deliver. This may also be supported by the Directive on the Application of Patients' Rights in Cross-Border Healthcare, which obliges Member States to ensure transparency about quality and safety standards.

The Commission published a first report in 2012, which demonstrated progress in the development of national policies on patient safety and identified areas requiring further action, including the education and training of healthcare

125 European Commission (2017). *Patient Safety*. European Commission DG Research and Innovation. 7 April 2017.

126 Council of the European Union (2009). Council recommendation on patient safety, including the prevention and control of healthcare-associated infections. *Official Journal*, C 151:1.

workers in patient safety.[127] In a second report published in 2014,[128] the Commission reported that although the 2009 recommendation had raised awareness at the political level and triggered changes, it had not necessarily promoted a patient safety culture at the healthcare setting level. Patient safety recommendations remain based on the 2009 documents.

4.6.4 Pharmacy

Pharmacies and pharmacists receive much less attention in European policy debates than pharmaceuticals, but it is worth noting the complexity and importance of the field (independent of the issues of drug pricing and parallel trade which we do not cover[129]). "Pharmacy" means many different things in different countries, and there are often strict rules regarding pharmacies' locations, hours, ownership and staffing. There has been a long series of challenges to these regulations as contraventions of the freedom to provide services, e.g. from firms that wanted to sell online prescriptions across the EU. The Court of Justice, so often open to that kind of deregulatory challenge to apparently discriminatory national policies, has been much less open to them in the case of pharmacy.[130]

Pharmacists were involved in containment and mitigation efforts during the COVID-19 crisis. In most European countries their role was legally expanded in the face of the pandemic. Pharmacists were temporarily allowed to prepare hand and surface disinfectants if they were experiencing shortages (for instance, in Czechia, Finland, France, Germany, Poland), renew chronic treatment prescriptions (France), set up remote consultations with patients to ensure continuity of pharmaceutical care (the Netherlands), ensure medicines home delivery to vulnerable patients (Croatia, Italy, Portugal, Spain), prescribe, sell or provide controlled substances in limited circumstances or transfer prescriptions for controlled substances (United Kingdom), help victims of domestic violence

127 European Commission (2012). *Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections* (COM(2012)658 final).

128 European Commission (2014). *Report from the Commission to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare-associated infections*. Brussels, 19 June 2014.

129 For a starting point in the public health politics of drug pricing, see Hancher L (2010). The EU pharmaceuticals market: parameters and pathways, in Mossialos E et al. (eds) *Health Systems Governance in Europe*. Cambridge: Cambridge University Press, pp. 635–82. Jarman H, McKee M & Hervey TK (2018). Health, transatlantic trade, and President Trump's populism: what American Patients First has to do with Brexit and the NHS. *The Lancet*, 392:447–50. For a valuable political analysis that has not dated much, see Permanand G (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester: Manchester University Press; and Permanand G & Mossialos E (2005). Constitutional asymmetry and pharmaceutical policy-making in the European Union. *Journal of European Public Policy*, 12(4):687–709.

130 For a relatively critical but thorough and lucid analysis of the pharmacy cases to 2011, see Hancher L & Sauter W (2012). *EU competition and internal market law in the health care sector*. Oxford: Oxford University Press.

(France, Netherlands), and, to a lesser extent, administer the COVID-19 vaccine (France, Ireland, Switzerland, United Kingdom).[131] Court cases brought against pharmacy regulations had often been based on the claim that their regulatory structure was protective and anticompetitive, and pharmacy policy was defended on the basis that they were an important part of local healthcare infrastructure. The COVID-19 experience may have added important new evidence in this debate.

The EU's role in medicines shortages and their prevention is outlined in Box 4.8.

4.7 Conclusion

The EU shapes every facet of healthcare systems in Member States, through regulations on healthcare financing, resources such as staff and pharmaceuticals, and directives on patients and their access to care. Its priorities, shaped by its legal and regulatory nature, have been somewhat partial and limited some of its options: ensuring cross-border patient mobility under internal market law on the freedom to provide services would not be an ideal starting place for making healthcare policy. It was nevertheless the initial point for much of what now makes up EU health law. Likewise, it can affect access, but only within tight limits determined by the cross-border patient mobility directive and within the larger constraints of a Union in which poorer Member States cannot possibly pay for all their citizens to receive treatment in richer ones at the richer countries' prices (see Sections 1.2 and 1.3).

The internal market (along with social security coordination) has been, over time, the most demonstrably important face of the EU for healthcare policy. It underpins the wide variety of important policies we have discussed in this chapter. But to dismiss the EU as a simple market-making machine is a mistake. Rather, we note the wide variety of policies that have important health dimensions and are grounded in internal market law. They include a number of policies with potential value for health systems, such as HTA and workforce, as well as policies which help citizens, such as social security mobility, and ones whose positive contribution is largely unclear, such as the European Court rulings on patient mobility or the application of state aid law. If we widen the perspective still further, we note that many broader policies affecting health were made as

131 Merks P et al. (2021). The legal extension of the role of pharmacists in light of the COVID-19 global pandemic. *Research in Social and Administrative Pharmacy*, 17(1):1807–12. Paudyal V et al. (2021). Pharmacists' involvement in COVID-19 vaccination across Europe: a situational analysis of current practice and policy. *International Journal of Clinical Pharmacy*, 43:1139–1148. doi:10.1007/s11096-021-01301-7.

Box 4.8 *Medicine shortages and prevention: the EU's role*

Medicines shortages have become a critical issue in the EU and globally, a concern that was exacerbated by the COVID-19 pandemic. The root causes of shortages are complex. They are caused by demand (e.g. unexpected surges of disease or inadequate forecasting) and supply (e.g. manufacturing challenges such as limited suppliers of raw and intermediate materials, who are concentrated in a few countries, pricing and procurement policies, and parallel trade).

Addressing medicines shortages has been an EU priority and was emphasised in Commissioner-designate Várhelyi's mission letter.

For example, the Falsified Medicines Directive (Directive 2011/62/EU) introduced harmonized measures across the EU to fight medicine falsifications, ensuring their safety and strict control over their trade.[a] Additionally, the 1988 Transparency Directive (89/105/EEC) ensured that decisions regarding the pricing and reimbursement of medicines were transparent, timely and based on verifiable criteria. Under Directive 2001/83/EC on the Community code relating to medicinal products for human use, companies have a legal obligation to "ensure appropriate and continued supplies" to meet the needs of patients in EU Member States and notify supply interruptions to competent authorities.

Directive 2004/27/EC amended Directive 2001/83/EC to strengthen pharmacovigilance and improve the regulation of medicinal products in the EU. Further pharmacovigilance legislation (Directive 2010/84/EU and Regulation EU No 1235/2010) strengthens the system for monitoring the safety of medicines after they have been approved for use. This legislation enhances the collection, assessment and management of information on the safety of medicines in the EU, and it establishes the Pharmacovigilance Risk Assessment Committee (PRAC) within the EMA.

Additional updates have been made over the years, such as adjustments to the rules on marketing authorizations, the introduction of the Falsified Medicines Directive mentioned above, and other measures to ensure the safety, efficacy and availability of medicinal products within the EU.

Trade policies, such as mutual recognition agreements (MRAs), ensure that pharmaceuticals produced outside the European Union meet EU quality standards, eliminating the need for additional testing and inspections. Joint procurement, for instance under the Joint Procurement Agreement (JPA), can pool demand across EU Member States and negotiate better terms with pharmaceutical suppliers, including on availability. The EU works with WHO to address medicine shortages on a global scale and engages in bilateral agreements with non-EU countries to ensure a steady supply of critical medicines and foster international cooperation.

Finally, research and innovation aiming to improve pharmaceutical supply chains, develop new manufacturing technologies, and improve logistics in the EU are further supported through programmes such as Horizon Europe (2021–2027).

In the wake of the COVID-19 pandemic, the EU has taken concrete steps to specifically address the

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increasingly crucial issue of shortages, not least through its commitment to a European Health Union.[b]

One of the four pillars of the Pharmaceutical Strategy for Europe (2020) is "enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, [towards] addressing medicines shortages" and includes proposed actions to guarantee the availability of medicines and reduce reliance on non-EU countries for raw materials and active pharmaceutical ingredients.

Under the European Health Union, the regulation on EMA's reinforced role (Regulation 2022/123) introduced the Medicine Shortages Steering Group (MSSG) at the EMA. Its tasks include, inter alia, developing and publishing a list of critical medicines, monitoring the supply and demand of critical medicines to identify (potential) shortages, providing recommendations and coordinating activities to prevent or mitigate shortages, and providing recommendations on relevant actions to be taken at EU level. The first version of the EU list of critical medicines was published by the EMA in December 2023, with over 200 active substances for which continuity of supply is a priority. The Medicine Shortages Single Point of Contact (SPOC) Working Party, also at the EMA, is responsible for monitoring and reporting events that could affect the supply of medicines in the EU.[c]

The Commission's proposal for revising the EU's pharmaceutical legislation, presented in April 2023, includes measures to strengthen the security of supply of the most critical medicinal products, including mandatory shortage prevention and mitigation plans for all medicines from manufacturers, and the expansion of the remits of the MSSG and SPOC beyond crisis times.[d]

First mentioned in the Commission's Communication on addressing medicines shortages in the EU and launched in April 2024,[e] the Critical Medicines Alliance (CMA), is a consultative mechanism hosted by HERA. It brings together stakeholders from EU Member States, key industries, civil society and the scientific community to identify priorities for action and propose solutions to strengthen the supply of critical medicines in the EU, with a view to addressing medicines shortages. The CMA's work is meant to also feed into a possible legislative initiative for an EU Critical Medicines Act in the future. The communication also introduced the Voluntary Solidarity Mechanism for medicines, which allows Member States to report their needs for medicines in critical shortage to other Member States, so that they can indicate potential available stock that could be redistributed.

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a European Parliament and Council (2011). Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011. *Official Journal* (accessed 17 June 2024).

b European Commission (2024). *The European Health Union: acting together for people's health*. Brussels (accessed 17 June 2024).

c European Medicines Agency (n.d.). Medicine Shortages Single Point of Contact (SPOC) Working Party. Available at: https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party (accessed 18 July 2024).

d European Commission (2024). *EU Pharmaceutical Reform: Addressing shortages of medicines and ensure security of supply*. Available at: https://health.ec.europa.eu/latest-updates/factsheet-addressing-shortages-medicines-and-ensuring-security-supply-2024-03-11_en (accessed 18 July 2024).

e European Commission (2023). *Addressing medicine shortages in the EU*. Brussels. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190 (accessed 18 July 2024).

part of the single market for a long time, since setting regulatory floors often involves raising regulatory standards.

For better or for worse, the regulation of the single internal market is at the core of EU powers. That means that internal market principles – freedom of movement and non-discrimination – are powerful bases for action that courts will support. It means that much of the EU's positive effect on health is through regulations grounded in the internal market. The question for health is: how do we ensure that the regulations governing the internal market not only align with but actively support and advance valuable health policies and objectives?

Chapter 5

Social, digital and green transitions

5.1 Transitions: social, digital and green

The EU's 2030 agenda, which is primarily focused on the SDGs (see Annex), has three axes of overall ambition: the green transition (to a carbon-neutral economy), the digital transition and the social transition.[1] The green and digital transitions are frequently linked, often explicitly by the Commission: policy documents about the one will take note of the other, and in some cases, such as the Commission Communication on implementing the European Pillar of Social Rights (EPSR, see Annex and Section 4.2), they are linked as the context and policy challenge.[2] As a Joint Research Centre report put it, these agendas amount to a European Union that "aims to be sustainable, fair and competitive".[3]

5.1.1 Social transition

The social transition is at its core the implementation of the EPSR,[4] notably in the 2021 Porto Summit. The focus of the social transition, as affirmed in Porto, is on employment, with three goals for 2030: at least 78% of people aged 20 to 64 should be in employment; at least 60% of all adults should participate in training every year, and the number of people at risk of poverty or social exclusion should be reduced by at least 15 million, including at least 5 million

1 European Commission (2023). Sustainable Europe: 30-01 Report. European Commission. Available at: https://commission.europa.eu/document/download/3dab8f75-8c9d-4cf2-b215-d9098e69b654_en?filename=rp_sustainable_europe_30-01_en_web.pdf (accessed 11 August 2024).

2 European Commission (2020). Commission notice — Guidance on the implementation of the rules on market surveillance and compliance of products. European Commission. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:e8c76c67-37a0-11ea-ba6e-01aa75ed71a1.0003.02/DOC_1&format=PDF (accessed 11 August 2024).

3 González, L., De Groeve, T., Poljanšek, K., Corban, C., Tereanu, A., Jansen, C., et al. (2022). European overview of risks from climate change: JRC PESETA V final report. Publications Office of the European Union. https://publications.jrc.ec.europa.eu/repository/handle/JRC129319

4 Council of the European Union (2023). Draft Council conclusions on strengthening preparedness and response planning to safeguard critical infrastructure. Council of the European Union. https://data.consilium.europa.eu/doc/document/ST-15732-2023-INIT/en/pdf

children.[5] Member States are to present plans based on agreed indicators. Students of the EU social agenda since at least the Maastricht Treaty will recognize the characteristic model of EU social policy in which data, benchmarking and aspiration are used as key mechanisms to develop a policy that the EU budget, regulatory character and legal framework do not easily fit. The social transition involves a number of workstreams, notably the European Pillar of Social Rights Action Plan,[6] which, like the EPSR itself (see Annex) goes beyond the particular priorities of the Porto goals.

One of the core objectives of this transition is to ensure that a significant portion of the European population is engaged in employment or training each year, thereby promoting active participation in the economy. Additionally, the social transition aims to provide all workers with fair wages that offer decent standards of living. To support this transition, Member States are undertaking comprehensive reforms of their social protection systems. These reforms are designed to make social safety nets more adaptable and responsive to the rapidly changing economic, technological and environmental landscape. This includes modernizing unemployment benefits, pensions and healthcare systems to better meet the needs of a mobile and diverse workforce, as well as to protect Europeans from new risks arising from economic, technological and environmental changes.

The status of health in the social transition is ambiguous. On the one hand, the social transition in health is threaded through a variety of different social transition agendas, notably the governance of healthcare systems (discussed in Section 4.2) and the impact of the social transition on determinants of health (discussed in Section 3.2). Health in the workplace is specifically included as part of the social transition through the EU's work on occupational safety and health (discussed in Section 3.2). More broadly, health systems are in themselves powerful economic actors, and healthcare policy decisions about matters such as employment conditions affect labour markets and the broader economy in ways that can be more or less positive.[7] On the other hand, overall health objectives are not explicitly part of the social transition.

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5 Council of the European Union (2021). The Porto Declaration. Council of the European Union. https://www.consilium.europa.eu/en/press/press-releases/2021/05/08/the-porto-declaration/

6 European Commission (n.d.). European Pillar of Social Rights. Publications Office of the European Union. Available at: https://op.europa.eu/webpub/empl/european-pillar-of-social-rights/en/ (accessed 11 August 2024).

7 Greer, S. L., Falkenbach, M., Siciliani, L., McKee, M., Wismar, M., & Figueras, J. (2022). From health in all policies to health for all policies. *The Lancet Public Health*, 7(8), e718-e720. Greer, S. L., Falkenbach, M., Figueras, J., & Wismar, M. (2024). *Health for All Policies*. Cambridge University Press.

5.1.2 Digital transition

The digital transition is both an industrial policy challenge, since digital industries and technologies are crucial to sustainable growth, and a regulatory challenge, since technological change raises serious issues such as privacy. The EU has a long track record of policy to support high-technology industries and nearly as long a record of efforts to regulate the use of data, as well as other potentially related technologies such as pharmaceuticals and medical devices, and medical research. There are often tensions within the digital transition agenda, mostly stemming from the inherent, almost structural conflict between the industrial policy goal of thriving high-tech industries and the regulatory goals of safe products and personal data.

This underlying tension between industrial policy goals and public regulatory goals very much shapes the digital transition in health. Each here combines a technology or policy that has the potential to attain industrial policy goals of lucrative new products for health but also could threaten values such as data protection or safety regulation. Pooling health data across borders, for example, could enable and stimulate valuable research, but raises issues of consent and privacy, while regulation of artificial intelligence faces the challenge of identifying and managing threats without trying to block a rapidly developing new industry with potential to bring significant improvements for health. Compared to other major economies, the EU puts more effort into balancing these issues, as seen in the European Declaration on Digital Rights and Principles for the Digital Decade, signed by the Presidents of the Commission, Parliament and Council in January 2022,[8] which explicitly balances values such as equity, economic growth and privacy.

When she was a candidate for the Commission Presidency in 2019, Ursula von der Leyen stated that a priority would be a "Europe fit for the digital age", meaning one that is "grasping the opportunities from the digital age within safe and ethical boundaries".[9] These priorities became the priorities of her Commission and developed in the context of a strategy that addresses the linked issues of data, artificial intelligence (AI), industrial policy and rights (including privacy), and security. It tries to balance the different demands, as in the linking of opportunities with safe and ethical boundaries. This approach differs from, for example, the United Kingdom, which is much more laissez-faire with regards to AI but largely still adheres to EU privacy law, or the United States, which generally eschews

8 European Commission (2022). Declaration on European digital rights and principles. European Commission. https://digital-strategy.ec.europa.eu/en/library/declaration-european-digital-rights-and-principles#Declaration

9 European Commission (2019). Political guidelines for the next European Commission 2019–2024. European Commission. https://commission.europa.eu/document/download/063d44e9-04ed-4033-acf9-639ecb187e87_en?filename=political-guidelines-next-commission_en.pdf

regulation with a few exceptions such as certain kinds of personal health data, let alone other digital powers such as China.

As with the other main agendas, the result is a mixture of legislative changes, targets and budgets. Data and AI strategies, discussed below, lay out ways to regulate and use the technologies, while the 2030 Digital Decade agenda includes specific targets such as a larger and more skilled IT workforce, digital business, secure infrastructure and 100% digitalized government services by 2030.[10] As with other EU agendas, the Commission monitors progress and reports on it in an annual Cooperation Cycle since while the EU can contribute to cross-border projects, infrastructure standards and investment at the margins, it has neither the power nor the money to take on the heavy lifting for these changes within the Member States, such as training workers or digitizing a country's tax authority.

5.1.3 Green transition

The European Green Deal is the policy approach supporting a carbon-neutral and environmentally sustainable EU by 2050. The agenda was laid out in a Commission communication[11] on 11 December 2019 that was promptly echoed and supported by Council conclusions on 12 December 2019.[12] As with some of the most ambitious EU policy agendas of the past, it combines an overall agenda with a commitment to review and amend existing legislation as well as legislate in diverse new areas. The 2021 European Climate Law entrenches the 2050 goal in legislation.[13]

The green transition's goals are to cut emissions, making the EU carbon-neutral by 2050, and to decouple economic growth from increased resource consumption while preserving equity. It comes with extensive funding that is intended to help ease the shift from a fossil fuel economy to a more innovative and carbon-neutral one. The two largest funding instruments are the Just Transition Fund (€20 billion for 2021–2027) to support local economies most negatively affected,

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10 Council of the European Union (2022). Council Decision (EU) 2022/2481 of 12 December 2022 on the signing of the Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, in view of its accession by the European Union. *Official Journal of the European Union*. https://eur-lex.europa.eu/eli/dec/2022/2481/oj

11 European Commission (2019). Communication on the European Green Deal. European Commission. Available at: https://commission.europa.eu/publications/communication-european-green-deal_en (accessed 11 August 2024).

12 Council of the European Union (2019). European Council conclusions, 12 December 2019. Council of the European Union. Available at: https://www.consilium.europa.eu/en/press/press-releases/2019/12/12/european-council-conclusions-12-december-2019/ (accessed 11 August 2024).

13 European Parliament & Council of the European Union (2021). Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ("European Climate Law"). *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R1119

and the Social Climate Fund (€86.7 billion for 2026–2032),[14] which will be financed by proceeds from sales in the expanded European Emissions Trading System (ETS2)[15] and is intended to help Member States aid individuals and households who personally might suffer from higher energy prices. These are large sums of money by EU standards but, as with most EU budget allocations, Member States and their societies will have to do much of the work to make the investments and derive their benefits.

The work to implement the Green Deal is wide-ranging, extending from energy-efficient building standards, to regulation of specific pollutants, to extension of a European carbon market scheme. They will affect the health sector in often intricate and unexpected ways. For example, regulation of specific materials such as fluorinated greenhouse gases can require that specific materials used in healthcare be changed.[16]

Another example of recent legislative progress is the adoption of the Energy Performance Building Directive (EU)2024/1275 on 24 April 2024. This directive introduces a series of measures designed to enhance the efficiency of buildings across the EU with the ultimate goal of achieving a zero-emission building stock by 2050.[17] This directive may have several indirect but significant effects on the health sector. First, the directive mandates that all new buildings must meet zero-emission standards by 2030, with public buildings, including hospitals and healthcare facilities, required to comply by 2028. This shift towards energy-efficient construction and renovation is expected to result in improved indoor air quality, which can foster healthier environments for both patients and healthcare professionals. Additionally, the focus on energy efficiency is likely to lead to a reduction in operational costs for healthcare facilities. Lower energy bills mean that financial resources can be reallocated to other critical areas, such as patient care, medical research, and the acquisition of advanced medical technologies. Finally, this directive is expected to raise awareness and enhance education among healthcare professionals about the link between building performance, energy efficiency and health outcomes.

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14 European Commission (n.d.). Social Climate Fund. European Commission. Available at: https://climate.ec.europa.eu/eu-action/eu-emissions-trading-system-eu-ets/social-climate-fund_en (accessed 11 August 2024).

15 European Commission (n.d.). ETS2: Buildings, road transport and additional sectors. European Commission. Available at: https://climate.ec.europa.eu/eu-action/eu-emissions-trading-system-eu-ets/ets2-buildings-road-transport-and-additional-sectors_en (accessed 11 August 2024).

16 European Parliament & Council of the European Union (2024). Regulation (EU) 2024/573 of the European Parliament and of the Council of 22 March 2024 on [specific details]. *Official Journal of the European Union*. https://eur-lex.europa.eu/eli/reg/2024/573/oj

17 European Union (2024). Directive (EU) 2024/1275 of the European Parliament and of the Council of 24 April 2024 on the energy performance of buildings (recast). *Official Journal of the European Union*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401275

Consensus on the Green Deal has eroded in recent years, in particular as the major election year of 2024 approached. The Russian Federation's invasion of Ukraine, in particular, both made a case for renewables (which do not depend on the politics of countries outside the EU) and created a shock that increased resistance to regulations on energy sources such as coal. Intense conflict erupted in the run up to 2024 around a number of contentious policies on topics from rural land use to automobile energy sources. Long-established interests in Member State governments, and European parliamentarians courting groups such as the automobile industry or farmers, still had substantial capacity and political incentive to publicly oppose components of the green agenda, and it slowed down as a result. Reflecting these pressures, Commission President von der Leyen's State of the Union address in 2023 framed the new era as one of implementation rather than legislation and emphasized that "one thing will never change: we will keep supporting European industry throughout this transition".[18]

5.1.4 What do the social, digital and green transitions mean for health?

These three broad agendas all have different implications for health and health systems. The rest of this chapter discusses the impact of the digital and green transitions on health and health policy. This is because the social transition's principal goals are focused on employment, where the contribution of health is often more indirect, and because we discuss its broader goals from the EPSR in Chapters 3 (determinants of health) and 4 (governance).

The digital transition brings together a wide variety of issues in a form that will be familiar to the health sector. On one hand, health research, drugs and devices development, and treatment might all benefit substantially from the development of new data sources and analyses as well as artificial intelligence. On the other hand, the commercial and research use of health-related intimate private data is controversial, especially in the EU, and artificial intelligence in healthcare creates a variety of opportunities and threats. The EU's commitment both to further digitalization and to a relatively strong regulatory framework for data and AI give it a distinct set of health policy challenges and policies.

The Green Deal involves health in two ways. With regards to overall health, there is the impact of healthcare systems themselves on the environment (and therefore health). It is reasonable to critique schools or businesses for needlessly carbon-intensive activities, but it is also reasonable to critique the healthcare

18 European Commission (2023). 2023 *State of the Union Address by President von der Leyen*. European Commission. Available at: https://ec.europa.eu/commission/presscorner/detail/en/speech_23_4426 (accessed 11 August 2024).

sector itself for choices in infrastructure, energy sources, materials, supply chain and training that are incompatible with sustainability.

A second dimension of health and the green transition is through One Health, the name for the broad intellectual and policy agenda that focuses on the linkages between human health, animal heath and determinants of both that are found in food systems and the environment. The EU's power in food safety as well as broader agricultural and environmental policy make it an important player in the implementation of One Health policies within the internal market and globally. Commissioner-designate Várhelyi's mission letter explicitly called upon him to advance One Health in his DG's work.

5.2 The digital transition and health[19]

Digital health is part of the larger digital agenda of the EU, discussed above. Digital health specifically encompasses tools and services that use information and communication technologies (ICTs) to help prevent, diagnose, treat, monitor and manage health-related issues.[20]

While the Treaty has a specific article for data protection under Article 16 TFEU, it does not have specific provisions on ICTs.[21] However, digitalization in health encompasses many policy areas where the EU can act, based on the EU's legal power to ensure the functioning of the European internal market in Article 114 TFEU, such as policies that touch on industry, competition and trade. While the EU has had a digital agenda since the Lisbon strategy of 2010 and important achievements were reached in the period between 2010 and 2020, the COVID-19 pandemic pushed the momentum for further steps regarding digitalization across the region, prompting a range of actions, from regulation to investments and the stimulation of research.

Europeans' personal and medical information is protected under primary Union law in the fundamental rights framework, through the legal interplay between the Council of Europe's European Court of Human Rights (ECtHR) case law regarding the European Convention on Human Rights (ECHR) on the protection of privacy in the EU, and the Charter on Fundamental Rights of

19 James Hazel co-authored this section.

20 European Commission. *eHealth : Digital health and care*. Available at: https://health.ec.europa.eu/ehealth-digital-health-and-care/overview_en (accessed 20 June 2024).

21 European Commission. *Fact sheet for the European Union: Digital Agenda for Europe*. Available at: https://www.europarl.europa.eu/factsheets/en/sheet/64/digital-agenda-for-europe (accessed 20 June 2024).

the EU (CFREU).[22] Health data and medical secrecy in the aftermath of World War II have progressively become protected as a way of ensuring trust in the medical profession and health systems more generally in EU Member States. This is mirrored in European fundamental rights developments. Medical data are protected under Article 8 ECHR as part of the protection of private life, and the ECtHR has included health data and medical data as types of data that need strong protection.[23] Article 7 CFREU on privacy and Article 8 CFREU on the protection of personal data mirror the legal protections that were developed in the context of ECtHR case law on health data.

In the field of health in the Member States generally, the protection of the right to privacy and data protection has the function of ensuring trust so that patients can be truthful about their medical condition to their physician, which can avoid a wrong medical diagnosis, and they can believe their reputation and dignity is safeguarded, to prevent them from forgoing care altogether. Hence the starting point for regulating health data in the EU lies in first protecting individuals' interests, including their dignity, through protecting their privacy and data. At the same time, health information has a long history of being shared by patients for the purposes of medical research or the protection of public health.[24] In the EU policy landscape, health data are increasingly part of a larger digital economy agenda, as outlined below.

5.2.1 The EU´s overall digital agenda

The EU´s first digital agenda for Europe (2010–2020) focused on promoting digitalization by fostering digital skills, high-performance computing, the digitalization of European industry, the development of artificial intelligence, and the modernization of public services. To achieve the strategic direction set out in the Digital Single Market Strategy,[25] milestone regulatory acts were passed, including among others consumer and data protection measures (General Data Protection Regulation [GDPR], Regulation 2016/679; establishment of the BEREC agency, Regulation 2018/1971), data portability (Regulation 2017/1128) and cybersecurity (Regulation 2019/1024). The first von der Leyen Commission (2019–2024) had "a Europe fit for the digital age" as one of its six

22 de Ruijter A (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. Oxford University Press. Ch 3 (regarding the application of fundamental rights on EU health policy and law).

23 European Court of Human Rights. *L.H. v. Latvia*, Application No. 52019/07, 29 April 2014, §30.

24 Bak M et al. (2022). You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly. *Frontiers in Genetics 13*. Available at: <https://www.frontiersin.org/journals/genetics/articles/10.3389/fgene.2022.929453/full> (accessed 29 April 2024). Bak M et al. (2023). Towards Trust-Based Governance of Health Data Research. *Medicine, Health Care, and Philosophy*, 26:185–200.

25 European Commission (2015). *A Digital Single Market Strategy for Europe*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52015DC0192 (accessed 20 June 2024).

political priorities;[26] this is also reflected in the EU's second digital agenda for Europe (2020–2030), which emphasizes the EU's technological and geopolitical goals, and in one of its main vehicles, Europe's Digital Decade.

The Digital Decade has its foundations in the Commission's Communication on the 2030 Digital Compass (COM/2021/118). It is a comprehensive framework that includes the Digital Decade policy programme, targets, objectives, multi-country projects, and rights and principles.[27] The Digital Decade policy programme 2030 was established in December 2022 (Decision 2022/2481) and comprises an annual monitoring and cooperation mechanism that aims to help Member States reach desired targets by collecting and publishing key performance indicators.[28] Key target areas include skills, the digital transformation of businesses, secure and sustainable digital infrastructures, and the digitalization of public services. The latter include health-related targets, such as patients having 100% online access to their electronic health records. To help Member States achieve these targets, the Commission has committed to funding and helping implement multi-country projects in key areas, including common data infrastructures and services; blockchain; low-power processors; the pan-European deployment of 5G corridors; high-performance computing; secure quantum infrastructure and network of cybersecurity centres; digital public administration; digital innovation hubs; and high-tech partnerships for digital skills.

Multi-country projects under the Digital Decade are expected to pool investments from EU funding sources and the Member States themselves, as well as other public and private entities where appropriate. In general, the EU has a multitude of instruments that can provide funding for digitalization.[29] For example, funding provided under the Recovery and Resilience Facility in the wake of the COVID-19 pandemic had a quota of 20% to be dedicated to actions supporting digital transformation in Member States. But also other general instruments such as the Connecting Europe Facility, joint actions, partnerships, the cohesion funds, InvestEU and the Technical Support Instrument can also be used to boost digitalization. The Digital Europe Programme (introduced by Regulation

26 European Commission (2020). *Shaping Europe's Digital Future*. Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/shaping-europes-digital-future_en (accessed 20 June 2024).

27 European Commission (2023). *Europe's Digital Decade*. Available at: https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade#tab_3 (accessed 20 June 2024).

28 European Commission (2023). *Report on the state of the Digital Decade*. Available at: https://digital-strategy.ec.europa.eu/en/library/2023-report-state-digital-decade (accessed 20 June 2024).

29 Fahy N, Mauer N, Panteli D (2021). *European support for improving health and care systems*. Copenhagen: European Observatory on Health Systems and Policies. Policy Brief, No. 43. Available from: https://www.ncbi.nlm.nih.gov/books/NBK577002/

2021/694) is a dedicated initiative allocating €7.5 billion to digital technology projects in the areas falling under the Digital Decade priorities for 2021–2027.[30]

Key strategic areas for regulatory initiatives with relevance for health within the EU's second (current) digital agenda pertain to data, cross-border collaboration, artificial intelligence, strengthening the single market, e-governance, and cybersecurity:

- The EU data strategy published in 2020 introduced the notion of common EU data spaces in nine sectors, one of them health. The Regulation on the European Health Data Space (EHDS) was passed in 2024 and is discussed in more detail below; it makes the EHDS the first of the data spaces to receive regulatory legs. With the GDPR and General Data Protection Directive (GDPD) providing key foundations, the European Data Governance Act (Regulation 2022/868) sets out clear common standards for data availability and fostering trust, and the European Data Act (Regulation 2023/2854) ensures the protection of personal data, stipulating criteria for fair access and enshrining.

- The Interoperable Europe Act (Regulation 2024/903) sets out rules and obligations to facilitate cross-border data exchange and drive the digitalization of public services across the Union, a prerequisite for the implementation of the EHDS, among others.

- The Artificial Intelligence Act was adopted in March 2024, the first regulation of its kind worldwide, aiming to ensure responsible use of AI and the protection of citizens from misuse; it reflects the common principles outlined in the Commission's White Paper on Artificial Intelligence – A European approach to excellence and trust.[31] The Act establishes obligations for AI based on risk and potential impact (see also Section 5.1.2). Additional provisions around the use of AI (e.g. a directive on AI liability) are in preparation, and a dedicated AI office was established at the Commission's DG CONNECT in 2024, as part of the AI innovation package.[32]

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30 European Commission (2021). *"Digital Europe Programme"*. Available at: https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/digital-europe-programme_en (accessed 20 June 2024).

31 European Commission (2020). *On Artificial Intelligence - A European approach to excellence and trust*. Brussels. Available at: https://commission.europa.eu/document/download/d2ec4039-c5be-423a-81ef-b9e44e79825b_en?filename=commission-white-paper-artificial-intelligence-feb2020_en.pdf (accessed 20 June 2024).

32 European Commission (2024). European *AI Office*. Brussels. Available at: https://digital-strategy.ec.europa.eu/en/policies/ai-office (accessed 20 June 2024).

- The Digital Services Act (DSA, Regulation 2022/2065) and the Digital Markets Act (DMA, Regulation 2022/1925) were adopted in 2022 and came into effect in May 2023; they provide foundational rules for online platforms and data collection and sharing, respectively.

- In March 2024, an agreement was reached on a Cyber Solidarity Package, which includes a Cyber Solidarity Act, aiming among others to increase awareness and detection of significant cybersecurity threats and improve preparedness and protection of critical entities, such as hospitals.[33] The package also includes amendments to the Cybersecurity Act of 2019, which are yet to be implemented.

Given the dynamic nature of digitalization and its many implications for so many areas with EU competencies, it is to be expected that the issue will remain on the agenda of the next Commission.

5.2.2 The EU's focus on digital health

Within the general context of digitalization described above, the EU traditionally focused on e-health, defined as "the application of ICT across the whole range of functions that affect health".[34] Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare provided a legal basis for measures aiming to ensure continuity of care for EU citizens across borders. This entailed setting out provisions for Member States to exchange health data in a secure and interoperable way, for instance to enable the dispensation of medicines in a different Member State from the one where a prescription was issued (e-prescription/e-dispensation) or to provide patient summaries containing background information on important medical aspects that would be digitally accessible in the event of a medical (emergency) visit in another EU country. Both services were implemented through the eHealth Digital Service Infrastructure,[35] which connects e-health national services, allowing them to exchange health data. This infrastructure is funded by the Commission's Connecting Europe

33 Council of the EU (2024). *Cyber solidarity package: Council and Parliament strike deals to strengthen cyber security capacities in the EU*. Available at: https://www.consilium.europa.eu/en/press/press-releases/2024/03/06/cyber-solidarity-package-council-and-parliament-strike-deals-to-strengthen-cyber-security-capacities-in-the-eu/ (accessed 20 June 2024).

34 European Parliament and Council (2011). Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. *Official Journal*, L 88:45. BEUC (2011). *E-Health Action Plan 2012–2020 public consultation*. Brussels: BEUC – The European Consumer Organisation. Available at: http://www.beuc.org/publications/2011-00398-01-e.pdf (accessed 3 July 2014). Iakovidis I & Purcarea O (2008). E-Health in Europe: from vision to reality, in Blobel B, Pharow M & Nerich M (eds). *EHealth: combining health telematics, telemedicine, biomedical engineering and bioinformatics to the edge*. Amsterdam: IOS Press, pp. 163–8.

35 European Commission (2024). *Electronic cross-border health services*. https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en Accessed 20 June 2024.

Facility, with additional support for implementation in Member States coming from the EU4Health programme.[36] The cross-border directive also established a voluntary network connecting national authorities for e-health designated by Member States (the eHealth Network) in order to address practical issues (such as interoperability) and the use of e-health to enable use of medical information for public health and research[37].

Increasingly, the concept of e-health is being broadened to talk about "digital health", which expands the concept of e-health to incorporate the use of data and related systems, such as personal data (e.g. genomic data) or data to support better health and care (e.g. through the use of algorithms or artificial intelligence). In April 2018, the Commission published a communication on enabling the digital transformation of health and care in the digital single market, empowering citizens and building a healthier society.[38] The communication identified three pillars for action: secure data access and sharing (building on the provisions of the cross-border care directive and setting the foundation for developing a common electronic health record exchange format); connecting health data to support medical research and personalized medicine; and strengthening citizen empowerment while enabling innovative, person-centred care models. A range of actions followed across the pillars. For instance, based on inputs from the eHealth Network, the Commission adopted in 2019 a recommendation on the European electronic health record exchange format, which will feed into the implementation of the European Health Data Space.[39] Box 5.1 outlines the potential impact of EU digital health standards.

Health was the core area in which the value of digitalization was starkly demonstrated during the COVID-19 pandemic. This was not only reflected in the increased use of digital tools across a range of applications in EU Member States (from contact tracing, to information, to remote consultations and catalysing research),[40] but also prompted a range of activities at EU level. Perhaps most obviously, the EU's Digital COVID Certificate (EU DCC) trust framework allowed the issuance and verification of common and interoperable COVID-

36 Ibid.

37 European Commission (n.d.). *eHealth Network*. https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en Accessed June 20 2024.

38 European Commission (2018). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Empty on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*. Brussels. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018DC0233 Accessed 20 June 2024.

39 European Commission (2019). *Commission Recommendation on a European Electronic Health Record exchange format*. Brussels.

40 Fahy, N., Williams, G. A., Habicht, T., Köhler, K., Jormanainen, V., Satokangas, M., et al. (2021). *Use of digital health tools in Europe: Before, during and after COVID-19*. European Observatory on Health Systems and Policies.

Box 5.1 *The potential of EU standards for digital health*

Health systems are a sector with enormous potential for improving quality and productivity through application of information and communication technologies, and given the sheer size of health systems in Europe, such improvements would have a major impact on the European economy as a whole.[a] The textbook example of the potential for EU standards to generate a market that can drive innovation is the Global System for Mobile Communication (which provides standards for mobile phones) where, by establishing a single standard, the EU collectively developed a much more advanced mobile phone sector than the other major market at the time, the United States.[b] The equivalent for healthcare is the concept of interoperability, i.e. the idea that individual e-health systems may be different but can still exchange information in a way that can be understood by both (see above on the EU's Interoperable Europe Act).[c] This is straightforward in principle but extremely difficult to make work in practice, and depends on a range of additional elements such as reliable means of identifying individual patients and exchanging highly sensitive data securely.

a European Commission (2012). *EHealth Action Plan 2012–2020: innovative healthcare for the 21st century* (COM(2012)736). Luxembourg: Publications Office of the European Union.

b Pelkmans J (2001). The GSM standard: explaining a success story. *Journal of European Public Policy*, 8(3):432–53.

c See European Commission (2008). *Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (2008/594/EC). Official Journa*l, L 190:37.

19 certificates as proof of vaccination, test or recovery.[41] The Commission also established the European Federation Gateway Service, which facilitated interoperability to ensure national contact tracing apps could be linked and work across borders. The success of these initiatives was leveraged to support WHO towards building a global digital health certification network.[42] Furthermore, EU initiatives launched during the pandemic aimed to improve data access for public and population health (such as the Population Health Research Infrastructure, PHIRI) and support research into repurposing existing drugs towards COVID-19 therapeutics by leveraging supercomputing capabilities.[43] When it comes to financial support for Member States, next to the required quota for digitalization investment for national recovery and resilience plans (see above), the EU4Health programme explicitly includes digital health as a priority.

In the wake of the pandemic, the French Presidency of the Council proposed a set of European principles for ethics in digital health, which were approved by the eHealth Network. The principles cover four key areas: basing digital health

41 European Commission (n.d.). *eHealth and COVID-19*. Brussels.

42 World Health Organization (2023). *The European Commission and WHO launch landmark digital health initiative to strengthen global health security*. Geneva/Brussels.

43 Williams, GA., Fahy, N., Aissat, D., Lenormand, MC., Stuwe, L., Zablit-Schmidt, I., et al. (2022). COVID-19 and the Use of Digital Health Tools: Opportunity Amid Crisis that Could Transform Health Care Delivery. *Eurohealth*. 28:1.

on humanistic values; enabling individuals to manage their digital health and data; making digital health inclusive; and implementing eco-responsible digital health. In 2024, and in anticipation of the incoming European Parliament and the new European Commission, the European Observatory on Health Systems and Policies published the results of a public consultation on the EU's future health priorities (see Box 8.1).[44] While "digital solutions and AI" were consistently ranked towards the lowest end of the spectrum, three core themes for EU action emerged from the various consultation phases: digital inclusion (equity); digital solutions to improve service delivery, including prevention; and challenges to implementation, including safety, privacy and trust.[45]

5.2.3 Regulating digital health solutions

As discussed, health technologies need to go through approval processes of varying rigour to enter the EU market, and the EU sets out different provisions depending on the technology in question. Digital health solutions cover a broad range of applications, and may be accordingly governed by different rules.[46] A common characteristic of these technologies, however, is the use of software, be it physically (as part of a medical device) or as a standalone.[47] This spans applications ranging from surgical robots to glucose monitoring apps. The introduction of the MDR and the IVDR in 2021 tightened regulatory requirements for medical devices, including software as a medical device. In particular, the regulations set out the instances when software is considered a medical device (and must therefore obtain a CE mark) based on its intended use (namely: diagnosis, prevention monitoring, prognosis, treatment or alleviation of disease, injury or disability; the provision of information from in vitro examination of specimens derived from humans; or the investigation, replacement or modification of anatomical/physiological or pathological elements).

Software is considered a medical device both if it is needed to influence the performance of a device, or if it is an accessory, e.g. to collect information.[48] This means that, in practice, the vast majority of digital solutions employed in the

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44 Mauer, N., Scarpetti, G., and Wismar, M. (2024). *A Public Debate on Future Health Priorities of the European Union: Outcomes, Insights, and Ideas for Action*. European Observatory on Health Systems and Policies.

45 World Health Organization (2023). *The European Commission and WHO launch landmark digital health initiative to strengthen global health security*. Geneva/Brussels.

46 European Commission Directorate-General for Health and Food Safety, Lupiáñez-Villanueva F., Gunderson L., Vitiello S., et al. (2022). *Study on health data, digital health and artificial intelligence in healthcare*. Publications Office of the European Union. Available at: https://data.europa.eu/doi/10.2875/702007

47 Ludvigsen, K., Nagaraja, S., & Daly, A. (2022). When Is Software a Medical Device? Understanding and Determining the "Intention" and Requirements for Software as a Medical Device in European Union Law. *European Journal of Risk Regulation,* 13(1), 78–93. doi:10.1017/err.2021.45

48 European Commission (2017). Is your software a Medical Device? European Commission. Available at: https://ec.europa.eu/docsroom/documents/17921 (accessed 11 August 2024).

delivery are considered medical devices, albeit in different risk categories. As for other medical devices, bottlenecks were identified in the transition to the MDR/IVDR regime; however, software as a medical device faces additional challenges pertaining to the comparatively shorter lifecycles, the need for continuous updates for security reasons, and the evolving landscape of artificial intelligence. For example, this complicates possible study designs for the evaluation of such technologies in a manner that aligns with regulatory requirements.[49] The EHDS regulation introduced new rules for electronic health records (EHRs), because these largely fell between regulatory frameworks such as the MDR; it also imposed additional provisions for devices claiming interoperability with the harmonized components of the EHR system, and foresees the streamlining of processes when multiple conformity assessments are needed for different components of an application.[50]

While the EU does not have a remit in shaping how its Member States organize the delivery of health services, including reimbursement and pricing policies, there is a common need to understand how the broad range of digital health solutions can be evaluated to ensure that their benefits and risks are properly identified, and only those that improve the way the health system performs are used (and financed through public funds). Different countries in Europe are at different stages of incorporating the evaluation of digital health applications into their overall processes for determining how care is provided and paid for. For instance, Germany and France are considered pioneers in the evidence-based inclusion of patient-facing apps into general reimbursement.[51] In line with the overall goals of the health technology assessment regulation (HTAR; see Section 4.3.3), the EU has been supporting collaborative efforts to develop common frameworks for the evaluation of digital health technologies, including through Horizon Funding (e.g. the EDiHTA and ASSESS-DHT consortia, funded in 2023) or the European Taskforce for Harmonised Evaluation of Digital Medical Devices, supported by EIT Health following the initiative of the French Presidency of the Council.[52]

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49 Stoppacher, S., Müllner, P.S. (2023). Software as Medical Device in Europe. In: Baumgartner, C., Harer, J., Schröttner, J. (eds) *Medical Devices and In Vitro Diagnostics*. Reference Series in Biomedical Engineering. Springer, Cham. https://doi.org/10.1007/978-3-031-22091-3_2

50 European Commission (2024). *European Health Data Space*. Online at: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en Accessed 20 June 2024.

51 Mezei, F., Horváth, K., Pálfi, M., Lovas, K., Ádám, I., & Túri, G. (2023). International practices in health technology assessment and public financing of digital health technologies: recommendations for Hungary. *Frontiers in Public Health*, 11, 1197949. https://doi.org/10.3389/fpubh.2023.1197949. Lantzsch, H., Panteli, D., Martino, F., Stephani, V., Seißler, D., Püschel, C., et al. (2022). Benefit Assessment and Reimbursement of Digital Health Applications: Concepts for Setting Up a New System for Public Coverage. *Frontiers in Public Health*, 10, 832870. https://doi.org/10.3389/fpubh.2022.832870

52 EIT Health (2024, March 8). *European taskforce for harmonised evaluations of Digital Medical Devices (dmds)*. EIT Health. https://eithealth.eu/external-collaborations/european-taskforce-for-harmonised-evaluations-of-digital-medical-devices-dmds/

5.2.4 Digital innovation for research and precision health

Digitalization has been revolutionizing the way clinical research is conducted, from data collection and management, to clinical trial protocol and participant management modalities, to analytics. Leveraging blockchain technology[53] and artificial intelligence is expected to further optimize future research approaches,[54] and the EU provides the necessary regulatory frameworks across the relevant acts described earlier in this book (including the GDPR, the Data Act, the Data Management Act and the Clinical Trials Regulation).

In line with its strategic goals in the area of digitalization and digital health outlined above, the EU supports a range of initiatives that aim to foster innovation in health research and the personalization of prognostic, diagnostic and therapeutic care. Two examples are the European Virtual Human Twins initiative and the 1+ Million Genomes initiative, both in the context of advancing personalized care, which is a core priority for the EU.

Under the Virtual Human Twins (VHT) initiative, the Commission is investing in supercomputing capacities and artificial intelligence to facilitate collaborative VHT research and technology development. VHTs are digital representations of a human health or disease state, referring to different levels of human anatomy (e.g. cells, tissues, organs or organ systems). They are designed to mimic and predict the behaviour of their physical counterparts, with enormous potential for clinical trials for medicines and devices, medical training and surgical intervention planning. Box 5.2 highlights the research and development actions under the VHT initiative, funded via different instruments in the 2023–2024 cycle.

The EU's flagship 1+ Million Genomes (1+MG) initiative was launched in 2018 with the aim of facilitating secure access to genomic and related clinical data across Europe and enhancing research, personalizing healthcare and informing health policy decisions. Since 2018, 25 EU countries, as well as the United Kingdom and Norway, have signed a declaration committing to the development of a European data infrastructure for genomic data and working towards implementing national regulations that allow federated access to these data. The initiative's 2023–2027 roadmap envisions the initial operation of a technical infrastructure with research pilots for clinical cases, the generation of additional quality data, the creation of national coordination mechanisms, and the connection of this infrastructure

53 Hang, L., Chen, C., Zhang, L., & Yang, J. (2022). Blockchain for applications of clinical trials: Taxonomy, challenges, and future directions. *IET Communications*, 16(20), 2371-2393. https://doi.org/10.1049/cmu2.12488

54 Chopra, H., Annu, Shin, D. K., Munjal, K., Priyanka, Dhama, K., & Emran, T. B. (2023). Revolutionizing clinical trials: the role of AI in accelerating medical breakthroughs. *International Journal of Surgery* (London, England), 109(12), 4211–4220. https://doi.org/10.1097/JS9.0000000000000705

Box 5.2 *Research and deployment actions of the European Virtual Human Twin (VHT) initiative*

- The European Virtual Human Twin (EDITH) project (coordination and support action funded under the Digital Europe programme [DIGITAL]) and its roadmap to identify the necessary building blocks to evolve towards integrated VHTs;
- €80 million of research and innovation actions under Horizon Europe on "integrated, multi-scale computational models of patient patho-physiology for personalised disease management";
- A €24 million state-of-the-art digital platform for advanced virtual human twin models' integration and validation funded under the Digital Europe programme (DIGITAL);
- The deployment of a €5 million pan-European federated infrastructure for Intensive Care Units' (ICU) data and data intensive computational model-based tools for decision support and risk prevention, funded under DIGITAL;
- Additional €20 million funding under the Innovative Health Initiative (IHI) for actions on comprehensive stroke management with predictive computational models, integrated patient health data and improved visualization.[a]

a European Commission (n.d.). *European Virtual human twins initiative. Shaping Europe's digital future*. https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins

with the EHDS and other pertinent EU initiatives.[55] Linked to the initiative, the Genome of Europe project, starting in 2024, will build on whole genome sequencing to create a network of linked national genomic reference cohorts representative of the European population. This will bring together data from over 100 000 citizens, to be leveraged for medical research and innovation, personalized approaches in healthcare and disease prevention measures.

5.2.5 Protection of health data

The central instrument in secondary EU law for the protection of medical data is GDPR, which harmonizes national laws on data protection. The regulation applies to all personal data and is directly applicable to the national legal orders of the EU (Articles 1–3 GDPR). The regulation requires that personal data are processed in a lawful manner, which means that the data subject has given consent for the processing of their data, or that there is another reason stipulated by law that legitimates the processing of personal data (Articles 6 and 7 GDPR). In the case of personal data being processed the GDPR ensures a right to information and access, and the option to withdraw consent (Articles 12, 13, 15 and 7[3]

55 European Commission (n.d.). European "1+ million genomes" initiative. Shaping Europe's digital future. https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes

GDPR). These rights also infer specific duties for those processing the health data (Articles 24–43 GDPR).

Health data are considered "sensitive data" under Articles 4 and 9 of the GDPR. Article 4(15) GDPR defines health data as "data concerning health" which means "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status". In a recent case the Court of Justice of the EU determined that this definition includes the medical records containing information such as diagnoses, examination results, assessments by treating physicians, and any provided treatment or interventions.[56]

Article 9(1) GDPR prohibits the processing of data

> revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation ... .

There are many derogations from this general prohibition for health Article 9(1)(h)(i) provides legitimate reasons for data procession of sensitive personal data either related to public health threats, such as communicable diseases, or the management of public health systems and in cases of occupational health. When it comes to health, Article 9(4) of GDPR allows for Member States to adopt stricter national rules to ensure the protection of health data. Article 22 GDPR protects the right to not be subject to automated decision-making, which can be of special importance in the field of health, where there is increasing use of artificial intelligence, particularly also with regard to diagnosis and assessing different treatment options.[57]

5.2.6 EU Artificial Intelligence Act

On 21 May 2024, the Artificial Intelligence Act was formally adopted by the European Parliament.[58] As previously mentioned, the current trend in health AI applications involves processing personal data due to the wide definition of personal data under the GDPR. The EU AI Act acts like a product safety regulation, with the act aiming to ensure the safe technical development and

56 CJEU. Case C-307/22 (*FT v. DW*) of 26 October 2023 (DW requested medical records regarding received dental care and refused to pay a processing fee).

57 Van Kolfschooten H. (2022). EU Regulation of Artificial Intelligence: Challenges for Patients' Rights. *Common Market Law Review* 59 https://kluwerlawonline.com/journalarticle/Common+Market+Law+Review/59.1/COLA2022005> accessed 29 April 2024.

58 Artificial Intelligence Act (2021/0106 COD), at time of writing (July 2024) not yet published in the Official Journal.

use of AI systems. Unlike the GDPR, an instrument geared towards granting individuals agency regarding their data, the EU AI Act does not generally distinguish individual rights, with a few exceptions. In this regard, the GDPR complements the EU AI Act by addressing situations where AI systems process personal data and potentially conflict with individual rights.

The act regulates AI applications according to a risk-based approach. High-risk AI systems are those used as a safety component or a product covered by EU laws in Annex I to the directive, which includes medical device regulations.[59] The AI Act will be implemented in a staggered approach over a 36-month period. Six months after it enters into force, prohibitions on unacceptable risk AI will take effect, followed six months later by provisions on notifying authorities,[60] general purpose AI models,[61] governance,[62] and confidentiality and penalties.[63] After 24 months, the remainder of the AI Act will enter into effect, with the exception of obligations related to high-risk AI,[64] which will only take effect 36 months after the Act enters into force.

In some way, there is a conflict between the GDPR and AI. The latter often involves the collection of large quantities of data, especially during the training phase. Simultaneously, there is a significant overlap between many data protection principles and the principles and requirements set forth by the EU AI Act for the safe development and use of AI systems. The EU AI Act explicitly acknowledges the relationship between AI and data protection, stating that it does not affect the GDPR. In drafting the EU AI Act, the European Commission partly relied on Article 16 TFEU, which requires the EU to establish rules for protecting individuals concerning the processing of personal data.

The key to changes in the processing of medical data for health AI is the fragmented legal landscape of how Member States are handling health data at the national level.[65] In this regard, the European Health Data Space should make a significant contribution.

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59 European Parliament and Council (2017). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. *Official Journal* L 117, 5.5.2017, p. 1).

60 Section 4: Notifying Authorities and Notified Bodies. https://artificialintelligenceact.eu/section/3-4/

61 European Parliament (2024). Chapter V: General Purpose AI Models. *Artificial Intelligence Act, Corrigendum*. https://artificialintelligenceact.eu/chapter/5/

62 European Parliament (2024). Chapter VII: Governance. *Artificial Intelligence Act, Corrigendum*. https://artificialintelligenceact.eu/chapter/7/

63 European Parliament (2024). Article 78: Confidentiality. *Artificial Intelligence Act, Corrigendum*. https://artificialintelligenceact.eu/article/78/

64 European Parliament (2024). Article 6: Classification Rules for High-Risk AI Systems. *Artificial Intelligence Act, Corrigendum*. https://artificialintelligenceact.eu/article/6/.

65 European Commission (2021). Assessment of the EU Member States' rules on health data in the light of GDPR. https://health.ec.europa.eu/document/download/a7f11827-f4ca-4e4d-bd7a-c15c39664010_en?filename=ms_rules_health-data_en.pdf

5.2.7 European Health Data Space

The European Health Data Space (EHDS) is a new regulatory framework designed to facilitate the cross-border exchange of health information.[66] As of mid-2024, the regulation was in its final stages of adoption, after the European Parliament and the Council reached a decision on the text.[67] One of the key objectives of the EHDS is to make use of the data-rich environment that is offered by the healthcare sector. Therefore, facilitating the availability and reuse of health data for health-related research, policy-making and innovation (known as secondary use) is a key objective of the proposed regulation. Furthermore, the EHDS aims to "empower individuals to take control of their health data and facilitate the exchange of data for the delivery of healthcare across the EU".[68]

Among other things, the EHDS intends to create a standardized European format for electronic health records. For such harmonization of methods and systems to succeed across borders data systems in Member States need to be able to talk to each other. As this interoperability is not only a challenge across borders but also within countries, this requirement will be a difficult hurdle. Already in 2008, the EU-funded EPSOS project developed a concept for a cross-border interoperable infrastructure. Also the 2011 patients' rights in cross-border healthcare directive established both the eHealth Network, which has since developed standards for various applications, and the European Reference Networks, which can exchange data across borders in the area of rare diseases. In 2019, the Commission issued a Recommendation for a European Electronic Health Records Exchange Format (EEHRxF); building on this recommendation, different consortia, such as XpanDH and XtEHR, are currently working to facilitate implementation for the Member States and pave the way for the primary use of health data within the EHDS.

One of the more controversial topics within the discussion on the use of health data in the context of the EHDS was that of the secondary use of data. The primary use of data refers not only to the access of patients to their own health records but also, for instance, the data that are needed for insurance purposes. In this regard the EHDS allows Member States to completely opt out of the EHDS. For the secondary use of health data, the EHDS will provide researchers and innovators with access to data under specific conditions. Citizens retain the right to opt out of sharing their data for secondary use, which means an active

66 European Commission (2022). *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197. Accessed 20 June 2024.

67 Council of the European Union (2024). *European Health Data Space: Council and Parliament strike deal*. https://www.consilium.europa.eu/en/press/press-releases/2024/03/15/european-health-data-space-council-and-parliament-strike-provisional-deal/ (accessed 20 June 2024).

68 Ibid.

choice of European patients not to have their health data used for e.g. research purposes. The agreement introduces a harmonized opt-out approach, requiring Member States to implement "an accessible and easily understandable opt-out mechanism". However, the opt-out can be overridden if a public health body, EU institution, or office requests data for "scientific research for important public interest". The term "office" refers to specific EU entities with the authority to access health data under regulated conditions and for specific purposes, such as scientific research that serves an important public interest. A specific example of an office within the context of the EHDS is Eurostat, the EU's statistical office. Eurostat collects data from Member States and can potentially access health data under the EHDS framework for public health statistics and research purposes. Member States also retain the right to implement additional safeguards at the national level for specific categories of data, such as genomic data, wellness application data and biobanks/databases.

Overall, along with the MDR (see Section 4.3.2) the Data Governance Act (DGA), the Data Act,[69] the AI Act and the GDPR, the EHDS proposal will finalize the regulatory framework for health data usage in the EU. The complexities of this overlay in regulatory regimes will be of key importance to policy-makers, market actors and patients in the future of health and a new generation of health applications in the EU.

5.3 Green transition and One Health

The European Green Deal (EGD) is a large part of the agenda of the von der Leyen Commission[70] but draws on years of development and commitment in EU institutions.[71] Put forth in numerous public presentations including a 2019 communication,[72] it states that it

> resets the Commission's commitment to tackling climate and environmental-related challenges that is this generation's defining task. The atmosphere is warming and the climate is changing with each passing year. One million of the eight million species on the planet are at risk of being lost. Forests and oceans are being polluted and destroyed.

69 https://digital-strategy.ec.europa.eu/en/policies/data-act (Accessed 16 September 2024).

70 Kergueno, R. (2020). *100 days of Commission lobbying*. Transparency International EU. Retrieved from https://transparency.eu/100-days-lobbying

71 European Commission(2019). *Reflection Paper: Towards a Sustainable Europe by 2030*. https://commission.europa.eu/document/download/3dab8f75-8c9d-4cf2-b215-d9098e69b654_en?filename=rp_sustainable_europe_30-01_en_web.pdf (accessed 23 June 2024).

72 The European Green Deal, COM/2019/640 final.

In the next two paragraphs come a pair of statements that are no novelty in EU politics: "It is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use" – in other words, that it is a map for economic policy, albeit one with an explicitly green goal – and then that "it also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts. At the same time, this transition must be just and inclusive."[73]

The scale of the risks to health associated with climate change are so immense as to make a zero-carbon society and mitigation of damage that is already inevitable, key health policies. Equally, those interested in the specific sectors of healthcare and public health will find a great deal to interest them, e.g. "focus should also be put on renovating schools and hospitals, as the money saved through building efficiency will be money available to support education and public health".[74] The EU's decisions about what kinds of construction to support can have impressively large effects and so, subsidiarity notwithstanding, this kind of commitment could affect the funding options, decisions and effects of the health sector. It also affects policy in a variety of the areas in which the EU has a major impact on health, for example by shaping the Farm to Fork strategy which is intended to redirect agricultural and food safety policy towards more sustainable practices.

Key objectives of the European Green Deal include achieving carbon neutrality by 2050, promoting clean energy, transitioning to a circular economy model, safeguarding biodiversity, and ensuring an equitable transition to a green economy.[75] Specifically, this policy framework proposes reducing greenhouse emissions to net zero by 2050, primarily through energy production, transportation and agriculture.[76] The Green Deal also promotes the development and use of renewable energy sources such as wind, solar and hydroelectric power, while encouraging private and public stakeholders to invest in research and innovation for new technologies. In terms of circular economy, the policy encourages efficient resource use, waste reduction, product durability and sustainable consumption patterns. Additionally, the Green Deal outlines measures seeking to preserve and restore biodiversity, including the conservation of natural habitats, protection of endangered species and sustainable management of ecosystems. Finally, the framework aims to provide support for workers and communities affected by

73 All quotes from the first page of the European Green Deal, COM/2019/640 final.

74 The European Green Deal, COM/2019/640 final, 2.1.4.

75 Dupont, C., & Torney, D. (2021). European Union Climate Governance and the European Green Deal in Turbulent Times. *Politics and Governance*, 9(3S3), 312+. http://dx.doi.org.proxy.lib.umich.edu/10.17645/pag.v9i3.4896

76 Samper, J. A., Schockling, A., & Islar, M. (2021). Climate politics in green deals: Exposing the political frontiers of the European Green Deal. *Politics and Governance*, 9(2), 8–16.

the shift away from fossil fuels and traditional industries, ensuring that the transition to a green economy is fair and inclusive.

The European Green Deal brought together the traditionally separate policy areas of environmental protection and economic development.[77] The Commission defined the Green Deal as a growth strategy.[78] At its core, this policy framework aims to overhaul key consumption and production systems within the economy, focusing on five specific systems known to have a significant impact on the environment: energy, industry, buildings, mobility and food. However, despite its ambitious agenda, the Green Deal faces certain limitations and criticisms. One notable limitation revolves around its policy omissions. For instance, it has been faulted for sidelining issues such as the international trade of waste and the proliferation of plastic waste, which are critical aspects of environmental protection.[79] The Green Deal programme, while substantial in its aspirations, was criticized by some as too modest,[80] particularly in its ability to exert constraints on Member States, while critics on the other side saw it as a set of measures that could endanger European competitiveness.[81]

5.3.1 Health systems and the green transition

Climate conditions impact health, driving discussions around how health systems can adapt to climate change.[82] The 2023 *State of Health in the European Union* addresses health concerns arising from pollution and environmental harm.[83] At the same time, the contribution of healthcare itself to pollution and global warming is not always well understood. However, there is growing awareness of the impact of the healthcare sector on the environment. Studies have found, for example, that healthcare can contribute up to 5% of environmental impact globally, with the share surpassing 5% for some countries.[84] For some EU

77 Bloomfield, J., & Steward, F. (2020). The politics of the green new deal. *The Political Quarterly*, 91(4), 770–779.

78 Samper, J. A., Schockling, A., & Islar, M. (2021). Climate politics in green deals: Exposing the political frontiers of the European Green Deal. *Politics and Governance*, 9(2), 8–16.

79 Eckert, E., & Kovalevska, O. (2021). Sustainability in the European Union: Analyzing the discourse of the European green deal. *Journal of Risk and Financial Management*, 14(2), 80

80 Bloomfield, J., & Steward, F. (2020). The politics of the green new deal. *The Political Quarterly*, 91(4), 770–779.

81 See Orbán, V. Hungary's plan to make Europe competitive again. *Financial Times*, 1 July 2024.

82 Greer, S.L., Falkenbach, M., Siciliani, L., McKee, M., Wismar, M., Vissapragada, P., et al. (2023). *Making Health for All Policies*. European Observatory on Health Systems and Policies.

83 European Commission (2023). *State of Health in the EU: Synthesis Report 2023*. European Commission DG SANTE. Found here: https://health.ec.europa.eu/system/files/2023-12/state_2023_synthesis-report_en.pdf

84 Lenzen, M., Malik, A., Li, M., Fry, J., Weisz, H., Pichler, P.-P., et al. (2020). The environmental footprint of Health Care: A Global Assessment. *The Lancet Planetary Health*, 4(7). https://doi.org/10.1016/s2542-5196(20)30121-2

Member States, healthcare as a share of the Member State's carbon footprint can be as high as 8%.[85]

As discussed in ongoing research, healthcare burdens the environment through different pathways, including waste generation, pollutant emission and resource use (including energy and water).[86] Wasteful habits during the lifecycle of health products, from production to disposal, and the delivery of healthcare, such as during the transportation involved in healthcare supply chains, can exacerbate these effects.[87] Just like any other sector, the healthcare sector can create negative environmental externalities while focusing on efficiently performing its key functions. Given the absolute size of the healthcare sector, this makes it a challenge for carbon neutrality and a clean environment.

The EU has a number of policies, more or less closely related to the formal health competence, that can influence the carbon and pollution contributions of the healthcare sector. We can understand them in terms of the mechanisms framework presented in Chapter 2.

In terms of *regulation*, the EU has a wide variety of tools under its environmental and internal market competences that can be and are often used to restrict the emission of harmful chemicals, ranging from complete bans on some to carbon trading markets. The REACH directive, in particular, affects a wide range of chemicals used in healthcare and the production of items for healthcare. Changes under the European Green Deal, discussed earlier in this chapter, also apply to healthcare.

In terms of *resources*, EU funding outside the RRF (cohesion funds and the European Investment Bank, for example) is heavily focused on infrastructure. The EU budget might have neither the funds nor the political support to pay for the running costs of healthcare systems, but it can be used to make infrastructure investments that will shape the delivery of healthcare for decades. This infrastructure focus creates an opportunity to use EU funding to drive healthcare in a greener, more sustainable direction. There are a variety of ways to do this, but including carbon neutrality in investment decisions could be powerful. Carbon neutrality need not mean prestigious new buildings with green certifications; it could encourage re-use (new construction in general and new concrete in particular have a very heavy carbon impact), thoughtful siting

85 Pichler et al. (2019). International comparison of health care carbon footprints. *Environmental Research Letters*, 14(6):064004.

86 Sijm-Eeken M, Jaspers M, Peute L. (2023). Identifying Environmental Impact Factors for Sustainable Healthcare: A Scoping Review. *International Journal of Environmental Research and Public Health*. 2023 Sep 12;20(18):6747.

87 Janik-Karpinska E, Brancaleoni R, Niemcewicz M, Wojtas W, Foco M, Podogrocki M, Bijak M (2023). Healthcare Waste-A Serious Problem for Global Health. *Healthcare* (Basel); 11(2):242. doi: 10.3390/healthcare11020242. PMID: 36673610; PMCID: PMC9858835.

(central locations close to established neighbourhoods and public transport can be good for urbanism and equalities as well as sustainable re-use), and investment in systems that sterilize and re-use products instead of depending on wasteful single-use disposable medical equipment. Recent work from the European Observatory on Health Systems and Policies identified a range of EU instruments that can be used to support the greening of health facilities next to the RRF, the cohesion funds and the EIB, including InvestEU, the Just Transition Mechanism and the LIFE programme.[88] Next to infrastructure projects, instruments such as ERASMUS+ or the Technical Support Instrument can facilitate the development of the necessary skills and policies to implement the greening agenda.

In terms of *information*, the EU can facilitate lesson learning and a shared understanding of good practice. In part, established EU ways of working such as research funding and joint action can disseminate knowledge about how best to comply with regulations and access useful resources, as well as about best practice in creating more sustainable healthcare infrastructure and organizations. Comparative data on Member States' (and even regional governments') performance in sustainable healthcare is a potential stimulus to lesson learning and prioritizing sustainability. In short, EU action can provide policy-makers and managers with a path into the issue that is aligned with funding and governance of healthcare systems. What is more, funding under Horizon Europe has been earmarked to support collaborative research projects towards improving the environmental sustainability of European health systems.

Governance, finally, is an area with two relevant faces (as discussed in Section 4.2). On one hand, it can mean the governance of EU health policy itself. Just as much of the social transition already appears in documents about the governance of healthcare systems, the green transition could be incorporated into decision-making and policy analysis by the EU and its agencies, whether in investment decisions or in decisions about research expenditure or grants. On the other hand, it can also mean the impact of the EU on the governance of healthcare systems. If healthcare systems adapt, with EU-supported information, to European financial incentives and regulations, that could contribute to incorporating sustainability and carbon neutrality as stable priorities across the healthcare sector.

5.3.2 One Health and food systems

One Health is both a specific agenda, originally launched by the United Nations, and an epidemiologically unavoidable complex of issues that are becoming harder to avoid in the context of climate change and changing food systems worldwide. One Health, according to WHO, "is an integrated, unifying approach to balance

88 Mauer, N., Durvy, B., and Panteli, D. (2003). *EU resources for investing in and strengthening health systems Tailored options for Austria, Belgium and Slovenia*. European Observatory on Health Systems and Policies.

and optimize the health of people, animals and ecosystems. It uses the close, interdependent links among these fields to create new surveillance and disease control methods."[89] In other words, it addresses problems like zoonotic spillover, in which a disease jumps from animals to humans. This is an issue with which the EU has clear experience, notably in the BSE scandals and response of the 1990s (see Chapter 1), but also with more recent respiratory and other outbreaks. This experience is important, because it shows that One Health is not just a concern of poorer countries; European food systems, too, can create zoonotic spillover and novel threats to human and animal health (see, for example, Box 5.3 on antimicrobial resistance).

One Health and food systems are both contributors to climate change and an important part of resilience in the face of climate change. They are contributors, insofar as certain agricultural practices contribute substantially to climate change (e.g. in the production of some meats) and environmental degradation that indirectly contributes (e.g. the overuse of fertilisers that damages waterways). The vast edifice of EU food safety law was mostly built before One Health became a policy framework, but it can be understood as a contributor to a more resilient food system in the face of climate change[90]. That outlook obscures the scale, complexity and ambition of what the EU has done to construct an effective food safety regime and its contribution to public health. Food safety which, along with public health, is the core of DG SANTE's responsibilities, is a broad area of impressive regulatory complexity stretching from agriculture to restaurants, involving a variety of organizations at every level (from farm to fork in the language of the field). A 2019 EU fact sheet claimed that it involved 100 000–120 000 staff with specific inspection competencies regarding 25 million operators along the agrifood chain, a large regulatory apparatus and task.[91]

Food safety has been a major issue for the EU since the close integration of the food chain and food sector has led to scandals, of which the most politically consequential was BSE (see Chapter 1).[92] While there is constant pressure to reduce regulatory burdens on affected industries, the history of cross-border

89 World Health Organization (2023). *Fact Sheet: One Health*. https://www.who.int/news-room/fact-sheets/detail/one-health. Accessed 19 July 2024.

90 Grant W (2012). Agricultural Policy, Food Policy, and Communicable Disease Policy. *Journal of Health Politics, Policy and Law,* 37(6):1031–48. Lang IG (2017). Public health in European Union food law, in Hervey T, Young C & Bishop L (eds). *Research Handbook on EU Health Law and Policy*. Cheltenham: Edward Elgar Publishing, pp. 398–428.

91 Available at: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_infograph_from-farm-to-fork_en.pdf (accessed 23 February 2022).

92 Ansell C (2006). *What's the beef?: the contested governance of European food safety*. MIT Press. Ansell C & Gingrich J (2007). The United Kingdom's Response to the BSE Epidemic, in Gibbons D (ed.). *Communicable crises: Prevention, response, and recovery in the Global Arena*. Information Age Publishing, pp. 169–202. Caduff L & Bernauer T (2006). Managing risk and regulation in European food safety governance. *Review of Policy Research*, (1):153–68.

Box 5.3 *Antimicrobial resistance*

Antimicrobial resistance (AMR)has been shown to lead to increased mortality rates, disability rates and medical costs. It is driven by inappropriate antimicrobial use, as well as insufficient prevention and control across human, animal, plant and environmental health settings. Tackling AMR can be a combined effort to successfully implement AMR education, ongoing support (funding and infrastructure) for AMR research, and policies that address the well-known needs. Encouraging regulation and biosecurity, as well as continuing to support vaccination, are essential in preventing AMR issues.[a] The European Health Union, HERA and the Pharmaceutical Strategy all refer to the threat of AMR.

In 2017, the Commission published the One Health Action Plan against Antimicrobial Resistance (AMR). This set out an integrated approach to tackling the issue for both human health and animal health, drawing on the EU's powers to address both and the links between the use of antibiotics in animals and in humans. Nevertheless, high levels of certain types of resistant pathogens remain in the EU,[b] and in 2022 the Commission named AMR as one of the top three health threats. In 2023, the Council of the European Union released a recommendation to step up the EU's approach towards addressing AMR through WHO's One Health lens. This recommendation not only introduced targets to reduce antimicrobial use by 2030 both for human consumption and farm animals/aquaculture, but also pointed towards the substantial funding provided through EU4Health. The plan pointed to gaps in national responses, and began to set up minimum requirements including monitoring and surveillance of sources of potential AMR concerns, including antimicrobial medicinal products available to humans and animals.[c] The ongoing partnerships between international organizations like WHO and the EU, as well as the partnerships between the EU and the Member States will be vital to effectively addressing AMR concerns.

a Anderson, M., Panteli, D., Mossialos, E (2024). Strengthening the EU response to prevention and control of Antimicrobial Resistance (AMR). Copenhagen: WHO Regional Office for Europe.

b European Centre for Disease Prevention and Control (2018). Surveillance of antimicrobial resistance in Europe – Annual report of the European Antimicrobial Resistance Surveillance Network (EARS-Net) 2017. Stockholm: ECDC.

c Council of Europe (2023). Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach 2023/C 220/01. Official Journal.

food safety and fraud crises in the EU creates a countervailing constituency for EU action. Scandals, whether they concern contaminated sprouts in Germany or mislabelled horsemeat in Ireland, regularly recur, showing gaps in the system and diminishing the effectiveness of those who might urge deregulation.

A 2002 General Food Law Regulation[93] both set out a philosophy for food safety whose recitals are unusually readable and established the European Food Safety Authority, based in Parma.[94] Its Treaty bases are diverse but in this case mutually reinforcing and powerful – the powers to establish a Common Agricultural Policy, to consolidate the internal market, to establish a Common Commercial Policy, and the element of the public health article which allows regulation of veterinary and phytosanitary issues with an impact on health. (Note that consumer protection is missing and the public health Treaty base reference is circumscribed.)[95]

In 2017 the citizens' initiative "Ban [the herbicide] glyphosate and protect people and the environment from toxic pesticides"[96] bore fruit in increased transparency. The Commission decided that glyphosates are not a threat to health and the environment, but it did agree to the second part of the initiative, which calls for the scientific evaluation of pesticides for EU regulatory approval based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry. The consequent reform to the General Food Law, passed in the summer of 2019, expands the transparency of the assessment system, including that used by the European Food Safety Authority (EFSA), by reducing commercial secrecy (e.g. use of copyright to avoid making toxins data public).[97]

The EU's basic approach, which has shaped international perceptions of best practice, explicitly invokes the precautionary principle.[98] It focuses on four main

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93 European Parliament and Council (2002). *Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*.

94 The location was chosen after a well-publicized argument between Finland and Italy, whose then prime minister grounded his case for a seat in Italy on his view that Italian cuisine was superior. The allocation of agencies at the Laeken summit was a nice example of the politics of agency allocation discussed in Section 2.1.6. See BBC News (16 December 2001). *Food row blocked key EU decisions*. Available at: http://news.bbc.co.uk/1/hi/world/ europe/1714264.stm (accessed 23 February 2022).

95 In the Amsterdam-era Treaty Articles cited in the legislation: Article 37, establishing CAP; Article 95, the procedural article for implementing Article 14, which is general internal market development; Article 133 establishing a common commercial policy; and Article 152(4)(b), concerning public health.

96 Commission registration number: ECI(2017)000002. Date of registration: 25 January 2017. "We call on the European Commission to propose to Member States a ban on glyphosate, to reform the pesticide approval procedure, and to set EU-wide mandatory reduction targets for pesticide use."

97 Council of the European Union (2018). *Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) 1829/2003 [on GM food and feed], Regulation (EC) 1831/2003 [on feed additives], Regulation (EC) 2065/2003 [on smoke flavourings], Regulation (EC) 1935/2004 [on food contact materials], Regulation (EC) 1331/2008 [on the common authorization procedure for food additives, food enzymes and food flavourings], Regulation (EC) 1107/2009 [on plant protection products] and Regulation (EU) 2015/2283 [on novel foods]*.

98 Grant W (2012). Agricultural Policy, Food Policy, and Communicable Disease Policy. *Journal of Health Politics, Policy and Law*, 37(6):1031–48.

Box 5.4 *International dimensions of food safety policy*

Sanitary and phytosanitary standards cover definitions and safe practices and are crucial to the operation of trade in food, plants and animals. The EU is embedded in the complex network of agreements that regulates these issues. That includes the Codex Alimentarius Commission, of which it and the Member States are members and which sets basic food standards; the World Organisation for Animal Health (OIE), in which the EU is a formal observer and coordinates Member State positions; and the International Plant Protection Convention, which all Member States have signed and which focuses on pest control. It also includes extensive and detailed bilateral agreements. Trade agreements can affect all of these areas of regulation, e.g. permissible levels and kinds of pesticides or genetically modified organisms (GMOs), which can make these seemingly technical issues very contentious. A look at the complexities of Brexit and United Kingdom–EU trade relations since 2020 shows the importance and power of EU standard-setting. The EU is one of the key actors in these fields, influencing standards and procedures far beyond its borders.

areas: food hygiene, animal health, plant health, and contaminants and residues. It is worth noting that it is a food safety regime, not one focused on nutrition. Safe food need not be nutritious or otherwise healthy. There is, in fact, a certain tension between the highest standards of food safety as conventionally defined and some of the more artisanal production methods found in Europe.

Food safety policy is of international concern and the EU is a key player, as can be seen in Box 5.4.

The overall EU approach is to maintain the security of the food chain from farm to fork, which entails a focus on traceability at every step – through agriculture in all its complexity, transport, retailing and food service. This is an ambitious goal, which the EU arguably takes more seriously than almost any other food system (contrast the United States, where traceability is far more primitive due to well-documented industry lobbying). Implementing it is not just a technical challenge, though; the establishment of the system also meant so-called Europeanizing of very different and often well-established organizations and regulatory regimes.

It is worth noting the difference in how subsidiarity works in food safety compared to public health. The EU's powers in human public health are limited by subsidiarity to issues with potential cross-border implications. In food safety and animal health, by contrast, the powerful agriculture treaty bases permit EU action to protect the integrity and quality of the system even if the problem is limited to within a single country.

The resulting system is complex and evolving.[99] Member States are responsible for policing each stage of the farm to fork chain according to legislated EU standards, as well as coordinating to cope with the problem of cross-border food movements (e.g. through implementing a livestock tracking scheme).

Policing cross-border food movement is both a raison d'être of EU food safety policy, since the added value of EU action is obvious and considerable, and a major challenge. In 2013's so-called Horsegate scandal for example, it emerged that horsemeat from Romania was being fraudulently sold as beef by major supermarkets in the United Kingdom and Ireland. Further investigation found that the product had moved around five EU countries (Romania, France, Belgium, the United Kingdom and Ireland), partially orchestrated by a firm based in a sixth, the Netherlands, with investigators considering at least three Member States as the source of the meat as they tried to identify the stage at which it had been wrongly labelled, and by whom.[100] This was a case of food fraud, an area that is closely related to the food safety policies that fraud undermines, and also a DG SANTE competency but one that relies on police and the courts to investigate and prosecute. As a team of researchers concluded in 2017, "Horsegate raised the profile of food fraud and crime in supply chains and despite improvements to date, further collaboration between industry and government is required in order to align fully with the recommendations."[101]

The governance structure that is set up to deal with this wide variety of issues is built at the Member State level through Member State implementation and enforcement of EU law, and coordination through EU-level mechanisms to manage cross-border movements. The food safety agency EFSA is designed to be a source of scientific advice and communication, rather than an executive agency making or implementing policy. This makes it closer to the ECDC, reliant on scientific expertise and credibility, than to EMA, which is a de facto regulator.[102] The Member States are the regulators and enforcers in this highly Europeanized area of policy.

In 2020, the Commission introduced a new Farm to Fork Strategy for a fair, healthy and environmentally friendly food system as part of the European Green

99 Caldeira S et al. (2016). *Overview of the food chain system and the European regulatory framework in the fields of food safety and nutrition*. European Commission.

100 Available at: https://www.theguardian.com/uk/2013/feb/15/horsemeat-scandal-the-essential-guide (accessed 19 February 2022). Eventually the case led to the prosecution in Dutch courts of a meat dealer based in the Netherlands whose warehouse was located in Belgium.

101 Brooks S et al. (2017). Four years post-Horsegate: an update of measures and actions put in place following the horsemeat incident of 2013. *npj Science of Food*, 1(1):5.

102 Krapohl S (2004). Credible commitment in non-independent regulatory agencies: a comparative analysis of the European agencies for pharmaceuticals and foodstuffs. *European Law Journal*, 10(5):518–38.

Deal. This strategy, introduced in a communication,[103] emphasized sustainability and resilience, including resilience in the face of the kinds of supply and demand shocks that COVID-19 presented. It included a range of health issues across multiple policy and legislative proposals, with discussions of obesity and health effects of poor quality foods (e.g. cancer) and the safety of workers in the food industry as well as food safety. It included a commitment to a proposed revision to the relevant legislation in order to promote food safety in 2022. To date (mid-2024), many of the policies included in the communication have not moved forward, despite some progress in food marketing, pesticides, food security and agriculture. Some measures have been proposed by the Commission but have yet to be moved forward by other EU institutions. Other policies have not been proposed, notably legislative proposals or revisions on sustainable food systems, food labelling, animal welfare, nutrient profiles and food contact materials.[104]

Food standards may also be affected by international trade agreements, as outlined in Box 5.5.

5.4 Conclusion

The leadership of the EU has made three clear commitments since 2019: to the green, digital and social transitions. Each of these commitments includes a wide range of policies and funding mechanisms that have effects in and far beyond health. Each of these commitments also builds on years of policies and advocacy; none of them are just creatures of particular politicians or a particular few years of policy. Even if the names change, the EU has a longstanding commitment to all three goals of sustainability, fairness and a balanced approach to digital technologies. Not all EU political leaders are equally committed to the three goals or the policies in support of them, but they are entrenched in much EU policy and law.

The health effects and health policies of the transitions range from obvious to obscure, but the transitions and associated policies will affect health sectors and offer new opportunities and challenges. Using EU funds to systematically make healthcare green, or viewing food safety and food systems as part of One Health, could contribute not just to carbon neutrality but also increase resilience in the face of climate change and environmental shocks that can easily produce health

103 European Commission (2020). *A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system*. COM/2020/381 final.

104 Rossi R, Šajn N. (2024). *EU 'Farm to Fork' Strategy: State of Play*. European Parliamentary Research Service, Members' Research Service briefing, February 13th. Available at https://epthinktank.eu/2024/02/13/eu-farm-to-fork-strategy-state-of-play/.

Box 5.5 *Food standards and trade agreements*

Why are Europeans concerned about chlorinated chicken and hormone-treated beef? The conclusion of the EU–Canada Comprehensive Economic Trade Agreement (CETA) and negotiations with the United States on a possible transatlantic trade and investment agreement, as well as the Brexit negotiations, were met with widespread protests that, among other objections, raised concerns about food safety standards in countries outside the EU and the potential for trade agreements to lower the quality of food available in the single market.

Chlorinated chicken and hormone-treated beef are not allowed to be sold within the EU. To date, the EU has supported trade policies which are in line with its internal commitment to supporting a high level of human, animal and plant life and health. But a high level of health in law does not guarantee a high level of health in practice.

Trading with countries that have different food safety standards presents several distinct challenges to balancing economic growth and health. First, officials have to formally agree on how their food standards will be treated in one another's legal jurisdictions. This negotiation process is highly detailed, politically sensitive and often not publicly accessible. The extent to which health is prioritized in negotiations depends on a combination of legal constraints and political pressures on the negotiators and their relative bargaining power. A lack of transparent information about proceedings can fuel concern among the public and public health advocates.

Once an agreement is in place, other countries (and, in the case of investment agreements, companies) can challenge its content through a number of dispute settlement mechanisms. Disputes can be lengthy and expensive and are not particularly transparent. The EU's positions on hormone-treated beef and chlorinated chicken have been the subject of trade disputes within the WTO system, putting EU officials under pressure to change these policies. EU officials have, to date, resisted these pressures.

Furthermore, realizing food safety standards in practice rests upon national competencies and capacities, with Member States responsible for conducting compliance checks on imported goods. Regardless of what is decided in a trade agreement, the reality of enforcement and compliance may not match up with the legal intent.

threats. Likewise, the EU already has a distinctive approach to digital law and policy. By international standards, EU law is unusually concerned with balancing industrial policy goals (in the face of global norms that are often quite laissez-faire about personal data) against an entrenched commitment to privacy and control over the gathering and use of data. This means that digital health policy in the EU balances complex ethical and normative issues with the unknown but impressive appeal of data-intensive, AI-based health technologies that promise economic and health rewards to those who develop them.

Part of the reason to speak of the three transitions is to give coherence to agendas, but another reason is to impart urgency to the tasks involved. The three transitions might be quite different, and success or failure in each agenda may look quite different, but in each there is not just a clear EU impact on health systems and health but also a set of important opportunities for health policy-makers in the EU, Member States and health systems.

Chapter 6

Fiscal governance and health

6.1 How fiscal governance came to exist and matter to health

The EU Treaties specify that the organization and finance of healthcare is a Member State competence (Article 168 (7) TFEU). However, this exclusivity belies the increasing role of the EU in shaping the fiscal policies, and thus health policies, of its members. In the decade from 2010 the most significant area of European integration, and of growth in EU influence, was that of fiscal governance. The term means EU powers to shape the fiscal policies and stances of Member States. The EU does this both directly, via oversight of budgeting decisions, and indirectly, by guiding the kinds of economies that governments shape and the risks they create. Established with the goal of supporting monetary union by coordinating national economic policies, contemporary fiscal governance is used to steer individual and collective progress towards a broad array of objectives, including the Sustainable Development Goals, the European Pillar of Social Rights and the EU's climate targets.

The EU's fiscal governance framework has evolved to comprise an ongoing cycle of target setting, monitoring, reporting and assessment, underpinned by sanctions and penalties, and is applied across the full range of national policies. Since health is both an expensive item of national expenditure and a precursor to a productive and sustainable workforce, it is of direct and indirect relevance to fiscal governance and regularly targeted within these processes. In 2015, for instance, France was instructed to review the *numerus clausus* for health professional education, and Austria to set and hit quantitative targets for moving treatments out of hospital environments.[1] In 2020 fiscal recommendations on health were made to every Member State – the first time that this has been the case – and almost exclusively focused on strengthening the resilience of the health

1 Greer SL, Jarman H & Baeten R (2016). The New Political Economy of Health Care in the European Union: The Impact of Fiscal Governance. *International Journal of Health Services*, 46(2):262–82.

system, reflecting the priorities and concerns of the COVID-19 period.[2] This aspect of European Union health policy – the impact of fiscal governance on health systems and policies – has evolved over three broad stages: the creation of the Stability and Growth Pact (SGP) at Maastricht, the strengthening of the framework after the debt crisis and economic recession of 2010–2011, and the (temporary) adaptation of the framework in response to the COVID-19 pandemic. During this time the inclusion of health within the scope of fiscal governance has become clearer and the attention paid to fiscal governance by health actors has increased, to the point where we can identify a distinct fiscal aspect of health policy.

Fiscal governance in the EU is intimately associated with the project of monetary union that created the Euro.[3] Consequently, the template for fiscal governance that came to apply to health after 2010 was developed over decades by policy-makers whose concerns were far from those of health systems and health policy-makers. Rather, their objective was to make a set of dissimilar economies into similar ones, by encouraging the adoption of comparable policies on debt, deficits, inflation and macroeconomic structures, so as to stabilize exchange rates and facilitate monetary union. In an individual country this might be achieved via redistributive policy, equalizing across regions and between groups using public sector systems such as healthcare, pensions, education and unemployment benefits. As mentioned, the EU has no such redistributive role and there is little public support for its development – although in the face of the crises in 2020, the EU took steps in that direction. It can make use of its structural funds to equalize between governments, as a federation might. However, while they are important to some of the poorer Member States, these funds comprise too small a proportion of GDP to equalize among EU regions and produce real convergence across the EU as a whole.

The solution devised at Maastricht was an increase in the intensity and importance of fiscal governance.[4] Two core targets were adopted: government deficits should be less than 3% of national GDP, and total public debt should be less than 60% of GDP. These were enshrined within the SGP, which linked them to a

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2 It is worth noting that the general escape clause, which suspends the corrective dimensions of the Semester, had already been triggered before the 2020 Country Specific Recommendations, which is an important context for understanding the priority given to health.

3 The history of the experiments and developments that brought the initial fiscal governance framework into being is described in detail in the second edition of this volume and readers are encouraged to consult it. See Greer SL et al. (2019). *Everything You Always Wanted to Know About European Union Health Policy But Were Afraid to Ask*. Second edition. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies.

4 Dyson K (2014). *States, Debt, and Power: "saints" and "sinners" in European History and Integration*. Oxford: Oxford University Press. James H (2012). Making the European Monetary Union. Cambridge: Harvard University Press. Dyson K, Dyson KH & Featherstone K (1999). *The road to Maastricht: Negotiating economic and monetary union*. Oxford University Press.

surveillance and penalty mechanism, as well as an element of fiscal governance: the Broad Economic Policy Guidelines (BEPGs). The BEPGs reviewed Member State public policies and their effects on their overall fiscal future, as well as SGP compliance, and were a direct forerunner to the European Semester process (see Section 6.4 below). The purpose of the SGP was to make patterns of deficit and debt across Member States more similar, and thus to ensure the stability required to sustain the monetary union.

The history of the SGP limits is one of weak implementation and they have been breached by large and small Member States without penalty. Only one Member State – Ireland – was ever criticized under the BEPG, and it ignored the criticism.[5] Tellingly, rather than enforcing or strengthening the rules in response to non-compliance, Member States chose in 2005 to water them down, reducing their effectiveness further. Consequently, when the global economic crisis hit in 2010, there was considerable variation in the structure of EU economies and their exposure to the impacts of the financial crisis. So-called creditor states, which had built up trade surpluses, mostly those in the north, were less severely affected than those whose economies depended upon those creditor states' demand and investment. Although subsequent analyses would find little support for it, the explanation that dominated among EU policy-makers at the time was that the effect of the crisis in Europe was exacerbated by irresponsible borrowing and spending on the part of governments in the debtor countries.[6]

The EU responded to the crisis on two fronts. In the short term it established a series of bailout programmes to support those Member States at risk of insolvency, namely Greece, Cyprus, Ireland, Portugal and Romania. These governments signed memorandums of understanding with the institutions of the so-called Troika – the European Commission, the European Central Bank and the International Monetary Fund[7] – agreeing to programmes of structural reform

5 Deroose S, Hodson D & Kuhlmann J (2008). The Broad Economic Policy Guidelines: Before and After the Re-Launch of the Lisbon Strategy. *JCMS: Journal of Common Market Studies*, 46:827–48.

6 The best explanations find little support for the idea that overspending governments were to blame and instead focus on structural internal imbalances within the eurozone and the flow of speculative capital. See Pérez SA (2019). A Europe of creditor and debtor states: explaining the north/south divide in the Eurozone. *West European Politics*, 42(5):989–1014. Johnston A & Regan A (2016). European monetary integration and the incompatibility of national varieties of capitalism. *JCMS: Journal of Common Market Studies*, 54(2):318–36. Johnston A (2016). *From convergence to crisis: labor markets and the instability of the Euro*. Ithaca, NY: Cornell University Press. Dyson K (2012). "Maastricht Plus": Managing the Logic of Inherent Imperfections. *Journal of European Integration*, 34(7):791–808. Dooley N (2019). Who's Afraid of the Big Bad Wolf? Rethinking the Core and Periphery in the Eurozone Crisis. New Political Economy, 24(1):62–88. These authors do not agree completely with one another, but they are united in finding little or no support for the theory that self-indulgent public policy in debtor states caused the crisis.

7 Sokol T & Mijatović N (2017). EU health law and policy and the Eurozone crisis, in Hervey TK, Young C & Bishop L (eds). *Research Handbook on EU Health Law and Policy*. Cheltenham: Edward Elgar Publishing, pp. 291–313.

in return for financial assistance.[8] In the longer term the EU initiated a series of reforms to strengthen the fiscal governance framework, creating the preventive and corrective arms that would monitor compliance and sanction bad behaviour. Under this system – which is the fiscal governance system described under Section 6.2 below – it is easier than before to issue fines and other sanctions against states since the Commission's powers of surveillance and monitoring have been significantly increased. The idea of this dual approach was to arrange bailout mechanisms at the same time as making budget constraints for EU Member States harder and more effective, so as to offset the moral hazard created by the precedence of issuing bailouts.

The logic was partly an effort to address the crisis and its underlying roots, and partly a political response to outrage in creditor countries at the size of the bailouts they were supporting. Even before it was tested and found wanting in 2020, however, it was clear that the central logic of this system was flawed. Its core weakness is that it treats the eurozone as the sum of its parts: if every Member State were equally prudent, runs the logic, then the whole eurozone would be stable. The problem is that while individual EU Member States are relatively small, open economies, the size of the EU as a whole makes it a large and relatively closed economy more comparable to the United States than to any individual EU Member State. It was therefore unclear, prior to the COVID-19 pandemic, whether a fiscal governance system based on the enforcement of prudence between Member States with long-term structural imbalances could be effective. Awareness of these flaws informed the response to the pandemic, which sought to avoid a repeat of the measures taken in the aftermath of the economic crisis, and underpinned debates about reform of the fiscal governance system that have gained salience in the pandemic's wake.

The policies and debates of EU fiscal governance might seem far removed from the concerns of health actors but since the launch of the strengthened framework in 2011 in particular, their impact on and importance for health are increasingly recognized. Initially, this was linked to the austerity agenda. The early iterations of the fiscal governance system described in Section 6.2 were built around a commitment to reducing and reforming public expenditure, including on health. A body of research soon emerged documenting the impacts of cuts to health services,[9] and the inherent biases which led the fiscal governance system

8 Greer SL (2014). Structural adjustment comes to Europe: lessons for the Eurozone from the conditionality debates. *Global Social Policy*, 14(1):51–71.

9 Karanikolos M et al. (2013). Financial crisis, austerity and health in Europe. *The Lancet*, 381(9874):1323–31. Legido-Quigley H & Greer SL (2016). Austerity, health and the Eurozone. *International Journal of Health Services*, 46(2):203–7. Quaglio GL et al. (2013). Austerity and health in Europe. *Health Policy*, 113(1):13–19. Rajmil L et al. (2020). Austerity policy and child health in European countries: A systematic literature review. *BMC Public Health*, 20(564). Kentikelenis A, Stubbs T (2023). *A thousand cuts: social protection in the age of austerity*. Oxford University Press.

to prioritize economic over social objectives.[10] The system has since responded to these concerns and its relevance to health has consequently become more strategic. Rather than reacting to the threat posed by an unfamiliar and exclusionary fiscal governance system, health actors engage with and make use of the system to further their goals. To describe EU fiscal governance as a tool of EU health policy might be to overstate but, rather than targeting health systems and policies with limited input from health actors, it is now a site of inclusive health policy discussion and debate.[11]

6.2 The EU's fiscal governance framework

The EU's existing fiscal governance system, which developed in the aftermath of the debt crisis, comprises a series of legislative pillars which establish preventive and corrective arms. The former are designed to monitor trends and spot problematic macroeconomic imbalances before they have a chance to destabilize the European economy; the latter provide mechanisms for correcting persistent imbalances, by force of sanction where necessary. The framework and its various instruments are closely linked to sources of EU funding, including the Structural and Investment Funds (ESIF), the EU's primary tool for reducing inequalities in development between regions (see Section 6.3).

6.2.1 The pillars of EU economic governance

Following reform in 2011, the EU's fiscal governance has four main legal pillars (see Table 6.1). We discuss these briefly here; earlier editions of this book provide a more detailed analysis of the legal arrangements, and readers are encouraged to consult them.[12]

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10 Fahy N (2012). Who is shaping the future of European health systems? BMJ, 344:e1712. Maricut A & Puetter U (2017). Deciding on the European Semester: The European Council, the Council and the enduring asymmetry between economic and social policy issues. *Journal of European Public Policy*, 25(2):193–211.

11 Greer SL & Brooks E (2020). Termites of solidarity in the house of austerity: Undermining fiscal governance in the European Union. *Journal of Health Politics, Policy and Law*, 46(1):71–92. Verdun A & Vanhercke B (2022). Are (some) social players entering European recovery through the Semester back door?, in Vanhercke B & Spasoca S (eds). *Social Policy in the European Union: State of Play 2021*. Brussels: ETUI/OSE, pp. 103–25.

12 Greer SL et al. (2014). *Everything You Always Wanted to Know About European Union Health Policy But Were Afraid to Ask*. First edition. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies. Greer SL et al. (2019). *Everything You Always Wanted to Know About European Union Health Policy But Were Afraid to Ask*. Second edition. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies.

Table 6.1 *The four main legal pillars of the fiscal governance framework*

The Stability and Growth Pact (SGP)
Originally adopted in 1997, the SGP was reinforced as part of the Six Pack in 2011. Its overarching goal is to maintain budget discipline through a series of preventive and corrective measures which ensure fiscal policy is conducted sustainably and excessive deficits are corrected quickly.
The Six Pack
The Six Pack[a] entered into force in December 2011. Importantly, it codifies the European Semester (see Section 6.4) and makes a number of changes to the process, such as the introduction of the macroeconomic imbalance procedure (MIP). The Six Pack consists of two regulations addressing macroeconomic imbalance surveillance, and four pieces of legislation – three regulations and a directive – which address fiscal surveillance.
The Treaty on Stability, Coordination and Governance (TSCG)
Incorporating the Fiscal Compact Treaty, the TSCG was finalized in January 2012.[b] It is not part of EU law but rather is an international treaty. Its elements of fiscal policy coordination run parallel to the SGP and, in some areas, strengthen its provisions[c]. For signatories, it tightens the deficit and debt limits, gives the Court of Justice of the EU a role in enforcing the SGP, and requires the medium-term objective (MTO) to be transposed into binding national law. In addition to these sticks, it provides a carrot, in the form of the European Stability Mechanism (ESM) – a common financial assistance fund for eurozone countries.
The Two Pack
Adopted in March 2013, the Two Pack[d] is a pair of regulations, applicable to eurozone Member States only, which contributes to the further strengthening of budgetary surveillance. The regulations provide for a separate European Semester for eurozone states, with enhanced monitoring and assessment of draft budgetary plans and greater surveillance of Member States experiencing or threatened by financial difficulty.

Notes:

a The Six Pack: European Parliament and Council (2011). Regulation (EU) 1175/2011 of 16 November 2011 amending Council Regulation (EC) 1466/97 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies, Council Regulation (EU) 1177/2011 of 8 November 2011 amending Regulation (EC) 1467/97 on speeding up and clarifying the implementation of the excessive deficit procedure, Regulation (EU) 1173/2011 of 16 November 2011 on the effective enforcement of budgetary surveillance in the eurozone, Council Directive 2011/85/ EU of 8 November 2011 on requirements for budgetary frameworks of the Member States, Regulation (EU) 1176/2011 of 16 November 2011 on the prevention and correction of macroeconomic imbalances. Luxembourg: Publications Office of the European Union.

b The TSCG was not signed by Czechia or the United Kingdom, and pre-dates Croatia's membership. Croatia and Czechia have since joined the TSCG and the United Kingdom has left the EU.

c European Commission (2021). How Economic and Monetary Union Works. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/economic-and-monetary-union/how-economic-and-monetary-union-works_en#scgfiscal-compact (accessed 1 July 2021).

d The Two Pack: European Parliament and Council (2013). Regulation (EU) 473/2013 on common provisions for monitoring and assessing draft budgetary plans and ensuring the correction of excessive deficit of the Member States in the eurozone, Regulation 472/2013 on the strengthening of economic and budgetary surveillance of Member States in the eurozone experiencing or threatened with serious difficulties with respect to their financial stability. Luxembourg: Publications Office of the European Union.

The relationship between the pillars is one of reinforcement. The Six Pack and Two Pack strengthen the SGP considerably, while the TSCG runs in parallel and extends some elements of the SGP framework for contracting states. The resulting framework has both preventive and corrective arms.

A fifth element of the framework, with a different legal character, was adopted in March 2011 by 23 Member States.[13] The EuroPlus Pact is a soft law commitment to closer coordination of economic policy and tighter surveillance at the EU level. Signatory countries agreed to adopt targets in four broad areas of policy, including labour market and employment reforms, competitiveness, fiscal policy, and financial stability measures, with the goal of increasing competitiveness. Pledges are voluntary and vary in area targeted and specificity, but are monitored via the European Semester in an effort to avoid overlap and duplication. A 2015 review of the pact by the Commission's internal think tank described it as "largely dormant and receiv[ing] little attention in Member States" and found that it had failed to incentivize significant structural reforms.[14]

6.2.2 The preventive arms of fiscal governance

The SGP's preventive arm was established by Article 121 TFEU and was designed to "prevent fiscal policies from heading in potentially problematic directions" by establishing a cycle of economic and budgetary monitoring and assessment.[15] States are set medium-term budgetary objectives (MTOs) and must describe how they will achieve these objectives every April, via three-year budget plans known as Stability Programmes and Convergence Programmes (SCPs).[16]

Stability Programmes are submitted by eurozone states, while Convergence Programmes, which also contain monetary strategies, are submitted by non-eurozone states. With the adoption of the Six Pack, this preventive monitoring process was strengthened. The European Semester was created to coordinate the SCPs and other monitoring activities, and the MTOs were supplemented with an expenditure benchmark, to ensure that shorter-term spending does not move a country away from progress towards its MTO.[17] The TSCG required signatory Member States to transpose their MTO in national law, and committed them

13 In addition to the eurozone countries, the Pact includes six non-eurozone countries: Bulgaria, Denmark, Latvia, Lithuania, Poland and Romania.

14 EPSC (2015). *The Euro Plus Pact*. Brussels: European Commission. Available at: https://wayback.archive-it.org/12090/20191129101020/https://ec.europa.eu/epsc/publications/strategic-notes/euro-plus-pact_en (accessed 5 June 2021).

15 European Commission (2021). *Applying the rules of the Stability and Growth Pact*. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact/applying-rules-stability-and-growth-pact_en (accessed 6 June 2021).

16 European Commission (2021). *Stability and convergence programmes*. Brussels: European Commission. Available at https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact/stability-and-convergence-programmes_en (accessed 18 January 2022).

17 European Commission (2021). *The expenditure benchmark*. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact/preventive-arm/expenditure-benchmark_en (accessed 6 June 2021).

to lower SGP ceilings: 1% of GDP for States with debt below 60% of GDP, and 0.5% for those with debt above 60% of GDP. The Two Pack strengthened the Commission's oversight role further, giving it the power to assess the draft budgetary plans (DBPs) of eurozone Member States against the economic governance rules.[18] The DBPs are submitted in October and the Commission issues an opinion for each country, as well as for the eurozone as a whole. If an individual country's plan is found to be non-compliant under the SGP, the Commission can request a revised draft.

Separate from the SGP but with complementary goals, the Six Pack also created the Macroeconomic Imbalance Procedure (MIP).[19] The MIP is much broader in scope than the SGP, reflecting the criticism that many of the policies and trends that exacerbated the debt crisis and economic recession in the late 2000s are outside the mandate of the SGP, which focuses on deficits and debt. The MIP enables the Commission to analyse and respond to the potential long-term impacts of housing bubbles, private debt levels, unemployment and many other economic trends, and its process is integrated into the European Semester. It launches in November with the publication of the Alert Mechanism Report (referred to in these documents as the AMR). Any countries found to require further analysis are subject to in-depth reviews (IDRs), published within the country reports in February. The IDRs draw conclusions about the severity of any imbalances, and those deemed excessive may be subject to policy recommendations, enhanced monitoring and/or the excessive imbalance procedure (EIP), the MIP's corrective arm (see below).

6.2.3 The corrective arms of fiscal governance

The SGP's corrective arm is established by Article 126 TFEU and centres around the excessive deficit procedure (EDP). The EDP is designed to ensure that

18 This section draws heavily on European Commission (2021). *Draft budgetary plans*. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact/annual-draft-budgetary-plans-dbps-euro-area-countries_en (accessed 6 June 2021).

19 European Commission (2021). *Dealing with macroeconomic imbalances*. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/macroeconomic-imbalances-procedure/dealing-macroeconomic-imbalances_en (accessed 6 June 2021).

Member States comply with the deficit and debt rules as defined in the TFEU (and it is used to enforce both rules, in spite of its name).[20]

Under the EDP, the Commission monitors Member States' financial status. If the Commission decides that a Member State has breached or is at risk of breaching a rule, the EDP begins. The Commission informs the Member State and the Council. Exceptions can be granted for Member States that have faced events outside their control, such as natural disaster or severe economic downturn, but only if the excess is close to the threshold and considered to be temporary. The Council decides if an excessive deficit exists. If so, the Commission proposes and the Council adopts recommendations to correct the situation. If the Member State does not comply with the recommendations, a range of actions can be taken by the Council under the rules introduced by the Six Pack. The Council can require the Member State concerned to publish additional information, specified by the Council, before issuing bonds and securities; can invite the European Investment Bank (EIB) to reconsider its lending policy towards the Member State concerned; can require the Member State concerned to make a non-interest-bearing deposit of an appropriate size with the EU until the excessive deficit has been corrected; or can impose fines. For those states under the TSCG, instead of the Council and the Commission, the CJEU can issue a ruling requiring implementation of the rules and can impose a financial sanction amounting to 0.1% of GDP if the state fails to comply with the ruling. Penalties for non-compliance also exist under the preventive arm. The Six Pack introduced a requirement to lodge an interest-bearing deposit of 0.2% of GDP, which, if non-compliance continues, can turn into an annual fine, and the possible suspension of cohesion fund money until the excessive deficit is corrected.

The corrective arm of the MIP operates in a similar manner. Where "excessive imbalances with corrective action" are identified, the EIP is triggered. Following the Council's action on recommendation from the Commission, the Member State concerned is required to prepare a corrective action plan (CAP) and is subject to monitoring of its progress. If implementation of the CAP is insufficient and the Council declares a state to be non-compliant, a system of deposits and fines similar to that under the EDP can be initiated.

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20 The Maastricht reference values are defined in the TFEU, Protocol 12; A "satisfactory rate of debt reduction is reduction by 1⁄20th annually on average taken over a period of three years". This is known as the 1⁄20 rule. See European Commission (2011). Press release: *EU economic governance "six-pack" enters into force* (MEMO/11/898). Brussels: European Commission. Available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_11_898 (accessed 6 June 2021). See also European Commission (2021). The corrective arm. Brussels: European Commission. Available at: https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact/corrective-arm-excessive-deficit-procedure_en (accessed 6 June 2021).

Box 6.3 *DG REFORM*

The Commission's Directorate-General for Structural Reform Support (DG REFORM) helps Member States create and carry out reforms to maximize sustainable growth and job creation. Established in July 2015 as the Structural Reform Support Service (itself the consolidation of national task forces set up as part of the EU's response to the 2008–2009 global financial crisis), DG REFORM coordinates and provides tailor-made technical support to EU countries in various areas, including healthcare and long-term care systems, governance and public administration, education and climate change. At the request of a national government, DG REFORM discusses technical support needs, agrees to a cooperation and support plan with the Member State, provides financing, and coordinates experts from the public and private sectors. Financial support is provided by a Technical Support Instrument, with a budget of €864 million over the period 2021–2027.

6.3 EU funds for health

In addition to monitoring and steering national fiscal policies, the EU manages and makes available some direct funds. The majority of these are gathered under the umbrella of the Cohesion Policy Funds (known as the European Structural and Investment Funds [ESIF] under the previous MFF) or supported by the EIB. The third, newer and important, Recovery and Resilience Facility (RRF) is discussed in Section 6.5.

As outlined in Box 6.3, support for health sector improvements can also be offered in both financial and non-financial ways through DG REFORM.

6.3.1 Cohesion Policy Funds

The Cohesion Policy Funds are an envelope of funding programmes, making up the EU's regional development aid. The aim of these programmes is to reduce inequalities in development across different EU regions. The Cohesion Policy Funds are the closest thing that the EU possesses to the kind of redistributive fiscal tool needed for promoting cohesion and supporting the European monetary union. As more (and often poorer) Member States have joined the EU, so the budget of these funds has increased. The scale of funding should be kept in perspective; it represents a small portion of total EU wealth. However, the Cohesion Policy Funds compare well to other health funds, with their global envelope (covering all policy and economy sectors) offering tens of billions of euros a year, far more than health-specific research funds and the EU health programmes (even the EU4Health programme, with its greatly increased budget). As such, when targeted on specific initiatives, the Cohesion Policy Funds can make a real difference to health and the reduction of inequalities.

There are three main funds:

The European Regional Development Fund (ERDF) is focused on growth, regional economies and infrastructure. It funds investments within a set of priority themes, including innovation and research, the digital agenda, support for small and medium-sized enterprises (SMEs), environment and the net-zero-carbon economy. The ERDF and the ESF+ (see below) are open to all EU regions. The ERDF can fund investments in health infrastructure, medical equipment, digital health infrastructure and services, and innovative solutions for healthcare.

The European Social Fund Plus (ESF+) is focused on labour markets, education and training, and social inclusion. For 2021–2017 the ESF+ combines the pre-existing European Social Fund (ESF), the Youth Employment Initiative (YEI), the Fund for European Aid to the Most Deprived (FEAD) and the Employment and Social Innovation Programme (EaSI). The ESF+ is the financial instrument implementing the EPSR. The ESF+ can support investments in health promotion, disease prevention programmes, and measures to improve access to health care, as well as training for healthcare professionals.

The Cohesion Fund (CF) is aimed particularly at poorer Member States (for 2021–2027 this includes Bulgaria, Croatia, Cyprus, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia and Slovenia) and supports investment in environmental infrastructure and trans-European transport networks.

There are also other, smaller instruments and tools to support the use of the funds.[21] A pre-accession assistance instrument provides funding and support for potential and candidate countries and the EU Solidarity Fund exists as a separate emergency assistance fund. Furthermore, the 2021–2027 programme includes a new European Cross-Border Mechanism to facilitate harmonization of legal frameworks and the development of joint services, as well as an initiative to support interregional innovative investments to support clusters of states to work on priority sectors. The REACT-EU programme grouped funds from various instruments in order to react quickly with full EU funding for Member States as they sought to cope with the COVID-19 pandemic. It was later extended to support Member States accepting Ukrainian refugees.

The Cohesion Policy Funds are linked to the fiscal governance framework and can be leveraged by the EU. In principle, Member States that violate the fiscal rules

21 European Commission (2021). *New Cohesion Policy*. Brussels: European Commission. Available at: https://ec.europa.eu/regional_policy/en/2021_2027/ (accessed 28 June 2021).

will have their access to funds reduced; in practice, this has not been the case.[22] For 2021–2027 the link also operates in the reverse direction, with the Semester priorities shaping the allocation and content of the Cohesion Policy Funds. The allocation of ERDF and CF for each region will depend on an analysis and programming process which takes account of, among other things, the Country Specific Recommendations (CSRs, see Section 6.4) given as part of the Semester. Similarly, for the ESF+, the CSRs and other key policy challenges "will be the starting point of … programming" and states must allocate an "appropriate amount of their ESF+ share to addressing the challenges identified within their CSRs". Monitoring of the funds will also take place within the Semester cycle.[23]

Historically, the type of project funded under the ESIF was a large-scale, complex infrastructure project, rather than initiatives that focused on "softer" sectors like health. However, from 2010 Member States were encouraged to make use of the ESIF to fund health-related projects and, more broadly, there was greater recognition of the potential economic contribution of health.[24] Following the 2010 Council Conclusions on modern, responsive and sustainable health systems and the Joint Report on health systems prepared by the Commission and the Economic Policy Committee, both of which made reference to the importance of the ESIF for health, DG SANCO (as it then was) published its Investing in Health staff working document. This promoted the use of ESIF as a powerful instrument for health investment and offered guidance on designing health system reforms.[25] Specifically, the document advises that Member States could use the funds to best effect by:

- investing in health infrastructure that fosters a transformational change in the health system, in particular reinforcing the shift from a hospital-centred model to community-based care and integrated services;
- improving access to affordable, sustainable and high-quality healthcare, in particular with a view to reducing health inequalities between regions and giving disadvantaged groups and marginalized communities better access to healthcare;

22 Sacher M (2019). Macroeconomic Conditionalities: Using the Controversial Link between EU Cohesion Policy and Economic Governance. *Journal of Contemporary European Research*, 15(2):179–93. For why it should not be surprising, see Kleine M (2013). *Informal governance in the European Union: How governments make international organizations work*. Ithaca, NY: Cornell University Press.

23 European Commission (2021). *Questions and answers on the EU Cohesion policy legislative package 2021–2027*. Brussels: European Commission. Available at: https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_3059 (accessed 28 June 2021).

24 Watson J (2009). *Health and structural funds in 2007–2013: country and regional assessment*. Brussels: European Commission DG Health and Consumer Protection. Available at: https://ec.europa.eu/health/sites/default/files/ health_structural_funds/docs/watson_report.pdf (accessed 28 June 2021).

25 European Commission (2013). *Staff Working Document SWD(2013)43: Investing in Health*. Luxembourg: Publications Office of the European Union.

- supporting the adaptation, up-skilling and lifelong learning of the health workforce; and
- fostering active, healthy ageing to promote employability and employment and to enable people to stay active for longer.

In the 2014–2020 period, although health was still not listed as an objective in and of itself, health-related actions were identified among the 11 thematic objectives of the ESIF. These actions encouraged projects that focused on, for example, ensuring access to care with a view to reducing inequalities, investing in health infrastructure, and capacity-building for stakeholders delivering health policies.[26] A review of the extent and outcomes of health investments supported by ESIF during the 2014–2020 period mapped over 7000 projects, worth more than €8 billion, or approximately €1.2 million per project.[27] The largest numbers of health-related projects were found in Poland, Spain, Germany, Bulgaria and Italy, and the majority of projects supported healthy ageing, health promotion, reform of health systems, and research and innovation.

The 2021–2027 framework has five main objectives, one of which focuses on investments to drive a more social Europe, delivering on the EPSR and supporting equal access to healthcare. This is the first time that health has been explicitly identified in a headline objective of the Cohesion Policy Funds and it has been heavily affected by efforts to prioritize investments that mitigate the impact of the COVID-19 pandemic. Early programming for the period is described in Section 6.5.1 below and the extent to which this supports further utilization of the Cohesion Policy Funds for health investment, and in what specific areas, remains to be seen.

A major success of the Cohesion Policy Funds has been their increasing attention to health and the more explicit space within its remit to fund health investments. However, challenges remain. Early health-related projects understandably mirrored the funds' emphasis on large infrastructure programmes; the example of Hungary, which allocated €1.8 billion in ESIF support to health infrastructure projects in the 2007–2013 period, is a case in point.[28] Although the 2014–2020 framework encouraged a shift towards the social aspects of health services with some success, a review concludes that there remains a preference for larger capital expenditure projects in many countries, "due to their higher political profile and clearly visible return on investment".[29] This is particularly challenging for

26 European Commission (2012). *Staff Working Document SWD(2012)61: Elements for a common strategic framework 2014 to 2020*. Luxembourg: Publications Office of the European Union.

27 McGuinn J et al. (2019). *ESI Funds for Health: Final report of the EUFundsforHealth Project*. Available at http://www.esifundsforhealth.eu/sites/default/files/2019-03/Final%20Report%20ESI%20Funds%20for%20Health_3.pdf (accessed 28 June 2021).

28 Gaál P et al. (2011). Hungary: Health system review. *Health Systems in Transition*, 13(5):1–266.

29 Idem, p. 74.

investments that target reducing health inequities, for instance, where outcomes are long-term and a tangible return on investment is harder to demonstrate.[30]

A further challenge for the Cohesion Policy Funds is the extent to which they are used as a tool to enforce the rule of law. In December 2020 new legislation was adopted which created rule of law conditionality for all EU funds, including the Cohesion Policy Funds. Regulation 2092/2020 provides that, following assessment of a rule of law violation, the Commission can propose that a Member State's payments from the EU budget be suspended.[31] The Council votes by qualified majority within one month (or three in exceptional circumstances) on the proposal and appropriate measures are adopted within nine months. The Cohesion Policy Funds are a particular target of the regulation because of their scale but also because two of the largest Cohesion Policy Funds recipients – Poland and Hungary – have a long history of rule of law infringements.

6.3.2 The European Investment Bank

Founded in 1958 and located in Luxembourg, the European Investment Bank (EIB) provides funding for projects that seek to achieve EU goals, within or outside the EU. It was historically a little-known institution but the creation of the Investment Plan for Europe, a key pillar of Commission President Jean-Claude Juncker's efforts to strengthen the European economy, elevated the importance of investment banks in the EU's political economy. Although still maintaining a low profile, the EIB plays an important role in the EU's governance system, providing a kind of "European investment state" that can compensate for the EU's lack of fiscal capacity.[32] Its relevance and importance for health stems primarily from the scale of the funding that it offers, but it also plays a key role (which some describe as a policy-making role) in shaping the investment landscape by promoting particular models of investment, such as public and private partnerships (see Section 4.5.2).[33]

The EIB funds a wide range of health projects, including hospitals and other health infrastructure investments, medical equipment, medical research, education and

30 Neagu OM et al. (2017). Addressing health inequalities by using Structural Funds: A question of opportunities. *Health Policy*, 121(3):300–6.

31 European Parliament and Council (2020). Regulation 2020/2092 of 16 December 2020 on a general regime of conditionality for the protection of the Union budget. *Official Journal*, L 433I, 22 December 2020, pp. 1–10.

32 Mertens D & Thiemann M (2019). Building a hidden investment state? The European Investment Bank, national development banks and European economic governance. *Journal of European Public Policy*, 26(1):23–43.

33 Liebe M & Howarth D (2020). The European Investment Bank as policy entrepreneur and the promotion of public-private partnerships. *New Political Economy*, 25(2):195–212.

training, health informatics and information, and healthcare networks.[34] As of mid-2024, the bank was funding 19 new health-related projects within the EU.[35] Since it started investing in the health sector in 1997, the bank has lent approximately €42.7 billion in support of health projects (the average lending is around €1.52 billion per year for 22 projects annually).[36] In 2022, for example, the EIB provided €5.1 billion for health and life sciences projects.[37] These figures include responses to COVID-19 (€9.2 billion was allocated to pandemic-related projects in 2020), such as through the InnovFin Infectious Diseases Finance Facility, which helped support the development of the BioNTech vaccine.[38]

The Investment Plan for Europe, better known as the Juncker Plan, was developed at the start of the Juncker Commission in 2014 in response to the fallout from the economic crisis. By providing budget guarantees intended to unlock other investment, the initiative funded a large number of health projects. By 2019 it had exceeded its expenditure target, eventually raising €547 billion in investments in all sectors of the economy, although the European Court of Auditors pointed out in March 2019 that much of the expenditure could have been provided by either the private sector or other EIB programmes.[39] It was nonetheless renewed and expanded for 2021–2027, with 13 other small funding programmes folded in, as the InvestEU programme. InvestEU aims to mobilize €372 billion and is a core part of the COVID-19 recovery measures.[40]

The EIB is one of the world's largest lenders – its balance sheet is more than double that of the World Bank – and yet it attracts relatively little policy attention, and even less academic attention.[41] Its approach is generally one of caution: the *Financial Times* notes that "its modus is to lend big and lend safe" and reports on calls for the bank to reform its "conservative" lending practices to better serve

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34 European Investment Bank (2021). *Health and the Life Science sector*. Available at: https://www.eib.org/en/projects/sectors/health-and-life-science/index.htm (accessed 24 June 2021).

35 European Investment Bank (2024). Projects and loans: Health sector projects 2024. Available at: https://www.eib.org/en/projects/loans/index.htm?q=&sortColumn=loanParts.loanPartStatus.statusDate&sortDir=desc&pageNumber=0&itemPerPage=25&pageable=true&language=EN&defaultLanguage=EN&loanPartYearFrom=2024&loanPartYearTo=2024&orCountries.region=true&orCountries=true&sectors=5002&orSectors=true (accessed 13 August 2024).

36 European Investment Bank (2023, March 14). *Overview of EIB financing in health*. Available at: https://www.eib.org/attachments/lucalli/20220314_health_overview_2023_en.pdf (accessed 13 August 2024).

37 Idem, p.2

38 European Investment Bank (2021). *Health and the Life Science sector*. Available at: https://www.eib.org/en/projects/sectors/health-and-life-science/index.htm (accessed 24 June 2021), pp. 3–5.

39 European Court of Auditors (2019). *Special report 03/2019: European Fund for Strategic Investments: Action needed to make EFSI a full success*. Luxembourg: European Court of Auditors.

40 European Commission (2021). *InvestEU*. Brussels: European Commission. Available at: https://europa.eu/investeu/home_en (accessed 24 June 2021).

41 Toplensky R & Barker A (2019). European Investment Bank: the EU's hidden giant. *Financial Times*, 15 July 2019. Available at: https://www.ft.com/content/940b71f2-a3c2-11e9-a282-2df48f366f7d (accessed 29 June 2021). Clifton J, Diaz-Fuentes D & Gomez AL (2018). The European Investment Bank: Development, integration, investment? JCMS: *Journal of Common Market Studies*, 56(4):733–50.

the public interest.[42] Over the last decade it has greatly increased its financing of climate-related projects, and during the COVID-19 pandemic it similarly stepped up its support for health-related projects.

6.4 The European Semester

The European Semester is an annual cycle of goal-setting, coordination and review, used to implement the fiscal governance framework. It is based on the Six Pack and Two Pack (see Section 6.2) and draws on a long legacy of EU initiatives in public policy surveillance and coordination, such as the BEPGs and the Open Method of Coordination. As such, it is not entirely innovative but it is arguably much more important on account of the scope of its objectives and its targets. Although originally designed to achieve the quite narrow goals of fiscal sustainability and austere budgeting, the Semester (now adapted to integrate the RRF; see Section 6.5.2) is now used to pursue a range of objectives, including the European Pillar on Social Rights and the United Nations Sustainable Development Goals. Moreover, since its remit is anything that might affect SGP compliance or macroeconomic imbalances, it targets virtually all policy sectors. From a health perspective, it is effectively the open invitation to engage in detailed discussion of health policy that the Treaties previously lacked.

6.4.1 The European Semester: process

The Semester represents the first of two stages and is dedicated to coordination at the EU level to agree overarching priorities and intentions for all Member States. In a second stage, which happens at national level, governments incorporate Semester decisions into their budgets and policy plans. The Semester cycle begins in the autumn, when eurozone governments are required to submit drafts of their national budget plans to the Commission, which assesses their compatibility with the 3% and 60% deficit and debt limits. This is followed in November by the publication of the Commission's Annual Sustainable Growth Survey (ASGS). The ASGS identifies priorities for the EU as a whole, based on economic trends and forecasts. Traditionally published in February and more recently in May or June, the Country Reports offer the first country-specific analysis of the cycle. In 2019 a separate annex (annex D) for guidance on cohesion fund investments was introduced into the Country Reports; in 2020 this was pivoted to advise on investments under the Just Transition Fund and a new annex (annex E) was added to assess progress towards the SDGs.

42 Toplensky R & Barker A (2019). European Investment Bank: the EU's hidden giant. *Financial Times*, 15 July 2019.

In late spring each country submits (1) a National Reform Programme (NRP), outlining specific policies under way or upcoming, and (2) a Stability or Convergence Programme (SCP), presenting their final three-year budget plans.[43] These programmes must take account of the ASGS, the Alert Mechanism Report (AMR), the eurozone recommendation and a raft of other reports produced by the Commission, and are scrutinized for their response to these documents. This iterative process of reporting and assessing culminates in the publication of the Country Specific Recommendations (CSRs; see Box 6.1). Drawing on the ASGS, NRPs, SCPs, in-depth reviews triggered by the Alert Mechanism Report, and various other reports and analysis, the Commission drafts three or four CSRs for each Member State, describing the measures which should be taken to ensure healthy public finances and achieve various social and green transition goals. The final adoption of the CSRs by the Council signals the end of the first stage of the Semester; Member States now take these recommendations back to their national discussions and integrate them into domestic budgets and reform strategies. See Table 6.2 for health-related 2024 CSRs.

The Semester is a powerful tool for coordinating policy. It gives the EU unprecedented oversight of national policies and reform plans, covering virtually all sectors. This enables it to make recommendations encouraging, for instance, the diversification of the structure of the economy (as in the case of Cyprus in 2012), the phasing-out of environmentally harmful subsidies (as in France in 2014), the removal of barriers to hiring staff on permanent contracts (as in Malta in 2016) and measures to increase the housing stock (as in the United Kingdom in 2018). The Semester framework also enables the EU to link these recommendations to other policies and disbursements, such as the Cohesion Policy Funds and the Recovery and Resilience Facility, and provides valuable data to support other surveillance programmes, such as those under the TSCG, the Euro Plus Pact and the MIP. Most importantly, the breadth and potential for linkage across programmes mean that the Semester's core instrument, its CSRs, can be much stronger than their formally non-binding nature would suggest. Countries identified under the EDP or the MIP – i.e. countries with deficits or imbalances deemed risky and in need of correction – can find that Semester recommendations become requirements to avoid penalties under these mechanisms. Similarly, those in receipt of Cohesion Policy Funds support can be requested by the Commission to direct part of that funding to the fulfilment of the country's CSRs, with the potential for payment to be suspended where insufficient progress is made.[44]

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43 Stability Programmes are submitted by eurozone states; Convergence Programmes are submitted by non-eurozone states.

44 Bocquillon P, Brooks E & Maltby T (2020). Speak softly and carry a big stick: hardening soft governance in EU energy and health policies. *Journal of Environmental Policy and Planning*, 22(6):843–56.

Table 6.2 *Semester health recommendations for 2024*

Subhead	Semester recommendation
Austria	Improve the fiscal sustainability of the healthcare and long-term care systems.
Belgium	Address the cost of the long-term care system.
Croatia	Address delays in the recovery and resilience plan.
Cyprus	Take action towards addressing the needs in prevention and preparedness against climate-change risks, including in the health system.
Czechia	Strengthen the public administrative and IT capacity, targeting structurally impacted regions.
Denmark	Focus on sustainable agriculture by addressing reducing crop nutrient losses.
Estonia	Improve access and financing of healthcare and long-term care.
Finland	Ensure that the reform of healthcare improves access and efficiency of delivery.
France	Address skill shortages through participation in training to address healthcare workforce shortages.
Germany	Address labour shortages in the health and long-term care systems.
Ireland	Address healthcare's cost-effectiveness in the space of ageing. Increase investments in drinking water.
Latvia	Strengthen the adequacy of healthcare protection.
Lithuania	Provide adequate financing for healthcare. Improve the performance outcomes and resilience by strengthening primary care and expanding preventive care.
Netherlands	Address expected increases in age-related expenditure; work on making long-term care more cost-effective.
Poland	Improve process and quality of formal home and community-based care.
Romania	Improve quality and accessibility of healthcare for vulnerable populations.
Slovakia	Maintain momentum in the investment of healthcare.
Slovenia	Continue to monitor fiscal sustainability in healthcare and long-term care spending.
Spain	Improve the quality, efficiency and equity of public spending, including areas pertaining to healthcare.

Source: https://commission.europa.eu/business-economy-euro/economic-and-fiscal-policy-coordination/european-semester/european-semester-your-country_en (accessed 3 July 2024).

6.4.2 Evolution of the European Semester

The extent to which the European Semester targets health policy and the way in which its health-related elements have been framed have evolved considerably since its launch in 2011. The initial cycles of the Semester treated health crudely, monitoring health expenditure as a cost rather than an investment, contextualizing it only against coarse measures of life expectancy and infant mortality, and advising on health system reforms without drawing the views of health sector actors.[45] By 2020 a significant shift had occurred. More nuanced data, more inclusive policy discussions and a broader set of goals have led to more refined policy recommendations on health.

45 Azzopardi-Muscat, N., Clemens, T., Stoner, D., & Brand, H. (2015). EU Country Specific Recommendations for health systems in the European Semester process: Trends, discourse and predictors. *Health Policy*, 119(3), 375-383.

Box 6.1 *How to read Semester documents*

A Semester Country Specific Recommendation is both a legal document and a statement of priorities since there are far more policy issues than there are opportunities for CSRs. As Table 6.2 shows, recommendations can often be vague or somewhat opaque, necessitating careful interpretation.

Decoding the CSR: a focus on France's 2024 recommendations

As illustrated in Table 6.2, the recommendations may not always provide detailed action plans but rather point towards broader objectives. For example, the 2024 Semester Specific Recommendations for France highlight declining educational performances and significant challenges in recruitment due to a shortage of skilled workers, particularly in critical sectors such as healthcare and occupations related to the green transition.[a] In the long run these shortages could threaten to undermine France's ability to meet its environmental goals and maintain robust health services.

In response to these challenges, the European Commission's recommendations to France include several strategic priorities. Towards the end of the document, the Commission writes that France should:

> Further address skills shortages, including in green transition occupations, and foster participation in training, in particular among the low-skilled. Improve the performance and equity of the education system. Strengthen the teaching profession, including by improving working conditions and training. [b]

Some of the recommendations presented by the Commission are relatively straightforward, while others pose greater challenges in terms of their interpretation or implementation. For instance, the Commission highlights the importance of strengthening the teaching profession, which includes improving working conditions and providing better training for educators. As specified earlier in the text, this could involve simple measures such as providing pay rises to teachers.

The recommendations also call for systemic improvements in France's education system, with a particular focus on enhancing equity. Rather than introducing entirely new reforms, the Commission appears to advocate for the continuation and refinement of existing measures. These include "the halving of class size in 'priority education areas'" and having "a non-binding target to reduce social segregation in public schools by 20% in 2027 and signing a memorandum of understanding with private schools".

Moreover, the document suggests that France should continue to evaluate the effectiveness of these reforms while "adapting resources and methods to local circumstances and students' needs" in order to "further help improve the performance and equity of the education system." However, this guidance is somewhat vague and leaves room for interpretation. The emphasis on local adaptation implies a need for flexibility and decentralization in the implementation process. This approach appears to be slightly at odds with France's highly centralized educational system, which could present challenges in aligning national standards with localized decision-making.

a European Commission (2024). Document COM(2024) 610 final. Available at: https://commission.europa.eu/document/download/7660130e-4170-41d0-81cc-deacf90ce0d4_en?filename=com_2024_610_1_en.pdf (accessed 13 August 2024).

b Idem, p.13.

This evolution was instigated by health actors, concerned at their exclusion from the process. The early Semester cycles were led by the directorates-general for Employment (EMPL), Taxation (TAXUD) and, chiefly, Economic and Financial Affairs (ECFIN). The Council formation overseeing and making the ultimate decisions on the Semester was ECOFIN, the Council of Finance Ministers. From some perspectives, it was essentially a vehicle for a network of finance ministries to tighten their control over key areas of revenue and expenditure such as health.[46] This was concerning for health actors and pressure was soon exerted to widen the scope of involvement to include DGs SANTE and REGIO, the EPSCO configuration of the Council, and the advisory committees on Social Protection (SPC) and Employment (EMCO). Moreover, under the Juncker Commission, the Secretariat-General became more important in the process, especially vis-à-vis DG ECFIN, and TAXUD became less visible.

The EPSCO Council's pressure on the Commission led to the Commission's 2014 Communication on effective, accessible and resilient health systems, which emphasized the need to strengthen health systems and lent extra authority to the participation of DG SANTE in health systems discussions. This expansion and diversification of actors, in turn, broadened the goals of the Semester. The initial set of priorities – budgetary discipline, growth, macroeconomic stability – have been redefined, nuanced and supplemented by a range of social objectives. The monitoring and reviewing processes of the Social Investment Package, the Employment Package and the EPSR have all been subsumed into the Semester, and a suite of more nuanced and appropriate indicators to monitor health and social trends has been introduced.[47] As a result, a process that was initially quite exclusive and focused on narrow fiscal policy goals was broadened out as other affected interests sought participation and other priorities were pushed onto the agenda. This has led to more discussion and more sophisticated analysis of health and healthcare, and more sensitive policy recommendations. Furthermore, it now seems plausible to see the Semester as an evolution of the OMC as much as an instrument for fiscal control. That will no doubt disappoint those who appreciated it precisely for its focus on fiscal policy, apparent automaticity, and lack of engagement with details of policy.

The apparent vagueness of some recommendations is therefore balanced in some cases by more precision in the text (see Box 6.1). Some countries have neither recommendations nor discussion in the text, which presumably means that no attribute of their healthcare policies has been deemed a threat to fiscal

46 Stamati F & Baeten R (2015). *Healthcare Reforms and the Crisis*. Brussels: European Trade Union Institute.

47 Greer SL & Brooks E (2021). Termites of solidarity in the house of austerity: Undermining fiscal governance in the EU. *Journal of Health Politics, Policy and Law*, 46(1):71–93.

Box 6.2 *How to find Country Specific Recommendations*

Country Specific Recommendations are published in draft form by the Commission and then in final form, after Council approval, in the Official Journal. The easiest current way to find them is a searchable database maintained by DG ECFIN, the Secretariat-General and DG REFORM. This Country Specific Recommendation database is housed at https://ec.europa.eu/economy_finance/country-specific-recommendations-database/

sustainability. See Box 6.2 on finding CSRs, including to compare over time; see the second and third editions of this book for more detail on CSRs.[48]

From a health perspective, what is most striking about the European Semester is how a governance framework that was little known among health actors and that was created to institutionalize austerity in the aftermath of the economic crisis has become an important element of EU health governance. DG SANTE's contribution to the process has increased significantly, supported by projects such as the State of Health in the EU initiative and expansion of its expertise in, for example, health economics. EPSCO, SPC and EMCO continue to counterbalance ECOFIN's dominance over the process, and civil society organizations now routinely coordinate activity and analysis around the Semester.[49]

This increased attention and input from health interests has reformed the way in which health is framed and the kind of policy content included in the Semester. In case after case, the equity, effectiveness and quality of the healthcare system are raised as issues. This is a much subtler and more health-informed approach than was seen in the early years of the Semester, and one that values a broader range of outcomes and appreciates the logic of longer-term investments. It is evidence of the process of "socialization" described above, in which the Semester acquires social policy goals.[50] Member State ownership is in general a value in the Semester process as it operates now, which effectively means that the Commission tries to

48 Greer, S. L., Fahy, N., Rozenblum, S., Jarman, H., Palm, W., & Wismar, M. (2019). Everything you always wanted to know about European Union health policies but were afraid to ask (2nd ed.). European Observatory on Health Systems and Policies. Greer, S. L., Rozenblum, S., Fahy, N., Brooks, E., Jarman, H., de Ruijter, A., et al. (2022). *Everything you always wanted to know about European Union health policies but were afraid to ask* (3rd ed.). Copenhagen: WHO Regional Office for Europe.

49 See, for example, a review of the health and equity dimensions of the Semester, with case studies and suggestions for further improvement: EuroHealthNet (2019). *The European Semester 2019 from a health equity perspective*. Available at: https://eurohealthnet.eu/sites/eurohealthnet.eu/files/publications/FINAL%20The%20European%20Semester%202019%20from%20a%20health%20 equity%20perspective.pdf (accessed 25 June 2021).

50 Zeitlin J & Verdun A (eds) (2018). *EU Socio-Economic Governance since the Crisis. The European Semester in Theory and Practice*. Abingdon: Routledge. Zeitlin J & Vanhercke B (2018). Socializing the European Semester: EU social and economic policy co-ordination in crisis and beyond. *Journal of European Public Policy,* 25(2):149–74.

avoid recommendations that lack support within the Member State.[51] Compared to the earlier handling of health in CSRs, this is a dramatic difference.

There might still be some way to go before the Semester's approach to health aligns more fundamentally with the approach of the wider health community. Recommendations continue to emphasize a medical, healthcare paradigm, and miss opportunities to address the broader social determinants of health and well-being.[52] However, Commission President Ursula von der Leyen pledged to use the Semester in a more coherent way and, as Section 6.5 discusses, the increased salience of health in the wake of the COVID-19 pandemic offers an opportunity for further reform. Thus, for example, the 2022 Commission Communication on economic governance after COVID-19 was clear that health investment was now a legitimate priority.[53]

6.5 Fiscal governance and the COVID-19 recovery

The EU's fiscal response to COVID-19 involved some contributions to short-term resourcing, mostly via reallocation of existing funds, but mainly focused on long-term recovery from the crisis. The long-term recovery programme requires close monitoring and, therefore, has been integrated into the Semester, with an adapted cycle for 2021 and further changes for 2022, 2023 and 2024. This section reviews the content of the COVID-19 response and changes to fiscal governance processes made to accommodate it, as well as the space made for health reform and investments.

6.5.1 The fiscal response to COVID-19: short term flexibility and long-term adjustment

Central to the EU's short-term fiscal response to COVID-19 was the Coronavirus Response Investment Initiative (CRII) and its successor, the CRII Plus (CRII+),

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51 Tkalec I (2019). The Council's Amendments to the Country-Specific Recommendations: More than just Cosmetics? *Journal of Contemporary European Research*, 15(2):212–27. For an illuminating study of the Semester's changing policy role, see Heinonen, N., Koivusalo, M., Keskimäki, I., & Tynkkynen, L. K. (2024). Is the EU steering national social and health policy making? A case-study on Finland's national reform. *Health Policy*, 145, 105078.

52 EuroHealthNet (2020). *Recovering from the COVID-19 pandemic and ensuring health equity – the role of the European Semester*. Available at: https://eurohealthnet.eu/sites/eurohealthnet.eu/files/Recovering%20from%20the%20COVID-19_The%20role%20of%20the%20European%20Semester_Report%20final.pdf (accessed 25 June 2021).

53 European Commission (2021). "Additional investment is also needed to improve the EU's economic and social resilience, including in healthcare, education and training, research and development, innovation, and transport." *The EU Economy after COVID-19: implications for economic governance*. COM 2021(662), p. 6.

adopted in April 2020. Under these instruments, unspent funds from the 2014–2020 ESIF programmes were made available for crisis response, while new flexibilities made all pandemic-related spending eligible for cohesion funding, permitted countries to transfer funds between existing programmes, and expanded the scope of the EU Solidarity Fund to cover public health emergencies. In a similar vein an instrument of temporary Support to mitigate Unemployment Risks in an Emergency (SURE) was created, issuing loans to fund expenditure for the preservation of employment, such as short-term work schemes. These fiscal measures were complemented by monetary policy interventions. The ECB's Pandemic Emergency Purchase Programme (PEPP) committed €750 billion for purchasing bonds and other assets to free up lending in the eurozone, and the EIB issued a €200 billion European Guarantee Fund (EGF) aimed at supporting small and medium-sized enterprises (SMEs).[54]

While these efforts provided valuable resources and assistance in the immediate crisis period, it was clear that the majority of short-term stimulus responses would have to come from national budgets rather than EU funds. As such, perhaps most important among the EU's short-term actions was the decision to activate the SGP's "general escape clause" and suspend the deficit and debt limits that underpin the fiscal governance framework. This decision, taken in March 2020, reflected the impossibility of restricting government spending during a pandemic. It also indicated a recognition that the approach taken in the aftermath of the economic crisis in 2011, wherein struggling states were encouraged (or forced) to balance budgets despite the ongoing recession, caused further damage to economies and weakened health systems, ultimately exacerbating the impacts of COVID-19.[55]

The relaxation of fiscal limits permitted Member States to spend, and spend they did. The EU's collective deficit and debt ratios soon reached their highest point since the strengthened surveillance procedures were introduced within the Six Pack in 2011. By the end of 2020 only Denmark had maintained a deficit within the 3% limit, and 14 Member States had reported a debt ratio

54 European Central Bank (2021). *Press release: ECB announces €750 billion Pandemic Emergency Purchase Programme (PEPP)*. Available at: https://www.ecb.europa.eu/press/pr/date/2020/html/ecb.pr200318_1~3949d6f266.en.html (accessed 26 June 2021). European Investment Bank (2021). *Coronavirus outbreak: EIB group's response*. Available at: https://www.eib.org/en/about/initiatives/covid-19-response/index.htm (accessed 26 June 2021).

55 Dubin KA (2021). Spain's Response to COVID-19, in Greer SL et al. (eds). *Coronavirus Politics: The Comparative Politics and Policy of Covid-19*. Ann Arbor, MI: University of Michigan Press, pp. 339–60. Falkenbach M & Caiani M (2021). Italy's Response to COVID-19, in Greer SL et al. (eds). *Coronavirus Politics: The Comparative Politics and Policy of Covid-19*. Ann Arbor, MI: University of Michigan Press, pp. 320–38. Stuckler D et al. (2017). Austerity and health: the impact in the UK and Europe. *European Journal of Public Health*, 27(suppl.4):18–21.

exceeding 60% of GDP.[56] It was also apparent that this level of spending was unlikely to decrease in the short term. In March 2021 the decision was taken to extend the suspension of the SGP limits into 2022 and the EU turned its focus to longer-term support.

The EU's more substantial response to COVID-19, a long-term adjustment, came via the renegotiated MFF and the Next Generation EU (NGEU) recovery package. Next Generation EU provides €806.9 billion[57] of additional funding to support recovery from the pandemic and mitigation of its economic impact. Its largest component is the Recovery and Resilience Facility (RRF), a fund to support reforms and investment in Member States. Of the €723.8 billion available to national governments under the RRF, €385.8 billion is to be issued as loans and €338 billion will be issued as grants (see Table 6.3). The remaining €83.1 billion of the NGEU package is made up of various top-up funds, designed to supplement specific EU programmes and priorities, such as rural development, transitions under the European Green Deal and civil protection. REACT-EU (Recovery Assistance for Cohesion and the Territories of Europe), for instance, tops up the allocation for cohesion under the MFF and makes the ESIF envelope the largest single policy grant instrument in the EU budget.

Table 6.3 *Overview of Multiannual Financial Framework (MFF) and Next Generation EU (NGEU) allocations (current prices, billions of Euros)*

MFF 2021–2027 and NGEU total allocations		
	MFF	**NGEU**
1. Single market, innovation and digital	€149.5	€11.5
2. Cohesion, resilience and values	€426.7	€776.5
3. Natural resources and environment	€401.0	€18.9
4. Migration and border management	€25.7	–
5. Security and defence	€14.9	–
6. Neighbourhood and the world	€110.6	–
7. European public administration	€82.5	–
Total	**€1,210.9**	**€806.9**

NGEU breakdown	
RRF	€723.8
Of which, loans	€385.8
Of which, grants	€338.0
ReactEU	€50.6
Horizon Europe	€5.4
InvestEU	€6.1
Rural Development	€8.1
Just Transition Funds	€10.9
RescEU	€2.0
Total	**€806.9**

Source: https://op.europa.eu/en/publication-detail/-/publication/d3e77637-a963-11eb-9585-01aa75ed71a1/language-en (accessed 12 January 2022).

56 Eurostat (2021). *Government Finance Statistics, April 2021 update*. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Government_finance_statistics (accessed 26 June 2021).

57 Current prices.

Next Generation EU marks a significant step in several regards. For the first time Member States agreed that the EU should raise the funds needed for the package directly itself, on the capital markets. The process was delayed by the requirement for ratification of this "own resources" decision by national parliaments, but all governments had notified the Council of their agreement by 31 May 2021, enabling the Commission to start borrowing funds from 1 June. Moreover, this borrowing, and the debt incurred, is in common, and to be issued in the form of both loans and grants. These features again mark a deliberate change from the approach taken in 2011, when common Eurobond debt was rejected and financial support was made available only in the form of conditional loans. The political debate was fraught, culminating in the second-longest Council Summit on record in July 2020, but produced a combination of low-conditionality loans and grants, funded by common debt and managed by the Commission. This was new territory for the EU and represents perhaps the most significant innovation to result from the crisis.

The RRF, as the core instrument of the NGEU package, has a dual aim. It seeks to mitigate the impact of the pandemic, but to do so in a way which accelerates the transition towards a green and digital economy. To ensure that the package achieves these goals, the Commission has sought to guide and steer the use of the funds from the outset. Early in the process, seven flagship areas for investment were identified: clean technology and renewables, energy efficiency, sustainable transport, broadband services, digitalization of public administration, data cloud and sustainable processor capacities, and education and training for digital skills. In addition to serving these priorities, specific targets were set, requiring that a minimum of 37% of planned spending is dedicated to climate investments and reforms, and no less than 20% is earmarked to foster the digital transition. Finally, proposed spending plans should address countries' CSRs and the four dimensions – environmental sustainability, productivity, fairness and macroeconomic stability – outlined in the 2021 ASGS.

The aims of the RRF, and the kinds of investments and reforms that have been made eligible for RRF funds, are long term and structural in nature.[58] A key battle in the RRF's early existence was therefore to frame it as a structural adjustment programme, rather than a short-term stimulus package. The Commission has created templates and collated examples of the kinds of investments that it wants the RRF to support. These refer to large-scale, complex infrastructure projects, with long lead-in times, similar to those that have traditionally been supported by the Cohesion Policy Funds (and their predecessor ESIF). Their contribution to employment and growth, as well as to green, digital and sustainable economic

58 European Commission. *Recovery and Resilience Scoreboard*. Available at: https://ec.europa.eu/economy_finance/recovery-and-resilience-scoreboard/index.html (accessed 27 January 2022).

transitions, will thus materialize in the medium to long term. Commentary on the RRF's early operation emphasized that it must not be mistaken for a short-term stimulus package by either the Member States or the Commission. Proposed reforms and investments should be carefully planned and ambitious, and accompanied by continued flexibility in the fiscal governance framework, to allow national governments the policy space to take a longer-term approach.[59]

The RRF entered into force in February 2021. Member States were immediately tasked with preparing their Recovery and Resilience Plans (RRPs) and submitting these to the Commission for review by May 2021. The RRPs outlined a package of investments and reforms, in line with the guidance and eligibility criteria set out by the Commission, to be implemented by 2026. After Commission assessment, the Council signed off the plans and the Member States in question received 13% of the total support up front, to kick start investments. Remaining disbursements can be requested by governments up to twice a year, on meeting interim targets and milestones, and are assessed by the Commission and an assisting expert committee. Following lengthy negotiations at the July 2020 Council Summit, it was agreed that Member States would not be able to veto one another's spending plans but would be able to temporarily halt disbursements if they were concerned about "serious deviations" from another state's milestones and targets. Implementation of the RRF is overseen by the Recovery and Resilience Task Force (RECOVER) – a steering group based in the Secretariat-General and supported by DG ECFIN – and coordinated via a temporarily adapted European Semester framework.

6.5.2 Health in the COVID-19 recovery programme

What have these changes meant for the content and framing of health in EU fiscal governance? Logically, the short-term measures sought to directly fund health systems and public health interventions. The impact of the RRF and changes to the Semester process will be longer term but the way in which health is presented in the documents and guidance that underpins these structures gives a good indication of the kinds of reforms and initiatives that might be expected.

59 Pisani-Ferri J (2021). *European Union recovery funds: Strings attached but not tied up in knots*. Bruegel Policy Contribution. Available at: https://www.bruegel.*org/wp-content/uploads/2020/10/PC-19-2020-261020.pdf (accessed 26 June 2021). Mollet F (2021). The European Semester must acknowledge that the EU recovery fund is not a stimulus package*. European Policy Centre Commentary. Available at: https://epc.eu/en/publications/The-European-Semester-must-acknowledge-that-the-EU-recovery-fund-is-no~3a51b0 (accessed 26 June 2021).

6.5.2.1 Use of short-term response measures for health

The CRII and CRII+ packages liberated funds from existing programmes to support pandemic-related spending in three defined areas: the health system, SMEs and labour markets. Within the area of health, funds were designed to support the financing of medicines, testing and treatment facilities, medical equipment (including ventilators and masks), training and supplementary wage support to health personnel, and support to vulnerable groups. The CRII and CRII+ packages were later supplemented by REACT-EU, the strand of the NGEU package that tops up the 2021–2027 budget for cohesion policy, which explicitly supports the continuation and extension of investments made under CRII and CRII+. As of July 2024, the flexibilities and additional resourcing made available under CRII and CRII+ had resulted in €9.5 billion of reallocation for health spending, representing a net increase of €8.9 billion available to fund health-related investments.[60]

In 2023, the European Union Solidarity Fund (EUSF) approved over €454 million in aid to address disasters that occurred in 2022 and 2023.[61] In addition, during the same year the fund evaluated four further applications, ultimately disbursing more than €755 million to four Member States for recovery and reconstruction efforts related to natural disasters in 2021 and 2022. Additionally, five new applications related to natural disasters were submitted to the EUSF in 2023. Two of these applications were fully assessed within the year, while the evaluation of the remaining three began in 2023 and extended into 2024.

According to Council Regulation 2024/765 adopted in February 2024, the annual allocation for the Solidarity and Emergency Aid Reserve (SEAR) was increased for the 2024–2027 period. The EUSF and the Emergency Aid Reserve (EAR) were separated, each receiving a guaranteed budget allocation. As a result, the European Solidarity Reserve, which finances the EUSF, will have a total annual budget of €1,016 million (in 2018 prices), representing an increase of €216 million per year. The EAR's budget was also increased, amounting to €508 million annually (in 2018 prices), including a €108 million annual increase. When adjusted to 2024 prices, the EUSF's yearly allocation is set at €1,144.1 million, with €50 million specifically reserved for advance payments.

60 European Commission (2021). *European Structural and Investment Funds data: Coronavirus dashboard*. Available at: https://cohesiondata.ec.europa.eu/stories/s/CORONAVIRUS-DASHBOARD-COHESION-POLICY-RESPONSE/4e2z-pw8r/#2.1-a-sharp-increase-in-the-eu-allocation-to-health-actions (accessed 26 June 2021).

61 European Commission (n.d.). European Union Solidarity Fund performance. Available at: https://commission.europa.eu/strategy-and-policy/eu-budget/performance-and-reporting/programme-performance-statements/european-union-solidarity-fund-performance_en (accessed 13 August 2024).

6.5.2.2 Inclusion of health in long-term response measures

Perhaps the most important instrument for steering the recovery and shaping its impact on health is the regulation establishing the RRF. This defines the scope of the RRF across six pillars, the fifth of which covers "health, and economic, social and institutional resilience, with the aim of, inter alia, increasing crisis preparedness and crisis response capacity".[62] A political battle over the precise provisions of the regulation immediately commenced, as the European Parliament sought to direct the RRPs to, for instance, exclude investments in fossil fuels.[63] The resulting text provides that the Commission's assessment of the RRPs will be made against 11 criteria, including whether they adequately address the six pillars and the CSRs, whether they respect the "do no significant harm" principle in their environmental implications, and whether they are effective, efficient and coherent.

Over time, the RRF has become clearly focused on the green and digital transitions. There are also a series of benchmarks for RRF expenditure, including a requirement that no less than 20% of funds should be directed towards the digital transition, encompassing measures on e-health, for example. While contribution to strengthening the health system or public health is not explicitly listed in the regulation, the Commission's extensive guidance for drafting the RRPs invites plans to explain how proposed investments will strengthen "the health and care systems (in relation to the resilience, effectiveness and accessibility of care provision)".[64] It urges Member States to provide data on health outcomes, on how reforms will ensure an inclusive health system for disadvantaged populations, and how proposed policies will impact on access to healthcare.

The Commission has also provided templates to gather standardized information from the RRPs and issued examples of reforms and investments that might be included under the seven flagship themes. The templates include a section in which Member States should describe the expected impacts of each proposed measure on, among other things, progress towards their CSRs, growth potential and job creation, and implementation of the EPSR.[65] Health features prominently

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62 European Union (2021). Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility. *Official Journal*, L 57, 18 February 2021, pp. 17–75.

63 Their success was only partial. The "do no significant harm" principle states that investments are only eligible for RRF funding if they do not harm environmental objectives, but loopholes (for example, the framing of gas as a "bridge" fuel) mean that projects creating fossil-based infrastructure may be funded. See European Environmental Bureau (2021). *Fossil gas included in guidelines for EU recovery plans*. Available at https://eeb.org/fossil-gas-included-in-guidelines-for-eu-recovery-plans/ (accessed 30 June 2021).

64 European Commission (2021). *Staff Working Document SWD(2021) 12 final: Guidance to Member States, recovery and resilience plans.* Brussels: European Commission.

65 European Commission (2021). *Guidance to Member States, recovery and resilience plans, tables for the templates*. Available at: https://ec.europa.eu/info/files/annex-guidance-member-states-recovery-and-resilience-plans-tables-template-0_en (accessed 26 June 2021).

under flagship 5 of the RRF (digitalization of public administration) and examples of measures that might be proposed focus on digital health as a tool for improving access to services in rural areas and supporting development of health data infrastructure. Specific examples include investment in the digitalization of healthcare systems, the European Health Data Space, e-health infrastructure, electronic health records, telehealth, mhealth (mobile health), and the creation of registries and data repositories for specific diseases and reference networks.[66]

6.6 The future of the fiscal governance framework

The EU's fiscal governance framework exists to support the pursuit of economic and monetary union. It is limited to coordination and governance of Member States' fiscal policies; the EU does not have a large redistributive fiscal policy akin to those found at national level. Historically, this has meant that the fiscal governance framework sought to control health spending and investment in the service of austerity, stability and economic growth. However, since the contemporary system was established in 2011, it has undergone two major changes. The first, taking effect through the middle of the last decade, saw the increasing involvement of health actors, objectives and analysis in the Semester process, the implications of which can be seen in the evolution of the health-related CSRs. A second major change is taking place in the aftermath of the COVID-19 pandemic. This includes the creation of a temporary but substantial fiscal resource at EU level, via the NGEU package. For the first time the EU has a significant carrot with which to incentivize structural reforms and directly shape, rather than simply coordinating, national fiscal policies.[67] Early indications suggest that health is well represented within the NGEU.

A continuing unknown is the rule of law conditionality. The objective of the regulation is to protect the EU budget; as such, breaches of the rule of law must have an impact on the EU budget that is "sufficiently direct" – wording added to the original Commission proposal by the July 2020 European Council, at the behest of Hungary and Poland – in order to fall under the regulation.[68]

The adapted fiscal governance framework, and in particular the NGEU package, has already achieved three things: it has demonstrated the spirit of solidarity

66 See the projects discussed on the RRF scoreboard website, which monitors progress towards country goals: https://ec.europa.eu/economy_finance/recovery-and-resilience-scoreboard/health.html (accessed 26 August 2024).

67 Vanhercke B & Spasova S (eds) (2021). *Social Policy in the European Union: State of Play 2021*. Brussels: ETUI/OSE.

68 Łacny J (2021). The Rule of Law conditionality under Regulation 2092/2020: Is it all about the money? *Hague Journal on the Rule of Law*, 13:79–105.

that underpins the EU and its reaction to crises; it has provided temporary but precedent-setting mechanisms that might feasibly support further fiscal integration in future, and it has inspired both popular support for and market confidence in the EU.[69] It has thus succeeded in introducing elements of a stronger fiscal governance framework, such as common debt and a more central role for the Commission, that were mooted but not sufficiently palatable during the aftermath of the economic crisis in 2011. What remains to be seen is whether it can also succeed where the European Semester has so far largely failed, by increasing the resilience and sustainability of the European economy.

69 Jones E (2021). *Next Generation EU: Solidarity, opportunity and confidence*. SIEPS European Policy Analysis. Available at: https://www.sieps.se/en/publications/2021/next-generation-eu-solidarity-opportunity-and-confidence/ (accessed 30 June 2021).

Chapter 7

Global health

7.1 Introduction

The EU is a major global health actor. One of the world's largest economies, markets, scientific powers, donors and regulators, it constantly takes actions that influence health, whether directly (as with aid, intellectual property law or regulations on carbon and food safety) or indirectly (as with the green transition, which will affect the health of billions, or the digital transition, which sets globally influential technical, data and other standards. Member States largely support the idea of an EU global health policy, even if they might differ about its contents. While the EU can negotiate agreements as a bloc where it chooses, it must act collectively externally where there are internal EU competences.[1] Yet here too, the EU's powers in the area of trade and development give rise to external engagement regarding health. While some of the Member States have vigorous global health policies of their own, Member States have also delegated health policies to the EU (as is substantially the case with development aid), created explicit EU powers (such as negotiating trade agreements) that make it a superpower in that area, or chosen to work together in order to be more visible and effective in multilateral arenas.

What does the EU do with its global health power? An answer to this question has taken time to emerge. Historically, EU action in the field of global health has been undermined by the fragmentation of the EU global health community, a lack of common understanding as to what the EU's involvement in global health should consist of, and the resistance of some Member States to ceding control over this domain. The ongoing policy challenge lies in identifying goals and implementing actions to meet them, given the complexity of the issues at

1 De Ruijter A (2018). EU External Health Security Policy and Law, in Blockmans S & Koutrakos P (eds). *Research Handbook on the EU's Common Foreign and Security Policy*. Edward Elgar Publishing. Dijkstra H & de Ruijter A (2017). The Health-Security Nexus and the European Union: Toward a Research Agenda. *European Journal of Risk Regulation*, Sept 2018:1–13.

hand and the need to engage multiple stakeholders.[2] Just as the EU has health policies but has not always made policy for health, the EU has global health policies and is starting to make them for global health.

2022 saw the EU start to answer this question, with a Commission Global Health Strategy backed up by Council conclusions on global health in 2024, discussed in Section 7.2. This strategy promises to give coherence and direction to the EU's many ongoing engagements that shape global health and global health governance.

Engagement tends to happen when there are interests of mutual concern. Most often, this happens because of externalities – the effects on others of one's own domestic policy. The kinds of externalities that matter vary with the relationship; the United Kingdom's impact on EU labour markets is through its immigration controls, whereas Libya's impact is due to its problems after a civil war and military intervention. The arenas in which the EU engages are also different because of the different numbers and kinds of issues in which there are shared interests and externalities. Over time the EU has built up a set of foreign policy structures that differ significantly from the arrangements in the other policy fields discussed here.

After presenting the externalities, arenas and structures that form the context of EU global health policy in the remainder of this section, we move on to strategy in Section 7.2, in particular the EU's 2022 Global Health strategy, the 2024 Council conclusions on global health, and the tools that the EU can use to pursue global health. The power of the EU in the world is such that almost any policy area affects global health and is affected by global health (e.g. agriculture and climate change clearly have powerful global health impacts). In Section 7.3 we show how a range of EU policy tools can be used to shape global health far beyond the EU Global Health Strategy. In Section 7.4 we move on to the particular health policies, problems and bilateral relationships of the EU's neighbourhood, a diverse place encompassing very different countries and challenges. Then in Section 7.5 we cover vaccination politics and we reach some conclusions in Section 7.6.

7.1.1 Externalities

Why does the EU have a global health profile and policy at all? There is a variety of reasons, ranging from ethical to pragmatic, from maintaining post-colonial

2 Greer, S. L., Falkenbach, M., Wismar, M., & Figueras, J. (Eds.) (2023). Health for All Policies: Health Policy and the Sustainable Development Goals. Copenhagen: WHO Regional Office for Europe and European Observatory on Health Systems and Policies. Available at: https://eurohealthobservatory.who.int/publications/i/making-health-for-all-policies-harnessing-the-co-benefits-of-health (accessed 11 August 2024).

relationships to developing stronger ties with rising economies and strategic states. But the key reasons for the EU to have global health policies lie in the externalities of other policies which cross borders.

On one hand, EU policies in many areas creates externalities for health, for other countries and the planet, which then require management. Thus, for example, trade and investment policy decisions influence all kinds of areas of health and the economy, from tobacco control to medicines development and export agriculture. On the other hand, in an interconnected world, the activities of others also affect the EU. State failure, war and authoritarian regimes can produce refugee crises that affect European countries. Trade means that the regulatory standards of trading partners, and their enforcement, affect what European economies consume. Much EU policy towards its neighbours is directed at pre-emptively managing these externalities. Since 2015, for example, the guiding – and hotly debated – theme of EU policy in the Mediterranean has been reduction in the number of refugees arriving at EU borders.

7.1.2 Arenas: internal, neighbourhood and global

The EU operates in three international arenas.[3] One is within its own borders, the focus of most of this book. The second is its immediate region – the accession candidates and other states close to its borders. To some extent this includes the whole WHO European Region as well as the countries formally identified in the EU's European Neighbourhood Policy. This extraordinarily diverse set of countries, from Switzerland to Libya, Tunisia to Belarus, the Syrian Arab Republic to the United Kingdom, is united by little other than proximity to the EU; it presents a wide variety of concerns, and requires a wide variety of policy tools. The third and final arena is global, concerned with global issues such as climate change, and organized into global organizations such as the UN family. The externalities that drive engagement – or that affect people's lives whether or not there is a policy – change with the different arenas.

7.1.3 Structures

The EU's foreign policy structure is extremely complex, built up in a series of compromises between Member States' desire to guard their sovereignty and freedom of action, and their desire to give coherence and strength to their shared interests. It starts with the European Council, which can speak for Member States collectively. Statements by the Council are in a sense the most powerful

3 European Observatory on Health Systems and Policies & McKee M (2021). *Drawing light from the pandemic: a new strategy for health and sustainable development. A review of the evidence*. Copenhagen: WHO Regional Office for Europe.

because in a world of states, other governments understand heads of government as the most powerful credible actors. In particular, the European Council is the level that most plainly unites the power of the Member States, including their military power, with the EU's own resources and activities. The Foreign Affairs Council, then, is tasked in Article 16 TEU to "elaborate the Union's external action on the basis of strategic guidelines laid down by the European Council and ensure that the Union's action is consistent".

The EU's High Representative of the Union for Foreign Affairs and Security Policy is chosen by Member States by qualified majority vote with the agreement of the President of the Commission (note that the European Parliament has no power to veto the appointment; Member States do not see their shared foreign policy stance as a fit topic for accountability to the Parliament). The High Representative for Foreign Affairs and Security Policy after November 2024 is Kaja Kallas, the former Prime Minister of Estonia. She was selected by the European Council to succeed Josep Borell. High Representative is an intriguing hybrid post. It is supported by the European External Action Service (EEAS), the EU's diplomatic body, which is not part of the Commission, but the High Representative has the status of a Commission Vice-President. A small DG, the Service for Foreign Policy Instruments, supports the EEAS in the areas which are still part of the Commission. The High Representative also presides over meetings of the Foreign Affairs Council. The High Representative does not directly control some of the key levers of EU power, especially those most relevant to global health such as trade, development and civil protection; these are all overseen by other commissioners, particularly those of DGs ECHO (Civil Protection and Humanitarian Aid), CLIMA (Climate), NEAR (Neighbourhood and Enlargement), INTPA (International Partnerships) and TRADE (Trade). The actual activity and powers of the High Representative, even more than other top jobs in politics, change with the occupant of their post and their ability to forge an agenda that has the support of the Member States while cohering with the activity of the EU institutions.

On a day-to-day basis, the dimensions of EU activity most important for global health take place outside this structure and within the more conventional EU processes discussed in Chapter 2. Trade and investment policy, foreign and development aid, and contributions to civil protection and global emergency response all operate through normal Commission, Council and Parliamentary channels, but interact with this structure, especially in times of crises. As part of the broad system of EU budgeting, legislation and accountability, these channels are more predictable and accountable, and less affected by divergent Member State interests and geopolitical crises. The High Representative role is shaped more as an after-effect of high politics, and its policy importance or

health impact depends on its occupant and on what Member State governments let that person do.

7.2 European Global Health Strategy

The development of the EU's Global Health Strategy has come relatively slowly, starting with an appreciation of the role of health in overseas development and only recently starting to encompass a broader range of EU concerns and policy tools.

The first significant strategy document was the European Consensus on Development, released in 2005. It emphasized the importance of the United Nations Millennium Development Goals (predecessors to the SDGs) with a specific focus on health-related goals.[4] Global health was put at the forefront of the EU political agenda in the early 2010s, with the publication of the EU's first health strategy and policy framework in 2007, the Council Conclusions on Global Health in 2010, and the EU Communication on the EU role in global health in 2010. This document stated that the EU's global health commitment included promoting inclusive global health governance, achieving universal health coverage, creating policy coherence, investing in health research, and ensuring that knowledge creation benefits all.[5] The subsequent Council conclusions urged a more central EU role in global health. These documents, however, largely remained statements rather than operationalizable action plans.[6]

The European Union's global health posture took a decisive turn towards more integration in May 2022, when the commissioners for SANTE and INTPA (the DG for development) announced that they were working on a global health strategy. The strategy was adopted by the Commission on 30 November 2022. The Council then echoed and endorsed the strategy in its 29 January 2024 Conclusions on global health.

The EU Global Health Strategy lays out three overarching priorities and twenty guiding principles that aim to steer future global health initiatives (see Box 7.1). The three overarching priorities are:

1. Delivering better health and well-being of people across the life course.

4 Steurs L, Van de Pas R, Delputte S & Orbie J (2018). The Global Health Policies of the EU and its Member States: A Common Vision? *International Journal of Health Policy and Management*, 7(5):433–42. doi:10.15171/IJHPM.2017.112.

5 Aluttis C, Krafft T & Brand H (2014). Global Health in the European Union – a review from an agenda-setting perspective. *Global Health Action*, 7:1. doi:10.3402/gha.v7.23610.

6 Berner-Rodoreda A et al. (2019). Where is the "global" in the European Union's Health Research and Innovation Agenda? *BMJ Global Health*, 4(5):e001559. doi:10.1136/bmjgh-2019-001559.

2. Strengthening health systems and advancing universal health coverage.

3. Preventing and combatting health threats, including pandemics, applying a One Health approach.

The principles listed in Box 7.1 mean enhancing the capacity and resilience of health systems through increasing workforce capacity and capability, keeping abreast of technology, and integrating health policies across sectors. The principles and priorities influence each other. For instance, the first principle focuses on tackling the root causes of ill health, specifically for women, girls and previously overlooked populations. This directly maps onto the first and second priorities.

The Global Health Strategy was followed in January 2024 by the *Council Conclusions on EU Global Health Strategy: better health for all in a changing world*. This follows a common pattern in which the Commission's views are endorsed by the Council, albeit in somewhat amended form. Council conclusions which agree with the Commission are a powerful support for implementing a strategy because they show that the Member States are also committed to the agenda. Council conclusions are also worth reading in detail because they are formulated in careful diplomatic negotiations, so nuances of language and inclusion or exclusion of topics are important.

Commission strategies matter, but in a really forceful and durable EU policy approach the Commission's approach is echoed in Council conclusions. The January 2024 External Relations (RELEX) Council meeting endorsed the Commission's Global Health Strategy and a shared commitment of the EU and its Member States to a "leading role" in global health. It reaffirmed the Council's commitment to the principles of "solidarity, humanity, equity, gender equality, and respect for human rights" (see Box 7.2 on gender). It further asserted that

> the Council remains committed to policy coherence and a human-rights based approach and further acknowledges that EU contributions to global health go beyond the health sector, including in areas such as peace and security, agriculture, climate and environment, education, research and innovation, nutrition and food security, social protection, trade and water, sanitation and hygiene.

The Council meeting endorsed the three priorities of the Commission strategy and characterized it as a "new paradigm that engages all relevant areas of external policy, with an important link to internal policies".

The Council conclusion calls on the Commission, the High Representative and Member States to "apply the guiding principles and implement" the strategy by means including:

Box 7.1 *EU Global Health Strategy's 20 guiding principles*[a]

1. Prioritize tackling the root causes of ill health, paying particular attention to the rights of women and girls, and to vulnerable populations and disadvantaged groups.
2. Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable and non- communicable diseases.
3. Improve primary healthcare with built-in surge capacity, and enhance core public health capacities to meet the requirements of the International Health Regulations.
4. Foster digitalization as a fundamental enabler.
5. Boost global health research to develop the technologies and countermeasures which are necessary to improve health.
6. Address workforce imbalances and foster skills.
7. Strengthen capacities for prevention, preparedness and response and early detection of health threats globally.
8. Work towards a permanent global mechanism that fosters the development of and equitable access to vaccines and countermeasures for low- and middle- income countries.
9. Negotiate an effective legally binding pandemic agreement with a One Health approach and strengthened International Health Regulations.
10. Build a robust global collaborative surveillance network to better detect and act on pathogens.
11. Apply a comprehensive One Health approach and intensify the fight against antimicrobial resistance.
12. Link effectively all policies and measures that have an impact on global health within the Commission, EU agencies and EU financing institutions.
13. Better link and coordinate policies and measures of the EU and its Member States to speak with one voice and deliver effective action worldwide.
14. Support a stronger, effective and accountable WHO.
15. Steer the new global health governance by filling gaps and ensuring coherence of action.
16. Ensure a stronger EU role in international organizations and bodies.
17. Expand partnerships based on equal footing, co-ownership, mutual interest and strategic priorities.
18. Strengthen engagement with key global health stakeholders.
19. Enhance EU finance for global health with maximum impact.
20. Assess progress and ensure the accountability of the EU's global health action through permanent monitoring and assessment.

a European Commission (2022). EU Global Health Strategy. Further information found: https://health.ec.europa.eu/system/files/2023-10/international_ghs-report-2022_en.pdf

concrete action to promote global health across relevant sectors ... ;

strengthening capacity and enhancing coordination, including through informal cooperation, to boost the efficiency and impact of initiatives

> and actions, ensure that the EU and its member states are speaking with one voice in relevant international fora and intensifying dialogue and joint communication efforts at multilateral, regional and national level;
>
> taking a proactive and constructive role to strengthen multilateral cooperation by filling existing gaps in global governance and ensuring complementarity and coherence of action, European support for improving global health systems and policies and with a strengthened and more effective, accountable, and sustainably financed WHO at its core, noting that the EU seeking formal observer status at WHO could be addressed and decided upon in the relevant Council structures;
>
> expanding bilateral, regional, trans-regional and global partnerships ... ;
>
> regularly taking stock of progress and impact.

It finally commits to a broad range of partnerships inside and outside the EU and invites the Commission and EEAS to "develop a coherent EU global health diplomacy, ... augment global health capacity in key EU delegations, ... monitor and evaluate the implementation and impact of the Strategy."

Box 7.2 *The EU, global health and gender*

Various global entities have discussed the need for increased global health and gender access to health. The United Nation SDGs have a large focus on promoting gender equity as seen in Goal 5 being gender equality.[a] The Commission and Council have made a strong commitment to gender equity, reaffirming their stance with the third Gender Action Plan as well as the Agenda for Gender Equality and Women's Empowerment through EU External Action 2021–2025.[b]

At the beginning of 2024, the Council reaffirmed the importance of gender equality in their conclusions on global health, emphasizing the EU commitment to gender equality through fighting stereotypes, stigma and discrimination.[c] This included supportive policies in mental health, discrimination and stigma, reproductive rights, particularly for women, girls, children and youth, and all vulnerable and marginalized individuals.

a United Nations. The 17 Goals. Find more details here: https://sdgs.un.org/goals

b European Union External Action (2020). *Gender Action Plan III: towards a gender-equal world*. Found at: https://www.eeas.europa.eu/eeas/gender-action-plan-iii-towards-gender-equal-world_en

c European Commission (2024). *Council conclusions on the EU Global Health Strategy*. Further information found here: https://data.consilium.europa.eu/doc/document/ST-5908-2024-INIT/en/pdf

7.3 European global health policy tools

The Global Health Strategy was born in DGs SANTE and INTPA, and its substantive policy focus is primarily on the health and international development goals of those DGs, even though other DGs such as ECHO, AGRI, CLIMA, GROW, ENV and TRADE also have powerful policy tools to affect global health.

Important EU global health policy tools include trade, investment and international economic governance, as well as public investment and European development aid. This allows us to classify tools by both their relevance to global health goals and their appropriate uses.

Figure 7.1 shows key global health tools in five broad areas relevant to the current EU strategy. The tools are listed below and each is examined in more detail in Sections 7.3.1–7.3.5.

- **Trade in goods and services:** Instruments included in this policy area pertain to the area of trade, reflecting how trade affects different types of product (e.g. potentially hazardous commercial goods such as cigarettes, medicines or medical devices), intellectual property and services (e.g. cross-border healthcare and mobility of the health workforce).

- **Public investment and fiscal instruments:** The EU has adopted a new global investment strategy, the Global Gateway, which will leverage different types of instruments to boost growth and attract investment for infrastructure, digitalization and the modernization of health systems. Some of the instruments included in this area take a global approach, while others, which are primarily dedicated to internal actions, have important spillover effects on third countries.

- **Overseas development assistance (ODA) and humanitarian aid** is arguably the oldest EU policy area understood as global health policy. There are several tools by which assistance is provided to third countries, which reflect the geographical idiosyncrasies of the different beneficiary countries. Support for human development, rights and health systems strengthening is at the centre of EU development and humanitarian action.

- **Solidarity, voice and multilateralism:** The EU is an advocate for multilateral cooperation and cooperates with a wide range of actors in the global health arena to strengthen health systems in beneficiary countries, while also empowering them and forging partnerships. This policy area captures the most important multilateral cooperations and

partnerships, and explores how the EU shapes its position and voice within these forums.

- **Research and training partnerships:** The category of research and training partnerships encapsulates the policy area through which EU instruments support scientific excellence and training beyond the EU's borders.

For a more detailed understanding of the method and the specific policies, please see the European Observatory on Health Systems and Policies policy brief *European support for improving global health systems and policies*.[7]

7.3.1 Trade, investment and international economic governance

The EU is a powerful actor in international trade, aiming to represent its Member States with a single voice in trade and investment negotiations and disputes. The EU has exclusive competence in almost all areas to conduct international negotiations on trade deals, although some practical difficulties remain regarding the sometimes blurred dividing line between international trade and domestic EU policy areas, including health. The EU's current and future trade and investment commitments remain intimately connected to the ways in which health service providers, medical professionals, patient mobility and products affecting public health – from food, alcohol and tobacco to pharmaceuticals and medical devices – are regulated within the EU. Awareness of the EU's trade policies is therefore vital for health officials within the EU and at Member State level and dialogue between trade and health officials should be promoted.

The EU is party to many different trade and investment agreements that have implications for health policies. Of the multilateral agreements governed by the World Trade Organization, the most significant for health are the General Agreement on Tariffs and Trade, which governs trade in goods; the General Agreement on Trade in Services, which permits members including the EU to make commitments to liberalize their services markets; the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement, which notably affects patents and access to medicines and has been the subject of much dispute; the Agreement on the Application of Sanitary and Phytosanitary Measures, which addresses the application of food safety and animal and plant health standards with a view to identifying protectionist measures; and the Agreement on Technical Barriers to Trade, which focuses on the identification of regulatory barriers to trade and has been central to a number of tobacco-related trade disputes.

7 Greer et al (2024). *European support for improving global health systems and policies*. European Observatory on Health Systems and Policies.

Fig. 7.1 *Map of EU global instrument*

	Trade in goods and services	Public investment and fiscal	ODA and humanitarian aid	Solidarity, voice and multilateralism	Research and training partnerships
Policy				Commission communication on the EU role in Global Health	Science for diplomacy
				Joint Communication on strengthening the EU's contribution to rules-based multilateralism	AU-EU Partnership
	Sanitary and phytosanitary standards (SPS)	Global Gateway	European Consensus on Development	Team Europe and Team Europe Initiatives	
	Trade agreements	Team Europe	European Neighbourhood Policy and Enlargement Negotiations		
	Trade arrangements		European Consensus on Humanitarian aid		
	Consultation mechanism		Civil Protection Mechanism		
	Trade defence				
	Policy reviews				
Funding	Aid for Trade	Global Europe	Funding for humanitarian aid	Transversal (shown in other columns)	Horizon Europe
		Instrument for Pre-accession Assistance (IPA III)	Global Europe		Vocational training (VET)
		Interreg	Solidarity and Emergency Aid Reserve (SEAR)		
		InvestEU			
		EIB Global	Instrument for Pre-accession Assistance (IPA III)		
		EU4Health			
	Manufacturing pharmaceuticals agreement with Africa (Global Gateway)	Connecting Europe Facility			
	Manufacturing pharmaceuticals agreement with Latin America and the Caribbean (Global Gateway)				European and Developing Countries Clinical Trials Partnership (EDCTP)
Technical assistance			European Civil Protection Pool		Opportunity Driven Vocational Training (Team Europe Initiative)
			Technical Assistance and Information exchange instrument (TAIEX)		Marie Sklodowska-Curie Actions
			TWINNING		
			MediPIET		
Information	Analysis and assessment				Knowledge4Policy

Source: Greer et al (2024). *European support for improving global health systems and policies*. European Observatory on Health Systems and Policies.

Notes: AU: African Union; EIB: European Investment Bank; MedPIET: Mediterranean and Black Sea Programme for Intervention Epidemiology Training; ODA: overseas development assistance.

Outside these multilateral negotiations, the EU has concluded many regional and bilateral trade and investment agreements. These agreements tend to mirror the breadth of the existing multilateral agreements and frequently go beyond them in terms of the level of trade liberalization, intellectual property protections or investor protections that they contain.

Trade agreements and institutions present opportunities to govern the trade of goods and services in ways which can affect health. How this plays out in practice depends not just on the framing of health within these institutions and laws, but also on the intent of the actors operating within them.[8] The extent to which the global trading system impacts health depends upon the ways in which political actors use the system and the goals that they pursue – which may or may not be health goals.

To date, the EU has shown considerable reluctance to make liberalizing commitments directly affecting health services under its trade agreements and has striven to balance access to medicines with protecting its pharmaceutical industry in TRIPS-related discussions and debates. This reflects both the unease of Member States regarding EU policies that could destabilize their healthcare systems, and the concerns of the public and public advocacy groups surrounding health access. Under the TFEU, the EU's trade policy became part of the ordinary legislative procedure, granting an expanded role for the European Parliament in trade policy decision-making. Nevertheless, any agreement in health services "where these agreements risk seriously disturbing the national organization of such services and prejudicing the responsibility of Member States to deliver them" (Article 207 TFEU) requires unanimous approval from Member States.

Public health advocates have strongly criticized what they view as a lack of transparency and attention to public interest issues in trade negotiations. In the case of the Anti-Counterfeiting Trade Agreement (ACTA), an intellectual property agreement negotiated among the EU, the United States and nine other industrialized states, these concerns were shared by the European Parliament, which in 2012 voted against the legislation by 478 votes to 39, with 165 MEPs abstaining. This vote reflected "unprecedented direct lobbying by thousands of EU citizens who called on it to reject ACTA, in street demonstrations, e-mails to MEPs and calls to their offices". Similar concerns were raised by advocacy groups regarding the now defunct Transatlantic Trade and Investment Partnership, particularly in regard to proposals to include an Investor-State Dispute Settlement (ISDS) procedure – a type of redress mechanism that allows firms to initiate

8 Jarman H (2019). Normalizing tobacco? The politics of trade, investment, and tobacco control. *Milbank Quarterly*, 97(2):449–79.

international commercial arbitration directly against governments in response to policies perceived as unfair, unreasonable or disproportionate.[9]

The EU and its Member States can also be the targets of trade or investment disputes. Firms have used these mechanisms to challenge the regulations in a number of health-related areas, including chemicals, medicines, the environment and tobacco. Globally, the tobacco industry has demonstrated its willingness to utilize trade and investment disputes to challenge countries' tobacco control policies, although challenges within the EU have been brought before the CJEU and have so far not proven fruitful for opponents of tobacco control (see Section 3.2).

7.3.2 Public investment

European public investment is a mechanism in which the EU partners with public and private bodies to mobilize investment and manage the risk involved.

There are several instruments that the EU uses towards public investment in global health. The most recent policy strategy is Global Gateway, meant to leverage and boost investments in infrastructure, digitalization and modernization of health systems. Global Gateway is a strategy that focuses on global action and the spillover effects from internal action. An example of a funding instrument is EU4Health, which dedicates budgets to health initiatives and can incorporate global partners.

Overall, EU public investment plays a small role in global health as currently understood (especially relative to development aid, see Section 7.3.3) but it is important to note that health is not excluded from these instruments, which often include international partners of various kinds, and that it might be an area where the EU can develop a mutually beneficial role in global health finance.

7.3.3 European development aid

The EU is the world's largest donor and health is a major component of European aid. If we consider the collective impact of the EU and its Member States, Europe's importance is even greater – the EU and its Member States provided 46.2% of the world's total overseas development assistance (ODA) in 2020.[10] We can

9 For ISDS and health in general, see Jarman H (2014). *The politics of trade and tobacco control*. London: Palgrave Macmillan. For more detail on the EU dimensions, see Jarman H & Koivusalo M (2017). Trade and health in the European Union, in Hervey TK, Young C & Bishop L (eds). *Research Handbook on EU Health Law and Policy*. Cheltenham: Edward Elgar Publishing, pp. 429–52. For TTIP in particular, see Jarman H (2014). Public health and the Transatlantic Trade and Investment Partnership. *European Journal of Public Health*, 24(2):181.

10 Annual Report 2021 to the European Council on the EU Development Aid Targets: Council conclusions (14 June 2021).

only give here a very abbreviated account of this complex world in which the EU is a very important actor.

Broadly, aid comes in two categories: relief and development. Relief is aid in response to particular humanitarian situations such as war, natural disasters, displacement of peoples and famine. Development aid is geared towards longer-term assistance in areas such as education, health and economic development. The leading DG for development is DG INTPA, the Directorate-General for International Partnerships. For humanitarian crises and relief, the lead DG is DG ECHO, the DG for European Civil Protection and Humanitarian Aid Operations. In relief, the EU provides aid and also operates RescEU, the EU Civil Protection Mechanism (see Section 3.3) which assists victims of natural or human-caused disasters globally and, more recently, in the EU.

European Union development aid touches on many areas of health. Health priorities[11] range from strengthening health systems, to assistance with international health regulation implementation, to contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria. It provided around €2 billion annually of total development in the budget ending in 2020. Climate finance and sustainable growth are the key EU priorities, although the EU endorses all of the SDGs in its foreign aid. The 2017 EU Consensus on Development calls for the EU to spend 20% of aid on health and social inclusion.[12] That said, the EU global health budget probably undercounts the contribution to EU development aid to health, since aid in areas such as nutrition and literacy almost certainly contributes to better health.[13]

The COVID-19 pandemic has not increased European governments' sense that they can afford international development aid, and Commission proposals for a substantial expansion of the ODA budget were rebuffed. The EU ODA budget largely remains flat in the 2021–2027 MFF, and a number of Member States are cutting their ODA commitments. The new vehicle for ODA is Global Europe, with a commitment of just under €80 billion for the seven years of the MFF, with a mixture of geographic (e.g. neighbourhood, the Americas) and thematic

11 Available at: https://ec.europa.eu/europeaid/sectors/human-development/health_en (accessed 20 February 2022).

12 European Commission (2017). *The New European Consensus on Development, "Our World, Our Dignity, Our Future"*. Joint statement by the Council and the Representatives of the Governments of the Member States meeting within the Council, the European Parliament and the European Commission. *Official Journal*, 2017/C 210/01.

13 Greer, S. L., Falkenbach, M., Wismar, M., & Figueras, J. (Eds.). (2023). Health for All Policies: Health Policy and the Sustainable Development Goals. Copenhagen: WHO Regional Office for Europe and European Observatory on Health Systems and Policies. Available at: https://eurohealthobservatory.who.int/publications/i/making-health-for-all-policies-harnessing-the-co-benefits-of-health (accessed 11 August 2024). Siciliani L & Cylus, J (eds) (2024). How do Health Systems and Health contribute to the Sustainable Development Goals? *Health Policy*. https://www.sciencedirect.com/special-issue/109ZSZT6Q78.

commitments. There is no specific health theme but themes such as Global Challenges and Civil Society Organizations obviously have health dimensions.

7.3.4 Solidarity, voice and multilateralism

An organization such as the EU affords its Member States, and civil society, a strong voice in global politics.[14] Some regional organizations in the world, such as ASEAN, try to develop a common voice in order to influence donors. In the case of the EU, the common voice gives it weight in international organizations, where meetings of the World Health Assembly feature EU Member States speaking in coordinated statements.

The same 2010 Communication and Council Conclusions[15] that underpin the EU's development aid also encourage the EU to develop its own policy coherence among different elements of the EU that affect global health, including trade policy, health policy, civil protection policy and development aid. It also calls on EU institutions and Member States to support WHO, including a reduction in earmarked funding.[16]

It is important to distinguish between the voice of the EU itself, typically speaking through the Presidency of the Council, the High Representative or sometimes the Commission, and coordinated or other statements by its Member States. In a venue such as the G20, the EU voice need not echo Member States and speaks only for its own budgets and policies; the EU can be a vehicle for coordination of Member State views but in the absence of specific legislation cannot constrain what they do in their own diplomacy and with their own budgets. If we bear this in mind, the extent to which EU Member States do coordinate with one another and the EU institutions is impressive.

7.3.5 Research and training partnerships

Research and training continues to be an essential part of the EU's science diplomacy strategies. Science diplomacy is a method by which the EU overcomes

14 Greer SL, Amaya AB, Jarman H, Legido-Quigley H & McKee M (2022). Regional International Organizations and Health: A Framework for Analysis. *Journal of Health Politics, Policy and Law*, 47(1):63–92. doi: 10.1215/03616878-9417456.

15 European Commission (2010). *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions. The EU Role in Global Health and Council Conclusions on the EU role in Global Health*. COM(2010)128 final. 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.

16 For a broader and more reflective analysis, see Hervey TK (2017). The EU's (emergent) global health law and policy, in Hervey TK, Young C & Bishop L (eds). *Research Handbook on EU Law and Policy*. Cheltenham: Edward Elgar Publishing, pp. 453–78.

limitations placed by international borders,[17] using global health initiatives to form partnerships that improve global health schemes. The EU's place in global policies and use of research and training partnerships to further global health research "cannot be understated".[18] This is reflected in the EU's 2022 Global Health Strategy, in which research and training partnerships help support healthcare capacity (Principles 3, 6), address information imbalances (Principles 6, 7, 8), and expand on current partnerships (Principles 17, 18).[19]

Research and training partnerships are not only exchanges of information. There are a variety of methods in which the EU supports research and training. Strategies vary depending on their intended usage. The EU continues to establish partnerships with more regions, with the recent Global Health Strategy including expanding their partnerships with Africa and Latin America.[20] At the same time, other partnerships focus on specific health research goals, such as vocational training (VET programmes) or the European and Developing Countries Clinical Trials Partnership (EDCTP).[21] Thus, differing intended uses lead to differing strategies.

These strategies use the tools of funding, information and technical assistance as ways to support research. Examples of research instruments include Horizon Europe (a funding instrument), the EU–AU Partnership (an information instrument) and Marie Sklodowska-Curie Actions (a technical assistance instrument). These instruments work towards using science as a method to connect the EU to other countries. These partnerships also further global health through their cooperation.

7.4 The European Union's neighbours

The EU's borders are not hard and fast. It has diverse relationships with its near neighbours as different as Türkiye, Liechtenstein and the United Kingdom. Given the very different politics of neighbouring countries, the EU has very different kinds of relationships that have different effects on the health of different people.

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17 EEAS (2022). What is Science Diplomacy? European Union External Action Service. Further information found here: https://www.eeas.europa.eu/eeas/ what-science-diplomacy_en

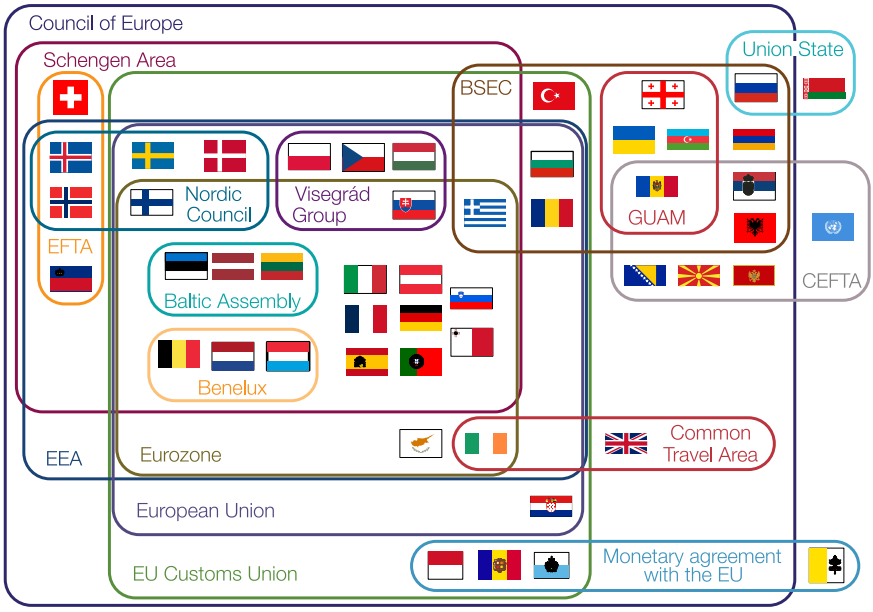
18 Greer et al (2024). *European support for improving global health systems and policies*. European Observatory on Health Systems and Policies.

19 European Commission (2022). *EU Global Health Strategy: Better Health for All in a Changing World*. Public Health: Background document. https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en

20 Ibid.

21 EDCTP (2022). *EDCTP Annual Report*. The Hague, European and Developing Countries Clinical Trials Partnership. Further information found here: http://www.edctp.org/publication/5797/#

Fig. 7.2 *Key EU relationships*



Source: Authors' compilation.

Notes: BSEC: Black Sea Economic Cooperation; CEFTA: Central Europe Free Trade Agreement; EEA: European Economic Area; EFTA: European Free Trade Association; GUAM: GUAM (Georgia, Ukraine, Azerbaijan, Republic of Moldova) Organization for Democracy and Economic Development

Figure 7.2 shows the key relationships in and around the EU: EFTA, the EEA, the Schengen border system and the complexities of United Kingdom relations after Brexit. It shows that there is a variety of ways to engage with the EU for countries that are willing to commit to preserving its standards in relevant areas, and that while the EU is strongly committed to the integrity of its internal market, it is willing to negotiate coherent relationships on other bases such as the customs union with Türkiye or the inclusion of Switzerland in many relationships.

7.4.1 EFTA and Switzerland

The European Economic Area is made up of the EU and three member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway (it excludes Switzerland). EFTA has an interesting history, having originally been led by the United Kingdom as an alternative to the more integrating European communities that led to what is now the EU, but by now is essentially a free trade area, with its own secretariat and tribunal, that is closely integrated with the EU. The complexities of EFTA and the EEA typically have little impact on health policy, although EFTA does have its own arbitration system which could

potentially impact regulatory decisions in health among its members.[22] For most health-related purposes, it simply means that the EEA member states act like members of the EU, as most EU legislation has "EEA relevance".

Switzerland, being an EFTA country but not an EEA one, has a more complex relationship governed by multiple bilateral agreements with the EU.[23] In recent years the EU has become less tolerant of special bilateral arrangements for Switzerland and a health agreement, in discussion since 2008, has not been signed although formal negotiations on a broad package of measures (including health) were resumed in spring 2024.

7.4.2 The United Kingdom

Since Brexit the United Kingdom has had a bilateral relationship with the EU, which is governed by bilateral negotiations and agreements.[24] The 2016 Brexit referendum vote did not specify the form of relationship voters wanted the United Kingdom's relationship with the EU to take.[25] In the subsequent negotiations, Conservative British governments opted for a very so-called hard Brexit model in which there was as little formal integration with the EU as possible. That included refusal of any model in which the European Court of Justice or even ad hoc tribunals (similar to the EFTA court) had jurisdiction over the United Kingdom and an absolute minimum level of commitment to shared regulatory standards. The problem this creates for the EU is that the EU is still very tightly integrated with a country that refuses on principle to adopt the prerequisites of mutual recognition or broad legal frameworks of the sort preferred in EU law. The enormous complexity of EU politics means that written texts are more permanent and important than in the executive-dominated world of British politics, where a majority government can usually rewrite law it finds inconvenient.[26] The result is that the United Kingdom's difficulty committing to agreed legal texts make it an awkward negotiating partner for the EU.

Brexit's biggest health impact is on the wider British economy and politics, and thus on the ability of the United Kingdom to finance and staff its health service,

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22 For example, see *Philip Morris Norway AS v. The Norwegian State*, Case E-16/10, Court of Justice of the European Free Trade Association States (EFTA) Court (2011).

23 Dardanelli P & Mazzoleni O (eds) (2021). *Switzerland-EU Relations: Lessons for the UK After Brexit?* Routledge.

24 For the overall situation, see Greer SL & Laible J (eds) (2020). *The European Union after Brexit*. Manchester: Manchester University Press.

25 This section draws on a series of articles and an ongoing Brexit and health monitoring project led by the Nuffield Trust and supported by the Health Foundation. See: McCarey M, Dayan M, Jarman H, Hervey T, Fahy N, Bristow D and Greer SL (2022). Health and Brexit: six years on. Research report, Nuffield Trust. https://www.nuffieldtrust.org.uk/research/health-and-brexit-six-years-on

26 Jarman H, Greer SL & McKee M (2020). Brexit is just a symptom: the constitutional weaknesses it reveals have serious consequences for health. *Journal of Public Health*, 42(4):778–83.

but from an EU perspective there are three key areas of problematic impact – workforce, health-related products and Northern Ireland. On workforce, the British health services have long had a particular reliance on staff from outside the United Kingdom. The end of free movement for EU citizens to the United Kingdom and the United Kingdom's establishment of an immigration system which puts a premium on a high salary level for entry is likely to exacerbate existing staff pressures in the health service, and even more so for social care (in addition to the effect of pandemic-related stressors on workforce exit). On health-related products, the United Kingdom will now have its own separate market for products such as pharmaceuticals and medical devices. For those products, as well as others that are important to health such as fresh food, Brexit has increased customs requirements at British borders, impacting timely access to the British market for EU producers. Any future movement by the United Kingdom away from EU product regulatory standards will exacerbate this problem.

The impact of being a smaller market with specific rules has been felt in Northern Ireland across a range of sectors, and is likely to also have an impact on health. Northern Ireland has the United Kingdom's only land border, and the particular circumstances of Northern Ireland's peace process mean that a physical, staffed land border is not an option. Simply opening the border, on the other hand, would be an invitation to organized crimes of all sorts (e.g. tax fraud, counterfeiting, food fraud, smuggling). The EU cannot tolerate an open land border, the United Kingdom does not want to adopt EU standards, and so the United Kingdom and EU agreed that there would be checks at the Irish sea crossing between Northern Ireland and the rest of the United Kingdom, with Northern Ireland functionally inside the EU for many regulatory purposes. This solution caused further problems since it creates what amounts to an international border for goods within the United Kingdom. British governments are understandably concerned about an arrangement that affects their sovereignty and leaves them with a free trade area that is actually smaller than their country. From the EU point of view, credible commitment by the United Kingdom to harmonization in specified areas, and a pragmatic agreement on an Irish sea customs border, would resolve the problems, but those are the two things that up until now United Kingdom governments would absolutely refuse. A series of temporary solutions (called grace periods) were eventually replaced by the Windsor Framework, negotiated in early 2023, which brings in new arrangements, including for medicines, from 1 January 2025. In essence, these involve the EU accepting that some products will not move from Northern Ireland into the EU, and therefore should not be treated as crossing the EU's external border when they move from the rest of the United Kingdom into Northern Ireland.

However, the picture is not all negative. In some areas bilateral arrangements are working so far. Patient mobility is beneficial to the United Kingdom and a

few Member States (e.g. Spain), so it has not turned out to be a major issue in negotiating the relationship. The United Kingdom has prioritized participation in EU research funding programmes and in 2023 it was announced the United Kingdom would become an associate member of Horizon Europe.[27] Reciprocal arrangements for social security, including access to healthcare, have been largely carried over into the new relationship between the United Kingdom and the EU. In the longer term the United Kingdom has scope to exercise its new policy scope in areas such as public procurement in ways that may make life easier for its health system (and which might give EU policy-makers some ideas).

The effects on the policies and health of the rest of the EU are less clear. The departure of the United Kingdom reduces the size of the EU population, economy and budget, with effects on its position in world affairs. It also has more impact on those parts of the EU that are closest to the United Kingdom – in the first instance Ireland, where managing the political and practical issues around Northern Ireland have already proved difficult. There is also an impact on those states that have been politically close to the United Kingdom, or where there are specific links related to health. One example is medicines supply in Ireland, Cyprus and Malta. Another is healthcare professional capacity building in Central and Eastern European states.[28] More broadly, the United Kingdom's new position as a distinct regulatory regime next to one of the largest economies in the world not only means loss of regulatory capacity from the EU, particularly in bio-medicine, but also will create challenges, and the choices that the United Kingdom makes in the coming years will have an impact on health and healthcare.

The EU after Brexit does not just have the ongoing policy agenda of managing relations with the United Kingdom or rebuilding policy expertise in areas where it depended on the United Kingdom. It also has a new politics in which liberalization is less politically powerful, and France is relatively empowered. Brexit weakened the liberal block in the EU that has promoted deregulation through the internal market.[29] Crudely, Germany used to be a hinge that could side with the United Kingdom or France; the departure of the United Kingdom means that France is a veto player, a development that empowers France and like-minded Member States. Brexit expands their options while constraining Germany and northern so-called liberal countries. That will be a new experience for those most familiar with the EU since British accession in 1973.

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27 United Kingdom Government (2023). *UK joins Horizon Europe under a new bespoke deal*. Available at: https://www.gov.uk/government/news/uk-joins-horizon-europe-under-a-new-bespoke-deal (accessed 5 June 2024)

28 T Hervey, et al (2021). Health "Brexternalities": The Brexit effect on health and healthcare outside the EU, in K Fierlbeck, ed, special issue on Health Care and the Fate of Social Europe. *Journal of Health Politics, Policy and Law* (2021) 46:177-203.

29 Greer SL & Laible J (eds) (2020). *The European Union After Brexit*. Manchester University Press.

The United Kingdom and the EU are not entirely comparable and do not have a symmetrical relationship. In most of the United Kingdom-EU debates, the United Kingdom matters less to the EU than vice versa, simply because the United Kingdom is a smaller economy. The EU makes up a much larger share of British trade than the United Kingdom does of any Member State's economy, and some Member States have very low economic exposure to the United Kingdom. Furthermore, United Kingdom–EU relations have been a major point of domestic political contention in the United Kingdom while they are of little interest to voters in any EU Member State. This means that the EU can tolerate damaging blockages more easily than the United Kingdom, but also means that the importance of EU relations to British governments is much higher. In general, there is no off-the-shelf EU formula for managing relations with a country as large, tightly integrated and independent-minded as the United Kingdom. A stable relationship might demand that the United Kingdom modify its approach to the EU over time, by for example committing long-term to the same food safety, sanitary and phytosanitary, and medicine and medical devices standards as the EU. It also might hinge on mechanisms for adjudicating disputes, given that the EU views the CJEU (or EFTA court, where appropriate) as the final arbiter of its law and that the United Kingdom has so far resisted giving any such post-Brexit authority to those courts. Some framing ideas for models for future EU–United Kingdom health relationships are in Box 7.3.

7.4.3 Accession candidates

Being a candidate for EU accession is a distinctive legal status. Candidates must satisfy the EU Member States that they have fulfilled rule of law and democratic criteria, and adopted the entire body of EU law (*acquis communautaire*) as well as fiscal governance. Member States can have permanent opt-outs and special dispensations, but candidates have much less leeway to diverge from standard EU laws and procedures. In addition to fulfilling shared requirements, the terms of the accession are negotiated country by country, and any EU Member State can veto admission or stop negotiations. Once a country is a Member State, many of the obligations placed on candidates go away. For example, the EU's ability to police the rule of law is much greater before accession than after, although this may be changing in response to persistent and serious violations of the rule of law by some Member States.

The nine recognized candidates for accession to the EU are Albania, Bosnia and Herzegovina, Georgia, the Republic of Moldova, Montenegro, North Macedonia,

Box 7.3 *How might EU–United Kingdom relationships change in relation to health?* [a]

As has been illustrated earlier in this section, there are many more possible models for relationships between the EU and the United Kingdom than the binary question of "in or out". The United Kingdom is unlikely to seek to rejoin the EU in the foreseeable future, to say nothing of how acceptable such an aim would be to the EU. But equally, staying as far "out" as at present is likely to be undesirable for both the United Kingdom and the EU in the long run. This is the case for many reasons, and health policy is one of them. The over 40 years of collaboration, harmonization and integration between the EU and the United Kingdom in many things relevant to health, such as people, products, services, research and health security, have left connections and dependencies that the current arrangements do not address effectively.

There is no single model for the character that a closer future relationship might take. Rather, there are a number of dimensions along which this relationship could develop that are of relevance to the health community.

Memoranda of understanding, e.g. mutual recognition of qualifications arrangements made by professional organizations	"Enhanced" third country status e.g. Horizon Europe; European Research Networks	Renegotiated EU-United Kingdom TCA with either more or less alignment (e.g. no longer data adequacy of United Kingdom; no longer GMP recognition for medicines)

E.g. collaboration on social security coordination; cooperation on infectious diseases and AMR	E.g. clinical trials collaboration including data sharing; epidemiological data sharing	Health treaty (taking areas of health outside of EU–United Kingdom TCA, for mutual benefit)

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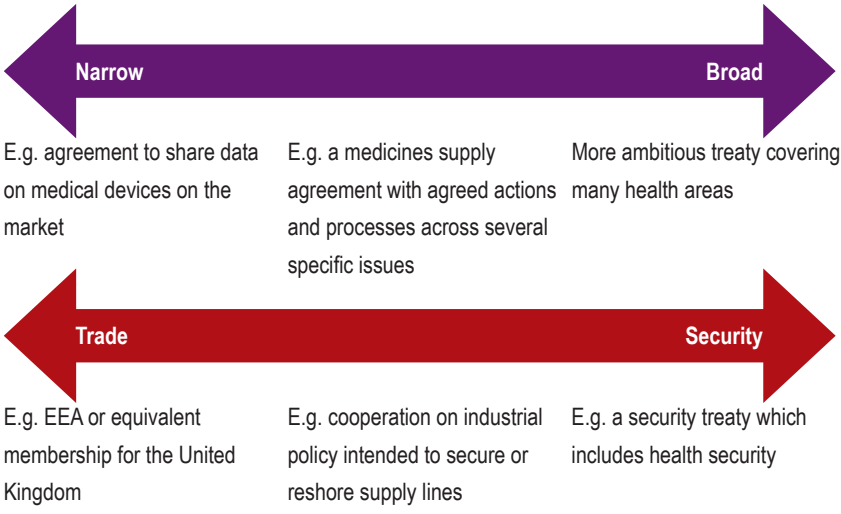

Where on these dimensions the United Kingdom's future relationships with the EU land will depend on factors well beyond health. These include the political willingness of the EU and the United Kingdom to make concessions, considerations of trade and economic advantage across sectors, and the institutional arrangements seen as acceptable to both the EU and the United Kingdom.[b]

Notes: AMR: antimicrobial resistance; EEA: European Economic Area; GMP: good manufacturing practice; TCA: Trade and Cooperation Agreement.

a This Box is co-authored with Mark Dayan and Tamara Hervey.

b Dayan M, Hervey T, McCarey M, Fahy N, Flear M, Greer S, Jarman H (2024). *The future for health after Brexit*. London: Nuffield Trust.

Serbia, Türkiye and Ukraine. Kosovo[30] is recognized by the EU as a potential candidate, although there are some important barriers to its candidacy (for example, not all EU Member States recognize Kosovo as a state). The candidacies of the Republic of Moldova and Ukraine were recognized in 2022 and that of Georgia in 2023. Not all these candidacies are proceeding at the same pace and some might never lead to accession.

Accession candidates have strong political and legal incentive to align their policies with the EU as they start to adopt the acquis communautaire. They can also receive EU aid directly intended to assist them in preparing for accession, organized by DG Neighbourhood Policy and Enlargement (DG NEAR) through the Instrument for Pre-Accession Assistance (IPA III) and participate in or benefit from EU policies such as EIB loans. The status of enlargement negotiations is

30 Note that the designation of Kosovo is without prejudice to positions of status, and in line with the United Nations Security Council Resolution 1244/99, and the International Court of Justice opinion on the Kosovo declaration of independence.

kept up to date on the DG NEAR website. There are particularly serious concerns for all the accession candidate states in the area of food and phytosanitary safety, and social policy and employment.

7.4.4 European neighbourhood policies

Neighbourhood policies refer to those directed at the EU's close southern and eastern neighbours. To the south, that means Algeria, Egypt, Israel, Jordan, Lebanon, Libya, Morocco, State of Palestine, Syrian Arab Republic and Tunisia. To the east, that means Armenia, Azerbaijan, Belarus and Georgia. As the list makes clear, Europe lives in a complex and diverse neighbourhood, and it is hard to develop policies for relations with these countries as a group. Tunisia and Libya, or Belarus and the Republic of Moldova, are in quite different situations with quite different orientations towards Europe. There has been relatively little health content in recent neighbourhood policies, which tend to be focused on a variety of security issues, although the new approach to southern neighbourhood countries includes substantially more references to healthcare and health.[31]

The Russian Federation participated in some neighbourhood policies but generally preferred to deal bilaterally with EU Member States. In the past the Russian Federation and some of its regional governments did participate in some surveillance and other networks, e.g. the communicable disease surveillance joint action EPINORTH (which ended in 2012). A Dialogue on Public Health took place from 2009 but did not result in any concrete, operational policy. Given that the Russian Federation's 2022 invasion of Ukraine led to the freezing of most EU–Russian collaboration, it is not reasonable to expect much more.

Issues of migration and security, not health, dominate relations to the south,[32] and so the health dimensions of these relations emerge from a policy focused on migration. Türkiye had received €6 billion through a programme called the EU Facility for Refugees in Turkey by the end of 2020 and which is programmed to run through to 2025. The explicit goal of this programme is to allow Türkiye to manage flows of refugees who would otherwise attempt to enter the EU. It was created in 2016 and was substantially responsible for the end of 2015's highly controversial refugee movements. It is linked with discussions of liberalizing EU visas for Turkish citizens. Libya is a failed state, a zone of serious human rights violations, and a jumping-off point for many refugees and undocumented migrants in the extremely dangerous sea crossing to Europe. European Union

31 European Commission (2021). Renewed Partnership with the Southern Neighbourhood Economic and Investment Plan for the Southern Neighbours (SWD(2021)23 final). Brussels, 9 February 2021.

32 Del Sarto RA & Steindler C (2015). Uncertainties at the European Union's southern borders: actors, policies, and legal frameworks. European Security, 24(3):369–80. Del Sarto R & Tholens S (2020). *Resisting Europe: practices of contestation in the Mediterranean middle east*. University of Michigan Press.

interests in a stable Libya that can control both outbound migratory flows and the organized crime associated with undocumented migration, let alone one with any respect for human rights and democratic governance, have not been easy to realize.

In this broader context, the European Neighbourhood Policy has changed quickly. The year 2020 marked the conclusion of the European Neighbourhood Instrument, which was the 2013–2020 funding programme, and saw the integration of neighbourhood funding into the broader Global Europe programme, which guaranteed just under €20 billion over the seven years of the current MFF. Thematic areas of Global Europe and the emergency unallocated so-called cushion in Global Europe could also lead to support for neighbourhood policies.

Most EU neighbourhood policies involve bilateral cooperation, given the diverse political difficulties in the region. It also supports regional groupings such as the Eastern Partnership and Union for the Mediterranean. The EU suspended all bilateral cooperation with the Syrian government in 2011. The EU Regional Trust Fund in Response to the Syrian Crisis supports refugees from the Syrian Arab Republic and locals affected by the refugee flows and crisis in Lebanon, Egypt, Türkiye, Jordan, Iraq and the Western Balkans, and the previously mentioned separate Facility for Refugees in Turkey supports refugees in Türkiye. Its health dimension, which complements other aspects of the programme such as education, water and sanitation, supports primary care and access to medicines, and targets over a million refugees.

The lead DGs for neighbourhood issues are, unsurprisingly, DG NEAR (DG European Neighbourhood and Enlargement Negotiations) and to a lesser extent DG ECHO (European Civil Protection and Humanitarian Aid Operations) and the European External Action Service, which is not part of the Commission and responds to the EU's High Representative of the Union for Foreign Affairs and Security Policy. DG REFORM is responsible for a number of functions to do with Cypriot reunification.

Health is not one of the four neighbourhood policy priority areas, which have been recast around governance, economic and social development, security and cooperation against radicalization, and migration and mobility. It is not even in the second tier of priorities around energy, security and climate action. Some health projects are being funded, but primarily under other priorities. This is in contrast to the older iterations of the European Neighbourhood Policy, which pre-dated many of the current security concerns arising both east and south of the EU and which included more cooperative work on topics such as surveillance, phytosanitary standards and veterinary health. There is a larger component of health-related EU assistance and cooperation with the accession candidate states, particularly those in the Balkans.

The Russian Federation's invasion of Ukraine in 2022 rapidly changed EU priorities. In addition to other forms of aid from individual Member States, the EU set up an aid package of €550 million, much of it health-related humanitarian aid, while the Civil Protection Mechanism provided relevant supplies. The EU also supported the Republic of Moldova, financially and with Frontex deployment, as it sought to manage large refugee inflows. Perhaps most dramatically, Ukraine was agreed as an accession candidate to the EU in 2022. Like the Republic of Moldova and Georgia, Ukraine is a long way away from compliance with EU accession criteria and was much poorer than any EU Member State even before the invasion, but EU candidacy on its own brings tangible as well as symbolic and geopolitical benefits to Ukraine and new engagements to the EU.

7.5 Vaccination politics: the EU, COVID-19, COVAX and beyond

The COVID-19 pandemic presented significant challenges for the EU in global health. One core challenge for low and middle-income countries was procuring vaccines. The key trade-offs for rich powers, including the EU, were between vaccines for themselves and vaccines for others, between vaccine production abroad and domestic producers' intellectual property and interests, and the extent to which the undeniable moral and public health benefits of global vaccination would be a politically advantageous use of money. The fact that many in public health regard each of these trade-offs as having clear answers does not mean that politicians, attentive to industry interests, voters and bond markets, agreed.

Big vaccine-producing powers including China, the EU, the Russian Federation, the United Kingdom and the United States all adopted different strategies. Other active players included countries such as Cuba, with its own vaccine, or production and supply chain powers such as India, which is often nicknamed the "world's pharmacy" for the scale of its production facilities. Most of the big powers opted for various forms of competitive vaccine diplomacy, playing favourites for geopolitical reasons, making decisions with limited transparency, and competing for the favour of public opinion and governments in different countries. The EU, seeing its affinities with multilateral organizations, opted to secure its own supplies, as discussed in Chapter 3, and focus its global vaccines policy on WHO's COVAX facility.[33]

33 Perroud, J. (2025). Multilateral approaches to COVID-19 vaccines. In S. L. Greer, H. Jarman, E. J. King, & E. Massard da Fonseca (Eds.), *Vaccination Politics: The comparative politics and policy of COVID-19 vaccination*. University of Michigan Press. Greer, S. L. (2024). The European Union. In S. L. Greer, H. Jarman, E. J. King, & E. Massard da Fonseca (Eds.), *Vaccination Politics: The comparative politics and policy of COVID-19 vaccination*. University of Michigan Press.

COVAX was set up by WHO in April 2020 to procure vaccines and either sell or donate them to countries, depending on the country's income (in early 2020, placing bets on multiple vaccines was sensible because it was not clear that so many of the vaccines would be so effective). The basic moral commitment of COVAX was that no country should be more than 20% vaccinated until all countries were vaccinated. Unsurprisingly, COVAX immediately hit a series of problems.[34] Rich and vaccine-producing countries might consider it as a global health policy but were reluctant to depend on it when they had the option of just negotiating advance purchase agreements to secure vaccines for their own populations. EU Member States could participate in COVAX or the Vaccines Strategy; unsurprisingly, they all opted for the Vaccines Strategy route. Once COVAX became a tool of global health aid for them, it immediately fell prey to the temptations of vaccine diplomacy and underfunding.

The EU became one of the biggest contributors to COVAX, using it, and its allocation priorities, as its main tool for promoting vaccination. On 21 May 2021 European Commission President von der Leyen announced that the EU would share at least 100 million doses with low and middle-income countries by the end of 2021, mainly via COVAX. Von der Leyen then announced in July that the EU and its Member States were "on track" to share 200 million doses.[35] By October the EU had delivered 87 million doses via COVAX, and could claim to be the largest exporter of COVID-19 vaccines in the world.[36] Aside from donating vaccine doses, the EU and its Member States contributed close to €3 billion to COVAX, and the Commission has striven to boost vaccine manufacturing capacity in Africa, an initiative backed by €1 billion from the EU budget and European development finance institutions such as the European Investment Bank (EIB). Individual Member States could donate vaccines as they chose. For example, in August 2021 France donated 10 million doses to Africa through COVAX and the African Union (AU). But overall, the EU as a whole became a much more central part of COVAX's support than any one Member State. Without the EU's support for COVAX, the level of global inequality in vaccinations would have been even worse.

Defining vaccination as a form of foreign aid was problematic from a public health perspective. Not only do many see the scale of international inequality in vaccines as an outrage, but the failure to have any credible plan to vaccinate billions of people maximizes the odds that the evolution of the virus defeats the

34 Phelan AL, Eccleston-Turner M, Rourke M, Maleche A & Wang C (2020). Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access. *The Lancet*, 396(10254):800–2.

35 European Commission (2021). *Vaccinating the world: 'Team Europe' to share more than 200 million doses of COVID-19 vaccines with low and middle-income countries by the end of 2021*. Press release, 22 July 2021. Brussels.

36 Statement by President von der Leyen on Vaccine Exports. 18 October 2021. Brussels. Available at: https://ec.europa.eu/commission/presscorner/detail/en/statement_21_5341 (accessed 20 February 2022).

very effective vaccines used in rich countries. One of the obvious solutions is to relax or end patents on the vaccines so that low and middle-income countries can produce them. The EU, like other big powers, has not shown much interest in this despite pressure from civil society. It remains an open question whether the global public good of vaccine protection can be provided if most of the world depends on charity in the context of rigidly enforced property rights. Judging by the underfunding of COVAX and the limited vaccines distributed through vaccine diplomacy, the answer is no.

7.6 Conclusion

It is tempting to think of global health governance, trade or other such policy areas as separate from health policy or even public health. That is not possible in the context of the EU. The EU is a major actor in global health by virtue of its economic size and power, its considerable status as an international donor, and its influence on global governance. It is not possible for an economy as large and globally connected as the EU to avoid creating externalities for other countries, or to avoid the externalities of their policies. We saw this connectedness at work with the spread of the 2008 financial crisis to the EU's public debt markets, and the spread of COVID-19 from 2020 onwards.

This chapter has very briefly shown some of the externalities that drive health engagement by the EU and the arenas in which the EU engages, from its near neighbours to global health debates. Any Member State economy is a small, open economy, but the EU collectively is a powerful economic actor which shapes global economic governance and global health policies. It had a global health policy long before it had a Global Health Strategy; the strategy starts to make clear what that policy should be and what its goals should be. Both Europe and global health can be more than the sum of their parts.

There are a number of tensions in EU policy which stem from not just its own complex politics but also the difficulties of managing diverse problems in an increasingly fragmented and contested world political arena. How do EU policy-makers balance their intense interest in border security and migration against their commitments to human rights and stable, just development in their neighbourhood? How do they balance their own interest in high-technology industries dependent on intellectual property rights with their commitment to development and global health (a particularly challenging issue given the very unequal distribution of COVID-19 vaccines and the resistance of industry to more global, diffuse production)?

The EU Global Health Strategy is now an established framework guiding the EU's approach to global health. The strategy reflects the EU's commitment to playing a leading role in global health, particularly in the context of increasing global challenges such as pandemics and climate change. The strategy emphasizes improving global health security, ensuring equitable access to healthcare, and promoting better health outcomes worldwide.

Since the launch of the strategy in 2022, the EU has positioned itself as a more central actor in global health governance, fostering stronger collaborations with international organizations such as WHO and the G7/G20. The strategy has also increasingly been integrated with other EU policies, including climate action, digitalization and trade. By doing so, the EU ensures that health considerations are embedded across its broader policy agenda. Finally, a new monitoring framework has also been established to track the implementation and impact of the strategy. This framework includes regular assessments and reporting mechanisms that track progress, identify challenges, and adapt strategies to meet evolving global health needs. The EU has long been a major power in global health; it is now committed to using at least some of that power in a more strategic and coherent way.

Chapter 8

Conclusion

8.1 Why is it hard to see EU health policies?

The abiding irony of EU health policy is that most of it has not been made as a health policy in any normal sense of the term. The interests, organizations and arguments that are common in the health policy arena of the Member States are fragmented and poorly represented at the EU level. Payment systems, hospital management, primary care coverage or technology diffusion might be the sorts of issues health ministries think about all day in the Member States, but in the EU they are scarcely visible.

When health policy issues do appear on the EU agenda, they do not look the same. Health policy issues, including very important ones, often appear in forms that are difficult to understand in the traditional language of health policy. Workforce reappears as discussions of professional qualifications, primary care as part of fiscal governance, technology as a debate about EU-level health technology assessment programmes, and finance as an intricate set of compliance issues to do with state aid and competition.

Policies are not just reframed in different languages and conceptual frameworks, but also reflect the different, asymmetric institutions of the EU. That is, because as discussed throughout this book, EU policies affecting health are made in all sorts of other ways, under all sorts of guises, and in all sorts of other venues: as fiscal governance, as environmental, labour or social policy, or as internal market law and regulation.

European Union public health policy, discussed in Chapter 3, is closest to what health policy means in the Member States: actions taken to address causes of avoidable morbidity and mortality, whether through ensuring the safety of blood products, by developing epidemiological capacity through ECDC, by facilitating data gathering and comparison, or by supporting investments in healthcare infrastructure. These are areas in which the EU can and does take direct action to promote health.

They are also the areas with the weakest policy instruments, grounded in a Treaty article that is a lexicon of words used to limit EU action and which has an entire section underlining that the organization and finance of healthcare services is the responsibility of the Member States. The 2017 White paper on the future of Europe (the so-called five futures report) by the Commission suggesting post-Brexit options for the EU went so far as to suggest that the EU could exist without activity in public health at all.[1] No serious report, by contrast, suggests wholly eliminating EU market integration or product regulation. There would be little left of the EU were that to happen.

Market integration and regulation are more important health policy mechanisms, as discussed in Chapter 4. They are the basis on which the EU as we know it was built, and they are the basis on which the most important policies affecting health have been made to date, including laws directly affecting healthcare issues such as professional mobility, patient mobility, pharmaceutical and medical devices regulation, competition law and law on state aid to industry. They mean different things, however, depending on the policy sector. The EU's legal commitment to a single internal market, one that much of its machinery is set up to enact, is deregulatory and good at undermining Member State protectionism. It is also good at re-regulating at the EU level, replacing varied Member State regulatory regimes with a European baseline set of rules that enable mutual recognition. The result is a pattern of deregulation at the Member State level and, often, of re-regulation within a European structure. We see this, for example, when EU professional mobility rules come with reforms of professional training that allow Member States to have greater trust in the training and qualifications of each others' practitioners – and allow Member States an opportunity to reform their own workforce policies if they so choose.

The re-regulatory aspect of European internal market policies has not always been appreciated in health policy conversations. The impact of many EU internal market policies on healthcare systems has had much more immediately visible costs than benefits. The benefits of applying competition, state aids or even patient mobility law to healthcare systems are less obvious to health systems than the costs of lobbying and compliance that they initially created.

Further, many of the health benefits of the deregulatory/re-regulatory dynamic did not travel through the healthcare system. Instead, they travelled through other areas of the Treaties discussed in Chapter 2, especially environmental law, consumer protection and social policy law. Addressing issues such as food safety, pollution, occupational health and safety and climate change undoubtedly saved many lives by attacking major determinants of health, but was not cast in health policy terms and the positive impacts for health were thus less recognized. Of

1 European Commission (2017). *White Paper on the Future of Europe: Five Scenarios*.

course, for all the good they did, they also regulated healthcare systems, creating compliance issues for healthcare systems just as they did for any regulated organization. In the most striking case, the Working Time Directive, a measure that was almost certainly good for population health and well-being, created enormous headaches for healthcare systems that were dependent on very long hours worked. It is easy to find complaints about the Working Time Directive and its impact on healthcare providers in the healthcare literature, particularly the English language literature; far rarer, to find estimates or appreciation of its health benefits in reduced harm to both patients and professionals. Put together, the result is that many of the biggest positive health effects of the EU have been outside healthcare, while many of the specific extensions of internal market law to healthcare have caused visible new problems with less visible initial benefit.

The second reason that the impact of the EU on health has not always been appreciated is that the EU, for all the force and potential benefit of its regulations, is still fundamentally a regulatory state. If the goal can be addressed with regulation and law, whether it is deregulating telecommunications or promoting gender pay equity, the EU is powerful. If other mechanisms such as governance, information or targeted funding can work, then the EU can be effective (see Chapter 2). But if it requires redistribution, either between Member States or between people, the EU is extremely weak. It can make and regulate markets, and make limited investment in infrastructure to support them, but compensating people who face losses in those markets is up to the Member States.

This is the underlying constitutional asymmetry of the EU. It can make rules and markets but not compensate for their effects. The ability of the EU to effect change through law, deregulation and regulation far exceeds its ability to effect change through funding or the direct provision of services.

Furthermore, the EU has been better at deregulation than re-regulation. The principle of non-discrimination that underlies so much EU law and policy is best used as a tool for undoing Member State regulation through legal challenge, while re-regulating that which has been deregulated through EU law is a slow and awkward process that has lost momentum in recent years as the EU's overall political complexion has changed. Put another way, the EU's real ability to make and correct markets is far greater than its ability to compensate for the effects of those markets.

Nor is it clear that the EU fiscal governance approach, which focuses on reducing imbalances and promoting budgetary rigour in each Member State, will prevent crises arising from the large internal imbalances and persistent divergences within the EU. The EU's fiscal governance system might have become more subtle and useful as a policy tool, and even given some additional health-promoting content and political force to its social policy suggestions, but there is room to doubt

whether it will fulfil its key goal of preventing future crises. The mutualized EU debt that underpins the RRF might look in historical perspective like a big shift towards an EU that supports its Member States on more than an individual project basis, but that remains to be seen.

8.2 From COVID-19 to the next MFF: where does EU health policy go next?

COVID-19 prompted dramatic changes to EU health policy, as detailed in Chapter 3. The sums of money involved and the scale of institution-building in both the ECDC's expansion and in plans for HERA are impressive, and the Vaccines Strategy a significant moment for EU solidarity. They show that Member States could indeed open the gate with no fence. The reasons are no surprise: EU Member States discovered in a crisis that they could not go it alone.

The changes to EU health policy are nonetheless striking. The Member States did not open the gate to just anything. They are still clearly interested in containing EU health policy entrepreneurship, as shown by their choice of policy instruments (existing ones and new executive agencies rather than freestanding agencies; see Chapters 2 and 3). They are not interested in subsidizing each others' healthcare costs nor in significant redistribution between Member States. That is both politically easy to understand and a problem given that convergence between poorer and richer Member States in a highly unequal union is slow, and was sent into reverse by the 2008 global financial crisis.[2]

The risk to the new EU health policy approach discussed in Chapter 3 is that Member States and EU politicians will lose interest in it. On one hand, it is a regular feature of public health that it gains attention and support in crises and loses it as the threats lose their salience. The 2020 discovery of stockpiles full of items that were purchased in 2009 to respond to H1N1 and expired in 2019 are a testament to that problem. What seemed urgent in 2009 – and in 2020 – did not seem as important in 2018 and 2019.

On the other hand, there is scope for the EU to disappoint Member State politicians. The first months of the Vaccines Strategy highlighted this risk, with the EU in legal disputes with AstraZeneca and the British government and blamed for a lack of vaccine supply, with Member State governments and regulators often uncoordinated and more interested in their own projects. EU Member States had adequate vaccine supplies by the summer of 2020 such that some had achieved

2 See https://www.eurofound.europa.eu/en/resources/eu-convergence-monitoring-hub (accessed 23 July 2024).

excellent vaccination coverage by the end of August, but it is worth reflecting on the experience to understand ways in which the EU could be perceived to have underperformed when all this investment comes up for review in the next round of budget negotiations. The immense sums of money flowing through EU health and civil protection policy offer many opportunities for mistakes, and the credibility of EU action on health will be best served by avoiding them.

In a sense, these two risks amount to the same thing: the risk that Member State governments, in particular, will cease to see the case for EU health policy, whether through disillusion or complacency. The task for EU institutions and advocates of a larger role for the EU in health policy will be to work against that risk. Because so much of the EU's post-pandemic health policy is in budgetary instruments, such as EU4Health and RescEU as well as support for ECDC, HERA and such, it is vulnerable to budget cuts, as has already been seen with EU4Health. Public health suffers from a cycle of panic and neglect, and we are entering into the neglect phase of the cycle.[3] If we are still in the neglect phase come the negotiations for the next MFF budget framework (see Chapter 2), we may see 2020's advances rolled back. The politics will be difficult, and the imperative will be to show the value of EU health policy to governments of every stripe.

Against this, we can note considerable reserves of European popular support for the EU's capabilities and role in health crisis management. In June 2024, 61% of respondents told Eurobarometer that they expected the EU's response to a future health crisis such as a pandemic to be effective or very effective (35% expected it to be ineffective or very ineffective), 55% said they thought the EU was better equipped to respond to a major crisis than in 2019, and a striking 81% agreed or "tend[ed] to agree" that the EU should be more involved in crisis preparedness.[4] There is no evidence of a pre-existing collective scepticism about shared European health security and crisis response, or of widespread hostility to the new EU role.

8.3 Rethinking the European health policy space

COVID-19 may have changed health policy and fiscal governance substantially, but the legacy of the EU in health still goes far beyond those areas. A regulatory and deregulatory approach grounded in subsidiarity and the construction of

3 The phrase "panic-neglect cycle" was coined by journalist Ed Yong. Yong, E. (2022). America Is Zooming through the Pandemic Panic-Neglect Cycle. *The Atlantic*, March 22.

4 Eurobarometer (June 2024). *Perceptions of EU crisis management*. https://europa.eu/eurobarometer/surveys/detail/3220.

a single European market might be logically coherent and well established in practice, but it has its limits. There are multiple contradictions in the politics of EU health policy. On the one hand, surveys show popular desire for EU policies that improve health, and working for better health is an obvious way to show the citizens of Europe the benefits of the EU. On the other hand, there is very little support among EU governments for a bigger EU budget or ambitious EU actions that might infringe on Member State responsibility for health policy. Likewise, the EU does much for health, but much of that is understood as something else – as environmental policy, or labour law, or health and safety law, or consumer protection law. Those actions, beneficial for health, often manifest as additional regulation which can irritate people with affected interests while the health benefits are not well recognized. The result is a set of tensions: the most effective EU actions for health are not always understood as health policies, while general popular support for EU actions to improve health collides with weak Treaty bases and weaker political support for explicit EU health actions. But simply announcing that the EU will de-emphasize public health would not solve the problem, since the EU has powerful tools to influence health that it uses in the course of other activities, from digital policy to pharmaceuticals policy to trade policy.

In terms of health policy issues on which the EU is acting, but with questionable policy and uncertain effects, policies to do with ageing are an important issue. Fiscal governance is concerned with the liabilities of governments and the Semester has over various years produced repeated calls for later retirement ages and often-unspecified policy changes to ensure the fiscal sustainability of health systems (see Section 6.4). There is scope for this debate to be more sophisticated, understanding the promotion of active and healthy ageing not just as a way to enable later retirement ages or reduce healthcare needs among older people, but as a way to invest in people across their life course in order that they may make the greatest and most satisfying contribution to their own and others' lives. The Semester has become much more sophisticated in its recommendations, but it, and the EU's overall role in promoting thinking about ageing and health, could still be improved.[5]

If there were support for a stronger and more health-focused EU policy, the response to the COVID-19 pandemic has shown that there is legal space and a range of creative political possibilities. Box 8.1 reports the results of a large public debate on future health priorities for the EU. The policy mechanisms exist: the State of Health in the EU is an instrument to shape the whole narrative of health

5 Cylus J, Normand C, Figueras J, 2019. *Will population ageing spell the end of the welfare state? A review of evidence and policy options*. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies. Greer, S., Lynch, J., Reeves, A., Kalousova, L., Gingrich, J., Falkenbach, M., et al. (2021). *Ageing and Health: The Politics of Better Policies*. Cambridge University Press.

policy in the EU and the Member States. One way is through direct, visible EU health policies with output legitimacy, such as initiatives for research and action against cancer, antimicrobial resistance or the communicable diseases that climate change is bringing back to Europe. Another is through the utilization of powerful EU powers that are not part of Article 168 but which name health. Public concern about chemicals and about the safety of the food system is important across Europe, as is public health concern for the effects of contemporary diets. These are core areas of EU competence and activity, especially in veterinary, agricultural, environmental protection, chemical regulation and food safety issues, and there is great scope for EU leadership should the key political interests align. Likewise, EU law affecting the economy and labour is a powerful force, with consequences for important social determinants of health including gender equality and occupational health and safety issues such as hours of work.

There might be support for a stronger and more focused EU health policy (see Box 8.1). Challenges such as populism, increasingly threatening geopolitics, threats to the rule of law and popular dissatisfaction with many different issues all give leaders at the EU level opportunities to formulate more ambitious plans that can legitimize the EU through action on major issues of popular concern in visible ways. Brexit has changed the politics of the EU by removing one of its most consequential, and liberal, Member States. There is scope to imagine something new and better in EU health policy: approaches that focus on health and well-being, on the rule of law and protection of the vulnerable, or on fulfilling the Pillar of Social Rights and SDGs (see Annex), are all possibilities. If the EU institutions were to declare that good health for all is a priority, this book has shown that it would be easy to both demonstrate EU success to date and identify powerful new policy options for the future. Likewise, a renewed commitment to well-being or to the European Pillar of Social Rights could put the spotlight on existing EU achievements and potential policy options in health.

One way to emphasize the real and potential contribution of the EU to health is through the SDGs, which are the basis of the EU's 2030 strategy. The EU has a history of developing ambitious policy agendas as a way to give coherence and political force to its projects: the market integration of the Single Europe Act, the Lisbon Agenda, Europe 2020. The SDGs are somewhat different. They are goals agreed globally by the United Nations. While often associated with low and middle-income countries, they are also goals that no country has fully achieved, such as gender equality, good work and a sustainable environment, as well as good health and well-being. The EU's adoption of the SDGs, including as Semester goals, means that the fulfilment of the SDGs might be an opportunity to shape an agenda and narrative in which health becomes directly and indirectly a focus of EU policies. There is also abundant space for the EU to shape global health in many areas of standard-setting, reproductive health aid and surveillance

Box 8.1 *Key findings from the public debate on the future health priorities of the European Union*

Background

In the run up to the 2024 European elections, the European Observatory on Health Systems and Policies was commissioned by DG SANTE to conduct a public debate on the EU's future health priorities. The public debate aimed to:

- raise awareness of the opportunities for EU action in the field of health
- explore key health topics, gauging public sentiment on needs and actions, and
- gather ideas from the public on what the EU's future health priorities and mandate could look like following the European elections.

The debate was delivered across three formats: a set of opinion polls directed at audiences of two leading public health and health policy conferences; a series of interactive webinars; and an open online stakeholder survey.

A framework of nine priority topics was used to guide the debate process, which included: 1) health security; 2) health determinants; 3) health system transformation; 4) health workforce; 5) universal health coverage; 6) digital solutions and AI; 7) health systems performance and resilience; 8) long-term challenges such as climate change and ageing; and 9) the EU's global role. Participants also had ample opportunities to expand the list of priority topics and offer their own inputs.

Key findings

- Topics with the highest consensus in the framework were those least controlled by the health sector alone, including long-term challenges like climate change and population ageing, and tackling health determinants through health in and for all policies. Calls for greater cross-sectoral collaboration and coordination, including within the Commission, echoed these findings.
- Even though not a competence of the EU, the health workforce received considerable attention throughout all formats and with all audiences.
- Although repeatedly mentioned in participant discussions, health security and the EU's global role were not prioritized in the same way, suggesting public support for and acknowledgement of the Commission's existing portfolio and ongoing work in this area.
- Several topics beyond the framework came up consistently across different constituencies and focused on: non-communicable diseases (including cancer, cardiovascular diseases); mental health; equity; public health, prevention and health promotion; political determinants of health; and health services and provision to meet patients' needs.
- Although two-thirds of survey respondents supported a stronger mandate for DG SANTE, discussions in the interactive webinars also acknowledged political sensitivities

>> continues

and challenges; proposals in this setting were pragmatic and mostly focused on actions within current Treaty provisions.

- The scope of actions that participants want the EU to take were surprisingly similar across different constituencies and topics, and included:
  - Developing and strengthening **legal frameworks and EU instruments**
  - Better (cross-sectoral) **cooperation and coordination**, both within the Commission and with Member States and other actors
  - **Awareness raising and communication**
  - Providing **funding and investment**
  - **Standardization**, through developing **common methodologies and indicators**
  - Issuing **technical frameworks and guidance**
  - **Knowledge and best practice** generation and sharing
  - Health **leadership**, including globally, and **stakeholder participation**
  - **Monitoring and evaluation** of progress and performance
  - Stimulating **innovation** and supporting **implementation**.

Source: Adapted from Mauer, N., Scarpetti, G., and Wismar, M. (2024) *A Public Debate on Future Health Priorities of the European Union: Outcomes, Insights, and Ideas for Action*. European Observatory on Health Systems and Policies. https://eurohealthobservatory.who.int/publications/m/a-public-debate-on-the-future-health-priorities-of-the-european-union-outcomes-insights-and-ideas-for-action

that are valuable. Mobilizing the considerable European role in global health sketched in Chapter 7 with more coherence and focus on health might have a powerful effect on global health debates and policies.

The important thing to remember with all of these statements and agendas is that the EU, like any sophisticated political organization, can easily rebadge its existing and planned activity and expenditure as part of a new agenda. However, by the same token, declaring a new political priority that includes health will be an effective way to mobilize resources, energy and attention, as has been the case with cancer. COVID-19 has led to a substantial increase in the prominence of the EU in some areas of absolutely classic public health: the surveillance and control of communicable diseases, biomedical preparation and civil protection. But as a cursory glance at research on the pandemic shows, it has had serious effects on other parts of life, from gender equality to health and safety, to old age policy, to pollution that raises respiratory risks. Member States interpreted the biggest health crisis of our lifetimes to justify a major investment in communicable disease control and civil protection, but the EU also has substantial powers to work for health by, for example, using health and safety Treaty bases to protect people working in the care sector and their clients. Furthermore, addressing the broader weaknesses in European societies that the pandemic revealed will involve areas where the EU counts, such as creating more resilient workplaces (so that abattoirs are not hotspots of infection in the next pandemic) and addressing

gender inequalities and other forms of discrimination that often became much worse during the pandemic. COVID-19's lessons and the imperative to build resilience justify attention to environmental occupational and consumer health as much as to communicable disease control and emergency response.

8.4 Choosing a path

The message of this book can ultimately be summarized in a few sentences. First, EU health policy exists and affects both health and health systems. It is an awkward shape and has unusual features, procedures and priorities, but that hardly makes it unique among political systems of the world.

The impact of the EU on health and health systems does not mean that there has ever been any pressure for an integrated European health system, whether that is taken to mean financing of healthcare delivery, standard European entitlements or homogenization of the organizational features of healthcare systems. There is an almost complete absence of political or intellectual support for such an agenda. The reason is simple enough: the EU brings together very different Member States, with larger gaps in GDP per capita than found in any other federation. Established federations around the world have powerful mechanisms that redistribute money between people and governments, reflecting and enabling unity.[6] The EU has, at most, taken an early step in that direction with the post-COVID-19 RRF.

After the COVID-19 pandemic, there is political and intellectual support for a broader EU role in managing the externalities of its integrated market. The sums of money being directed towards public health preparedness and emergency response as well as the fiscal governance revisions show that clearly. It is less clear whether the EU will take new opportunities to promote health across all determinants, such as the green transition. We are in an exciting era for European Union public health, and we hope that this book has made clear some of the opportunities as well as challenges. The existence of EU policies affecting health is unavoidable. The question is whether the EU will use them for health.

6 Greer SL, Béland D, Lecours A, Dubin K (2023). *Putting Federalism in Its Place: The Territorial Politics of Social Policy Revisited*. University of Michigan Press. Greer SL, Elliott H, eds. (2019). *Federalism and Social Policy: Patterns of Redistribution in 11 Democracies*. University of Michigan Press.

Annex

I. Treaty articles relevant to health today in the Treaty on European Union

Source: Treaty on European Union (Consolidated Version),[1] with reference to articles in the Treaty establishing the European Community (TEC) where relevant.

TITLE I

COMMON PROVISIONS

Article 2

The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.

TITLE II

PROVISIONS ON DEMOCRATIC PRINCIPLES

Article 9

In all its activities, the Union shall observe the principle of the equality of its citizens, who shall receive equal attention from its institutions, bodies, offices and agencies. Every national of a Member State shall be a citizen of the Union. Citizenship of the Union shall be additional to and not replace national citizenship.

1 Council of the European Union (2012). Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal*, C 326:1–12.

II. Selected articles relevant to health in the Treaty on the Functioning of the European Union (TFEU)

Source: Treaty on the Functioning of the European Union (Consolidated Version),[2] with reference to articles in the Treaty establishing the European Community (TEC) where relevant.

From Part 1: Principles

Title 1, Categories and Areas of Union Competence

Article 4

1. The Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Articles 3 and 6.

2. Shared competence between the Union and the Member States applies in the following principal areas:

(a) internal market;

(b) social policy, for the aspects defined in this Treaty;

…

(k) common safety concerns in public health matters, for the aspects defined in this Treaty.

Article 6

The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be:

(a) protection and improvement of human health;

…

2 Council of the European Union (2012). Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal*, C 326:1–12.

Article 9

In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.

Title II, Provisions having general application

Article 15 (ex Article 255 TEC)

1. In order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible.

2. The European Parliament shall meet in public, as shall the Council when considering and voting on a draft legislative act.

3. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union institutions, bodies, offices and agencies, whatever their medium, subject to the principles and the conditions to be defined in accordance with this paragraph.

General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the European Parliament and the Council, by means of regulations, acting in accordance with the ordinary legislative procedure.

Each institution, body, office or agency shall ensure that its proceedings are transparent and shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents, in accordance with the regulations referred to in the second subparagraph.

The Court of Justice of the European Union, the European Central Bank and the European Investment Bank shall be subject to this paragraph only when exercising their administrative tasks.

The European Parliament and the Council shall ensure publication of the documents relating to the legislative procedures under the terms laid down by the regulations referred to in the second subparagraph.

Article 16 (ex Article 286 TEC)

1. Everyone has the right to the protection of personal data concerning them.

2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall lay down the rules relating to the protection of individuals with regard to the processing of personal data by Union institutions, bodies, offices and agencies, and by the Member States when carrying out activities which fall within the scope of Union law, and the rules relating to the free movement of such data. Compliance with these rules shall be subject to the control of independent authorities.

The rules adopted on the basis of this Article shall be without prejudice to the specific rules laid down in Article 39 of the Treaty on European Union.

From Part 3: Union Policies and Internal Actions

Title I, The Internal Market

Article 21 (ex Article 18 TEC)

1. Every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give them effect.

2. If action by the Union should prove necessary to attain this objective and the Treaties have not provided the necessary powers, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may adopt provisions with a view to facilitating the exercise of the rights referred to in paragraph 1.

3. For the same purposes as those referred to in paragraph 1 and if the Treaties have not provided the necessary powers, the Council, acting in accordance with a special legislative procedure, may adopt measures concerning social security or social protection. The Council shall act unanimously after consulting the European Parliament.

Title II, Free Movement of Goods

Article 26 (ex Article 14 TEC)

1. The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties.

2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.

3. The Council, on a proposal from the Commission, shall determine the guidelines and conditions necessary to ensure balanced progress in all the sectors concerned.

Article 36 (ex Article 30 TEC)

The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Title IV, Free Movements of Persons, Services and Capital

Article 48 (ex Article 42 TEC)

The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers; to this end, they shall make arrangements to secure for employed and self-employed migrant workers and their dependants:

(a) aggregation, for the purpose of acquiring and retaining the right to benefit and of calculating the amount of benefit, of all periods taken into account under the laws of the several countries;

(b) payment of benefits to persons resident in the territories of Member States.

Article 49 (ex Article 43 TEC)

Within the framework of the provisions set out below, restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State shall be prohibited. Such prohibition shall also apply to restrictions on the setting-up of agencies, branches or subsidiaries by nationals of any Member State established in the territory of another Member State.

Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms within the meaning of the second paragraph of Article 54, under the conditions laid down for its own nationals by the law of the country.

Article 50 (ex Article 44 TEC)

1. In order to attain freedom of establishment as regards a particular activity, the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall act by means of directives.

2. The European Parliament, the Council and the Commission shall carry out the duties devolving upon them under the preceding provisions, in particular:

(a) by according, as a general rule, priority treatment to activities where freedom of establishment makes a particularly valuable contribution to the development of production and trade;

(b) by ensuring close cooperation between the competent authorities in the Member States in order to ascertain the particular situation within the Union of the various activities concerned;

(c) by abolishing those administrative procedures and practices, whether resulting from national legislation or from agreements previously concluded between Member States, the maintenance of which would form an obstacle to freedom of establishment;

(d) by ensuring that workers of one Member State employed in the territory of another Member State may remain in that territory for the purpose of taking up activities therein as self-employed persons, where they satisfy the conditions which they would be required to satisfy if they were entering that State at the time when they intended to take up such activities;

(e) by enabling a national of one Member State to acquire and use land and buildings situated in the territory of another Member State, in so far as this does not conflict with the principles laid down in Article 39(2);

(f) by effecting the progressive abolition of restrictions on freedom of establishment in every branch of activity under consideration, both as regards the conditions for setting up agencies, branches or subsidiaries in the territory of a Member State and as regards the subsidiaries in the territory of a Member State and as regards the conditions governing the entry of personnel belonging to the main establishment into managerial or supervisory posts in such agencies, branches or subsidiaries;

(g) by coordinating to the necessary extent the safeguards which, for the protection of the interests of members and others, are required by Member States of companies or firms within the meaning of the second paragraph of Article 54 with a view to making such safeguards equivalent throughout the Union;

(h) by satisfying themselves that the conditions of establishment are not distorted by aids granted by Member States.

Article 52 (ex Article 46 TEC)

1. The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.

2. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure, issue directives for the coordination of the above mentioned provisions.

Article 56 (ex Article 49 TEC)

Within the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended.

The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may extend the provisions of the Chapter to nationals of a third country who provide services and who are established within the Union.

Article 57 (ex Article 50 TEC)

Services shall be considered to be "services" within the meaning of the Treaties where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.

"Services" shall in particular include:

(a) activities of an industrial character;

(b) activities of a commercial character;

(c) activities of craftsmen;

(d) activities of the professions.

Without prejudice to the provisions of the Chapter relating to the right of establishment, the person providing a service may, in order to do so, temporarily pursue his activity in the Member State where the service is provided, under the same conditions as are imposed by that State on its own nationals.

Article 62 (ex Article 55 TEC)

The provisions of Articles 51 to 54 shall apply to the matters covered by this Chapter.

Title VII, Common Rules on Taxation, Competition and the Approximation of Laws

Article 114 (ex Article 95 TEC)

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

…

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

Title X, Social Policy

Article 151 (ex Article 136 TEC)

The Union and the Member States, having in mind fundamental social rights such as those set out in the European Social Charter signed at Turin on 18 October 1961 and in the 1989 Community Charter of the Fundamental Social Rights of Workers, shall have as their objectives the promotion of employment, improved living and working conditions, so as to make possible their harmonisation while the improvement is being maintained, proper social protection, dialogue between

management and labour, the development of human resources with a view to lasting high employment and the combating of exclusion.

To this end the Union and the Member States shall implement measures which take account of the diverse forms of national practices, in particular in the field of contractual relations, and the need to maintain the competitiveness of the Union's economy.

They believe that such a development will ensue not only from the functioning of the internal market, which will favour the harmonisation of social systems, but also from the procedures provided for in the Treaties and from the approximation of provisions laid down by law, regulation or administrative action.

Article 153 (ex Article 137 TEC)

1. With a view to achieving the objectives of Article 151, the Union shall support and complement the activities of the Member States in the following fields:

(a) improvement in particular of the working environment to protect workers' health and safety;

(b) working conditions;

(c) social security and social protection of workers;

(d) protection of workers where their employment contract is terminated;

(e) the information and consultation of workers;

(f) representation and collective defence of the interests of workers and employers, including co-determination, subject to paragraph 5;

(g) conditions of employment for third-country nationals legally residing in Union territory;

(h) the integration of persons excluded from the labour market, without prejudice to Article 166;

(i) equality between men and women with regard to labour market opportunities and treatment at work;

(j) the combating of social exclusion;

(k) the modernisation of social protection systems without prejudice to point (c).

2. To this end, the European Parliament and the Council:

(a) may adopt measures designed to encourage cooperation between Member States through initiatives aimed at improving knowledge, developing exchanges of

information and best practices, promoting innovative approaches and evaluating experiences, excluding any harmonisation of the laws and regulations of the Member States;

(b) may adopt, in the fields referred to in paragraph 1(a) to (i), by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.

The European Parliament and the Council shall act in accordance with the ordinary legislative procedure after consulting the Economic and Social Committee and the Committee of the Regions.

In the fields referred to in paragraph 1(c), (d), (f) and (g), the Council shall act unanimously, in accordance with a special legislative procedure, after consulting the European Parliament and the said Committees.

The Council, acting unanimously on a proposal from the Commission, after consulting the European Parliament, may decide to render the ordinary legislative procedure applicable to paragraph 1(d), (f) and (g).

3. A Member State may entrust management and labour, at their joint request, with the implementation of directives adopted pursuant to paragraph 2, or, where appropriate, with the implementation of a Council decision adopted in accordance with Article 155.

In this case, it shall ensure that, no later than the date on which a directive or a decision must be transposed or implemented, management and labour have introduced the necessary measures by agreement, the Member State concerned being required to take any necessary measure enabling it at any time to be in a position to guarantee the results imposed by that directive or that decision.

4. The provisions adopted pursuant to this Article:

- shall not affect the right of Member States to define the fundamental principles of their social security systems and must not significantly affect the financial equilibrium thereof,

- shall not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties.

5. The provisions of this Article shall not apply to pay, the right of association, the right to strike or the right to impose lock-outs.

Article 156 (ex Article 140 TEC)

With a view to achieving the objectives of Article 151 and without prejudice to the other provisions of the Treaties, the Commission shall encourage cooperation between the Member States and facilitate the coordination of their action in all social policy fields under this Chapter, particularly in matters relating to:

- employment,
- labour law and working conditions,
- basic and advanced vocational training,
- social security,
- prevention of occupational accidents and diseases,
- occupational hygiene,
- the right of association and collective bargaining between employers and workers.

To this end, the Commission shall act in close contact with Member States by making studies, delivering opinions and arranging consultations both on problems arising at national level and on those of concern to international organisations, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

Before delivering the opinions provided for in this Article, the Commission shall consult the Economic and Social Committee.

Title XIV, Public Health

Article 168 (ex Article 152 TEC)

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information

and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures

which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Title XV, Consumer Protection

Article 169 (ex Article 153 TEC)

1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.

2. The Union shall contribute to the attainment of the objectives referred to in paragraph 1 through:

(a) measures adopted pursuant to Article 114 in the context of the completion of the internal market;

(b) measures which support, supplement and monitor the policy pursued by the Member States.

3. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 2(b).

4. Measures adopted pursuant to paragraph 3 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. The Commission shall be notified of them.

Title XX, Environment

Article 191 (ex Article 174 TEC)

1. Union policy on the environment shall contribute to pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment,
- protecting human health,
- prudent and rational utilisation of natural resources,
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.

2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.

3. In preparing its policy on the environment, the Union shall take account of:

- available scientific and technical data,
- environmental conditions in the various regions of the Union,
- the potential benefits and costs of action or lack of action,
- the economic and social development of the Union as a whole and the balanced development of its regions.

4. Within their respective spheres of competence, the Union and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Union cooperation may be the subject of agreements between the Union and the third parties concerned.

The previous subparagraph shall be without prejudice to Member States' competence to negotiate in international bodies and to conclude international agreements.

Title XXIII, Civil Protection

Article 196

1. The Union shall encourage cooperation between Member States in order to improve the effectiveness of systems for preventing and protecting against natural or man-made disasters.

Union action shall aim to:

(a) support and complement Member States' action at national, regional and local level in risk prevention, in preparing their civil-protection personnel and in responding to natural or man-made disasters within the Union;

…

2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure shall establish the measures necessary to help achieve the objectives referred to in paragraph 1, excluding any harmonisation of the laws and regulations of the Member States.

III. Evolution of public health Treaty Article

Treaty on European Union (Maastricht, 1992)

Title XI, Consumer protection

Article 129a EC Treaty

1. The Community shall contribute to the attainment of a high level of consumer protection through:

(a) measures adopted pursuant to Article 100a in the context of the completion of the internal market;

(b) specific action which supports and supplements the policy pursued by the Member States to protect the health, safety and economic interests of consumers and to provide adequate information to consumers.

2. The Council, acting in accordance with the procedure referred to in Article 189b and after consulting the Economic and Social Committee, shall adopt the specific action referred to in paragraph 1(b).

3. Action adopted pursuant to paragraph 2 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.

Treaty of Amsterdam, 1999

Article 152 EC Treaty

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee

of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonization of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Treaty of Lisbon, 2007

Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It

shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2) (k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonization of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

IV. EU social policies and principles

EU Charter of Fundamental Rights

Article 35 – Health Care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

The European Pillar of Social Rights

The Pillar of Social Rights builds upon 20 key principles, structured around three categories:

I. Equal opportunities and access to the labour market

II. Fair working conditions

III. Social protection and inclusion.

I. Equal opportunities and access to the labour market

1. Education, training and lifelong learning
2. Gender equality
3. Equal opportunities
4. Active support to employment

II. Fair working conditions

5. Secure and adaptable employment

6. Wages
7. Information about employment conditions and protection in case of dismissals
8. Social dialogue and involvement of workers
9. Work–life balance
10. Healthy, safe and well-adapted work environment and data protection

III. Social protection and inclusion

11. Childcare and support to children
12. Social protection
13. Unemployment benefits
14. Minimum income
15. Old age income and pensions
16. Healthcare
17. Inclusion of people with disabilities
18. Long-term care
19. Housing and assistance for the homeless
20. Access to essential services.

V. United Nations Sustainable Development Goals

The European Union has committed to implement the SDGs in both its internal and its external policies. The SDGs are:

1. To end poverty in all its forms everywhere
2. To end hunger, achieve food security and improved nutrition, and promote sustainable agriculture
3. To ensure healthy lives and promote well-being for all at all ages
4. To ensure inclusive and equitable quality education and promote life-long learning opportunities for all
5. To achieve gender equality and empower all women and girls

6. To ensure availability and sustainable management of water and sanitation for all
7. To ensure access to affordable, reliable, sustainable and modern energy for all
8. To promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all
9. To build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
10. To reduce inequality within and among countries
11. To make cities and human settlements inclusive, safe, resilient and sustainable
12. To ensure sustainable consumption and production patterns
13. To take urgent action to combat climate change and its impacts
14. To conserve and sustainably use oceans, seas and marine resources for sustainable development
15. To protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss
16. To achieve peaceful and inclusive societies, rule of law, effective and capable institutions
17. To strengthen means of implementation and revitalize the global partnership for sustainable development.

VI. Mission Letter to the Commissioner designate for Health – Brussels, 17 September 2024

Ursula van der Leyen
President of the European Commission

Brussels, 17 September 2024

Olivér Várhelyi
Commissioner-designate for Health and Animal Welfare

Dear Olivér,

The Commission we will serve in together will be called upon to make choices that will shape our Continent and our Union for years and decades to come. In a time of great global instability and great expectations of Europeans, we must live up to that responsibility. **We must deliver and lead from the front**, working closely with the people and regions of Europe and the parliaments, governments and institutions that serve them.

This was the spirit of the Political Guidelines which I presented to the European Parliament in July 2024 - our common plan for European strength and unity. It focuses on ensuring our **security** in every sense in a more dangerous and turbulent world, on supporting people and citizens by strengthening our **prosperity**, our social market economy, green and digital transitions and sustaining our unique quality of life. We will strengthen our **democracy**, rally around our values and ensure that we are stronger at home. We will work with our partners and better assert our interests around the world.

Together, we will respond to the real and legitimate concerns and expectations that Europeans expressed at the last elections. We will be closer to people and businesses where it really matters with practical support and sustained investment. We will strive to **make Europe faster and simpler** in the way that we act - and in the way we interact with people. And we will work towards European unity at every turn, starting from within our College.

I am convinced that your experience, motivation, and European commitment will be an essential part of this team. This letter sets out my expectations for our collective work, as well as for your own mission.

New Commission, new approach

The priorities that I have set out in the Political Guidelines are not standalone areas of work. They are all connected and they will all impact each other. The same will be true for the work of the College as a whole and for each of its Members working together in a spirit of **collegiality**. I expect every Member of College to take **full ownership** of what is agreed.

Every Member of College is equal and every Member of College will have an equal responsibility to deliver on our priorities. With this in mind, I expect cooperation at all levels and for you to take an active role across all priorities and to facilitate access to your services where other Commissioners' responsibilities require it.

You will work with myself and the Commissioner for Budget, Anti-Fraud and Public Administration for a **simpler, more focused and responsive long-term budget** that reflects European strategic priorities and our ambition to be an **Investment Commission**.

Given the transformative nature of the next long-term budget - and in order to adapt to our modern approach and new spending priorities - **I will review the structure of the College and the missions** of each Member of College.

I would also like you all to play an active role in **supporting candidate countries to prepare for joining our Union** in your respective policy areas. I count on you when it comes to the pre-enlargement policy reviews and for our broader **ambitious reform agenda**.

I expect you to all contribute to achieving our agreed climate objectives, notably those set for 2030 and the climate neutrality goal for 2050.

As we head to 2030, each Member of College will ensure the delivery of the EU targets and objectives defined for that year, as well as of the United Nations Sustainable Development Goals within their policy areas. The College as a whole will be responsible for the overall implementation of the Goals.

Beyond what is listed in your individual mission below, I would like all Members of College to draw on recent or upcoming reports. This notably includes the **Draghi Report** on the future of European competitiveness, the **Niinistö Report** on how to enhance Europe's civilian and defence preparedness and readiness,

the report from the **Strategic Dialogue on the future of EU agriculture**, as well as the **Letta report** on the future of the Single Market.

Working together for Europe, working closer to Europeans

To ensure trust and confidence of Europeans, I also want the College to lead when it comes to openness, transparency and representation.

First, **this Commission will strengthen its relationship with EU institutions**. I expect all Commissioners to be present in the European Parliament, both in plenary debates, in Committee meetings and in trilogues. Equally, I expect all Commissioners to engage with Member States and participate in the relevant Council formations. This is essential for ensuring accountability and better communicating our work and our planning.

I will ask you to organise a **structured dialogue** with your respective Parliamentary Committee to chart a way forward for any Article 225 Resolutions adopted by the Parliament calling for legislative proposals. This will be part of our work in ensuring **transparency and information flow** with the Parliament and Council, notably before major events and at key stages about international negotiations.

Second, this Commission will be **more present on the ground, more often and in more regions**. I would like you to visit Member States regularly. I encourage you to go local, visit places and meet Europeans from across our Union, including in cities, rural and sparsely populated areas. Our network of Representations will support you in this. You should meet with representatives from regional or local areas, notably relying on our network of EU Local Councillors, and to give **more visibility to EU projects** making a difference to people's lives on the ground. When engaging with our international partners you will also be supported by our network of EU delegations around the world.

I expect you to **actively communicate** on the Commission's actions and decisions and explain the benefits and opportunities stemming from our work. You should also help **tackle disinformation**, notably by providing clear and accurate information at all times.

Third, this Commission will start **a new era of dialogue** with citizens and stakeholders. You should organise a first edition of the **annual Youth Policy Dialogues** within the first 100 days so that young people can be heard and can help shape your work.

This will be part of our work in embedding **citizen participation** in our work. We will build on the Conference on the Future of Europe to instil a true and **lasting culture of participative democracy**. We will choose policy areas and

proposals where recommendations from a European Citizens' Panel would have the greatest value and follow up on their proposals.

Fourth, every Member of College must show a **true European commitment** beyond doubt and be fully independent in their action. I expect full adherence to all applicable integrity, impartiality and ethical rules from all, starting with the **Code of Conduct**. You will ensure that the rules on transparency and meetings with interest representatives are fully respected, including for your staff and services. We will **strengthen our transparency system** by extending the requirements of the Transparency Register to all managers.

Fifth, we will ensure that the Commission becomes **more representative** of the people we serve. We have made a lot of progress in terms of gender balance across management but there is clearly more to be done. Reflecting the EU's strength in diversity, your Cabinet should ensure **gender and geographical balance**.

While the Berlaymont will remain your primary headquarters, you will also have an office within your Directorate-General and be expected to be present on a regular basis to **work closely with your staff and services**. We will collectively ensure that the Commission is an inclusive, respectful and safe workplace.

Making Europe simpler and faster

The success of this new Commission will be measured against our ability to meet the targets and objectives we set, notably as part of the **European Green Deal**.

You will be responsible for the delivery of the policy objectives and targets within your portfolio. To achieve this, you should make full use of all instruments for implementation and enforcement, including infringement proceedings.

You will ensure that existing rules are fit-for-purpose and focus on reducing administrative burdens and simplifying legislation. You must contribute to reducing reporting obligations by at least 25% - and for SMEs at least 35%. You should leverage the power of digital tools to deliver better and faster solutions. We must listen to all companies and stakeholders who work on a daily basis to comply with EU legislation. You will organise at least two **Implementation Dialogues** per year with stakeholders to align implementation with realities on the ground. You will prepare an **Annual Progress Report on Enforcement and Implementation** for your respective Parliamentary committees and Council formations.

You will also work to **stress test the EU acquis** and table proposals to eliminate any overlaps and contradictions and be fully digitally compatible, while maintaining high standards.

New legislation must ensure that our rules are simpler, more accessible to citizens and more targeted. You will ensure the principles of **proportionality, subsidiarity and Better Regulation** are respected, including through wide consultations, impact assessments, a review by the independent **Regulatory Scrutiny Board** and a new **SME and competitiveness check**. Proposals must be evidence-based and the Joint Research Centre, our internal scientific service, can support you in that work.

Your mission

I would like to entrust you with the role of Commissioner for Health and Animal Welfare.

Europe has taken historic steps following the COVID-19 pandemic and the challenges that it brought for our health systems and societies and economies. As we overcame the pandemic, new health threats and challenges have emerged and we must continue to strengthen our prevention, resilience and competitiveness through our health policies.

You will focus on **completing the European Health Union**, by further diversifying supply chains, improving access to the most advanced treatments, boosting the competitiveness, resilience and security of health systems and working on strategic inventories.

You will also continue to build on the **One Health** approach, recognising the connection between people, animals, plants and their shared environment. You will be responsible for **animal welfare**. The last few years highlighted the importance of this approach and demonstrated the need for a true European Health Union.

- You will propose a **Critical Medicines Act** to address the sever shortages of medicines and medical devices and reduce dependencies relating to critical medicines and ingredients, as well as to ensure the supply of affordable medicines.

- Europe needs a strong, competitive, and innovative pharmaceutical sector. You will lead efforts to support the European Parliament and the Council to conclude work on the **pharmaceuticals** reform and follow up on its implementation.

- I would like you to lead the work on a new **European Biotech Act**, focusing on the need for a regulatory environment conducive to innovation in areas of health technology assessment, clinical trials and others.

- You will ensure the availability and competitiveness of **medical devices**, including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes.

- I want you to step up our work **on preventive health**, ensuring a comprehensive approach to health promotion and disease prevention across the life course. Investing in effective prevention measures will reduce the burden of non-communicable diseases, helping to lighten the load on healthcare systems and supporting healthy longevity.

- As part of this, I would like to ensure the implementation of the **European Beating Cancer Plan**. You should draw on this work to design a common approach in other areas, looking in particular at mental health, cardiovascular diseases, degenerative illnesses, autism and other non-communicable diseases.

- As part of work on preventive health, you should address other risk factors. This includes evaluating and revising the **tobacco** legislation, notably by addressing concerns about young people's access to novel tobacco and nicotine products.

- You will **continue the work on anti-microbial resistance (AMR)** as one of the major threats to health, working with Member States to reach the 2030 targets.

- I would like you to focus on the impact of social media and excessive screen time on people, especially young people, and their wellbeing and **mental health**. You will lead an **EU-wide inquiry on the broader impacts of social media** on wellbeing to start an evidence-based debate on the issue.

- Building upon the existing animal welfare legislation, you will **modernise the rules on animal welfare**, including on the import of exotic animals, standards while addressing sustainability, ethical, scientific and economic considerations, and citizens expectations.

- You will propose actions to **prevent and reduce food waste**. You will work to improve the sustainability, safety and affordability of food production and consumption across the food chain, including through **organic production** and the accelerated use of bio-controls.

- You will ensure a high level of trust by users and consumers and work to increase controls on imported products. You will be responsible for the enforcement of **food safety standards**. Food safety standards should

be based on the independent scientific advice and in consultation with EU Member States and stakeholders.

- I would like you to work together with the Executive Vice-President for Tech Sovereignty, Security and Democracy to prepare a European action plan on the **cybersecurity of hospitals and healthcare providers** in the first 100 days of the mandate.

- You should work to complete the **European Health Data Space**. You will promote the uptake of artificial intelligence, notably through clear and timely guidance on its use in the lifecycle of medicines. You will make proposals to **scale up genome sequencing capacities**.

As a rule, you will work under the guidance of the Executive Vice-President for a Clean, Just and Competitive Transition in your role as Commissioner for Health and Animal Welfare. You will also work under the guidance of the Executive Vice-President for People, Skills and Preparedness on issues linked to health preparedness.

The Directorate-General for Health and Food Safety and the Health Emergency Response Authority will support you in this role.

Way forward

The actions listed in this letter will shape your work. However, we will need to complete and adapt as we go along and I count on your ideas and expertise in this regard. In addition to College meetings and our continuous discussions, I will invite you every six months for a structured reporting meeting to discuss progress and challenges in delivering on your mission.

Reflecting the evolving nature of political priorities, the Commission must remain agile in allocating staff where most needed. I expect you to play a collegial role in this, by working with your services to identify efficiencies and contributing to corporate redeployment efforts across the Commission.

Given the scale of the challenges and the many issues in our in-tray, we must **hit the ground running on day one**. I invite you to take contact with your future services to prepare your hearing and the work ahead.

I look forward to working closely together for Europe.

Yours sincerely,

Dr. Ursula van der Leyen
President of the European Commission

What does the European Union mean for health? What can it mean for health?

This comprehensively revised fourth edition answers these questions. It provides a broad and up-to-date review and analysis of European Union public health policies. It begins by explaining the basic politics of European integration and European policy-making in health, including the basic question of how the European Union (EU) came to have a health policy and what that policy does. Thereafter, it moves on to the three faces of European Union health policy.

The first face is explicit health policy, both public health policy and policies to strengthen health services and systems in areas such as cancer, and communicable diseases. The second face is internal market building policies, which are often more consequential for health services, but are not made with health as a core objective. These include professional and patient mobility, regulation of insurers and health care providers, and competition in health care. They also include some of the policies through which the EU has had dramatic and positive health effects, namely environmental regulation, consumer protection and labour law. The third face is fiscal governance, in which the EU institutions police member state decisions, including relating to health.

Each face has different politics, law, policy, and health effects. The book provides a synthesis of the different faces and the different ways in which they have been used to strengthen or weaken public health and health systems in Europe. It shows the many, often unappreciated, ways that the EU has worked for health, as well as the opportunities to further strengthen the EU's positive impact on health.

This book is aimed at policy-makers and students of health systems in the EU who seek to understand how the influence of the EU on health policy affects those systems and their patients. To ensure that the EU's impact on health is wholly positive, the wider health community must understand and engage with the EU in the future – something this book aims to encourage.

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