What does the European Union mean for health? What can it mean for health?
This comprehensively revised second edition answers these questions. It provides a broad review and analysis of European Union public health policies to mid-2019. 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.

The authors
Scott L. Greer – University of Michigan School of Public Health and European Observatory on Health Systems and Policies.
Sarah Rozenblum – University of Michigan.
Eleanor Brooks – University of Edinburgh.
Holly Jarman – University of Michigan.
Anniek de Ruijter – University of Amsterdam.
Willy Palm – European Observatory on Health Systems and Policies.
Matthias Wismar – European Observatory on Health Systems and Policies.

Health Policy Series No. 59
Everything you always wanted to know about European Union health policy but were afraid to ask

Third, revised edition
The European Observatory on Health Systems and Policies supports and promotes evidence-based health policy-making through comprehensive and rigorous analysis of health systems in Europe. It brings together a wide range of policy-makers, academics and practitioners to analyse trends in health reform, drawing on experience from across Europe to illuminate policy issues.

The Observatory is a partnership, hosted by WHO/Europe, which includes other international organizations (the European Commission); national and regional governments (Austria, Belgium, Finland, Ireland, 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.
Everything you always wanted to know about European Union health policy but were afraid to ask

Third, revised edition

Edited by:

Scott L. Greer
University of Michigan and European Observatory on Health Systems and Policies

Sarah Rozenblum
University of Michigan and European Observatory on Health Systems and Policies

Nick Fahy
RAND Europe and European Observatory on Health Systems and Policies

Eleanor Brooks
University of Edinburgh

Holly Jarman
University of Michigan

Anniek de Ruijter
University of Amsterdam

Willy Palm
WHO Europe

Matthias Wismar
European Observatory on Health Systems and Policies
# Table of contents

List of tables, figures and boxes ix  
Foreword xi  
List of acronyms and abbreviations xiii  
Acknowledgements xv

## Chapter 1: Introduction 1  
1.1 The three faces of European Union health policy 2  
1.2 Constitutional asymmetry and the regulatory state 7  
1.3 Origins of EU health policy 9  
1.4 The EU during and after COVID-19 20  
1.4.1 EU pandemic response 20  
1.4.2 The European Health Union 22  
1.5 Three dynamics of EU health policy 24  
1.6 The emergence of a variable EU health policy arena 25  
1.7 Health, convergence and the EU 26  
1.8 Conclusion 29

## Chapter 2. The European Union: institutions, processes and powers 33  
2.1 European political institutions 34  
2.1.1 The European Commission 34  
2.1.2 European Parliament 40  
2.1.3 Council of the European Union and the European Council 43  
2.1.4 Court of Justice of the European Union 45  
2.1.5 Other treaty bodies: European Central Bank, European Investment Bank, Economic and Social Committee, Committee of the Regions, European Court of Auditors, and the Ombudsman 51  
2.1.6 Agencies 53  
2.1.7 Executive agencies: HaDEA 54  
2.1.8 How do EU institutions take account of the EU’s indirect impact on health? 55  
2.2 Budget 56  
2.3 Health policy processes 57  
2.3.1 State of Health in the EU cycle 58  
2.3.2 Expert Group in Health System Performance Assessment 59
Chapter 3. Public health

3.1 What is European Union public health policy? 77
3.2 Tobacco control 79
3.3 Diet, nutrition and physical activity 85
3.4 Alcohol 87
3.5 Communicable diseases and threats to health 91
  3.5.1 Monitoring and surveillance of communicable diseases 92
  3.5.2 Managing and responding to threats 93
  3.5.3 Preparing for the next pandemic 96
3.6 Vaccines and Vaccination 97
  3.6.1 Routine EU vaccine and vaccination policies 98
  3.6.2 COVID-19 and the EU Vaccines Strategy 102
3.7 Joint procurement 104
3.8 Pharmaceuticals and health emergencies 106
3.9 Civil protection: RescEU and the European Medical Corps 107
3.10 EU4Health and the preceding Health Programmes 110
  3.10.1 Health Programmes to 2020 110
  3.10.2 EU4Health 112
3.11 Substances of human origin 113
3.12 Health in All Policies 115
3.13 Conclusion 117
## Table of contents

**Chapter 4. EU Action for Health outside public health**

4.1 Introduction 121
4.2 Environment 121
   4.2.1 Climate change 124
   4.2.2 An example of environmental regulation: fine particle pollution 125
   4.2.3 The environment at the heart of Europe’s post-COVID recovery plans 125
4.3 Health and safety at work 126
   4.3.1 Occupational health and safety 126
   4.3.2 Working Time Directive 127
   4.3.3 Social partners in EU law 130
   4.3.4 Equalities and nondiscrimination 130
4.4 Consumer protection 131
4.5 Food safety 133
4.6 Research 136
4.7 Conclusion 140

**Chapter 5. The EU market shaping health**

5.1 Goods 141
   5.1.1 Pharmaceuticals 142
   5.1.2 Medical devices 147
5.2 People 151
   5.2.1 Health workforce 152
   5.2.2 Social security coordination and the European Health Insurance Card 155
   5.2.3 Migrants and health 160
5.3 Services 163
   5.3.1 Cross-border healthcare and patient mobility 164
   5.3.2 European Reference Networks 167
   5.3.3 The information society and e-health 168
   5.3.4 European prescriptions and the eHealth Digital Service Infrastructure (eHDSI) 170
   5.3.5 Patient safety and healthcare quality 171
   5.3.6 Pharmacy 172
5.4 Competition, state aids and services of general interest 174
   5.4.1 Public and private partnerships 177
5.5 Health technology assessment 179
5.6 Conclusion 182

**Chapter 6. Fiscal governance of health**

6.1 How “fiscal governance” came to exist and matter to health 184
6.2 The EU’s fiscal governance framework 187
   6.2.1 The pillars of EU economic governance 187
   6.2.2 The preventive arms of fiscal governance 189
6.2.3 The corrective arms of fiscal governance 190
6.3 EU funds for health 191
6.3.1 Cohesion Policy Funds 191
6.3.2 The European Investment Bank 195
6.4 The European Semester 197
6.4.1 The European Semester: process 197
6.4.2 Ten years of health in the European Semester 199
6.5 Fiscal governance and the COVID-19 recovery 208
6.5.1 The fiscal response to COVID-19 208
6.5.2 The 2021 European Semester: An extraordinary cycle 213
6.5.3 Health in the COVID-19 recovery programme 214
6.6 The future of the fiscal governance framework 219

Chapter 7. Global health 223

7.1 Introduction 223
7.1.1 Externalities 225
7.1.2 Arenas: Internal, Neighbourhood and Global 225
7.1.3 Structures 226
7.2 The EU's near neighbours 227
7.2.1 EFTA and Switzerland 227
7.2.2 The United Kingdom 228
7.2.3 Accession candidates 231
7.2.4 European neighbourhood policies, Russia and Turkey 232
7.3 Global health and Global Economic Governance 235
7.3.1 Trade, investment and international economic governance 235
7.3.2 European development aid 237
7.3.3 Global health voice 239
7.3.4 COVID-19 and COVAX 239
7.4 Conclusion 241

Chapter 8. Conclusion 243

8.1 The four freedoms, constitutional asymmetry and health 243
8.2 Consolidating the first face 245
8.3 Rethinking the European health policy space 246
8.4 Choosing a path 249

Appendices

I. Treaty articles relevant to health today in the Treaty on European Union 250
II. Selected articles relevant to health in the Treaty on the Functioning of the European Union (TFEU) 251
III. EU Charter of Fundamental Rights. Article 35 – Health Care 265
IV. Mission Letter to the Commissioner-designate for Health – Brussels, 10 September 2019 266
List of tables, figures and boxes

Tables

- Table 2.1 Order of presidencies of the Council of Ministers, 2019–2030
- Table 3.1 EU Member States’ performance against WHO tobacco control targets
- Table 3.2 Summary of EU tobacco control legislation
- Table 4.1 Some health impacts and associations with environmental and lifestyle factors: a list of examples
- Table 5.1 Comparison between cross-border healthcare rules under the Regulation on Coordination of Social Security and the Directive on Patients’ Rights in Cross-Border Healthcare
- Table 6.1 The legal pillars of the fiscal governance framework
- Table 6.2 Country Specific Recommendations with reference to health: 2011, 2014, 2019
- Table 6.3 Overview of MFF and NGEU allocations (current prices)

Figures

- Fig. 1.1 Table 2.1 GDP per capita, PPP (current international $)
- Fig. 1.2 Life expectancy at birth
- Fig. 1.3 Life expectancy at age 65 (2019)
- Fig. 1.4 EU health policies as a gate with no fence and Gatecrashing EU health policies
- Fig. 3.1 Global vaccine confidence before the COVID-19 pandemic
- Fig. 6.1 Cohesion policy expenditure
- Fig. 6.2 Public balance, 2019 and 2020
- Fig. 6.3 The aligned timing of the 2021 European Semester Cycle
- Fig. 7.1 Overlapping EU memberships

Boxes

- Box 1.1 EU health policies
- Box 1.2 EU contributions to tackling cancer
- Box 1.3 Rule of law and the EU budget
- Box 1.4 The evolution of treaty articles on health over time
- Box 1.5 Bricolage at work: Homelessness policy in the EU
- Box 1.6 Well-being
- Box 2.1 Commission proposal development
- Box 2.2 EU legislative processes
Everything you always wanted to know about EU health policy but were afraid to ask

Box 2.3  Political groups in the 2019–2024 European Parliament and percentage of members  43
Box 2.4  Commonly used legal instruments in European Union law  46
Box 2.5  Key concepts in European integration  49
Box 2.6  Sustainable Development Goals in the EU  70
Box 2.7  The European Pillar of Social Rights  72
Box 3.1  European Centre for Disease Prevention and Control (ECDC)  94
Box 3.2  Revised Regulation on Cross-Border Threats  95
Box 3.3  Article 196 TFEU  107
Box 3.4  The EU4Health Programme  113
Box 3.5  Antimicrobial resistance  118
Box 4.1  Health and safety in the COVID-19 pandemic  128
Box 4.2  International dimensions of food safety policy  135
Box 4.3  Food standards and trade agreements  137
Box 5.1  International dimensions of healthcare goods  144
Box 5.2  International travel restrictions and COVID-19  156
Box 5.3  General Data Protection Regulation (GDPR)  170
Box 6.1  How to read Semester documents  206
Box 6.2  DG Reform  209
Box 6.3  The 2020 country specific recommendations relating to health  218
Not long ago it was possible to deny the existence of EU health policy. In 2019 it was reasonable to fear that it would be extinguished as a serious area of EU focus. After the coronavirus pandemic, though, few deny its growth and importance. An existing trend towards increasing focus on health across EU policy, at least on paper, coincided with the COVID-19 pandemic to make clear the scope of the potential and real EU role, and prompt important changes.

This book, a completely revised third edition of our previous two volumes on the subject, maps out the nature of EU health policies, their logic and reason for being, and their potential to affect the health of Europeans. It is written in the belief that understanding the breadth and diversity of EU health policies, and the distinctive institutional structure that explains them, will improve our collective abilities to make policy for health in any sphere, from food to healthcare services and from occupational safety to international trade.

We had not planned to write a new edition until the next renewal of mandates in 2024, but the events of 2020 and 2021 were so dramatic as to oblige us to produce this new edition. This volume is updated as of late January 2022 to reflect major changes in EU health policies that resulted from its COVID-19 response. This includes substantial change in health and civil protection and fiscal governance, as well as in internal market issues such as pharmaceuticals. The book is not about the COVID-19 crisis or the responses in the EU and Member States. Rather, it is about EU health policy after the shock of 2020 and the changes to EU politics and policy that resulted. We have also revised the text thoroughly to incorporate changes that might not be caused by COVID-19 but

---


that will be necessary to better understand the EU’s health policies from 2021 onward, such as developments in Health Technology Assessment, food safety regulation, and the EU in global health policy.

We hope that this book makes it impossible to deny the scale, diversity and often indirect impact of EU health policy. EU health policies extend far beyond Article 168 of the Treaty on the Functioning of the EU (TFEU) on Public Health, as discussed in Chapter 3. They include the environmental, social policy and consumer protection policies discussed in Chapter 4, which might actually be the area where the EU has had its most beneficial impact to date. They include the extensive internal market laws that have made so much EU regulatory policy in areas such as environmental protection and labour regulation not always considered “health”, discussed in Chapter 5. They also include the ambitious fiscal governance agenda discussed in Chapter 6, which has increasingly developed a health focus and seen considerable change since 2019. Finally, they include the EU’s actions in a global context (Chapter 7), where its size and power as one of the world’s biggest economies and donors give it an outsize role in global health policy that we briefly review. Across a broad sweep of policies, from civil protection to the regulation of pharmacies, the EU is omnipresent in health and health policy. It should be understood as such. The question is not whether we want an EU health policy, for EU health policy is inevitable. The question is how does it come to be, and for what ends.

---

## List of acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTA</td>
<td>Anti-Counterfeiting Trade Agreement</td>
</tr>
<tr>
<td>BEPG</td>
<td>Broad Economic Policy Guidelines</td>
</tr>
<tr>
<td>CJEU</td>
<td>Court of Justice of the European Union</td>
</tr>
<tr>
<td>CPMS</td>
<td>Clinical Patient Management System</td>
</tr>
<tr>
<td>CSR</td>
<td>Country Specific Recommendation</td>
</tr>
<tr>
<td>DG CLIMA</td>
<td>Directorate-General for Climate Action</td>
</tr>
<tr>
<td>DG DEVCO</td>
<td>Directorate-General for International Cooperation and Development</td>
</tr>
<tr>
<td>DG ECFIN</td>
<td>Directorate-General for Economic and Financial Affairs</td>
</tr>
<tr>
<td>DG ECHO</td>
<td>Directorate-General for Humanitarian Aid and Civil Protection</td>
</tr>
<tr>
<td>DG EMPL</td>
<td>Directorate-General for Employment, Social Affairs and Inclusion</td>
</tr>
<tr>
<td>DG HERA</td>
<td>Health Emergency Preparedness and Response Authority</td>
</tr>
<tr>
<td>DG INTPA</td>
<td>Directorate-General for International Partnerships</td>
</tr>
<tr>
<td>DG NEAR</td>
<td>Directorate-General for Neighbourhood and Enlargement</td>
</tr>
<tr>
<td>DG REFORM</td>
<td>Directorate-General for Structural Reform Support</td>
</tr>
<tr>
<td>DG SANCO</td>
<td>Directorate-General for Health and Consumer Protection</td>
</tr>
<tr>
<td>DG SANTE</td>
<td>Directorate-General for Health</td>
</tr>
<tr>
<td>DG TAXUD</td>
<td>Directorate-General for Taxation</td>
</tr>
<tr>
<td>ECDC</td>
<td>European Centre for Disease Control and Prevention</td>
</tr>
<tr>
<td>ECI</td>
<td>European Citizens’ Initiative</td>
</tr>
<tr>
<td>ECJ</td>
<td>European Court of Justice</td>
</tr>
<tr>
<td>EEAS</td>
<td>European External Action Service</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
</tr>
<tr>
<td>EHIC</td>
<td>European Health Insurance Card</td>
</tr>
<tr>
<td>EIB</td>
<td>European Investment Bank</td>
</tr>
<tr>
<td>EIF</td>
<td>European Investment Fund</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EPSCO</td>
<td>Employment, Social Policy, Health and Consumer Affairs Council</td>
</tr>
<tr>
<td>EPSR</td>
<td>European Pillar of Social Rights</td>
</tr>
<tr>
<td>ERDF</td>
<td>European Regional Development Fund</td>
</tr>
<tr>
<td>ERN</td>
<td>European Reference Networks</td>
</tr>
<tr>
<td>ESIF</td>
<td>European Structural Investment Funds</td>
</tr>
<tr>
<td>ESF</td>
<td>European Social Fund</td>
</tr>
<tr>
<td>EXPH</td>
<td>Expert Panel on Effective Ways of Investing in Health</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (US)</td>
</tr>
<tr>
<td>GDPR</td>
<td>General Data Protection Regulation</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>IMF</td>
<td>International Monetary Fund</td>
</tr>
<tr>
<td>IOM</td>
<td>International Organization for Migration</td>
</tr>
<tr>
<td>MFF</td>
<td>Multiannual Financial Framework</td>
</tr>
<tr>
<td>MIP</td>
<td>Macroeconomic Imbalance Procedure</td>
</tr>
<tr>
<td>NB</td>
<td>Notified Body</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>OMC</td>
<td>Open Method of Coordination</td>
</tr>
<tr>
<td>PPP</td>
<td>Public and Private Partnership</td>
</tr>
<tr>
<td>RRF</td>
<td>Recovery and Resilience Facility</td>
</tr>
<tr>
<td>QMV</td>
<td>Qualified Majority Voting</td>
</tr>
<tr>
<td>RQMV</td>
<td>Reverse Qualified Majority Voting</td>
</tr>
<tr>
<td>SARS</td>
<td>Severe Acute Respiratory Syndrome</td>
</tr>
<tr>
<td>SDG</td>
<td>Sustainable Development Goals</td>
</tr>
<tr>
<td>SGEI</td>
<td>Services of General Economic Interest</td>
</tr>
<tr>
<td>SGI</td>
<td>Services of General Interest</td>
</tr>
<tr>
<td>SGP</td>
<td>Stability and Growth Pact</td>
</tr>
<tr>
<td>SRSS</td>
<td>Structural Reform Support Service</td>
</tr>
<tr>
<td>TEC</td>
<td>Treaty Establishing the European Community</td>
</tr>
<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade-related aspects of international property rights</td>
</tr>
<tr>
<td>TSCG</td>
<td>Treaty on Stability, Coordination and Governance</td>
</tr>
<tr>
<td>UHC</td>
<td>Universal Health Coverage</td>
</tr>
</tbody>
</table>
We would like to thank Paula Franklin, our anonymous reviewers, and colleagues at the European Commission for their helpful comments. All errors of fact remain ours.
Chapter 1

Introduction

There is no European Union health system but there is EU health policy. The European Union 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 many ways, most of them poorly understood.

This book, a completely revised third edition of our previous volumes on the subject, maps out the nature of EU health policies, their logic and reason for being, and their potential to affect the health of Europeans. Almost every section has been revised and the overall structure changed to reflect changing politics and policies. We hope that it will encourage appreciation of two things. First, we hope that readers appreciate the extent to which the realization of EU health policies lies outside the organizations, legal bases and people most conventionally associated with the health policy of the EU. Second, we hope that they appreciate the extent of change in EU health politics and policy since the arrival of COVID-19 in 2020.

The book itself has expanded to reflect this complexity and flux, with extensive new discussion of public health and fiscal governance. Its changing table of contents, relative to the previous edition, shows the changing and expanding scope of EU health policy. We have separated the increasingly substantial EU public health policy underpinned by Article 168 TFEU and civil protection (Chapter 3) from the many policies based on the other Treaty articles that mention health (Chapter 4). We also separated out the discussions of the EU as a global health actor into a short, new chapter (Chapter 7) that briefly introduces the different ways in which the EU interacts with the rest of the world in health areas. The fact that there is now so much EU public health policy to cover that it takes two chapters, in particular, is notable as it means that the health dimensions of EU policies are becoming more explicit and turned into a basis for action to create EU health policy.

The book is written in the belief that understanding the breadth and diversity of EU health policies, and the distinctive institutional structure that explains them, will improve our collective abilities to understand how health is affected by policy-making in any sphere, from food to healthcare services and from occupational health and safety to international trade.

Above all, we hope that this book illustrates the scale and often indirect impact of EU policy on health. Boxes 1.1 and 1.2 show the EU’s impact on health and its diverse forms of influence. Box 1.1 shows how the EU is engaged in many ways in the essential functions of a health system. Box 1.2, by contrast, shows how the EU shapes one issue: cancer prevention and treatment.

This chapter maps key concepts needed for understanding the EU, discussing the different faces it presents, of health policy actors, of internal market actors and of a form of fiscal governance. It then discusses the asymmetries between the EU’s different roles and policy tools, and the broader range of EU powers for health that you might miss if you focus on the EU’s named healthcare and public health policy.

1.1 The three faces of European Union health policy

There are three broad faces of EU health policy. Each works in a different manner and each is authorized by a different body of law that obliges or allows the EU to act. The first, and most obvious, face is explicit health policies, based on the Treaty on the Functioning of the EU (TFEU) provision Article 168 TFEU entitled “Public health”. Action in this area is initiated by the European Commission, the EU’s executive, by its Directorate-General for Health, known as DG SANTE, and legislation is usually considered by the European Parliament ENVI Committee and the health formation within the EPSCO configuration of the Council of (health) ministers. It is a mixture of some hard powers – binding legal instruments and laws – in specific areas, such as regulation of substances of human origin, supportive activity such as the joint procurement of equipment and vaccines during the COVID-19 pandemic, and programmatic activity such as the EU4Health (Box 3.4) or the State of Health in the European Union (Section 2.3.1). The Treaty language in Article 168 TFEU that authorizes this work is clear: the organization and finance of healthcare is a Member State power, and the EU’s work in public health and healthcare cannot harmonize Member State laws generally (Article 168 (5) (7) TFEU),3 but the EU can ensure helpful

---


3 Except in some clearly demarcated areas such as the safety of medicines.
coordinating measures. In this regard the EU’s role is nonetheless diverse and often effective, as Box 1.2 shows.

The second face of EU health policy is less intuitive to those versed in Member State health policy. It is health policy made on the legal basis of its internal market (Article 114 TFEU), and it is far more consequential for health and healthcare than the first face. The basic logic is that the EU has great powers to promote the development and regulation of its internal market. In particular, eliminating measures that discriminate on the basis of Member State (e.g. protectionism for one’s own citizens or businesses) is a core and deeply entrenched EU principle that ensures market integration. This legal basis to develop an internal market means that the most effective way to regulate, for example, pharmaceuticals or professional qualifications is as a part of a market for services or goods. That means both overriding discriminatory Member State regulations and raising the floor of standards at the same time, so that there cannot be a race to the bottom. The result is a set of powerful EU laws across a range of areas, but also a persistent tendency for them to be developed as a means to deepening market integration rather than as a means to better health. The case law and Directive on the cross-border mobility of patients, the most visible EU healthcare policy issue for many years, was a good example (see Section 5.3.1). It was, at every stage, built around making publicly financed healthcare systems compatible with the law of the internal market of services, rather than promoting health or the sustainability of healthcare systems. Those issues were important for EU market making, not people – cross-border patient mobility is a bigger issue in EU law than it is for any health system. The extensive and powerful EU food safety system is based on a law, the General Food Law, which is explicitly based on powerful agriculture and internal market law bases rather than Article 168 TFEU and is powerful precisely because there is much more lawmaking power to be had in the internal market and Common Agricultural Policy treaty bases than in public health (Chapter 4). In some cases, such as tobacco control (see Section 3.2), health advocates and policy-makers have had to manage legal and political complexities in using internal market rules to regulate an industry that damages health.

The third face of EU health policy is fiscal governance: European surveillance of Member State fiscal policies including taxes, spending and policies that affect the state’s fiscal trajectory. Fiscal governance efforts date back decades, but after the 2010 start of the European sovereign debt crisis, it was greatly strengthened, becoming more ambitious, automatic and punitive in an effort

---


## Box 1.1  EU health policies

<table>
<thead>
<tr>
<th>Essential public health operations</th>
<th>Health legal bases</th>
<th>Market and wider policies shaping health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance of population health and well-being</td>
<td>X X X X X X X</td>
<td>X X</td>
</tr>
<tr>
<td>Monitoring and response to health hazards and emergencies</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Health protection including environmental, occupational, food safety and others</td>
<td>X X X X X</td>
<td></td>
</tr>
<tr>
<td>Health promotion</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Disease prevention</td>
<td>X X</td>
<td>X</td>
</tr>
<tr>
<td>Assuring governance for health and well-being</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Assuring a sufficient and competent public health workforce</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Assuring sustainable organizational structures and financing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advocacy communication and social mobilization for health</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Advancing public health research to inform policy and practice</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domains of health systems</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Service delivery</td>
<td>X</td>
</tr>
<tr>
<td>Health workforce</td>
<td>X X X</td>
</tr>
<tr>
<td>Information</td>
<td>X</td>
</tr>
<tr>
<td>Medical products, vaccines and technologies</td>
<td>X</td>
</tr>
<tr>
<td>Financing</td>
<td></td>
</tr>
<tr>
<td>Leadership/governance</td>
<td></td>
</tr>
</tbody>
</table>
**Box 1.1  EU health policies [continued]**

<table>
<thead>
<tr>
<th>Market and wider policies shaping health</th>
<th>European Semester and funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free movement – goods</td>
<td>Freedom, security and justice</td>
</tr>
<tr>
<td>Free movement – workers</td>
<td>European Semester and RRF</td>
</tr>
<tr>
<td>Free movement – services</td>
<td>Cohesion policy</td>
</tr>
<tr>
<td>Research</td>
<td></td>
</tr>
<tr>
<td>Competition</td>
<td></td>
</tr>
<tr>
<td>Procurement</td>
<td></td>
</tr>
<tr>
<td>Taxation</td>
<td></td>
</tr>
</tbody>
</table>

**Essential public health operations**

- Surveillance of population health and well-being
  - X
  - X

- Monitoring and response to health hazards and emergenices
  - X

- Health protection including environmental, occupational, food safety and others
  - X

- Health promotion
  - X
  - X

- Disease prevention
  - X

- Assuring governance for health and well-being
  - X

- Assuring a sufficient and competent public health workforce
  - X
  - X
  - X

- Assuring sustainable organizational structures and financing
  - X
  - X

- Advocacy communication and social mobilization for health
  - X

- Advancing public health research to inform policy and practice
  - X

**Domains of health systems**

<table>
<thead>
<tr>
<th>Service delivery</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health workforce</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical products, vaccines and technologies</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financing</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership/governance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Box 1.2  EU contributions to tackling cancer

One way of illustrating the range of EU action with an impact on health is to look at different aspects of health policy in relation to a specific disease. Here we look at cancer, as the condition with the longest history of specific EU action, across the dimensions of prevention, diagnosis and treatment, research and monitoring, and infrastructure and policy.

EU contributions to tackling cancer

For more information, including links to the 2021 Europe Beating Cancer Plan, see:

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Diagnosis and treatment</th>
<th>Research and monitoring</th>
<th>Infrastructure and policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary prevention • European Code against Cancer; 12 evidence-based recommendations for people to minimize their cancer risk • Regulation of potential cancer risks in the environment (e.g.: air, soil and water quality), food safety, health and safety at work, and of tobacco products, advertising and taxation, and the creation of smoke-free environments</td>
<td>• Regulation of medical products, devices • Cross-border care provision (e.g.: through European Reference Networks for rare diseases) • Cross-border care financing • Regulation of healthcare professional qualifications • Information portal for rare cancers and other rare diseases: Orpha.Net • European guidelines, e.g.: clinical guidelines on nutrition for cancer patients, and on Comprehensive Cancer Control Networks • Anti-discrimination protection for cancer patients and survivors under European legislation on disability</td>
<td>• Europe-wide comparative data about cancer health services and outcomes, such as from Eurostat and via cancer-specific studies such as EUROCARE and the European Network of Cancer Registries • Financing of European research on cancer • Regulation on use of personal data, for example in relation to cancer registries • Regulation of clinical trials</td>
<td>• Overall policy statements by the Council of Ministers and the European Parliament on cancer • Financing of cooperation between Member States on cancer, including multiple Joint Actions • European guidance on comprehensive cancer control strategies, i.e. Commission Expert Group on Cancer Prevention • Financial support to health infrastructure including in relation to cancer from the European Structural and Investment Funds, the Structural Reform Support Programme, and the European Investment Bank</td>
</tr>
<tr>
<td>Secondary prevention • Council recommendations on population-based cancer screening and support to implementation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As this shows, despite the primary responsibility of Member States for the organization and delivery of health services and medical care, in practice the European Union takes action in a wide range of areas that have direct relevance to cancer, which also illustrates the need to look across the full range of EU activities to understand its impacts on health.
to ensure that there would be no need for future bailouts because Member States would be deterred from short-sighted policies. The ambition of the fiscal governance architecture assembled in 2011–2013 is impressive, and it led to some things one might never have expected. For example, consider the 14 July 2015 Country Specific Recommendation (CSR), theoretically backed by threat of punishment, that France review its *numerus clausus* for health professionals’ education.⁶ That is a detailed policy intervention that few would have thought possible five years earlier. This third face of EU health policy has been evolving quickly, with debates about both its power and the ends to which it is being used. The process has clearly evolved a great deal when we compare that French CSR of 2015 to the CSRs of four years later, which encouraged Cyprus to continue its universalizing reforms and invited Italy to reduce north-south variations in health care quality.⁷, ⁸, ⁹ Evaluations of its actual workability and impact vary and the goals it claims to promote are broadening.

Finally, each of the three faces has an international dimension. One of the functions of regional international organizations, including ones less ambitious than the EU, is to coordinate positions and present a united front in global health.¹⁰ The EU is a large and important global actor, one of the world’s largest aid donors, a principal architect of international economic governance, and a giant economy. It influences health governance and health around the world; the question is, with what coherence and intent? Chapter 7 briefly presents key dimensions of the EU’s impact on global health.

### 1.2 Constitutional asymmetry and the regulatory state

The EU’s three faces are quite different. They authorize different kinds of action and the exercise of greater or lesser power at the EU level. The result is what

---

⁹ Council recommendation on the 2019 National Reform Programme of Italy and delivering a Council opinion on the 2019 Stability Programme of Italy (5.6.2019).
scholars call the EU’s “constitutional asymmetry”. 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 usually has a more general mandate to legislate.

The result of this structure is that the EU, compared to Member States, is enormously strong as a regulatory actor 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 and direct deployment of its own resources. It regulates the actions of others, achieving public policy ends not so much through its own actions or spending as by shaping the actions 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. Its executive, the Commission, employs fewer people than many local governments in Europe. The structure of EU law means that Member State administrations implement EU law while Member State legal systems enforce it.

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, this 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, as in challenges brought under EU law to alcohol minimum pricing (see Section 3.4) or in the string of patient mobility cases in which 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, direct effect of Union law and the rule of law itself, which is


why authoritarian backsliding and calls for “legal pluralism” that undermines EU law are such existential challenges to the EU.\textsuperscript{14}

EU spending is focused in agriculture, where the health effects are still not clearly beneficial overall, and in structural funds, its aid to infrastructure and development in poorer regions. These are large areas of spending, especially given their focus in a few particular countries. They are not, however, the core of EU power. The real power in the EU lies in the development of regulatory policies that harmonize standards for key products at a high level (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.\textsuperscript{15} 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 called EU4Health, civil protection via the RescEU programme, and support for old and new agencies. While still smaller than some of the EU’s traditional expenditure lines, it marked a serious and new EU budgetary commitment to health. Chapter 3 explores these expenditures in more detail.

1.3 Origins of EU health policy

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 goods, services and labour necessarily involves decisions with implications for the health of workers, consumers and people in the broader environment. In the case of the EU, as might be expected, health has been part of social security coordination since its establishment (see Sections 5.2.2 and 5.3.1). 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. In the EU, correspondingly, the only healthcare issues for many years were the coordination of social security benefits that might include health, occupational safety legislation applied to healthcare workers, and pharmaceutical


Box 1.3  Rule of law and the EU budget

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 an increasing number of Member States, pressure has grown to ensure the upholding of the rule of law and to use the EU’s powers to do so. The constitutional asymmetry of the EU plays out here as well: the Commission, in response to a backsliding on rule of law protections within certain Member States, adopted a Rule of Law Framework\(^a\) that it updated in 2019,\(^b\) much of which was focused on identifying legal bases for support of the rule of law in Treaty bases.

One of the most legally solid and politically promising ways to promote the rule of law was seen through viewing it as a threat to the budget, using the logic that good budgetary governance cannot happen without the rule of law. The Commission consequently proposed a Regulation “on the protection of the Union’s budget in case of generalised deficiencies as regards the rule of law in the Member States”\(^c\) that would cause the suspension of some or all EU payments to a Member State in the event that it was found to have “generalised deficiencies”. Such a policy would have dramatic effects on the policies and politics of the countries that most benefit from cohesion policy funds\(^d\) (see Section 6.2.4). Note, though, the title, which is focused on the protection of the EU budget. Although there are provisions in the Treaties to sanction individual Member States for breaching the fundamental values on which the EU is based,\(^e\) these are seen as an extreme option. However, in recent years discussion has become more focused, with specific proposals from the Commission on making these requirements more applicable in practice by linking them more tightly to the budget in particular.

Discussions about the Rule of Law, a 2019 Finnish Presidency priority,\(^f\) are not just an issue for the EU budget. Commission research has found that healthcare is one of the sectors of the whole EU most plagued by corruption.\(^g\) Expanding the effectiveness of the rule of law could have important benefits for health budgets that cannot afford corruption.\(^h\)

---


\(^b\) Brussels, 3.4.2019 COM(2019)163 final 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”.


\(^e\) Article 7, Treaty on European Union.


legislation. Otherwise, “public health” 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 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.\textsuperscript{16}

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. It was, and is, difficult to argue against agreeing to low-budget cooperation against a problem like cancer, or, later, AIDS, or harmful drug use. But, set against the rising profile of healthcare in many national polities and the rising profile of the EU in those years, it began to normalize the idea that effective European public health action was possible.\textsuperscript{17} 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 would mean Member States, once they had hit an EU-wide regulatory minimum, would mutually recognize one another’s regulations. In these measures were some of the first European policies affecting healthcare, including the start of European regulation of pharmaceuticals and medical devices.\textsuperscript{18}

The amendments to the Treaties as a result of the Maastricht Treaty was a major step forward on the trajectory of institutionalizing public health as a European power. It created, for the first time, 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) were limited and reflected the politics of the day, with action against the misuse of 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 (later in the TFEU with the amendments of the Treaty of Lisbon) (see Box 1.4).

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 further European integration that had been developing apace in the form of individual disease programmes such as Europe against Cancer, so it is not completely clear that it was 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 (OMC) with the goal 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.19

This background activity was overshadowed by what might be thought of as the EU’s “foundational” health crisis, the BSE episode.20 Bovine Spongiform Encephalopathy (BSE), nicknamed “mad cow” disease by the media, could, if ingested by humans, 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


Box 1.4  The evolution of treaty articles on health over time

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.

>> continues
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
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 UK, and the UK press and government responding robustly to the insults being aimed at the national icon of British beef.21 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. The public health article, renamed Article 152 EC Treaty through the amendments of the 1997 Treaty of Amsterdam, effective in 1999, became longer, wordier and more ambitious, 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 in the Treaty for health, 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 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 Public Health and Consumers, known as DG SANCO, under the Irish Commissioner David Byrne (1999–2004). There were two basic reasons. 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, the Directorate-General for Agriculture. Moving health regulation away from its previous home in industry-promoting directorates such as agriculture 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 Directorate-General for Health and Consumer Protection (DG SANCO at the time) 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.

Even as the EU’s public health apparatus and ambition expanded, creating the first face of EU health policy as we know it, the second face made itself very visible to the health sectors of the EU 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. 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. 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 5.3.1. While formally it was an internal market policy, its passage at least established that healthcare services are not like any other services and health stakeholders were politically strong enough to defend such an assertion of separateness against those who would treat healthcare like some other service.

More consensually, European authorities established the European Medicines Agency (EMA) in London in 1995, although it did not fall under 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.

EU public health policy, meanwhile, took its next steps forward with strong tobacco control legislation (see Section 3.2) 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 UK, the result was support for a strong EU role in communicable disease control. Using Article 152 EC, the EU institutions created the European Centre for Disease Prevention and Control 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.

EU 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”, and gave a strong impression that health was a “small thing”. In the aftermath of the UK’s 2016 Brexit vote, the Commission even produced a strategy paper with one of the five options being an EU that did nothing on or for health. Despite this broad trend, EU health policy did not go away. DG SANTE spearheaded a number of important policies for health and over the five years before the COVID-19 pandemic steadily incorporated health goals into key policy areas including the internal market (Chapter 5) and fiscal governance (Chapter 6). The Juncker Commission priorities allowed Commissioner Andriukaitis to place health and food safety priorities in other policy areas and there were also advances in SDGs during his term (Box 2.6). Moreover, the Commissioner went beyond his limited mission letter in introducing a range of initiatives and legislative changes such as in tobacco control and general food legislation.

For most of the EU, the five years of the Juncker Commission were focused on economic issues, including battles about austerity and the nature and speed of the economic recovery, on the rule of law, and on arguments about migration. The UK, though, created a special set of problems with its Brexit vote in 2016 (see Section 7.2.2).

The von der Leyen Commission, led by a German with public health training, entered office in 2019 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, and even by the end of the previous 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 mission letter than Juncker gave Andriukaitis (reproduced in the Appendix). The implementation of that mandate, as well as much else, was for ever thrown off course by the COVID-19 pandemic.

1.4 The EU during and after COVID-19

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 why we wrote this third edition and will be discussed throughout the book.27

1.4.1 EU pandemic response

The first reaction of governments at all levels, worldwide, was often nationalistic—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 3.9). The voices in the media which predict a terminal crisis whenever the EU faces a problem predicted a terminal crisis. But instead, what happened was that the EU and its Member States, with remarkable speed, realized that their integration was too deep to avoid collaborating on their response.

In terms of the first face, 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 organization to be called HERA. 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).28 Legally and organizationally, civil protection is not part of


public health (see Section 3.9 below), 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
perhaps particularly important, for it meant EU governments pooling their
resources on the single most important issue they faced.

In terms of the second face, the initial challenge in spring 2020 was simply to
keep the internal market 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 supply chains for almost anything turned out to cross borders,
making autarchy impossible. 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 second face was,
unusually for EU health policy, less important than the other two, but the
maintenance of the internal market was an achievement in itself and a testament
to the depth of EU integration.

In terms of the third face, fiscal governance, the crisis came when the existing
system of fiscal governance had already lost its coherence and focus on austerity.
The incoming von der Leyen Commission had stated that the whole of the
United Nations Sustainable Development Goals could inform the evaluation
of Member State policies. 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 Resilience Facility
(RRF), which directs funds to Member States for general budgetary support
(see Section 6.4). This is a contrast to existing EU funding models, which
fund specific projects or goals such as agricultural policy. The RRF comes with
conditionality which means that Member States must specify the use they will
make of it, but it could nonetheless have set a very important precedent and
made the EU start to approximate its structure to the world’s federations, all of
which have some level of intergovernmental risk pooling.29 The Semester and
its legal underpinnings have not gone away. EU policy instruments generally do
not vanish – careful readers can find vestiges of fiscal governance instruments
created and forgotten years ago, such as the Broad Economic Policy Guidelines.
They are instead absorbed into other, newer systems. But the commitment to
budgetary austerity that EU Member States adopted in the aftermath of the

2008 financial crisis weakened, and the future politics of fiscal governance in the EU are likely to 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, we are already discussing its more indirect effects because political institutions and party politics changed so little, even if so much was revealed by their crisis response.\(^30\) 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.\(^31\) The question now is whether, over the next five years, this newly ambitious and protective EU health policy will convince Member States and others of its utility and value.

1.4.2 The European Health Union

In November 2020 the European Commission produced a set of proposals that together would jumpstart the building of a “European Health Union” focusing on preparedness and resilience. The European Health Union is a set of regulatory proposals to expand the mandate of the European Medicines Agency and the European Centre for Disease Control, and the proposal to adopt a new regulation regarding the manner in which the EU generally can respond and coordinate serious disease outbreaks. These three proposals formed the first step in the building of the European Health Union, and then the new Pharmaceuticals Strategy, the HERA (Health Emergency Response Authority) and the Europe Beating Cancer plan were also presented as part of the “European Health Union” set of proposals. As it stands, the term of a European Health Union is used to refer to a set of proposals, but which exact ones is not entirely clear, nor what exactly the end goal is of the building of this Health Union (these proposals are covered in more detail in Section 3.5 below).\(^32\)

A Regulation on cross-border health threats (Box 3.2) is of particular interest. It draws on a decade of thinking and reflecting on responses to previous threats. It creates a blueprint for Member State responses, gives the Commission a broader

\(^{30}\) 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 than as a force for change. De Waal A (2013). \textit{AIDS and Power: Why there is no political crisis yet}. Zed Books; Greer SL, King E, Massard da Fonseca E & Peralta-Santos A (2021). \textit{Coronavirus politics: The comparative politics and policy of COVID-19}. University of Michigan Press, p. 663.


right to declare a public health emergency, and formalizes the Health Security Committee’s role – a role that had been formalized by a 2013 Commission decision\(^{33}\) but that remained limited. Note that to move from a Decision to a Regulation is a very significant legal upgrade (Box 2.4).

A last important change deals with the joint procurement of medical goods. Here, the Commission proposes to really exclude the possibility for Member States to hold parallel negotiations with (vaccine) manufacturers as long as they want to be part of the joint efforts that are organized by the Commission. On the whole, these legislative steps are big in the field of health, but they also remain limited, and in the discussions in the Council it is already noted that Member States worried about the EU “auditing” their countries for having implemented national preparedness plans. Also, they were concerned about losing the right to hold parallel negotiations with the industry, once they have entered a joint procurement for medical goods – even when that of course really undermines EU solidarity – was criticized by some States.

As with most of the EU response, it is a much more vigorous use of existing policy tools rather than a novel form of integration. Most of the plans have basically been piloted under ad hoc legislation during COVID and were already recognized as weak spots in the existing legislation. That does not make them politically uncontroversial, as becomes very clear upon reading the initial response of the Member States to these plans.

However, in parallel to this focus on crisis response, the European Health Union is also intended to address longer-term challenges like antimicrobial resistance, the health impacts of climate change, ageing population 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 development, manufacture and distribution of COVID-19 vaccines, including via joint procurement by the European Commission, whilst the Pharmaceutical Strategy seeks to address structural issues within the pharmaceutical sector, primarily by revising the regulatory framework.

1.5 Three dynamics of EU health policy

What does this history tell us about the evolution of European Union health policies? Broadly, there are three themes. The first is that integration begets integration. Integration of agricultural markets led to pressure for integration of regulatory frameworks after BSE struck. Integration of internal market law led to its application to healthcare services, which led to health stakeholders establishing a presence in Brussels and seeking to create legislation that better suited the health sector.34

The second theme follows logically: integration exists regardless of whether it is wanted, but what it means and how much it matters can vary and is responsive to the preferences of Member States and health stakeholders. The debate about EU policy on healthcare services regulation was about what kind of regulatory framework it would be, what it would try to do, what policy instruments it would use, which parts of the Council and Commission would manage it, what the role of the courts would be, and what its priorities would be – in other words, almost everything. The fact that an EU health policy exists is less important than what is done with it and to whom it matters. Sometimes there is a debate about whether EU policies in an area should be viewed as a policy area, as with debates about the presence of a European health law,35 or the struggles over whether the many EU actions that affect the consumption and effect of alcohol or food should be viewed as a coherent policy area that should take health seriously (Chapter 3).

The third dynamic is that crises and shocks get attention and provoke responses. It is a staple of public health history that crises can provoke action and public health initiatives arise after outbreaks. EU health powers have been expanded in the wake of sudden problems, including severe acute respiratory syndrome (SARS) or the scandal of blood infected with the human immunodeficiency virus (HIV), which led to EU powers on blood safety and quality. In 2017 European authorities reinforced the oversight for medical devices in the aftermath of the breast implants and replacement hips scandals, although such reforms did not substantially change the EU regulatory framework for medical devices.

It is important not to overstate the determinate impact of crises. Most public health advances seem to follow crises but not all crises produce public health policy, and some crises or responses can lead to worse public health policy. Crises push public health onto the political agenda, but what that means depends on


complex politics and can be hard to determine.\textsuperscript{36} Furthermore, there are many kinds of policy responses; for example, it was not obvious in the late spring of 2020 that the EU’s COVID-19 response would take the form it did.

The big steps in EU public health policy thus do seem to follow threats, in particular with BSE and the creation of the health DG and then the increased number of communicable disease crises and the creation of the ECDC. Crises are what political scientists call “focusing events” – they focus attention on the issue. Public health crises put public health on the agenda, bringing seemingly technical microbiology and epidemiology out of the shadows into the centre of public attention, and are an opportunity for entrepreneurs to push forth public health initiatives that were being neglected. Crises can also take legal and political forms. European individuals took action via court cases – on EU law on patient mobility for instance – and instigated major policy changes in the absence of significant political demand. For a time, Brexit looked as though it might be such a crisis, focusing attention on issues such as the meaning of EU membership. However, the COVID-19 pandemic has thoroughly displaced Brexit as a focus for policy attention.

1.6 The emergence of a variable EU health policy arena

We have spoken so far mostly about the areas in which the EU acts in traditional and core areas of health policy: healthcare and public health. But there are four parts of the Treaty on the Functioning of the European Union that explicitly make better health a European Union goal, as discussed in Chapter 2. Alongside the public health Article 168 TFEU, there are articles about the environment (Article 191 TFEU), labour in the Social Policy chapter (Arts. 153 TFEU, 156 TFEU) and consumer protection (Article 169 TFEU) that specify health as an objective. These are fields in which the EU already does much for health – some of its individual environmental policies, in particular, might have prevented more avoidable deaths than all the policies it has made in the name of health and healthcare. Finally, Article 9 TFEU calls for all EU activity to “take into account” a “high level of protection of human health”.

In other words, the Treaties lay out areas where there is clear authorization to act with health as an objective, and it is hard to argue that health is an illegitimate or unusual goal in environmental, labour and consumer protection. These are not just areas where the EU’s health effects are already visible and often positive; they are areas where there is an authorization in the Treaties for more, and more coordinated, efforts to improve health.

Beyond those treaty articles, the three faces of the EU health policy look upon many of the social determinants of health, from regulating food labelling to subsidizing agriculture, to encouraging raising pension ages, to making trade agreements, to building infrastructure that might or might not encourage walking and cycling. Within Member States, it has long been recognized that the healthcare system is only one contributor to health. The EU has policy levers over many of the most powerful determinants of health and in some areas such as agriculture or trade is one of the most powerful actors in Europe or the world. Even areas such as homelessness, which seem distant from EU policy, turn out to have a significant EU role which can be used for good (Box 1.5). To promote health is to understand and seek to use this EU leverage.

1.7 Health, convergence and the EU

The European Union has 27 Member States and around 447 million people, making it one of the world’s largest political units compared to the US (327 million), China (1 386 million), India (1 399 million), Nigeria (201 million) and Japan (126 million). It is also extremely diverse – economically, culturally, politically and in health terms. For understanding the background of health policy in particular, it is worth remembering both the different economic and health outcomes and the extent of convergence. In particular, it is worth noting the extent to which convergence between different Member States is not happening.

In other words, convergence within the EU is neither inevitable nor necessarily proceeding under the current policy regime. Figure 1.1 shows trends in convergence in GDP per capita since 1995, showing that overall economic convergence is not the main story of the twenty-first-century EU. Trends in health show a similar pattern. Lack of convergence between EU Member State economies is already a problem for the EU’s health and broader political economy; the longer divergence continues, the greater the stresses it will place on the EU. Figures 1.2 and 1.3 show the still different life expectancies across Europe. Life expectancy at birth shows the expected longevity at birth; life expectancy at 65 is net of infant mortality and is an insight into the welfare of people alive in Europe who, in the United States, would probably be dead.

37 Consider one example of European integration with health consequences: the European Road Safety Observatory, born of EU-funded research projects but now maintained by the Commission’s transport DG, making its contribution to Europe’s world-leading road safety: available at: https://ec.europa.eu/transport/road_safety/statistics-and-analysis/methodology-and-research/about-european-road-safety-observatory_en (accessed 19 February 2022). Or, still in the field of transport, consider EU vehicle safety rules made as part of the single internal market. EU legislation frames the safety of vehicles in terms of deaths in and outside the vehicle, while US law defines safety purely in terms of the effects of crashes on people inside the vehicle. This basic difference in legal framework means there are tens of thousands of people alive in Europe who, in the United States, would probably be dead.

Box 1.5  **Bricolage at work: Homelessness policy in the EU**

Readers of the EU Treaties will probably not expect to find much about homelessness, nor will they. A right to “housing of good quality” appears in the 2018 European Pillar of Social Rights but there is nothing obvious in the foundational TEU and TFEU. And why should there be? Addressing homelessness and its causes, which range from property markets to mental health systems, is traditionally local and not even necessarily national. The principle of subsidiarity (Box 2.5) suggests that the EU would not be the natural policy leader, Member State governments might not be eager to spend money on homeless people who might be in a different country entirely, and the logic of the internal market does not obviously point to a right to adequate housing.

That makes homelessness a perfect case study of an area that is important to health, far from the core of EU competencies, and yet an area where there is an EU effect. One of the principal civil society groups advocating for the homeless at the EU level, FEANTSA, constantly reiterates that it supports “making more effective use of existing policy instruments” as well as promoting constants of EU policy such as monitoring and benchmarking (just as in healthcare). Those existing policy instruments are actually impressive, if we look at them as a set of opportunities to affect a seemingly local problem like homelessness. Structural funds (Section 6.2.4) and EIB loans can directly support housing, or, if misdirected, can damage housing opportunities. The priorities of the EU fiscal governance system (Chapter 6) can have powerful effects on homelessness and homeless people, whether by deregulating housing markets (as the Troika promoted) or by encouraging more universal healthcare (as the Semester has in some cases). Indirectly, causes of homelessness such as untreated mental illness, poverty or discrimination all respond to EU policies. The result is that a policy area just about as far from the EU as it is possible to get turns out to have a significant EU dimension.

---

older people. Both show significant variation between countries and regions. Noticeably, the example of German reunification proved that health outcomes can be substantially equalized between poorer and richer regions – but at a high cost in government expenditure.39

---

Box 1.6 Well-being

The Treaties state the overall aim of the EU as being “to promote peace, its values and the well-being of its peoples” (emphasis added).\(^a\) Although not directly a reference to health, this of course echoes both the World Health Organization’s definition of health (“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”)\(^b\) and the objectives for improving well-being set by the WHO’s European “Health 2020” strategy.\(^c\)

The Treaty aim does not have any specific powers attached to it – rather, all the powers in the Treaties are intended to help to achieve this overall aim. There has been some specific work related to this, however, centred on the idea of developing broader measures of progress in European countries than the traditional summary of GDP,\(^d\) within which health is one of the main dimensions. This has been followed by a range of reports and publications by the EU, by Member States and by other international bodies.\(^e\)

It has received a push in 2019. The Council adopted Conclusions (ref: 13423/19) in October 2019 under the Finnish Presidency on the economy of well-being as a “policy orientation and governance approach” that “brings into focus the raison d’être of the EU as enshrined in the Treaties and in the Charter of Fundamental Rights of the European Union”. An economy of well-being, it continues, entails cross-sectoral collaborations (noting Health in All Policies) and includes access to healthcare, “promotion of health and preventative measures” and “occupational health and safety”.\(^f\)

However, although there is by now an extensive range of reports and evidence highlighting the relevance of these broader concepts of development and well-being and the importance of health as one of the key issues, it is not clear that this evidence has yet brought about any substantive changes in policy-making. With the agreement of the Sustainable Development Goals (SDGs) in 2015, it may be that in practice the SDGs and their monitoring will prove to be the primary focus for efforts to take a broader perspective on development, rather than the concept of well-being.

---

\(^a\) Treaty on the European Union, Article 3.

\(^b\) Preamble to the Constitution of the WHO as adopted by the International Health Conference, New York, 19–22 June 1946, signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.


\(^e\) See http://ec.europa.eu/environment/beyond_gdp/index_en.html for more information.

1.8 Conclusion

In the EU a legal basis can create a starting point for policy entrepreneurship, but the public health legal base was not written to permit much policy entrepreneurship. To sharpen the point, the EU Treaties prevent much activity grounded in the public health article, but that manifestly does not mean that the EU lacks health policy. Instead, it means 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 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

---

**Fig. 1.2 Life expectancy at birth, EU, 2002–2019**

![Graph showing life expectancy at birth, EU, 2002–2019 with males and females represented.](image)


**Fig. 1.3 Life expectancy at age 65 (2019)**

![Map showing life expectancy at age 65, EU, 2019 with various EU countries represented.](image)

operate their health systems, but they cannot primarily be made with health, as against fiscal sustainability, as their goal.

In the 2019 second edition of this book, we pictured Article 168 TFEU as a gate with no fence: a solid gate, one that would close tightly and open easily if Member States chose. As EU health policy constantly showed, in the absence of a fence all sorts of policies were made by simply going around the gate – the bulk of Chapters 4–7 in this book. But in 2020 Member States decided to open the gate – leading us to commission a new cartoon update (see Figure 1.4).

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.

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 and an overall EU political agenda that was focused elsewhere. 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 result has shaped health outcomes and shows how powerful, and inescapable, EU health policy can be.
**Fig. 1.4a** EU health policies as a gate with no fence

![EU health policies as a gate with no fence](image1)

*Source: © Floris Oudshoorn/ComicHouse.nl, reproduced with permission*

**Fig. 1.4b** Gatecrashing EU health policies

![Gatecrashing EU health policies](image2)

*Source: © Floris Oudshoorn/ComicHouse.nl, reproduced with permission*
Chapter 2

The European Union: institutions, processes and powers

This chapter introduces the EU institutions and a few key points for the analysis and interpretation of EU health policy. EU institutions are complex – there is a special web page to help people understand the different roles and functions of the various EU presidents\(^1\) – but there are a few particularly important institutions and threads to follow.

For health policy-makers, the first key point is that EU regulation and law are powerful tools to promote health, but those tools are often organized – bureaucratically, politically and legally – under some other title such as environmental, civil protection or social policy. Neither healthcare nor health outcomes in the EU can be understood without considering the full range of legal bases and tools the EU can use.

The second key point is that the EU’s impact on healthcare has been mostly indirect or limited. The limited action on health and healthcare comes about for deep legal and political reasons. Despite consensus on the importance of good and generally egalitarian health as one of Europe’s Member States’ most distinctive features,\(^2\) in successive Treaty revisions national governments have preferred to keep health issues primarily at national level and so have provided only limited powers for EU action in pursuit of health. However, health is affected by many wider social and environmental factors on which the EU has its own impact, and health systems form one of the largest sectors of the European economy.\(^3\) In 2018 health spending accounted for nearly 10% of GDP in the EU, with France and Germany allocating more than 11% of their GDP to health spending.\(^4\) As a result, health and health systems are most affected at EU level by policies born

---

in other sectors, particularly those affecting the determinants of health (such as environmental policy), the integration of the internal market (through issues such as cross-border healthcare or professional mobility) and health regulation (as with regulations on labour and pharmaceuticals). Reflecting the origins of the EU, these are policy areas where the EU is built to produce market integration, economic growth and development through the extension of single market law.

The third key point is that this could always change, and indeed has changed: the EU’s response to the COVID-19 pandemic was to use a variety of powers, which had always been available, to dramatically increase the scope and importance of its work in health. The Treaty article for public health (Article 168 TFEU), and indeed the structure of the institutions associated with health policy in the EU, always permitted a bigger and more ambitious health policy than the EU had traditionally pursued. The constraining legal language of the treaty article, and indeed the broader politics of EU health policy, had always permitted EU health policy initiatives if the Member States wanted them and in 2020 they did. In Figure 1.4a we showed Article 168 TFEU as a gate with no fence; in 2020 the Member States opened the gate and went through it (Figure 1.4b). The EU has new entities (HERA, HaEDA) and expanded mandates for older agencies such as EMA and ECDC; it has a far larger health and civil protection budget; and it has taken a leading role in vaccines acquisition and future pharmaceutical strategy. Old institutional forms and powers were adequate for Member State governments when they chose to have a strong EU public health policy for the first time.

2.1 European political institutions

The EU has three core institutions: an executive (the European Commission), two legislative bodies (the European Parliament, with members (MEPs) elected by direct vote in each Member State, and the Council of the European Union, comprising national ministers from each Member State, 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. 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. Commission vice-presidents chosen from among the commissioners oversee groups of individual commissioners on broad topics.

The lead for health in the Commission is the Commissioner for Health and Food Safety, Stella Kyriakides of Cyprus. The lead DG for health issues is the Health and Food Safety Directorate-General, known from its acronym in French as DG SANTE (and known, until 2014, when it lost consumer protection, as the Directorate-General for Health and Consumers, or DG SANCO). DG SANTE is responsible for EU policies and actions in public health and food safety, which include cross-border healthcare and tobacco control, as well as pharmaceuticals, State of Health in the EU, and medical devices (which was moved over from the reputedly more pro-industry DG Enterprise, now DG Internal Market, Industry, Entrepreneurship and Small and Medium-sized Enterprises, aka DG GROW). Other DGs have more specialized but consequential roles to play for health systems (leaving out DGs with indirect responsibility for health, e.g. reducing carbon emissions or promoting sustainable agriculture; see Chapter 5 for some discussions). Each of the policy areas that lead to their involvement will be 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 aids, 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 (Chapter 7) as well as the civil protection mechanism, including the stockpiling system RescEU (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 of cross-border patient and health professional mobility (on account of its competency in recognition of health professionals’ qualifications);

DG Health Emergency and Preparedness Response (HERA) is the new DG responsible for administering the EU’s new health emergency response and preparedness system, which will take additional legal and organizational shape from 2022 onwards (see Chapter 3);

DG Structural Reform Support (REFORM), born in 2015 as the Structural Reform Support Service (SRSS), became a full-scale DG in January 2020. SRSS had been consolidating ad hoc groups associated mostly with the response to the financial crisis, including oversight of the Greek Economic Adjustment Programme (see our second edition). DG 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;

DG Regional and Urban Policy (REGIO) is responsible for managing the cohesion funds, the EU’s regional development aid system, which is important to the finances of recipient regions and finances 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 and in other trade agreements.

Each commissioner receives their mandate in the form of a “mission letter” from the Commission President. As part of her mission letter, Kyriakides was asked to help ensure that the European Union has a steady supply of affordable

---

medicines and will be responsible for the effective implementation of the new framework on medical devices adopted in 2017. She was to give special attention to health technologies and e-health, through the creation of a European Health Data Space that will promote health-data exchange and support research on new preventive initiatives.\(^8\) She was also asked to focus on the implementation of the European One Health Action Plan against Antimicrobial Resistance. Finally, the mission letter mentions that all commissioners will be asked to contribute to the implementation of the Sustainable Development Goals.

In pursuing these goals, Commissioner Kyriakides’ mission letter directed her to work with the Vice-President for the European Green Deal, Frans Timmermans, on food safety and animal and plant health, and with the Vice-President for Protecting Our European Way of Life, Margaritis Schinas, on public health.\(^9\)

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, which administers and helps to shape EU food and agriculture policy; and DG Environment, 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, DG European Civil Protection and Humanitarian Aid Operations (ECHO), and DG European Neighbourhood Policy and Enlargement Negotiations, 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 these new policies through the other EU institutions.

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 (although

---

\(^8\) Idem.

Everything you always wanted to know about EU health policy but were afraid to ask

at 32,281 staff\(^\text{10}\) – as of 1 January 2021 – it is still substantial). 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 it does not have employees who sweep streets or inspect abattoirs or drive buses or even work out the detailed application of much of its 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.\(^\text{11}\)

The Commission then 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 of a proposal (though given that both Councils 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 2.4 below). The Commission does not just act through legislative proposals, of course; 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 leadership will often still be taken as the authorization for certain policies or ways of thinking until it is explicitly overruled or replaced. The Commission has the power to take

---


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, or anti-fraud, or humanitarian action. In health we saw only very narrow examples such as the European Health Insurance Card. However, the pandemic saw the Commission taking on an executive role more like a national administration, such as through joint procurement of vaccines and personal protective equipment, and working 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.

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 six initiatives that have successfully reached the required number of statements of support since 2012 deal with health issues. In the first ECI made in 2012, 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 to take a series of actions reinforcing implementation of EU water quality legislation.

More recently, 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. Although the Commission concluded in December 2017 that there were “neither scientific nor legal grounds to justify a ban of glyphosate”, DG SANTE responded quickly. A proposal on transparency and sustainability of the EU risk

assessment in the food chain was adopted by the Commission in April 2018\textsuperscript{17} 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. Although only partially successful, these ECIs have impacted the EU health policy-making process.\textsuperscript{18}

The Commission also has a role as the “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 Member States to the Court of Justice of the European Union over failure to implement and obey EU law. In January 2019, for instance, the Commission sent letters of formal notice to Austria and the Netherlands, requesting the Austrian and Dutch authorities to comply with the rules on the level of reimbursement laid out in the EU Cross-border Healthcare Directive (Directive 2011/24/EU).\textsuperscript{19} Regarding air quality, the Commission called on France and Sweden to bring their air quality legislation in line with European rules on ambient air quality and cleaner air for Europe (Directive 2008/50/EC).

The legislative processes and the voting procedures that underwrite them (qualified majority voting (QMV) and reverse qualified majority voting (RQMV)) are outlined in Box 2.2.

### 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 within the legislature, the Parliament now acts as co-legislator with the Council of Ministers in nearly all areas. The Parliament is elected by direct vote 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.


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 that goes 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 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. 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 debated draft proposal and specific political circumstances. The institutionalized use of trilogues seems to have strengthened transparency and accountability within the Parliament.

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 but 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 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
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.

In practical terms, the Parliament works principally through 20 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 is the Environment, Public Health and Food Safety Committee (ENVI), although other committees also play a significant 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.
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) – have lost their combined majority in the Parliament in the 2019 European elections. Their partnership, known as the “Grand coalition”, held 54% of the seats before the vote but is now down to 45% of the seats. S&D won 154 seats (20.51%) while EPP won 182 seats (24.23%), out of 751 seats. Other parties made substantial gains, including the Group of the Alliance of Liberals and Democrats for Europe + Renaissance + USR (ALDE&R), now Renew Europe, with 108 seats (14.38%), the Group of the Greens/European Free Alliance (ECR) with 74 seats (9.85%), up from 52 seats in 2014. Right wing nationalist and Eurosceptic groups also saw gains. 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 (Box 2.2), and makes the EU agenda less predictable.

### Box 2.3 Political groups in the 2019–2024 European Parliament and percentage of members

- Group of the European People’s Party (Christian Democrats): 24.23%
- Group of the Progressive Alliance of Socialists and Democrats: 20.51%
- Renew Europe: 14.38%
- Groups of the Greens/European Free Alliance: 9.85%
- Europe of Nations and Freedom Group now known as Identity and Democracy: 9.72%
- European Conservatives and Reformists Group: 8.26%
- Confederal Group of the European United Left/Nordic Green Left: 5.46%
- Non-Attached Members 7.59%

---

20 Available at: https://www.election-results.eu (accessed 19 February 2022).

### 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 configurations (e.g. the Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO) will be composed of the ministers responsible
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 a single body for multiple policies: although technically one body, in practice the Council for Agriculture and Fisheries is not made up of the same national representatives as the Council for Employment, Social Policy, Health and Consumer Affairs. This approach 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 variable success, the result is that a level of fragmentation exists in the heart of the EU legislative process.

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). 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. Both the Council and the Parliament can also agree on political statements, which are not legally enforceable but which clearly state priorities and policies. The Council can also adopt Recommendations; these are legal acts but without any legal mechanism of enforcement. Nevertheless, the political weight of such a commitment is substantial, and they have proved effective in the health area on subjects such as cancer screening.

The European Council is made up of the heads of state and government of the Member States; this 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.

---

has an elected president. 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.

There is a variety of types of EU legal instruments specified in the Treaties, and the differences between them are legally and politically significant (see Box 2.4).

### 2.1.4 Court of Justice of the European Union

Finally, the EU has a court, the CJEU. Formerly known as the European Court of Justice, it is the most powerful supranational court in history. 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.

EU 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 (Box 2.5). EU 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

---

Box 2.4  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 provisions on 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).

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.

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 the “comitology” decision of the Council. This provided for a range of different procedures with differing degrees of oversight from the Council (and the Parliament, though 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.

It replaced the previous systems of delegated powers with two types of delegated power. These are described in the treaty itself.
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”;

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, 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.

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).

---

f See Article 2(b)(iii).
qualifications, every EU Member State court has accepted both of these doctrines). EU institutions can bring cases directly to the CJEU, 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. 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 of learning how to adapt internal market principles to the specific politics and issues in healthcare.

On 7 October 2021 Poland’s constitutional Tribunal ruled that Polish laws have supremacy over those of the European Union in areas where they clash. The European Commission responded quickly to this direct challenge to the primacy of European law, by asserting that the Court of Justice of the European Union has primacy over national courts or constitutional tribunals in Member States.

The accession to the European Union of new states with different healthcare systems raises uncertainties regarding the applicability of EU health laws. National courts have used the preliminary reference procedure to seek answers through the CJEU. In Georgi Ivanov Elchinov v. Natsionalna zdravnoosiguritelna kasa, for instance, a Bulgarian Administrative Court asked the CJEU whether a “national court [is] obliged to take account of binding directions given to it by a higher court when its decision is set aside and the case referred back for reconsideration if there is reason to assume that such directions are inconsistent with Community law”. The Bulgarian court also asked the CJEU about the payment of costs incurred in a hospital located in another EU Member State (Germany), because the patient could not materially receive treatment in his

28 For the debate in EU law, which is normally framed as being about “constitutional pluralism”, see Kelemen R & Pech L (2019). The Uses and Abuses of Constitutional Pluralism: Undermining the Rule of Law in the Name of Constitutional Identity in Hungary and Poland. Cambridge Yearbook of European Legal Studies, 21:59–74. doi:10.1017/cel.2019.11.
30 CJEU (2010). Judgment of the Court (Grand Chamber) of 5 October 2010, Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa.
Box 2.5 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 on its 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. 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.

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 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
home country, Bulgaria, where there is an alternative treatment, which is both less effective and more radical than the treatment available in Germany.\(^{31}\)

Regarding the first issue, the CJEU ruled that “lower courts whose decisions were set aside by a higher court could, relying on that case-law, and when the case was referred back to them, disregard the setting-aside of their judgment by the higher court when, in their opinion, it was contrary to European Union law. In the conflict between national procedural autonomy and the opportunity, which was thus reopened, to assert the primacy of European Union law, priority was given to the latter” (para 21). Regarding the second issue, the CJEU ruled that prior authorization may be refused if the medical benefits provided abroad are not covered under 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.\(^{32}\)

---


2.1.5 Other treaty bodies: European Central Bank, European Investment Bank, Economic and Social Committee, Committee of the Regions, European Court of Auditors, and the Ombudsman

The European Central Bank (ECB), although not part of the EU legislative process, is particularly important as it is the central bank of the Eurozone. It has a high level of autonomy entrenched in Treaties that also give 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 Christine Lagarde, former finance minister of France and managing director of the IMF, was appointed president of the ECB.

On paper, the ECB has a narrowly limited remit that has little to do with health. In practice, it is very 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. The ECB demonstrated this over the decade since the financial crisis began, with unconventional monetary policy whose relationship to its mission could be unclear, and its participation in the “Troika” 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. 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 Section 6.2.4) provides funding for projects that seek to achieve EU goals, within or outside the European Union. It has, over the last decade, increased its exposure to health and sought to improve the sophistication of its lending, in particular to health systems.

In addition to the ECB and the EIB, 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 mis-spent money. Most recently, it evaluated the impact of the directive on cross-border patient mobility (see Section 5.3.1).36 In general, its reports are well done, even if they can be very awkward for the rest of the institutions.

In the same vein, the European Ombudsman is a person elected by the European Parliament under Article 228 with a mission to “receive complaints from any citizen of the Union or any national 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.” The Ombudsman’s term coincides with that of the European Parliament. The Ombudsman since 2014, Emily O’Reilly, has proved adept at using the position to raise inconvenient questions about decision-making processes.37 At the end of 2019, for example, the Ombudsman opened an inquiry into corporate sponsorship of EU Council presidencies, including the Finnish presidency’s links with car maker BMW and the Romanian presidency’s sponsorship by Coca-Cola.38 It was responding to a complaint by a civil society organization, Foodwatch International, which singled out the contribution of Coca-Cola’s products to obesity and diabetes.39

Finally, the EU legislative process also includes the Economic and Social Committee, which represents social partners (employers and workers), and the

38 Letter to the Secretary-General of the Council of the European Union, Mr Jeppe Tranholm-Mikkelsen, concerning commercial sponsorship of Presidencies. 14 July 2019. Case 1069/2019/MIG.
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 of the coalitions for and against an idea, or they can choose champions who are effective at influencing the agenda on a specific point. They are not, however, regularly 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), the European Environment Agency (EEA), the European Medicinals Agency (ECHA), the Community Plant Variety Office (CVPO), and the European Agency for Safety & Health at Work (EU-OSHA). Agencies are not the same thing as Executive Agencies (see Section 2.1.7 below), which are specialist parts of the Commission without their own legislative bases.

These agencies are part of a large set of EU agencies working in technical areas. 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.

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 “mission creep”. Member States are represented in 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. 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. 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.

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 about to get some empirical tests, with the move of the European Medicines Agency from London to Amsterdam, and the move of the European Banking Authority to Paris. How far related activity also follows these moves will be an interesting gauge of how valuable it is to have an EU agency in your country.

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. 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; there is no one single model of an “EU agency” and 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: HaDEA

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.\footnote{Council 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. \textit{Official Journal}, L 011, 16/01/2003 P. 0001–0008.} 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 Commission. Now it means a new 2021 agency related to pandemic preparedness and response: HaDEA, the European Health and Digital Executive Agency.

HaDEA takes on the work of CHAFEA in administering health and safer food programmes, including the Health Programme EU4Health, and became active in April 2021. As with CHAFEA, it 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 de-linking executive agencies focused on management of grants and programmes from the policy units can lead to poor communication about goals and performance. Managing this problem is difficult but entirely possible.

The lead DG for HaDEA is SANTE and it 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).

2.1.8 How do EU institutions take account of the EU’s indirect impact on health?

The question this leaves is: how do the key actors in the EU make sure that as European action is developed and implemented, the EU understands the effect it is having on health and guides its action accordingly?

The Commission’s answer has been discussed above. There is a high degree of internal coordination before policies are proposed (although whether this is always fully effective is a matter of debate; and as it is part of internal processes which are not public, the trade-offs made are not transparent to the outside).\footnote{Ståhl T et al. (eds) (2006). \textit{Health in all policies: prospects and potentials}. Helsinki: Ministry of Social Affairs and Health.}
The Parliament has explicit mechanisms for incorporating different perspectives within its process; if several different committees all have an interest in a file, they have an opportunity to be consulted and put forward amendments for their areas of responsibility. Where disagreements remain, these can be taken to the full plenary session of Parliament and sorted out there. Moreover, as the various meetings, amendments and discussions of the Parliament are public, it is much easier to understand what interests have been taken into account and how they have been balanced.

The Council, however, takes a different approach and one that gives rise to particular tensions. Although the Council meets in different thematic formations (see Section 2.1.3), it does not allow a Council 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 will be decided upon 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 equally effective, and for a subject such as health it can be very frustrating for national health ministers to find that they have no way to express themselves directly in Brussels on most of the decisions that affect them (see Chapter 6). In an attempt to increase transparency and policy coherence, the concept of a “roadmap” has been established (see Box 2.4).

2.2 Budget

The constitutional asymmetry of the EU is particularly visible in its limited finances. Overall government expenditure tends to be 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 around 1.5% of the EU’s gross national income (although this has been temporarily raised to 2% to cover additional expenditure related to the coronavirus pandemic).

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 over that period. Although the detailed EU budget is still negotiated and agreed annually,

---

this takes place within the overall Multiannual Financial Framework, and thus these total amounts are unlikely to shift substantially over this period.

There has been a steady shift in the EU budget over time away from agriculture and towards newer priorities such as research and innovation and climate change. Nevertheless, agriculture remains one of the largest areas. It takes around one third of the total budget, with the cohesion funds taking another third and other areas making up the rest. In terms of the major areas of public finances in Europe as a whole, therefore, only in agriculture is European funding predominant; in all other sectors, national (or regional) funding is the principal source, and this is certainly true for health.

There are two important areas of funding specifically allocated to health (the cohesion funds, discussed in Section 6.2.4, often finance health-related projects but are not specifically designed to finance health work). The first, and the one with the highest profile in health policy circles, has historically been the EU health programme (see Section 3.11), now renamed EU4Health and substantially increased in size. The second is the allocation for health within the research programme of the EU, Horizon Europe. This is both much larger and more targeted (being only for research), although it is still small in comparison with expenditure on research by national governments and the private sector, in particular by the pharmaceutical industry.

The coronavirus pandemic has led to a novel addition to the EU’s funding, an additional recovery fund (NextGenerationEU) of €750 billion to help finance the EU’s recovery from the coronavirus pandemic, including by providing additional funding to existing instruments. Unusually, this is being financed by borrowing, supported in the future by new revenue streams for the EU. While at the moment these novel revenue streams are focused on issues outside health, such as carbon emissions and a financial transactions tax, this also opens up the possibility of novel revenue streams related to health.

### 2.3 Health policy processes

The EU tends to have a variety of specific policy processes in different areas. In health, there are some specific policy processes that have developed over time as politics, policies, law and problems interact. Health, in part because of the limits Article 168 TFEU places on legislation, has been the scene of quite a lot of experimentation in newer forms of governance that seek to coordinate and change policy through means other than hard law. This section presents some of the key governance mechanisms intended to address health policies and systems, which means that it does not cover measures built primarily out of internal market law or fiscal governance. Those are discussed in Chapters 5 and 6. In particular,
Directive 2011/24/EU on Patients’ Rights in Cross-Border Healthcare was a response to Member State and European courts’ application of internal market law to healthcare, discussed in Section 5.3.1. It emerged from debates about the proper application of internal market law even if by the end the Directive recognized the specificity of health thanks to interventions such as the 2006 Council Conclusions (see Section 1.5). It became the basis for initiatives in areas such as e-Health and healthcare quality that are discussed in Sections 5.3.3–5.

2.3.1 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 two-year initiative undertaken by the European Commission that aims to provide health policy-makers and other relevant actors with comparative data into health systems in EU countries.

Launched in 2016, the two-year *State of Health in the EU* cycle consists of four stages. The first began with the publication of *Health at a Glance: Europe*, a comparative overview of EU health systems. This 2018 joint report of the European Commission and the OECD found that the steady increase of life expectancy in Europe has slowed down, and that health disparities according to sex and socioeconomic status persist both within and between EU Member States. The report also called for improving mental health, after 84 000 people died of the consequences of mental illness in 2015, and the total cost arising from lack of or undertreatment amounts to €600 billion per year. It also called for ensuring universal access to care, addressing risk factors such as smoking and drinking, and strengthening the resilience of health systems through, for instance, the pricing of pharmaceutical drugs through health technology assessment.

The second step in the cycle is the periodic publication of *Country Health Profiles* for all EU Member States. This joint publication of the European Commission, the OECD and the European Observatory on Health Systems and Policies gives a snapshot of each country’s population’s state of health and key risk factors, along with an analysis of each health system’s performance in terms of effectiveness, accessibility and resilience. The third step is the publication of a Companion Report, to be released alongside the Country Health Profiles, which links common policy priorities across EU Member States. Finally, when the project reaches the end of the two-year cycle, health authorities will be able to request voluntary exchanges with the experts behind the studies to discuss potential policy responses. This is not just an academic exercise. It substantially informs the European Semester (Chapter 6, e.g. see Section 6.3).

---

2.3.2 Expert Group in Health System Performance Assessment

Given the increased interest in monitoring EU Member States’ health systems and assessing their comparative performance, also in the context of the European Semester, the Commission in 2014 set up an Expert Group on Health Systems Performance Assessment (HSPA), consisting of representatives from all EU Member States (and Norway). The aim was to develop a common understanding on HSPA approaches, tools and methodologies, through sharing national experiences in this field. Experts from WHO, OECD and the European Observatory on Health Systems and Policies provide additional support and advice. Work so far has focused on how to assess performance in specific domains including quality, efficiency, primary care, integrated care and resilience.

2.3.3 Expert Panel on Effective Ways of Investing in Health

To ensure timely, scientific, non-binding advice on strategically relevant health matters, the European Commission set up in 2012 a multidisciplinary independent Expert Panel on Effective Ways of Investing in Health. Its overall aim is to make scientific contributions to the effectiveness, accessibility and resilience of European health systems. At the same time, the work of the panel acknowledges the contribution of public health and health systems to health and wealth in the European Union. This contrasts with mere cost-containment or austerity policies as promoted by other Directorates-General. The panel consists of 14 members who serve a three-year term. The panel has continuously produced a large number of opinions concerning, for example, digital transformation, cross-border care and vaccination.

2.3.4 The EU Health Policy Platform

The EU Health Policy Platform is a consultation mechanism funded by the Health Programme, the largest and one of a long series of institutionalized consultative mechanisms organized by the health DG. 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, not a stance, as seen in the presence of industry. It has a variety of activities, including an annual meeting, an award and thematic groups that can formulate agendas to develop over a year,

---


48 All opinions are available online at: https://ec.europa.eu/health/expert-panel-effective-ways-investing-health/overview_en (accessed 19 February 2022).
with participation voluntary and a presentation at the annual meeting. As with most of these consultative groups, it is a way for stakeholders, including poorly resourced ones, to maintain some contact with the Commission and one another and remain informed, and for the Commission to validate thinking and test out support for different policy ideas. Its importance varies with the importance the Commission assigns to it, which participants can easily monitor by, for example, seeing who participates from the Commission. It diffuses technical and political information, formally and informally, but its impact on policy or its members is not fixed.

2.3.5 The Working Party on Public Health at the Senior Level

The Working Party on Public Health at the Senior Level is a Council working group which can provide input on behalf of ministers on a wide range of topics. In the fiscal governance system (Chapter 6), it has a role in consultation on health recommendations. As a Council formation, its importance can vary with the presidency; for example, the 2018 Austrian presidency tended to call meetings only at the attaché level.

2.3.6 The Steering Group on Health Promotion, Disease Prevention and Management of Non-communicable Diseases

The Steering Group on Health Promotion, Disease Prevention and Management of Non-communicable Diseases – also known as “the Steering Group” – was set up by the European Commission to help Member States reach the health targets of the Sustainable Development Goals (SDGs). This entity is tasked with providing expert advice to the Commission on creating and implementing activities in the field of health promotion, disease prevention and the management of non-communicable diseases. This group is also responsible for promotion exchanges of relevant practices between Member States.

2.4 Strengthening the legitimacy of EU health policy: civil society and stakeholders

The European Union, in important ways, is unlike any of its Member States. It grew from different roots, born of the complex accommodations needed if such different societies are to work together. It is larger, more fragmented, more complex and does different things in different ways. One result is that the interest

---

group landscapes of the different Member States do not resemble the interest group landscape of the EU. There are different rules, stakeholders and jargon, as well as different problems. If the EU lobbying landscape resembles that of any other polity, it is the US that it most resembles in its fragmentation, complexity and the preponderance of business interests. This section discusses some of the interest representation and stakeholders. But it also is a polity that, in lieu of the legitimacy its Member States enjoy, has been particularly attentive to and engaged in developing legitimacy for itself and its policies – becoming, at times, more open and transparent than many states.

2.4.1 Making EU policy legitimate

There are three basic kinds of legitimacy in democratic politics. The EU’s search for legitimacy in a crowded political landscape shapes both its choices and its constraints, and makes the institutional analysis of the EU as well as its policy outcomes more intelligible. It also explains the creativity of the EU in developing ways to engage with stakeholders and promote diversity of voices in policy.

Input legitimacy is the legitimacy that comes from democracy: a government is legitimate if created through a legitimate democratic process that gives voice to citizens. Most EU Member State governments and their decisions are regarded as legitimate because they were elected in free and fair elections. The EU has had a difficult time gaining input legitimacy for a variety of reasons, ranging from the diversity of its many peoples to its perceived institutional distance from many voters. Direct elections to the European Parliament, the citizens initiative and the spitzenkandidat procedure that elected Jean-Claude Juncker but was abandoned in 2019 are all efforts to give the EU input legitimacy for its actions.

Output legitimacy is the legitimacy that comes from being seen to take creditworthy actions. It is the historical basis for EU legitimacy: the case for the EU is that it works. It is what we see in pro-EU arguments that point to Europe-wide mobile phone roaming or low-cost aviation as achievements that legitimize the EU. One key constitutional instrument to “qualitatively measure” the EU’s output legitimacy in the field of health is to see if its efforts and policies adhere to Article 35 of the EU Charter of Fundamental Rights that holds that:

“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.”

This Article echoes the “mainstreaming” aspect of health in all EU policies, as we have also seen in Article 9 TFEU and in Article 168 TFEU. It does, however, bring health in the EU within the realm of fundamental rights, even as the text of the article emphasizes the key role of the Member States. Furthermore, appeal to output legitimacy has not always worked: some EU actions (e.g. food safety or much environmental law) are so technical that voters do not see them, connect them with outcomes or attribute responsibility correctly. Others are unpopular with narrow groups in the short term but broadly beneficial in the longer term, such as many rules about health and safety in the workplace. Member State governments generally try to take credit for popular policies and blame others, including the EU, for less attractive results. Even the most directly visible kind of EU action, cohesion funds with their obligatory EU symbols, do not always produce the magnitude of legitimacy that one might expect (as we see from popular anti-EU sentiment in areas that have received considerable EU funds, notably in the UK and Central and Eastern Europe (CEE) states). Output legitimacy worked well when the EU’s legitimacy had to be in the eyes of Member State governments. They had the technical expertise to see the advantages of EU structures and policies. They could also value their ability to cast blame on the EU. It is harder to gain in the eyes of citizens, who are not always interested in tracing a benefit to any particular government (and who might still find it hard to find out who to thank or blame in EU politics).

Throughput legitimacy is the third kind of legitimacy that the EU seeks: emphasizing the legitimacy of its actions through extensive consultation, efforts at transparency and the cultivation of links with stakeholders including interest groups and civil society. It is perhaps most developed in the area of trade policy but it is a strategy deployed throughout EU governance. Throughput legitimacy, in other words, amounts to the proposition that even if the EU lacks the input legitimacy that Member States enjoy, and even if Member State governments try to take the credit for successful policies and blame the EU for unpopular policies, its policy process legitimates the outcomes and builds legitimacy among groups in civil society and elsewhere who appreciate the opportunity to participate.

EU stakeholder politics and political process are distinctive because of a widespread assumption that it must develop its input and output legitimacy, and compensate for any failings with superior throughput legitimacy. In other words, lacking a clear demos and often making policies which are not very visible, understood and attractive, its governance relies particularly heavily on listening to stakeholders

---

and even helping to create them when the existing interest group ecology of Brussels does not produce them. The result is an interest group environment that is fragmented and open to money, yet at the same time attentive to diverse interests that wield little political power.

2.4.2 Identifying stakeholders in Brussels

In other words, stakeholders in EU policy are very important, for assisting with throughput legitimacy and for helping policy-makers understand the complexities of a union with over 447 million people. Identifying key stakeholders interested in health in the European Union is not as easy as it may sound. Researchers have used a variety of techniques, but each has drawbacks born of a simple problem: the EU makes it easy to engage at a very superficial level, but there are major time and resource constraints that mean the actual number of reliably engaged stakeholders who are seen as serious is much smaller. Time and resource constraints also mean that money is empowered, for it can buy staff time and capacity. In the particular context of the EU, throughput legitimacy also means that poorly resourced interests are often better positioned and supported to act in policy than their equivalents in Member States which are less concerned about throughput legitimacy.

One alternative option is to consult the various lists of organizations that respond to consultations, join consultative forums, appear in lobbying directories sold around Brussels, and send representatives to public meetings. This produces a long list of organizations. The EU Health Policy Platform has around 11 110 registered members as of January 2022 and it is not easy to find out what they are (EU stakeholder transparency initiatives have a strange way of making such information less accessible and transparent with each initiative). We can take it as a given that they are not all equally influential in policy debates. Statistical research, albeit rather old, has indeed found that most of the organizations that appear as interested in EU health policy are not really very interested and are not very influential.\(^{53}\) In many cases, especially with local and regional governments and Member State level associations, the main function of the office in Brussels is to watch for funding opportunities and take note of consequential policies rather than lobby. In particular, the EU has an institutional bias towards interacting with “Eurogroups”, EU-level associations, rather than organizations set up at Member State level (though individual MEPs and others obviously interact intensively with local interest groups). The reliance on Eurogroups can appear to freeze out national expertise, but it has two compelling advantages: it obliges Eurogroups, rather than the Commission, to aggregate diverse preferences, and it obliges

---

stakeholders to formulate broad appeals rather than speak in the particularistic languages of national politics and special interests.

The main alternative is to ask practitioners which the key organizations are. This method has several drawbacks. One is that it risks mapping networks rather than the whole field: if you start by asking public health advocates, you will end with a better map of public health advocates than of, for example, anti-deregulation advocates employed by industry. The second is that the field of health policy is essentially contested – are manufacturers of sugary industrial sweets part of the health policy world, in their own eyes or in the eyes of others? They are certainly to be found in the Health Policy Platform and other consultative bodies. The third is that Brussels, like any heavily lobbied political system, has lobbying firms with the capacity to rapidly expand their operations at every level, from junior to senior, when an industry with money finds that an issue is on the agenda and wants to influence it. Temporary lobbying operations of great size can be set up almost overnight if there is enough money. Fourth and finally, lobbying can be murky. Not all organizations like to represent themselves publicly as such. Industries with serious opposition in the health world, notably the tobacco industry, frequently have incentives to work through other organizations, funding and supporting groups and people whose link to the underlying industry support is not made clear.

There are some clear repeat players in EU health policy with credibility and a health agenda, such as the European Public Health Alliance (EPHA) made up of public health NGOs, the more academic European Public Health Association (EUPHA), EuroHealthNet, the European Consumer Organization (BEUC), and the European Patients Forum, to name just a few. Many NGOs with strong roots outside healthcare now occupy key positions in health-related discussions such as transport (TE – Transport Environment), housing/homeless (FEANTSA – European Federation of National Organisations Working with the Homeless) and environment (HEAL – European Health and Environment Alliance) to name but a few. There are also Member State level organizations that have credibility even if they must often formally act through Eurogroups.54

In most cases, the size of these organizations’ staff is very small and the number of their senior or long-term staff smaller still. This means that their credibility and profile in Brussels can rise and fall quickly with internal politics and the career choices of individuals – while it is easy to staff these organizations at the junior level, thanks to the large Brussels labour market in public affairs staff, it is relatively hard to find or train people who will develop technical and political credibility over years. Many of the most effective organizations are precisely the ones which have been able to retain staff for years, keep in touch with “alumni” who have moved on, and develop strong cadres of junior and mid-level staff. Succession and workforce planning are therefore crucial in these organizations, and for outside observers it is important to pay attention to individual people’s careers as well as their organizations.

2.4.3 Forums, platforms, consultations and meetings

Throughout this book, there will be references to a variety of forums, platforms and consultations. These are different ways in which the EU attempts to gain information, perspective and throughput legitimacy for its actions.

Consultations are mandatory (Box 2.1) as part of the proposal process and solicit views on proposed legislation (the EP, the Council and other EU institutions view themselves as having legitimacy by election and do not consult, though they can and do make many kinds of inquiries). Most consultations receive relatively few responses, though a few have been “flooded” by organized interests.

The Commission, including DG SANTE, has also worked through a large number of forums, notably the Health Policy Forum, platforms and regular meetings. Their goals range from seeking information to educating participants to making commitments to policy actions. They are discussed throughout Chapter 3.

2.4.4 Supporting stakeholders: money, media, industry and civil society

“Follow the money” is always good advice. In the relatively open and fragmented world of EU interest groups, it is particularly good advice. It leads to both attentiveness to lobbying strategies that might not be obvious, such as sponsoring events with no clear lobbying content in order to build credibility, and to the ways in which the Commission, seeking information and throughput legitimacy, has historically sought to provide resources to civil society organizations that can break what might otherwise be a steady diet of industry-funded lobbying.

One of the key issues in any area of EU policy is the extent of Commission support for civil society organizations. A basic fact of interest representation in Brussels,
as in most political systems, is that business organizations far outnumber and are far better resourced than other parts of society. Throughput legitimacy, as well as informed policy, requires broader participation than industry lobbies will ever provide.\textsuperscript{55} The Commission, in any policy field, thus supports Eurogroups and others to connect with broader social interests and represent views from those sectors.\textsuperscript{56}

There are a number of structural threats to this arrangement. One is that Brussels organizations become more focused on getting and keeping Commission funding, which can often come through distorting programmes, than on serving their members. Maintaining responsiveness and accountability to complex membership bases with different understandings of the EU is a structural problem for any Eurogroup. Another is that the political leadership of the EU might decide that it can do with less throughput legitimacy and civil society information, and reduce the funding for civil society. More serious, and more common still, political leaders can also pick and choose the organizations they fund, shaping the civil society they want to hear from. If the political leadership of the EU feels confident, then it might not see the case for subsidizing those with contrary views.

Beyond the visible and formal world of advocates and lobbies in Brussels, there are other ways that moneyed interests can influence policy. “Think tanks” of various sorts regularly appear in Brussels with background interests and funding that are unclear. Even long-established think tanks with some credibility will often have funders who shape their agendas and policy interests. Industries that know they are divisive will frequently have the most incentive to act through think tanks and public affairs consultants, but almost any interest can be found doing it. Civil servants and academics face reputational and professional risks in being seen as advocates or lobbyists, but it is wise to assume that anybody involved in politics is explicitly involved in advocating for a position, and is being held accountable for their effectiveness at it.

Finally, Brussels media suffers from a particularly severe version of the problems affecting media across Europe. Not only is it difficult to find a business model today that will sustain expert and investigative journalism, but the EU media sphere is fragmented, the audience for EU politics is small and specific, and EU activities are often technical and of interest to small groups. The result is a variety of media at work: elite global press with strong EU coverage but their own biases, especially with a global audience.


The European Union: institutions, processes and powers 67

clear points of view and lack of interest in most EU dossiers (e.g. the Financial Times, Economist, Le Monde, Bloomberg); EU-focused generalist press, often very influential in Brussels, whose business model makes them prone to dependence on advertising and sponsorship from interest groups which can include tobacco or other problematic industries (e.g. Euractiv, EUObserver, Politico.eu); and specialist industry press which focuses on the issues of interest to particular industries and is typically expensive and targeted at narrow, business, audiences. Surrounding this media is a blizzard of newsletters and policy reports of varying quality from trade associations, law firms, consultants, lobbyists and others, of often unknown motivations, who view production of news as a useful way to advertise, and shape agendas and thinking. Meanwhile, most Member State media, if they report EU affairs, report it in the context of domestic politics. It is even harder to navigate this landscape than it is to work out what is happening in Member State capitals. It is no wonder that many groups decide the solution is to employ Brussels staff just to figure out what is going on.

2.5 Agendas and the Sustainable Development Goals in the EU

Every government wants to have some document or plan to show its coherence, for public consumption and to steer its members and officials towards key goals. The EU is no different, and its fissiparous nature means that its leadership is particularly prone to lead and govern through large programmatic agendas that are supposed to direct all the institutions, though in practice such agendas come from the Commission and Council and, to the extent that they bind, they bind the Commission.

2.5.1 European Green Deal

The European Green Deal is a large part of the agenda of the von der Leyen Commission. Put forth in numerous public presentations including a 2019 Communication, 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.” In the next two paragraphs come a pair of statements that are no novelty in EU politics: “It is a

58 The European Green Deal, COM/2019/640 final.
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.”

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, a key health policy. 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.”

As subsequent chapters, notably Chapters 6 and 7, will make clear, 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 effect on health, by for example shaping the Farm to Fork strategy which is intended to redirect agricultural and food safety policy towards more sustainable practices.

2.5.2 Europe and the Sustainable Development Goals

From the Single Europe Act, with its ambition of internal market unification by 1992, to the Lisbon Agenda, the EU has adopted overarching goals. For the first time the EU has adopted global goals as the replacement for its Europe 2020 agenda: the Sustainable Development Goals (SDGs). Just as the SEA or Lisbon Agenda or Europe 2020 authorized action and policy development, the SDGs authorize thinking and even action on a broad range of globally important issues.

In her speech to the European Parliament before it voted on her appointment as President of the European Commission, Ursula von der Leyen announced that she would “refocus our European Semester to make sure that we stay on track with our Sustainable Development Goals”.

The SDGs are the 17 goals, with 169 discrete targets, agreed by the United Nations (see Box 2.6) in 2015 as part of its Agenda 2030 programme. They are the

59 All quotes from the first page of the European Green Deal, COM/2019/640 final.
60 The European Green Deal, COM/2019/640 final, 2.1.4.
61 The lead author for this section was Tugce Schmitt.
successors to the Millennium Development Goals but, unlike the MDGs, they go far beyond development policy. A 2016 Commission Communication\(^{63}\) adopted them as broader unifying goals for the EU. According to the 2016 “Key European action supporting the 2030 Agenda and the Sustainable Development Goals”, the Commission has confirmed its commitment to sustainable development and its intention to further mainstream it into its policy-making.\(^{64}\) In line with the principle of subsidiarity, the key European actions supporting the 2030 Agenda and the SDGs that would affect Member States differ from one SDG field to another. Depending on the SDG and its main policy fields, the EU is committed to putting a framework in place/supporting and complementing/promoting the achievement of particular SDGs within the EU. There is a detailed EU policy action overview for each SDG. In the case of health, the obvious focus is SDG 3, which is a commitment “to ensure healthy lives and promote well-being for all at all ages”. This includes universal health coverage as well as attention to the many determinants of health that the EU can affect.

A Multi-Stakeholder Platform was commissioned to report on ways the EU budget can support the SDGs.\(^{65}\)

In October 2018 the European Council welcomed the intention of the Commission to publish a Reflection Paper to pave the way for a comprehensive implementation strategy in 2019. This paper puts forward three different scenarios following the European Council’s guidance to lead the discussion on how the implementation of the SDGs could best be achieved and what would be the most effective division of roles. Three scenarios of the Commission as well as their advantages and disadvantages are published in this document (pp. 34–9), proposing different enforcement levels of the Commission on the Member States.

Eurostat has since 2017 published a review of progress towards the SDG goals within the EU that builds on its SDG indicator set.\(^{66}\) The reviews are instructive, reminding us that much needs to be done in rich countries as well as in poorer

\(^{63}\) COM(2016)739 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Next steps for a sustainable European future. European action for sustainability.


Box 2.6  **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

ones, in particular to achieve goals such as “Sustainable Consumption and Production” and even in areas where the EU is ahead of other rich polities, such as “sustainable cities and communities” and “climate action”.

In terms of their potential for health, most if not all of the SDGs have clear co-benefits: they are unlikely to be achieved without investment in health and health systems, and they are likely to have benefits for health and health systems. Exploring co-benefits is a way to give some coherence to intersectoral conversations and authorize advocates to push for these objectives in the face of bureaucratic, political and other pressures to de-emphasize these goals and the broad policy work needed to achieve them.
2.6 Health systems values

What has the EU done to shape health systems thinking, or at least the impact of EU policies on health systems? The EU has produced a number of key statements that guide its policies and enable or constrain new initiatives. In healthcare, the 2006 Council conclusion on health systems values has helped to shape the place 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 help to influence broader EU policy such as the Semester by making it clear what values, besides fiscal sustainability, the Member States agreed.

Note the different objectives and uses of these statements and their evolution over time. The earlier statements were often reactive, trying to shape debates that were couched in the terms of markets or fiscal governance. To this day, part of the purpose of enunciating health systems values is to engage in debates about what the EU should and should not do as part of fiscal governance or internal market development in healthcare. But they also increasingly represent efforts to define a different EU, one with broader goals that give it more legitimacy and a more popular impact on its peoples. Compare the 2006 statement on health systems, which was fundamentally a reaction to those who wanted to integrate health into the internal market, with the European Pillar of Social Rights, which is deliberately set up as an aspirational, even constitutional, framework.

2.6.1 Charter of Fundamental Rights

With the amendments of the Treaty of Lisbon, the Charter of Fundamental Rights (CFREU) that was 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 constitutionalizes some of the understandings of “Social Europe”. Generally the EU is to ensure that its institutions and the Member States, when they are implementing EU law, adhere to the rights as laid out in the Charter (Article 51 CFREU). However, the articles that fall under the “solidarity chapter” are taken to be ‘principles’ rather than rights, which makes them non-justiciable for individuals. For health in this regard some of the stronger proclamations on dignity, where a specific reference is made to informed consent, or equality, might prove to be more relevant than the specific Article 35 CFREU, as mentioned above.67 Importantly, 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 legal interpretation of the CFREU articles, this case

---

law can also inspire EU case law that addresses the role of the EU institutions, or the Member States in the application of EU health law, through provision of Article 52 CFREU.

2.6.2 2006 statement on health systems values

The 2006 Council Conclusions on Common values and principles in European Union Health Systems \(^{68}\) is in part a creature of its time, reflecting a specific agreement by Member States under the UK presidency that contemporary efforts to incorporate healthcare into the general internal market for services (e.g. with the

---

\(^{68}\) Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01).
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.

2.6.3 Effective, accessible and resilient health systems

The next key statement of values and priorities came from the EPSCO Council in late 2013 (Conclusions) and was followed by the Commission with a 2014 Communication. The Council Conclusions were a wide-ranging statement of health values and priorities, and the value of health as a general European priority. It was, among other things, a response by health ministers to the reinforced fiscal governance system’s inroads into health policy (see Chapter 6), reiterating the importance of health and health systems and encouraging the EU in a supportive role. The Commission translated this request into the 2014 Communication. These two documents superseded the 2006 Council Conclusions. The Communication sets 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 of the actions necessary to achieve these goals are by design to be taken at the Member State level, the Communication lists a variety of EU actions from Health Systems Performance Assessment (HSPA) to Health Technology Assessment (HTA) that contribute to Member States’ policies and effectiveness.

The issue of resilience has of course become central during the COVID-19 pandemic. As well as defining in more details what resilience might mean, 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). Although this Facility is not specific to health systems, several countries have chosen to make health one of their priorities for funding under the scheme. This represents a milestone in the EU moving from stating the importance of strong and resilient health systems towards providing substantial funding to help achieve this.


2.6.4 The European Pillar of Social Rights

The European Pillar of Social Rights (EPSR) was declared by the Council, Parliament and European Commission in 2017.\(^\text{72}\) It has twenty principles – twenty rights – in the categories of “Equal opportunities and access to the labour market”, “Fair working conditions” and “Social protection and inclusion”. 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 the evidence is impressive that supporting parents in their work reaps health benefits for everybody in the family. “Fair working conditions” also includes an explicit right to a healthy workplace, for workplaces and work practices are indeed a key source of ill- or good health and employers do not always provide them without regulation. “Gender equality”, for a fourth example, is in “Equal opportunities and access to the labour market” but is a key determinant of the well-being and health of all genders.

That said, there is healthcare content, in the simple: “Everyone has the right to timely access to affordable, preventive and curative health care of good quality.” It 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.” It is worth underlining that the EPSR is, by the standards of most political systems, 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, and its ambitions are impressive.\(^\text{73}\)

2.7 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 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. They show,

---


in part, how legal bases are crucial but do not always determine what happens. Environmental policy in the EU was improving health from at least 1975 under internal market treaty bases, but environmental policy only appeared in the Treaties in 1992, at the same time as public health. The difference was not in the Treaties; it was in the willingness of the EU’s leadership to use internal market policies to make environmental law.

The next four chapters discuss the three faces of the EU health policies that have emerged from the interplay of institutions, legal bases and politics. The first is explicit policies for health. The second face is internal market policies that affect health, from medicines regulation to competition law. The third face, finally, is fiscal governance. Each works in quite different ways but all three can contribute to health.
3.1 What is European Union public health policy?

The first face of EU health policy is made up of actions to improve public health. Of the three faces of EU health policy, it has historically been the least important. The treaty language authorizing public health action (Chapter 1) was careful and constraining, enabling the EU institutions to take actions that complemented and supported, rather than leading or constraining, the Member States. 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, 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 (see Figure 1.4). 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. Chapters 5–8 discuss those important dimensions of health policy.

In 2020 the European Union’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) in 1992,¹ the challenge of EU public health policy has been striking 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 drafting of that article, in particular the requirement that the Union “respect the responsibilities of the Member States” for their health systems.\textsuperscript{2} 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 the area of health, is “common safety concerns in public health matters”;\textsuperscript{3} for the wider objective of the “protection and improvement of human health”\textsuperscript{4} the EU may only “support, coordinate or supplement” Member States’ actions.\textsuperscript{5}

Article 168 TFEU (Box 1.4 and the Appendix) 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, 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 where binding legislation is called for covers concerns of quality and safety standards for substances of human origin, blood and blood derivatives.\textsuperscript{6} Article 168 TFEU does also provide for the EU to give financial support for actions more broadly in support of public health,\textsuperscript{7} 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,\textsuperscript{8} but this does not in itself provide a basis for additional measures.

There are also some additional tools provided in Article 168 TFEU. One is the power for the Council of the EU 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

\textsuperscript{2} TFEU, Article 168, paragraph 7.
\textsuperscript{3} TFEU, Article 4, paragraph 2(k) j; Article 114 TFEU.
\textsuperscript{4} TFEU, Article 6, subparagraph (a).
\textsuperscript{5} TFEU, Article 6.
\textsuperscript{6} TFEU, Article 168, paragraph 4.
\textsuperscript{7} TFEU, Article 168, paragraph 5: “incentive measures” refers to financing tools, not binding legislation.
\textsuperscript{8} TFEU, Article 168, paragraph 1; see also Article 9.
good effect in the health area, such as establishing a European commitment to cancer screening.  

Another form of policy-making power is the provision in the Treaty for Member States to coordinate their own policies on areas too sensitive for legislation or outside their scope, working through “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 rest of this chapter focuses on areas commonly understood as being part of public health, justified primarily by Article 168 TFEU, and led or implemented by DG SANTE within the Commission. This includes 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. Chapter 4 discusses other ways in which EU policy contributes to health through areas such as social policy and workplace regulation. In previous editions, we covered this ground in one chapter; the division reflects the increasing extent and importance of a recognized EU health policy arena that has become too big to cover in one chapter.

We also include the Civil Protection system here. While Civil Protection is not authorized under Article 168 TFEU (rather, Article 196), its role in health since 2020 has become so dramatic as to merit discussion here. This is despite its distinctive politics and organizational as well as legal footing.

### 3.2 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 recent years, the disparity among states in levels of smoking remains large. Concerns have also been raised about the potential health effects of the increasing use of non-traditional tobacco products such as e-cigarettes.

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.

---

10 TFEU, Article 168, paragraph 2.
The EU and its Member States have been successful in some of these areas but less so in others (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. Since 2017 youth smoking rates have also fallen, although more young people are using novel tobacco products such as e-cigarettes where the health risks are less well known.11 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 2010. This is also good news, as research suggests that rising prices deter consumption.12 Implementation of restrictions on exposure to second-hand smoke and regulation of tobacco depictions in mass media remain relatively patchy, however.13

The EU’s first tobacco policy was actually in support of tobacco, with the Common Agricultural Policy providing subsidies to tobacco growers from 1970 onwards. Considering that starting point, the EU has greatly improved its contribution to tobacco control over time. From the 1980s onwards, EU policy-makers adopted a wide variety of tobacco control measures (summarized in Table 3.1) 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).

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 global Sustainable Development Agenda.

The core of current tobacco regulation in the EU is the Tobacco Products Directive (TPD) (2014/40/EU). 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 (based on recent scientific studies, this category

---

## Table 3.1  EU Member States’ performance against WHO tobacco control targets

<table>
<thead>
<tr>
<th>Member State</th>
<th>Adult Daily Smoking Prevalence 2019</th>
<th>Monitoring Smoke-Free Policies</th>
<th>Cessation</th>
<th>Health Warnings</th>
<th>Mass Media</th>
<th>Advertising Bans</th>
<th>Taxation</th>
<th>Affordability Less Affordable Since 2010?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>21%</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>74.5% Yes</td>
</tr>
<tr>
<td>Belgium</td>
<td>19%</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>76.9% Yes</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>32%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>85.3% No</td>
</tr>
<tr>
<td>Croatia</td>
<td>31%</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>83.6% Same</td>
</tr>
<tr>
<td>Cyprus</td>
<td>29%</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>74.4% Yes</td>
</tr>
<tr>
<td>Czechia</td>
<td>24%</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>77.2% Yes</td>
</tr>
<tr>
<td>Denmark</td>
<td>15%</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>78% Same</td>
</tr>
<tr>
<td>Estonia</td>
<td>21%</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>87.6% Same</td>
</tr>
<tr>
<td>Finland</td>
<td>15%</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>88.2% Yes</td>
</tr>
<tr>
<td>France</td>
<td>28%</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>83.2% Yes</td>
</tr>
<tr>
<td>Germany</td>
<td>18%</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>63.5% Yes</td>
</tr>
<tr>
<td>Greece</td>
<td>27%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>80.8% Yes</td>
</tr>
<tr>
<td>Hungary</td>
<td>28%</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>72.7% Yes</td>
</tr>
<tr>
<td>Ireland</td>
<td>18%</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>78.9% No</td>
</tr>
<tr>
<td>Italy</td>
<td>20%</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>76.6% Yes</td>
</tr>
<tr>
<td>Latvia</td>
<td>30%</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>79.9% Same</td>
</tr>
<tr>
<td>Lithuania</td>
<td>22%</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>74% Same</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>17%</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>68.3% Same</td>
</tr>
<tr>
<td>Malta</td>
<td>19%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>77.6% No</td>
</tr>
<tr>
<td>Netherlands</td>
<td>17%</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>77.2% Yes</td>
</tr>
<tr>
<td>Poland</td>
<td>21%</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>78.4% Same</td>
</tr>
<tr>
<td>Portugal</td>
<td>20%</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>78.6% Same</td>
</tr>
<tr>
<td>Romania</td>
<td>27%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>69.6% Yes</td>
</tr>
<tr>
<td>Slovakia</td>
<td>24%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>76.3% Yes</td>
</tr>
<tr>
<td>Slovenia</td>
<td>20%</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>78.7% Same</td>
</tr>
<tr>
<td>Spain</td>
<td>25%</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>78.2% Same</td>
</tr>
<tr>
<td>Sweden</td>
<td>9%</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>68.1% Yes</td>
</tr>
</tbody>
</table>

Worst performance against WHO standards > 1 2 3 4 < Best performance against WHO standards

### Table 3.2  Summary of EU tobacco control legislation

<table>
<thead>
<tr>
<th>Name (year) of measure</th>
<th>Number</th>
<th>Key requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling directives (1989, 1992)</td>
<td>89/622/EEC</td>
<td>Requires rotating health warnings on tobacco products</td>
</tr>
<tr>
<td></td>
<td>92/41/EEC</td>
<td>Ban on the marketing of certain tobacco products for oral use</td>
</tr>
<tr>
<td></td>
<td>97/36/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>98/43/EC</td>
<td>Ban on tobacco advertising in the press, radio and on the Internet</td>
</tr>
<tr>
<td></td>
<td>2003/33/EC</td>
<td>Ban on tobacco sponsorship of events with cross-border effects</td>
</tr>
<tr>
<td></td>
<td>92/79/EEC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>92/80/EEC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>95/59/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2002/10/EC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2011/64/EU</td>
<td></td>
</tr>
<tr>
<td>Tobacco Product Regulation Directive (2001)</td>
<td>2001/37/EC</td>
<td>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)</td>
</tr>
<tr>
<td>Workplace Air Quality directives (1989, 1992)</td>
<td>89/654/EEC</td>
<td>Require employers to ensure that workers have access to fresh air and ventilation</td>
</tr>
<tr>
<td></td>
<td>92/57/EEC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>92/91/EEC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>92/104/EEC</td>
<td></td>
</tr>
<tr>
<td>Framework Directive on Health and Safety in the Workplace (1989)</td>
<td>89/391/EEC</td>
<td>Requires a health assessment to be carried out by employers, which should include exposure to second-hand smoke in the workplace</td>
</tr>
<tr>
<td>Asbestos Directive (1983)</td>
<td>83/477/EEC</td>
<td>Prohibits smoking in areas where asbestos is handled</td>
</tr>
<tr>
<td>Resolution on Smoking in Public Places (1989), Smoke-free Environments Recommendation (2009)</td>
<td>92/85/EEC</td>
<td>Invites Member States to adopt measures protecting people from exposure to smoke in indoor workplaces, public places and public transport</td>
</tr>
<tr>
<td>Pregnant Women Directive (1992)</td>
<td>90/394/EEC</td>
<td>Restricts smoking in workplace areas where carcinogenic substances are handled</td>
</tr>
<tr>
<td>Council Resolutions and Proposals to Member States and the Commission (1993, 1996, 1999) on measures to combat smoking (non-binding)</td>
<td>Various measures to combat smoking</td>
<td></td>
</tr>
</tbody>
</table>
could also include menthol). The 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 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

<table>
<thead>
<tr>
<th>Name (year) of measure</th>
<th>Number</th>
<th>Key requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Council recommendation (2003)</td>
<td>2003/54/EC</td>
<td>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</td>
</tr>
<tr>
<td>WHO FCTC, Protocol to Eliminate Illicit Trade in Tobacco Products (ratified 2016)</td>
<td>2016/1749/EU and 2016/1750/ EU (Council adoption decisions)</td>
<td>Addition to the FCTC focusing on control of illicit trade in tobacco products</td>
</tr>
<tr>
<td>Tobacco Products Directive (2014)</td>
<td>2014/40/EU</td>
<td>Major legislation on tobacco products (see text)</td>
</tr>
</tbody>
</table>

justified in order to enable functioning of the internal market, in particular for local products (e.g. parasols and other articles used in hotels).

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.14 A further revision of the Directive could potentially address some of these issues and the demands of tobacco control advocates for tighter regulation in areas such as characterizing flavours, heated tobacco products and plain packaging, although the previous revision took over five years and was highly contested by the tobacco industry. The Commission’s ambitious Europe’s Beating Cancer Plan, 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 2025.15 Achieving these goals is likely to require stronger regulation, better implementation and enforcement at national level, and higher taxation.

A significant current and future challenge for the EU lies in the increasing diversity of tobacco 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 less about the long-term health risks of

newer tobacco products such as e-cigarettes and heated tobacco products. There are three 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, differences between national approaches to newer tobacco products may have a deleterious effect on policy-making at the EU level. And third, 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 “characterizing flavours” ban, which 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. But the tobacco market evolves quickly, with new products (e.g. heated tobacco products) entering the market before any scientific evidence of potential long-term harm emerges to balance out industry-funded studies. In practice, it has been difficult to apply the TPD to novel tobacco products, resulting in variation at Member State level and across different types of novel products. It remains to be seen to what extent the EU can continue to build a political and legal consensus in favour of a strong and coordinated set of tobacco control policies and move towards the goal of a tobacco-free generation.

3.3 Diet, nutrition and physical activity

Noncommunicable diseases are a major health threat in the European Union, 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. The European Union’s contribution to the prevention of noncommunicable diseases is multiple and ambiguous: food safety, infrastructure investment, protected designation of origin law, fiscal governance, infrastructure support (cohesion funds and EIB loans), climate change policy, trade policy and agricultural policy all affect diet,

---

16 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 Exercise – The Miracle Cure. London: Academy of Medical Royal Colleges, 2015. Available at: https://www.aomrc.org.uk/reports-guidance/exercise-the-miracle-cure-0215/ (accessed 19 February 2022).

17 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.
nutrition and physical activity for better or for worse. There is scope for a great deal of policy coherence – or policy incoherence.18

“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 and a 2005 Nutrition Strategy White Paper,19 and Health Programme initiatives as well as the innovative Platform on Diet, Nutrition and Physical Activity. The initiative was enterprising but was led by DG SANCO in an environment in which restrictive legislation on the topic was hard to imagine. As a result, it was creative but it left largely untouched important EU tools in areas such as agricultural policy and infrastructure. Instead, the strategy focused on a collaborative approach of looking for win-win solutions. The Platform brought together different kinds of organizations, from Member States to industry to NGOs. It informed them of the Commission’s thinking and they informed the Commission of their thinking, but the Platform’s hope and promise were located in a system of commitments in which members would make commitments to improve diet, nutrition or physical activity (e.g. improving the nutritional quality of a food by a specified amount).

It was easy to criticize the Platform since participants made their own commitments and self-reported their performance. Some NGOs saw it as a way for industry to pre-empt real regulation and make itself look good but nonetheless continued to participate because it was a structured way to engage with the Commission. That said, there are two conditions under which industry self-regulation is likely to work, and the EU is not as far from them as some Member States are. One condition for self-regulation is the threat of regulation – the explicit or implicit threat that if the industry does not improve its behaviour, policy-makers will force it to. That condition has been absent from EU food policy for some years and the senescence of these initiatives reflects that. The other condition is predictability. If industry is confident that any given policy initiative will end with the departure of the sponsoring minister, then it will have little incentive to change. If a stable institutional and legal structure gives industry incentive to act in a trustworthy manner and encourages longer-term reciprocity, then self-regulation and public-private initiatives can work.20 The EU’s very rigidity, born of its complex lawmaking procedure, makes it relatively predictable and therefore a potentially hospitable environment for effective self-regulation.

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. The Platform lost momentum when senior Commission officials ceased to attend; after a few meetings at which the Commission sent substitutes, most other organizations started to send junior staff as well. The political turn against regulation and in favour of growth in Europe reduced the threat of legislation and regulation that makes self-regulation effective, and the Platform, along with the similar Alcohol Forum, ceased to look relevant. In July 2019 health-oriented civil society organizations (including BEUC, the European Heart Network and EPHA) walked out of the Platform, arguing that the “Platform, as it is currently constructed, is not fit for purpose and cannot therefore adequately contribute to reverse this tide. Indeed, the continual decreases in resources, time and attention afforded to the Platform over the years point to an acknowledgement of the limited impact that this forum, and the voluntary approach it embodies, can have.”21 This demarche both was predictable – the changing political scene constrained the possible relevance of such a Platform more every year since it was created – and means that there is a clear field for new policy and process thinking on food and public health.

3.4 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),22 although there has been an overall but uneven decline in (recorded) alcohol consumption since the early 1990s. Although alcohol is considered to be the third largest risk factor for ill-health in the EU,23 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),24 alcohol in its various forms is a central part of European culture and politics.25 The EU’s now-expired strategy regarding alcohol and health 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. 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). 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?

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 in Europe with new products such as alcopops. Policy-makers who defend traditional alcohol use and regulatory patterns sometimes rethink in the face of such homogenizing new products. Moreover, the relationship between public policy and alcohol consumption is not straightforward. The AMPHORA (Alcohol Public Health Research Alliance) project has brought together evidence on alcohol and policy across Europe; this shows that, 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), as well as the history of different countries.

Nevertheless, although the relationship is complex, the AMPHORA alliance concluded that the evidence shows more-restrictive alcohol policies do have an impact in reducing harm from alcohol. So could the EU do more to address this, using stronger tools than used so far? This can be considered for three key aspects of alcohol policies: physical availability, economic availability, 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.31 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.32

For economic availability, the central tool is taxation; increasing the cost of the product reduces consumption. Conversely, the main impact of the internal market on increased alcohol consumption in Sweden and Finland has not come from any increases in physical availability but rather from the increased availability of alcohol at much lower prices because of lower rates of excise duty in neighbouring countries to the south.33 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.34 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 proposal35 to at least upgrade the current minimum levels of excise duty on alcohol has 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 von der Leyen Commission is reviewing EU legislation on the taxation of alcohol, though it remains to be seen if any resulting proposals will be more successful.36

31 European Court of Justice. Case C-189/95 Franzén.
In fact, the EU’s constitutional asymmetry has slowed efforts to reduce alcohol use through minimum price legislation. Scotland introduced a minimum price for alcohol in its 2012 Alcohol (Minimum Pricing) Act. The alcohol industry, led by the Scotch Whisky Association, argued that it was discriminatory under EU law, and a preliminary reference was filed. The CJEU ruled that minimum pricing was permissible under Article 36 TFEU, which is the Article allowing for public health exceptions to free trade within the EU. It ruled, however, that a proportionality test applies and should be carried out by Member State courts, which gives them considerable latitude.

The story is similar for the advertising and labelling of alcohol. 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 more-restrictive advertising or labelling rules.

Another tool to prevent or reduce the harm from alcohol is labelling. The Commission audited in 2013–2014 the use of health-related messages on alcoholic beverage labels. The study aimed to address the lack of information on the extent to which alcohol labelling was implemented in that period. The Commission found that fewer than one in five alcohol labels (17%) contained a health-related message in addition to the alcohol content information mandatory in each country. Wine labels most often carried health-related messages (19%), with messages less frequently found on spirits (15%) and beers (14%). The research also revealed wide divergence in the type and form of health-related messages on alcohol labelling across Europe and highlighted the need for more stringent legal requirements regarding health-related labels. The Commission plans to propose a mandatory indication of ingredients on alcoholic beverage

---


38 This association represents producers of single malt whiskies, which are always priced far above the minimum price. Those producers are, however, an important Scottish export industry, tourist attraction and famous part of Scottish heritage, so it was a political tactic to have them lead the litigation instead of the less prestigious alcohol producers and retailers (e.g. fortified wine makers and discounting supermarkets) that would actually be affected.


labels before the end of 2022 and of health warnings on labels before the end of 2023.\textsuperscript{41}

At the national level some Member States have adopted more voluntarist measures on the matter, including France and Lithuania, where labels on alcoholic beverages 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 saw in food policy (see Section 3.3) 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. They included the European Public Health Alliance (EPHA), the Standing Committee of European Doctors (CPME) and Eurocare, a Eurogroup focused on preventing and treating alcohol abuse. Their departure was a 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 the von der Leyen Commission are not specific to alcohol; rather, they are part of “Europe’s Beating Cancer Plan”, though they include the specific target of reducing the harmful use of alcohol by at least 10% by 2025. 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.

### 3.5 Communicable diseases and threats to health

One of the most consistent areas of EU health action has been on communicable disease and other cross-border threats to health.\textsuperscript{42}

The logic of an EU role in the area is inexorable. 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 are very varied, with different organizations, resources and skills.\(^{43}\)

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 in crises, countries can sometimes overcome the barriers to 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.\(^{44}\) Both infectious disease outbreaks (including SARS and influenza H1N1 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.\(^{45}\) 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.

### 3.5.1 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.\(^{46}\) However, this overarching network had evolved from a series of disease-specific networks and depended on ad hoc coordination between national authorities, coordinated

---


\(^{44}\) TFEU, Article 168(1).

\(^{45}\) TFEU, Article 168(7).

by the Commission. The anthrax alerts of 2001 in the United States combined with the sudden global spread of the virus causing SARS in 2003, followed by pandemic influenza threats, abruptly focused attention on the weaknesses of these arrangements, and a specialist agency, the ECDC, was established instead to coordinate surveillance and monitoring of communicable diseases.47

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 as the Centers for Disease Control and Prevention (CDC) have in the United States. Rather, Europe has 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. ECDC played a very visible role in COVID-19 response and has gained new roles, resources, and powers (Box 3.1). It can use them, along with its existing networks and stature, to bolder EU-level public health.

3.5.2 Managing and responding to threats

The responsibilities of the ECDC are centred in monitoring and surveillance, and to some extent capacity building and research. The responsibility for the policy 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”,48 which addresses issues such as preparedness and response for public health emergencies, as well as coordinating responses in


Established in 2004, 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 indeed 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 2020 was €60.4 million. The agency employed 286 staff members (compared to the $6 billion and approximately 20 000 employees assigned to the US Centers for Disease Control). The ECDC has therefore been described as a “hollow core” rather than a “hub of communicable disease control in the EU”.

During the COVID-19 pandemic, the ECDC released periodically updated “rapid risk assessments” and provided scientific advice to Member States and the Commission on topics such as the use of face masks, contact tracing and surveillance in long-term care facilities. The agency created a COVID-19 website, developed an infrastructure to monitor COVID-19 vaccine effectiveness across the EU and set up the European surveillance portal for infectious diseases (EpiPulse) to collect and analyse disease data for threat detection and response. The limits of its capacities were soon made apparent. The ECDC was criticized for initially understating the likelihood of the spread to Europe, and for lacking data-sharing capacity, legal authority and executive power.

The ECDC faced two main obstacles highlighted by the pandemic. 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 upon national public health capacities and resources, which vary considerably from a Member State to another. Responding to these limitations, the European Commission proposed in November 2020 to bolster the agency’s legal mandate and strengthen its role in coordinating surveillance, preparedness, and response to health crises. The European Parliament’s Committee on the Environment, Public Health and Food Safety adopted its report in June 2021.


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 swine flu pandemic in 2009, when 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 Sections 3.6 and 3.7 below).\footnote{European Commission (2019). Memo. Framework contracts for pandemic influenza vaccines 28 March 2019. Available at: https://ec.europa.eu/health/system/files/2019-03/ev_20190328_memo_en_0.pdf (accessed 19 February 2022).}

Box 3.2 Revised Regulation on Cross-Border Threats

The new Regulation on Cross-Border Threats has received less interest than HERA, but is actually one of the more interesting proposals that is currently on the table for a decision in the European Parliament and the Council. Here, we see some legislative ideas that were in some shape or form tabled before, by the Commission after Swine Flu, that were then not at all seen as acceptable by the Member States.

First of all, there is a strong proposal on creating a blueprint for national response plans and even the possibility for the EU to audit Member States on the implementation of these plans. The Commission under this new Regulation would also have a broader right to declare a public health emergency for the whole of the EU, which, beyond the legal effect of allowing the fast tracking of medicine approval processes and taking other countermeasures, can also have important political implications, where – as we see with the WHO – afterwards there are always huge debates on: were they too late with their declaration, too early; was it serious enough, etc.

Another important proposed change is that the Health Security Committee – which after the 2001 Anthrax attacks only existed in a formal status; and after Swine Flu, in the Decision on Cross-Border Threats of 2013, only became formalized in Article 17, almost at the end of the Decision – will become one of the central bodies for coordination of big health threats in the EU. In the Health Security Committee, Member States are represented at a ministerial decision-making level immediately under the auspice of the Commission. This is a relatively odd figure in the EU’s institutional structure, to the extent that the Council, in response to the proposal, has even asked questions about what the role is of the Council formation at the ministerial level in the field of health, vis-à-vis the Health Security Committee.
3.5.3 Preparing for the next pandemic

Finally, 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 expenditures and changes including, specifically, the European Health Emergency Preparedness and Response Authority, aka HERA.

HERA is to be a core part of the EU’s response to COVID-19 and efforts to be more resistant and resilient to similar health crises in the future. 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.” Its €6 billion budget over the six years of the current budget period (MFF, see Section 2.2) will be in addition to other expenditures such as RescEU and EU4Health and the budgets of agencies such as ECDC. Its board and director will have some autonomy within the Commission, and the board will include 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.

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. This would be modelled on the United States’ Biomedical Advanced Research and Development Authority (BARDA), which plays a similar role to 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.

HERA is a General Directorate within the Commission (see Section 2.1.7), announced in a Communication of September 2021 after discussions of the appropriate legal form for the agency.\(^{50}\) It will have an annual budget of around €1 billion. HERA’s core missions, according to that Communication, will be:

“To strengthen health security coordination within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;

“To address vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures;

“To contribute to reinforcing the global health emergency preparedness and response architecture.”

### 3.6 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, saving millions of lives.\(^{51}\) Vaccines are responsible for the eradication of smallpox and Europe’s polio-free status.\(^{52}\) 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 vaccine; a vaccination is the actual administration of that vaccine. 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

---


51 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.

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 to Member States.

3.6.1 Routine EU vaccine and vaccination policies

Vaccination is certainly an important public health issue across Europe. In terms of routine vaccination, coverage rates for certain 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. Subpar herd immunity 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 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 (see Figure 3.1). 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 policy-makers setting vaccine policy as well as distrust of 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 does the spread of disinformation via social media and the politicization of vaccination. Pro-vaccination public health messages are often ineffective in the context of the strong emotional responses elicited by this combination of factors. 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.55

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.56 Influenza vaccines for use in the single market must be authorized through a centralized authorization 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 other vaccines.

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 nine Member States and voluntary in the other 19 countries. Other measures such as vaccine requirements for children entering the school system complicate this picture.57 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.58

For these reasons, 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.59 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.

55 Ibid.
58 Ibid.
Fig. 3.1  Global vaccine confidence before the COVID-19 pandemic (% model-based estimates)

This figure shows changes in estimated vaccine confidence between 2015 and 2019. Positive values indicate increasing agreement that vaccines are “safe, important, and effective”, and negative values indicate decreasing agreement. See the source for important methodological information.
**Fig. 3.1** Vaccine confidence in the EU prior to the COVID-19 pandemic (%), model-based estimates [continued]

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. However, to the extent that anti-vaccination remains a politically popular position in Europe, we can expect some Member States to be themselves hesitant to act.

### 3.6.2 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 5.1.1).

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. 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, 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 (discussed in Section 3.7 below). 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 (see Section 5.1.1), and in September 2021 the Commission established the European Health Emergency Preparedness and Response Authority (HERA). It remains to be seen to what extent these actions will be effective.

Facing mounting pressure over vaccine shortages in several Member States in 2020, the EU announced that it would empower countries to block exports of vaccines and require pharmaceutical manufacturers to seek authorization before exporting their doses. Additionally, on 19 January 2021 the European Commission called on Member States to speed up the distribution of vaccines across the EU. Placed under the authority of the Commissioner for the Internal Market and the Commission for Health and Food Safety, a special Task Force was established on 4 February 2021 with the goal of ramping up production capacity for vaccines in the EU. The task force was designed to act as a one-stop-shop for vaccine manufacturers and help them address problems they encountered in production capacity and supply chains. By mid-July 2021 the EU had at its disposal enough vaccine doses to vaccinate 70% of the EU adult population.

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. 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. By early 2022, low vaccination rates were primarily a problem in central European countries.

There remains a minority of people in each Member State who do not want to be vaccinated, but, as the example shows, Member State policies can increase vaccination uptake. Uneven rates of vaccination in an integrated market might

---

continue to lead to localized surges and transmission. 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.

3.7 Joint procurement

Within the context of EU action to cross-border health threats (see Section 5.3.1) a new tool was introduced in 2013 to strengthen preparedness. With Decision 1082/2013/EU, the possibility was introduced for Member States to engage on a voluntary basis in a procedure to jointly procure medical countermeasures, particularly vaccines (Article 5). This process was accelerated by the H1N1 flu pandemic in 2009, when countries were competing to purchase and stockpile available flu vaccine supplies and antiviral medication, for which they paid relatively high amounts without using them. 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.

In 2014 the EU Joint Procurement Agreement (JPA) was adopted and entered into force after 14 Member States had signed it. In June 2019 Bulgaria became the 25th Member State to join the agreement. 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.

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. Procedures for other countermeasures, including personal protective equipment, are still under way. While the Decision leaves some discretion to Member States to determine the scope for joint procurement per purchase, under the Joint Procurement Agreement it 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. These could include communicable diseases, bio-toxins, and chemical and environmental events.

The idea of using joint procurement, also outside the emergency scope, has attracted interest in recent years, especially in the context of the growing problem of high-priced medicines, which was triggered in 2014 with the Hepatitis C drug sofosbuvir. In a resolution adopted in 2017 the European Parliament called upon the Commission and the Council to develop new measures and tools that could help to ensure affordable patient access to medicines without having an unacceptable impact on public healthcare budgets, including voluntary joint procurements and voluntary cooperation in price negotiations. This avenue was further explored under the Maltese EU presidency in 2017, which drew attention to the specific challenges in purchasing health technologies for smaller populations and promoted the idea of enhanced voluntary cooperation between countries. Various European countries have meanwhile engaged in regional collaborations, such as the BeNeLuxA initiative (started in 2015) or the Valletta Declaration (2017). These projects essentially aim at improving transparency, sharing experience and enhancing bargaining power for procurement agencies. They are focused on collaboration along the whole procurement process, from horizon scanning, through health technology assessment, to price negotiations.

The system of joint procurement for health emergencies as managed by DG SANTE (based on the Health Threats Decision 1082/2013/ EU) was under significant pressure during the COVID-19 outbreak. The JPA system depends on the relative contributions of the participating Member States, and it allows for parallel purchases by Member States. At the same time, there is a centralized procurement system, the RescEU, that works under the heading of the Union Civil Protection Mechanism (UCPM) (see section 3.9). This system is more general, less health specific, and designed to foster cooperation in preventing and protecting against natural or man-made disasters. During COVID-19, when the first discussions were held about purchasing medical supplies and vaccines, these systems worked in parallel. But as RescEU created more centralized control at the EU level for the purchase of emergency medical supply, the available budget was

70 European Commission (2014). Medical countermeasures that could be procured in common under the Joint Procurement Agreement. December 2014.
73 Available at: https://www.southeusummit.com/about/valletta-declaration/ (accessed 19 February 2022).
initially a lot lower than what could be put together under the health procurement mechanism. Yet the ability to create joint procurement agreements and in parallel negotiate purchases with vaccine manufacturers was considered problematic during COVID-19 as undermining EU solidarity. In the end, for COVID-19 vaccines a Decision was adopted under the aegis of which the Commission was given the mandate to negotiate Advance Purchase Agreements on behalf of the Member States, using the existing governance mechanisms that the JPA system in health had set up. 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.\footnote{Commission 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).}

\subsection*{3.8 Pharmaceuticals and health emergencies}

The COVID-19 pandemic highlighted challenges of supply of medicines (including dependence on supply from outside the EU, and inequities in access across the Union) and the role of public authorities in actively supporting the development of new medicines where necessary to meet public needs. As part of its “European Health Union” package of proposals (see Section 1.4.2), 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.\footnote{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). European Commission.} 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.

The new pharmaceutical strategy\footnote{European Commission (2020). Pharmaceutical Strategy for Europe (COM(2020)761).} also envisages 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. After many years of EU pharmaceutical regulation remaining relatively unchanged in its substance, these proposals suggest a broader and more active role for the EU in this area in the coming years.
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. 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 two 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 situations. The Union’s measures and those of the Member States shall complement and reinforce each other.” Article 196 TFEU (Box 3.3) 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.

---

77 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.
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, “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. It will continue to have an expanding role within the EU, notably with investment in emergency management equipment and expertise. It has marshalled and shared resources from firefighting equipment to sophisticated satellite geospatial data (through the Copernicus Emergency Management Service) to search and rescue teams in its eighteen years of existence.

In March 2019 the mechanism was upgraded and renamed RescEU. 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. 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 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

79 And Iceland, Norway, Serbia, North Macedonia, Montenegro and Turkey.
through coordination, joint planning, joint preparation and exercises, and joint service in crises.

The Civil Protection Pool includes the European Medical Corps, which was set up in the aftermath of the 2014 Ebola outbreak in West Africa and began operating in February 2016. It is the EU’s principal contribution to the 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 will continue in this range for three years, peaking at €786.5 million in 2023, and then drop by two-thirds to around €245 million per year through to the end of the current budget at the end of 2027.

That rather 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 Medical Pool). 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 pandemic, sustaining stockpiles is politically hard; masks

acquired in response to the 2009 H1N1 turned out to have expired in 2019 and not been replaced, which is easy enough to understand 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 poorer 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, spans 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.

3.10 EU4Health and the preceding Health Programmes

The Health Programme had been a mainstay of the EU health policy world since its inception in 2003 when it was supposed to support the EU’s first ever Health Strategy (see Section 1.3 but by 2019 it was widely expected to be wound down as a separate programme. It was to be folded into the broader cohesion funds (see Section 6.3) which might have offered the prospect of pursuing health in broader policy but would have certainly reduced the institutional autonomy and consolidation that even the small sums in the Health Programme had created. The COVID-19 pandemic changed politics dramatically.

3.10.1 Health Programmes to 2020

A core tool for the EU’s specific action on health has been financing collaborative projects on health. This started as a series of topic-specific programmes (e.g. on cancer) before being integrated into a single funding programme for health. The third health programme\(^{82}\) finances a range of collaborative projects across Europe around the three broad headings of health threats, health determinants

---

and health information. However, the key point about the programme is its size, or rather lack of it; a budget of around €46 million a year equates to 0.000058% of publicly funded health expenditure in the EU, or around one half of one millionth part. Even if compared with only the preventive part of national expenditure (around 3%), the programme’s resources remain relatively tiny. This small sum means that the EU cannot provide most of what a health system does; it does not, and will never, have enough money to do so, and it will always be engaged in supplementary actions.

Despite this relative lack of resources, the health programme has been effective in sharing knowledge, supporting collaborations between countries and generating comparable data for benchmarking; such European projects have changed the direction of entire national health systems, such as in the case of cancer, by highlighting comparisons. They show a strong bias towards supporting capacity building, often among EU-level groups such as the Association of Schools of Public Health of the European Region, and conferences to identify and promote good practice. A mid-term evaluation found that the health programme excelled in promoting networking but appeared to distribute its projects rather thinly. Nevertheless, this limited volume of resources inevitably affects the scope for EU-financed action on health.

In 2019 the Commission proposed ending the health programme as a separate funding stream and instead integrating it within the European Social Fund Plus (ESF+) as part of the European Structural and Investment Funds. This would have represented more than an administrative reorganization; it represented rather a fundamental shift in the EU’s support for health, potentially offering additional funds, but not ring-fencing these for health purposes. The debate as to whether this was an opportunity or a threat to health investment became moot in 2020. The COVID-19 pandemic reframed the EU’s role in public health and the health programme, as discussed in the next section.

---


3.10.2 EU4Health

In March 2021 the Commission proposed that the Health Programme be (re) created and named EU4Health. Ultimately, when the Commission reissued its MFF proposals in the wake of the COVID-19 pandemic, the integrated Health Programme had gone, replaced with a new, standalone, and significantly strengthened programme called EU4Health.

After much negotiation (see Section 2.2) a budget of €5.3 billion was agreed, more than ten times the budget of the previous health programme, and the scope of the new plans is ambitious. Programmes to date have contained similar sets of objectives, such as preventing disease, improving health security and generating health knowledge, and have been proposed in documents of between 10 and 15 pages. By contrast, the EU4Health proposal is 56 pages long and retains the “traditional” objectives, as well as adding new ones (for instance to improve the availability of medicines) and widening the scope of the EU’s health policy (to encompass health system strengthening, for example).

The health programme does not compel or require Member States to act in a particular way or change national policies. Rather, it provides funds for collaborative projects and facilitates voluntary cooperation, exchange of best practices and sharing of information between health officials, civil society actors and health professionals. Its scope, however, is still determined by the health mandate given to the EU in the founding Treaties. What makes the EU4Health programme significant is the potential to extend EU activity into areas where the EU has previously played a lesser role. Health systems strengthening is a good example here. Article 168 (7) TFEU states that “the organisation and delivery of health services and medical care”, under which most of these factors fall, are responsibilities of Member States. The EU4Health programme does not alter the balance of competencies here, but it does establish a significant “carrot” to encourage cooperation and engagement with common capacity-building actions. For example, it envisages the provision of training and temporary exchange programmes for medical and healthcare staff. The extent to which the EU will be able to encourage, support and bring about change to strengthen national health systems will depend upon the willingness of national governments to engage with these efforts, but the EU4Health programme presents the potential for a Europeanization of health systems, as well as of vaccine policy, emergency preparedness planning, health data reporting and surveillance, and many other aspects of health policy.

Substances of human origin

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.88

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.89

The actual legislation on blood, blood products, tissues and cells itself is relatively limited, reflecting the narrow Treaty mandate.90 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.91 This reflects the perennial concern of national administrations about granting powers to the EU relating to the organization of their health systems.92 The European Commission carried out in 2017 and 2018 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 (tissues and cells).93

90 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.”
92 Article 168 (7): “These measures (para 4(a)) shall not affect national provisions on the donation or medical use of organs and blood.”
The background to European action on organs, however, is a more positive one; a good example in one country (Spain) regarding organ transplantation provided the inspiration for collective action at European level, to try to overcome the persistent shortage in organs for transplantation that affects Europe. Accordingly, the EU action in this area is much broader than the specific legislation on quality and safety; it also encompasses a wider action plan aimed at increasing organ availability and enhancing the efficiency and accessibility of transplantation systems, as well as supporting improvements in quality and safety.

### 3.12 Health in All Policies

There is extensive evidence about the importance of factors beyond health for health itself and therefore there is a need for health issues to be taken into account in other areas of public policy. This has been a part of the European approach to health since the introduction of the specific article on health into the Treaties, with the requirement (strengthened over the years) that health protection requirements be integrated throughout the EU’s action. The EU has a history of adopting principles that are to be taken into account across government, such as the precautionary principle, Health in All Policies, or less obviously useful ones such as the “innovation principle”, which was backed by a coalition of chemical, tobacco and other industries which have an interest in allowing greater risks from their products, to public health and in general.

Alongside the Commission’s initial strategy for implementing its new treaty mandate on health in 1993, the Commission took internal steps to ensure the integration of health into other policies.

---


97 The European Parliament passed this in 2019. Its principal backers were in the European Risk Forum, which hides its membership and purports to be a think tank focused on excellence in risk management. The innovation principle is that any regulation should consider its impact on “innovation” as a competitor to, for example, the precautionary principle. This will present another hurdle to, for example, regulation of innovative tobacco products such as heat-not-burn, or to regulation of novel chemicals in the food system. As with Health in All Policies, though, its actual impact will depend on how seriously the Commission takes it, and how much pressure the Council and Parliament put on it to take it seriously.

• the reinforcement of interservice consultation prior to Commission decisions whenever a decision might have implications for public health;

• the setting up of an Inter-Service Group on Health to ensure mutual exchange of information and internal coordination with regard to health and health protection aspects of policies and legislative proposals;

• as well as publishing annual reports on this process of integration.

However, although initially voluminous and covering a wide range of potential impacts, the reports became shorter and less regular,99 and ultimately the Commission decided to abandon providing regular reports on the overall integration of health protection requirements across European policies in 1999. Instead, attention turned to developing methodologies for assessing the impact of the EU on health, with the Commission funding development of a methodology that could be used for health impact assessment at European level,100 as well as a specific impact assessment tool for impact on health systems.101

However, by then the overall approach within the Commission had changed. Health was not the only area that the Treaties required to be taken into account across other policies; other objectives such as the environment, consumer protection, culture, regional policy, animal welfare and development cooperation also had their own “mainstreaming clauses”, which led to a proliferation of impact assessments and methodologies. There was also increasing pressure on the Commission to consider all the impacts of its proposals more carefully and to do so in a systematic way. The Commission responded by replacing these different sector-specific impact assessments within a single integrated impact assessment process covering all the different dimensions of a proposal’s potential impact, grouped under the three headings of economic, social and environmental impact;102 impacts on health were included under the “social” pillar, and the


tools developed specifically for assessing impact on health and health systems became just a part of this wider evaluation.

The process for evaluating these impact assessments was then further strengthened in 2006 with the establishment of an internal Impact Assessment Board within the Commission, which would review impact assessments of proposals before they were submitted to the Commission for adoption. Today, Commission impact assessments are drafted by the Regulatory Scrutiny Board. The Board is an appointed group of three senior Commission officials and outside experts with backgrounds in law, economics, and EU affairs. They have full-time appointments. The Board is chaired by a Commission Director-General. The Board’s task is to provide “central quality control and support for Commission impact assessments and evaluations at early stages of the legislative process.” It was set up as part of the Better Regulation initiative, with all the organizational hallmarks of that approach, and its membership and tasks represent an economic and legal approach rather than one focused on subject matter expertise or policy agendas that are at odds with the Better Regulation approach. Externally, doubts have also been expressed about how far health impacts are really assessed in these integrated impact assessments.

There is also a fundamental structural issue, which is the nature of European legislation. While regulations have direct effect, and their impact could in principle be assessed up front, the ultimate impact of directives depends substantially on how they are implemented by Member States into national legislation – a process that can vary quite substantially and puts in doubt how far it is actually possible for the European Commission to know the impact of proposals that have such national variability built in by design. Nevertheless, this process of understanding the impacts of other policies on health is a vital one, as the impact of other areas of European action on health is in many ways larger than the impact of the EU’s actions that have health as a specific objective.

3.13 Conclusion

EU public health policy was, for a long time, 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 choose to 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 second-face 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, 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, a new HERA entity, a vastly expanded and more flexible RescEU, a rebooted and much larger health programme (EU4Health), a Pharmaceuticals Strategy, support for COVAX (see Section 7.3.4) 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

---

**Box 3.5 Antimicrobial resistance**

One area where the different powers of the European Union related to health can come together effectively is in tackling antimicrobial resistance. The Commission’s “One Health Action Plan against Antimicrobial Resistance (AMR)” sets 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. The European Health Union (see Section 1.4.2), HERA and the Pharmaceuticals Strategy all refer to the threat of AMR. The Action Plan outlines a range of actions involving better monitoring and surveillance, coordination across the EU and supporting prevention and control through more prudent use of antibiotics in both people and animals, as well as more research, and the EU is pushing for stronger global action. Nevertheless, high levels of certain types of AMR remain in the EU, and the variations between countries in their rates suggest that there is still much work to be done in addressing the challenge within the EU.

---

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, immediate responses to COVID-19 such as the Vaccines Strategy, and 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. Noncommunicable 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 budget 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, the pandemic forgotten, have refocused on other topics? 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 before governments start to scrutinize the EU budget in preparation for 2027.

4.1 Introduction

How many times is health referenced in the EU Treaties? The obvious answer is once: Article 168 TFEU, the core of Chapter 3. Twice, some might point out: Article 168 TFEU and Article 9 TFEU, the latter committing the EU to a high level of human health protection. In reality, there are three other treaty bases that clearly identify health as the justification and goal of policy, and more that effectively include health in their goals (a simple search of the text of the Treaties will also find a number of health exceptions, in which risk to public health is grounds for an exception to a policy or a basis on which to block it).

Chapter 3 discussed the increasingly important first-face EU policies developed on the treaty base of Article 168 TFEU. A focus on the article titled “Public Health” should not distract us from the other places in the Treaties, and the EU’s politics, in which health is a specific and important objective. For all the exciting developments in EU public health policy, there is still a strong chance that EU policies with regard to the environment, health and safety at work, and consumer protection have saved more lives and avoided more mortality. This chapter discusses those areas: environmental protection, health and safety at work, and consumer protection. All of them are areas in which the EU works for health protection and improvement, even if they are often understood as some other policy area, all of them address health in ways that the COVID-19 pandemic revealed, and all are areas in which the EU could work more to promote health within its treaty bases. Like Molière’s bourgeois gentleman, the EU has been speaking public health for a long time without necessarily knowing it.

4.2 Environment

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

1 TFEU, Article 191, paragraph 1.
European 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 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.² Like health, environment also has a “mainstreaming clause”, requiring environmental protection requirements to be integrated throughout the EU’s policies and activities.³

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. EU 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.⁴ The central importance of such environmental protection is illustrated by some of the links between health and environmental factors shown in Table 4.1; indeed, the World Health Organization estimates that environmental causes account for 18–20% of the overall burden of disease throughout the WHO European region (though more of that burden is in the eastern part of the WHO region than in the EU).⁵

Despite the progress made in many areas, challenges remain for environmental impact on health.⁶ 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. 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

---

² TFEU, Article 192.
³ TFEU, Article 11.
### Table 4.1  Some health impacts and associations with environmental and lifestyle factors: a list of examples

<table>
<thead>
<tr>
<th>Health impact</th>
<th>Association with some environmental exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infectious diseases</strong></td>
<td>Water, Air and food contamination, Climate change-related changes in pathogen lifecycles</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Cardiovascular diseases</strong></td>
<td>Air pollution (carbon monoxide, ground-level ozone, PMs), Smoking and ETS, Lead, Noise, Inhalable particles, Food (e.g. high cholesterol), Alcohol, Stress, Poor exercise levels, Salt</td>
</tr>
<tr>
<td><strong>Respiratory diseases including asthma</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Skin diseases</strong></td>
<td>Ultraviolet radiation, Some metals (e.g. nickel), Pentachlorophenol, Dioxins</td>
</tr>
<tr>
<td><strong>Diabetes, obesity</strong></td>
<td>Foods (e.g. high fat), Poor exercise levels</td>
</tr>
<tr>
<td><strong>Reproductive dysfunctions</strong></td>
<td>PCBs, DDT, Cadmium, Phthalates, Endocrine disruptors, Pharmaceuticals</td>
</tr>
<tr>
<td><strong>Developmental (fetal and childhood) disorders</strong></td>
<td>Metals (cadmium, lead, mercury), Endocrine disruptors, Infectious diseases, Alcohol, Some pesticides, Infectious diseases</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td>Metals (lead, manganese), Some solvents, Organophosphates</td>
</tr>
<tr>
<td><strong>Immune dysfunction</strong></td>
<td>Ultraviolet-B radiation, Some pesticides</td>
</tr>
<tr>
<td><strong>Increased chemical sensitivity</strong></td>
<td>Multiple chemical exposures at low doses</td>
</tr>
</tbody>
</table>


*Notes: ETS: Environmental tobacco smoke; PCBs: Polychlorinated biphenyls; PM: Particulate matter.*
concern about the real-world impact of cumulative exposure to many different chemicals over time.

### 4.2.1 Climate change

Climate change is probably the single biggest threat to human health. Not only does climate change result in crop failures, which have an impact on nutrition, but many human diseases have been linked to climate fluctuations, including cardiovascular disease, respiratory illness in heatwaves, and changes in the transmission of infectious, especially vector-borne, diseases such as malaria.\(^7\) In 2009 the Commission published a working paper on the health impacts of climate change,\(^8\) 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.

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).\(^9\) 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.

It is worth noting that the healthcare sector is itself a meaningful contributor to climate change. A range of decisions, from the choice of technique in anaesthetic to the location and design of healthcare facilities, can influence carbon consumption. 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. 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 “green” the EU through healthcare infrastructure approaches.

4.2.2 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 section 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 hampered due to poor air quality, especially in urban areas.10 The EU’s action to improve air quality is based on three main pillars:11 the ambient air quality standards set out in the Ambient Air Quality Directives (EU 2004, 2008) that require countries to adopt and implement air quality plans; the national emission reduction targets established in the National Emission Ceilings Directive (EU, 2016) that requires 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 and transport fuels, etc.12 In addition to these directives, the Clean Air Programme for Europe (CAPE), adopted in 2013, seeks 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.13

4.2.3 The environment at the heart of Europe’s post-COVID recovery plans

The COVID-19 pandemic has created extraordinary challenges, and the EU has put in place the largest financial stimulus package in its history in order to support its recovery14 (see also Chapter 6 below). Although this does include

11 Ibid.
13 Ibid., p. 17.
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 pandemic.

4.3 Health and safety at work

The large Title in the TFEU called “social policy” is substantially about what we might otherwise call labour law and equalities legislation. In terms of impact on health, it operates through several different mechanisms.

4.3.1 Occupational health and safety

Among the EU’s list of social policy objectives, the first objective is “improvement in particular of the working environment to protect workers’ health and safety”. The powers provided are broad in scope but quite specific in their nature, being limited to “directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtained 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 health and safety at work powers of the Treaties described above 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, there is a wide range of detailed and sectoral provisions. Two European agencies – the European Agency for Safety and Health at Work and the European Foundation for Living and Working Conditions – also support the implementation of European action in this area. This includes a directive on sharps (e.g. safe handling of needles and other products that can pose a hazard to workers) specifically focused on workers in the health sector, although many of the other provisions are also highly relevant to healthcare workers.

15 TFEU, Article 153, paragraph 1(a).
16 TFEU, Article 153, paragraph 2(b).
Finally, the Council formally adopted the Regulation establishing the European Labour Authority on 13 June 2019. This new Authority will ensure that Union rules on labour mobility are enforced in a fair, simple and effective way. More specifically, the Labour Authority will be responsible for supporting Member States in facilitating access to information for individuals and employers about their rights and obligations in the areas of labour mobility and social security coordination; for supporting operational cooperation between national authorities in the cross-border enforcement of relevant Union law, including facilitating joint inspections; and for providing mediation and facilitating solutions in cases of disputes between national authorities.¹⁹

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, as workers previously viewed as lower status (such as grocery employees) were recognized to be essential, and as 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.²⁰ Close to 40% of European workers began teleworking fulltime as a direct result of the pandemic. More than half of them had no prior experience with teleworking, which made the transition to telework particularly challenging for some workers with limited equipment or digital literacy. Other professionals were constrained to go to work and were disproportionately impacted by the virus. 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%).²¹ COVID-19 became the second most common occupational disease reported in the Netherlands from March to September 2020 (33% of all reported illnesses), with most cases being reported in nursing and caring homes (79% of notified cases).²²

### 4.3.2 Working Time Directive

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

---

²⁰ European Commission (2020). Telework in the EU before and after the COVID-19: where we are, where we head to. Science for policy brief.
Box 4.1  Health and safety in the COVID-19 pandemic

The 1989 EU framework directive on OSH specifies a legal obligation for employers to provide healthy and safe workplaces. COVID-19, which can easily spread in workplaces, presented an obvious challenge for occupational health and safety as well as a complex set of political problems for different interests.

The European Agency for Safety and Health at Work (EU-OSHA) issued a series of non-binding guidelines to help workers stay safe during the pandemic, adapt workplaces while minimizing exposure to the virus, and help recovering COVID-19 patients return to work. The European Commission issued recommendations highlighting the importance of telework in preserving jobs and ensuring the continuity of economic activity. The Commission also adopted the EU strategic framework on health and safety at work 2021–2027. Announced in the European Pillar of Social Rights action plan (see Box 2.7), the new 2021–2027 OSH framework identifies key priorities aiming at improving workers’ health and safety in the context of the post-pandemic world, with a specific focus on three crosscutting key objectives: to anticipate and manage change in the world of work, to improve prevention of work-related diseases and accidents, and to increase preparedness for possible future health threats. The European Commission will also produce recommendations on mental health at work before the end of 2022 that will incorporate lessons drawn from the COVID-19 crisis. The proposed actions in the Strategic Framework are “characterised by a high degree of voluntarism”.

The pandemic revealed the many complexities and failures to communicate between public health and occupational safety and health (OSH) organizations and experts. One of the politically sensitive issues is the extent to which it is employers’ responsibility to protect staff against a widely circulating virus. Just as it was a struggle to establish that secondhand smoke made smoking in public places into a risk (e.g. to bar staff), it is a struggle to establish and implement policies that account for the fact that workplaces present a risk of COVID-19 transmission, and some workplaces such as restaurants and abattoirs present a very high risk. In both cases, basic business interests in getting staff to work and minimizing disruption contend with the legal obligation to ensure health and safety, and the argument used by those who wish to avoid special OSH requirements is that employees could have caught the virus elsewhere. It is important to avoid forgetting the health dimension in OSH: just because a workplace does not definitively cause a particular problem does not mean the workplace is innocent of creating risks.

---


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. The directive was controversial, at least in the United Kingdom, which unsuccessfully tried to contest the original directive before the CJEU. Health ministries also had mixed feelings about the proposal. On the one hand, protecting workers against long hours 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, 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 also protect these excluded categories of workers. The situation of doctors in training was given particular attention, with work for the Commission identifying a range of options that Member States could take, 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 who currently leave career grades, recruiting more junior doctors, and sharing the workload with other facilities, including in the private sector. Accordingly, in 1998 the Commission proposed extending the directive to cover excluded sectors including doctors in training. The updated directive agreed on this basis in 2000 did extend the original directive to cover doctors in training but provided a specific further transitional period of up to eight years with higher limits on working time for doctors in training (an average of 58 hours a week, progressively falling to 52 hours a week). This again was in order to take account of the specific difficulties of health system organization, in particular those put forward by the United

---

24 European Court of Justice. Case C-84/94 United Kingdom v Council of the European Union.
Kingdom. These directives were then further amended and consolidated in 2003, with broadly the same provisions although with a cap on weekly working hours of 48 hours. The directive included similar derogations for longer working hours for doctors in training as the 2000 directive. 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. 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. However, the criticisms that the EU working time legislation had been developed without taking account of its impact on health systems is more difficult to understand, given that this had been a central part of the European debate since the original directive in 1993, as is the general absence of engagement of health professionals from this debate until the stage of 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 formal basis of the working time directives was health and safety at work, rather than the article on public health, and discussion largely took place in employment-related forums rather than the Health Council, for example.

4.3.3 Social partners in EU law

As mentioned above, social policy also has a unique additional legislative route, which is by direct negotiation and agreement between management and union representatives (aka social partners); these agreements can then be implemented into normal EU law by a Commission proposal and Council decision. The only use of this procedure in healthcare was the directive on sharps, such as used needles, which are a major health and safety issue in healthcare.

4.3.4 Equalities and nondiscrimination

One key area where there are strong EU measures is that of nondiscrimination. 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\textsuperscript{30} – and it has put in place wide-ranging legislation to combat discrimination on these grounds. The EU is also a signatory to the United Nations Convention on the Rights of Persons with Disabilities.\textsuperscript{31} The United Nations Convention, intriguingly, 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”.\textsuperscript{32} People with chronic conditions could be considered to fall within this definition (e.g. people needing dialysis, the provision of which prevents them from being able to keep a full-time job). However, patient groups have been reluctant to claim the label of disability, despite the strong EU legal protections that it brings. Ill-health as such is not a protected ground of discrimination.

4.4 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, now Article 169) did not mean that it only became a concern then but rather that it became an additional treaty base useful 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).\textsuperscript{33} 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, but it was delinked and moved to the DG for Justice and Consumers (DG JUST) under the Juncker Commission.

\textsuperscript{30} TFEU, Articles 10 and 19.
\textsuperscript{33} TFEU, Article 169.
The keystone of EU consumer protection law is found in two old directives, updated in 2012 and 2019. 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”. There is a substantial focus on nondiscrimination, e.g. in the presence of a network of European Consumer Centres (ECC-net), which provide 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 nonbinding, 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 State implementation, and also responded to the rise of online markets, personalization of various sorts, and other new internet-enabled interactions between buyers and sellers.

Application of EU consumer protection law is a potentially thoroughgoing agenda with implications for both healthcare services and for public health in general. It has had relatively little impact on healthcare services because most healthcare providers and professionals have clearly defined professional scope of practice and remedies exist for underperformance. It might be used more forcefully on the edges of the healthcare sector, e.g. with the regulation of vitamins, supplements and m-health such as fitness trackers. It might theoretically also be used on products with serious health consequences, such as alcohol or fast food, though that would take a major reorientation of the law. It is not clear that any such reorientation is coming. The Commission’s last major strategic document was published in 2012 and is filled with the language and preoccupations of that era. While there are obvious industry lobbies, including healthcare lobbies, that

---


would oppose a revival of the consumer protection agenda, it also has potential as a way for the EU to both promote health and make clear its contribution to health, while still operating within a clear treaty base and mandate to pursue the four freedoms.

4.5 Food safety

While nobody can deny the importance of food safety and the closely linked area of veterinary health to overall human public health, food safety is generally seen as a world distinctive from the public health world. That outlook obscures the scale, complexity and ambition of what the EU has done to construct a distinctive 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 very large regulatory apparatus and task.

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. While there is constant pressure to reduce regulatory burdens on affected industries, the history of cross-border 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 both set out a philosophy for food safety whose recitals are unusually readable and established the European Food Safety

---


Authority, based in Parma. 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.)

There was a reform to the General Food Law in 2019. In 2017 the citizens’ initiative “Ban [the herbicide] glyphosate and protect people and the environment from toxic pesticides” 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 reform, passed in the summer of 2019, expands the transparency of the assessment system, including that used by EFSA, by reducing commercial secrecy (e.g. use of copyright to avoid making toxins data public).

The EU’s basic approach, which has shaped international perceptions of best practice, explicitly invokes the precautionary principle (Box 3.3). It focuses on four main areas: food hygiene, animal health, plant health, and contaminants and residues. Note 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.

---

40 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).

41 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.

42 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.”


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 “Europeanizing” 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. 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 “Horsegate” scandal, for example, it emerged that horsemeat from Romania was being fraudulently sold as beef by major supermarkets in the UK and Ireland. Further investigation found that the

---

product had moved around five EU countries (Romania, France, Belgium, the UK, 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. This was a case of food fraud, an area that is closely related to the food safety policies that fraud undermines, and also a 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.”

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. EFSA, the agency, 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. The Member States are the regulators and enforcers in this highly Europeanized area of policy.

The Commission introduced a new strategy for food safety in 2020 as part of the “European Green Deal”. This strategy, introduced in a Communication, emphasized sustainability and resilience, including resilience in the face of the kinds of supply and demand shocks that COVID-19 presented. It addressed a range of health issues, 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.

4.6 Research

Research has long been a major EU priority, with clear potential added-value from collaboration between scientists across Europe, with the largest part of the EU budget after the Common Agricultural Policy and the structural funds.

---

46 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 Netherlands-based meat dealer whose warehouse was located in Belgium.


In general, research policy anywhere has some combination of three points of focus: it can be industrial policy (promoting industry and economic growth), science policy (promoting basic research, science infrastructure and knowledge), or substantive (focused on generating knowledge about a particular topic, such as climate change or health). EU research policy has never been primarily a science
policy and has always had a strong industrial policy component. In the last decade in particular, it has been especially focused on industrial policy objectives.\textsuperscript{50}

Health has been a major priority within that, and the EU has funded thousands of health-related research projects.\textsuperscript{51} Despite the collective challenges facing the EU in terms of public health and health systems, described above, health-related research has tended to avoid these topics, primarily funding biomedical research of more general application instead.\textsuperscript{52} This may change in the coming decades. The EU’s research programme Horizon 2020\textsuperscript{53} already had a broader focus than in the past on “health, demographic change and well-being”.

COVID-19, falling during the renegotiation of the 2021–2027 MFF, affected research as well as health policy. Research was one of the primary areas where the EU mobilized a collective response to the COVID-19 pandemic, with a €1 billion research commitment specifically for coronavirus, building on many years of related funding for infectious disease research. This funding covered a very wide range of activities; as well as providing rapid funding for classic research projects on diagnostics, treatments and vaccines related to coronavirus, funding was used to support private sector initiatives (including for the CureVac and BioNTech COVID-19 vaccines), improving development and manufacturing capacity of relevant supplies, and facilitating data and information infrastructure.\textsuperscript{54} The Commission also explicitly relaxed state aid rules in order to facilitate Member States providing support to research and development related to coronavirus.

Horizon Europe, the 2021–2027 funding programme, has €95.5 billion across that period. Its four goals include support for the “digital and green transitions”, “restoring Europe’s ecosystems and biodiversity”, creating a “circular, climate-neutral and sustainable economy” and, perhaps most obviously relevant to health, “creating a more resilient, inclusive and democratic European society, prepared and responsive to threats and disasters, addressing inequalities and providing high-quality health care, and empowering all citizens to act in the green and digital transitions”.\textsuperscript{55} Health is also one of the key “clusters” of projects. Its goal is to “increase Europe’s autonomy in delivering health care


by contributing to safer, trusted, more effective and efficient, affordable and cost-effective tools, technologies and digital solutions for improved (personalised) health promotion and disease prevention, diagnosis, treatment and monitoring for better health outcomes and well-being, by integrating people in the design and decision-making, based on expected health outcomes and potential risks involved. It will also contribute to a health-related industry in the EU that is more competitive and sustainable, ensuring European leadership in breakthrough health technologies and open strategic autonomy in essential medical supplies and digital technologies, contributing to job creation and economic growth, in particular Small and Medium-sized Enterprises (SMEs).”56 Note, among other things, the reference to Europe’s autonomy57 and the discussion of outcomes and risks. This is a turn away from the focus on a relatively narrow set of industries, especially IT, medical devices and medicines, in older research strategies.

Of course, the EU’s funding for research is only a small part of the total public funding for research in the EU. The bulk of funding comes from national governments, directly or through higher education, and through industry (mostly for more applied technology). National, regional and private strategies are not coordinated, and many EU countries have lacked overall strategies for health research.58 Consequently part of the EU’s role has become not only to fund research but also to help coordinate European funding of research more generally to maximize effectiveness and avoid duplication. This has been the case through examples of “joint programming initiatives”, including on the specific health topics of Alzheimer’s disease and other neurodegenerative diseases, healthy diet and physical activity, antimicrobial resistance and the implications of demographic change.59 Horizon Europe builds on this approach through “partnerships”, which provide a basis for collaboration between the Commission and other public or private sector actors. There are multiple candidate partnerships within Horizon Europe’s cluster for health, including on Personalised Medicine, Rare Diseases, Pandemic Preparedness, Transforming Health and Care Systems and the Innovative Health Initiative (the successor to the Innovative Medicines Initiative).

56 Ibid., p. 8.
4.7 Conclusion

It is a truism of public health policy that the determinants of health often lie outside the healthcare system or the control of any individual. Climate change, pollution, safe workplaces and safe consumer products are all important determinants of health and health inequalities – and they are among the areas where the EU has some of its strongest powers.

The COVID-19 pandemic has increased the salience of public health policy and civil protection, in particular the surveillance of communicable diseases and preparation and responses to health emergencies that we discussed in Chapter 3. The scientific literature on the impact of the pandemic, though, highlights the extent to which the issues discussed in this chapter drove exposure and fatalities.60 Safe and healthy environments, which encompass issues from pollution in residential areas, to good infection control in workplaces, to strong consumer protection, all helped to reduce risk factors for COVID-19 infection and death. Likewise, the pandemic has in many cases exacerbated inequalities which can be partially remedied by action in these policy areas. The pandemic should not just focus us on the new extent to which the EU can directly address health emergencies, but also the extent to which its powers can be used to improve resilience and lower risks in facing the next pandemic.

---

The second face of the EU in health policy is its action in the internal market. The internal market has been of constitutional importance in the process of EU integration, as the EU has been given the exclusive right to legislate against anti-competitive behaviour of market actors, and a strong shared competence in Article 114 TFEU to legislate in order to establish a well functioning internal market. At the same time, on the basis of the principles of the free movement of goods, services, persons, capital and the right to establishment, there is a large body of case law, where national laws have been quashed as “barriers” to internal trade. In this context, core legal concepts developed such as nondiscrimination, proportionality and mutual recognition (Box 2.5) to facilitate the construction of the EU internal market. The build-up of the internal market has had important impacts on health and health systems. Beside the core internal market impact, the EU increasingly also has an important role more generally in shaping economies and providing the basis for fiscal governance. It thereby is at the root of the fiscal governance discussed in Chapter 6.

The internal market built around the four freedoms is not always the basis of law and legislation that has held to health and health systems as its core objective. But it is worth remembering that a great deal of useful policy has been made on internal market treaty bases, often well beyond what is warranted by more apparently relevant treaty articles (Health Technology Assessment, for example, is a health policy on internal market treaty bases, as was environmental or consumer protection policy until 1992). What the second face does, however, is limit the policy instruments to law and regulation with some plausible connection to the market. In other words, the second face is about deregulation at the Member State level and reregulation at the EU level. The EU’s greatest powers are legal and regulatory, and they mostly grow from internal market bases. Hence the importance of the EU’s second face.

5.1 Goods

Health-related products are a major part of the internal market and have become one of the most European of sectors, with highly detailed European requirements
governing them.¹ 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.

5.1.1 Pharmaceuticals

Since 1965² the EU has been steadily harmonizing the rules governing the requirements to allow the sale of medicinal products in the EU, to the extent where this is now one of the most regulated sectors of the European market.³ Initially focused on setting common standards for national licensing bodies, the EU now has different options for licensing pharmaceuticals at either national or European level. The “centralized” 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, and for those containing a new active substance licensed after May 2004 and intended to treat the priority conditions of HIV/AIDS, cancer, neurodegenerative diseases or diabetes. Otherwise, applications can be made to individual national authorities, with an approval granted by one national regulator then being recognized by others as and when applications are made to other countries. The European processes are run by one of the major health-related European agencies, the European Medicines Agency (EMA),⁴ 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).

As discussed above (in Section 3.8), the COVID-19 pandemic exposed systemic weaknesses in Europe’s pharmaceutical supply chains. 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. In recognition of these challenges, the European Commission published a specific Pharmaceuticals Strategy, a Commission Communication which encompassed four pillars of action:⁵

---

¹ “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 3.12 above.
• “ensuring access to affordable medicines for patients, and addressing unmet medical needs (in the areas of antimicrobial resistance and rare diseases, for example);

• “supporting competitiveness, innovation and sustainability of the EU’s pharmaceutical industry and the development of high quality, safe, effective and greener medicines;

• “enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages;

• “ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.”

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). Revisions to existing legislation, including on rare diseases and child health, as well as to the general pharmaceutical legislation, are likely to follow.

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.

---

Everything you always wanted to know about EU health policy but were afraid to ask

The legislation also formally establishes the Medicines and Medical Devices Shortages Steering Group and the Emergency Task Force, working on the above tasks.”

The licensing process for pharmaceuticals is lengthy, with a sequence of three phases of clinical trials required before licensing in order to progressively provide the data necessary about the safety and efficacy of the product for the application to be evaluated. The conduct of clinical trials is itself regulated

---

**Box 5.1  International dimensions of healthcare goods**

Pharmaceutical supply chains are global, which means that detailed regulation of production and logistics is necessary 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 US, as well as a similar agreement with Israel. 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, both of which 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. 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 though, 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 (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.

---


---

at EU level, although this has been controversial, with debate about whether the requirements imposed are too onerous, in particular for non-commercial applicants. Following pressure from patient groups, information about clinical trials is available through a database at the European level.

The lengthy process that is required before authorization creates a different challenge, which is that companies developing new drugs have a period of several years between when they patent their potential products and when they are actually licensed and can be sold. For this reason, pharmaceutical products in the EU can have an extension of up to five years on top of the normal 20-year patent protection period. The EU has also 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 after they are licensed.

So far, the regulatory regime resembles that of the world’s other giant pharmaceutical market, the United States. However, when it comes to the stage of pricing, marketing and availability of pharmaceuticals, the EU looks very different. This is because, unlike the United States, more than half of pharmaceuticals are paid for by public funds, not privately, and 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 pricing models and markets remain fragmented between the Member States. They take quite different approaches and thereby produce the issue of “parallel trade” in pharmaceuticals that exploits inter-country price differentials. The most that the EU has agreed on with regard to pricing is that the different regimes for pricing should at least be transparent in terms of providing information about the decisions they make, and they should do so within a reasonable time. The actual transparency afforded by the Transparency Directive is by now negligible, since undisclosed rebates make published prices uninformative.

---


Although the EU’s powers regarding the process under which medicines may be marketed and sold in the Member States is well established, the situation has been different in procurement. The baseline expectation is that member states organise procurement of medicines. Ever since the 2009 H1N1 (swine flu) outbreak, there has been a voluntary mechanism for Member State cooperation and joint purchasing, with no centralized power. This arrangement falls fully in line with the general division of power between the EU and the Member States, which is that regulation can be done at EU level, but redistribution and purchasing of products and services remains with the Member States, given the link with taxes and national budgets. COVID19 outbreak revealed many problems with the existing voluntary system that slowly had been used and experimented with under Decision 1082/2013 on health threats. The mechanism of the Joint Procurement Agreement based on Article 5 of Decision 1082/2013 was dependent on funding Member States were able to make available for purchasing, which meant it was not in place at the time that purchasing needed to be done at a fast pace. Furthermore, there were no agreements in place for how to block Member States from having separate negotiations with pharmaceutical manufacturers or medical product suppliers. As a response to the COVID19 outbreak the Commission on 16 December 2021 decided to create the new HERA as a DG (3.5.3 above). However, to realize a renewed role for the Commission in the purchasing process of emergency medical countermeasures the Commission proposed in 2021 for the adoption of a new Council regulation that establishes a Health Crisis Board to ensure procurement and purchasing during an emergency. At the time of writing political agreement has been reached regarding this new regulation. The Health Crisis Board is to coordinate the supply and access to medical countermeasures. The Board is there to control the European Commission’s executive powers in case it engages in negotiations with manufacturers regarding the purchase of countermeasures to medical emergencies.


Within this picture of a fragmented market for pharmaceuticals, however, there are some areas of European consensus, the principal one being the horror with which European regulators (in particular in the European Parliament) view the widespread direct marketing of pharmaceuticals to consumers that is allowed in the United States. Such direct-to-consumer advertising for prescription pharmaceuticals remains prohibited in Europe. Articles 86 to 100 of Directive 2001/83/EC on the Community code relating to medicinal products for human use contain the general principles governing the advertising of drugs in the European Union. There is much ongoing debate about how to reconcile this with the recognized value to patients of having access to accurate information about pharmaceuticals and questions about which sources are likeliest to provide such information.20 Efforts to liberalize direct-to-consumer “information” launched in 2008 were withdrawn in 2014 after it became clear that the proposal would not pass.21

The von der Leyen Commission was already looking to intervene more actively in the pharmaceutical market before the COVID-19 pandemic. In her mission letter to the Health Commissioner, President von der Leyen set a priority of ensuring Europe has “the supply of affordable medicines to meet its needs”.22 We discussed the EU’s dramatic responses to the pharmaceuticals issues revealed by the pandemic in Section 3.8, though they will involve internal market treaty bases and actors (e.g. in the efforts to monitor supply chains).

5.1.2 Medical devices

If regulation 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 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.23 While the relevant EU legislation has some requirements for initial scrutiny, these are lighter than for pharmaceutical

---

23 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.
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. As of January 2022, there are 58 such NBs in Europe.24

The requirements for marketing medical devices in the EU vary according to the level of risk that different medical products represent. At the low-risk end (class I devices), manufacturers themselves may simply declare that the products meet relevant standards. At the high-risk end (class III devices), NBs must be involved throughout their design and manufacture.25 However, again unlike pharmaceuticals (and unlike the regulatory regime for medical devices in the United States), 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. In practical terms, this means that higher-risk medical devices tend to be authorized more quickly in the EU than in the United States, where clinical trials are required – but also that patients in Europe may thereby be exposed to medical devices with potentially adverse consequences that are not brought to light by the more limited assessment required.26 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 fulfill their obligations with the need also to continue to receive approvals business from manufacturers. There is also a serious lack of data about how effective the controls are in practice, with a lack of public access to data about product licensing or adverse events.27

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.28 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 US 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

28 Available at: https://www.icij.org/investigations/implant-files/ (accessed 13 January 2022).
(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 has 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.29

In 2017 the EU passed two new laws intended to address the deficiencies in medical devices regulation.30 They were originally intended to be effective in 2020 and 2022, replacing the three previous directives on medical devices, but the COVID-19 pandemic delayed their full implementation. 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.31 Second, the directives also require the creation of a central register of supply chain operators and NBs, as well as the centralization of serious incident reports. Regarding patients, implant recipients 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 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.32 Industry representatives have raised strong concerns that the timetable for adapting to the new regulations is too tight. As of early January 2022, of the 58 NBs in the EU, 24

---


had been approved for NB status under the EU MDR.\(^{33}\) Additionally, there remain five NBs designated under the EU IVDR as of late December 2021.\(^{34}\) Failing to approve enough NBs would result in significant consequences for patient access to medical devices across the EU.

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 FDA, private actors and NBs lobbied against it.\(^{35}\) Taken together, both regulations maintain – and only marginally improve – a dangerous situation, which resulted in the past in poor health outcomes for patients receiving defective implants.\(^{36}\)

The COVID-19 pandemic disrupted the application of the new regulations for medical devices and in vitro diagnostic devices. Regulation 2017/745 (the Medical Devices Regulation, MDR) was due to be applied from 26 May 2020, whilst Regulation 2017/746 (the In Vitro Diagnostic Medical Devices Regulation) 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 personal protective equipment (PPE), 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.\(^{37}\) The Medical Device Regulation (MDR) became applicable in the EU on 26 May 2021.

The COVID-19 crisis significantly increased the demand for vital medical devices, such as ventilators, in vitro diagnostics and personal protective equipment (PPE, some of which, such as surgical masks, are classed as a medical device). Almost all Member States grappled with severe mask shortages throughout the spring of 2020. In France, for instance, there were only 117 million surgical masks available in March 2020, compared to 714 million in 2017.\(^{38}\) Regulatory agencies

---

revised their medical devices directives to address these shortages. The US Food and Drug Administration, for instance, issued an Emergency Use Authorization (EUA) to allow healthcare providers to use or modify critical devices including certain types of ventilators and positive pressure breathing devices.

In March 2020 the European Commission temporarily allowed the commercialization of non-CE marked PPEs intended to protect healthcare professionals through Commission Recommendation (EU) 2020/403. National competent authorities could authorize the commercialization of non-CE marked medical devices for which no alternatives were available. As new economic actors got involved in the supply and verification chain of medical devices, the EU issued a guidance document, “Current performance of COVID-19 test methods and devices and proposed performance criteria”, intended to help manufacturers assess their products before marketing them. As stated above, the In Vitro Diagnostic Medical Devices Regulation was planned to become effective on 26 May 2022. Due to a shortage of NB capacity, the European Commission proposed a progressive roll-out of the IVD Regulation in October 2021 to prevent disruption in the supply of these critical products in the context of the ongoing COVID-19 pandemic. Under the new proposal, higher risk devices such as HIV or hepatitis tests have a transition period until May 2025 and 2026 whilst lower risk products have a transition period until May 2027.

Finally, the pandemic severely disrupted medical devices supply chains and highlighted the European Union's reliance on imports. The European Commission created a “Clearing House for medical equipment (COVID-19)”, which worked closely with EU Member States, manufacturers and other stakeholders to identify available medical devices supplies and match their respective needs. The Clearing House complemented the Commission’s work on joint procurement and stockpiling of medical equipment via RescEU.

5.2 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 to ensure that 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.\textsuperscript{42} 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 under 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.

5.2.1 Health workforce

With 18.6 million workers in 2018, amounting to 8.5\% of the total EU workforce, the health workforce is the largest segment of the European labour market.\textsuperscript{43} Although the health workforce has grown over the last two decades, this growth was more significant for medical doctors and nurses in the “older” EU Member States. The demand for healthcare professionals in Europe will increase significantly in the next decade as the European population ages and as the number of patients with chronic conditions grows. Such demographic changes will impact the European healthcare workforce in several ways. The growing number of elderly patients with chronic pathologies will require new models of healthcare delivery, which involves expanding physician training. It is also likely to exacerbate the shortage of healthcare professionals that most EU Member States are already facing today. Such shortages are 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.

The 2011 EU research project on Health Professionals Mobility and Health Systems (PROMeTHEUS) showed that for 17 European countries – including Denmark, Finland, France, Germany and Romania – there was a chronic undersupply of health professionals in rural and sparsely populated areas, and an oversupply of doctors in urban areas, most notably in Germany. The study also showed an oversupply of nurses in Belgium. The PROMeTHEUS study also focused on healthcare professionals’ intra-European mobility and concluded that there were significant differences in cross-border movements, with an east-west asymmetry for doctors, nurses and dentists. Western and northern EU


countries both experience migration of their healthcare professionals and receive professionals from other countries, while other EU Member States mostly see their clinical workforce shrink due to the departure of their healthcare workers. Given the huge disparities in wealth between Member States, it is unlikely that all Member States can simply pay their healthcare workers well enough to avoid such “brain drain”.

In this context, intra-EU health workforce mobility increased over the last two decades in order to address local shortages and as an expression of multiple and sometimes contradictory professional needs at individual and national levels. The intensification of healthcare professionals’ mobility therefore “happened in a context of growing clinical shortage, geographical mis-distribution of skills and staff, as well as of demand for new clinical competencies”.44 However, variations in curricula development and acquired knowledge and skills remain. In 2012 the European Commission released an “Action Plan for the EU Health Workforce” in order to propose concrete actions in the following areas: forecasting workforce needs and improving workforce planning methodologies, anticipating future skills needs in the health professions, and sharing good practice on effective recruitment and retention strategies for health professionals.45

The Action Plan for the EU Health Workforce was followed by a Joint Action on Workforce Planning and Forecasting (2013–2016), which aimed to advance the issue of healthcare professionals’ intra-Europe mobility. Finally, building on the work of the Joint Action for the health workforce, SEPEN – Support for the health workforce planning and forecasting expert network (2017–2018) – was established to develop expert networking to structure and exchange knowledge, map out national health workforce policies in EU countries, foster the exchange of knowledge and good practices on the health workforce through European workshops, and provide support to EU countries on national implementation of health workforce planning.

Finally, recent revisions to the European legal framework on professional qualifications also helped support these workforce flows. Harmonizing higher education systems has been a priority for the European Union over the last twenty years. 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.\textsuperscript{46} Healthcare qualifications may therefore still vary significantly between countries. A few notable exceptions to this observation include the 2005 Professional Qualification Directive,\textsuperscript{47} which established the rules for temporary mobility and a system of recognition of qualifications for “professions with harmonized minimum training conditions (i.e. nurses, midwives, doctors (general practitioners and specialists), dental practitioners, pharmacists, architects and veterinary surgeons”). Other healthcare workers, including physiotherapists, do not enjoy automatic recognition.\textsuperscript{48}

Free cross-border travel for health workers is essential for many European health systems to ensure the functioning and delivery of services, particularly in times of the pandemic when the health workforce is under enormous pressure. Cross-border travel for health workers is important and well documented for medical doctors. More than 40\% of medical doctors in Ireland and Norway and over 30\% in Switzerland and Sweden are foreign trained. Countries with large health labour markets, like Germany and France, have more than 10\% of foreign trained doctors in their health workforce.\textsuperscript{49} Many of these health workers return frequently to their countries of origin for private reasons. But there are also many health workers who do not reside in the country of employment and case studies have demonstrated that they include daily commuters, health workers travelling for weekend shifts and seasonal health workers.\textsuperscript{50}

The example of a contentious travel ban introduced by German authorities in February 2021 shows that the importance of cross-border travel for health workers was acknowledged.\textsuperscript{51} German authorities, deeply worried about COVID-19 outbreaks across the border and the emergence of variants of concern, introduced


\textsuperscript{47} Directive 2005/36/EC.


in February 2021 a controversial entry ban for travellers of the Austrian region Tyrol and from the Czech Republic. Health workers were still allowed to enter on the same terms as Germans or non-German residents, going through the same testing regime. Retaining free cross-border movement of health workers in a health crisis was part of a travel ban exemption for critical occupations issued through a Communication of the European Commission. Transport workers were also included in the Communication as a critical occupation; their exemption from the travel ban, however, was not respected by the German authorities, which led to sharp criticism from stakeholders, governments and the European Commission.

5.2.2 Social security coordination and the European Health Insurance Card

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. Social security coordination 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 is separate from the issue of “posted workers”, which refers to arrangements for people who are employed by a firm in one Member State and sent to work in another. 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

Box 5.2  International travel restrictions and COVID-19

In early 2020, when the virus arrived in Europe, international travel measures were introduced in an uncoordinated manner. Member States implemented bans for arrivals via air, land and sea. For those travellers allowed into the country, quarantine and testing regimes were introduced. Countries also introduced testing requirements before departure and detailed travel monitoring for return travel. Exemptions for certain types of travel and certain types of travellers were also allowed.\(^a\) These early international travel measures were implemented and lifted by countries at different times, in different combinations and with different stringency. This led to confusion and all too often to disruption of cross-border travel for health workers.

To mitigate the effects of the uncoordinated implementation of international travel measures, the European Commission published as early as 30 March 2020 guidelines concerning the exercise of the free movement of workers during COVID-19 outbreaks.\(^b\) These guidelines dealt with frontier workers, posted workers as well as seasonal workers. They were particularly but not exclusively geared towards health workers, and workers in the pharmaceutical and medical device industries. The guidelines were applicable to both salaried and self-employed workers. With regards to health systems, the list included the following critical occupations:

- Health professionals including paramedical professionals;
- Personal care workers in health services, including care workers for children, persons with disabilities and the elderly;
- Scientists in health-related industries;
- Workers in pharmaceutical and medical devices industry;
- Workers involved in the supply of goods, in particular for the supply chain of medicines, medical supplies, medical devices and personal protective equipment, including in their installation and maintenance.

The guideline urged Member States to establish specific burden-free and fast procedures for border crossings with a regular flow of frontier and posted workers, to ensure a smooth passage for them. It was also stipulated that health screening for frontier and posted workers must be carried out under the same conditions as for nationals.

The guidelines also addressed the proportionality of implementing international travel measures vis-à-vis this group of critical occupations. But Member States at this time did not share a common system of risk-assessment of cross-border travel, leaving proportionality consideration to individual country judgement. This common system of risk-assessment was established later, when the European Union stepped up coordination efforts for international travel measures. The Council of the European Union adopted in October 2020 a recommendation on a coordinated approach to the restrictions on free movement\(^c\) in response to the COVID-19 pandemic which was updated\(^d\) in January 2021 and expanded by adding a common framework.

\(^a\) Addo J, Lindmark S, Schmidt T, Enderlein U & Perehinets I (2021). What travel policies have allowed or restricted
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.

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.\textsuperscript{56} An EHIC is the tangible and portable manifestation of the two following European rights that the (limited) data on it helps 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 an economic growth strategy for the sunny parts of Spain where they congregate. It is administered by DG Employment, Social Affairs and Inclusion. 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 this stands. 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”.\textsuperscript{57} Modernized 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). A model built around single male guest workers was modernized for the 21st-century European economy.

The 2016 Commission Work Package responded to pressure from, in particular, the UK to reduce the benefits available to EU citizens in other countries with


a further legislative proposal.\textsuperscript{58} It reflected a British political reaction to the large inflow of EU Member State citizens since 2004 and a perception, often exaggerated by the UK media, that immigrants from the rest of the EU were attracted by the UK benefit system and were exploiting it. In the run-up to the Brexit referendum, when the EU was trying to adopt policies that would respond to British preferences, the solution was a proposal for a new Regulation focused on fighting fraud, by enabling better information exchange (by establishing a “further permissive legal basis”\textsuperscript{59}), and on tying the location of work more closely to the location in which benefits were paid. The UK was the principal EU Member State in which intra-EU immigration, or the perception of unfair advantages to immigrants from other EU Member States, was a difficult political issue. This was in large part because the UK and Sweden were the only Member States that opened their labour markets to citizens of the CEE accession states in 2004, and therefore saw the largest number of arrivals. Predictably, some other Member States were happy to let the UK draw fire for pressing a restrictionist case they supported. While those tensions around intra-EU migration were present in other Member States, it is unlikely that this issue will retain such prominence after Brexit.\textsuperscript{60} The health effect of the change should lie in two areas: in limiting the number of people in certain categories (e.g. short-term residence) who can claim social security benefits, and in incorporating long-term care into social security coordination.

One point worth underlining in the discussion of social security health mobility is that it is \textit{far more important to patients and health systems than patient mobility under internal market law}. The integrating dynamics of the EU mean that while internal market law, discussed in Section 5.3.1, 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, 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 \textit{Kohll} and \textit{Decker} decisions, and which provisionally ended with the Directive on patient rights in cross-border healthcare, was about whether healthcare was a service under normal EU law, and thus whether some of that potential control

\begin{itemize}
\end{itemize}
would be wrested away from national authorities. It was not primarily about the patients. 61 It was about who would make health law in Europe, and to what end.

5.2.3 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, in particular, triggered talk of a migration “crisis” 62 Unsurprisingly (but not predictably), perceptions of crisis led to both increasing Europeanisation, new tensions, and new actors in the migration policy area. 63 There were some very disparate political responses within different EU Member 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. Their alleged risk of contracting or spreading communicable diseases, it was felt, required a response. Even if this in the first place was the responsibility of reception countries, the visibility and geographic localization 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 7.2.4, the EU also gave significant aid to countries on its borders, especially Turkey, 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

---


62 It is worth noting that, compared to either the numbers of migrants in states in the European neighbourhood today, or to the numbers of migrants at various times in 20th-century European history, the numbers of migrants are not large.

European “essential workforce” in 2020. They were overrepresented 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, mobile plants and food processing operators. A report published by the European Commission Joint Research Centre highlighted some of the difficulties encountered by migrant workers in the European Union 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. In Spain, for example, unemployment within the migrant population rose to almost 25% by early September 2020.

Healthwise, migrants had limited access to healthcare services, sick pay, unemployment or social benefits and linguistically relevant health information about infection prevention measures. As a result, migrant workers made up one of the groups most at risk of contracting COVID-19. This was especially the case if their migration status was undocumented or they worked in the informal economy, but administrative burdens could also prevent their easily accessing benefits due to them. They were also more likely to be exposed to the virus because they tend to live in more densely populated areas, work in crowded conditions or in more direct contact with potentially sick individuals in healthcare facilities or elderly homes. These professions are not “teleworkable” and expose them to a higher risk of contagion than the rest of the population. Widespread contagions occurred, for instance, in meat-processing plants in Germany which primarily employ migrant workers. COVID-related mortality and infection rates for immigrants ended up exceeding those of the native-born population in several EU Member States. In France, for instance, a study reported that individuals born in Africa or Asia and living in the Paris metropolitan area were twice as

---

66 Ibid.
likely to die from COVID-19 than their French-born counterparts during the first wave of the pandemic (spring 2020).  

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 (France). Others sought to protect the status of their migrant workforce. In Slovakia the government extended residence permits and temporarily relaxed some employment conditions for migrant workers. Portuguese authorities granted temporary residence permits to migrants who had pending applications for residence permits when the state of emergency was issued in the spring of 2020. The Spanish government extended residency permits for young migrant agricultural workers to make up for a seasonal migrant agricultural workers shortage induced by pandemic restrictions. Spain also suspended several administrative deadlines related to residence and work permits. In Italy, where the agricultural sector is also highly dependent on migrant labour, the government approved pathways for the regularization of status for agricultural and domestic care workers.

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, there were about 14 000 foreign-trained physicians waiting to get their medical credentials recognized when the pandemic broke out. Several German Länder, 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 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 the European Commission released the “New Pact on Migration and Asylum”, proposing to overhaul the European Union’s long ailing policies in this area.76 The Russian invasion of Ukraine in February 2022 led many Ukrainians to flee, with as many as four million entering the EU by mid-April. EU and Member State responses were mostly quite unlike their responses to refugees in 2015-16. In March 2022, the 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 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 has been no organized effort to send refugees to different Member States. The situation is quickly developing at the time of writing in mid-April, but the EU has deployed resources and created legal flexibility to support Ukrainian refugees. It is possible that the experience of Ukrainian refugees will influence the direction of the rapidly developing EU approach to refugees and borders.

5.3 Services

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 5.3.6), but it was as a service across borders that the Court 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.

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).
5.3.1 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 5.2.2, 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).77

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.78 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 Patients’ Rights in Cross-Border Healthcare in 2011.79 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 5.1.

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,80 at around 200 000 per year (though slowly rising), 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.

78 European Court of Justice. Cases C-158/96 Kohll, C-120/95 Decker.
However, the Directive has had larger impacts in other ways. One way has been through domestic measures taken in response to the Directive that have a potential impact 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. 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. The private sector is a very complex sector with high levels of variation between countries, and one effect of the debate 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,

Table 5.1  
**Comparison between cross-border healthcare rules under the Regulation on Coordination of Social Security and the Directive on Patients’ Rights in Cross-Border Healthcare**

<table>
<thead>
<tr>
<th></th>
<th>Regulation on Coordination of Social Security</th>
<th>Directive on Patients’ Rights in Cross-Border Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior authorization</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>Tariffs</td>
<td>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)</td>
<td>The State where the person is covered (up to the level of actual cost)</td>
</tr>
<tr>
<td>Payment method</td>
<td>Publicly funded element settled between national ministries/insurers</td>
<td>Paid by the patient with subsequent reimbursement by the State where they are covered (unless the State makes direct arrangements to pay)</td>
</tr>
<tr>
<td>Provider</td>
<td>Only providers affiliated with the State of treatment social security system</td>
<td>All providers who legally provide healthcare in the State of treatment</td>
</tr>
<tr>
<td>Travel and accommodation costs</td>
<td>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</td>
<td>Covered to the same extent as they would be domestically – although by virtue of being travelling abroad and thus different, what this means in practice is unclear</td>
</tr>
</tbody>
</table>


However, the Directive has had larger impacts in other ways. One way has been through domestic measures taken in response to the Directive that have a potential impact 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. 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. The private sector is a very complex sector with high levels of variation between countries, and one effect of the debate 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 below).

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.\(^{82}\) There is still a risk of that in healthcare.\(^{83}\) Another is to enhance patients’ rights – which makes little sense given that we are still discussing people who choose to seek non-emergency treatment abroad, pay out of pocket and then seek reimbursement. That is a very small and very specific segment of European society.

A third is to try to improve European healthcare policy by adding dimensions of healthcare improvement to the Directive. That certainly happened. 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 (discussed in more detail above) and European Reference Networks, despite the reticence of some Member States in both cases. These measures are the subject of Sections 5.3.2–5.

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.\(^{84}\) The guidelines outlined


key elements of cross-border care, such as emergency transport of patients, reimbursement of the 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 Länder offered intensive care beds and hospital treatment to French and Italian patients in the spring of 2020, but these practices were not generalized.

5.3.2 European Reference Networks

Under the chapter on cooperation in healthcare within Directive 2011/24/EU, 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.

In a Delegated Decision, the Commission further specified the legal criteria and conditions that ERNs and participating healthcare providers must fulfil.85 Simultaneously, in an implementing Decision, it detailed the criteria for establishing and evaluating ERNs and their members and for facilitating exchange of information and expertise on establishing and evaluating such networks.86 In this voluntary process, a strong role was attributed to the Member States. The 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.

Following the first call for proposals in July 2016, 24 thematic ERNs were approved in December 2016, each one focused around a specific disease area such as bone disorders, haematological diseases, childhood cancer and immuno-deficiency. At their inception in March 2017 the networks comprised more than 900 highly specialized healthcare units located in 313 hospitals in 25 Member States (plus Norway).


86 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.
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 (Health Programme, Connecting Europe Facility and Horizon 2020) are financially supporting 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 provides 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.

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. A first evaluation of the ERN initiative was announced in 2020 but has not appeared. Researchers have noted challenges ranging from Brexit (and the loss of UK participants) to organizational issues, as well as achievements.

5.3.3 The information society and e-health

The concept of e-health can be defined as “the application of information and communications technologies (ICT) across the whole range of functions that affect health”. Increasingly, this concept is being broadened to talk about “digitalization”, which expands the concept of e-health to also 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). Health systems are a sector with enormous potential for improving quality and productivity through application of these 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.90 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.91 The equivalent for healthcare is the concept of “interoperability”: the idea that individual e-health systems may be different but can still exchange information in a way that can be understood by both.92 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.

The Directive on Patients’ Rights in Cross-Border Healthcare provides a legal basis for establishing a network on e-health in order to address such practical issues, focusing in particular on cross-border aspects (such as summary records for cross-border care, identification and secure sharing of information), as well as the vital strategic issue of methods for using e-health to enable use of medical information for public health and research – potentially an answer to address the delays that currently plague health data. The European Commission also finances a wide range of projects developing and piloting e-health technologies and applications, for example in support of the European Innovation Partnership on Active and Healthy Ageing.93 E-health is presented as a way to address the shortage of health professionals in the European Union, to ensure better care of ageing populations and chronic diseases putting pressure on health budgets, as well as to remedy unequal quality and access to healthcare services in Europe.

Reflecting the greater shift towards digitalization, in April 2018 the Commission released a Communication on enabling the digital transformation on health and care in the Digital Single Market,94 in which it set out its intention to take action in three areas: “citizens’ secure access to and sharing of health data across borders; better data to advance research, disease prevention and personalized health and care; digital tools for citizen empowerment and person-centred care”.

---

5.3.4 European prescriptions and the eHealth Digital Service Infrastructure (eHDSI)

Although planned cross-border healthcare is relatively rare, a much more frequent issue is people travelling abroad who, for some reason, need to have a prescription dispensed – perhaps because they have a chronic condition that requires frequent medication. Yet despite the strongly harmonized European system for licensing pharmaceuticals, such recognition of prescriptions has been historically tricky as it raises a host of practical issues, such as prescriptions written in other languages, or how a pharmacist can be sure of the validity of the prescription or the authority of the doctor to issue it.

This was another issue where the Commission took the opportunity of the Directive on Patients’ Rights in Cross-Border Healthcare to make provision for improving European cooperation, through putting in place measures to address such practical database issues (such as by stipulating information to be included on prescriptions that would allow a pharmacist to identify doctors and if necessary contact them).95

Directive 2011/24 aims to ensure continuity of care for EU citizens across borders. The Directive allows Member States to exchange health data in a secure and interoperable way. As a result, several services are currently being introduced in all Member States. First, an ePrescription and an e-Dispensation allow any EU citizen to retrieve their medicines from a pharmacy located in another Member State. This is made possible through the electronic transfer of the prescription from the

---

country of residence to the country of travel. Second, Patient Summaries provide background information on important medical aspects, including allergies, current medication, previous illness, surgeries, etc. This information is digitally accessible in the event of a medical (emergency) visit in another country. The Commission adopted, in 2019, a Recommendation on the European Electronic Health Record Exchange Format. Both services were implemented through the eHealth Digital Service Infrastructure, which connects the eHealth national services, allowing them to exchange health data. Such infrastructure is funded by the Commission’s Connecting Europe Facility.

Since 21 January 2019, for instance, Finnish patients are able to go to any pharmacy in Estonia and retrieve medicines prescribed electronically by their doctor in Finland. The initiative applies to all ePrescriptions prescribed in Finland and to the Estonian pharmacies that have signed the agreement. Patients do not have to provide a written prescription: ePrescriptions are visible electronically to participating pharmacists in the receiving country via the new eHealth Digital Service Infrastructure. As of January 2019, 22 Member States are part of the eHealth Digital Service Infrastructure and are expected to exchange ePrescriptions and Patient Summaries by the end of 2021. By 2025 both services will be gradually implemented in 25 countries. In 2018 the Court of Auditors was very critical of the management of this project, which drew on funds from a variety of EU sources; the information exchange between Finland and Estonia was years late, far more limited than originally planned – and hardly EU-wide.

5.3.5 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.99

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 2009.100 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 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 workers in patient safety.101 In a second report published in 2014,102 the Commission reported that although the 2009 Recommendation raised awareness at the political level and triggered changes, it did not necessarily promote a patient safety culture at the healthcare setting level.

5.3.6 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

---

The EU market shaping health

Pharmacists were involved in containment and mitigation efforts during the COVID-19 crisis. In most European countries their role has been 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 the Czech Republic, Finland, France, Germany, Poland), renew chronic treatment prescriptions (France), set up remote consultations with patients to ensure continuity of pharmaceutical care (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 (France, Netherlands), and, to a lesser extent, administer the COVID-19 vaccine (France, Ireland, Switzerland, United Kingdom). Court cases brought against regulations on pharmacy had often been based on the claim that their regulatory structure was protective and anticompetitive in some way, and pharmacy policy was defended on the basis that they were an important part of local healthcare infrastructure. The COVID-19 experience might lead to reconsideration in this debate.


5.4 Competition, state aids 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 aids. This is likely to be very relevant for the health sector, with a predominance of public funding and the presence of a variety of actors with variable degrees of scale, autonomy and business orientation.\(^{106}\)

Whereas the rules on competition are specified directly in the TFEU,\(^ {107}\) the question as to whether and how competition rules apply to health systems remains a source of uncertainty.\(^ {108}\) First, it depends upon 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.\(^ {109}\) From this case law, it appears that it is not the legal status but rather the nature of the activity that is determinant.\(^ {110}\) Even non-profit-making institutions are considered undertakings if they are engaged in activities of an economic nature.\(^ {111}\) However, institutions entrusted with the administration of mandatory schemes of social security, which are based on solidarity and serve an exclusively social function, were excluded from the application of EU competition law as the activities they performed were considered non-economic.\(^ {112}\)

Even if competition rules apply in principle, which seems to be likely for the actual provision of healthcare, the specificity and non-commercial motivations


\(^{107}\) TFEU, Chapter 1 of Title VII, Articles 101–9.


\(^{111}\) European Court of Justice. Cases C-41/90 Höfner and Eber, C-475/99 Ambulanz Glöckner, C-67/96 Albany, C-180/98–C-184/98 Pavlov.

\(^{112}\) European Court of Justice. Cases C-159/91 and C-160/91 Poucet-Pistre, Garcia, Cisal, FENIN, AOK.
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). 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.

Later, 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. While a derogation needs to be interpreted strictly and with due respect to proportionality, the new legal base of Article 14 of the 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 achieving their mission. In a Protocol attached to the TFEU the concept and role of SGEIs, as well as their underpinning principles and values, are further elaborated, 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.

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, 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

---

113 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. One of the problems with the concept is that it therefore generates misunderstanding 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.

114 TFEU, Article 106(2).


services were excluded from the Services Directive,\(^{118}\) they were also excluded from the scope of this Communication in 2006,\(^ {119}\) the claim being that they would be covered in the upcoming Directive on Patient 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 particular area that has attracted attention in the health sector is “state aid”. State aids refer to assistance from public bodies to private undertakings, for example subsidies. 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\(^ {120}\)), which is also known as the Monti–Kroes package,\(^ {121}\) 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,\(^ {122}\) 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.\(^ {123}\) 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


\(^{120}\) European Court of Justice. Case C-280/00 Altmark.


\(^{122}\) European Court of Justice. Cases C-280/00 Altmark, C-53/00 Ferring.

and other care organizations. 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. 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.

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. 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 for the reason that 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.

### 5.4.1 Public and private partnerships

The EU position with regard to public and private partnerships (PPPs) 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. 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.

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 Memorandum.\(^\text{128}\) The Memorandum 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 actually 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.”

This puts the focus on the bigger issue with PPPs: not whether the EU is using them in its programmes for financing action but rather whether the EU is failing to strike 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,\(^\text{129}\) followed by a consultation and a 2005 Communication.\(^\text{130}\) In the Communication the Commission concluded that further legislation would probably introduce new complexity and that the implementation of public procurement law need not present difficulties to public or private sector participants. In particular, the procedure of “competitive dialogue” 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).\(^\text{131}\)


In practice, making use of PPPs is risky and requires considerable expertise.\textsuperscript{132} This is one of the key issues highlighted by national representatives themselves in the “toolbox” on the use of the structural funds for health (Section 6.2.4).\textsuperscript{133} It remains to be seen whether Member States (separately or working together) can build up greater expertise in using PPPs for health investing in the light of increasing pressure on public budgets. There is also the question of how far liabilities built up through PPP projects do or should count as public debt; in the United Kingdom, for example, which has made extensive use of PPPs in sectors including health over recent decades, these additional liabilities have been estimated at £33 billion, and concern has been expressed that financing is being sought through the PPP route even where this does not represent best value for money in order to keep the resulting liabilities from counting as public debt.\textsuperscript{134}

Concern about the promotion of PPPs by the Commission and within EU funds has re-arisen in the aftermath of the 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.\textsuperscript{135}

5.5 Health technology assessment

Health technology assessment (HTA) is the activity of assessing the effectiveness of medical procedures and technologies. It normally does this by comparing treatments in light of therapeutic effectiveness, side-effects, administration and impact on the patient’s quality of life. In the famous UK case of NICE, the National Institute for Health and Clinical Excellence, it also involves price,
determining whether a given intervention at a given price is justified.\textsuperscript{136} Most other HTA agencies focus on value for money, comparing the other dimensions of a treatment’s effectiveness (e.g., assessing whether a new treatment’s method of administration or therapeutic effectiveness is superior to the existing treatments and leaving it to some other part of the health system to decide whether it is included in the basket of covered services and at what price).

While there is no imperative to pursue European HTA action,\textsuperscript{137} there is a case for European coordination and resource pooling in the area of HTA: it is often expensive, requires a range of diverse skills and has a high price of entry, there is an endless supply of medical treatments and technologies that could benefit from HTA, and the EU can seek added value by reducing duplication through better coordination of Member State initiatives. It can also thereby overcome the collective action failure we currently see, in which not all Member States invest in HTA,\textsuperscript{138} which means the developing international HTA literature does not reflect their needs and priorities while also putting more of the burden on a smaller number of Member States which are investing primarily for their own reasons. On the other hand, HTA is not an obvious political winner. It has upfront costs, diffuse and uncertain benefits, and can incur instant opposition from industry, mobilized patients and providers,\textsuperscript{139} which explains why its diffusion is not as rapid or extensive as it promises to rationalize health technology and care might lead one to expect.\textsuperscript{140}

The EU has been involved in HTA for almost as long as there has been such a field: the \textit{International Journal of Technology Assessment} dates to 1985 and the European “Methodology of Economic Appraisal of Health Technology” to 1986.\textsuperscript{141} EU-funded programmes have 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 diffusing assessments to facilitating its members in conducting joint assessments on technologies. It also has a collaboration with EMA and a joint work plan focused on connecting market authorization with HTA. The Directive on Patients’ Rights in Cross-Border Healthcare created a Health Technology Assessment Network (HTA Network) of Member States, which has been meeting since 2013 and is in principle supported for scientific purposes by EUnetHTA. It is a “formalistic grouping of officials from Member States’ health ministries, rather than a collaboration of HTA experts”.

So far we can view this as a classic case of how European integration develops: by gradually creating a European constituency that sees value added, collectively and individually, in pooling their efforts via EU-level mechanisms, in the same way that communicable disease control or medicines regulation was gradually Europeanized. Predictably enough, after some soundings with Parliament and Council, the next step was a Commission proposal for legislation to institutionalize HTA at the European Union level. The instrument chosen by the Commission surprised some observers: a Regulation that would create a formal structure of collaboration between Member States overseen by an EU-level committee. There would be “joint clinical assessments”, classic HTA work, as well as more forward-looking “joint scientific consultations” on developing technologies and “horizon-scanning” reports on “emerging health technologies”. The Commission would be the secretariat for this structure, providing scientific (advice and stakeholder management) as well as administrative support. In contrast to much of the HTA work at the Member State level, the EU HTA system is focused on medicines, and the pharmaceutical industry was heavily involved in promoting the idea and moving it onto the actual legislative agenda.

The Commission proposal was published in January 2018. By the end of the Juncker Commission it was the only health dossier of consequence still open, despite the support of the 2019 Romanian and Finnish presidencies. The key obstacle was a variety of Member States that objected on grounds including subsidiarity. The response of the Romanian and Finnish presidencies was to lead the redrafting of large parts of the proposal, emphasizing its technical nature and non-duplication of Member State efforts. COVID-19 naturally pushed it off the

---

142 Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare.
agenda for much of 2020, but in 2021 the Parliament and Council negotiated a finished version and it was passed on 13 December 2021.145

The new Regulation creates a coordination group made up of representatives of Member States’ HTA organizations. They will lead four areas: joint clinical assessments; joint scientific consultations; identification of emerging health technologies; and voluntary cooperation. Joint clinical assessments will pool resources for major new technologies. 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.

5.6 Conclusion

The internal market is, over time, the most demonstrably important face of the EU. It undergirds the wide variety of important policies we have discussed here. But to dismiss the EU as a simple market-making machine is a mistake. Rather, note the wide variety of policies that are made 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 aids law. If we widen the perspective still further, we note that many broader policies affecting health were for a long time made as part of the single market, 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 nondiscrimination – 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 second face of EU health policy smiles on valuable health policies and objectives?

Chapter 6

Fiscal governance of 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. “Fiscal governance” 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. 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 system, reflecting the priorities and concerns of the COVID-19 period (see Box 6.3 below). This is the third face of European Union health policy: the impact of fiscal governance on health systems and policies. It has evolved over three broad stages: the creation of the Stability and Growth Pact at Maastricht, the strengthening of the framework after the debt crisis and economic recession

---


2 It is worth noting that the General Escape Clause had already been triggered before the 2020 CSRs, which is an important context for understanding the priority given to health.
of 2010/11, 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 face of health policy.

6.1 How “fiscal governance” came to exist and matter to health

Fiscal governance in the EU is intimately associated with the project of monetary union that created the Euro. Consequently, the template for fiscal governance that came to apply to health after 2010 was developed over decades by policymakers whose concerns were far from those of health systems and health policy-makers. Rather, their objective was to make similar a set of dissimilar economies, 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, however, the EU has no such redistributive role and there is little public support for its development – though in the face of 2020’s crises, the EU took steps in that direction. It can make use of its structural funds to equalize between governments, as a federation might. However, whilst 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. 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 Stability and Growth Pact (SGP), which linked them to a 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

---

3 The history of the experiments and developments that brought the initial fiscal governance framework into being is described in detail in the previous 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.

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. 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. “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. Though subsequent analyses would find little support for it, the explanation that dominated among EU elites 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.

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 Troika – the European Commission, the European Central Bank and the International Monetary Fund – agreeing to programmes of structural reform in return for financial assistance. 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 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 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 has informed the response to the pandemic, which has 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, and the inherent biases which led the fiscal governance system to prioritize economic over social objectives. 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.  

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; the previous editions of this book provide a more detailed analysis of the legal arrangements, and readers are encouraged to consult them.  

The relationship between the pillars is one of reinforcement. The Six Pack and Two Pack strengthen the SGP considerably, whilst 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. The EuroPlus Pact is a soft law commitment to closer coordination of economic policy and tighter surveillance at the EU

---


13 In addition to the Eurozone countries, the Pact includes six non-Eurozone countries: Bulgaria, Denmark, Latvia, Lithuania, Poland and Romania.
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

Table 6.1 The legal pillars of the fiscal governance framework

<table>
<thead>
<tr>
<th>The Stability and Growth Pact</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The Six Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Six Pack(^a) entered into force in December 2011. Importantly, it codifies the European Semester (see below) 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The Treaty on Stability, Coordination and Governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorporating the Fiscal Compact Treaty, the TSCG was finalized in January 2012.(^b) Consequently, 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 euro area countries.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The Two Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adopted in March 2013, the Two Pack(^d) is a pair of regulations, applicable to euro area Member States only, which contributes to the further strengthening of budgetary surveillance. The regulations provide for a separate European Semester for euro area states, with enhanced monitoring and assessment of draft budgetary plans and greater surveillance of Member States experiencing or threatened by financial difficulty.</td>
</tr>
</tbody>
</table>

---


\(^b\) 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 UK has left the EU.


\(^d\) 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 euro area, Regulation 472/2013 on the strengthening of economic and budgetary surveillance of Member States in the euro area experiencing or threatened with serious difficulties with respect to their financial stability. Luxembourg: Publications Office of the European Union.

### 6.2.2 The preventive arms of fiscal governance


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 MTO was supplemented with an expenditure benchmark, to ensure that shorter-term spending does not move a country away from progress towards its MTO.\footnote{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/stability-and-convergence-programmes_en (accessed 6 June 2021).} The TSCG required signatory Member States to transpose their MTO in national law, and committed them 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 euro area Member States against the economic governance rules.\footnote{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).}

DBPs are submitted in October and the Commission issues an opinion for each country, as well as for the euro area 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 Imbalances Procedure (MIP). 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 (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 Section 6.2.3 below).

6.2.3 The corrective arms of fiscal governance

The SGP’s corrective arm is established by Article 126 of the TFEU and centres around the Excessive Deficit Procedure (EDP). The EDP is designed to ensure that 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).

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.

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 below.

6.3.1 Cohesion Policy Funds

The ESIF is 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. As discussed above, the ESIF are the closest thing to the kind of redistributive fiscal tool needed for promoting cohesion and supporting the EMU, that the EU possesses. As more (and often poorer) Member States have joined the Union, so the budget of the ESIF has increased (Figure 6.1). The scale of ESIF funding should be kept in perspective; they represent a small portion of total EU wealth. However, the ESIF compare well to other health funds, 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 ESIF 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 **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 **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. A pre-accession assistance instrument provides funding and support for (potential) 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 program 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 ESIF are linked to the fiscal governance framework and can be leveraged by the EU. In principle, Member States that violate the fiscal rules will have their access to funds reduced; in practice, this has not been the case. For 2021–2027 the link also operates in the reverse direction, with the Semester priorities shaping the allocation and content of the ESIF. The allocation of ERDF and CF for each region will depend upon 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.

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, since 2010, Member States have been encouraged to make use of the ESIF to fund health-related projects and, more broadly, there has been greater recognition of the potential economic contribution of health. 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 promotes the use of ESIF as a powerful instrument for health investment and offers guidance on designing health system reforms.\(^\text{25}\) Specifically, the document advises that Member States can 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;
- 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, though 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.\(^\text{26}\) 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.\(^\text{27}\) The largest numbers of health-related projects were found in Poland, Spain, Germany, Bulgaria and Italy, and the majority of projects supported healthy ageing, 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 ESIF 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 ESIF for health investment, and in what specific areas, remains to be seen.

A major success of the ESIF has been its 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 Though 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 investments that target reducing health inequities, for instance, where outcomes are long-term and tangible “return on investment” is harder to demonstrate.30

A further challenge for the ESIF 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 ESIF. 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 will vote within one month (or three in exceptional circumstances), by qualified majority, on the proposal and appropriate measures will be adopted within nine months. The ESIF are a particular target of the regulation because of their scale but also because two of the largest ESIF 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 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

29 Ibid., p. 74.
EU’s political economy. Though 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. 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-Private Partnerships (see Section 5.4.1).

The EIB funds a wide range of health projects, including hospitals and infrastructure investments, medical research, education and training, health informatics and information, and healthcare networks. As of mid-2021, the bank was funding 82 health-related projects within the EU and since 2000 it has lent approximately €35 billion in support of health projects (the average lending is around €1.4 billion per year for 20 projects). 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.

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, though 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. It was nonetheless renewed and expanded for 2021–2027, with 13 other small funding programmes folded in, in the InvestEU programme. InvestEU aims to mobilize €372 billion and is a core part of the COVID-19 recovery measures.

---

37 Ibid., pp. 3–5.
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.\(^4\) 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 the public interest.\(^1\) Over the last decade it has greatly increased its financing of climate-related projects, and over the period of the pandemic it has 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 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. Though 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 UN’s 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 euro area 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, 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.

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. These programmes must take account of the ASGS, the AMR, the euro area 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). Drawing on the ASGS, NRPs, SCPs, in-depth reviews triggered by the AMR, and various other reports and analysis, the Commission drafts a CSR for each Member State, describing the measures which should be taken to ensure healthy public finances. 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. The 2021 Semester cycle looked different, having been adapted to accommodate the RRF (see Section 6.5.2). The 2022 ASGS was published in November 2021, “resuming” the Semester’s focus on broad economic and employment policy coordination, whilst institutionalizing some of the changes made in 2021. It emphasizes the minimization of obligations on Member States and constant dialogue as well as increased engagement by social partners and other EU institutions.

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 UK in 2018). The Semester framework also enables the EU to link these recommendations to other policies and disbursements, such as the ESIF, and provides valuable data.

42 Stability Programmes are submitted by euro area states; Convergence Programmes are submitted by non-euro area states.
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 ESIF 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.45

6.4.2 Ten years of health in 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 this against coarse measures of life expectancy and infant mortality, and advising on health system reforms without close involvement of health actors. By 2020 a significant shift had occurred. More nuanced data, more inclusive policy discussion and a broader set of goals have led to more refined policy recommendations on health.

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 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. 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 of health and healthcare, 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.

Table 6.2 gives a snapshot of how the content of the health-related CSRs changed over this period. It lists the formal recommendations as agreed by the Council in 2011, 2014 and 2019. In most cases a country with a recommendation has a paragraph-long discussion in the text summarizing some key healthcare issues and challenges (some of which is quoted in the box). 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 sustainability.

What is most striking about the European Semester, from a health perspective, 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 pillar 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 around and analysis of the Semester.

---


Table 6.2  *Country Specific Recommendations with reference to health: 2011, 2014, 2019*

*Note: Where there is substantial text discussion of the healthcare system but no health-related recommendations, some of the text is excerpted.*

<table>
<thead>
<tr>
<th>Country</th>
<th>2011 CSRs</th>
<th>2014 CSRs</th>
<th>2019 CSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Take further steps to strengthen the national budgetary framework by aligning responsibilities across the federal, regional and local levels of government, in particular by implementing concrete reforms aimed at improving the organization, financing and efficiency of healthcare and education.</td>
<td>Further improve the cost-effectiveness and sustainability of healthcare and long-term care services.</td>
<td>Ensure the sustainability of the health, long-term care and pension systems, including by adjusting the statutory retirement age in view of expected gains in life expectancy.</td>
</tr>
<tr>
<td>Belgium</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>No recommendation but in preamble &quot;the pension reform decided in 2010 is not linked to life expectancy or to the situation of the health and long-term care system&quot;.</td>
<td>Ensure cost-effective provision of healthcare including by improving the pricing of healthcare services while linking hospitals’ financing to outcomes, accelerating the optimization of the hospital network and developing outpatient care.</td>
<td>Improve access to health services, including by reducing out-of-pocket payments and addressing shortages of health professionals.</td>
</tr>
<tr>
<td>Croatia</td>
<td>No recommendations.</td>
<td>Strengthen the cost-effectiveness of the healthcare sector, including hospitals.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Improve the long-term sustainability of public finances by implementing reform measures to control pension and healthcare expenditure in order to curb the projected increase in age-related expenditure [...] For healthcare, take further steps to accelerate implementation of the national health insurance system.</td>
<td>N/A (countries with Economic Adjustment Programmes do not receive CSRs)</td>
<td>Take measures to ensure that the National Health System becomes operational in 2020, as planned, while preserving its long-term sustainability.</td>
</tr>
</tbody>
</table>
Table 6.2  Country Specific Recommendations with reference to health: 2011, 2014, 2019 [continued]

<table>
<thead>
<tr>
<th>Country</th>
<th>2011 CSRs</th>
<th>2014 CSRs</th>
<th>2019 CSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>No recommendations.</td>
<td>“Improve tax compliance with a particular focus on VAT and reduce the costs of collecting and paying taxes by simplifying the tax system and harmonizing the tax bases for personal income tax and social and health contributions. Take measures to improve significantly the cost-effectiveness and governance of the healthcare sector, in particular for hospital care.”</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Denmark</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Estonia</td>
<td>No recommendations.</td>
<td>No recommendations. (Noted in text: “Further efforts are necessary to address growing workforce shortages, including those caused by ageing and health and disability-related exits from the labour market.”)</td>
<td>No recommendations. (Noted in text: “Challenges point to the need to deliver affordable and good quality social and healthcare services in an integrated way and to develop a comprehensive long-term care framework.”)</td>
</tr>
<tr>
<td>Finland</td>
<td>No recommendations.</td>
<td>Ensure effective implementation of the ongoing administrative reforms concerning municipal structure and social and healthcare services, in order to increase cost-effectiveness in the provision of public services.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>France</td>
<td>No recommendations.</td>
<td>“[…] social security spending from 2015 as planned, by setting more ambitious annual healthcare spending targets … Beyond the need for short-term savings, take steps to tackle the increase in public expenditure on health projected over the medium and long term, including in the area of pharmaceutical spending …”</td>
<td>No recommendations. (Noted in text: the overall fiscal targeting’s “success will depend on meeting planned expenditure targets defined for the central and local governments and for the healthcare system.”)</td>
</tr>
</tbody>
</table>
### Table 6.2  

<table>
<thead>
<tr>
<th>Country</th>
<th>2011 CSRs</th>
<th>2014 CSRs</th>
<th>2019 CSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>Maintain a growth-friendly consolidation course, in particular by safeguarding adequate expenditure on education and by further enhancing the efficiency of public spending on healthcare and long-term care.</td>
<td>Make additional efforts to increase the cost-effectiveness of public spending on healthcare and long-term care.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Greece</td>
<td>N/A (countries with Economic Adjustment Programmes do not receive CSRs)</td>
<td>N/A (countries with Economic Adjustment Programmes do not receive CSRs)</td>
<td>Focus investment-related economic policy on sustainable transport and logistics, environmental protection [...] health, and the renewal of urban areas, taking into account regional disparities and the need to ensure social inclusion.</td>
</tr>
<tr>
<td>Hungary</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>Improve health outcomes by supporting preventive health measures and strengthening primary healthcare.</td>
</tr>
<tr>
<td>Ireland</td>
<td>No recommendations.</td>
<td>Advance the reform of the healthcare sector initiated under the Future Health strategic framework to increase cost-effectiveness. Pursue additional measures to reduce pharmaceutical spending, including through more frequent price realignment exercises for patented medicines, increased generic penetration and improved prescribing practices. Reform the financial management systems of the national health authority to streamline systems across all providers and to support better claims management. Roll out individual health identifiers starting by the end of the first quarter of 2015 at the latest.</td>
<td>Address the expected increase in age-related expenditure by making the healthcare system more cost-effective and by fully implementing pension reform plans. (A longer text discussion notes that “The planned reform represents a credible vision for making the health system universally accessible and sustainable, meeting the demands of an ageing population and shifting care into the community, with a stronger focus on prevention. This is likely to have a positive impact in reducing the reliance on acute care, thereby making healthcare more cost-effective. However, implementation is endangered by the health system’s difficulties in addressing the duplicate health insurance market and effectively managing its own budget, performance and workforce in the short term.”)</td>
</tr>
</tbody>
</table>

>> continues
Table 6.2  
**Country Specific Recommendations with reference to health: 2011, 2014, 2019 [continued]**

<table>
<thead>
<tr>
<th>Country</th>
<th>2011 CSRs</th>
<th>2014 CSRs</th>
<th>2019 CSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations. (Noted in text: “The outcome of the health system overall is good, despite below-EU average spending. Nevertheless, the provision of healthcare largely varies across regions, affecting access, equity and efficiency, and could be improved through better administration and by monitoring the delivery of standard levels of services.”)</td>
</tr>
<tr>
<td>Latvia</td>
<td>No recommendations.</td>
<td>Improve the cost-effectiveness, quality and accessibility of the healthcare system.</td>
<td>Increase the accessibility, quality and cost-effectiveness of the healthcare system.</td>
</tr>
<tr>
<td>Lithuania</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>Increase the quality, affordability and efficiency of the healthcare system.</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Malta</td>
<td>No recommendations.</td>
<td>Ensure that a comprehensive reform of the public health system delivers a cost-effective and sustainable use of available resources, such as strengthening primary care.</td>
<td>Ensure the fiscal sustainability of the healthcare and pension systems, including by restricting early retirement and adjusting the statutory retirement age in view of expected gains in life expectancy.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td>Poland</td>
<td>No recommendations.</td>
<td>Minimize cuts in growth-enhancing investment, improve the targeting of social policies and the cost-effectiveness of spending and the overall efficiency of the healthcare sector …</td>
<td>Focus investment-related economic policy on innovation, transport, notably on its sustainability, digital and energy infrastructure, healthcare and cleaner energy, taking into account regional disparities.</td>
</tr>
<tr>
<td>Portugal</td>
<td>No recommendations.</td>
<td>Control healthcare expenditure growth and proceed with the hospital reform.</td>
<td>No recommendations. (Noted in text: “Portugal’s public finances are under continuous pressure from adverse demographic trends, notably the ageing population, with negative consequences, especially for the sustainability of the pension and health systems.”)</td>
</tr>
</tbody>
</table>

>> continues
### Table 6.2  

<table>
<thead>
<tr>
<th>Country</th>
<th>2011 CSRs</th>
<th>2014 CSRs</th>
<th>2019 CSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Romania</strong></td>
<td>No recommendations.</td>
<td>Step up reforms in the health sector to increase its efficiency, quality and accessibility, including for disadvantaged people and remote and isolated communities. Increase efforts to curb informal payments, including through proper management and control systems.</td>
<td>Improve access to and cost-efficiency of healthcare, including through the shift to outpatient care.</td>
</tr>
<tr>
<td><strong>Slovakia</strong></td>
<td>No recommendations.</td>
<td>Improve the long-term sustainability of public finance by increasing the cost-effectiveness of the healthcare sector, in particular by rationalizing hospital care and management and by strengthening primary care.</td>
<td>Achieve the medium-term budgetary objective in 2020. Safeguard the long-term sustainability of public finances, notably that of the healthcare and pension systems. Focus investment-related economic policy on healthcare, research and innovation, transport, notably on its sustainability, digital infrastructure, energy efficiency, competitiveness of small and medium-sized enterprises, and social housing, taking into account regional disparities.</td>
</tr>
<tr>
<td><strong>Slovenia</strong></td>
<td>No recommendation but in the preamble “comparatively low spending efficiency, for example in healthcare and education, implies that Slovenia may have additional scope for expenditure-based consolidation without compromising the quality of public services”.</td>
<td>Launch a comprehensive review of expenditure covering state and local government levels, direct and indirect budget users and municipality-owned providers of utilities and services in the area of healthcare by the end of 2014 with a view to realizing budgetary savings in 2015 and beyond.</td>
<td>Adopt and implement reforms in healthcare and long-term care that ensure quality, accessibility and long-term fiscal sustainability.</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>No recommendations.</td>
<td>Continue to increase the cost-effectiveness of the healthcare sector, in particular by further rationalizing pharmaceutical spending, including in hospitals, and strengthening coordination across types of care, while maintaining accessibility for vulnerable groups.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td><strong>Sweden</strong></td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td>No recommendations.</td>
<td>No recommendations.</td>
<td>No recommendations.</td>
</tr>
</tbody>
</table>

*Source: Compiled from relevant collections at https://ec.europa.eu/info/publications_en (accessed 23 February 2022).*
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 somewhat opaque on their own. What, exactly, does it mean that in 2019 Lithuania was advised to “Increase the quality, affordability and efficiency of the healthcare system?” The answer in these cases is to work backwards. First, consult the “recitals” – the long section at the top of the CSRs that explains the rationale and context. Paragraph 12 of the Commission’s proposed CSRs explains:

“Weak health outcomes and low investment in healthcare are persisting challenges. There remains significant potential to rationalise the use of resources through a further shift from inpatient to outpatient care. The consumption of hospital services continues to be high, with high rates of hospitalisations for chronic diseases coupled with relatively low bed occupancy rates. Further rationalisation of hospital resources use, together with targeted investments to strengthen primary care services, including in the healthcare workforce, are necessary to drive efficiency gains and improve health outcomes. The quality of care remains one of the main reasons for poor health outcomes. Measures to improve the quality of care are fragmented, with very low take-up of accreditation in the primary care sector and a lack of application of the accreditation system in hospitals. Investment in disease prevention measures is particularly low. Moreover, steps taken to strengthen disease prevention measures at local level lack an overarching vision and are impaired by a lack of systemic co-operation between public health offices and primary care. Lastly, low levels of health spending coupled with relatively high informal payments and high out-of-pocket payments have negative implications for equity of access to healthcare.”

The evidence base for this analysis, as with most such analyses in the Semester, is in the Country Report (in this case published as Commission Staff Working Document SWD (2019) 1014, published alongside the CSRs). The evidence base and intellectual structure of the discussion of health is rooted one step further back, in the State of Health in the EU report on Lithuania, which is part of the series jointly produced with the OECD and the European Observatory on Health Systems and Policies.

The process of feeding information into the Semester can be read in reverse, as a funnel whose widest part is the State of Health in the EU Country Health Profiles, narrowing to the discussion of health in the Country Reports, narrowing further to the recitals of the CSRs, and ending in the sentence that makes up a normal CSR. At each stage there are consultations within the Commission and with Member States, as well as with at least some interested parties in the Member States. Member States have great influence over which parties can engage with the Commission, e.g. some decline to let regional governments and the Commission interact in Semester discussions.
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 and noted by scholars. Therefore, we can see that countries such as Latvia and Lithuania are given advice to improve the quality and affordability of their health systems, and Italy to redress its regional inequalities, while Cyprus and Ireland receive endorsement of their moves towards universal health coverage (with a particularly supportive discussion of the Irish policy challenge: see Table 6.2). Member State ownership is in general a value in the Semester process as it operates now, which effectively means that the Commission tries to avoid recommendations that lack support within the Member State. 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. The Semester was built, after all, to align policy with constraining fiscal rules, and it was doing so through 2019. To take a specific example, the linkage between the fiscal sustainability of the healthcare system and that of the long-term care and pension systems – a common theme in the CSRs – often results in recommendations that treat both pensions and health as costs, and prescribe blunt reductions in pension liabilities (see Austria, Ireland, Malta, Portugal and Slovenia in 2019). This kind of framing is representative of a broader failure of the Semester to adopt a holistic approach to health. Recommendations continue to emphasize a medical, healthcare paradigm, and miss opportunities to address the broader social determinants of health and well-being. However, Commission President Ursula von der Leyen pledged to use the Semester in a more coherent way and, as Section 6.5.3 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.52

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 will require close monitoring and, therefore, has been integrated into the Semester, with an adapted cycle for 2021 and further changes for 2022. 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

Central to the EU’s short-term fiscal response was the Coronavirus Response Investment Initiative (the CRII) and its successor, the CRII Plus, adopted in April 2020. Under these instruments, unspent funds from the 2014–2020 ESIF programmes were made available for crisis response, whilst 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 euro area, and the EIB issued a €200 billion European Guarantee Fund (EGF) aimed at supporting SMEs.53

52 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, p. 6. COM 2021(662).

Box 6.2  DG Reform

The Commission’s Directorate-General for Structural Reform Support (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 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. Examples of support provided in the healthcare arena include primary healthcare reforms (Austria), cancer screening programmes (Italy, Slovakia and Romania), health system performance assessment (Latvia and Slovenia), spending review on medicines, and functional integration of hospitals, etc. In Italy, Romania and Slovakia the national health authorities submitted a request for support to the Commission in 2017. The SRSS helped them improve the implementation of EU colorectal cancer screening guidelines, through the training and empowering of senior health managers and health professionals, development of communication campaigns, organization of country visits, etc. Austria also requested support from the SRSS, in order to speed up the implementation of a primary healthcare reform the country had previously adopted to establish 75 primary healthcare units by 2022. The SRSS created a website, a communication strategy and support material to enable health professionals to start their own primary healthcare unit. DG REFORM’s creation reflects the importance that EU leaders assigned to this activity.


Whilst these efforts provided valuable resources and assistance in the immediate crisis period, it was clear that the majority of short-term stimulus response 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, reflects the infeasibility of restricting government spending during a pandemic. It also indicates 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.\textsuperscript{54}

The relaxation of fiscal limits permitted Member States to spend, and spend they did (Figure 6.2). 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 exceeding 60% of GDP.\textsuperscript{55} 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.

Long-term adjustment

The EU’s more substantial response to COVID-19 came via the renegotiated MFF and the Next Generation EU (NGEU) recovery package. NGEU provides €806.9 billion\textsuperscript{56} 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

---


\textsuperscript{56} Current prices.
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 (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.

NGEU marks a significant step in several regards. For the first time Member States have 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 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 is

Table 6.3  Overview of MFF and NGEU allocations (current prices)

<table>
<thead>
<tr>
<th>MFF 2021–2027 and NGEU total allocations</th>
<th>NGEU breakdown</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MFF</strong></td>
<td><strong>NGEU</strong></td>
</tr>
<tr>
<td>1. Single market, innovation and digital</td>
<td>€149.5b</td>
</tr>
<tr>
<td>2. Cohesion, resilience and values</td>
<td>€426.7b</td>
</tr>
<tr>
<td>3. Natural resources and environment</td>
<td>€401.0b</td>
</tr>
<tr>
<td>4. Migration and border management</td>
<td>€25.7b</td>
</tr>
<tr>
<td>5. Security and defence</td>
<td>€14.9b</td>
</tr>
<tr>
<td>6. Neighbourhood and the world</td>
<td>€110.6b</td>
</tr>
<tr>
<td>7. European public administration</td>
<td>€82.5b</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€1,210.9b</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€806.9b</strong></td>
</tr>
</tbody>
</table>

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 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. A key battle in the RRF’s early existence has therefore been 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 green, digital and sustainable economic transitions, will thus materialize in the medium-to-long term. Commentary on the RRF’s early operation has 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.

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 outline 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 is to sign off the plans and the Member States in question are to receive 13% of the total support up front, to kick-start investments. Remaining disbursements can be requested by governments up to twice a year, upon meeting interim targets and milestones, and will be assessed by the Commission and an assisting expert committee. Following lengthy negotiation at the July 2020 Council Summit, Member States will not be able to veto one another’s spending plans but will be able to temporarily halt disbursements if they are 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 DG Secretariat-General and supported by DG ECFIN – and coordinated via a temporarily adapted European Semester framework.

6.5.2 The 2021 European Semester: An extraordinary cycle

To facilitate the planning and monitoring of the RRF, and avoid duplication with similar fiscal governance processes, the European Semester was temporarily adapted in 2021 (Figure 6.3) and will continue to accommodate the RRF in 2022. The 2021 cycle was launched by the ASGS, published earlier than usual, in September 2020, to inform the development of the RRPs. States were given the opportunity to submit NRPs and RRPs in a single, integrated document, though some chose to submit separately, and the Commission’s assessment of these replaced the Country Reports for this cycle. There were no structural CSRs in the 2021 cycle; although the activation of the general escape clause means that the deficit and debt rules are suspended, the associated monitoring processes
of the SGP continue, as does monitoring of macroeconomic imbalances. For the former, the Commission decided not to issue EDPs in 2021; for the latter, in-depth reviews were conducted for 12 Member States where imbalances were flagged in the 2021 AMR.

The 2022 Semester cycle reverses some of the changes made in 2021 but retains others. The ASGS was published at the “usual” time in November 2021 and full CSRs will be issued in 2022. The Country Reports also return, but will be published later, alongside the CSRs, in May. The NRPs and SCPs will be submitted as usual, in April, but will fulfil a dual role, serving as the first of the two bi-annual reporting requirements under the RRF. The Commission describes the 2022 cycle as “resuming” the Semester’s focus on broad economic and employment policy whilst also supporting the RRF, indicating that this format is likely to prevail until at least the end of the RRF financing period.

### 6.5.3 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, and initial data on uptake and utilization of these funds, are already available. 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.

#### Utilization 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. CRII and CRII+ 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 June 2021, the flexibilities and additional resourcing made available under CRII and CRII+ had resulted in €8.4 billion of reallocation for health spending, representing a net increase of €8.1 billion available to fund health-related
investments. Spain, Italy, Poland and Romania had made the greatest use of these funds, and the majority of expenditure had been on medical equipment and PPE.

The adapted EU Solidarity Fund (EUSF) received 20 applications, from 17 Member States and 3 accession countries, for financial support to tackle COVID-19 under its new public health emergencies mandate. The total value of the approved disbursements was €530 million. Furthermore, the SURE instrument had, as of June 2021, disbursed €90 billion in loans to support employees and firms in 19 Member States.

Inclusion of health in long-term response measures

The 2021 ASGS, published in September 2020, offered a clear statement of the importance of health to a strong and sustainable recovery. It noted that:

“… the full impact of COVID-19 on public health will persist for years. Ensuring the provision of high quality health care services that is fiscally sound, affordable and accessible, contributes to a healthy and resilient society and to ensuring a productive workforce.”

The ASGS also launched the period in which Member States were to begin drafting their RRPs and advised that, in so doing, national governments should “focus on those challenges and priorities that will generate the most lasting impact and will strengthen the growth potential, job creation, health systems and economic and social resilience and regional cohesion of the Member State”.

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.” A political battle over the

---


63 Ibid., p. 5.

precise provisions of the Regulation immediately commenced, as the European Parliament sought to direct the RRP's to, for instance, exclude investments in fossil fuels. The resulting text provides that the Commission's assessment of the RRP's 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. 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 eHealth, for example. Whilst contribution to strengthening of the health system or public health is not explicitly listed in the Regulation, the Commission’s extensive guidance for the drafting of the RRP's 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)”. 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 upon access to healthcare.

The Commission has also provided templates to gather standardized information from the RRP's 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. Health features prominently 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, eHealth infrastructure, electronic health records, tele-health, m-health, and the creation of registries and data repositories for specific diseases and reference networks.

---

65 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).


Health in the (adapted) Semester and Recovery and Resilience Plans

Another indicator of the potential implications of the EU’s adapted fiscal governance framework for health can be found in the most recent CSRs. The RRF is designed, among other things, to accelerate progress towards the CSRs, further increasing the salience of the most recent round of recommendations. The 2020 CSRs, issued in May 2020, were unique. For the first time, all Member States received a CSR relating to health (Box 6.3). Specifically, all CSRs included a recommendation to strengthen, improve or reinforce the resilience of the health system, with some then elaborating with additional elements (in the main recommendations, not merely the preamble) such as addressing the supply and working conditions of healthcare workers (21 out of 28 recommendations), securing the supply of medical products (13), improving healthcare accessibility (11) and implementing eHealth initiatives (7). These recommendations clearly reflect the weaknesses exposed by the COVID-19 pandemic but also build upon themes – health workforce, eHealth, accessibility and sustainability – that had evolved through previous Semester cycles.

The potential significance of these recommendations will become clear as Member States submit their national recovery and resilience programmes (NRRPs) in application for their allocated RRF funds. This process is ongoing and will continue for some years as the programme evolves (in the same way that the Semester of 2015 was unlike the Semester of 2019). The content of the initial round of NRRPs approved by the Commission varies but some patterns can be observed. Plans should outline a series of “components” and list specific investments and reforms under each component. The scale and ambition of the plans range from three components proposed in the Luxembourghish plan to 30 proposed in the Spanish NRRP. Among these, the vast majority dedicate a specific component or sub-component to health (Slovakia, in fact, dedicates three of its 18 components to health). Austria and Belgium are the exceptions to this trend, instead identifying health-related reforms and investments only under other components (such as those on “a just recovery”, “public administration” and “training and labour market”).

Perhaps more remarkably, very few of the plans submitted frame their investments and reforms in the context of COVID-19 or weaknesses exposed by the pandemic. The Danish plan targets stocks and supply of critical medicines, the Spanish plan addresses vulnerabilities vis-à-vis global health crises and the German plan includes investments in R&D targeting COVID-19. But the rest make little or no mention of the pandemic in relation to the investments and reforms that they propose, focusing instead on wider, more fundamental and pre-existing issues. These include the creation of infrastructure for health data, eHealth,

69 Since the CSRs were issued prior to 31 December 2020, the UK received a (health-related) CSR.
Box 6.3  The 2020 country specific recommendations relating to health

<table>
<thead>
<tr>
<th>Country</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Improve the resilience of the health system by strengthening public health and primary care.</td>
</tr>
<tr>
<td>Belgium</td>
<td>Reinforce the overall resilience of the health system and ensure the supply of critical medical products.</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Mobilize adequate financial resources to strengthen the resilience, accessibility and capacity of the health system, and ensure a balanced geographical distribution of health workers.</td>
</tr>
<tr>
<td>Croatia</td>
<td>Enhance the resilience of the health system. Promote balanced geographical distribution of health workers and facilities, closer cooperation between all levels of administration and investments in e-health.</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Strengthen the resilience and capacity of the health system to ensure quality and affordable services, including by improving health workers’ working conditions.</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Ensure the resilience of the health system, strengthen the availability of health workers, primary care and the integration of care, and deployment of e-health services.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Enhance the resilience of the health system, including by ensuring sufficient critical medical products and addressing the shortage of health workers.</td>
</tr>
<tr>
<td>Estonia</td>
<td>Improve the accessibility and resilience of the health system, including by addressing the shortages of health workers, strengthening primary care and ensuring the supply of critical medical products.</td>
</tr>
<tr>
<td>Finland</td>
<td>Address shortages of health workers to strengthen the resilience of the health system and improve access to social and health services.</td>
</tr>
<tr>
<td>France</td>
<td>Strengthen the resilience of the health system by ensuring adequate supplies of critical medical products and a balanced distribution of health workers, and by investing in e-Health.</td>
</tr>
<tr>
<td>Germany</td>
<td>Mobilize adequate resources and strengthen the resilience of the health system, including by deploying eHealth services.</td>
</tr>
<tr>
<td>Greece</td>
<td>Strengthen the resilience of the health system and ensure adequate and equal access to healthcare.</td>
</tr>
<tr>
<td>Hungary</td>
<td>Address shortages of health workers and ensure an adequate supply of critical medical products and infrastructure to increase the resilience of the health system. Improve access to quality preventive and primary care services.</td>
</tr>
<tr>
<td>Ireland</td>
<td>Improve accessibility of the health system and strengthen its resilience, including by responding to health workforce’s needs and ensuring universal coverage to primary care.</td>
</tr>
<tr>
<td>Italy</td>
<td>Strengthen the resilience and capacity of the health system, in the areas of health workers, critical medical products and infrastructure. Enhance coordination between national and regional authorities.</td>
</tr>
<tr>
<td>Latvia</td>
<td>Strengthen the resilience and accessibility of the health system including by providing additional human and financial resources.</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Strengthen the resilience of the health system, including by mobilizing adequate funding and addressing shortages in the health workforce and of critical medical products. Improve the accessibility and quality of health services.</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>Improve the resilience of the health system by ensuring appropriate availability of health workers. Accelerate reforms to improve the governance of the health system and e-Health.</td>
</tr>
<tr>
<td>Malta</td>
<td>Strengthen the resilience of the health system with regard to the health workforce, critical medical products and primary care.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Strengthen the resilience of the health system, including by tackling the existing shortages of health workers and stepping up the deployment of relevant e-Health tools.</td>
</tr>
</tbody>
</table>
Fiscal governance of health

<table>
<thead>
<tr>
<th>Country</th>
<th>Measures Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>Improve resilience, accessibility and effectiveness of the health system, including by providing sufficient resources and accelerating the deployment of ehealth services.</td>
</tr>
<tr>
<td>Portugal</td>
<td>Strengthen the resilience of the health system and ensure equal access to quality health and long-term care.</td>
</tr>
<tr>
<td>Romania</td>
<td>Strengthen the resilience of the health system, including in the areas of health workers and medical products, and improve access to health services.</td>
</tr>
<tr>
<td>Slovakian</td>
<td>Strengthen the resilience of the health system in the areas of health workforce, critical medical products and infrastructure. Improve primary care provision and coordination between types of care.</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Ensure the resilience of the health and long-term care system, including by providing an adequate supply of critical medical products and addressing the shortage of health workers.</td>
</tr>
<tr>
<td>Spain</td>
<td>Strengthen the health system’s resilience and capacity, as regards health workers, critical medical products and infrastructure.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Ensure the resilience of the health system, including through adequate supplies of critical medical products, infrastructure and workforce.</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Strengthen the resilience of the health system.</td>
</tr>
</tbody>
</table>

Telemedicine and digitalization, the building and renovation of hospitals, clinics and research institutes, and the development of national strategies for primary care, prevention services, mental health care, health research and governance of the system. Many of the investments and reforms proposed in these initial plans were already foreseen, or even under way, a situation necessitated largely by the speed at which NRRPs had to be devised and the complexity of the kind of project eligible for funding. In spite of this, the challenge will now be implementation, as Member States seek to overcome domestic opposition – Spain’s plan, for instance, is already proving contentious at the national level⁷⁰ – and the EU institutions seek to monitor the application of the funds.

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.\footnote{For excellent coverage of the overall social policy approach, see Vanhercke B & Spasova S (eds). \textit{Social Policy in the European Union: State of Play 2021}. Brussels: ETUI/OSE.} Crucially, early indications suggest that health is well represented within the NGEU and that the package presents an opportunity to strengthen health systems and policies.

The NGEU and post-COVID recovery faces a number of challenges, however. Within Member States, ambitious and complex plans must now be delivered upon. Based on the experience of the ESIF, a major challenge already identified is the ability of national administrations to absorb the available funds; some of those due to receive the highest payments from the RRF score lowest on absorption of the 2014–2020 ESIF allocations (namely Italy and Spain).\footnote{Darvas Z (2020). \textit{Will European Union countries be able to absorb and spend well the bloc’s recovery funding?} Bruegel Blog, 24 September 2020. Available at: https://www.bruegel.org/2020/09/will-european-union-countries-be-able-to-absorb-and-spend-well-the-blocs-recovery-funding/ (accessed 30 June 2021).} Data from the 2007–2013 ESIF indicate that funds continue to be allocated and utilized three years after the end of the funding period, suggesting that the 2014–2020 uptake rates might not be as bad as they currently appear, but there is still a need to support administrative capacity in some receiving states.\footnote{Alvarez MC (2020). \textit{What the absorption of structural funds says about the EU recovery plan}. Funcas. Available at: https://www.funcas.es/articulos/what-the-absorption-of-structural-funds-says-about-the-eu-recovery-plan/ (accessed 30 June 2021); Incaltarau C, Pascariu GC & Surubaru N (2020). Evaluating the Determinants of EU Funds Absorption across Old and New Member States – the Role of Administrative Capacity and Political Governance. \textit{JCMS: Journal of Common Market Studies}, 58(4):941–61.} Similar issues of capacity will also present themselves within the European Commission. In order to fulfil its roles, the executive will need to raise large sums on the capital markets, set up the instruments needed for its own resources and, perhaps most complex of all, administer and monitor the implementation of the NRRPs. In addition to simple quantity of human resources, these tasks will require increased technical and political capacity within the Commission.

Beyond these capacity challenges, the details of how the RRF will function in reality are yet to be made clear. How, for example, will the emergency brake mechanism, introduced at the insistence of the “frugal” Member States during the July 2020 Council Summit, be used? Political sign-off on the CSRs by the Council has historically been a bland affair, with changes to the Commission text rarely made. But the NRRPs are different and, if it proves difficult to demonstrate “good” implementation and fulfilment of interim targets, disbursement might be delayed. Another 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 Union 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.74 It is not yet clear how this provision will be applied and, dissatisfied with the speed at which the Commission is bringing forward its proposals for implementation of the mechanism, the Parliament threatened in June 2021 to take the executive to court.75

The adapted fiscal governance framework, and in particular the NGEU package, has already achieved three things: it has demonstrated the spirit of solidarity that underpins the Union 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.76 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 and increase the resilience and sustainability of the European economy.

Chapter 7

Global Health

7.1 Introduction

The European Union is a major global health actor and is deeply engaged in complex relationships with many countries. Global health is a major policy area with high stakes and large sums of money involved, and we can give only a brief account here of its health dimensions. Major issues that loom large in the EU’s global engagement, such as climate change, receive only limited treatment here despite their existential importance. We nonetheless want to highlight the importance of the EU’s role, and its opportunities. Global health has increasingly gained importance in the European Union since the 2000s and became a focus of political attention from the start of the COVID-19 pandemic.

The European Consensus on Development, released in 2005, emphasized the importance of the “Millennium Development Goals” with a specific focus on health-related goals. 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. The subsequent Council Conclusions urged for a more central EU role in global health. These documents, however, largely remained statements rather than operationalizable action plans.

The EU’s 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

---


Everything you always wanted to know about EU health policy but were afraid to ask

Despite these difficulties, the Sustainable Development Goals remain a core framework for guiding EU action in global health until 2030. The Commission has pledged to assist Member States in meeting goals in areas that include reductions in non-communicable disease, increasing capacity to prevent and manage global health threats, eliminating HIV/AIDS and TB, and implementing the Framework Convention on Tobacco Control.\(^4\)\(^,\)\(^5\) The ongoing policy challenge lies in identifying and implementing actions to meet these goals, given the complexity of the issues at hand and the need to engage multiple stakeholders.\(^7\)

The COVID-19 pandemic created a new policy window to bolster global health initiatives at the EU level and to further refine “global health” as a policy concept and field of intervention.\(^8\) The Global Health Summit, co-hosted on 21 May 2021 by the European Commission and Italy as chair of the G20, resulted in the development of the “Rome Declaration” of principles. The principles aim at furthering multilateral cooperation to prevent future global health crises, recognizing that maintaining global supply chains and free movement of goods, and avoiding economic nationalism, are key components of successful global health response.\(^9\) It remains to be seen how this statement of purpose will be implemented in practice.

While the EU can negotiate agreements as a bloc where it chooses, it must act collectively externally where there are internal EU competences.\(^10\) Yet, also here, the EU’s powers in the area of trade and development give rise to external engagement regarding health. 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 UK’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.

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 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, the EU creates externalities 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. Trade policy may be seen as many kinds of policy – economic development, geopolitical competition or human rights. We approach it from an EU health perspective, focusing on the health system and the consequences of international trade regimes for the EU. The consequences for lower- and middle-income countries of trade, intellectual property and investment decisions that the EU strongly influences can be even more important for them and merit attention and consultation with global civil society.

On the other hand, in an interconnected world, the activities created by others 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 theme of EU policy at its Mediterranean borders has been reduction in the number of refugees arriving at EU borders. This focus has been hotly debated.

7.1.2 Arenas: Internal, Neighbourhood and Global

The EU operates in three international arenas. 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 European region of WHO as well as the countries formally identified as being part of the European “Neighbourhood”. This extraordinarily diverse set of countries, from Switzerland to Libya, Tunisia to Belarus, Syria to the

---

United Kingdom, is united by little other than proximity to the EU, presents a wide variety of concerns, and requires a wide variety of policy tools. The third and final arena is the global arena, 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 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 European 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 does not get to veto the appointment; Member States do not see their shared foreign policy stance as a fit topic for accountability to the EP). The current High Representative is Josep Borrell. 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 some of 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 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. This makes them more predictable and accountable because they are part of the broad system of EU budgeting, legislation and accountability and are less affected by divergent Member State interests and geopolitical crises. The High Representative’s role is shaped more as an after-effect of high politics, and its policy importance or health impact depends on its occupants and on what Member State governments let that person do.

### 7.2 The EU’s near neighbours

The European Union’s borders are not hard and fast. It has diverse relationships with its near neighbours as different as Turkey, 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.

Figure 7.1 shows the key relationships in and around the EU: EFTA, the EEA, the Schengen border system and the complexities of UK-relations after Brexit. What it shows is 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 Turkey or the inclusion of Switzerland in many relationships.

#### 7.2.1 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 (excluding Switzerland). EFTA has an interesting history, having originally been led by the UK 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. 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. 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. In May 2021 Switzerland decided to stop the discussions for an Institutional Framework Agreement, thereby stopping all the negotiations with the EU.

### 7.2.2 The United Kingdom

The UK, since Brexit, has a bilateral relationship with the EU governed by bilateral negotiations and agreements. The 2016 Brexit referendum vote did not specify

---

12 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).


the form of relationship voters wanted the UK’s relationship with the EU to take.  In the subsequent negotiations, Conservative UK governments opted for a very “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 UK and an absolute minimum level of commitment to shared regulatory standards. From an EU perspective, the problem this creates 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 UK politics, where a majority government can usually rewrite law it finds inconvenient.  The result is that the UK’s refusal to be bound by agreed upon legal texts make it an extremely awkward negotiating partner for the EU.

Brexit’s biggest health impact might be on the wider UK economy and politics, and thus on the ability of the UK to finance and staff its health service, but from an EU perspective there are three key areas of problematic impact – workforce, health-related products and Northern Ireland. On workforce, the UK health service has long had a particular reliance on staff from outside the UK. The end of free movement for EU citizens to the UK and the UK’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 UK will now have its own separate market for products such as pharmaceuticals and medical devices. For those products, as well as other products that are important to health such as fresh food, Brexit has increased customs requirements at UK borders, impacting timely access to the UK’s market for EU producers. It remains to be seen how long the UK and EU will stay in step with each other. Any future movement by the UK away from EU product regulatory standards will exacerbate this problem.


The impact of being a smaller market with specific rules is already being felt in Northern Ireland across a range of sectors, and is likely to also have an impact on health. Northern Ireland has the UK’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 UK does not want to adopt EU standards, and so the UK and EU agreed that there would be checks at the Irish sea crossing between Northern Ireland and the UK, 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 UK. UK 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 own country. From the EU point of view, credible commitment by the UK 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 the current UK government would absolutely refuse. The result is that the UK’s efforts to renegotiate or reinterpret existing agreements diminish its ability to credibly commit to any future agreements in the eyes of the EU without solving any of the basic problems.

The picture is not all negative, though. In some areas bilateral arrangements are working so far (the UK having failed in efforts to undercut the EU by developing bilateral agreements with EU Member States in areas of EU competence). Patient mobility is beneficial to the UK and a few Member States (e.g. Spain), so it has not turned out to be a major issue in negotiating the relationship. The UK has prioritized participation in EU research funding programmes and should be an Associated Member of Horizon Europe. Reciprocal arrangements for social security, including access to healthcare, have been largely carried over into the new relationship between the UK and the EU. In the longer term the UK 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 UK 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 UK – in the first instance Ireland, where the tensions around Northern Ireland have already proved difficult, but...
also the other EU countries that are geographically close to the UK (such as the Netherlands, France and Belgium). There is also an impact on those states that have been politically close to the UK; in particular, weakening the liberal block in the EU that has promoted deregulation through the internal market.\textsuperscript{18} More broadly, the UK’s new position as a distinct regulatory regime next to one of the largest economies in the world will create challenges, and the choices that the UK makes in the coming years will have an impact on health and healthcare.

The EU after Brexit will not just have the ongoing policy agenda of managing relations with the UK or rebuilding policy expertise in areas where it depended on the UK. It will also have a new politics in which liberalization is less politically powerful, and France is relatively empowered. Crudely, Germany used to be a hinge that could side with the UK or France; the departure of the UK means that France is a veto player, a development that empowers France and its allies. Brexit expands their options while constraining Germany and northern “liberal” countries. That will be a new experience for those most familiar with the EU since UK accession in 1973.

The UK and the EU are not entirely comparable and do not have a symmetrical relationship. In most of the UK-EU debates, the UK matters less to the EU than vice versa, simply because the UK is a smaller economy. The EU makes up a much larger share of the UK’s trade than the UK does of any Member State’s economy. Furthermore, relations with the EU are a major point of domestic political contention in the UK 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 UK, but also means that the importance of EU relations to UK 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 UK. A stable relationship might demand that the UK modify its approach to the EU over time, by for example committing long-term to the same food safety, sanitary and phytosanitary, and medicines standards as the EU.

### 7.2.3 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 (\textit{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 rule of law is much greater before accession than after, though this might be changing in response to persistent and serious violations of the rule of law by some Member States (see Box 1.3).

There are five recognized candidates for accession to the EU: Albania, Montenegro, North Macedonia, Serbia and Turkey. In principle, the four Balkan applicants could join the EU in 2025 or afterwards. Turkey’s application dates to 1987 but Turkish accession talks have been effectively frozen for years and have become highly politically sensitive on both sides. Bosnia and Herzegovina has applied and Kosovo\(^1\) is recognized by the EU as a potential candidate, though there are some important barriers to candidacy for both (for example, not all EU Member States recognize Kosovo as a state).

Accession candidates have strong political and legal incentive to align their policies with the EU as they start to adopt the *acquis*. 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 kept updated on the website of DG NEAR. There are particularly serious concerns for all the accession candidate states in the area of food and phytosanitary safety and social policy and employment.

### 7.2.4 European neighbourhood policies, Russia and Turkey

“Neighbourhood policies” refer to policies directed at the EU’s close southern and eastern neighbours. To the south, that means Algeria, Egypt, Israel, Jordan, Lebanon, Libya, Morocco, Palestine, Syria and Tunisia. To the east, that means Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine. 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 Ukraine, 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, though the new approach to southern neighbourhood countries includes substantially more references to healthcare and health.\(^2\)

---

\(^1\) 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.

Two large states in the neighbourhood are not covered by “neighbourhood” policies. Russia participates in some neighbourhood policies but generally prefers to deal bilaterally with EU Member States, and, if it deals with the EU, is reluctant to be clustered with smaller post-Soviet 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 has taken place since 2009 but it did not result in any concrete, operational policy. Given that managing tensions with Russia is more of a priority than closer integration at the moment, it is not reasonable to expect much more.

Turkey has been in a customs union with the EU since 1995 and a candidate Member State with theoretically ongoing accession negotiations, though as mentioned above the negotiations are frozen on a variety of grounds (including democratic backsliding and Cyprus, as well as the manifest hostility of a number of Member State governments to Turkish accession). They are unlikely to restart soon.

Issues of migration and security, not health, dominate relations to the south, and so the health dimensions of these relations are ones that emerge from a policy focused on migration. Turkey 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 Turkey 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, likewise, 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. EU 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 achieve.

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 “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 Syria and locals affected by the refugee flows and crisis in Lebanon, Egypt, Turkey, Jordan, Iraq and the Western Balkans, and the separate Facility for Refugees in Turkey supports refugees in Turkey. 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 for over a million refugees.

The lead DGs for neighbourhood issues are, unsurprisingly, DG NEAR (DG European Neighbourhood Policy and Enlargement Negotiations) and to a lesser extent DG ECHO (Humanitarian Aid and Civil Protection) 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. There are health projects being funded, but primarily under other priorities. This is in contrast to the older iterations of the ENP, which pre-dated many of the current security concerns arising both east and south of the EU and which had 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 European Union also sent health professionals and medical supplies to non-EU countries such as Tunisia in the summer of 2021, as these countries experienced a deadly third wave of COVID-19. Additionally, the European Commission supported efforts to share COVID-19 vaccines with countries outside the EU through the European Civil Protection Mechanism. The Commission coordinated the delivery and financed up to 75% of the vaccines transporting costs. Through this mechanism, which primarily benefited neighbouring countries, 250,000 vaccine doses were sent from Denmark to Kosovo and 50,400 doses from Latvia to Tunisia. In most cases these are bilateral donations from one Member State to a third country with historic or geographical connections, such as Austria’s donations to Bosnia and Herzegovina. Just as Member States could acquire

---

vaccines outside the EU vaccines strategies if they wished, they could also donate the doses they acquired via the EU to other countries. The EU’s principal engagement in global vaccine provision has been through the COVAX facility.

The Russian invasion of Ukraine in 2022 rapidly changed EU priorities. In addition to other forms of aid and aid from the Member States, the EU set an aid package of 550m EUR, much of it health-related humanitarian aid, while the Civil Protection Mechanism provided relevant supplies. The EU also supported Moldova, financially and with Frontex deployment, as it sought to manage large refugee inflows. Perhaps most dramatically, Ukrainian EU accession became a widely discussed possibility with strong support for candidacy or accession in the Commission, Parliament, and a number of Member States. Ukraine is a long way away from compliance with EU accession criteria and was much poorer than any EU Member State even before the war, but even EU candidacy brings tangible as well as symbolic and geopolitical benefits to Ukraine and new engagements to the EU.

7.3 Global health and Global Economic Governance

In many areas the European Union 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 section briefly covers the EU’s global role as a key part of global economic governance, which has big health effects, and its role in development aid and the governance of global health.

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 the 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.

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. 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, United States and nine other industrialized states, these concerns were shared by the European Parliament, which 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 international commercial arbitration directly against governments in response to policies perceived as unfair, unreasonable or disproportionate.24

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 3.1 above).

7.3.2 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 2020.25 We can 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 3.9) which assists victims of natural or human-caused disasters globally and, more recently, in the EU.

EU development aid touches on many areas of health. Health priorities 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, though 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. That said, the 5% 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.

The foundation of the EU approach as of now dates to a Commission Communication endorsed by the Council in 2010. It identifies as key challenges the achievement of universal health coverage (UHC), policy coherence (“health policy cannot be handled in isolation”) and knowledge (“research that benefits all”). It should “apply the common values and principles of solidarity towards equitable and universal coverage of quality health services in all external and internal policies and actions”, including inclusiveness with regards to stakeholders within and across countries.

The COVID-19 pandemic has not increased European governments’ sense that they could 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 new 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, Americas) and thematic commitments. There is no specific health theme but themes such as Global Challenges and Civil Society Organizations obviously have health dimensions.

7.3.3 Global health voice

An organization such as the EU affords its Member States, and civil society, a stronger voice in global politics. 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 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 the WHO, including a reduction in earmarked funding.

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.

7.3.4 COVID-19 and COVAX

The COVID-19 pandemic presented significant challenges for the EU in global health. One core challenge was procuring vaccines for low- and middle-income

---


countries. The key trade-offs for rich powers, including the EU, were between vaccines for themselves and vaccines for others, 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, Russia, the UK and the US 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 opted to focus its global vaccines policy on the WHO’s COVAX facility.

COVAX was set up by the 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. 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 hit the problems of any multilateral programme: the temptations of vaccine diplomacy, coupled with the temptation to underfund it.

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 with low and middle-income countries at least 100 million doses 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.

---


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. Aside from donating vaccine doses, the EU and its Member States have 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 the 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 alarming level of global inequality in vaccinations would be 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 outrageous, but the failure to have any credible plan to vaccinate billions of people maximizes the odds that the evolution of the virus defeats the very effective vaccines used in rich countries. One of the obvious solutions is to relax or end patents on the vaccines so that lower- and middle-income countries can produce them. The EU, like other big powers except the United States, 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 against COVID-19 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. It is unclear whether this will lead to new or more intense pressure on a set of rules and political priorities that treat vaccines as a charitable donation rather than a public good.

7.4 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’s size and wealth mean that it is an important part of the world’s health governance and an important influence on world health. 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.

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.

An integrated EU strategy for global health might not eliminate these tensions, but the process of articulating what the EU is trying to do with its enormous power in the world might be valuable. Creation and implementation of an integrated EU global health strategy would not just use the EU’s power across multiple domains for the better. It might even give the EU advantages in a geopolitical environment in which it could, despite its flaws, be the most generous major power.
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 poorly represented. 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. Instead, as discussed throughout this book, the EU’s 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.

8.1 The four freedoms, constitutional asymmetry and health

The three faces of EU health policy are quite different, in intention, politics, bureaucratic organization and legal base. The first face of EU health policy, discussed in Chapter 1, is the 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 a competence of the Member States. The 2017 “five futures” report 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 fiscal governance. There would be little left of the EU were that to happen.

The second face of EU health policy, market integration and regulation, is far more important and is discussed in Chapter 5. It is the basis on which the EU as we know it was built, and it is the basis under 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.

The underlying constitutional asymmetry of the EU lies in the disjunction between these two faces, which are not equal. 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 principle of nondiscrimination that underlies so much European Union law and policy is best used as a tool for undoing Member State regulation through legal challenge, while reregulating that which is deregulated, through EU law, is a slow and awkward process. Member States’ and EU legal systems have created a large body of law and policy that deregulates, while it is legislatures and elected politicians who must re-regulate at the European level. In recent decades they have chosen to do less European re-regulation. Put another way, the EU’s ability to make and correct markets is far greater than its ability to compensate for the effects of those markets.

The most recent and arguably changeable is the third face, the dimension of EU fiscal governance. Just as the Treaties provide no basis for the regulation of healthcare delivery on health grounds but permit it on the grounds of internal market law, EU law and the TSCG permit detailed attempts to regulate healthcare delivery on grounds of macroeconomic and fiscal management. It is less clear, as Chapter 6 showed, just what the effect of the fiscal governance machinery will be. On one hand, its uses are becoming less clear as the initial focus on budgetary austerity has become more diffuse and other priorities have entered the Semester agenda. On the other hand, compliance with the fiscal governance system has been problematic for decades, both in terms of Member State compliance with the overall fiscal targets and in terms of the adoption of specific policy proposals. It is far from clear that the punitive arm of the fiscal governance architecture, still largely unused, will be credible or helpful in the next downturn.

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.
8.2 Consolidating the first face

COVID-19 prompted dramatic changes to EU health policy, 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 was a significant moment for EU solidarity. They show that Member States could indeed open the gate with no fence. The reasons are no surprise: fundamentally EU Member States discovered in a crisis that they could not do it alone. They were too small and too interconnected to make autarchy a good option.

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 or 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 effectively ended more than a decade ago.

The risk to the new EU health policy approach – the first face – 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 2020 – did not seem so important in 2018 and 2019. There is still ample scope for the member states to resist any EU role in their health care systems, or in subsidising other member states’ health care systems, even if they accept the need for greater collaboration in public health. It is entirely possible that the effect of the pandemic, seen from 2024 or 2028, will be much stronger EU public health and little change in EU health care policy.

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 Astra-Zeneca and the UK government and blamed for 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 2021 such that some had achieved excellent vaccination coverage by the end of August 2021, 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 this policy initiative 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 disillusionment 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.

### 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 is still primarily in its markets and regulatory approaches, discussed in Chapters 4 and 5. A regulatory and deregulatory approach grounded in subsidiarity and the construction of 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 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 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. 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 cease to emphasize public health does not solve the problem, since the EU has powerful tools to influence health that it uses in the course of regulating markets, ensuring environmental protection and health and safety, and striving for fiscal sustainability. The existence of EU policies affecting health is unavoidable. The question is whether the EU will use them explicitly for health.

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. The third face of EU health policy, fiscal governance, is concerned about 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 6.2). 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.3

If there were support for a stronger and more health-focused EU policy, there is legal space and a range of creative political possibilities. The State of Health in the EU is an instrument to shape the whole narrative of health 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 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 hours of work, gender equality and occupational health and safety.

There might be support for a stronger and more focused EU health policy. The 2019 institutional renewal – with new leaders in every top job, a new European Parliament without the grand coalition that had held since 1979 and a shift of focus away from austerity – offered a great deal of potential. Challenges such as populism, 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 by addressing major issues in popular and visible ways. Brexit, finally, will change 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 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 (Box 1.6) or to the European Pillar of Social Rights (Box 2.7) 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 Sustainable Development Goals (Box 2.6), which are the basis of the EU’s 2030 strategy. The European Union 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 lower- 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 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 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. It is easy to be cynical, more so since anything as large and complex as the EU always has many agendas that might have little to do with one another. The Juncker Commission sought to be “big on the big things and small on the small things”, with health apparently a small thing. By the end of 2019 there was only one open legislative dossier in health and that was not moving quickly (HTA: Section 5.5). Did that mean that EU policies affecting alcohol or food safety vanished? Of course not, and in fact DG SANTE continued to work on the many health issues discussed in Chapter 3. Did it mean that consumer protection, transportation safety or nondiscrimination policies ceased to contribute to health? Of course not. “Health” lost strength as a constituency and a policy goal, and its advocates in and outside the EU institutions had to work hard to combat the Juncker Commission’s tendency to undervalue their goals and projects.

By the same token, though, declaring a new political priority that includes health will be an effective way to bring resources, energy and attention back. 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
paying 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,
European Union health policy exists and affects both health and health systems.
It is an awkward shape and has unusual features, procedures and priorities, but
that is the case for most policy areas in any political system. This does not mean
that there has ever been any pressure for a 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.

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 in the areas
discussed in Chapter 5. It is an exciting new era for European Union public
health, and we hope that this book has made clear some of the opportunities
as well as the challenges.
Appendices

I. Treaty articles relevant to health today in the Treaty on European Union

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.
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),¹ with reference to articles in the Treaty establishing the European Community (TEC) where relevant.

**From Part 1, 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; …

**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.

From Part Three, 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.

From Part 3, 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.

From Part One: Principles – 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, 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.
From Title IV, Chapter 3, “Services”

Article 62 (ex Article 55 TEC)

The provisions of Articles 51 to 54 shall apply to the matters covered by this Chapter.

From Part 3, 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.

From Part 3, 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; EN C 83/114 Official Journal of the European Union, 30.3.2010

(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. EN 30.3.2010 Official Journal of the European Union C 83/115.

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.

From 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.

From **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.
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.
III. 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.
IV. Mission Letter to the Commissioner-designate for Health - Brussels, 10 September 2019

Ursula von der Leyen
President-elect of the European Commission

Mission letter

Brussels, 10 September 2019

Stella Kyriakides Commissioner-designate for Health

Dear Stella,

Earlier this year, the people of Europe made their voices heard in record numbers at the European elections. They presented us with a mission to be decisive and ambitious on the big issues of our time that are shaping the future of our society, economy and planet.

Changes in climate, digital technologies and geopolitics are already having a profound effect on the lives of Europeans. We are witnessing major shifts all the way from global power structures to local politics. While these transformations may be different in nature, we must show the same ambition and determination in our response. What we do now will determine what kind of world our children live in and will define Europe’s place in the world.

Our job as the European Commission will be to lead, to grasp the opportunities and to tackle the challenges that these changes present, working hand in hand with people from across Europe and with the governments, parliaments and institutions that serve them.

This is the guiding principle behind my Political Guidelines for the next European Commission 2019-2024, which I presented to the European Parliament on 16 July 2019. I outlined six headline ambitions on which I want the European Commission’s work to focus. These priorities are interlocking and are part of the same picture. In this spirit, I have put together a College in which we will all work, decide and deliver together.
An open and inclusive way of working

This approach reflects the open, inclusive and cooperative way of working that I will instil throughout the Commission, as well as in our relationships with others.

The College: One team

The European Commission functions on the **principle of collegiality**. This means we are one team: we all work together following a whole-of-government approach, we all have our say, we all decide collectively and we all take ownership of what is agreed.

To help us deliver on our ambitions and commitments, **I will empower eight Vice Presidents** to steer and coordinate thematic Commissioners’ Groups on each of the Commission’s priorities. They will be supported in this role by the Secretariat-General. All Commissioners will be in one or more Groups. The Commissioner for Budget and Administration will report directly to me.

Of the eight Vice-Presidents, the **three Executive Vice-Presidents** will have a dual function. As Vice-Presidents, they will lead a Commissioners’ Group and be supported by the Secretariat-General. In addition, they will also manage a policy area and have a Directorate-General under their authority for this part of their job. One of the three Executives, First Vice-President Timmermans, will chair the College in my absence.

The High Representative/Vice-President will support me in coordinating the external dimension of all Commissioners’ work. To ensure our external action becomes more strategic and coherent, it will be systematically discussed and decided on by the College. To support this, all services and Cabinets will prepare the external aspects of College meetings on a weekly basis, mirroring the process already in place for interinstitutional relations. This should also better align the internal and external aspects of our work. This will be a ‘**Geopolitical Commission**’.

I believe that we need to **speak and listen more to one another**, starting from within the Commission. College meetings will be places of open and honest discussion. As President I will set the agenda, but all College decisions will be taken collectively. In line with our commitment to fully digitalise the Commission and the need to use resources conscientiously, College meetings will be paperless and digital.

Each Commissioner will ensure the delivery of the **United Nations Sustainable Development Goals** within their policy area. The College as a whole will be responsible for the overall implementation of the Goals.
Interinstitutional relations and better policy making

Along with our close relations with the Council, I want to strengthen the Commission’s special partnership with the European Parliament. This priority must cut through the work of each Member of the College, starting with myself.

I will expect you to ensure the European Parliament is regularly briefed, notably before major events and at key stages of international negotiations. In light of my support for a right of initiative for the Parliament, you should work closely with the relevant Committees, and be active and present during the preparation of resolutions requesting that the Commission legislate.

The more we build a consensus when designing policy, the quicker it can become law and make a difference to people’s lives. This is why we need an open and cooperative approach throughout the legislative process, from policy design to final agreement. I will expect you to attend all political negotiations, known as trilogue meetings, with the other institutions.

We need to ensure that regulation is targeted, easy to comply with and does not add unnecessary regulatory burdens. The Commission must always have the leeway to act where needed. At the same time, we must send a clear signal to citizens that our policies and proposals deliver and make life easier for people and for businesses.

In this spirit, the Commission will develop a new instrument to deliver on a ‘One In, One Out’ principle. Every legislative proposal creating new burdens should relieve people and businesses of an equivalent existing burden at EU level in the same policy area. We will also work with Member States to ensure that, when transposing EU legislation, they do not add unnecessary administrative burdens.

Proposals must be evidence based, widely consulted upon, subject to an impact assessment and reviewed by the independent Regulatory Scrutiny Board. You will ensure that they respect the principles of proportionality and subsidiarity and show the clear benefit of European action.

Given that any legislation is only as good as its implementation, I want you to focus on the application and enforcement of EU law within your field. You should provide support and continuous guidance to Member States on implementation, and be ready to take swift action if EU law is breached.

Bringing Europe closer to home

I want to strengthen the links between people and the institutions that serve them, to narrow the gap between expectation and reality and to communicate about what Europe is doing.
We must engage with all Europeans, not just those who live in the capitals or are knowledgeable about the European Union. I will expect you to visit every Member State within the first half of our mandate at the latest. You should meet regularly with national parliaments and take part in Citizens’ Dialogues across our Union, notably as part of the Conference on the Future of Europe.

A stronger relationship with citizens starts with building trust and confidence. I will insist on the highest levels of transparency and ethics for the College as a whole. There can be no room for doubt about our behaviour or our integrity. The Code of Conduct for Commissioners sets out the standards and the rules to follow.

You will ensure budgetary spending represents value for taxpayers and follows the principles of sound financial management.

Making the most of our potential

The gender-balanced College I am presenting today makes good on my pledge to put together a Commission that is more representative and draws on all of our potential. This is a good start, but there is plenty more work to be done.

I expect you to draw on all of Europe’s talents when it comes to setting up your own Cabinets. That means striking an appropriate balance in terms of gender, experience and geography.

The Commission should also lead by example when it comes to ensuring better representation and a diversity of voices in our public life. With this in mind, all public events organised by the Commission should aim to feature gender-balanced panels and a broad range of perspectives from across Europe.

Your mission

I would like to entrust you with the role of Commissioner for Health.

Europeans expect the peace of mind that comes with access to healthcare, safe food to eat and protection against epidemics and diseases. Europe has some of the world’s highest standards on animal and plant health, as well as the most affordable, accessible and high-quality health systems to deliver on these expectations.

At the same time, we are becoming an older society and need more complex and expensive treatments. This brings into sharp focus the need to support the health sector and the professionals working within it, to invest in new technologies, to promote healthy lifestyles and to cooperate better within the EU.
Protecting and promoting public health

Your task over the next five years is to support Member States in constantly improving the quality and sustainability of their health systems. You should find ways to improve information, expertise and the exchange of best practices for the benefit of society as a whole.

- I want you to look at ways to help ensure Europe has the supply of affordable medicines to meet its needs. In doing so, you should support the European pharmaceutical industry to ensure that it remains an innovator and world leader.

- I want you to focus on the effective implementation of the new regulatory framework on medical devices to protect patients and ensure it addresses new and emerging challenges.

- We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.

- Many of today’s epidemics are linked to the rise or return of highly infectious diseases. I want you to focus on the full implementation of the European One Health Action Plan against Antimicrobial Resistance and work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.

- I want you to prioritise communication on vaccination, explaining the benefits and combating the myths, misconceptions and scepticism that surround the issue.

- I want you to put forward Europe’s Beating Cancer Plan to support Member States to improve cancer prevention and care. This should propose actions to strengthen our approach at every key stage of the disease: prevention, diagnosis, treatment, life as a cancer survivor and palliative care. There should be a close link with the research mission on cancer in the future Horizon Europe programme.
Food safety and animal and plant health

Your work on food safety, animal welfare and plant health will play an important role in delivering on the European Green Deal.

- I want you to lead on a new ‘Farm to Fork’ strategy for sustainable food. This will cover every step in the food chain from production to consumption, and feed into our circular economy objectives. It should combine regulation with communication and awareness campaigns and have full buy-in from local, regional and sectoral actors, as well as Member States and European institutions.

- As part of delivering on our zero-pollution ambition and ‘Farm to Fork’ strategy, I want you to work on protecting plant health, reducing dependency on pesticides and stimulating the take-up of low-risk and non-chemical alternatives. You should help protect citizens from exposure to endocrine disruptors.

- Part of your work will be to focus on improving consumer information, notably by looking at ways to address demands for more visible and complete information, especially on the health and sustainability of food products.

- Animal health and welfare is a moral, health and economic imperative. You will ensure Europe is equipped to prevent and fight against animal diseases that can be transmitted. You should also ensure the enforcement of animal welfare legislation, review our current strategy and promote European standards globally.

- I want you to focus on the implementation and enforcement of the extensive legislation in the areas of food safety and animal and plant health. Audits will be a crucial tool for this, notably to ensure that food imports meet our safety standards.

- You should work with the Member States to develop a strategy with concrete measures against food fraud, drawing on the work of the European Anti-Fraud Office in this area.

As a rule, you will work under the guidance of the Executive Vice-President for the European Green Deal on issues relating food safety, animal and plant health, and the Vice-President for Protecting our European Way of Life on public health matters. The Directorate-General for Health and Food Safety will support you in your work.
The way forward

The mission outlined above is not exhaustive or prescriptive. Other opportunities and challenges will no doubt appear over the course of the next five years. On all of these issues, I will ask you to work closely with me, and with other Members of the College.

Once there is more clarity, we should be ready to pave the way for an ambitious and strategic partnership with the United Kingdom.

I look forward to working closely together at what is an exciting and testing time for our Union. You can of course count on my full personal and political support ahead of your hearing at the European Parliament and throughout our mandate.

Yours sincerely,

Ursula von der Leyen
President-elect of the European Commission
What does the European Union mean for health? What can it mean for health?

This comprehensively revised third 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.

The authors

Scott L. Greer – University of Michigan School of Public Health and European Observatory on Health Systems and Policies.
Sarah Rozenblum – University of Michigan and European Observatory on Health Systems and Policies.
Nick Fahy – RAND Europe and European Observatory on Health Systems and Policies.
Eleanor Brooks – University of Edinburgh.
Holly Jarman – University of Michigan.
Anniek de Ruijter – University of Amsterdam.
Willy Palm – WHO Regional Office for Europe.
Matthias Wismar – European Observatory on Health Systems and Policies.

Health Policy Series No. 59