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

34
Observatory Studies Series

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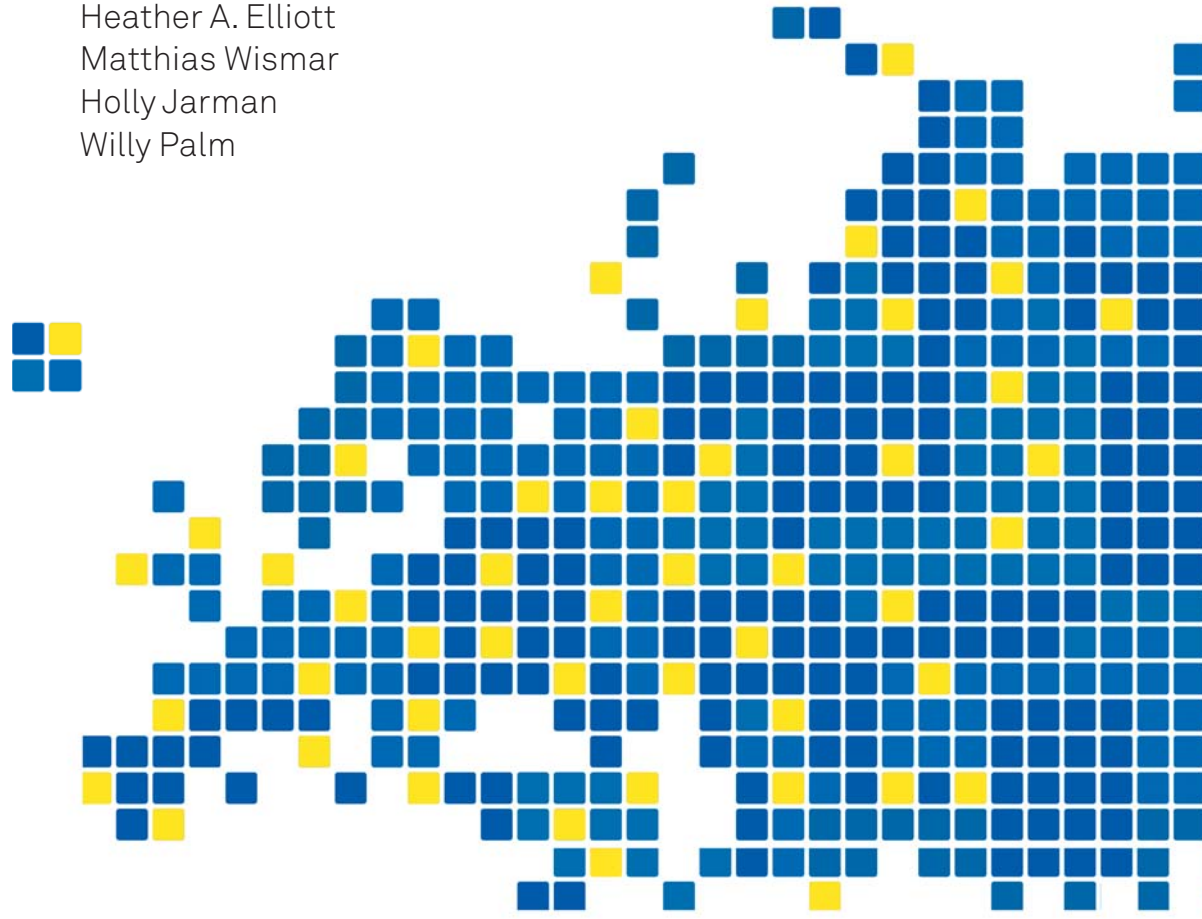

European Observatory on Health Systems and Policies
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Everything you always wanted to know about European Union health policies but were afraid to ask

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.

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List of acronyms and abbreviations

AIDS	Acquired immunodeficiency syndrome
CAP	Corrective Action Plan, also Common Agricultural Policy
CDC	US Center for Disease Control and Prevention
CJEU	Court of Justice of the European Union (was European Court of Justice, ECJ)
CSR	Country-Specific Recommendations
DG	Directorate-General
DG SANCO	Directorate-General for Health and Consumer Protection
EAP	Economic Adjustment Programme (aka Memorandum of Understanding)
ECB	European Central Bank
ECDC	European Centre for Disease Control and Prevention
ECFIN	Directorate-General for Economic and Financial Affairs
EDP	Excessive Deficit Procedure
EFSA	European Food Safety Authority
EIB	European Investment Bank
EMA	European Medicines Agency
ESAs	European Supervisory Authorities (comprising the European Securities and Markets Authority, the European Banking Authority and the European Insurance and Occupational Pensions Authority)
EU	European Union
Eurostat	EU Statistics Agency
GDP	Gross domestic product
HIV	Human immunodeficiency virus
IMF	International Monetary Fund

MEP	Members of the European Parliament
MIP	Macroeconomic Imbalance Procedure
OMC	Open Method of Coordination
PPP	Public–private partnership
QMV	Qualified majority voting
RQMV	Reverse qualified majority voting
SARS	Severe acute respiratory syndrome
SGEI	Services of general (economic) interest
SGP	Stability and Growth Pact
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Agreement on Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
TPD	Tobacco Products Directive (2014/40/EU)
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TSCG	Treaty on Stability, Coordination and Governance in the Economic and Monetary Union
WHO	World Health Organization

Summary

The idea of "European Union health policy" has always been somewhat paradoxical. On the one hand, the founding treaties of what has become the European Union (EU) included no specific EU article for health until 1992, and even then the role for the EU was a deliberately limited one. The absence of health from early treaties, and the limited provisions of the specific treaty article on health (Article 168 of the Treaty on the Functioning of the European Union (TFEU)), left the primary role to national regulation. On the other hand, there have been other provisions related to health as far back as the founding treaties in the 1950s, such as the coordination of social security systems, ensuring access to health care for migrant workers moving between EU Member States, and a strong role improving health in areas such as the environment and health and safety at work.[1] As a result, EU health policy has always been paradoxical. Its extensive internal market, regulatory and spending policies have a substantial and increasing impact on public health and health systems.

Understanding EU health policy is, therefore, particularly tricky. There is no single strategy with a neat body of legislation implementing it; rather, there are many different objectives and instruments, some of which appear in surprising places. How can all these different strands be drawn together into a single picture of what the EU means for health?

That is the aim of this book. It begins by describing the overall structure, processes and powers of the EU as they relate to health – those provisions that have a direct health objective (the health article itself, and also the EU's powers on the environment, health and safety at work, and consumer protection), as well as provisions in the treaties that pursue other objectives but nevertheless also have a major impact on health, in particular the internal market, the coordination of social security systems and the post-crisis strengthening of oversight of national budgets by the EU. The book focuses on the aspects of the EU that most affect health systems in Europe, with less discussion of EU policies that affect health indirectly (as with environmental protection) or that focus on health systems outside the EU (as with foreign aid). This book is aimed at policy-makers and

1 Treaties establishing the European Communities (and amending treaties and the Single European Act). Luxembourg, Office for Official Publications of the European Communities, 1987; see in particular Articles 36 and 51 of the Treaty establishing the European Economic Community.

students of health systems in the EU who want to understand how the EU affects those systems and their patients.

The book describes how these powers have come to be used and what this means for health. Chapter 3 focuses on the powers explicitly pursuing a health objective. The chapter describes how the EU has worked to improve health, and how those efforts have evolved from a few marginal initiatives to a specific treaty article and a wide-ranging set of activities. These activities cover the major determinants of health: tobacco, alcohol, diet and nutrition, environmental determinants, social determinants, injuries and other external causes, and misuse of drugs. There have also been disease-specific strategies, in particular for cancer, communicable diseases and rare diseases, being taken further now into a more general approach for chronic diseases. An underappreciated but important area of EU policy facilitates comparisons and benchmarking between European countries through developing data and indicators on health. Substances of human origin (blood and blood products, organs, tissues and cells) have their own legislative standards for quality and safety, and this illustrates how domestic crises can drive pressure for European action. And despite the ever-present sensitivities about European involvement in health care, there is action focused on health systems such as on patient safety, quality of care and health technology assessment.

The EU's impact on health is not limited to those parts of the treaties that have health as a specific objective – far from it. In many ways, the EU's greatest impact has been caused by EU actions that are justified by or aim at quite different objectives. Chapters 4 and 5 describe these more surprising areas. The internal market, subject of Chapter 4, has long had important consequences for health – most recently by providing explicit legislation on cross-border health care but historically across all its dimensions of free movement: services (including competition rules), goods (such as medicinal products and medical devices, as well as providing a basis for health legislation such as tobacco advertising), people (the mobility of health professionals being a key challenge) and capital (with the EU playing an increasing role in investing in health infrastructure). Health is the largest single topic within the EU's research budget and has also been addressed through social policy, in particular the "Open Method of Coordination" (OMC). Given this remarkable range of impacts on health, it is inevitable that questions will be asked about how well the EU takes health into account across this wide range of issues. Chapter 5 focuses on the new EU fiscal governance regime and its implications for health. Although the EU's overall strategy sees health as a positive contributor to growth, it also reveals concern about the cost of health systems to public finances, and the reinforced EU oversight of national budgets has fundamentally shifted the balance of power over health systems. As the EU's role strengthens, notably with the strengthening of fiscal governance, there are signs of tensions within

the EU institutions, which suggest that different institutional structures may be needed in the future.

Overall, the EU has done much to improve health, in particular by addressing environmental determinants; European citizens are among the best protected in the world in terms of exposure to chemicals or pollution, for example. The EU has made some progress in addressing key social determinants such as working conditions, but the impact of wider social inequalities on health remains.[2] This cannot be blamed on a lack of legal powers to act (unlike health, the social powers in the treaties are wide ranging) but rather on a clear preference by national governments to address social issues domestically rather than at European level. The EU has likewise made some progress in addressing the behavioural determinants of health, but most strongly for smoking. For diet and exercise, and the particularly European issue of alcohol, European action has been limited to providing information and leaving choices to individuals.

For the future, there are two key issues. Demographic ageing and the shift towards chronic conditions will be pivotal for health systems and their organization, meaning challenges about how to pay for health and social care and also how to provide it. Linked to this is the issue of the ageing health workforce; as the working-age population declines, how can we ensure that health systems still have the health professionals that they need throughout Europe?

The second issue is the fundamental shift in power towards the European level brought about by the financial crisis, and its consequences for health systems. The content of this impact is difficult to predict, not least because the evidence base for European analysis of health systems is largely lacking. Similarly, how this will affect related decision-making is unclear. At present, this issue is a clear example of the constitutional asymmetry that exists in the EU. This asymmetry has meant that the EU is much better equipped – by the Member States that signed its treaties – to create markets and regulate them, and promote its single currency, than it is to enact and finance compensating social, health or redistributive legislation. Fiscal governance so far has meant an increased role for Member State and EU finance officials, with limited health expertise and an interest primarily in budgetary rigour, taking decisions about Member State health budgets at tables that do not include health expertise and advocates. Just as it took time for health policy-makers, managers, analysts and professionals to grasp the unfamiliar forces of internal market or competition law that were affecting their systems, they now must start to understand the fiscal governance system that purports to shape health policy in the interests of fiscal rigour and efficiency.

2 Marmot M et al. WHO European review of social determinants of health and the health divide. *Lancet,* 2012, 380(9846):1011–1029; Mackenbach JP. The persistence of health inequalities in modern welfare states: the explanation of a paradox. *Social Science and Medicine,* 2012, 75(4):761–769.

One thing is clear. The impact of the EU on health is substantial and it is only likely to increase. It could hardly be otherwise, given how important both health and the EU are within the economies and societies of EU countries. To ensure that this impact is as positive for health as possible, it is essential that the wider health community understands and engages with the EU in the future. We hope that this book will help that to happen.

Chapter 1

Introduction

The idea of "European Union health policy" has always been somewhat contradictory. On the one hand, the founding treaties of what has become the EU set no specific EU objective for health until 1992, and even then the role for the EU was a deliberately limited one. On the other hand, there have been provisions related to health as far back as the founding treaties in the 1950s, such as the coordination of social security systems ensuring access to health care for migrant workers moving between EU Member States, and a strong role improving health in areas such as the environment and health and safety at work.[1] As a result, there are only limited provisions in the specific treaty article on public health, leaving the primary role to national regulation; alongside that are extensive internal market, regulatory and spending policies having a clear and substantial impact on public health and health systems.

This book aims to describe the reality of the EU's health policies, bringing together the range of EU activities that are relevant for health, whether they are explicitly being carried out in the name of health or not. Chapter 2 details the overall structures and processes of the EU as they relate to health: the key political institutions of the EU, its powers related to health, the "constitutional asymmetry" that makes it better at market integration than market regulation or stabilization, and the tools and processes that it uses. The next three chapters discuss the three faces of EU health policy.[2] Chapter 3 discusses the first face of the EU, examining the development of the EU's actions for health, how these powers have evolved and the main areas of action. Chapter 4 presents the second face of EU health policy: EU actions that are not working towards health objectives as such but which nevertheless have a substantial impact on health, such as increasing budgetary oversight of public finances at European level and the development of the internal market. Chapter 5 presents the third face of EU health policy: the development of

1 Treaties establishing the European Communities (and amending treaties and the Single European Act). Luxembourg, Office for Official Publications of the European Communities, 1987; see in particular Articles 36 and 51 of the Treaty establishing the European Economic Community.

2 Greer SL. Glass half empty: the eurozone and internal market overshadow the health effects of Maastricht. *European Journal of Public Health,* 2013, 23(6):907–908; Greer SL. The three faces of European Union health policy: policy, markets and austerity. *Policy and Society,* 2014, 33(1):13–24.

fiscal governance and its consequences for health and long-term care decisions in the Member States. Chapter 6, a short conclusion, gives an overall assessment of the EU's impact on health and highlights some important issues for the future.

Chapter 2

The EU: institutions, processes and powers

This chapter introduces the EU institutions and a few key points for the analysis and interpretation of EU health policy. For health policy-makers, there are a number of key points that emerge.

The first is that the EU's impact on health and health care has been mostly indirect and limited, although one of the consequences of the recent financial crisis has been to increase its direct influence. The limited action on health and health care comes about for deep legal and political reasons. Despite consensus on the importance of health and health care constituting one of Europe's most distinctive features,[1] 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.[2] 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

How to get hold of EU documents

The official documents of the EU can be accessed through the EUR-Lex database (http://new.eur-lex.europa.eu/homepage.html). Given the vast numbers of documents, the challenge is finding the right one. The easiest way to do this is to use the specific number of the document concerned (documents adopted by the institutions all have their own reference numbers). The other easy way is via the *Official Journal of the European Union*, which prints all legislation and most other official documents of the EU in all 24 official languages, published daily. The *Official Journal* (OJ) references give the series (L for legislation, C for information and notices) and number (perhaps with the specific page of the document – this will be the same in all languages) together with the date of publication. This book provides these *Official Journal* references wherever possible so that the documents can be accessed directly.

1 Council of the European Union. Council conclusions on common values and principles in European health systems. *Official Journal,* 2006, C 146:1–4.

2 OECD. *Health at a glance: Europe 2012*. Paris, Organisation for Economic Co-operation and Development, 2012.

environment policy), the integration of the internal market (through issues such as cross-border health care 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 thorough the extension of single market law.[3]

Despite this asymmetry in the EU's approach towards health, the EU does have a substantial range of policies that affect health, and an increasing number of initiatives that try to promote health or counteract potentially unhelpful effects of other policies on health. These are discussed at some length in Chapters 3 and 4 below.

2.1 European political institutions

The EU has four core institutions: an executive (the European Commission), two legislative bodies (the European Parliament, with members (MEPs) elected by direct vote in each Member State, and the Council of Ministers, comprising national ministers from each Member State) and a court.

2.1.1 European Commission

The executive body of the EU is the European Commission. The European Commission is made up of individual commissioners, one from each Member State (although this number may be reduced as of the new Commission to be appointed in 2014),[4] and appointed by agreement between the parliament and the Council. 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.[5] The most obvious actor for health and health systems is the DG for Health and Consumer Protection, known from its acronym in French as DG SANCO. It is responsible for EU policies in those two areas, which include cross-border health care, tobacco control, food safety and, more recently, pharmaceuticals and medical devices (which were moved over from the reputedly more pro-industry DG Enterprise). Other DGs have more specialized but consequential roles to play for health systems. Each of the policy areas that lead to their involvement will be discussed in this report:

3 European Commission. *Europe 2020: a strategy for smart, sustainable and inclusive growth*. Luxembourg, Publications Office of the European Union, 2010.

4 Council of the European Union. Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal*, 2012,C 326:1–12; Treaty on European Union, Article 17.

5 For a complete list, see European Commission. *Departments (Directorates-General) and service*s. Brussels, European Commission, 2014 (http://ec.europa.eu/about/ds_en.htm, accessed 14 July 2014). This structure may change with the arrival of the new Commission towards the end of 2014.

- DG Research and Innovation is in charge of the substantial EU research budget, which often finances biomedical and health-related research;
- DG Regional Policy is responsible for managing structural funds, the EU's regional development aid system, which is important to the finances of recipient regions and finances substantial health infrastructure;
- DG Competition is responsible for the development and application of competition law and state aids, which has touched on the organization of health care in a variety of cases;
- DG Communication Networks, Content and Technology is a major funder and policy-maker in health information technology and e-health;
- DG Internal Market and Services is the guardian of the internal market law and its enforcement, which made it a major part of the story of cross-border patient mobility;
- DG Employment, Social Affairs and Inclusion 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 health care; and
- DG Trade negotiates for the EU in its international trade dealings, including with the World Trade Organization and in bilateral trade agreements.

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, its important development, crisis response and, in some cases, neighbourhood policies, all of which influence global health, are the responsibility of DG Europe Aid Development and Cooperation, DG Humanitarian Aid and Civil Protection and DG Enlargement, 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), between the cabinets of the commissioners and through collective consideration by the College of Commissioners themselves.

By the standards of the national government of a large country such as the United Kingdom or France, say, the Commission is a relatively small body (although at 32 666 staff[6] 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 drive buses. The Member States do the implementation and much of the actual detailed policy formulation, in a system of outsourcing that makes the EU a remarkably efficient policy-making mechanism.[7] The Commission also has what is termed the "right of initiative". EU legislation, although decided by the Council and parliament, can only begin with a Commission proposal, which gives the Commission enormous influence in shaping what is ultimately decided. The Commission does not just act through legislative proposals, of course; it typically announces its priorities and approaches to its responsibilities in *Communications*, as well as using tools such as financing, and it has the power to take its own direct decisions in some areas, in particular for competition rulings.

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 transposition of EU legislation into Member State law and warning Member States 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 (CJEU) over failure to implement and obey EU law.

The legislative processes and the voting procedures that underwrite them (qualified majority voting (QMV) and reverse qualified majority voting (RQMV)) are outlined in Box 2.1.

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 colegislator 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.[8] No single

6 European Commission. *Human resources key figures card: staff members*. Luxembourg, Publications Office of the European Union, 2013.

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

8 See European Parliament. *Composition of parliament*. Luxembourg, European Parliament, 2014 (http://www.europarl.europa.eu/aboutparliament/en/004a50d310/Composition-of-Parliament.html., accessed 14 July 2014).

Box 2.1 *EU legislative processes*

The "ordinary legislative procedure", also known as "co-decision", starts with a Commission legislative proposal. The proposal is sent to the Parliament, which may amend it in a "first reading". 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. 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 (15 being a majority at the moment). Most votes use the qualified majority voting (QMV) rules, requiring 260 votes from at least 15 Member States. Some issues, such as regulation of social security (which includes the European Health Insurance Card) require unanimity in the Council. Fiscal governance issues sometimes require the newest voting rule, reverse qualified majority voting (RQMV), in which a qualified majority is required to reject the Commission proposal; this is a rule designed to strengthen the Commission. The Treaties spell out the voting rules for each issue. The treaties include a *passerelle* clause allowing voting rules to be changed from special to the ordinary legislative procedure, meaning to replace unanimity rules with QMV.

How to follow negotiations between the EU institutions

The European Parliament provides a "Legislative Observatory" (online at http://www.europarl.europa.eu/oeil/home/home.do) to enable the process of a particular legislative proposal to be followed in detail. The process can be followed in all the institutions from the Commission's initial proposal, and the current position can be seen. With some knowledge of the decision-making processes of the institutions, this provides an excellent overview and access to the individual documents and positions along the way.

political group has a majority within the parliament, and so decision-making in practice requires considerable collaboration across political groups.

Over time, the parliament has been gaining power, with more and more areas subject to ordinary legislative procedure (also known as co-decisions; see Box 2.1), 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.

Political groups in the 2014–2019 European Parliament and percentage of members

Group of the European People's Party (Christian Democrats): 29.4%

Group of the Progressive Alliance of Socialists and Democrats in the European Parliament: 25.4%

Alliance of European Conservatives and Reformists: 8.4%

Group of the Alliance of Liberals and Democrats for Europe: 7.9%

Group of the Greens/European Free Alliance: 7.1%

Confederal Group of the European United Left/Nordic Green Left: 6.9%

Greens: 7.1%

Europe of Freedom and Democracy: 6%

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, 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 the 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.

2.1.3 Council of Ministers and the European Council

The second EU legislative body is the Council of Ministers. This is made up of the relevant ministers from each Member State meeting in one of 10 topic-specific configurations (e.g. a Health Council will be composed of the ministers responsible for health);[9] 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

9 See Council of the European Union. *Council configurations*. Brussels, Council of the European Union, 2014 (http://www.consilium.europa.eu/council/council-configurations?lang=en, accessed 14 July 2014).

take account of the full range of views domestically (e.g. if health-related expenditure is being discussed in the Budget Council). Given that the Member States (and indeed the Commission) face the usual coordination problems of big bureaucracies and handle them with variable success,[10] 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. A pivotal role is that 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 (Table 2.1).[11] 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 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.[12]

Table 2.1 *Order of Presidencies of the Council of Ministers*

Period	Country
2014 (first half)	Greece
2014 (second half)	Italy
2015 (first half)	Latvia
2015 (second half)	Luxembourg
2016 (first half)	Netherlands
2016 (second half)	Slovakia
2017 (first half)	Malta
2017 (second half)	United Kingdom
2018 (first half)	Estonia
2018 (second half)	Bulgaria
2019 (first half)	Austria
2019 (second half)	Romania
2020 (first half)	Finland

10 The classic articulation of the problem is seen in Wright V. The national co-ordination of European policy-making: negotiating the quagmire. In: Richardson JJ, ed. *European Union: power and policy-making.* London, Routledge, 1996; see also Greer SL. Standing up for health? Health departments in the making of EU policy. *Social Policy and Administration,* 2010, 44(2):208–224.

11 Council of the European Union. Decision of 1 January 2007 determining the order in which the office of President of the Council shall be held. *Official Journal,* 2007, L 1/11.

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

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 Ministers (and cannot adopt legislation, for example), but as it is made up of the most powerful political figures in Europe, it has a leadership role in setting the overall direction of the EU and brokering solutions to its most intractable problems. Unlike the rotating Presidency of the Council of Ministers, the European Council has an elected president. A new President will take office at the beginning of December 2014.

There are a variety of types of EU legal instrument specified in the treaties, and the differences between them are legally and politically significant (Box 2.2).

2.1.4 Court of Justice of the European Union

Finally, the EU has a court. The CJEU was formerly known as the European Court of Justice and it is the most powerful supranational court in history.[13] It is made up of judges nominated by the Member States, sitting in Luxembourg. It is the final arbiter of EU law. 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 on 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 2.3). EU law has direct effect, meaning that it is directly applicable in Member States even if the Member State has not transposed it into domestic legislation, and supremacy, meaning that it overrides Member State law (with only a few qualifications, every EU Member State court has accepted both of these doctrines). 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. 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 health care 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 health care outside their home country.[14]

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

14 Obermaier AJ. The national judiciary: sword of European Court of Justice rulings – the example of the Kohll/Decker jurisprudence. *European Law Journal,* 2008, 14(6):735–752.

Box 2.2 *Types of EU legal instrument*

Regulations and directives

Regulations and directives are the EU's principal legal instruments. A regulation, once passed, is directly applicable. In health, a key regulation of relevance is that on coordination of social security systems, which also includes provisions on people receiving health care in other Member States. Regulations are also used to establish agencies, such as the European Medicines Agency. A directive 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

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. 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.[1]

Delegated and implementing acts

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. The exact procedures vary according to the specific legislation concerned; these used to be collectively termed *comitology*, but the term is becoming increasingly outdated. Changes following the Lisbon Treaty are replacing comitology with two new categories of secondary legislation, *delegated acts* and *implementing acts*, each with their own procedure. For example, no approval by a committee is compulsory for delegated acts, but the Parliament and Council have the opportunity to raise objections directly; implementing acts are similar to the previous *comitology* procedures, although somewhat simplified.

Social partners

An alternative legislative method allows the *social partners*, sectoral representatives of employers and labour, to negotiate legislation with each other 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).[2]

1 Page EC. The European Commission bureaucracy: handling sovereignty through the back and front doors. In Hayward J, Wurzel R, eds. *European disunion: between sovereignty and solidarity.* Basingstoke, Palgrave Macmillan, 2012.

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

Box 2.3 *EU legal tools and concepts*

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 a number of 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.[1] It is often used with a measure of harmonization that sets the floor: so the EU has mutual recognition of medical qualifications combined with limited harmonization of the requirements for getting 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 if 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.*[2]

Direct effect. Individuals may rely on rights provided by EU law directly (under certain circumstances), whether or not their Member State 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).

Precedence. The CJEU has also developed the doctrine of precedence, meaning that EU law is superior to Member States' law, and if a Member State law contradicts EU law, then the EU law is what shall be applied.

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1 Kalypso N. Globalization with a human face: managed mutual recognition and the free movement of professionals. In: Kostoris F, Schioppa P, eds. *The principle of mutual recognition in the European integration process.* Basingstoke, Palgrave Macmillan, 2005.

2 European Court of Justice. Case C-120/78 *Cassis de Dijon*.

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 the EU should not do things that the Member States could do better; whether Member States choose to go on and decentralize themselves is their business.

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

2.1.5 Other treaty bodies

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 it making loans to the 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-State 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.

The EU legislative process also includes the Economic and Social Committee, which represents social partners (employers and workers), and the Committee of the Regions, which agglomerates the opinions of subnational governments (and which the Commission sometimes uses to get a sense of how regional governments feel about legislative proposals). Both are strictly advisory, although consultation with them is mandatory in some areas of policy specified in the treaties.

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 Control and Prevention

(ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Monitoring Centre for Drugs and Drug Addiction, the European Environment Agency and the European Agency for Safety and Health at Work. (With a slightly different legal status, there is also the Consumers, Health and Food Executive Agency, formerly the European Agency for Health and Consumers, to which the Commission has delegated the implementation of the health programmes.)

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. At their most powerful, as with EFSA and EMA, they make technical assessments of issues such as medical device and drug safety, or food nutritional claims, and then control the documentation and access to market of different products.

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 staffing limits and priorities of the civil service (in this case, the Commission) and can 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 means that they can be trusted to carry out their tasks with a limit on their political engagement. Rightly or wrongly, Member States often express the view that the Commission will use any resources or mandates to expand its power.[15] Agencies' governing boards 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) and 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 oversee; 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.

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

2.1.7 How do the 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 that it is having on health and guides its action accordingly?

The Commission's answer has been discussed above and is returned to in section 3.6.1 on Health in All Policies.[16] 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).

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.[17] 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 (as described in 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 – all the subjects in Chapters 4 and 5, in principle – 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. One particularly striking and topical example of this is the impact of the European Semester process on health (see section 5.5), where health representatives from several Member States are pressing for a stronger direct engagement of health representatives in the process at EU level, while other countries are resisting any change to the current institutional processes.[18]

16 Ståhl T et al., eds. *Health in all policies: prospects and potentials*. Helsinki, Ministry of Social Affairs and Health, 2006.

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

18 General Secretariat of the Council. *Working party on public health at senior level on 8 October 2013*. Brussels, Council of the European Union, 2013.

In an attempt to increase transparency and policy coherence, the concept of a roadmap" has been proposed (Box 2.4).[19]

Box 2.4 *Commission proposal development*

In an attempt to increase transparency and policy coherence, the Barroso Commission introduced a requirement in policy-making that includes publishing the intention to present a proposal at the earliest stage on a publicly accessible roadmap.[1] Legislative and other important proposals should be introduced by a consultative document, followed by a public consultation and a Commission impact assessment focusing on economic, environmental and social aspects (including impact on public health and health systems under the social pillar). Any important proposal needs to pass the impact assessment board, composed of directors from the coordinating DGs and the economic, environmental and social DGs before it can be agreed internally.

1 European Commission. *2013 roadmaps*. Luxembourg, Publications Office of the European Union, 2013 (http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2013_en.htm#SANCO, accessed 4 July 2014).

2.2 Constitutional asymmetry

In essence, constitutional asymmetry refers to the imbalance in legal competencies and procedures provided by the treaties with regards to economic and social policies: EU activity in economic areas is not always matched by social action. In every political system, some things are easier and some things are harder. In the EU, the relatively easy task is to use its legal system to promote the "four fundamental freedoms": the free movement of goods, services, capital and people within the internal market. The EU treaties have strong and solid provisions, emphasized by a large CJEU jurisprudence and often called "constitutional" by EU lawyers, for laws that promote the Four Freedoms. There is a long record of legislation and court cases that carry out that objective, sweeping away Member State policies that had the effect of discriminating against other Member States' goods, services, capital and people in the eyes of courts, Commission or ordinary plaintiffs. There are also a number of other areas where EU law is powerful, such as trade policy (see section 3.5.1); social policy, including labour law; and much environmental policy, where its treaty powers are relatively strong. The EU's strongest powers are mostly to deregulate, and, if necessary, reregulate at the European level.

Against this are the areas where it is harder to see EU-wide governance, for a variety of reasons. As described above, the constituent countries of the EU have chosen not to give the EU strong powers to pursue health objectives (at least directly), preferring to address health issues principally at national level.

19 European Commission. *2013 roadmaps*. Luxembourg, Publications Office of the European Union, 2013 (http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2013_en.htm#SANCO, accessed 4 July 2014).

While this is understandable, given the close relationship between health systems and the character of individual societies across Europe, the consequence has been that much of the impact of the EU on health has come from legislation that does not have health as its primary objective, as section 3.1 describes in more detail.

The book *Health Systems Governance in Europe: The Role of EU Law and Policy* looks into different areas of EU policy and law-making that have an impact on national health care systems.[20] It provides a compelling and rigorous analysis of the real and potential impacts of EU integration on the organization of health care provision and the protection of public health, highlighting the need to balance economic and social imperatives.

Many areas are difficult because they actually do require EU legislation. The process of developing sufficient consensus and technical content for the Commission to make a proposal for legislation is lengthy and complex, with increasing scrutiny to demonstrate its utility and necessity. Although some kind of legal solution is almost always agreed once legislation is proposed, laws do not necessarily gain coherence or strength after they have been voted for and negotiated by a Council and parliament that have different interests and mandates. The quantity of EU legislation has also been declining in recent years and it is harder still to change the treaties. Neither negotiating nor passing a treaty is easy, and Member States have good reason to avoid doing it. The courts, in particular, have used the

Health systems governance in Europe: the role of EU law and policy

Edited by Elias Mossialos, Govin Permanand, Rita Baeten and Tamara K. Hervey

Cambridge University Press, 2010

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-systems-governance-in-europe-the-role-of-eu-law-and-policy

This book offers a state of the art analysis of academic discussion on a number of current and emerging governance issues in EU health care policy, including regulatory, legal, "new governance" and policy-making dynamics.

20 Mossialos E et al. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010.

slowness of legislation and treaty change to create extensive new law, as in the case of cross-border patient rights.

The result is the characteristic "constitutional asymmetry" of many areas of the EU: its powers and structure are focused more on economic market integration and regulation than on policies that require social policy or expenditure.[21] Since the early 2000s, although many areas of potentially beneficial cooperation have been identified, such as patient safety, the limited powers available at European level necessarily constrain any progress in areas that require money and health-specific legislation; this contrasts with great progress in regulation of areas such as patient mobility, which legally comes under the heading of the internal market.

The whole aim of the internal market is to remove barriers rather than to create them, and thus internal market legislation tends to have a liberalizing emphasis. The treaties also incorporate other values, including health, so they require all such rules to "take as a base a high level of [health] protection".[22] This means that even rules intended to remove national barriers typically also involve some common European regulation.[23] In the area of patient mobility, just as in food safety, labour or environmental law, legislation reflects a consensus that a common European legislative framework would be valuable. In many cases and countries, the framework raises standards, in particular for health, reflecting the treaty requirement above; where EU law sets a lower standard than exists in some Member States, it typically allows Member States applying higher domestic standards to keep them, for the same reason.

2.3 EU powers related to health

Everything about the EU – what it is, what powers it has, how things are decided – is ultimately defined in its constituting treaties. This is the fundamental guarantee of accountability of the EU. Each of these treaties has been negotiated and agreed by all the Member States of the EU, and only the powers that they have agreed to provide through the treaties can be used by the EU to take action (although over time, the EU's action in some areas may evolve beyond what the original drafters of the treaties had in mind). Indeed, the first piece of information in any legislation or other action is what is called its "legal base" – the specific part that provides the powers for the action in question. This already provides vital information; by giving a particular article as the legal base of an action, this immediately also makes clear the aims the action is working

21 Scharpf FW. The European social model: coping with the challenges of diversity. *Journal of Common Market Studies*, 2002, 40(4):645–670.

22 Council of the European Union. Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal*, 2012,C 326:1–12; see TFEU Article 114, paragraph 3.

23 Greer SL. *The politics of European Union Health policies.* Maidenhead, UK, Open University Press, 2009.

What are the EU Treaties and where can they be found?

There are two key treaties that together underpin the EU: the Treaty on European Union (TEU), which sets out the general principles and organisation of the EU, and the Treaty on the Functioning of the European Union (TFEU), which sets out the detailed provisions for the different areas. The texts are available from *Official Journal of the European Union* 2012, C 326 of 26.10.2012 (http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:C:2012:326:TOC).

There have actually been dozens of EU treaties, starting with the founding treaties back in the 1950s. There is no need to refer back to all of them; the relevant provisions that still apply have been brought together into the consolidated versions of the TEU and TFEU provided above. Some other treaties also remain in force, but the TEU and the TFEU are sufficient for the purposes of this book.

towards, what powers the EU has to achieve the aim, how any such action will be decided upon and by whom.

Part of the reason why the EU treaties are much longer than the American Federal Constitution, for example, is that all of this is laid down in precise and carefully negotiated detail and is different for each different area. For example, a particular article in the EU treaties – on social policy, say – might only allow binding legislation to achieve some of its objectives, but not others; it might require unanimous agreement on some points but allow majority voting in others; it might share power between the Council and the parliament on some points, but reserve others to the Council alone; or it might even empower the Commission to take some actions directly.

The treaties provide for a gradation of "competencies", meaning authority for EU action. There are exclusive EU competencies, such as some areas of trade and agricultural policy, where the EU is the only actor, just as there are some areas that are exclusive Member State competencies. There is a large, and increasingly growing, sector of policy made up of shared competencies – where the EU and Member States share powers and responsibilities, with the EU frequently involved in a supporting or coordinating role.

2.3.1 Powers with a direct health objective

Before describing EU action on health in more detail, the specific legal bases in the treaties related to health will be examined as these are the basis for all the different actions and areas of activity that will then be described through the rest of the book. Overall, the powers of the EU to take action in pursuit of health is substantially greater under the other provisions of the treaty, as described above, than under the health article itself. There is also scope for the EU to take

measures that include health objectives under provisions that are only indirectly related to health, as described below.

Public health

Right from the introduction of a specific article on health in the Maastricht Treaty (formally the Treaty on European Union) in 1992,[24] the issue with EU powers on health 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.[25] Legally this provision does not really add much to the formal division of powers throughout the treaties, but it highlights the concerns of national governments in drafting the treaty provisions on health.

The division of competencies is summarized at the start of the TFEU, which came into force in 2009. The only relevant area of shared competence between the EU and the Member States is "common safety concerns in public health matters";[26] for the wider objective of the "protection and improvement of human health",[27] the EU may only "support, coordinate or supplement" Member States' action.[28]

The first point to note about the main article (Article 168 of the TFEU, which is reprinted in the Appendix) is that it is not an article on health, but an article on *public* health. This again 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. This is reflected in the objectives of the Article, which are focused towards public health activities and health determinants (tobacco and alcohol being specifically mentioned).

The second point to note is that the powers given to the EU to achieve these public health objectives are very limited. The only area where binding legislation is provided covers concerns of quality and safety standards for substances of human origin, blood and blood derivatives.[29] Article 168 does also provide for the EU to provide financial support for actions more broadly in support of public health,[30] but this of course depends on the budgetary means available, which have in practice also been very limited. The Article does include an

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24 European Communities. *Treaty on the European Union*. Luxembourg, European Communities, 1992 (http://www.eurotreaties.com/maastrichtec.pdf, accessed 4 July 2014).

25 TFEU, Article 168, paragraph 7.

26 TFEU, Article 4, paragraph 2(k).

27 TFEU, Article 6, subparagraph (a).

28 TFEU, Article 6.

29 TFEU, Article 168, paragraph 4.

30 TFEU, Article 168, paragraph 5; "incentive measures" refers to financing tools, not binding legislation.

"integration clause" requiring health protection to be ensured in all EU policies and activities,[31] but this does not in itself provide a basis for additional measures.

There are also some additional and unusual tools provided in Article 168. One is the power for the Council of Ministers to adopt recommendations in support of the objectives of the Article. These recommendations are non-binding legal acts; while these are not exactly the most powerful of instruments, they have been used to good effect in the health area, such as establishing a European commitment to cancer screening.[32]

Another unusual power is the provision 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".[33] This type of non-legislative cooperation (otherwise known as the OMC) has been mostly applied in the social policy area; so far it has not been widely used in the health area.

Environment

As set by the treaties, the EU has broad objectives for the environment, which includes health:[34]

> 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 (emphasis added).

The powers to achieve this objective are wide ranging (unlike the health article), 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.[35] Like health, environment also has an "integration clause",

31 TFEU, Article 168, paragraph 1; see also Article 9.
32 Council of the European Union. Council recommendation 2003/878/EC on cancer screening. *Official Journal*, 2003, L 327/34.
33 TFEU, Article 168, paragraph 2.
34 TFEU, Article 191, paragraph 1.
35 TFEU, Article 192.

requiring environmental protection requirements to be integrated throughout the EU's policies and activities.[36]

Health and safety at work

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".[37] 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 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."[38]

For social policy, the EU has developed some unusual additional tools to accomplish its objectives. As well as standard legislation, the EU has developed a form of cooperation that effectively allows Member States to work together on issues where they hold them in common but they are too sensitive or too national for European legislation: the OMC approach is based on setting common objectives, sharing information, benchmarking and monitoring progress; unlike health policy (which also has specific provision for such cooperation), this has become a major means of action in the social policy area, including for health systems.

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.[39]

Consumer protection

The objectives of the EU on consumer protection also include contributing to "the *health*, safety and economic interests of consumers" (emphasis added).[40] These objectives are principally achieved through internal market legislation; consequently, 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. Examples include food safety, labelling and nutritional health claims.

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36 TFEU, Article 11.
37 TFEU, Article 153, paragraph 1(a).
38 TFEU, Article 153, paragraph 2(b).
39 TFEU, Article 153.
40 TFEU, Article 169.

2.3.2 Powers indirectly related to health

The EU has been granted a range of useful powers, but the EU was born in economic integration and its most powerful legal bases are in areas such as promotion of the internal market rather than health.

Internal market

Over time, the core of the EU has been its internal market; an area within which goods, services, people and capital should be able to move freely without being hindered by national borders or regulations. Health being such a significant part of the economy as well as of society, any such project of economic integration also has a major impact on health and the goods and services related to it.

The powers of the EU to achieve this internal market are correspondingly broad:[41]

> 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.

The need to protect health while legislating to create this internal market is recognized:[42]

> 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 (emphasis added).

In addition the clause "the protection of health and life of humans"[43] recognizes protecting health also as a reason to limit free movement. However, the key point here is that, while these powers require health considerations to be taken into account, health is not the objective as such. In practical terms, this means that, while internal market legislation can provide a powerful basis for establishing free movement in ways that also achieve health objectives (e.g. setting standards for pharmaceutical products), internal market legislation is harder to use where the health objective is to prevent or restrict something being sold (e.g. in relation to tobacco or alcohol), as will be discussed in more detail below.

41 TFEU, Article 114, paragraph 1.
42 TFEU, Article 114, paragraph 3.
43 TFEU, Article 36.

Coordination of social security systems

Very early in the history of the EU, policy-makers set out to promote labour mobility (for some of the original EU Member States, such as Italy, labour mobility under good circumstances for their citizens was a major purpose of integration).[44] The third law passed by the new European Economic Community, Regulation 3, was about the coordination of social security mechanisms. This was intended to ensure that as people built up rights to social protection linked to their employment those rights were not lost if they moved to another Member State, but rather aggregated and exported to the next country of stay.

Access to health care was a central aspect of the social protection that this regulation sought to ensure, and this was needed not only for people moving permanently to another country because of a new job but also for those moving temporarily, for example people who work across borders or people who are being posted to work abroad, going to a meeting in another country or on holiday and then requiring some form of urgent medical care. This Regulation on the coordination of social security systems (revised in 1971 and 2004) was for decades the only EU instrument enabling people to have access to health care in other countries – including, under exceptional circumstances (and subject to prior authorization by the payer in the competent Member State), travelling specifically to other countries for the aim of having health care. However, given the sensitivity of these issues, rights to health care under Regulation 3 were always tightly controlled, and the legal base in the TFEU reflected this; unlike the general shift towards majority voting across most of the TFEU, these provisions have required unanimity in the Council.

Fiscal governance

The EU has historically had very limited powers of oversight over national budgets and taxation, these being considered to be exclusively national decisions; the creation of a single currency has led to these issues being subjected to more intensive monitoring.[45] After a long history of currency coordination, the decision at Maastricht to establish a single currency (the euro) increased the degree of European integration in fiscal policy by specifying a variety of economic targets that Member States had to hit, or be on track to hit, in order to join the Eurozone. Two of them – a deficit of less than 3% and a total government debt below or on track to be below 60% – were thought to need enforcement after the establishment of the single currency, and so a Stability and Growth Pact (SGP) enshrined them in EU law, and a process to establish

44 Maas W. *Creating European citizens*. Lanham, MD, Rowman and Littlefield, 2007.

45 See in particular TFEU, Article 121, together with Article 136 for Member States whose currency is the euro.

the Broad Economic Policy Guidelines was initiated to provide some oversight of Member States' fiscal policies. This apparatus gained in complexity but did not prevent the build up of some significant fiscal policy and macroeconomic problems in the Eurozone.

Since the financial crisis of 2008, and in particular the sovereign debt crises around the Eurozone, there has been a substantial change in the nature and politics of the EU, and the collective EU control of national budgets has been dramatically increased. For those countries who have required emergency funds from the EU to stabilize their economies, these have come at the cost of detailed requirements for policy change, including (in some detail) for health systems.[46] To reinforce the legal weight of the EU's oversight of national budgets and policies more broadly, all EU countries apart from the Czech Republic and the United Kingdom have signed an additional treaty giving legally binding force to their budgetary and economic commitments,[47] including the possibility of enforcement through the CJEU. This strengthened EU oversight of national budgets cannot avoid having effects on health system priorities and expenditures, given that this is typically one of the two largest components of national budgets. Chapter 5 explains these issues and their implications for health in more detail.

2.4 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 itself has a budget capped at around 1% of the EU's gross national product (Fig. 2.1). Within the budget, the biggest area of expenditure is the agricultural budget (€59.7 billion), followed by the structural and cohesion funds (€54.5 billion) intended to reduce inequalities in development across the EU, and the EU's research programme (€10.9 billion) (Fig. 2.2). These three areas account for over 82% of the EU budget, with other areas (including specific expenditure on health care actions) being minor in comparison; EU administration requires around 5% of the overall EU budget.[48] 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.

46 Fahy N. Who is shaping the future of European health systems? *BMJ,* 2012, 344:e1712.

47 Council of the European Union. *Treaty on stability, coordination and governance in the economic and monetary union*. Brussels, Council of the European Union, 2012 (http://european-council.europa.eu/media/639235/st00tscg26_en12.pdf, accessed 4 July 2014).

48 European Commission. *EU budget 2013: investing in growth and jobs*. Luxembourg, Publications Office of the European Union, 2013.

Fig. 2.1 *EU Budget for 2012 in relation to its GDP*

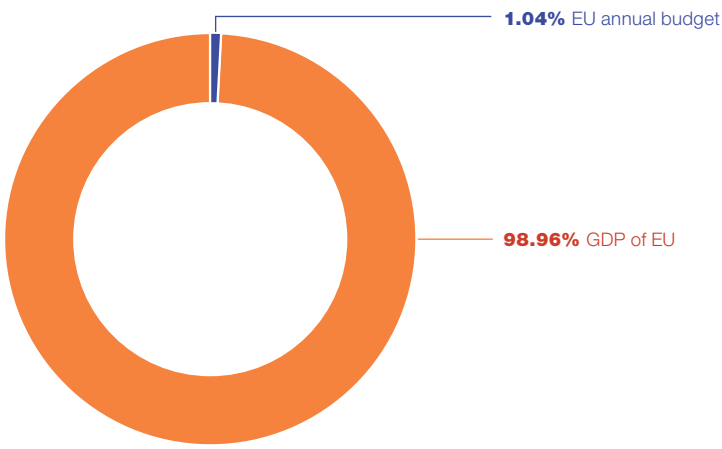
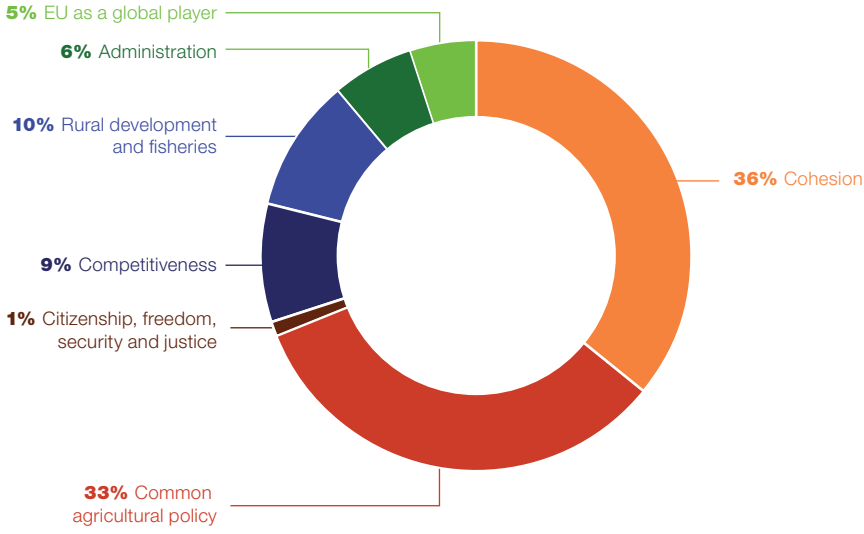


Fig. 2.2 *EU Budget for 2013*



In order to avoid annual rows over funding, the EU prefers to have one big argument every seven years and agree an overall allocation of funding for that whole seven-year period. This is called the Multiannual Financial Framework, and a new one was agreed in 2013 for the period 2014–2020.[49] Although the detailed EU budget is still negotiated and agreed annually, this takes place within

49 Council of the European Union. Council Regulation (EU, EURATOM) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014–2020. *Official Journal*, 2013, L 347/884.

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

There are two important areas of funding specifically allocated to health (structural funds, discussed in section 4.5, often finance health-related projects but are not specifically designed to finance health work). One is the allocation for health within the research programme of the EU (section 4.7). This is both much larger (at around €1 billion a year) and more targeted (being only for research), although it is still small in comparison with national expenditure on research, and, of course with private expenditure, in particular by the pharmaceutical industry. The second area of funding, and the one with the highest profile, is the EU health programme.

2.4.1 Health programme

The financial support for the EU's health policy comes from the EU health programme,[50] which 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; the outgoing programme had a budget of around €46 million a year, which equates to 0.000058% of publicly funded health expenditure in the EU,[51] 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 have and will never have enough money, 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.[52] There is a regularly updated list of the projects supported by the health programmes.[53] They show a strong bias towards supporting capacity building, often among EU-level groups such as the Association

50 European Parliament and Council. Regulation (EU) No 282/2014 on the establishment of a third programme for the Union's action in the field of health (2014–2020) *Official Journal*, 2014, 86:1–13; in general, see European Commission. *Health programme*. Luxembourg, Publications Office of the European Union, 2014 (http://ec.europa.eu/health/programme/policy/index_en.htm, accessed 4 July 2014).

51 Source for comparison figure of total public health expenditure: OECD. *Health at a glance: Europe 2012*. Paris, Organisation for Economic Co-operation and Development, 2012; source for comparison figure of total EU GDP (2010 figure): European Commission. *Eurostat statistics.* Brussels, Eurostat, 2014 (http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/, accessed 4 July 2014).

52 Briatte F. The politics of European public health data. In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:51–63.

53 Consumers Health and Food Agency. Project database [online database]. Brussels, Consumers Health and Food Agency, 2012 (http://ec.europa.eu/eahc/projects/database.html, accessed 4 July 2014).

of Schools of Public Health of the European Region, the European Federation of Associations of Dietitians, and conferences or research projects intended 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.[54] Nevertheless, this limited volume of resources inevitably affects the scope for EU-financed action on health.

The new EU health programme runs from 2014 to 2020 with €449.4 million to spend over that period. It continues within the framework of the health strategy *Together for Health* (see section 3.6)[55] as well as the broader "Europe 2020" objectives[56] and has more of a focus on health systems, specifically. Box 2.5 summarizes the objectives in the legislation. These are objectives that the EU will pursue in its funding decisions, and the purpose of the programme is to lend them coherence. Specific calls for funding and funding decisions will flesh them out.

2.5 New governance: comparison, benchmarking, experts and networks

Beyond the formal powers of the EU, there is much scope for the EU to play a highly influential role without any legal tools at all, simply by providing and facilitating political leadership and with other tools such as benchmarking. There are also a range of other people and organizations with an interest in EU action beyond the formal institutions described above. Hence the EU has progressively developed wider processes of transparency and engagement to enable it to act in wider areas than formal legal powers allow, and to bring wider groups of people into the EU processes.

The common threads of these initiatives were spelled out in a 2001 White Paper on Governance.[57] There are a number of reasons for these initiatives. First, they allow the EU to have a role, and aspire to ideational leadership, in areas where its formal powers are weak. Second, they prepare an agenda that can influence policy debate in the EU as well as in Member States. Third, at least in theory they increase participation in EU decisions and thereby increase the information, democratic legitimacy and likelihood of

54 Public Health and Impact Assessment Consortium. *Mid-term evaluation of the health programme (2008–2013).* Bologna, Public Health and Impact Assessment Consortium, 2011 (http://ec.europa.eu/health/programme/docs/mthp_final_report_oct2011_en.pdf accessed 4 July 2014).

55 European Commission. *Together for health: a strategic approach for the EU 2008–2013 (COM(2007)630).* Brussels, European Commission, 2007.

56 European Commission. *Europe 2020: a strategy for smart, sustainable and inclusive growth*. Brussels, European Commission, 2010.

57 European Commission. Governance in the European Union: a white paper (COM(2001) 428). *Official Journal,* 2001, C 287.

Box 2.5 *Objectives of the EU health programme 2014–2020*

The objectives of the EU health programme for 2014–2020 can be divided into general, specific and operational objectives.[1]

The four general objectives are:

- improve the health of EU citizens and reduce health inequalities
- encourage innovation in health and increase sustainability of health systems
- focus on themes that address current health issues across Member States
- support and encourage cooperation between Member States.

The specific objectives in doing so are to promote health, prevent diseases and foster supportive environments for healthy lifestyles by

- protecting citizens from serious cross-border health threats,
- contributing to innovative, efficient and sustainable health systems, and
- facilitating access to better and safer health care for Union citizens.

The operational objectives are to:

- identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective disease prevention and health promotion activities;
- identify and develop coherent approaches and implement for better preparedness and coordination in health emergencies;
- identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies;
- increase access to cross-border medical expertise and information for medical conditions of low prevalence, high specialization or rare diseases; and
- facilitate the application of research results and developing tools towards quality health care and patient safety.

1 European Parliament and Council. *Regulation (EU) No 282/2014 of 11 March 2014 on the establishment of a third programme for the Union's action in the field of health (2014–2020).* Luxembourg, Publications Office of the European Union, 2014.

compliance in the decision and implementation process. The initiatives all draw on a vast ecosystem of "Eurogroups": lobbies federating interests from across the EU, with business groups dominant but the Commission funding a counterbalancing variety of umbrella groups whose purpose is to represent groups that are poorly organized or resourced in order to bring their views into these debates.[58] Along with the lobbies in Brussels, they serve the valuable function of bringing information to the Commission

58 Greer SL, Massard da Fonseca E, Adolph C. Mobilizing bias in European Union health policy. *European Union Politics,* 2008, 9(3):403–433; Greenwood J. Organized civil society and democratic legitimacy in the European Union, *British Journal of Political Science,* 2007, 37(2):333–357.

and parliament, which lack the staff and research resources to learn about every issue.

2.5.1 The OMC

The OMC is the most visible of the EU's new governance mechanisms and the subject of by far the most academic research. It has its roots in the Broad Economic Policy Guidelines, a consultative mechanism for evaluating Member States' economic policies, but its extension into a wide range of areas came about as a part of the Lisbon Agenda, which included objectives such as the modernization of social protection that the EU could not easily legislate on.[59]

The basic OMC model developed in discussions of employment strategies and then other areas including pensions. It has been extended to a variety of areas including health systems and is easy to characterize. First, Member States set broad objectives for a policy area. These usually accord with previous statements by EU bodies (such as Council statements). For health systems, they are access, quality and sustainability. As the process develops, Member States, with Commission help, agree on specific objectives and indicators. Member States then enter an iterative process of writing national action plans detailing the policies and efforts that they will use to achieve the objectives. The whole process for the OMC social protection and social inclusion (including the health stream) is organized by the Social Protection Committee and is managed by DG Employment and Social Affairs. Over time, the objectives and indicators have become more precise, as well as easier to relate to the actual outcomes (Table 2.2).

There is a great deal of debate about the impact of the OMC process in any policy area where it has been applied, and if there is a consensus in the large academic literature it is that "as the OMC is voluntary and sanction-free, it depends heavily on how and the extent to which actors use it (agenda-setting, conflict resolution, maintaining focus on a policy issue, developing a policy dialogue, etc.)".[60] On the domestic level, this means that for the OMC to have an impact on policy in a Member State it must become a tool for some interest within that Member State that can point to a poor performance in order to call for policies that will allow it to catch up. If a State is, for whatever reason, not responsive to naming and shaming via the OMC, it will produce text for its plan stating that its present government's policies, whatever they are, will resolve the problem in the future. The basic issue is that Member States are not really accountable to the OMC, so its effectiveness depends on its influence over somebody with power at the Member State level.

59 Zeitlin J, Pochet P. *The open method of co-ordination in action: the European employment and social inclusion strategies*. Brussels, PIE/Peter Lang, 2005.

60 de la Porte C. *State of the art. Overview of concepts, indicators and methodologies used for analyzing the social OMC*. Brussels, Working Papers on the Reconciliation of Work and Welfare in Europe, 2010.

Table 2.2 *The OMC in health systems*

Areas	Objectives
Access to health promotion, disease prevention and curative care	Shorter waiting times Reaching all parts of the population through universal insurance coverage and affordable care Reducing geographical differences in availability and quality of care Addressing cultural and language barriers to using services
Quality	More patient-centred care Effective and safe treatment and equipment Greater use of evidence-based medicine and health technology assessment (EUnetHTA) Greater use of effective prevention, programmes for cancer, cardiovascular diseases and infectious diseases (vaccination) among others Better integration/coordination between primary, outpatient and inpatient secondary and tertiary care; between medical, nursing, social and palliative care
Sustainability	More rational use of financial resources via: • greater use of generic medicines • focusing on primary care – referral systems to secondary care • reducing inpatients, increasing outpatients • simplifying administrative procedures • concentrating specialized care in centres of excellence • strengthening health promotion and disease prevention Avoiding underresourcing of health care systems and establishing a viable contribution base via: • better coordination of care • ensuring sufficient human resources for health through good training, motivation and working conditions, addressing imbalances in different categories of staff

Sources: European Commission. *Modernising social protection for the development of high-quality accessible and sustainable health care and long-term care: support for the national strategies using the "open method of coordination"*. Brussels, European Commission, 2004 (http://ec.europa.eu/employment_social/soc-prot/healthcare/com_04_304_en.pdf, accessed 21 July 2014); European Commission. *Employment, social affairs and inclusion: health care* [web site]. Brussels, European Commission, 2014 (http://ec.europa.eu/social/main.jsp?catId=754&langId=en; accessed 21 July 2014).

The second use of the OMC is in debates about the appropriate direction of EU policy. The EU is heavily involved in the economic governance of its Member States, as described in Chapter 5, and both the making and the evaluation of policy involve identifying priorities and trade-offs. This means that OMC commitments and declarations of values by the Member States can be made a constraint on policy: if Member States have explicitly signed up to certain objectives at the EU level, it is possible to argue against economic reforms on the grounds that the reforms would make existing commitments impossible to achieve (e.g. it is possible to argue against budget cuts on the grounds that they would endanger progress on the target of short waiting lists).

The OMC itself has attracted more discussion than its policy effects probably merited. But it must be remembered that it is a *method* that is not just tied to the

particular form of the OMC committees: Member State target setting, benchmarking and peer review orchestrated by the Commission. It produces country-specific ideas, such as economic reform proposals that feed into the Country Specific Recommendations (CSRs) and "Troika" (International Monetary Fund (IMF), ECB and European Commission) decisions. It also produces forums, such as the Social Protection Committee, where advocates of health and other social policies can influence the EU.[61] In addition, the actions associated with the OMC are not confined to the OMC; the EU has a range of venues where OMC-like procedures work well despite not being part of the OMC.

2.5.2 The High Level Group and other groups

The OMC has been the subject of so much research because it has formed the centrepiece of a large part of the EU's overall social policy strategy and because it has a logic that is easy to articulate. That does not mean that it is the only, or even the most visible, initiative that the EU has taken to influence debate and identify shared goals in health. Other initiatives have also been set up in health-related domains. One was the High Level Reflection Process on Patient Mobility and Healthcare Developments in the EU, which brought together health care system stakeholders to discuss the consequences and possibilities of Court rulings on cross-border health care, described in more detail below. It gave way to a High Level Group in 2004 charged with monitoring and formulating recommendations on health systems policies for the EU. The High Level Group's agenda substantially prefigured all the topics being discussed today, mixing management of the consequences of EU health care law with opportunities to improve health systems by addressing issues such as health impact assessment, patient safety and e-health. It ceased to meet in 2007, when the breadth and complexity of the health agenda was clearly more than could reasonably be managed by one group, although certain of its working groups continue to meet.

The Working Party on Public Health at Senior Level is quite different; it is a group of top officials meeting within the Council structures rather than the Commission, normally once per Council Presidency. Its general purpose is to better connect the EU agenda with the Member States' agendas and preferences. In 2011, however, in the depths of the financial crisis, the Council for Employment, Social Policy, Health and Consumer Affairs charged the Working Party with carrying out a reflection process on modern, responsive and sustainable health care systems.[62]

61 Greer SL, Vanhercke B. The hard politics of soft law. In: Mossialos E et al., eds. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010:186–230; Vanhercke B. Under the radar? EU social policy in times of austerity. In Vanhercke B, Natali D, eds. *Social developments in the European Union 2012.* Brussels, ETUI/OSE, 2013.

62 Council of the European Union. *Council conclusions: towards modern, responsive and sustainable health systems*. Luxembourg, Publications Office of the European Union, 2011 (http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/122395.pdf, accessed 4 July 2014).

The focus of this work was enhancing the representation of health in the framework of the Europe 2020 strategy and in the process of the European Semester; defining success factors for the effective use of structural funds for health investments; achieving cost-effective use of medicines; developing integrated care models and better hospital management; and measuring and monitoring the effectiveness of health investments. In December 2013, the Council for Employment, Social Policy, Health and Consumer Affairs took the opportunity of commenting on the reflection process to highlight the importance of health investment, the Social Investment Package and the importance of attention to health in the reforms associated with enhanced fiscal governance.[63] The activities of the Working Party reflection process, like many consultative EU mechanisms, are here being incorporated into a broader effort to improve the health policy ideas and effects of fiscal governance.

The EU Health Policy Forum has had a more durable and stable existence. It combines a regular set of meetings with 50–60 stakeholders with an annual one-day forum in which EU-level organizations can inform policy and be informed about policy. It is a central mechanism to implement the EU's health strategy and tends to focus on health systems.[64] Its benefits are partly to the Commission – allowing it to hear ideas and test the support of different initiatives – and partly to the nongovernmental organizations, which appreciate the information and see an opportunity to influence policy development.

The newest advisory body associated with EU health policy is the Expert Panel on Effective Ways of Investing in Health.[65] This panel responds to questions ("mandates") from DG SANCO and is charged with providing expert answers from an outside perspective. Its mandates so far include some evergreen topics in EU health policy such as patient safety, but have mostly been about technically and politically difficult areas of health policy: defining primary care, competition between providers, public–private partnerships (PPPs) and criteria for the assessment of health systems.[66] They are fodder for advocates and policy-makers who want to improve the quality of EU health policies as well as the quality of EU policies that touch upon health by, for example, making more evidence-based arguments for what areas of health deserve investment. There are many other diverse expert groups advising the Commission, typically on narrower specialist

63 Council of the European Union. *Council conclusions on the reflection process on modern, responsive and sustainable health systems*. Luxembourg, Publications Office of the European Union, 2013 (http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/140004.pdf, accessed 4 July 2014).

64 European Union Health Policy Forum. *The Health Policy Forum: a renewed mandate*. Brussels, European Union Health Policy Forum, 2009.

65 European Commission. *Decision of 5 July 2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health (2012/C 198/06)*. Luxembourg, Publications Office of the European Union, 2012.

66 Expert Panel on Effective Ways of Investing in Health. *Mandates, members and views*. Brussels, DG Health and Consumer Protection (http://ec.europa.eu/health/expert_panel/index_en.htm, accessed 4 July 2014).

topics; such groups are a key way to keep the Commission informed and to enable a variety of experts and Member State policy-makers to engage with EU policies.

2.6 Crises and commitment

What drives EU health policy forward? The most obvious driver for action in health is crises. As described in Chapter 3, EU powers on health have been driven forward at different stages by sudden problems, such as the occurrence of the severe acute respiratory syndrome (SARS) and other communicable disease, or the scandal of blood infected with the human immunodeficiency virus (HIV), which led to EU powers on blood safety and quality. These drivers have also generated action related to other legal bases, such as the drive towards a safe regime for medicines throughout the single market in the aftermath of the thalidomide scandal, and the current reinforcement of oversight for medical devices after problems with breast implants and replacement hips. At present, the financial crisis is driving a fundamental shift in the EU's approach to health, with a rapidly strengthening European oversight of national health systems as a consequence of the wider pressures to keep control of public finances across the EU.

Crises can also take legal and political form. The EU is not a game between diplomats, as in international organizations; because the EU is an integrated part of domestic political and legal systems, individuals can take actions, such as court cases, that can drive major policy initiatives in the absence of significant political demand. This is the story of EU law on patient mobility. A very small number of patients sought to use EU law to seek treatment abroad. The CJEU, applying internal market rules, found a right to cross-border health care in the internal market provisions of the treaties and thereby opened the way to a major shift in the balance of power between the EU and its Member States in this area. This is a striking development in any political system – in most systems it takes more than a few individuals with a legal argument to set off the creation of a whole new balance of power and responsibility in a sector. Once the CJEU had assumed the driver's seat[67] and destabilized the existing structure of health care law in the EU, Member States[68] and interest groups quickly began to invest in Brussels debates, lobbying and political action. Their basic calculation was that once the EU mattered in health care provision, it was in their interest to shape EU policy through lobbying and legislation. Deprived of their historically preferred option of having no EU policy, the second best option was an EU policy that they could influence rather than leaving it up to the courts.

67 Wismar M, Busse R. Freedom of movement challenges European health care scenery. *Eurohealth,* 1998, 4:13–15; Greer SL. Uninvited Europeanization: neofunctionalism and the EU in health policy. *Journal of European Public Policy,* 2006, 13(1):134–152; Brooks E. Crossing borders: a critical review of the role of the European Court of Justice in EU Health Policy. *Health Policy,* 2012, 105(1):33–37.

68 Gobrecht J. National reactions to *Kohll* and *Decker. Eurohealth,* 1999, 5(1):16–17.

Crises are by their nature unpredictable and, therefore, the developments that they lead to can be quite unbalanced. The more positive approach of commitment by political leaders to address a key health concern has also driven major changes, with pressure from the then French holder of the Presidency being the origin of the EU's action against cancer (and the determination of the Slovenian Presidency of the Council in 2008 in putting it back on the agenda after the shift to a more horizontal approach). Another example was patient safety, which was increasingly recognized as an issue by health system leaders across Europe as evidence of its seriousness emerged but was given critical motivation by the United Kingdom Presidency of 2005.

Away from the political leaders, demand for further integration can come from the bottom, or at least middle, up. This is the case for many initiatives in public health and research. The EU has often financed EU-spanning networks for a variety of purposes: to disseminate best practice, to build capacity, to increase the diversity of information available to EU decision-makers[69] and to create a constituency for further EU action in a field. Once these networks have formed, developed shared objectives and policy initiatives and become accustomed to the ways of EU funding, they will often become reservoirs of ideas for new EU actions and of advocates who can promote the EU policy initiatives in their home countries.[70] Moreover, in any area such as health where there is a high degree of technical complexity, there is potential to gain from collaborating across a wide area and pooling expertise. Perhaps the clearest example is that of rare diseases.[71] There are thousands of rare conditions, with perhaps only a handful of patients in any one country (certainly in the many small countries in the EU); consequently, there is enormous benefit from linking up across countries to share knowledge and pool expertise and potentially resources. As the EU provides a more developed structure for such supranational cooperation than anywhere else in the world, it is logical that such cooperation will steadily develop, and this has been increasingly the case.

In the context of increasing budget austerity for Europe as a whole, therefore, the constitutional asymmetry of the EU is clear. The EU has a great impact in creating rules (in particular for the operation of the internal market) and increasingly requires countries to live within their budgetary means, but the EU cannot bring a counterbalancing support in the form of social expenditure (including for health), which Member States ensure themselves. Of course, the capacity to fund social programmes depends on the overall capacity of the economy, which

69 At least partially counteracting the well-documented preponderance of business groups among EU lobbyists; Coen D, Richardson J, eds. *Lobbying in the European Union.* Oxford, Oxford University Press, 2009.

70 Sanchez-Salgado R. *Comment L'Europe Construit La Société Civile.* Paris, Dalloz, 2007.

71 Rare diseases [web site]. Brussels, European Commission, 2014 (http://ec.europa.eu/health/rare_diseases/policy/index_en.htm, accessed 4 July 2014).

can be argued to be greater precisely because of EU support such as the internal market and the single currency, but in practical terms, this demonstrates the imbalance in tools available for action at EU level.

2.7 Summary

The EU is like a state in many ways, from its powerful judiciary to its dynamic legislative politics, but it is also very unlike a state in others. The power of the EU is traditionally seen as lying in the energy and entrepreneurialism of its executive and courts, and in their mandates to promote the internal market. It increasingly also lies in its powerful fiscal governance framework. But the EU has only weak powers to act in some of the areas regarded as most important for European citizens, such as health and social issues, precisely because Member States have preferred to keep such powers at national level; the EU also has a very small budget in comparison with national governments. For health, this can create a paradoxical situation, in which the EU has a strong indirect impact when pursuing other objectives but cannot always match that with a direct impact for health itself. Part of the response to those limitations has been to address health issues or to insert health issues into other debates with creative tools such as comparable information and benchmarking and multistakeholder platforms, the impact of which is more complex to assess and less easy to quantify than the traditional tools of law and money.

The situation for health is also complex because the powers for health are fragmented, with health-related actions being taken in many different parts of the Commission and the Commissioner for Health responsible for only a small part of these powers – those taken under the public health article. In Member States, the health ministry is typically responsible for most health-related action by the government.[72] This is not the case for the DG SANCO, and legislation affecting health is discussed in a range of forums within the parliament and the Council, not just those specifically concerned with health. This makes it difficult to get an overview of the impact of the EU on health, both for those within the system and for those outside it and trying to understand and engage with the actions of the EU on health. This difficulty has shown up in a number of areas where EU action of high relevance to health has seemed to pass by without the wider health community being engaged or even necessarily being aware of what is happening.

72 Greer SL. Editorial introduction: health departments in health policy. *Social Policy and Administration*, 2010, 44(2):113–119; more generally the whole of *Social Policy and Administration,* 2010, 44(2).

Chapter 3

EU action for health

The first face of EU health policy is its public health policies: policies justified by the need to protect and improve the health of Europeans, typically with reference to the treaty article on health (Article 168 of the TFEU). This chapter describes that first face: how the EU has worked to improve health, and how those efforts have evolved from a few marginal initiatives to a specific treaty article and a wide-ranging set of activities. These activities cover the major determinants of health: tobacco, alcohol, diet and nutrition, environmental determinants, social determinants, injuries and other external causes, and misuse of drugs. There have also been disease-specific strategies, in particular for cancer, communicable diseases and rare diseases; these are now being taken further into a more general approach for chronic diseases. A key area of added-value has been to enable comparisons and benchmarking between European countries through developing data and indicators on health. Substances of human origin (blood and blood products, organs, tissues and cells) have their own legislative standards for quality and safety, and this illustrates how domestic crises can drive pressure for European action. In addition, despite the ever-present sensitivities about European involvement in health care, there is action focused on health system issues such as patient safety, quality of care and health technology assessment.

3.1 Historical evolution

Although the founding treaties of what has become the EU date back to the 1950s, progress towards integration initially was slow. Cautious about this new form of cooperation, national governments insisted on unanimous agreement for decisions, which inevitably made agreement hard to negotiate, and there was no directly elected European Parliament to push for issues of direct interest to citizens. For decades, public health in the treaties was only a legitimate, if increasingly circumscribed, category for exceptions to internal market harmonization.

The big acceleration of European integration came with the Single European Act in 1987, which drove the establishment of the internal market.[1] The Act brought in key institutional changes to help drive through change, in particular shifting the balance of voting in the Council of Ministers more towards majority voting

1 Council of the European Communities. Single European Act. *Official Journal*, 1987, L 169.

instead of unanimity, and giving the European Parliament greater say. This led to a step change in the speed and effectiveness of European integration and set a clear focus around the internal market that still shapes the EU today. In terms of health, the Single European Act did make one major change, which was to add powers for the EU to adopt binding legislation to protect the health and safety of workers,[2] but the focus was clearly on establishing a fully integrated European market.

Alongside this, though, specific European action on health was already well underway. The highest profile example was the agreement by the European Council meeting in Milan in 1985 to a French suggestion that Europe should launch a specific programme of action against cancer, which was adopted the following year.[3] While less formally structured than the programmes that followed in later years, this already set the ground for subsequent achievements. It was the basis for the establishment of the *European Code Against Cancer*, an evidence-based set of advice for actions that citizens could take to protect themselves against cancer,[4] and led to other measures, for example against smoking and exposure to dangerous substances.[5] Cancer was only one area of action, however. National ministers had been discussing health issues at EU level since the late 1970s (and in the parliament since the early 1980s) and specific actions had been taken on topics including combating HIV infection and the acquired immunodeficiency syndrome (AIDS),[6] drug dependence and programmes of health-related research.

With the increasing pace of economic integration came political pressure to ensure that European integration should not only be about markets but should also be balanced by "softer" issues associated with the idea of a Social Europe. The Maastricht Treaty of 1992[7] thus formalized cooperation in a range of areas and introduced the bulk of EU provisions in pursuit of health: on environment[8] and consumer protection[9] as well as the health article itself.[10]

2 See Article 21 of the Single European Act adding Article 118a to the EEC Treaty.

3 Council of the European Communities and representatives of the Governments of the Member States. Resolution of 7 July 1986 on a programme of action of the European Communities against cancer. *Official Journal*, 1986, C 184:19–21.

4 See Association of European Cancer Leagues. *European code against cancer.* Brussels, Association of European Cancer Leagues (http://www.cancercode.eu, accessed 4 July 2014); also Briatte F. The politics of European public health data. In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:51–63; Trubek LG et al. Improving cancer outcomes through strong networks and regulatory frameworks: lessons from the United States and European Union. *Journal of Health Care Law and Policy*, 2011, 14(1):119–151.

5 Moliner AM. *European Union action against cancer*. (http://ihcp.jrc.ec.europa.eu/our_activities/public-health/cancer_policy_support/events/docs-seminar-13-1/presentations-19-03-2013/Michael%20Huebel%20Antoni%20Montserrat_EU%20Against%20Cancer.pdf, accessed 4 July 2014).

6 Steffen M. The Europeanization of public health: how does it work? The seminal role of the AIDS case. *Journal of Health Politics, Policy, and Law,* 2012, 37(6):1057–1089.

7 European Communities. *Treaty on the European Union*. Luxembourg, European Communities, 1992 (http://www.eurotreaties.com/maastrichtec.pdf, accessed 4 July 2014).

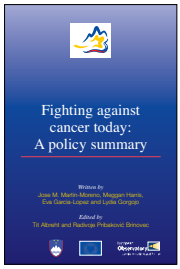
8 Treaty on European Community, Articles 130r and 130s, as amended by the Treaty on European Union (*Official Journal.* 1992, C 224).

9 Treaty on European Community, Article 129a as amended.

10 Treaty on European Community, Article 129 as amended.

Action against cancer in Europe

With more than 3 million new cases and 1.7 million deaths each year, cancer currently represents the second most important cause of death and morbidity in Europe.

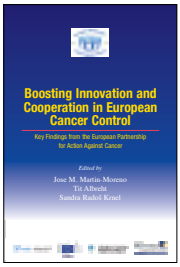


Fighting against cancer today: a policy summary

Jose M. Martin-Moreno, Meggan Harris, Eva Garcia-Lopez and Lydia Gorgojo (edited by Tit Albreht and Radivoje Pribaković Brinovec)

European Observatory on Health Systems and Policies, 2008

http://www.euro.who.int/__data/assets/pdf_file/0010/124867/e94392.pdf?ua=1

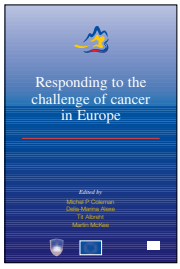


Boosting innovation and cooperation in European cancer control. Key findings from the European Partnership for Action Against Cancer

Edited by Jose M. Martin-Moreno, Tit Albreht and Sandra Radoš Krnel

European Observatory on Health Systems and Policies, 2014

http://www.euro.who.int/en/about-us/partners/observatory/studies/boosting-innovation-and-cooperation-in-european-cancer-control



Responding to the challenge of cancer in Europe

Edited by Michel P Coleman, Delia-Marina Alexe, Tit Albreht and Martin McKee

European Observatory on Health Systems and Policies, 2008

http://www.euro.who.int/en/about-us/partners/observatory/studies/responding-to-the-challenge-of-cancer-in-europe

The project Fighting Against Cancer Today (FACT) was initiated under the Slovenian Presidency of the EU (2008) and produced a review of the current status of cancer control in the European Union with the aim of summarizing the evidence that should underpin policy for the prevention, management and palliation of cancer in Europe. The cancer control approach rests on four main pillars of action: primary prevention, secondary prevention (screening), integrated care and research.

Under the follow-up European Partnership for Action Against Cancer (EPAAC), some of the innovative strategies being deployed against cancer in Europe were further explored. It also highlights some outstanding examples of how cooperation between national and international entities as well as policy-oriented innovations are contributing to the collective effort to combat the cancer burden.

The initial response to the formal mandate on health continued the focus on many of the themes already developed through earlier cooperation. Based on an overall evaluation of the burden of mortality and morbidity in Europe and the scope for European action,[11] eight specific programmes of cooperation were adopted through the rest of the 1990s:

- health promotion, information, education and training
- action plan to combat cancer
- prevention of HIV/AIDS and certain communicable diseases
- prevention of drug dependence
- health monitoring
- injury prevention
- rare diseases
- pollution-related diseases.

Decisions were also taken that established a network for the epidemiological surveillance and control of communicable diseases in the European Community combined with an early warning and response system. Over time, however, this approach was considered to be too fragmented, and cooperation moved away from sector- or condition-specific programmes towards an overall programme focused on the three overall objectives:[12]

- improving health information and knowledge;
- creating a rapid and coordinated response to health threats; and
- promoting health and preventing disease through addressing health determinants.

This, then, is the historical background to the action of the EU for health today. How have these different aspects of cooperation been taken forward, and what impact have they had?

3.2 Determinants of health

The origins of good health and ill health usually lie outside the health care system in determinants of health status such as tobacco use, obesity and social inequality. The EU has a variety of important policies that address the determinants of health.

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11 Commission of the European Communities. *Communication on the framework for action in the field of public health (COM(93)559)*. Brussels, European Commission, 1993.

12 European Parliament and Council. Decision No 1786/2002/EC adopting a programme of Community action in the field of public health (2003–2008). *Official Journal*, 2002, L 271:1–11.

3.2.1 Tobacco

Tobacco is one of the largest causes of sickness and death in the world. It is, unusually, a product that kills if used properly. The first real EU tobacco policy was actually in favour of tobacco, with subsidies to farmers under the Common Agricultural Policy in 1970. Considering that starting point, the EU has greatly improved its contribution to tobacco control, including phasing out its tobacco subsidies entirely by 2010.[13] Since then, EU policy-makers have taken a wide variety of measures in the teeth of opposition from the tobacco industry[14] and have assembled a substantial body of legislation, which is summarized in Table 3.1.

This body of legislation clearly illustrates the fragmented nature of health provisions and the constitutional asymmetry of the EU in regard to health, as outlined above. Although the aim of this body of legislation is tobacco control and, therefore, is a health objective, virtually none of it has been adopted under the health article itself. Much of the legislation has been adopted on the basis of the provisions for ensuring health and safety at work; the wider legislation on the labelling, advertising, content and taxation of tobacco products has been based on the internal market powers of treaties.

The limitations of using the internal market provisions were illustrated clearly with the annulment of the first tobacco advertising directive[15] by the European Court of Justice. This directive was also based on internal market provisions of the Treaty, but following legal action by Germany, the Court annulled the directive on the grounds that the ban it introduced went beyond what could be justified in order to enable functioning of the internal market, in particular for local products (e.g. parasols and other articles used in hotels).[16] This was not all bad news for health; the Court did explicitly recognize the legitimacy of integrating health objectives alongside internal market objectives in principle. Indeed, the Court later upheld[17] the second, narrower directive on tobacco advertising[18] when that was also contested by Germany on the grounds that its internal market legal base was not sufficient for its health effects. However, these cases highlighted the

13 European Commission. *Agricultural markets: raw tobacco*. Luxembourg, Publications Office of the European Union, 2014 (http://ec.europa.eu/agriculture/markets/tobacco/index_en.htm, accessed 4 July 2014).

14 ASPECT (Analysis of the Science and Policy for European Control of Tobacco) Consortium. *Tobacco or health in the European Union: past, present and future*. Luxembourg, Publications Office of the European Union, 2004.

15 European Parliament and Council. Directive 98/43/EC of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products. *Official Journal*, 1998, L 213, 41:9–13.

16 European Court of Justice. Case C-376/98 *Germany v. European Parliament and Council*.

17 European Court of Justice. Case C-380/03. *Germany v. European Parliament and Council*

18 European Parliament and Council. Directive 2003/33/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products. *Official Journal,* 2003, L 152:16–19.

Table 3.1 *Summary of EU tobacco-control legislation*

Name (year) of measure	Number	Key requirements
Labelling directives (1989, 1992)	89/622/EEC	Requires rotating health warnings on tobacco products
	92/41/EEC	Ban on the marketing of certain tobacco products for oral use
Advertising directives (1989, 1997, 1998, 2003)	89/552/EEC, 97/36/EC	Ban all forms of TV advertising for tobacco products
	98/43/EC	Ban on tobacco advertising in the press, radio and on the Internet
	2003/33/EC	Ban on tobacco sponsorship of events with cross-border effects
Tar Yield Directive (1990)	90/239/EEC	Sets a maximum tar yield of 15 mg per cigarette by 31 December 1992 and of 12 mg per cigarette from 31 December 1997
Tax directives, (1992, 1995, 2002)	92/78/EEC, 92/79/EEC, 92/80/EEC, 95/59/EC, 2002/10/EC	Set minimum levels of excise duties on cigarettes and tobacco
Tobacco Product Regulation Directive (2001)	2001/37/EC	Larger warning labels are required on all tobacco products; descriptors suggesting that one tobacco product is less harmful than another are banned; manufacturers and importers must submit a list of all ingredients used in the manufacture of tobacco products; maximum levels of tar, nicotine and carbon monoxide established for cigarettes (10 mg tar, 1 mg nicotine and 10 mg carbon monoxide per cigarette)
Workplace Air Quality directives (1989, 1992)	89/654/EEC, 92/57/EEC, 92/91/EEC, 92/104/EEC	Require employers to ensure that workers have access to fresh air and ventilation
Framework Directive on Health and Safety in the Workplace (1989)	89/391/EEC	Requires a health assessment to be carried out by employers, which should include exposure to second-hand smoke in the workplace
Asbestos Directive (1983)	83/477/EEC	Prohibits smoking in areas where asbestos is handled
Resolution on Smoking in Public Places (1989), Smoke-free Environments Recommendation (2009)		Invites Member States to adopt measures protecting people from exposure to smoke in indoor workplaces, public places and public transport
Pregnant Women Directive (1992)	92/85/EEC	Requires employers to take action to protect pregnant and breastfeeding women from exposure to an extensive list of substances, including carbon monoxide
Carcinogens Directive (1990)	90/394/EEC	Restricts smoking in workplace areas where carcinogenic substances are handled
Council Resolutions and Proposals to Member States and the Commission (1993, 1996, 1999) on measures to combat smoking (non-binding)		Various measures to combat smoking
Council recommendation (2003)	2003/54/EC	Concerns aspects of tobacco control that are the responsibility of the Member States, including tobacco sales to children and adolescents; tobacco advertising and promotion that has no cross-border effects; provision of information on advertising expenditure; environmental effects of tobacco smoke
WHO Framework Convention on Tobacco Control (2004)	2004/513/EC (Council adoption decision)	Wide-ranging global treaty on tobacco control
Tobacco Products Directive (2014)	2014/14/EU	Major legislation on tobacco products (see text)

Sources: ASPECT (Analysis of the Science and Policy for European Control of Tobacco) Consortium. *Tobacco or health in the European Union: past, present and future*. Luxembourg, Publications Office of the European Union, 2004; DG Health and Consumer Protection. *Tobacco*. (http://ec.europa.eu/health/tobacco/key_documents/index_en.htm#anchor1, accessed 14 July 2014).

limitations of using internal market legislation to achieve such health objectives, and there has only been limited further European legislation against tobacco since then. Indeed, the political sensitivity of tobacco issues was highlighted by the resignation of the Commissioner for Health John Dalli in 2012, which was linked to the proposed revision of the directive on tobacco products[19] (the Commission's proposal for which was issued later the same year[20]).

The Tobacco Products Directive (2014/40/EU), or TPD, is one of the most important recent pieces of EU legislation for health, replacing previous tobacco product legislation dating from 2001. While the legislation cites public health concerns as an important base, a central goal for the TPD is to facilitate functioning of the single market. The text states that "lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union", demonstrating yet again the importance of internal market regulation in the field of public health.

The TPD broadens the scope of EU tobacco regulation in some significant ways. It sets maximum permissible levels of tar, nicotine and carbon monoxide for cigarettes and sets up a framework to allow reporting on further ingredients and emissions. The legislation 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 could also include menthol[21]).

In terms of controlling the marketing 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 be a standard shape and contain at least 20 cigarettes.

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19 European Commission. *Press statement on behalf of the European Commission (MEMO/12/788)*. Brussels, European Commission, 2012 (http://europa.eu/rapid/press-release_MEMO-12-788_en.htm, accessed 4 July 2014).

20 European Commission. *Communication proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (COM(2012)788).* Brussels, European Commission, 2012.

21 See the evidence from United States Food and Drug Administration. *Tobacco Products Scientific Advisory Committee's report and recommendations on the impact of the use of menthol in cigarettes on the public health.* Rockville, MD, Center for Tobacco Products, United States Food and Drug Administration (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247605.htm, accessed 4 July 2014).

Significantly, the legislation regulates electronic cigarettes for the first time, categorizing them as consumer goods. The provisions stipulate various product characteristics such as the maximum permissible concentration of nicotine for these products.

The TPD also includes some important caveats. Although products with menthol additives are covered by the legislation, the ban for menthol products does not come into effect until 2020. The "characterizing flavours" ban does not apply at all to oral tobacco products (e.g. *snus*, which remain banned in all EU Member States except Sweden). Member States can decide to exempt other products from the Directive (e.g. cigarillos, pipe tobacco).

The TPD stops short of mandating plain packaging, but it does not preclude Member States from adopting more stringent packaging requirements providing those requirements are justifiable on public health grounds, proportionate and do not constitute a hidden barrier to trade. These three criteria lie in a legal grey area, and their application could well be tested through legal action, as has been the case in Australia and Uruguay.

These exceptions are symptoms of the highly controversial nature of the TPD. The TPD took five years to pass, and will take another two to implement. The initial introduction of the Directive was significantly delayed because of the sheer volume of response to the public consultation, leading some public health advocates to raise concerns that the tobacco industry was attempting to "flood" the consultation in order to buy time. The process was further disrupted by the abrupt departure of Commissioner Dalli, who was accused of holding off-the-record meetings with tobacco industry lobbyists, and by the subsequent theft of relevant information from the offices of public health advocacy groups working on the TPD.

The passage of the legislation itself was subject to intense lobbying and considerable public scrutiny – as seen in a number of industry documents that were leaked to the press detailing the high level of resources dedicated to lobbying the European Parliament by representatives of the tobacco industry. To date, the law remains controversial; Poland voted against the Directive and has subsequently threatened to challenge its legality via the CJEU.

Perhaps the main immediate opportunity for further EU action is on exposure to second-hand tobacco smoke. The Commission itself acknowledges that, while Member States have taken steps to reduce exposure to second-hand tobacco smoke, progress is patchy and incomplete, as shown in Table 3.2.[22] The treaties also provide legal powers for the EU to act, certainly for those areas that are also

22 European Commission. *Staff Working Document SWD(2013)56 final/2: report on the implementation of the Council recommendation of 30 November 2009 on smoke-free environments (2009/C 296/02).* Brussels, European Commission, 2013.

Table 3.2 *Overview of smoke-free legislation*

	General workplace	Enclosed public place	Restaurants	Bars	Health care facilities	Educational facilities	Public transport	Hotels & accommodation	Residential care	Prison
Austria	◍	◍	○	○	◍	◍	◍	◍	◍	◍
Belgium	◍	◍	◍	◍	◍	●	●	◍	◍	◍
Bulgaria	●	●	●	●	●	●	◍	●	●	●
Cyprus	◍	●	●	●	●	●	●	●	×	○
Czech Republic	○	○	×	×	◍	●	◍	○	◍	○
Denmark	◍	◍	◍	○	◍	◍	◍	○	◍	◍
Estonia	○	○	◍	◍	○	○	○	○	○	○
Finland	◍	◍	◍	◍	◍	◍	◍	◍	◍	◍
France	◍	◍	◍	◍	●	●	●	◍	◍	◍
Germany	◍	◍	○	○	◍	◍	◍	◍	◍	◍
Greece	●	●	●	○	●	●	●	●	●	●
Hungary	●	●	●	●	◍	●	●	◍	●	◍
Ireland	●	●	●	●	●	●	●	◍	◍	◍
Italy	◍	◍	◍	◍	◍	◍	◍	◍	◍	◍
Latvia	◍	◍	●	●	◍	●	◍	◍	◍	◍
Lithuania	◍	●	●	●	●	●	●	○	◍	◍
Luxembourg	◍	●	◍	○	◍	●	◍	◍	◍	◍
Malta	●	●	●	●	●	●	●	◍	●	●
The Netherlands	◍	◍	◍	○	◍	◍	◍	◍	◍	◍
Poland	◍	●	◍	◍	●	◍	◍	◍	◍	◍
Portugal	○	○	○	○	○	◍	●	○	○	◍
Romania	◍	◍	○	○	●	◍	●	○	◍	◍
Slovakia	◍	●	◍	×	●	●	◍	◍	◍	◍
Slovenia	◍	◍	◍	◍	●	●	◍	◍	○	◍
Spain	●	●	●	●	●	●	●	◍	◍	◍
Sweden	◍	◍	◍	◍	◍	◍	◍	◍	◍	◍
United Kingdom	●	●	●	●	●	●	●	◍	◍	◍
Turkey	●	●	●	●	●	●	●	◍	●	◍
FYR Macedonia	●	●	●	●	●	●	●	●	●	●
Norway	◍	◍	●	●	◍	●	◍	◍	◍	◍
Serbia	●	●	○	○	●	●	●	◍	◍	◍
Iceland	◍	◍	●	●	◍	●	●	◍	◍	○
Croatia	◍	●	●	○	●	●	●	◍	●	◍

Source: European Commission. *Staff Working Document SWD(2013)56 final/2: report on the implementation of the Council recommendation of 30 November 2009 on smoke-free environments (2009/C 296/02).* Brussels, European Commission, 2013.

Notes: This overview is based on analysis of the relevant legal provisions in each Member State at January 2013 but does not take into account enforcement nor does it reflect the forthcoming legislative changes or plans in Bulgaria, the Czech Republic, Denmark, Estonia, Finland, Hungary, Latvia, Luxembourg, Portugal, Romania, Sweden and Norway; ●: Total ban on indoor smoking; ◍: Ban on indoor smoking while providing for separate enclosed smoking rooms/obligation for employers to protect employees; ○: Partial ban on indoor smoking (e.g. smoking zones or exemptions for certain categories of venues; ×; Recommendations, suggestions but no ban.

workplaces, through the health and safety at work provisions (already used for legislation on tobacco) and arguably more comprehensively through the environment provisions, given the evidence of improvement to human health through smoke-free environments. As described above, both of these powers include health as an objective and so avoid the complications of the internal market provisions. Politically, however, the variation in national measures reflects the sensitivity of the issue within countries; building a sufficient majority in the parliament and the Council for such legislation might be challenging.

3.2.2 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),[23] although there has been an overall decline in (recorded) alcohol consumption since the early 1990s. This is not an even decline throughout the EU, however; in both the Nordic and the eastern Member States declines in the 1990s were followed by increases in the next decade to a higher level than before.

Although alcohol is considered to be the third largest risk factor for ill health in the EU,[24] 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[25]), alcohol in its various forms is a central part of European culture. The EU's strategy regarding alcohol and health is, therefore, much more nuanced and limited than that for tobacco, say.[26] It concentrates on five key areas:

- protecting young people, children and exposure to alcohol during pregnancy;
- reducing injuries and death from alcohol-related road accidents (mainly by encouraging Member States to reduce permissible blood alcohol concentration for drivers);
- preventing alcohol-related harm among adults and reducing the negative impact on the workplace;
- informing, educating and raising awareness on the impact of harmful and hazardous alcohol consumption, and on appropriate consumption patterns; and
- developing and maintaining a common evidence base across the EU.

23 WHO Regional Office for Europe. *Status report on alcohol and health in 35 European countries 2013*. Copenhagen, WHO Regional Office for Europe, 2013.

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

25 European Commission. *What is the current situation of the European Union's wine sector*? Brussels, European Commission, 2014 (http://ec.europa.eu/agriculture/markets/wine/index_en.htm, accessed 4 July 2014).

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

Even for this more targeted strategy, the means used are 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[27]). 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.[28] Moreover, the relationship between public policy and alcohol consumption is not straightforward. The AMPHORA (Alcohol Measures for Public Health Research Alliance) project[29] 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 socials norms are restrictive, such as in southern Europe, formal policies are relatively liberal, and vice versa),[30] as well as the history of different countries (Fig. 3.1).

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 and advertising and labelling.

Regarding physical availability, a key example is the restrictive retail monopolies on alcohol sale 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

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

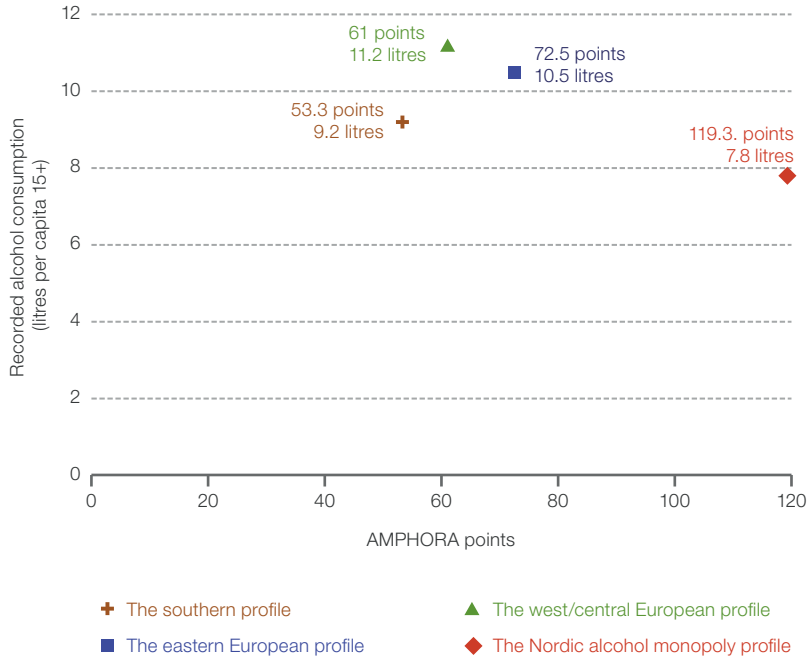
28 Although one dynamic, to which European integration has contributed, is the growth of very large international companies that have worked out how to homogenize products in Europe with new products such as alcopops. Policy-makers who defend traditional alcohol use and regulatory patterns sometimes rethink in the face of such homogenizing new products. Cisneros Örnberg J. Alcohol policy in the European Union. In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:168–180.

29 The AMPHORA (Alcohol Measures for Public Health Research Alliance) project [web site], 2012 (http://amphoraproject.net, accessed 4 July 2014).

30 Anderson B, Reynolds G, eds. *Making and implementing European alcohol policy*. The AMPHORA (Alcohol Measures for Public Health Research Alliance) project, 2012 (www.amphoraproject.net, accessed 4 July 2014).

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

Fig. 3.1 *Comparison of alcohol consumption and alcohol policies for people over 15 years (as rated on a composite scale by the AMPHORA project)*



Source: Anderson B, Reynolds G (eds.). *Making and implementing European alcohol policy. The AMPHORA (Alcohol Measures for Public Health Research Alliance) project, 2012* (www.amphoraproject.net, accessed 4 July 2014).

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,

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

33 Tigerstedt C et al. Health in alcohol policies: the European Union and its Nordic Member States. In: Ståhl T et al., eds. *Health in all policies: prospects and potentials*. Helsinki, Ministry of Social Affairs and Health, 2006:111–128.

34 Council of the European Union. *Directive 92/83/EEC on the harmonisation of the structures of excise duties on alcohol and alcoholic beverages, Directive 92/84/EEC on the approximation of the rates of excise duty on alcohol and alcoholic beverages*. Luxembourg, Publications Office of the European Union, 1992.

unlike for tobacco, that legislation has not been used to set a high minimum level of excise duty and thus price for alcohol throughout Europe. One does not have to look far to understand why; unlike tobacco (production of which has been relatively limited in the EU and concentrated in a few countries), alcohol production is spread much more widely throughout the EU – and for taxation legislation such as this, the unanimous agreement of EU Member States in the Council is required. Even a Commission proposal[35] 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 story is similar for 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 to be in itself an argument for EU action, it also underlines the likely difficulties on reaching agreement on more-restrictive advertising or labelling rules.

3.2.3 Environmental determinants

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.[36] The central importance of such environmental protection is illustrated by some of the links between health and environmental factors shown in Table 3.3; indeed, the World Health Organization (WHO) estimates that environmental causes account for 18–20% of the overall burden of disease throughout the WHO European region – more in the eastern than in the western part covered by the EU.[37]

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

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

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

Table 3.3 *Some health impacts and associations with environmental and lifestyle factors*

Health impact	Association with some environmental exposures
Infectious diseases	Water Air and food contamination Climate change-related changes in pathogen life cycles
Cancer	Air pollution (PMs, mainly $\leq PM_{2.5}$) 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
Cardiovascular diseases	Air pollution (carbon monoxide, ground-level ozone, PMs) Smoking and ETS Lead Noise Inhalable particles Food (e.g. high cholesterol) Stress
Respiratory diseases including asthma	Smoking and ETS Air pollution (sulphur dioxide, nitrogen dioxide, ground-level ozone, $PM_{2.5}$ and PM_{10}) Fungal spores Dust mites Pollen Pet hairs Skin and excreta Damp
Skin diseases	Ultraviolet radiation Some metals (e.g. nickel) Pentachlorophenol Dioxins
Diabetes, obesity	Foods (e.g. high fat) Poor exercise levels
Reproductive dysfunctions	PCBs DDT Cadmium Phthalates Endocrine disruptors Pharmaceuticals
Developmental (fetal and childhood) disorders	Metals (cadmium, lead, mercury) Smoking and ETS Some pesticides Endocrine disruptors
Nervous system disorders	Metals (lead, manganese) Methyl mercury Some solvents Organophosphates
Immune dysfunction	Ultraviolet-B radiation Some pesticides
Increased chemical sensitivity	Multiple chemical exposures at low doses

Source: EPHA. *Report on the status of health in the European Union: towards a healthier Europe (EUGLOREH Project).* Brussels, DG Health and Consumer Protection, 2008 (http://ec.europa.eu/health/reports/publications/index_en.htm, accessed 28 July 2014; summary at http://www.epha.org/spip.php?article3439).
Notes: ETS:Environmental tobacco smoke; PCBs: Polychlorinated biphenyls; PM: Particulate matter.

Despite the progress made in many areas, challenges remain for environmental impact on health.[38] For example, for air pollutants, there has been progress with some (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 concern about the real-world impact of cumulative exposure to many different chemicals over time.

Climate change

The specific issue of climate change is also relevant for health. Not only can climate fluctuations 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 heat waves and changes in the transmission of infectious diseases.[39] In 2009, the Commission published a working paper on the health impacts of climate change,[40] 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 health care. 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 by the "environment" department (and as of 2010 also a specific DG for action on climate change).[41] 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.

3.2.4 Diet, nutrition and physical activity

Diet, nutrition and physical activity are areas with a contradictory impact by the EU. On the one hand, the choices that people make about their diet and

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

39 Patz JA et al. Impact of regional climate change on human health. *Nature*, 2005, 438(17): 310–317.

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

41 Although there is an integrated approach set out by the European Commission: *European environment and health strategy (COM(2003)338).* Brussels, European Commission, 2003.

physical activity are inherently individual and shaped by local factors such as food availability or local transport infrastructure, over which the EU's influence is limited. On the other hand, the food choices available to them and the prices attached are heavily shaped by the EU through one of its most substantial areas of action, the Common Agricultural Policy.

The initial context for the Common Agricultural Policy was the aftermath of the Second World War and food shortages; the first priority was simply to improve food availability and to encourage production.[42] However, during the 1970s and the 1980s, the Common Agricultural Policy overshot, with massive production surpluses leading to "food mountains". Reforming the system took years, but eventually reform in the 2000s broke the link between subsidies and production. Nevertheless, the EU still provides substantial subsidies to farmers, and the distribution of subsidies is substantially shaped by the history of production-linked subsidies, which were not focused on health-friendly fruit and vegetables but rather on products such as cereals, beef, olive oil and milk.[43] Of course, a much wider set of factors is involved in how these then relate to health issues such as obesity,[44] but nevertheless the EU clearly has an impact. This is not to say that the Common Agricultural Policy does nothing for health – for example, it supports fruit, vegetable and milk consumption in schools,[45] and in the past a proportion of tobacco subsidies has been redirected to finance an EU-wide anti-smoking campaign. Given the vast resources invested by the EU in this Policy, it could certainly do more.[46]

Any successful effort to tackle obesity, however, will need to involve a wide range of actors, including the private sector and civil society alongside government.[47] In this context, the approach taken by DG SANCO is an interesting one, convening an "EU platform for action on diet, physical activity and health" in 2005,[48] bringing together this kind of broad range of actors and inviting them

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42 European Commission. *The common agricultural policy: a story to be continued*. Luxembourg, Publications Office of the European Union, 2012.

43 Schäfer EL, Lock K, Gabrijelči BM. Public health, food and agriculture policy in the European Union. In: Ståhl T et al., eds. *Health in all policies: prospects and potentials*. Helsinki, Ministry of Social Affairs and Health, 2006:93–110.

44 Swinburn BA et al. The global obesity pandemic: shaped by global drivers and local environments. *Lancet*, 2011, 378(9793):804–814.

45 Council of the European Union. *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1308/2013 and Regulation (EU) No 1306/2013 as regards the aid scheme for the supply of fruit and vegetables, bananas and milk in the educational establishments (COM(2014)32).* Brussels, European Commission, 2014.

46 Kurzer P. Non-communicable diseases: Europe declares war on "fat". In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:155–167.

47 Gortmaker SL et al. Changing the future of obesity: science, policy, and action. *Lancet*, 2011, 378(9793):838–847.

48 DG Health and Consumer Protection. *EU platform for action on diet, physical activity and health*. Brussels, DG Health and Consumer Protection, 2005 (http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm, accessed 4 July 2014).

to make their own commitments to help to tackle these issues. The effectiveness of this kind of "soft-law" approach is difficult to assess;[49] members monitor their own progress, and even if they do achieve what they say, how does this differ from what they would have done anyway? However, the range of participants is extensive and the platform for action may have created pressure to make commitments and, once made, to keep them. Further research on the effectiveness of these kinds of tool is needed.

One area where the EU has acted through legislation is the information provided to consumers about the nutritional content of food – how much energy it contains and its components such as fat and carbohydrates, as well as information on allergens. The revision of these requirements on the basis of a Commission proposal in 2008[50] proved particularly controversial in the European Parliament, where there was much debate over the introduction of "traffic light" information highlighting the health impact of processed foods; the idea was ultimately rejected.[51] Although at the time this was interpreted as a victory for industry interests over health, the evidence for effectiveness of such a traffic light scheme is not clear;[52] comparative research on the different approaches being taken by different European countries may help to clarify the most effective approaches.

3.2.5 Social determinants: health and safety and the Working Time Directive

The importance of social determinants of health has been described in detail in the WHO European review of social determinants of health and the health divide, among others.[53] European action to address these determinants, however, is heavily shaped by the division of powers between the EU and its Member States, as discussed above. Nevertheless, there are some areas where the EU has acted to address the social determinants highlighted by this review, most notably around ensuring safe and healthy workplaces. Wider issues of social policy and social determinants will be discussed in Chapter 4.

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

49 Jarman H. Collaboration and consultation: functional representation in EU stakeholder dialogues. *Journal of European Integration,* 2011, 33(4):385–399.

50 European Parliament and Council. *Proposal for a regulation of the European Parliament and of the Council on the provision of food information to consumers (COM(2008)40)*. Brussels, European Commission, 2008.

51 European Parliament. *MEPs set out clearer and more consistent food labelling rules*. Luxembourg, Publications Office of the European Union, 2010 (http://www.europarl.europa.eu/sides/getDoc.do?language=en&type=IM-PRESS&reference=20100615IPR76127, accessed 4 July 2014).

52 Sacks G, Rayner M, Swinburn B. Impact of front-of-pack "traffic-light" nutrition labelling on consumer food purchases in the UK. *Health Promotion International*, 2009, 24(4):344–352.

53 Marmot M et al. WHO European review of social determinants of health and the health divide. *Lancet,* 2012, 380(9846):1011–1029.

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. As described above, this includes a directive on sharps (e.g. safe handling of needles and other products that can pose a hazard to workers)[54] specifically focused on workers in the health sector, although many of the other provisions are also highly relevant to health care workers.[55]

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 striving to become more competitive by lowering employment standards. Reflecting this, in 1990 the Commission proposed setting minimum standards for certain aspects of working time, in particular a minimum of 11 hours of rest per 24-hour period and specific protection for night workers and shift workers.[56] The directive was controversial, at least in the United Kingdom, which unsuccessfully tried to contest the original directive before the CJEU.[57] 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, health systems were themselves dependent on historical practices of long hours being worked by junior doctors. The directive as agreed in 1993 reflected this,[58] 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,[59] 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

54 Council of the European Union. *Directive 2010/32/EU on prevention from sharp injuries in the hospital and healthcare sector of 10 May 2010 implementing the framework agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU*. Luxembourg, Publications Office of the European Union, 2010.

55 European Commission. *Occupational health and safety risks in the healthcare sector*. Luxembourg, Publications Office of the European Union, 2011.

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

57 European Court of Justice. Case C-84/94 *United Kingdom v Council of the European Union*.

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

59 Cambridge Policy Consultants. *Business impact assessment – working time: excluded sectors: supplementary report: doctors in training*. Cambridge, UK, Cambridge Policy Consultants (http://ec.europa.eu/social/BlobServlet?docid=2434&langid=en, accessed 4 July 2014).

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[60] 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 put forward by the United 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.

Given the size of changes brought by the directive in comparison with the historical practice of doctors working well over 100 hours a week, 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.[61] 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.

3.2.6 Consumer protection

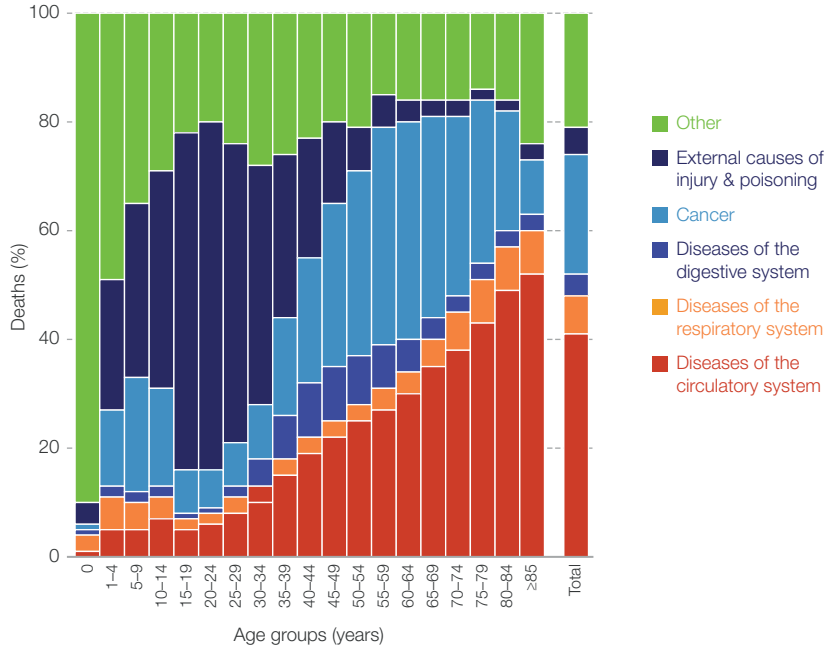
Injuries and other external causes of death (such as traffic accidents and intentional self-harm) are a major cause of death for younger adults in the EU, particularly

60 European Parliament and Council. Directive 2000/34/EC amending Council Directive 93/104/EC concerning certain aspects of the organisation of working time to cover sectors and activities excluded from that Directive. *Official Journal*, 2000, L 195:41–44.

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

men, as shown in Fig. 3.2. This highlights the importance of avoiding injuries in daily life, and this is the area where EU consumer protection actions have their main contribution to health. In particular, the General Product Safety Directive[62] obliges anyone selling consumer products to ensure that they are safe and it provides a range of mechanisms and reference points for doing so, as well as provisions for monitoring and enforcement.[63] One particularly important mechanism is that of European standards, which once developed form key benchmarks against which the safety of products is assessed.

Fig. 3.2 *Major causes of death by age group in the EU25, 2002*



Source: Eurostat. *Causes of death: annual data*. (http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hlth_cd_asdr&lang=en, accessed 4 July 2014).
Note: EU25: Member States in 2004.

There is also specific legislation on the safety of some specific products, of which the regulation of pharmaceuticals and medical devices is particularly relevant; this is discussed in Chapter 4. There is as yet no similar general European legislation on the safety of services (although the safety of some services is regulated, such as aspects of transport services).

62 European Parliament and Council. Directive 2001/95/EC on general product safety. *Official Journal*, 2002, L 11/4. The legal base of this directive is actually the internal market article, the first iteration of the directive in 1992 being adopted before the consumer protection article was introduced by the Maastricht Treaty, but it is considered to be part of the EU's consumer protection legislation and the revised version makes explicit reference to the consumer protection article.

63 Hancher L, Sauter W. *EU competition and internal market law in the health care sector.* Oxford, Oxford University Press, 2012.

3.2.7 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.[64] The logic is inexorable. Spillover from an increasingly integrated Europe creates incentives to coordinate knowledge and responses; integration means population movements, 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 organization, resources and skills.[65]

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). The EU and ECDC are both vehicles to ease collective action and an actor suggesting collective solutions.

Protection against health threats, accordingly, creates an interesting 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.[66] Both infectious disease outbreaks (including SARS and influenza 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 the national health care budgets.[67] 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.

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

64 See the special issue on the subject: *Journal of Health Politics, Policy, and Law*, 2012, 37 issue 6.

65 Elliott H, Jones DK, Greer SL. Mapping infectious disease control in the European Union. *Journal of Health Politics, Policy, and Law*, 2012, 37(6):935–954; Reintjes R. Variation matters: epidemiological surveillance in Europe. *Journal of Health Politics, Policy, and Law*, 2012, 37(6):955–965; Reintjes R et al. Benchmarking national surveillance systems: a new tool for the comparison of communicable disease surveillance and control in Europe. *European Journal of Public Health*, 2007, 17(4):375–380; Greer SL, Mätzke M. Bacteria without borders: communicable disease politics in Europe. *Journal of Health Politics, Policy, and Law*, 2012, 37(6):815–914. We would like to thank Anniek de Ruijter for her comments on this section.

66 TFEU, Article 168(1).

67 TFEU, Article 168(7).

and surveillance of communicable diseases, formalized in 1998.[68] However, this overarching network had evolved from a series of disease-specific networks and depended on ad hoc coordination between national authorities, coordinated by the Commission. The anthrax alerts of 2001 in the United States combined with the sudden global spread of the virus causing SARS in 2003 abruptly focused attention on the weaknesses of these arrangements, and a specialist agency was established instead to coordinate surveillance and monitoring of communicable disease, the ECDC.[69]

Reflecting the wider distribution of health powers between the EU and Member States, the ECDC has not become a single Europe centre in the same way as the Center for Disease Control and Prevention (CDC) has 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 (around 300) 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. Developing a role in the crowded and very political world of European communicable disease control is a challenge, and EU-level action can be overshadowed by failures in Member States' risk management and response systems. Like so much of European policy, the ECDC relies on networks of scientists as well as international organizations, and its effectiveness rests in its own effectiveness at inspiring and using them.

Managing and responding to threats

The responsibilities of the ECDC are centred in monitoring and surveillance, and to some extent in 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

68 European Parliament and Council. Decision No 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, *Official Journal*, 1998, L 268/1.

69 European Parliament and Council. Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control. *Official Journal*, 2004, L 142/1; Greer SL. The European Centre for Disease Prevention and Control: hub or hollow core? *Journal of Health Politics, Policy, and Law*, 2012, 37(6):1001–1030.

a "Health Security Committee",[70] which addresses issues such as preparedness and response for public health emergencies, as well as coordinating responses in crisis situations. The Health Security Committee's evolution has been interesting; many of its functions today accumulated informally as Member State officials found it was a useful venue to coordinate their activities.

Historically, crisis response and management has been the weak point of European action on health threats. Faced with urgent situations and domestic pressures, Member State governments have tended to revert to taking national measures, sometimes even against the interest 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 vaccine and antiviral medications they could, and declined to share. Perhaps in response to subsequent criticism,[71] it is noteworthy that the updated Decision now includes specific provision for joint procurement of medical countermeasures for serious cross-border threats to health.

3.3 Information, comparisons and benchmarking

One of the clearest areas where the EU can add value to national efforts on health is through comparison of information and data, and synthesizing evidence and best practice. This has been the case for areas of health beyond communicable diseases (described above). One of the strongest examples has been for cancer, where the ability to compare outcomes for cancer treatment between European countries through the EUROCARE projects revealed some startling and unexpected differences and led to several countries putting in place whole new strategies to reshape their approaches to cancer, drawing on identification of good practice from elsewhere in Europe.[72]

However, this work has suffered from some particular difficulties at European level. The impact of information and evidence on policy and practice is typically indirect and difficult to demonstrate. Particularly for institutions whose primary focus is producing legislation, this has undermined recognition of the European added-value of information as opposed to regulation, for example. The provision of information and evidence on policy and practice can, however, focus policy-makers' attention on specific issues – as when it directed attention

70 European Parliament and Council. *Decision No 1082/2013/EU on serious cross-border threats to health and repealing Decision 2119/98/EC*. Luxembourg, Publications Office of the European Union, 2013; de Ruijter A. *Uncovering European health law* [thesis]. Faculty of Law, University of Amsterdam, 2013.

71 Nicoll A, McKee M. Moderate pandemic, not many dead: learning the right lessons in Europe from the 2009 pandemic. *European Journal of Public Health,* 2010, 20(5):486–488.

72 Coleman MP et al., eds. *Responding to the challenge of cancer in Europe*. Ljubljana, Institute of Public Health of the Republic of Slovenia, 2008.

at various times to Dutch perinatal mortality, English cancer survival, accident rates among immigrant children in Germany and HIV transmission among the homeless in France.[73] It seems that this works best when the data present a country as doing worse than it expects it should and when there is a pre-existing network of professionals, policy-makers or advocates willing to treat a bad result as a justification for policy change.[74]

Sustainability has been another issue. Internationally comparable information systems are complex to develop, taking years if not decades, but these health information systems have lacked sustained structures to enable and support them, predominantly supported by individual projects under the various health programmes, typically for three years at maximum. The EU institutions recognized the limitations of this approach for communicable disease when they established the ECDC, but there is no similar structure or resourcing for health information data and evidence beyond communicable disease. Given the roughly 300 staff allocated to the comparatively small area of communicable disease in the ECDC, the dozen or so staff left handling information and evidence for health in the Commission represents a clear choice not to prioritize wider information on health.

Eurostat (the EU Statistics Agency) does, of course, collect statistical data more generally, but the EU statistical system has not adopted the range of health indicators developed by successive health programmes, an approach itself reflecting reluctance by national statistical offices. This is illustrated by the delay in the provision of data to the EU by national authorities even for the limited set of health statistics that are collected at European level. Typically, the basic EU health data from Eurostat, such as causes of death statistics, are years out of date; at time of writing in early 2014, the most recent statistics on causes of death available from Eurostat were from 2010[75] (and even then, not for all countries). This makes it impossible to use EU data to assess policy such as the health effect of the financial crisis or of other major policy issues in time for current policy-makers to respond and see the health consequences of their decisions.

One solution would be to extend the mandate of the ECDC to provide data and evidence on health issues more generally rather than only for communicable disease. This was discussed at the time of the ECDC's establishment, and its

73 Elliott H. European Union health information infrastructure and policy. In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:36–50.

74 Greer SL. The weakness of strong policies and the strength of weak policies: law, experimentalist governance, and supporting coalitions in European Union health care policy. *Regulation and Governance,* 2011, 5(2):187–203.

75 Eurostat. *Causes of death: standardised death rate per 100 000 inhabitants – annual data*. (http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hlth_cd_asdr&lang=en, accessed 4 July 2014).

Health in the European Union. Trends and analysis

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European Observatory on Health Systems and Policies, 2009

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-in-the-european-union.-trends-and-analysis

Good health is a fundamental resource for social and economic prosperity and Europe has seen improvements over the past few decades in both health status and living and working conditions.

Within the context of the EU, the range of living conditions has widened tremendously in recent years as the EU has gone through an enlargement process. This diversity has translated into varied patterns of health across the region. Inequalities in income, education, housing and employment have directly or indirectly affected public health. In addition, certain diseases and causes of death are more likely to affect young people, whereas most are associated with older ages. All these factors need to be taken into account, and this study addresses some of the complexities involved.

The book discusses and analyses the relationship between living conditions, socioeconomic factors and health, with the objective of framing a debate and policy action to create a healthier and fairer society across Europe.

founding regulation includes specific provisions on the possible expansion of the ECDC's mandate to cover health monitoring more generally.[76] So far, however, the Commission has made no proposal to do so.

3.4 Substances of human origin

Many of the changes in 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. One specifically European

76 European Parliament and Council. Regulation(EC/851/2004 establishing a European centre for disease prevention and control. *Official Journal*, 2004, L 142/1, see Article 31; Guigner S. L'européanisation cognitive de la santé: entre imposition et persuasion. In: Baisnee O, Pasquier R, eds. *L'Europe Telle Qu'elle Se Fait*. Paris, CNRS Editions, 2007.

aspect to this is that sometimes national governments see an advantage in passing responsibility for problematic issues to the European level. As well as pooling policy and technical resources, there is safety in numbers through acting at European level – whatever decisions are made, at least everyone is in it together. Substances of human origin is such an example. 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.[77]

The development of legislation on blood also illustrated another dynamic of EU policy development: the way 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.[78]

The actual legislation on blood, blood products, tissues and cells is relatively limited, reflecting the narrow treaty mandate, being 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;[79] this reflects the perennial concern of national administrations about granting powers to the EU relating to the organization of their health systems.

The background to European action on organs, however, is a more positive one; a shiningly good example in one country (Spain) regarding organ transplantation providing the inspiration for collective action at European level to try to overcome the persistent shortage in organs for transplantation that affects Europe.[80] Accordingly, the EU action in this area is much broader than the specific

77 Tabuteau D. La sécurité sanitaire, réforme institutionnelle ou résurgence des politiques de santé publique? *Les Tribunes de la santé*, 2007, 16(3):87–103.

78 Farrell A-M. *The politics of blood: ethics, innovation and the regulation of risk*. Cambridge, Cambridge University Press, 2012; Farrell A-M. The emergence of EU governance in public health: the case of blood policy and regulation. In: Steffen M, ed. *Health governance in Europe: issues, challenges and theories.* Abingdon, UK, Routledge, 2005:134–151.

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

80 DG for Health and Consumers. *Staff Working Document SEC(2008)2956: impact assessment and annexes accompanying the proposal for a directive on quality and safety of organ donation and transplantation and action plan*. Luxembourg, Publications Office of the European Communities, 2008.

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.[81]

3.5 Health outside the EU

Just as it would be hard for the EU to play its role without influencing health in Member States, it would be hard for the EU to have policies affecting the wider world that did not influence health. The EU is the world's largest market, the world's largest trading bloc and the world's largest source of foreign direct investment. The EU is a very significant provider of both overseas aid and humanitarian assistance, with EU Member States among the most substantial providers of overseas development assistance.

This prominent position in the international community means that the policies and principles set by the EU can significantly influence those adopted by other states, whether through formal channels, such as economic partnership agreements, action plans, bilateral and multilateral trade agreements, investment and intellectual property agreements, or through more informal mechanisms of soft power. These policies, in turn, often affect health and health care, even when they are not directly focused on health.

3.5.1 Trade and investment

The EU is a powerful actor in international trade, aiming to represent its Member States with a single voice in international trade and investment negotiations and disputes. The EU has exclusive competence in almost all areas to conduct international negotiations on trade deals,[82] although some practical difficulties remain regarding the sometimes blurred dividing line between international trade and "domestic" EU policy areas, including in health.[83] 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.

The EU is party to many different trade and investment agreements that have implications for health policies. Of the multilateral agreements governed by

81 European Commission. *Communication on an action plan on organ donation and transplantation (2009–2015): strengthened cooperation between Member States (COM(2008)819)*. Luxembourg, Publications Office of the European Communities, 2008.

82 TFEU, Article 3, paragraph 1(e).

83 Jarman H. Trade in services and the public's health: a "fortress Europe" for health? In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:110–123.

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 Agreement on Trade-Related Aspects of the Intellectual Property Rights (TRIPS), 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 (SPS), 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 (TBT), which focuses on the identification of regulatory barriers to trade and has been central to a number of tobacco-related trade disputes.[84]

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.

Under these agreements, the EU has shown reluctance to make liberalizing commitments directly affecting health services although it has made commitments that may indirectly affect health. The EU has also striven to balance access to medicines with protection of its pharmaceutical industry in TRIPS-related discussions.[85] This reflects both the unease of Member States regarding EU policies that could destabilize their health care 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, the TFEU states that "in the field of trade in social, education and health services, where these agreements risk seriously disturbing the national organization of such services and prejudicing the responsibility of Member States to deliver them",[86] unanimous approval is now required from Member States.

In recent years, several Member States have begun to develop multilateral trade and investment agreements outside of the purview of the World Trade Organization. Examples include the Transatlantic Trade and Investment Partnership, the

84 For a brief summary of these agreements, see World Trade Organization. *Understanding the WTO.* Geneva, World Trade Organization, 2012 (http://www.wto.org/english/thewto_e/whatis_e/tif_e/tif_e.htm, accessed 4 July 2014).); for a detailed discussion of their implications for public health, see McGrady B. *Trade and public health: the WTO, tobacco, alcohol, and diet.* Cambridge, UK, Cambridge University Press, 2012.

85 Massard da Fonseca E. Intellectual property enforcement in the European Union. In: Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013:126–137.

86 TFEU, Article 207, paragraph 4(b).

Trans-Pacific Partnership and the Anti-Counterfeiting Trade Agreement. These agreements are significant for health for several reasons.

First, all have implications for the health of EU citizens. The Transatlantic Trade and Investment Partnership negotiations between the United States and the EU, for example, raise issues regarding the regulation of medicines, medical devices and food, among other topics, aiming to increase the ease with which foreign firms on both sides can access each others' markets through regulatory harmonization or forms of mutual recognition and understanding.[87]

Second, public health advocates have criticized what they view as a lack of transparency and attention to public interest issues in these negotiations. In the case of the Anti-Counterfeiting Trade Agreement, 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 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 [Anti-Counterfeiting Trade Agreement], in street demonstrations, e-mails to MEPs and calls to their offices".[88] Similar concerns have been raised by advocacy groups regarding the Transatlantic Trade and Investment Partnership, particularly in regard to proposals to include an Investor-State Dispute Settlement 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.

The third and final issue for health policies for the EU and its Member States posed by the world trading system comes from the potential for the EU to be the target 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. The willingness of the tobacco industry to utilize these mechanisms against states regulating tobacco product packaging may well have implications for current and future tobacco control legislation within the EU.

3.5.2 European neighbourhood policy

One of the key tools that the EU has in relations with neighbouring countries is the promise of ultimate membership. However, it became increasingly clear as the EU worked towards accessing of the post-communist countries of eastern Europe in 2004 that the EU could not keep promising membership but needed

87 Jarman H. Public health and the Transatlantic Trade and Investment Partnership. *European Journal of Public Health*, 2014, 24(2):181.

88 European Parliament. *Press release: European Parliament rejects ACTA*. Brussels, European Parliament, 2012 ((http://www.europarl.europa.eu/news/en/news-room/content/20120703IPR48247/html/ European-Parliament-rejects-ACTA, accessed 15 July 2014).

to find another approach to ensure close and cooperative relations that were not necessarily aimed at such countries ultimately joining the EU. This was the background to the European Neighbourhood Policy, which was set out by the Commission in 2003.[89] It has distinct threads, including the Eastern Partnership, the Union for the Mediterranean (formerly known as the Barcelona Process) and the Black Sea Synergy.

The basic approach taken by the Neighbourhood Policy is that the EU should cooperate with neighbouring countries by providing support and cooperation that will enable them to participate as far as possible in the EU's own activities. However, for health this presents an immediate challenge, as the EU's own activities are themselves limited, as described above. DG SANCO has proposed, depending on an individual country's preferences, cooperation in particular fields including health system reform and policy dialogue, health information and knowledge, communicable disease surveillance and health security.[90] The health actions in the actual country plans tend to be focused on three areas. The countries, with some EU support, agree on upgrading their human, animal and plant health standards to international standards (the agreements frequently use specific international agreements as targets), and on improving their health systems through reform programmes as well as forward-looking projects such as e-health. The EU, meanwhile, provides some measure of support, including co-financing, that allows participation in EU programmes by organizations based in the neighbourhood countries.

After the major changes in the "Arab Spring" in particular, the EU has shifted the focus of the European Neighbourhood Policy[91] to strengthen its focus on promoting democracy and offering greater financial, economic and political support to countries who themselves make the strongest commitments to democratic reform. It is not clear what such strengthened cooperation might mean for health, although as described above, the ability for the EU to offer cooperation with neighbouring countries is limited by what the EU can itself do internally in this area.

3.5.3 Development assistance

Health is a central part of the EU's development aid and cooperation with developing countries. Collectively, the EU and its Member States constitute

89 European Commission. *European neighbourhood policy (ENP).* Brussels, European Commission, 2014 (http://ec.europa.eu/health/eu_world/policy/enp/index_en.htm, accessed 4 July 2014).

90 *European neighbourhood policy*.

91 European Commission and the High Representative of the European Union for Foreign Affairs and Security Policy. *Joint communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: a new response to a changing neighbourhood (COM(2011) 303 final)*. Luxembourg, Publications Office of the European Union, 2011.

the largest donor of official development assistance in the world, accounting for 54% of the global total.[92]

As a large donor coordinating the contributions and policies of other large donors, the EU's focus on improving health in developing countries is substantial. Under the overall heading of reducing poverty, the EU's aims for health in developing countries are focused on improving health and access to health services in developing countries (particularly for the poorest people); tackling HIV/AIDS, malaria and tuberculosis; promoting reproductive and sexual health; maximizing health benefits (and minimizing potential health harms) from the EU's support for other sectors; and supporting global public goods such as the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria.[93] The EU is also working towards ensuring universal coverage of health services, as well as supporting research on global health issues that will help to ensure that health care innovations are appropriate and feasible for developing countries, as well as for the rich world.[94]

In creating development assistance programmes for health, the EU, like any donor, faces some key challenges. Development assistance programmes for health may not provide sustainable funding streams. They may lack policy coherence as donors change their priorities along with their politics. They may specify only narrow policy goals that do not match those of the recipients. They may exacerbate strain on under-resourced administrative bodies. And coordination problems can often occur, as many different donors are often attempting to implement separate programmes in one country at the same time, causing less than optimal outcomes.[95]

The EU attempts to address these challenges through a combination of financial instruments, programme documents and formal agreements with developing countries. The EU uses two main financial instruments to deliver aid, which are frequently used to support health. The EU supports the African, Caribbean and Pacific Countries group through the European Development Fund (which will provide €29.1 billion from 2014 to 2020, outside the EU budget), and Latin American states, Asian states, the Gulf Region and South Africa through the Development Cooperation Instrument (providing €19.7 billion from 2014 to

92 European Commission. *EU aid explorer*. Brussels, European Commission, 2014 (https://euaidexplorer.jrc.ec.europa.eu/AboutAction.do, accessed 4 July 2014).

93 European Commission. *Health and poverty reduction in developing countries (COM(2002)129).* Brussels, European Commission, 2002.

94 European Commission. *The EU role in global health (COM(2010)128)*. Brussels, European Commission, 2010.

95 Ram R. Making development assistance for health more effective through HiAP. In: Leppo K et al., eds. *Health in all policies: seizing opportunities, implementing policies*. Helsinki, Ministry of Social Affairs and Health, 2013:286–306; Cook S, Zhang S, Ilcheong Y. Health and development: challenges and pathways to HiAP in low-income countries. In: Leppo K et al., eds. *Health in all policies: seizing opportunities, implementing policies*. Helsinki, Ministry of Social Affairs and Health, 2013:43–62.

2020, within the EU budget). The allocation of these funds is governed using Country and Regional Strategy Papers, which are produced in collaboration with recipient countries and outline key focus areas, and National/Regional Indicative Programmes, which are formal agreements to focus on specific areas (e.g. health, education, or governance) and co-signed by the EU and the recipient state.

3.6 An integrated strategy?

As this chapter has shown, EU action for health is wide ranging, disparate and goes far beyond actions specifically based on the main "health" provisions in the treaties, with most EU legislation for health being based on other treaty articles, in particular those on the environment and health and safety at work. This presents a challenge for those interested in what the EU does for health in terms of being able to find and understand all the different elements of health, as illustrated above. It also presents a challenge to the Commission and the other EU institutions themselves in trying to take a strategic approach to the overall issue of health.

In 2007, the Commission attempted to bring the different pieces together into an overall strategy document,[96] proposing four principles and three objectives. The first principle was "a strategy based on shared health values". It hoped to build on a statement on common values and principles in EU health care systems and proposed establishing a statement on common values for health policy more broadly that has yet to materialize. The second principle, "health is the greatest wealth", was aimed at highlighting the contribution of health to economic growth and development – although the near-total absence of health from the Commission's growth-focused overall Europe 2020 strategy[97] three years later suggests that this principle is not yet widely accepted across the European institutions. The fourth principle, "strengthening the EU's voice in global health", was discussed in section 3.5; the EU's role in global health is wide ranging and increasingly linked back to its own internal policies. The observant will notice that the third principle, that of health in all policies, was not listed and this will be returned to below.

The strategy then proposed three objectives. The first objective is "fostering good health in an ageing Europe". Demographic ageing is clearly a particular challenge for Europe and, as the Communication points out, is projected to push up health care spending by an average of 25% (or 1–2% of GDP). However, the Commission's projections also show that how healthy people are has a major impact on those likely costs, suggesting that if people can remain healthy as they

96 European Commission. *Together for health: a strategic approach for the EU 2008–2013 (COM(2007)630).* Brussels, European Commission, 2007.

97 European Commission. *Europe 2020: a strategy for smart, sustainable and inclusive growth (COM(2010)2020).* Brussels, European Commission, 2010.

live longer, the projected rise in health care spending would be halved. Promoting active and healthy ageing has, therefore, become a key area of action for the EU, and is discussed further in Chapter 4.

The second objective is "protecting citizens from health threats"; this encompasses action around issues such as communicable disease, climate change and consumer protection, as discussed above. The third objective is "supporting dynamic health systems and new technologies", which links to some of the more market-oriented actions of the EU, which will be described below. Although this strategy was stated as being for the period 2008–2013, this focus on health systems is clearly reflected in the Commission's proposal for the new health programme for 2014–2020, with its much stronger focus on health systems and innovative technologies.

3.6.1 Health in all policies

Here we return to the third principle, that of "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.[98] This has been a part of the European approach to health since the introduction of the specific article on health into the treaties, with its requirement (strengthened over the years) that health protection be integrated throughout the EU's action.

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:[99]

- 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,[100] and ultimately the Commission

98 Ståhl T et al., eds. *Health in all policies: prospects and potentials*. Helsinki, Ministry of Social Affairs and Health, 2006.

99 European Commission. *Report on the integration of health protection requirements in Community policies (COM(95)196)*. Brussels, European Commission, 1995, p. iii.

100 See the *Integration of health protection requirements in Community policies* Second Report (COM(96)407) of 1996, Third Report (COM(1998)34) of 1998 and Fourth Report (not officially issued by the Commission, but produced in 1999; http://ec.europa.eu/health/ph_overview/Documents/ke03_en.pdf, accessed 4 July 2014).

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,[101] as well as a specific impact assessment tool for impact on health systems.[102]

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 "integration 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 with 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;[103] 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,[104] which would review impact assessments of proposals before they are submitted to the Commission for adoption. This Board is made up of senior officials from the central Secretariat-General and the DGs with relevant economic, environmental and social expertise; there is no member from DG SANCO. However, despite this strengthening of the process, an evaluation for the Commission reported that the impact assessment process was not generally viewed internally as a credible or impartial one. Commission officials saw it more as an exercise in justifying the proposals concerned.[105] Externally,

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101 European Commission. *European policy health impact assessment* (http://ec.europa.eu/health/ph_projects/2001/monitoring/monitoring_project_2001_full_en.htm#11, accessed 4 July 2014) and *European policy health impact assessment guide* (http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf, accessed 4 July 2014). Brussels, European Commission.

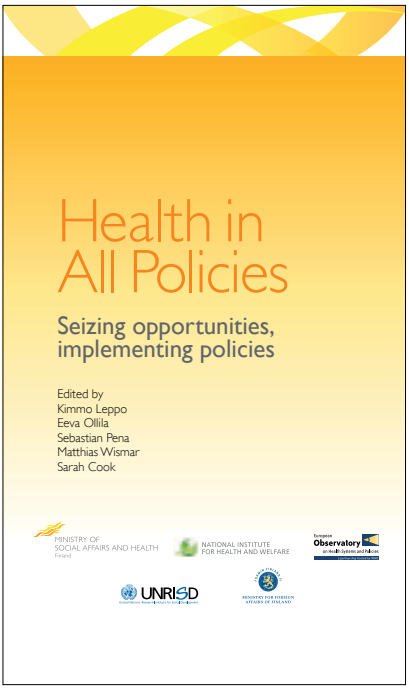
102 European Commission. *Policy health impact assessment for the European Union*. Brussels, European Commission, 2004 (http://ec.europa.eu/health/ph_projects/2001/monitoring/monitoring_project_2001_full_en.htm#11, accessed 28 July 2014).

103 European Commission. *Communication on impact assessment (COM(2002)276).* Brussels, European Commission, 2002.

104 European Commission. *Impact Assessment Board*. Brussels, European Commission, 2014 (http://ec.europa.eu/smart-regulation/impact/iab/iab_en.htm, accessed 4 July 2014.

105 Evaluation Partnership. *Evaluation of the Commission's impact assessment system: final report. Executive Summary*. Brussels, European Commission, 2007 (http://ec.europa.eu/smart-regulation/impact/key_docs/docs/tep_eias_final_report_executive_summary_en.pdf accessed 4 July 2014).

Health in All policies: seizing opportunities, implementing policies



Edited by Kimmo Leppo, Eeva Ollila, Sebastián Peña, Matthias Wismar and Sarah Cook

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http://www.euro.who.int/en/about-us/partners/observatory/studies/health-in-all-policies-seizing-opportunities,-implementing-policies

Health in All policies (HiAP) is an approach to policies that systematically takes into account the health and health system implications of decisions, seeks synergies and avoids harmful health impacts to improve population health and health equity. It is founded on health-related rights and obligations and has great potential to improve population health and equity.

However, incorporating health into policies across sectors is often challenging and even when decisions are made, implementation may only be partial or unsustainable.

This volume aims to improve understanding of the dynamics of HiAP policy-making and implementation processes. Drawing on experience from all regions, and from countries at various levels of economic development, it demonstrates that HiAP is feasible in different contexts, and provides fresh insight into how to seize opportunities to promote HiAP and how to implement policies for health across sectors.

doubts have also been expressed about how far health impacts are really assessed in these integrated impact assessments.[106]

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

106 Koivusalo M. The state of health in all policies (HiAP) in the European Union: potential and pitfalls. *Journal of Epidemiology and Community Health,* 2010, 64(6):500–503; Smith KE et al. Is the increasing policy use of impact assessment in Europe likely to undermine efforts to achieve healthy public policy? *Journal of Epidemiology and Community Health*, 2010, 64(6):478–487.

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 effects 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. It is to these other impacts that we now turn.

Chapter 4

How other European action affects health

The EU's impact on health is not limited to those parts of the treaties that have health as a specific objective – far from it. The second face of the EU is its economic face, and it matters very much. In many ways, the EU's impact on health is much greater from other aspects of its actions that aim at quite different objectives. This section describes one of those perhaps more surprising areas.

The internal market has long had important consequences for health – most recently by providing explicit legislation on cross-border health care – but historically across all its dimensions of free movement: services (including competition rules), goods (such as medicinal products and medical devices, as well as providing a basis for health legislation such as tobacco advertising), people (the mobility of health professionals being a key challenge) and capital (with the EU playing an increasing role in investing in health infrastructure). Health is the largest single topic within the EU's research budget and has also been addressed through social policy.

Given this remarkable range of impacts on health, it is inevitable that questions will be asked about how well the EU takes health into account across this wide range of issues. As the EU's role strengthens, notably with the strengthening of fiscal governance, there are signs of tensions within the EU institutions, which may need different responses in the future.

4.1 What is the EU trying to achieve?

The fundamental reason for the existence of the EU is peace. In the aftermath of two horrific wars within only a few decades, the vision of the founding fathers of European integration in the 1950s was to find a different way for European countries to relate to each other in their divided continent – to find areas of concrete cooperation and mutual interest and to create a framework within which differences over those common interests could be resolved by negotiation and the rule of law, not by force of arms. This basic commitment to using cooperation

and law in place of conflict and to consolidate democracy has remained, as shown by the EU's willingness to bring in southern members after the collapse of dictatorships in Greece, Spain and Portugal, and the post-communist countries of central and eastern Europe.

Although several different areas for cooperation were identified in the area, cooperation on coal and steel production being the first, from the start the aim has been for European cooperation to contribute to "economic expansion, growth of employment and a rising standard of living in the Member States",[1] and this aim of European cooperation generating growth has remained central to the EU. Following the acceleration of European integration after the Single European Act in the 1980s and 1990s and the multiplication of European initiatives in different areas, the EU took to setting out overall strategies in an effort to keep a core focus for all these different cooperation activities. The 10-year Lisbon strategy was agreed in 2000 at the Lisbon European Council with the aim for the EU "to become the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion",[2] although many of the aims that it set required action that was beyond the EU's power to ensure (in particular requiring domestic reforms by Member States).

At the end of that decade, however, the economic situation was more difficult. The aftermath of the financial crisis had left a number of EU Member States with severe sovereign debt crises, and many EU Member States found it difficult to create and implement sustainable growth strategies. This is reflected in the focus of the updated strategy Europe 2020,[3] which has a strikingly simple objective: "smart, sustainable, and inclusive growth." It starts with short-term fiscal policy issues in a section titled "exit from crisis", but its focus is on directing Member State reforms and EU actions towards clear policy goals. Table 4.1 presents the specific Europe 2020 targets. The challenge with setting targets such as these, however, is that they are beyond the scope of the EU alone to achieve, requiring substantial domestic actions by Member States. Indeed, some of them are arguably not within the power of government to achieve at all.

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1 Treaty establishing the European Coal and Steel Community, 1951, draft English text, Article 2 (http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_ecsc_en.htm, accessed 4 July 2014; the official text is only available in German, French, Italian and Dutch, the languages of the founding Member States.)

2 Council of the European Union. *Presidency conclusions, Lisbon European Council meeting, 23–24 March 2000*. Luxembourg, Publications Office of the European Union, 2000 (https://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/ec/00100-r1.en0.htm, accessed 4 July 2014).

3 European Commission. *Europe 2020: a strategy for smart, sustainable and inclusive growth (COM(2010)2020).* Brussels, European Commission, 2010.

Table 4.1 *Europe 2020 targets*

Areas	Target
Employment	75% of those aged 20–64 years will be employed
Research and development	3% of the EU's GDP will be invested in research and development
Climate change/energy	Greenhouse gas emissions will be 20% (even 30% if conditions are met) lower than in 1990
	20% of energy will come from renewable sources
	A 20% increase in energy efficiency
Education	Reduction in school drop-out rates to below 10%
	At least 40% of those aged 30–34 years will complete third level education
Poverty/social exclusion	At least 20 million fewer people will be living in or at risk of living in poverty and social exclusion

So, how does health fit within this overall strategy? Not very clearly. On the one hand, the contribution of health to the goals of Europe 2020 is clear and substantial: the employment rate is influenced by health (including public health measures, health care and social care to enable the disabled or elderly to work productively), and as health being one of the largest employment sectors itself within the European economy; health is a major area of productive research and development; health is a major, and growing, area of tertiary education; and ill health is a major risk for poverty and social exclusion. On the other hand, health is nearly invisible within Europe 2020 itself: the importance of reducing health inequalities and promoting active and healthy ageing (within the context of demographic ageing) and access to health services is referred to in passing, but health systems are seen as needing "structural reforms" to ensure sustainable levels of public expenditure, and, as seen above, none of the overall targets specifically refers to health.

4.1.1 Health systems values

In 2006, as part of the wider discussions that led to the directive on patient rights in cross-border health care, the Council sought to establish specific health system values separate from those of social policy or economic policy, and to steer debates such as those around patient mobility by stating the values that the Member States shared as regards health systems. This statement lacks binding legal force but is the clearest articulation of Member States' consensus on health system priorities. It emphasizes the "overarching values of *universality*, *access to good quality care*, *equity*, *and solidarity*" and "operating principles" of quality, safety, evidence and ethics, patient involvement, redress, and privacy and confidentiality.[4] However, this set of values has no direct mechanism for translation

4 Council of the European Union. *Council conclusions on common values and principles in European Union health systems (2006/C 146/01).* Brussels, European Commission, 2006.

into practice; it remains to be seen how far these values are translated into the wider policies of the EU.

In December 2013, the Council for Employment, Social Policy, Health and Consumer Affairs chose to highlight the importance of health investment, the Social Investment Package, and the importance of attention to health in the reforms associated with enhanced fiscal governance.[5] This statement is a reminder of the importance of health and the need to integrate it in the economic thinking of the EU.

4.1.2 Innovation Union Partnership on active and healthy ageing

One of the seven *flagship initiatives* proposed by the Commission to take forward the Europe 2020 strategy is the "Innovation Union",[6] the aim of which is to improve the innovativeness of Europe and ensure that research is effectively translated into practice in sectors including health. One of the key issues identified is the challenges brought by demographic ageing – while the increasing lifespan of Europeans is an excellent outcome of improving living standards and health systems, it also presents significant challenges, with increasing costs to health and social care systems alongside a relative reduction in the size of the working-age population that can keep working to pay for these systems.[7] While the relative size of increases in costs to health systems for the coming decades is actually smaller than the average increases in health care spending in the past decades of the EU, this is still a substantial shift and presents a major challenge to countries whose public budgets are already under serious pressure.

The Commission accordingly took this topic of "health and active ageing" as the focus of its first Innovation Union Partnership[8] proposed as part of the Innovation Union initiative. The aim of this Partnership is to bring together stakeholders and experts across the innovation chain from basic research to practical application in order to improve health, improve the sustainability of health systems and to create business opportunities for health industries – indeed, the Partnership aims to increase by two the years of healthy life lived throughout Europe by

5 Council of the European Union. *Council conclusions on the reflection process on modern, responsive and sustainable health systems*. Brussels, European Commission, 2013 (http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/140004.pdf, accessed 4 July 2014).

6 European Parliament, Council, European Economic and Social Committee and Committee of the Regions. *Communication: Europe 2020 flagship initiative innovation union (COM(2010)546)*. Brussels, European Commission, 2010.

7 European Commission (ECFIN) and the Economic Policy Committee (AWG). *The 2009 ageing report: economic and budgetary projections for the EU-27 Member States (2008–2060).* Brussels, European Commission, 2009 (http://ec.europa.eu/economy_finance/publications/publication14992_en.pdf, accessed 4 July 2014).

8 European Commission. *European innovation partnership on active and healthy ageing*. Brussels, European Commission, 2013 (http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=home, accessed 4 July 2014).

2020. This bold objective, however, does not have any additional resources provided to help to achieve it. Rather, the Partnership depends on existing funding streams at European or national level being voluntarily mobilized to support its priorities, and it relies on the power of its vision to convince actors in the area to take forward the issues that it identifies as priorities. Quite a number of organizations have become involved in the Partnership;[9] it remains to be seen whether an initiative on this relatively limited scale, with its disparate economic and public health priorities, will have any significant impact on the health and health systems of the EU as a whole.

4.2 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. Health has to be ensured for all products, whether they are specifically related to health or not, and this has been reflected in the wider rules for products within the EU.

4.2.1 Pharmaceuticals

Since 1965,[10] the EU has been steadily harmonizing the rules governing the requirements to allow sale of medicinal products in the EU, to the extent where this is now one of the most regulated sectors of the European market.[11] 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

9 See the Commission's report on achievements and impact: European Innovation Partnership on Active and Healthy Ageing. *Action groups: first year report.* Brussels, European Commission, 2013 (http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/achievements_2013.pdf#view=fit&pagemode=none, accessed 4 July 2014)

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

11 Principally governed by Directive 2001/83/EC and Regulation (EC) No 726/2004; see also Hauray B. *L'Europe Du Médicament: Politique – Expertise- Intérêts Privés.* Paris, Presses de Sciences, 2006. Permanand G. *EU pharmaceutical regulation: the politics of policy-making.* Manchester, Manchester University Press, 2006.

Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality

Edited by Elias Mossialos, Monique Mrazek and Tom Walley

Oxford University Press, 2004

http://www.euro.who.int/en/about-us/partners/observatory/studies/regulating-pharmaceuticals-in-europe-striving-for-efficiency,-equity-and-quality

The rising cost of pharmaceutical expenditure in many European countries is of concern to governments required to make effective use of health care budgets. Taking a broad perspective that encompasses the institutional, political and supranational aspects of pharmaceutical regulation, this book examines the approaches used to manage pharmaceutical expenditure across Europe and what impact they have had on the efficiency, equity, quality and cost of pharmaceutical care.

processes are run by one of the major health-related European agencies, the EMA[12] based in London. The EMA also oversees the systems for monitoring any problems that may become apparent with medicines after they are licensed: the pharmacovigilance system.

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.[13] The conduct of clinical trials is itself regulated at EU level,[14] 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 itself available through a database at the European level.[15]

12 European Medicines Agency [web site]. London, European Medicines Agency (http://www.ema.europa.eu/ema/ accessed 4 July 2014).

13 World Health Organization. *International clinical trials registry platform*. Geneva, World Health Organization, 2014 (http://www.who.int/ictrp/glossary/en/index.html for more information about clinical trials, accessed 4 July 2014).

14 European Parliament and Council. Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal*, 2001, L 121, p. 34.

15 European Medicines Agency. *EU clinical trials register*. Brussels, European Medicines Agency, 2014 (https://www.clinicaltrialsregister.eu/ctr-search/search, accessed 4 July 2014).

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. Because of this, pharmaceutical products in the EU can have an extension of up to five years on top of the normal 20-year patent protection period.[16] The EU has also attempted to promote the development of drugs for rare diseases (called orphan drugs) through similar mechanisms, providing orphan medicines with 10 years of market exclusivity after they are licensed.[17]

So far the regulatory regime resembles that of the world's other major pharmaceutical market, the United States. However, once we come to the stage of the 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 health care products varies substantially between different EU countries.[18] Therefore, although the EU has a reasonably unified market access regime, its pricing models and markets remain fragmented between the Member States, which take quite different approaches. 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 should do so within a reasonable time.[19]

However, as Member States established their agencies to license pharmaceuticals, they also steadily put in place agencies to evaluate the wider utility of such new health technologies.[20] These deal with questions such as how well these technologies work, what costs are involved, for whom it works well and how well they work compared with alternative technologies. It seems like a logical area for EU action, since there are obvious economies of scale – how well a particular health technology works and how it compares with available alternatives should not in principle be different in different countries. However, the funds available to pay for such technologies are different, of course, and in practice the methodologies used to make these assessments incorporate cultural values and vary substantially too.

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16 European Parliament and Council. Regulation (EC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products. *Official Journal*, 2009, L 152, p. 1.

17 European Parliament and Council. Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products. *Official Journal*, 2000, L 18, p. 1.

18 Ess SM, Schneeweiss S, Szucs TD. European healthcare policies for controlling drug expenditure. *Pharmacoeconomics,* 2003, 21(2):89–103; Leopold C et al. Impact of external price referencing on medicine prices: a price comparison among 14 European countries. *Southern Medical Review*, 2012, 5(2):34.

19 European Commission. Transparency Directive 89/105/EEC: transparency of measures relating to pricing and reimbursement of medicinal products. *Official Journal*, L 40, p. 8.

20 Velasco-Garrido M, Busse R. *Health technology assessment: an introduction to objectives, role of evidence, and structure in Europe*. Brussels, European Observatory on Health Systems and Policies, 2005.

Nevertheless, cooperation at European level has been quietly developing since the 1990s, initially through research projects financed by the European Commission. These have been slowly shifting towards more applied cooperation, with the establishment of the European Network for Health Technology Assessment (EUnetHTA), which now has partners from all the EU Member States as well as Norway and Switzerland[21] and which is complemented by a network of Member State agencies set up in the Directive on Patients' Rights in Cross-Border Healthcare.[22] It remains to be seen how effective this collaboration is in actually moving towards common assessments of health technologies, although the renewed attention to value for money after the recent financial crisis should logically increase the desire for Member States to assess their health technologies carefully. If such cooperation does prove valuable, a similar issue of sustainability and extension will arise in other areas: can the collaboration move beyond short-term project funding towards some standing structure (such as an agency) for health technology assessment at European level?

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 in the United States. Such direct to consumer advertising for prescription pharmaceuticals remains prohibited in Europe. 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.[23]

4.2.2 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.[24] While the relevant EU legislation has some requirements for initial scrutiny, these are lighter than for pharmaceutical products. Moreover, whereas licensing of pharmaceutical products is undertaken by public bodies (the EMA and national agencies), the scrutiny of medical devices is

21 EUnetHTA [web site]. Copenhagen, European Network for Health Technology Assessment, 2014 (http://www.eunethta.eu/contactus/all/356/all, accessed 14 July 2014).

22 European Parliament and Council. Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare. *Official Journal*, 2011, L 88/45.

23 See European Parliament. *Medicinal products for human use: information on products subject to medical prescription*. Luxembourg, Publications Office of the European Union, 2008 (http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2008/0256(COD)&l=en, accessed 14 July 2014).

24 A good account of the background can be found in Hancher L, Sauter W. *EU competition and internal market law in the health care sector.* Oxford, Oxford University Press, 2012.

Health technology assessment

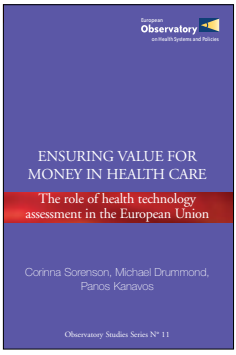
New technologies with the potential to improve the health of populations are continuously being introduced. But not every technological development results in clear health gains. Health technology assessment (HTA) provides evidence-based information on the coverage and usage of health technologies, enabling them to be evaluated properly and applied to health care efficaciously, promoting the most effective ones while also taking into account organizational, societal and ethical issues.

Health technology assessment and health policy-making in Europe. Current status, challenges and potential

Marcial Velasco Garrido, Finn Børlum Kristensen, Camilla Palmhøj Nielsen and Reinhard Busse

European Observatory on Health Systems and Policies, 2008

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-technology-assessment-and-health-policy-making-in-europe.-current-status,-challenges-and-potential



Ensuring value for money in health care: the role of health technology assessment in the European Union

Corinna Sorenson, Michael Drummond and Panos Kanavos

European Observatory on Health Systems and Policies, 2008

http://www.euro.who.int/en/about-us/partners/observatory/studies/ensuring-value-for-money-in-health-care-the-role-of-health-technology-assessment-in-the-european-union

These two studies provide a detailed review of the role of HTA in the EU and review the relationship between HTA and policy-making. By analysing the situation in Sweden, the Netherlands, Finland, France, Germany and the United Kingdom and examining both method and process in the prioritization and financing of modern health care, the authors identify ways to improve the HTA process in Europe and to increase its contribution in policy- and decision-making processes. They also highlight the contribution that HTA can make in supporting value and innovation in health care and ultimately in improving the health status of the population through the delivery of optimum health services.

undertaken by private companies that have been designated as "notified bodies" by the competent authority of the Member State in question; there are around 80 such bodies in Europe.

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 may simply declare that the products meet relevant standards themselves. At the high-risk end (class III devices), notified bodies 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 the medical device functions 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 shown by the more limited assessment required.[26] Doubts have also been expressed about the role of notified bodies in the regulatory process; as private companies whose income comes from the fees that they charge to manufacturers, the notified bodies face a complex set of objectives, balancing the need to fulfil 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]

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 recent serious problems with faulty breast implants and some hip replacements.[28] While these proposals may reinforce the existing regulations to some extent, they do not change the core features of the system in terms of the use of notified bodies, the narrower evaluation criteria in comparison with pharmaceuticals or the lack of public data that would allow independent evaluation of the effectiveness of regulation. The final nature of the revisions remains to be determined, however, as at time of writing these are still under discussion in the parliament and Council.

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25 Chai JY. Medical device regulation in the United States and the European Union: a comparative study. *Food and Drug Law Journal*, 2000, 55:57.

26 Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. *New England Journal of Medicine*, 2012, 366(9):848–855.

27 Kramer DB, Xu S, Kesselheim AS. How does medical device regulation perform in the United States and the European Union? A systematic review. *PLoS Medicine*, 2012, 9(7):e1001276.

28 European Commission. *Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals (COM(2012)540 final)*. Luxembourg, Publications Office of the European Union, 2012.

4.2.3 Food safety

One other key set of products with a high potential impact on health is food. Alongside the growth of the Common Agricultural Policy as a core European activity, it was clearly essential to ensure the safety of food products if consumers were to accept food produced anywhere within the EU. However, food safety issues also led to the EU's worst health-related crisis – the bovine spongiform encephalopathy crisis of the 1990s – with lax oversight blamed for the potential transmission to humans of variant Creutzfeldt–Jakob disease.[29]

This crisis prompted a major overhaul of both the EU's regulation of the area and its organization; it was the basis for the creation of DG SANCO within the European Commission, which brought together the food safety parts from the agriculture DG, public health from the employment and social affairs DG and the consumer policy service into a health-focused DG of the European Commission for the first time in 1999. It then also led to a comprehensive food safety strategy "from farm to fork" in 2000[30] and in 2002 to the establishment of the EFSA.[31] The combination of issues raised by food safety issues is illustrated by the range of legal bases for the regulation establishing the EFSA: agriculture, internal market, trade and public health. The EFSA has two major tasks, akin to those of the ECDC: risk assessment and risk communication. As with the ECDC, the implementation of regulations within the Member States is also the responsibility of national agencies, although unlike communicable disease (and very unusually for the EU), the Commission also plays a direct role in implementation of food safety legislation through its inspectorate, the Food and Veterinary Office, which is part of DG SANCO and based in Ireland. Also unlike communicable disease, the treaty provisions for the EU to act in the area of food safety are very wide indeed; the EU has extensive powers (both regulatory and financial) to make and enforce rules for food safety.

4.3 Services: cross-border health care and patient mobility

The central issue for health in terms of services is cross-border health care. This has been historically very limited within the EU. There are long-standing provisions on coordination of social security designed to ensure the free movement

29 See European Parliament. *Report A4-0020/97 on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts*. Luxembourg, Publications Office of the European Union, 1997; also Grant W. Agricultural policy, food policy and communicable diseases policy. *Journal of Health Politics, Policy and Law,* 2012, 37(6):1031–1048.

30 European Commission. *White paper on food safety (COM(1999) 719)*. Luxembourg, Publications Office of the European Union, 2000.

31 European Parliament and Council. Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matter of food safety. *Official Journal*, L 31, p. 1.

of workers (social security in EU terms is taken to include health care).[32] 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 health care) move with the person; similarly, if an individual temporarily travels to another EU country for a purpose such as work, study or holiday and falls ill, he or she is covered and will be treated by that country's health system.[33] However, if someone wishes to go abroad for the purpose of health care itself, then these provisions are highly restrictive; prior authorization is required from the domestic authorities, which is very rarely given (not surprisingly, as they have to pay the cost of such health care, and generally prefer to provide health care domestically). Reflecting these provisions, the volume of patients travelling to other countries in order to receive health care within the EU has historically been marginal.

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 health care in other EU countries and that preventing them from doing so was a barrier to the internal market;[34] the European Court of Justice agreed. This was easier to argue in the case of an insurance-based system such as Luxembourg, in which citizens pay for their health care initially and are then reimbursed – why should they not be able to purchase their health care from a provider just across the border if it does not cost any more? It was less obvious in a public provision system 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.

Nevertheless, 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. The first – and most logical – attempt was to incorporate the principles established by these cases into a looser version of the existing framework on coordination of social security rights. However, although there was a timely process of revising these regulations following the Court's judgements in 1998, no agreement could be found on including the Court's rulings,[35] particularly given that the legal base for these regulations requires the unanimous agreement of all Member States in the Council. National governments recognized, however, that some new kind of approach was required, and there were a series of EU-level discussions from 2003 onwards on cross-border

32 European Parliament and Council. Regulation (EC) No 883/2004 of 29 April 2004 on the coordination of social security systems. *Official Journal*, 2004, L 166, p. 1.

33 See European Commission. *European Health Insurance Card*. Brussels, European Commission, 2014 (http://ec.europa.eu/social/main.jsp?langId=en&catId=559, accessed 14 July 2014).

34 European Court of Justice. Cases C-158/96 *Kohll,* C-120/95 *Decker.*

35 Palm W, Glinos IA. Enabling patient mobility in the EU: between free movement and coordination. In: Mossialos E et al., eds. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010:509–560.

Cross-border health care in the European Union.
Mapping and analysing practices and policies

Edited by Matthias Wismar, Willy Palm, Josep Figueras, Kelly Ernst and Ewout van Ginneken

European Observatory on Health Systems and Policies, 2011

http://www.euro.who.int/en/about-us/partners/observatory/studies/cross-border-health-care-in-the-european-union.-mapping-and-analysing-practices-and-policies

Cross-border health care is a growing phenomenon in the EU. When in need of medical treatment, patients increasingly act as informed consumers who claim the right to choose their own providers, including those beyond borders. They are supported and encouraged by factors such as the Internet and more internationally trained health professionals, and often motivated by dissatisfaction with health care provision in their home country. Some authorities and health insurers even contract with health care providers abroad or inform patients of such options.

Cross-border health care also encompasses doctors and nurses who train and work abroad and increasingly cooperate with colleagues abroad. In some cases, health services themselves cross borders – through telemedicine – or providers collaborate with financing institutions in other countries.

This book explores these trends, looks at the legal framework and examines the legal uncertainties surrounding rights, access, reimbursement, quality and safety. It examines different approaches to these concerns and the methodologies to use to ease or resolve them.

health care and wider issues facing health systems, and how these might be addressed at European level.

The second attempt to deal with the Court ruling was more radical, with the Commission proposing to incorporate health services within a general directive on the free movement of services,[36] without any particular special treatment

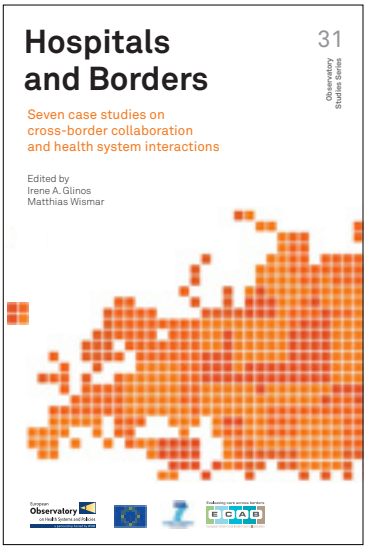
36 European Commission. *Proposal for a directive of the European Parliament and of the Council on services in the internal market (COM(2004)2).* Brussels, European Commission, 2004.

Hospitals and borders. Seven case studies on cross-border collaboration and health system interactions

Edited by Irene A. Glinos and Matthias Wismar

European Observatory on Health Systems and Policies, 2014

http://www.euro.who.int/en/about-us/partners/observatory/studies/hospitals-and-borders.-seven-case-studies-on-cross-border-collaboration-and-health-system-interactions



The EU Directive on Patients' Rights in Cross-Border Healthcare explicitly calls for Member States to cooperate in cross-border health care provision in border regions. Since this generally involves secondary care, hospitals that are close to national frontiers will play a key role.

Seven case studies examine the circumstances under which cross-border collaboration is likely to work, the motivations and incentives of health care actors and the role played by health systems, individuals and the EU in shaping cross-border collaboration. The study offers qualitative and analytical scientific evidence on aspects of cross-border collaboration involving hospitals in 11 EU and non-EU countries (Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, the Netherlands, Norway, Romania and Spain).

Questions on feasibility, desirability and implementation are at the core of the analysis. The book proposes a "toolbox" of prerequisites for starting or maintaining cross-border collaboration in health care.

beyond codifying the Court's principles on people being able to access cross-border health care without prior authorization, at least for non-hospital care. This time it was the European Parliament that objected, refusing to have health services treated like every other kind of service and insisting on proposals that would respect the specific character and particular risks of health services.

The third attempt was, therefore, a compromise between the controlled environment of the social security regulations on the one hand, and the unfettered internal market on the other, building on the emerging consensus that had been developing in parallel through the EU-level discussions described above.[37]

37 European Parliament and Council. *Proposal for a directive on the application of patients' rights in cross-border healthcare (COM(2008)414).* Luxembourg, Publications Office of the European Union, 2008.

Although still based on an internal market legal base (the basis of the Court's original rulings), this proposed directive created a specific framework for health services, clarifying issues such as the responsibility of a country for the quality and safety of all health care being provided on its territory, even if this is being paid for by a different EU country; responsibilities to ensure continuity of care; rights of access to medical records; prohibition of exploitative prices for people from abroad; and the possibility to restrict care to people coming from abroad where necessary to protect domestic provision.

After much discussion, this third attempt was ultimately successful, producing the Directive on Patients' Rights in Cross-Border Healthcare.[38] 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 health care running in parallel, as set out in Table 4.2.

Table 4.2 *Comparison between cross-border healthcare rules under the Regulation on Coordination of Social Security and the Directive on Patients' Rights in Cross-Border Healthcare*

	Regulation on Coordination of Social Security	**Directive on Patient Rights in Cross-Border Healthcare**
Prior authorization	Required for any planned health care in another EU Member State; not required for immediately necessary care while in another EU Member State for other reasons	May be required for hospital care (meaning inpatient care) and other cost-intensive treatments, health hazards and unsuitable providers
Tariffs	The State of treatment; the State where the person is covered if this means more than the State of treatment (up to the level of actual cost)	The State where the person is covered (up to the level of actual cost)
Payment method	Publicly funded element settled between national ministries/insurers	Paid by the patient with subsequent reimbursement by the State where they are covered (unless the State makes direct arrangements to pay)
Provider	Only providers affiliated with the State of treatment social security system	All providers who legally provide health care in the State of treatment
Travel and accommodation costs	State of coverage covers costs that are inseparable from the treatment if it would cover them domestically	Covered to the same extent as they would be domestically – although by virtue of being travel abroad and thus different, what this means in practice is unclear

Source: Greer SL, Sokol T. Rules for rights: European law, health care, and social citizenship. *European Law Journal,* 2014, 20(1):66–87.

Exactly what this additional system provided by the Directive will mean in practice will only emerge over the coming years; Member States had

38 European Parliament and Council. Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare. *Official Journal*, 2011, L 88/45.

Building European reference networks in health care. Exploring concepts and national practices in the European Union

Willy Palm, Irene A. Glinos, Bernd Rechel, Pascal Garel, Reinhard Busse and Josep Figueras

European Observatory on Health Systems and Policies, 2013

http://www.euro.who.int/en/about-us/partners/observatory/studies/building-european-reference-networks-in-health-care.-exploring-concepts-and-national-practices-in-the-european-union

The WHO European Observatory on Health Systems and Policies has produced a specific study on current practice in reference networks across Europe and how this might be developed.

until October 2013 to transpose the provisions of the directive into national legislation.

The Commission also 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.

4.3.1 European reference networks

Pooling and sharing expertise should, in principle, be a major area of European added-value by bringing together centres with particular expertise in different countries across the EU. As part of wider discussions on cross-border health care described above, this idea of linking together such centres in European reference networks emerged.[39]

The Commission has financed a series of pilot projects, in particular for rare diseases, and these have shown both the value and the feasibility of such

39 Palm W et al., eds. *Building European reference networks in health care*. Brussels, European Observatory on Health Systems and Policies, 2013.

cross-border cooperation.[40] Many Member States also have networks domestically but have approached them in quite different ways; an overview of such structures is provided in a recent study by the European Observatory for the European Commission.[41] Even if the concept of cross-border cooperation is clear and the added-value has been recognized by the European institutions in passing the Directive on Patients' Rights in Cross-Border Healthcare, these different approaches present many practical challenges for how to bring together such cooperation effectively at European level.

4.3.2 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".[42] 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.[43] The textbook example of the potential for EU standards to generate a market that can drive innovation is the Global System for Mobile Communication (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.[44] The equivalent for health care 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.[45] This is straightforward in principle but fiendishly 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.

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40 See European Networks of Reference for Rare Diseases [web site]. Brussels, European Commission (http://ec.europa.eu/health/rare_diseases/european_reference_networks/erf/index_en.htm#fragment5, http://ec.europa.eu/health/rare_diseases/european_reference_networks/erf/index_en.htm#fragment6, accessed 14 July 2014).

41 Palm W et al., eds. *Building European reference networks in health care*. Brussels, European Observatory on Health Systems and Policies, 2013.

42 European Parliament and Council. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. *Official Journal*, 2011, L 88/45; BEUC. *E-Health Action Plan 2012–2020 public consultation*. Brussels, BEUC (http://www.beuc.org/publications/2011-00398-01-e.pdf, accessed 3 July 2014); Iakovidis I, Purcarea O. E-Health in Europe: from vision to reality. In: Blobel B, Pharow M, Nerich M, eds. *EHealth: combining health telematics, telemedicine, biomedical engineering and bioinformatics to the edge*. Amsterdam, IOS Press, 2008:163–168.

43 European Commission. *eHealth action plan 2012–2020: innovative healthcare for the 21st century (COM(2012) 736)*. Luxembourg, Publications Office of the European Union, 2012.

44 Pelkmans J. The GSM standard: explaining a success story. *Journal of European Public Policy,* 2001, 8(3):432–453.

45 See Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (2008/594/EC). *Official Journal*, 2008, L 190, p. 37.

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 a 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 (see section 3.3). 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.[46]

4.3.3 European prescriptions

Although planned cross-border health care 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 databases (such as by stipulating information to be included on prescriptions that would allow a pharmacist to identify doctors and if necessary contact them).[47]

4.3.4 Patient safety and quality

Issues of patient safety do have a cross-border dimension, both for cross-border care and because health care-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.[48] While a variety of projects can and have been funded from

46 See European Commission. *Digital agenda for Europe: ehealth and ageing*. Brussels, European Commission, 2014 (http://ec.europa.eu/digital-agenda/en/life-and-work/ehealth-and-ageing, accessed 14 July 2014).

47 Commission implementing Directive 2012/52/EU. *Official Journal*, 2012, L 356, p. 68.

48 Council of the European Union. Council recommendation on patient safety, including the prevention and control of healthcare associated infections. *Official Journal*, 2009, C 151/1.

Clinical guidelines for chronic conditions in the European Union

Edited by Helena Legido-Quigley, Dimitra Panteli, Josip Car, Martin McKee and Reinhard Busse

European Observatory on Health Systems and Policies, 2013

http://www.euro.who.int/en/about-us/partners/observatory/studies/clinical-guidelines-for-chronic-conditions-in-the-european-union

Chronic noncommunicable diseases make up a large part of the burden of disease and make a huge call on health systems' resources. Clinical guidelines are one of the ways that European countries have tried to respond and to ensure a long-term perspective in managing them and addressing their determinants.

This study reviews the various national practices relating to clinical guidelines in 29 European countries (the EU, Norway and Switzerland).

The book explores those guidelines and whether they actually affect processes of care and patients' health outcomes. It analyses the regulatory basis, the actors involved and processes used in developing clinical guidelines across Europe as well as the strategies used to disseminate and implement clinical guidelines in various contexts. It explores innovative methods for cost-effective prevention of common risk factors, developing coordinated patient-centred care and stimulating integrated research. It also assesses the effectiveness of their utilization.

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.

4.4 People

Health professionals who are EU citizens enjoy the right to seek employment or to establish themselves in another country of the European Economic Area.[49] The free movement of workers and self-employed persons is, alongside the free

49 The EU plus Iceland, Liechtenstein and Norway.

movement of goods, services and capital, a fundamental policy stipulated in the TFEU and indispensable for the functioning of the single market.[50] The policy entails the abolition of all forms of discrimination between workers on the grounds of nationality with regard to employment, remuneration and other conditions of work and employment. Moreover the TFEU provides a mandate for legislation that facilitates cross-border professional mobility by flanking it with all necessary social security measures.[51]

Consequently, medical doctors, nurses, midwives, dentists, pharmacists and other allied health professions are crossing borders seeking employment and business opportunities as livelihood migrants, career-oriented professionals, backpackers or commuters.[52] Some countries have welcomed these professionals filling gaps in their workforce and some have even actively recruited from abroad, while others have raised concerns regarding the magnitude of qualified health workers leaving their country.[53]

Free mobility, however, is based on the portability of qualifications, which implies that the qualifications obtained in one country are similar enough to the qualifications required in another country. To this end, a system of mutual recognition was developed in the mid-1970s and the latest major revision took place in 2014. Five health professions are mentioned explicitly in the European Commission Directive on the Recognition of Professional Qualifications: medical doctors, general care nurses, midwives, dentists and pharmacists.[54] They can take advantage of the so-called automatic procedure that provides for recognition if the minimum requirements of number of hours and theoretical/practical training are met or, depending on the profession, if certain competencies are taught according to the curriculum. The recognition procedure is guaranteed to be completed within a three-month timeframe.

For those health professions and specializations not covered by this Directive, the "general system" applies. It requires national competent authorities to assess the qualifications of individuals on a one-by-one basis. In that case, the Member

50 TFEU, Article 45ff.

51 TFEU, Article 46.

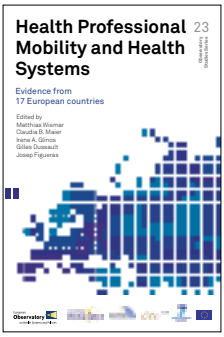
52 Glinos IA, Buchan J. Health professionals crossing the EU's internal and external borders: a typology of health professional mobility and migration. In: Buchan J et al., eds. *Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses*. Copenhagen, WHO Regional Office for Europe for the European Observatory on Health Systems and Policies, 2014:129–158.

53 Maier et al. Cross-country analysis of health professional mobility in Europe: the results. In: Wismar M et al., eds. *Health professional mobility and health systems evidence from 17 European countries*. Copenhagen, WHO Regional Office for Europe for the European Observatory on Health Systems and Policies, 2011:23–66; Ognyanova D et al. Mobility of health professionals before and after the 2004 and 2007 EU enlargements: evidence from the EU PROMeTHEUS project In: Buchan J et al., eds. *Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses*. Copenhagen, WHO Regional Office for Europe for the European Observatory on Health Systems and Policies, 2014:65–94.

54 European Parliament and Council. *Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications*. Brussels, European Commission, 2005.

Health professional mobility

Health professional mobility in Europe has become a fast-moving target for policy-makers as it increasingly affects the performance of health systems. It is evolving rapidly in direction and magnitude as a consequence of fundamental change caused by EU enlargement and the financial and economic crisis.



Health professional mobility and health systems. Evidence from 17 European countries

Edited by Matthias Wismar, Claudia B. Maier, Irene A. Glinos, Gilles Dussault and Josep Figueras

European Observatory on Health Systems and Policies, 2011

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-professional-mobility-and-health-systems.-evidence-from-17-european-countries

Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses

Edited by James Buchan, Matthias Wismar, Irene A. Glinos and Jeni Bremner

European Observatory on Health Systems and Policies, 2014

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-professional-mobility-in-a-changing-europe.-new-dynamics,-mobile-individuals-and-diverse-responses

The PROMeTHEUS project, funded under the EU's seventh Framework Programme for research, aimed at identifying and filling the gaps in knowledge about the numbers, trends, impacts and policy responses to this dynamic situation.

A first country case study volume specifically looked at the scale and characteristics of health professional mobility, the motivations of a mobile workforce, the impacts on health system performance and the policy responses. It analysed the situation in Austria, Belgium, Estonia, Finland, France, Germany, Hungary, Italy, Lithuania, Poland, Romania, Serbia, Slovakia, Slovenia, Spain, Turkey and the United Kingdom.

The second volume goes well beyond situation analysis as it presents practical tools such as a yardstick for registry methodology, a typology of mobile individuals, qualitative tools for studying the motivation of the workforce and a set of concrete policy responses at EU, national and organizational levels, including bilateral agreements, codes and workplace responses.

State where the individual has sought employment is not obliged to automatically recognize the qualifications and could impose, as appropriate, compensating measures such as an aptitude test or an adaptation period.[55]

Overall, the Directive has been deemed as functioning by the members of the network of the competent authorities and because, without the automatic procedure, authorities would not be able to cope with the requests for recognition on an individual basis. Some worries regarding mutual recognition were addressed in the 2014 revision of the Directive. For example the right to check adequacy of language to ensure quality and safety of care was strengthened. There are, however, some worries that could not be addressed by the Directive. Continuous professional development is often disrupted when changing countries. Another worry is that of mobility asymmetries. With the enlargements since 2004, the EU has become more diverse in terms of salary levels, career opportunities and working conditions. This has provided strong pull factors drawing health professionals from less affluent EU Member States to move to wealthier countries.

A precondition for a well-functioning labour market for health professionals is to have the right numbers and the right skills. But this is being jeopardized because as the EU population ages and shrinks, so does the health workforce. The European Commission has, therefore, tried to forecast future workforce supply and demand and has projected a shortage of two million health and social workers by 2020.[56] The supply of nurses is a particular concern. In addition to numbers, the skills and skill-mix of the workforce give rise to growing concerns. As Europe's population is ageing, chronic disease and multiple comorbidities have been increasing, requiring new technologies and increasingly coordinated and integrated forms of health service provision. More health promotion, prevention, rehabilitative and social services need to be developed. This implies that different cadres of health professionals will need to collaborate and communicate more effectively with each other and with the patients and their social environment. To facilitate this development, new skills and new skill-mixes are needed in the workforce. To address these challenges, the European Commission has launched a host of initiatives.

The European Commission has developed a comprehensive Action Plan for the EU Health Workforce.[57] This Action Plan has accompanied the EU sector-wide strategy for job-rich recovery and is, therefore, a centrepiece of actions confronting

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55 Peeters M, McKee M, Merkur S. EU law and health professionals. In: Mossialos E et al., eds. *Health systems governance in Europe: the role of European Union law and policy*. Cambridge, UK, Cambridge University Press, 2010:589–634.

56 Testori Coggi P. Foreword. In: Wismar M et al., eds. *Health professional mobility and health systems evidence from 17 European countries*. Copenhagen, WHO Regional Office for Europe for the European Observatory on Health Systems and Policies, 2011:ix.

57 European Commission. *Staff Working Document SWD(2012) 93 final: an action plan for the EU health workforce.* Luxembourg, Publications Office of the European Union (http://ec.europa.eu/dgs/health_consumer/docs/swd_ap_eu_healthcare_workforce_en.pdf, accessed 18 July 2014).

the recession and the financial and economic crisis. The Action Plan focuses on four topics including improving health workforce planning and forecasting, better anticipation of skills needs, stimulating exchange on recruitment and retention, and supporting ethical recruitment. To implement the Action Plan, the Commission commissioned a host of projects. This includes first and foremost the Joint Action on Health Workforce Planning and Forecasting. This is intended to create a European platform to share good practice and to develop methodologies on forecasting health workforce and skills needs.[58] The European Commission has also funded a project creating a pilot network of nurse educators and regulators. The project focuses on health care assistants defined as "persons working within healthcare with a qualification below the standard of registered nurses". The purpose of the project is to exchange best practices to improve the qualifications of health care assistants, with a particular emphasis on cross-border mobility. Other activities include an EU skills council in the area of nursing, and a care pilot EU sector skills alliance in the health care sector will seek to investigate the feasibility for developing new sector-specific curricula and innovative forms of vocational teaching and training. The implementation of the Action Plan and general workforce issues uses Member States' resources and a multitude of Commission instruments coming from a range of programmes under different DGs.[59]

4.5 Capital: structural funds and the Cohesion Fund

Right from the start, the EU had the objective of reducing the inequalities in development between different regions in the EU. As new countries have joined the EU over the decades, the disparities between the richest and poorest regions have also grown; alongside this, the resources allocated by the EU into countering those disparities have also grown. This should be kept in perspective; as outlined in section 2.4 on the EU budget, the investment through these funds still represents only around one-third of one per cent of the total wealth of the EU. Nevertheless, this is still tens of billions of euros a year, is new money not tied up in existing commitments and can make a real difference when focused on particular topics and areas in the poorer countries of the EU.

Indeed, although health has not been a priority for investment within the funds during the recently expired 2007–2013 programming period, a review carried out for the European Commission estimated that 1.5% of structural fund expenditure nonetheless had been invested in health. That may not sound like

58 European Commission. *Health workforce: improving workforce planning and forecasting*. Brussels, European Commission, 2012 (http://ec.europa.eu/health/workforce/policy/planning/index_en.htm, accessed 14 July 2014) and Joint Action on Health Workforce Planning & Forecasting [web site] (http://euhwforce.weebly.com/, accessed 14 July 2014).

59 Earlier DGs provided research funding for several health workforce-related projects, including PROMeTHEUS (health professional mobility in the EU), RN4Cast (registered nurse forecasting) and MoHProf (mobility of health professionals).

a lot – but because of the size of the structural funds overall, it means that the actual amounts invested from the structural funds compared well with the other major health-specific funds for health research and were much larger than those from the specific programme for health (Fig. 4.1).[60]

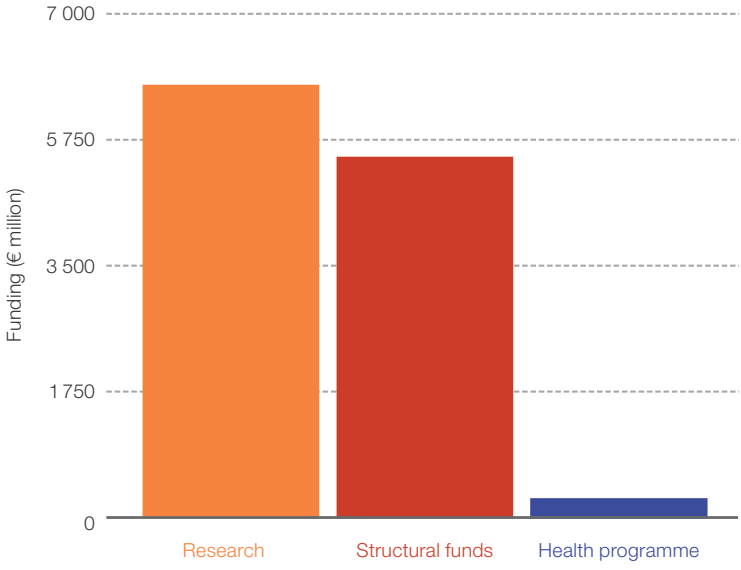
There are three main "structural funds".

The European Regional Development Fund. This fund finances direct aid to companies to create sustainable jobs, infrastructure development, financial instruments (e.g. local development funds) and technical assistance.

The European Social Fund. This is the "human resources" fund, focusing on worker adaptation (e.g. retraining of workers from declining industries), employment and social integration.

The Cohesion Fund. This fund is particularly focused on the poorer Member States – in particular the 10 eastern European countries (Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia). Examples of funding include trans-European transport networks and environment-related projects in particular.

Fig. 4.1 *EU funding for health, 2007–2013*



Sources: European Commission figures (for research and health programme) and estimate for structural funds; Watson J. *Health and structural funds in 2007–2013: country and regional assessment.* Brussels, DG Health and Consumer Protection, 2009 (http://ec.europa.eu/health/health_structural_funds/docs/watson_report.pdf, accessed 14 July 2014).

60 Watson J. *Health and structural funds in 2007–2013: country and regional assessment*. Brussels, DG Health and Consumer Protection, 2009 (http://ec.europa.eu/health/health_structural_funds/docs/watson_report.pdf, accessed 14 July 2014).

There are also other smaller instruments addressing specific priorities at European level (i.e. technical assistance to the "new" Member States in preparing projects, access to finance for small to medium-sized enterprises, urban investment and microfinance). The EU Solidarity Fund is a separate emergency assistance fund in the event of major natural disasters.

Historically, the use of the structural funds has reflected a fairly conservative model of economic growth, focusing on major infrastructure projects and not prioritizing "softer" sectors such as health. However, in recent years there has been somewhat greater recognition of the potential economic contribution of investing in health and health care.[61] Indeed, during the last programming period (2007–2013),[62] 13 national plans contained specific investment in health, including on infrastructure, e-health, improving aspects of care, providing medical equipment, health promotion, and education and training for health professionals themselves. Geographically, this investment is focused on eastern European countries. Specific investment to improve and modernize health infrastructure has been included in the programmes for Bulgaria, the Czech Republic, Greece, Hungary, Latvia, Lithuania, Poland, Romania and Slovakia. Modernization of information systems and increased use of e-health has also been a priority in the new Member States, and (to a lesser extent) human resources investment. However, there has also been investment from the structural funds in the health systems of western Europe, including in France, Germany, Greece, Italy, Portugal and Spain. Health systems can also benefit from investment by the structural funds in other sectors, such as in knowledge hubs, innovation clusters or in more general improvement in community facilities.

One striking example is Hungary, which made the most use of the structural funds for health during the 2007–2013 period of any Member State.[63] Over this period, the Hungarian authorities decided to allocate €1.8 billion of the structural funding to health care infrastructure projects.[64] This covered a wide range of projects, in particular the inpatient care sector (accounting for over three-quarters of funding). In fact, the structural funds have become the principal source of capital investment for the Hungarian health system. The detailed priorities of expenditure have changed somewhat under different governments during the programme period. Regional operational programmes have supported specific adaptations in different parts of the country, in particular strengthening primary

61 Suhrcke M et al. *The contribution of health to the economy in the European Union*. Luxembourg, Publications Office of the European Union, 2005.

62 Watson J. *Health and structural funds in 2007–2013: country and regional assessment*. Brussels, DG Health and Consumer Protection, 2009 (http://ec.europa.eu/health/health_structural_funds/docs/watson_report.pdf, accessed 14 July 2014).

63 Dowdeswell B. *EUREGIO III Case study: Hungary structural fund programme development and management 2007/13*. Brussels, EUREGIO III, 2011 (EUREGIO III Case study - Hungary.pdf, accessed 14 July 2014).

64 Gaál P et al. Hungary: Health system review. *Health Systems in Transition*, 2011, 13(5):1–266.

care through developing local health centres as well as establishing independent outpatient centres.

The structural and cohesion funds still do not have health as a specific objective, however. The Commission has proposed 11 thematic objectives for the new programming period.[65] Although health is not one of these 11 top-level objectives, health-related actions are identified in several of those thematic objectives (Table 4.3).

Table 4.3 *Health-related actions in the proposed thematic objectives*

Health-related actions	Which thematic objective?	Which fund?
Development of small to medium-sized enterprises reflecting new societal demands or products and services linked to the ageing population, care and health	3. Competitiveness of small and medium-sized enterprises	ERDF
Access to employment, including long-term employment opportunities created by structural shifts in the labour market, such as the care and health sectors	8. Promoting employment and supporting labour mobility	ESF
New business creation in sectors including care and health, including self-employment and entrepreneurship for young people	8. Promoting employment and supporting labour mobility	ESF, ERDF
Integrated employability measures including access to health services.	9. Promoting social inclusion and combating poverty	ESF
Modernization to improve the cost–effectiveness and adequacy of health care and social services	9. Promoting social inclusion and combating poverty	ESF
Integration of marginalized communities such as the Roma, including access to health care (e.g. prevention, health education, patient safety)	9. Promoting social inclusion and combating poverty	ESF
Specific actions targeting people with disabilities and chronic disease with a view to increasing their labour market participation, enhancing their social inclusion, and reducing inequalities in terms of education attainment and health status	9. Promoting social inclusion and combating poverty	ESF
Enhancing access to affordable, sustainable and high-quality health care with a view to reducing health inequalities, supporting health prevention and promoting e-health, including through targeted actions focused on particularly vulnerable groups; integrated approaches for early-childhood education and care services; support for the transition from institutional care to community-based care services for children without parental care, people with disabilities, the elderly, people with mental disorders, with a focus on integration between health and social services	9. Promoting social inclusion and combating poverty	ESF
Investment in health infrastructure to improve access to health services, and to contribute to the modernization, structural transformation and sustainability of health systems, leading to measureable improvements in health outcomes, including e-health measures	9. Promoting social inclusion and combating poverty	ERDF
Capacity-building for stakeholders delivering health policies, and sectoral and territorial pacts to mobilize for reform at national, regional and local level	11. Institutional capacity building and efficient public administration	ESF

Notes: ESF: European Social Fund; ERDF: European Regional Development Fund.

65 European Commission. *Staff Working Document SWD(2012)61: elements for a common strategic framework 2014 to 2020*. Luxembourg, Publications Office of the European Union, 2012.

This is both good news and bad news. The good news is that it is entirely possible to justify health-related expenditure under the structural funds, and a wide range of health expenditure at that. The bad news is that this expenditure has to be justified in terms of wider objectives than health alone – something that historically the health sector has not always been effective at doing. The Commission has engaged an external contractor[66] to provide support to Member States in order to make good use of the structural funds for health investments, building on a series of projects designed to support this kind of investment. The European Commission's recent Staff Working Paper on investing in health also makes some specific recommendations for how the structural funds should be used by Member States to invest in health.[67] The paper recommends that the funds be used by Member States 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 health care, in particular with a view to reducing health inequalities between regions and giving disadvantaged groups and marginalised communities better access to health care;
- supporting the adaptation, up-skilling and life-long learning of the health workforce;
- fostering active, healthy ageing to promote employability and employment and enable people to stay active for longer.

The Member States, through the Council of Ministers, have also called for greater use of the structural funds as a source of investment in health systems. Following a collective "reflection process" (led by Hungary, reflecting their clear interest in the topic), they have developed a "toolbox" of techniques for how health ministries across Europe can maximize investment in health from the structural funds.[68] This emphasizes the importance of including health in the strategic planning for the new 2014–2020 period, by identifying key challenges, setting key health-related objectives that fit with overall strategic priorities, identifying interventions and identifying corresponding funding sources. Key lessons learnt about how to improve on the past are also suggested – getting in early, while wider

66 See European Commission. *Service contract 431822-2013: call for tenders No EAHC/2013/Health/13 concerning the provision of support to the effective use of European Structural and Investment (ESI) funds for health investments*. Brussels, European Commission, 2013 (http://ted.europa.eu/udl?uri=TED:NOTICE:431822-2013:TEXT:EN:HTML, accessed 14 July 2014).

67 European Commission. *Staff Working Document SWD(2013)43: investing in health*. Brussels, European Commission, 2013.

68 General Secretariat of the Council. *Reflection process: towards modern, responsive and sustainable health systems (12981/13 ADD 2)*. Luxembourg, Publications Office of the European Union, 2013.

strategies are still being set; providing evidence and data to support the proposal; and taking a broad participative approach (building a wide consensus, noting that the programming period lasts longer than individual political mandates).

Overall strategic planning for expenditure under the current 2014–2020 period was underway at national and European level at the time of writing. It remains to be seen how much the Member States and the Commission will choose to make health a priority within those plans. Given the overall pressure on public budgets, and the emergence of the structural funds as the predominant source of capital investment in an increasing number of Member States, their choice will be critical in shaping the developing of European health systems and their response to issues such as demographic ageing.

4.5.1 The European Investment Bank

The European Investment Bank (EIB) is also an EU institution, created with the aim of supporting the balanced development of the EU (it also provides financing beyond the EU, for example in support of countries applying to the EU). Its shareholders are the Member States themselves; with their backing, it can borrow money at low interest rates and thus provide long-term loans at low rates for capital investment projects. Funds from the EIB can be a different European source of financing for health infrastructure; alternatively, an EIB loan can be combined with structural funds, for example by helping to provide the co-financing necessary for structural funds projects.

As with the structural and cohesion funds, health has been only a secondary aim for the EIB, but even so, the EIB has provided over €10 billion in loans, primarily for hospital infrastructure, since starting to finance health projects in 1997.[69] Given the importance of restructuring existing health care infrastructure in Europe to adapt to population ageing, integrated care and chronic conditions, this source of financing is likely to prove crucial in the coming years.

4.6 Competition, state aids and services of general interest

The EU has long had strong competition (anti-trust) law, with a powerful executive 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

69 European Investment Bank. *Evaluation of EIB financing of health projects*. Luxembourg, European Investment Bank, 2007 (http://eib.europa.eu/infocentre/publications/all/evaluation-of-eib-financing-of-health-projects.htm, accessed 14 July 2014).

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.[70]

Whilst the rules on competition are specified directly in the TFEU,[71] the question as to whether and how competition rules apply to health systems remains a source of uncertainty.[72] First, it depends upon the qualification of health services as "economic" and of the actors operating within health system as "undertakings". Given the absence of clear definitions of these concepts, this needed to be clarified by the CJEU, similarly to that which happened for the free movement of health services.[73] From this jurisprudence, it appears that it is not the legal status but rather the nature of the activity that is determinant.[74] Even non-profit-making institutions are considered undertakings if they are engaged in activities of an economic nature.[75] 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.[76]

Even if competition rules in principle apply, which seems to be likely for the actual provision of health care, the specificity and non-commercial motivations of many activities could justify exemptions or derogations. The legal concept that is used here to shield public, state and welfare services from competition and state aids law is "services of general (economic) interest" (SGEI). 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.[77]

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

70 Hancher L, Sauter W. *EU competition and internal market law in the health care sector.* Oxford, Oxford University Press, 2012.

71 TFEU, Chapter 1 of Title VII, Articles 101–109.

72 Mossialos E, Lear J. Balancing economic freedom against social policy principles: EC competition law and national health systems, *Health Policy*, 2012, 106:127–137.

73 See also Gekiere W, Baeten R, Palm W. Free movement of services in the EU and health care. In: Mossialos E et al., eds. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010:461–508.

74 Prosser T. EU competition law and public services In: Mossialos E et al., eds. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010:315–336.

75 European Court of Justice. Cases C-41/90, *Höfner and Elser,* C-475/99 *Ambulanz Glöckner,* C-67/96 *Albany,* C-180/98-C–184/98 *Pavlov*.

76 European Court of Justice. Cases C-159/91 and C-160/91 *Poucet-Pistre; Garcia, Cisal, FENIN, AOK.*

77 TFEU, Article 106(2).

and the EU to promote SGEIs.[78] 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. Although in a Protocol attached to the TFEU, the concept and role of SGEIs, as well as their underpinning principles and values, are further elaborated, a broader and consistent regulatory framework is still lacking, probably partly because of the diversity of legal traditions that use variations on the concept.[79]

Instead the European Commission has been developing – 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,[80] the Commission announced a specific Communication on Social and Health Services of General Interest, to identify and recognize these and to clarify the framework in which they operate and can be modernized. However, after health services were excluded from the Services Directive,[81] they were also excluded from the scope of this Communication in 2006,[82] the claim being that they would be covered in the upcoming Directive on Patient Rights' in Cross-Border Healthcare. 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 a lot of attention in the health sector was "state aid". State aid refers 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 elaborated framework to monitor and sanction financial discrimination of economic operators. As state aid is an exclusive EU competency, 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

78 Szyszcak E. Competition law and services of general economic interest. In: *ERA Conference on European integration and national social protection systems: towards a new form of internal market*, Brussels, 31 May to 1 June, 2007.

79 Schweitzer H. 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, 2011:11–62.

80 Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *White paper on services of general interest (COM/2004/0374 final).* Luxembourg, Publications Office of the European Union, 2004.

81 European Parliament and Council. *Directive 2006/123 on services in the internal market*. Luxembourg, Publications Office of the European Union, 2006.

82 European Commission. *Implementing the Lisbon programme: social services of general interest in the European Union (COM(2006) 177final).* Luxembourg, Publications Office of the European Union, 2006.

European Court of Justice case concerning Altmark, a German bus company awarded state aid[83]), which is also known as the Monti–Kroes package[84] and 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,[85] 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.[86] Even if not all of these Altmark criteria are fulfilled, state aids can still be declared compatible (in advance) without the need for prior notification to the Commission. This applies to a range of mostly social services of a local nature, including hospitals and other care organizations.[87] 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.[88] In this way it might seem as if the effect of competition and state aid rules on the health sector is only limited, 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.[89]

4.6.1 Public–Private Partnerships (PPPs)

The EU position with regard to PPPs, especially private finance initiative arrangements in which a private vendor supplies infrastructure or services on long contracts, 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.

83 European Court of Justice. Case C-280/00 *Altmark.*

84 European Commission. *Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC treaty to state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (2005/842/EC).* Brussels, European Commission, 2005.

85 European Court of Justice. Cases C-280/00 *Altmark,* C-53/00 *Ferring.*

86 European Commission. Communication on the application of the European Union state aid rules to compensation granted for the provision of services of general economic interest. *Official Journal*, 2012, C8 p. 4.

87 European Commission. Decision of 20 December on the application of Article 106(2) of the Treaty on the Functioning of the European Union to state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest. *Official Journal*, 2012, L 7 p. 3.

88 European Commission. Regulation (EC) No 1407/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid. *Official Journal*, L 352:1–8; see also *Block exemption regulations*. Brussels, European Commission, 2014 (http://ec.europa.eu/competition/state_aid/legislation/block.html, accessed 28 July 2014).

89 Hervey TK. If only it were so simple: public health services and EU law. In: Cremona M, ed. *Market integration and public services in the European Union.* Oxford, Oxford University Press, 2011:179–250.

The first issue, of 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.[90] 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,[91] followed by a consultation and a 2005 Communication.[92] 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); the European Parliament has recently adopted new rules on concessions, as well as updated rules on public procurement.[93]

90 European Commission. *MEMO/09/509: Commission communication on public private partnerships – frequently asked questions*. Brussels, European Commission, 2009 (http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/509&format=HTML&aged=0&language=EN&guiLanguage=en, accessed 14 July 2014).

91 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Green paper on public–private partnerships and community law on public contracts and concessions (COM(2004) 327).* Luxembourg, Publications Office of the European Union, 2004.

92 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Communication on public–private partnerships and community law on public procurement and concessions (COM(2005) 569).* Luxembourg, Publications Office of the European Union, 2005.

93 See European Parliament. *Press release: new EU-procurement rules to ensure better quality and value for money*. Brussels, European Parliament, 2014 (http://www.europarl.europa.eu/news/en/news-room/content/20140110IPR32386/html/New-EU-procurement-rules-to-ensure-better-quality-and-value-for-money, accessed 14 July 2014).

While this may be true in principle, in practice making use of PPPs is risky and requires considerable expertise.[94] This is one of the key issues highlighted by national representatives themselves in the "toolbox" on the use of the structural funds for health (see section 4.5).[95] 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.[96]

4.7 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. Health was a major priority within that, with a specific budget of €6.1 billion over the 2007–2013 period, and the EU has funded thousands of health-related research projects.[97] Despite the collective challenges facing the EU in terms of public health and health systems, described above, and the specificity of European countries in their collective commitment to tackling these challenges on the basis of a shared set of values, this health-related research has tended to avoid these topics, primarily funding biomedical research of more general application.[98]

This may change in the coming decades. The EU's updated research programme for the coming years, Horizon 2020,[99] has a broader focus on "health, demographic change and well-being", although this broader focus has yet to be reflected, with

94 Lieberherr E, Maarse H, Jeurissen P. The governance of public–private partnerships. In: Greer SL, Wismar M, Figueras J, eds. *Health systems governance*. Brussels, European Observatory on Health Systems and Policies/McGraw Hill, 2014: in press; see also Expert Panel on Effective Ways of Investing in Health. *Health and economic analysis for an evaluation of the public–private partnerships in health care delivery across Europe.* Brussels, DG Health and Consumer Protection, 2014 (http://ec.europa.eu/health/expert_panel/experts/working_groups/index_en.htm, accessed 14 July 2014).

95 General Secretariat of the Council. *Reflection process: towards modern, responsive and sustainable health systems (12981/13 ADD 2)*. Luxembourg, Publications Office of the European Union, 2013, see section 5.

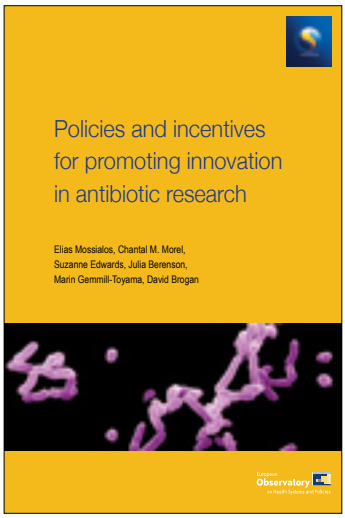
96 House of Commons Treasury Committee. *Private finance initiative: government, OBR and NAO responses to the seventeenth report from the committee (HC 1725).* London, The Stationery Office, 2012.

97 Charlesworth K et al. Health research in the European Union: over-controlled but under-measured? *European Journal of Public Health*, 2011, 21(4):404–406.

98 Walshe K et al. Health systems and policy research in Europe: horizon 2020. *Lancet*, 2013, 382(9893):668–669.

99 European Parliament and Council. Regulation (EU) No 1291/2013 establishing Horizon 2020 – the framework programme for research and innovation (2014-2020) – and repealing Decision No 1982/2006/EC. *Official Journal*, 2013, L 347, p. 104.

Policies and incentives for promoting innovation in antibiotic research



Elias Mossialos, Chantal M. Morel, Suzanne Edwards, Julia Berenson, Marin Gemmill-Toyama and David Brogan

European Observatory on Health Systems and Policies, 2010

http://www.euro.who.int/en/about-us/partners/observatory/studies/policies-and-incentives-for-promoting-innovation-in-antibiotic-research

High levels of pathogen resistance are rendering current antibiotics obsolete. Coupled with insufficient investment in discovering new treatments, multidrug-resistant infections are an increasingly urgent public health concern.

To curb the growth of antibiotic resistance and prevent major morbidity and mortality from multidrug-resistant bacterial infections, the overuse of antibiotics must be addressed and research and development for antibiotics with novel mechanisms of action actively promoted. This requires appropriately designed incentives for health and regulatory systems, in addition to economic incentives to attract academic interest and industry investment.

This book, commissioned by the Swedish Government from the European Observatory on Health Systems and Policies, analyses many proposed policies and incentive mechanisms and sheds light on the key issues that will help policy-makers to reach informed, concrete decisions on how to avert this potential public health crisis.

the first round of calls for projects still taking a resolutely biomedical approach. The increased EU focus on broader health system issues, for example the recommendations being made by the EU to Member States about health system reform through the processes of the European Semester, are likely to increase pressure to shift the focus of the EU's funding to more relevant research in the years to come.

Of course, the EU's funding for research is only a small part of total public funding for research in the EU, with the bulk of funding by national governments. Yet these national strategies are not coordinated, and many EU countries lack strategies for health research entirely.[100] So part of the EU's role has become not only to fund research but also to help to 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

100 Grimaud O, McCarthy M, Conceição C. Strategies for public health research in European Union countries. *European Journal of Public Health*, 2013, 23(suppl 2):35–38.

specific health topics of Alzheimer's disease and other neurodegenerative diseases, healthy diet and physical activity, antimicrobial resistance and the implications of demographic change.[101] There is, as yet, no more general strategy for coordination of research across Europe in relation to the challenges faced by health systems; again, this may emerge in the coming years with the increasing policy focus on these questions.[102]

4.8 Social policy

The pioneering work of the Commission on Social Determinants of Health led by Professor Sir Michael Marmot underlined the importance of social factors for health.[103] This, however, is the area where the "constitutional asymmetry" of the EU in regard to health is clearest. While the EU has taken significant action on some of the social determinants that the Commission identified (in particular working conditions, as discussed in section 3.2.5, and more general protection of employment conditions), questions of income, tax, social protection and the extent of solidarity within societies are some of the core areas reserved by Member States for national action rather than being EU responsibilities. So even if the powers of the EU to create an internal market have knock-on consequences (shifting employment in a particular profession from one country to another, for example), the social protection systems to ensure support such as unemployment protection and retraining, for example, are a national responsibility (albeit with potential support from sources such as the European Social Fund, but this is, of course, relatively marginal in comparison with the cost of social protection systems overall).

This is not to say that the EU has done nothing. The EU has focused attention on issues such as access for all to education, social protection and health care; creating jobs and equal opportunities; and promoting social inclusion;[104] it has also specifically highlighted issues of health inequalities.[105] A Charter of Fundamental Rights of the European Union has also been adopted,[106] which includes quite a range of social provisions. The problem is that the principal tools to meet these objectives and rights, both legislative and overwhelmingly financial, are at national level, not European.

101 European Commission. *Joint programming initiatives*. Brussels, European Commission, 2013 (http://ec.europa.eu/research/era/joint-programming-initiatives_en.html, accessed 4 July 2014).

102 Walshe K et al. Health systems and policy research in Europe: horizon 2020. *Lancet*, 2013, 382(9893):668–669.

103 Marmot M et al. Closing the gap in a generation: health equity through action on the social determinants of health. *Lancet,* 2008, 372(9650):1661–1669.

104 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Communication on renewed social agenda: opportunities, access and solidarity in 21st century Europe (COM(2008)412).* Luxembourg, Publications Office of the European Union, 2008.

105 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Communication on solidarity in health: reducing health inequalities in the EU (COM(2009)567).* Luxembourg, Publications Office of the European Union, 2009.

106 European Commission. Charter of Fundamental Rights of the European Union. *Official Journal*, 2010,C 83, p. 389.

One key area where there are strong EU measures is that of non-discrimination. Here the EU has strong powers to prohibit discrimination on six grounds: sex, racial or ethnic origin, religion or belief, disability, age, or sexual orientation,[107] 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.[108] 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".[109] People with chronic conditions could clearly 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.

4.9 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).[110] Although not directly a reference to health, this of course echoes the definition of health by the WHO: "Health is a state of complete physical, mental and social *well-being* and not merely the absence of disease or infirmity",[111] and the objectives for improving well-being set by the WHO's European "Health 2020" strategy.[112]

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 of European countries than the traditional summary of GDP,[113] within which health is one of the main dimensions. It seems too early to assess what influence this broader measurement perspective will have on policy-making.

107 TFEU, Articles 10 and 19.

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

109 United Nations. *Convention on the rights of persons with disabilities*. New York, United Nations, 2006.

110 Treaty on European Union, Article 3.

111 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.

112 WHO Regional Office for Europe. *The European health report 2012: charting the way to well-being* and *Health 2020: a European policy framework and strategy for the 21st century*. Copenhagen, WHO Regional Office for Europe, 2013.

113 European Commission. *Communication: GDP and beyond – measuring progress in a changing world* (*COM(2009)433).* Brussels, European Commission, 2009.

Chapter 5

Fiscal governance and what it means for health systems

The third and newest face of the EU is its fiscal governance.[1] There is a recurring pattern in health policy: for years after an EU policy has developed that will affect health systems, policy-makers, advocates and analysts ignore it and refuse to engage in discussions of how it will affect health. Eventually the health sector engages, be it with the internal market law in the aftermath of *Kohll, Decker* and *Watts*,[2] with competition and state aid law in the aftermath of *Altmark*,[3] or with labour law in the aftermath of implementation of the Working Time Directive. This pattern of delayed engagement has costs; it means that people who care about health systems generally enter the EU debate on the defensive rather than with a strong argument about how the involvement of the EU could do some good.

It is no surprise, therefore, that the increasing importance of fiscal governance in the EU is not well appreciated in the health policy world. But right now, the architecture, credibility and health system effects of the EU's new fiscal governance architecture are being determined. There is a good chance that what emerges will affect health and health systems at the core: in their budgets, their entitlements and their organization. The EU has suddenly built what might be an effective machine for controlling budgets. Just as health ministers need to justify themselves to finance ministers, they must now justify themselves in the EU's fiscal governance system.

EU fiscal governance has been in the background of European politics since the Maastricht Treaty (if not before), and the Maastricht criteria for accession to the Eurozone drove many domestic reforms and fiscal policy changes that affected health systems in the 1990s. Two of the Maastricht criteria for Eurozone accession – that Member States should have a debt-to-GDP ratio below 60% and a structural deficit below 3% – were entrenched in the Stability and Growth Pact (SGP) in 1992. Every Member State but Finland violated the SGP at some point. In 2005 France and Germany, both in violation, led a revision of the SGP that

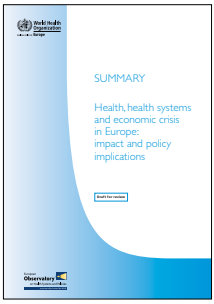
1 Greer SL. The three faces of European Union health policy: policy, markets and austerity. *Policy and Society,* 2014, 33(1):13–24.

2 European Court of Justice. Cases C-158/96 *Kohll,* C-120/95 *Decker*, C-372/04 *Watts.*

3 European Court of Justice. Case C-280/00 *Altmark.*

Health systems in economic crises

The global financial crisis of 2008 has turned into an economic crisis that, five years on, is far from over in Europe. Financial and economic distress has already had wide-reaching social and political consequences, but some of the most devastating consequences may be yet to come.

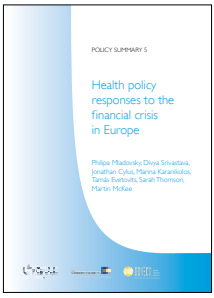


Health, health systems and economic crisis in Europe: impact and policy implications

Sarah Thomson, Matthew Jowett, Tamás Evetovits, Melitta Jakab, Martin McKee and Josep Figueras

European Observatory on Health Systems and Policies, 2013

http://www.euro.who.int/__data/assets/pdf_file/0011/186932/Health-and-economic-crisis-in-Europe4.pdf?ua=1



Health policy responses to the financial crisis in Europe

Philipa Mladovsky, Divya Srivastava, Jonathan Cylus, Marina Karanikolos, Tamás Evetovits, Sarah Thomson and Martin McKee

European Observatory on Health Systems and Policies, 2012

http://www.euro.who.int/__data/assets/pdf_file/0009/170865/e96643.pdf?ua=1

Despite the signs of slow economic recovery there is little reason to be optimistic when the human costs of falling incomes, growing inequalities and huge increases in unemployment, particularly among young people, are considered.

These two policy summaries provide an overview of the various impacts, the initial responses by governments, their wider policy implications and alternative options.

weakened its enforcement provisions but strengthened the dialogue between the Member States and Commission about desirable fiscal policies, including levels of health expenditure.[4] As the global financial crisis showed, the SGP was not wholly successful at limiting State liabilities or ensuring good statistics, and the macroeconomic imbalances such as property price bubbles or imprudent banking that brought down a number of Member States were wholly outwith the SGP's remit.

4 Schelkle W. EU fiscal governance: hard law in the shadow of soft law. *Columbia Journal of European Law,* 2006, 13:705; Servaas D, Hodson D, Kuhlmann J. The broad economic policy guidelines: before and after the re-launch of the Lisbon strategy. *Journal of Common Market Studies,* 2008, 46(4):827–848.

It was not until 2011, after the global financial crisis created a European sovereign debt crisis, that Member States were willing enough, and the EU institutions able enough, to consider strengthening the SGP. This built on the pre-existing apparatus of EU (especially Eurozone) fiscal governance including the once-reformed SGP and the process creating the Broad Economic Policy Guidelines. Ideas, such as EU scrutiny of budgets before governments present them to legislatures, that would become law after 2010 had been circulating around the Commission for years.

The 2011 and 2013 reforms of the SGP – known respectively as the "six-pack" and the "two-pack" – were the EU's response to the high and rising debt levels seen in a number of Member States both within and outside the Eurozone. The six-pack reforms are appropriately named. They considerably toughen the SGP both by making corrective measures such as fines easier to apply and by increasing the authority of the Commission to monitor the economies and budget decisions of Member States. The two-pack reforms built on the six-pack reforms by requiring States to provide more information to the Commission for monitoring purposes.

The reformed SGP now has two arms, a preventive arm and a corrective arm. The SGP's preventive arm is established by Article 121 of the TFEU. It is designed to "ensure that fiscal policy is conducted in a sustainable manner" by establishing a cycle of economic and budgetary monitoring and assessment.[5] States are expected to make progress towards predefined objectives, with this progress assessed during an annual review process called the European Semester (see below).

Stability Programmes and Convergence Programmes are terms used to describe the outlines of medium-term budget plans that are compiled by Member States.[6] They are submitted and assessed annually under the European Semester process. Stability Programmes are submitted by Eurozone States, while Convergence Programmes, which also contain monetary strategies, are submitted by non-Eurozone States. Stability and Convergence Programmes are used to put forward medium-term objectives: country-specific, medium-term budgetary objectives defined in terms of a State's structural budget balance.[7]

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5 European Commission. *EU economic governance: stability and growth pact*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/sgp/, accessed 14 July 2014).

6 European Commission. *Multilateral economic coordination and surveillance*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/sgp/convergence/, accessed 14 July 2014).

7 "The actual *budget balance* net of the *cyclical component and one-off and other temporary measures*. The structural balance gives a measure of the underlying trend in the budget balance." European Commission. *EU economic governance: stability and growth pact glossary*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/sgp/glossary_en.htm, accessed 14 July 2014); on the complexities of calculation involved in the new fiscal governance, see Mabbett D, Schelkle W. Searching under the lamp-post: the evolution of fiscal surveillance. In: *20th International Conference of Europeanists: Crisis & Contingency – States of (In) Stability,* 2013.

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.[8] Despite keeping its name, the EDP was expanded through the 2011 reforms and is now used to enforce both rules. The procedure can be invoked if one or both of the rules is broken, with the same procedure used for debt and deficit breaches (with some exceptions).[9]

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 or both rules, 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 over the deficit/debt is close to the threshold and considered to be temporary.

The Council decides if an excessive deficit exists. If the answer is yes, the Commission proposes and the Council adopts recommendations to correct the situation. These recommendations are not made public unless the Council thinks that the Member State has not responded according to the agreed timetable (usually six months, or three for severe cases).

If the Member State does not comply with the recommendations, a range of actions can be taken by the Council. The Council can require the Member State concerned to publish additional information, to be specified by the Council, before issuing bonds and securities, can invite the 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.

These changes certainly make the "corrective" elements of the SGP more stringent. But the real surprise for observers is that there are also strict penalties for non-compliance under the preventive arm, including the 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.[10]

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8 The Maastricht reference values are defined in the TFEU, Protocol 12; A "satisfactory" rate of debt reduction is reduction by 1/20th annually on average taken over a period of three years". This is known as the 1/20 rule. See European Commission. *Press release: European governance six-pack enters into force (MEMO/11/898).* Brussels, European Commission, 2011 (http://europa.eu/rapid/press-release_MEMO-11-898_en.htm, accessed 14 July 2014).

9 European Commission. *European economic governance: the corrective arm*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/sgp/corrective_arm/index_en.htm. accessed 14 July 2014).

10 For a critical view, see Geist R. Macroeconomic conditionality: another brick in the austerity wall. *Social Europe Journal Blog*, 2013, 28 October (http://www.social-europe.eu/2013/10/macroeconomic-conditionality-another-brick-in-the-austerity-wall/, accessed 14 July 2014).

5.1 Strengthening the SGP: the six-pack

As mentioned above, the 2011 reform of the SGP was carried out through a body of reforming legislation referred to as the six-pack.[11] The six-pack truly is an attempt to give the SGP more muscle. Examining the text of the six-pack regulations shows that far from being an incremental policy change the six-pack truly has formalized the new status quo that emerged in the wake of the economic crisis.

Regulation 1175/2011 lays out the preventive arm of the SGP. It empowers the Commission and Council to conduct multilateral surveillance via the European Semester, which includes the formulation of guidelines for economic and employment policy and the monitoring of their implementation; the submission and assessment of Member States' Stability Programmes, Convergence Programmes and National Reform Programmes; and surveillance to prevent and correct macroeconomic imbalances.

Regulation 1175/2011 is rather specific with regard to the data to be made available to the Commission. The surveillance is broader than just examining growth and public debt and includes big budget programmes such as pensions. The Regulation requires "quantitative assessment" of economic and budgetary policy, including cost–benefit analysis of major structural reforms; the European Semester focuses on economic criteria and not social policy objectives (although it does incorporate the Europe 2020 objectives). This is a very important point, because cost–benefit analysis can privilege economic data over other non-pecuniary concerns such as health or the environment.[12]

Based on this surveillance, the Council can issue guidance to Member States based on recommendations from the Commission. The Council is expected to "adopt or explain" these Commission recommendations, with adoption encouraged by use of the RQMV rule. This results in some interesting, publicly available, data. The side-by-side edited text of the original Commission recommendations show the Council often watering down the Commission's recommendations. In its explanation, the Council takes the line that, while the Commission should suggest goals, it should leave the choice of which policy mechanism to use to achieve those goals to Member States.

11 The six-pack: European Parliament and Council. *Regulation (EU) No 1175/2011 of 16 November 2011 amending Council Regulation (EC) No 1466/97 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies*, *Council Regulation (EU) No 1177/2011 of 8 November 2011 amending Regulation (EC) No 1467/97 on speeding up and clarifying the implementation of the excessive deficit procedure*, *Regulation (EU) No 1173/2011 of 16 November 2011 on the effective enforcement of budgetary surveillance in the euro area*, *Council Directive 2011/85/EU of 8 November 2011 on requirements for budgetary frameworks of the Member States*, *Council Directive 2011/85/EU of 8 November 2011 on requirements for budgetary frameworks of the Member States*, *Regulation (EU) No 1176/2011 of 16 November 2011 on the prevention and correction of macroeconomic imbalances*. Luxembourg, Publications Office of the European Union, 2011.

12 Jarman H. *The politics of trade and tobacco control*. Basingstoke, UK, Palgrave Macmillan, 2014.

Council Regulation 1177/2011 lays out the corrective arm of the SGP as implemented via the EDP. The regulation defines both what an acceptable rate of decline in public debt is and what exceptional circumstances allow Member States to break the deficit and debt rules. The Regulation establishes tighter time limits for State action to correct an excessive deficit: six months in most cases, but three months for the most severe cases.

However, the corrective arm is not just applied from offices in Brussels. For States under EDP, Regulation 1177/2011(Article 13(1)) mandates the Commission to "ensure a permanent dialogue with authorities of the Member States …in particular, carry out missions for the purpose of the assessment of the actual economic situation in the Member State and the identification of any risks or difficulties in complying with the objectives of this Regulation." In other words, the Regulation formalizes a way of working that the EU adopted during the economic crisis to address problems in its most beleaguered Member States. "Enhanced surveillance" can be conducted for those Member States subject to recommendations under the EDF.

Part three of the six-pack, Regulation 1173/2011, deals with the enforcement of both the preventive and the corrective arms of the SGP. In the preventive arm, where a Member State is non-compliant, the Regulation requires the Commission to recommend and the Council to approve the lodgement of an interest-bearing deposit of 0.2% of GDP within 20 days. This has been achieved by the introduction of a new voting rule, RQMV (see Box 2.1). Under RQMV, decisions to require a lodgement are adopted by the Council unless the Council votes with a qualified majority to reject the Commission's recommendation within 10 days of its adoption. The Council can amend the Commission's recommendation using a qualified majority. But an equal focus for State delegations is the Commission, which can hear appeals against the recommendation from Member States.

For sanctions under the corrective arm, Regulation 1173/2011 requires the Commission to recommend and Council to approve the lodgement of non-interest-bearing deposit of 0.2% of GDP for non-compliance within 20 days. Again, RQMV is used for the approval of these lodgements and fines, with the same caveats. The regulation also establishes sanctions for Member States who provide fraudulent statistics.

Council Directive 2011/85/EU, which was implemented in 2013, aims to coordinate the ways in which Member States create their national budgets. It requires States (except the United Kingdom) to adopt national fiscal rules that promote compliance with TFEU budgetary obligations such as the Maastricht reference values. These rules should reference the target, the procedure for monitoring compliance, and the consequences for non-compliance. States are required to adopt multiannual fiscal planning (budgeting over three-year periods), as well

as a medium-term budgetary framework. The Directive also requires certain budget information to be published.

5.2 Making economic governance predictive: the Macroeconomic Imbalance Procedure

The final two six-pack regulations lay out the Macroeconomic Imbalance Procedure (MIP). The MIP is a monitoring and correction procedure that "aims to prevent, identify, and correct macroeconomic imbalances".[13] Much broader in scope than the SGP, it operates in parallel, using many of the same mechanisms and rules. It is, in part, a response to the criticism that the SGP was, for a long time, too narrowly focused on limited rules, which prevented the EU from adequately predicting the consequences of long-term budgeting and finance decisions by its Member States.

Regulation 1176/2011 defines imbalances as "any trend giving rise to macroeconomic developments which are adversely affecting, or have the potential adversely to affect, the proper functioning of the economy of a Member State or of the economic and monetary union, or of the EU as a whole",[14] while excessive imbalances are "severe", including "imbalances that jeopardise or risks [sic] jeopardising the proper functioning of the economic and monetary union".[15] Informally, many recognize that the MIP could be used to put pressure on States to conduct labour market reform, although the regulation feebly states that the recommendations issued under it shall "respect national practices and institutions for wage formation".[16]

Much like the SGP, the MIP has preventive and corrective arms. The preventive arm aims to "identify macroeconomic imbalances at the early stage of their emergence so that necessary policy actions can be taken in due time and thus prevent the development of severe imbalances which are damaging for the Member State concerned and risk jeopardizing the functioning of the Economic and Monetary Union".[17]

The European Semester implements the preventive arm through an "Alert Mechanism". The Commission is tasked with creating a scoreboard of economic indicators and monitoring to identify sources of macroeconomic imbalance in

13 European Commission. *Economic and financial affairs: macroeconomic imbalance procedure*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/macroeconomic_imbalance_procedure/index_en.htm, accessed 14 July 2014).

14 *Regulation (EU) No 1176/2011,* Article 2(1).

15 *Regulation (EU) No 1176/2011*, Article 2(2).

16 *Regulation (EU) No 1176/2011*, Article 1(3).

17 European Commission. *Economic and financial affairs: the MIP framework*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/macroeconomic_imbalance_procedure/mip_framework/index_en.htm, accessed 14 July 2014).

EU Member States – both within and without the Eurozone. Alert Mechanism reports are assembled by the Commission that show "signs of potential emerging macroeconomic imbalances".[18]

The regulation is quite specific about the scope of the MIP. The scoreboard includes information about public and private indebtedness; financial and asset market developments; housing; private sector credit flows; the current account and net investment positions of Member States; real effective exchange rates; export market shares; changes in price and cost developments; non-price competitiveness; employment and unemployment performance; nominal and real convergence inside and outside the Eurozone; productivity developments, including research and development and foreign and domestic investment; and sectoral developments, including energy, that affect GDP and current account performance.[19]

When the scoreboard and the associated analysis indicate that a Member State is deviating too much from an acceptable path, the Commission can carry out an in-depth review to determine the extent of the potential imbalances, which can involve missions to the country concerned. While Alert Mechanism reports are discussed by Council and the Eurogroup, the Commission decides which countries will receive in-depth reviews. In addition to talking to State representatives, the Commission can hold dialogue with social partners and stakeholders; for countries of the Eurozone and exchange rate mechanism II, the Commission can invite members of the ECB along on missions.[20]

On the back of an in-depth review, the Commission formulates policy recommendations that form part of a package of recommendations made under the European Semester. The Commission can recommend opening an Excessive Imbalance Procedure, which takes place under the corrective arm of the MIP.[21]

If this happens, the Council can act on the Commission recommendation to declare an excessive imbalance and tell the Member State to correct it within a certain time period. The Member State then has to present a Corrective Action Plan (CAP) that contains specific policy measures and a timetable for implementing them. The Commission monitors the implementation of the CAP and can ask for progress reports from the Member State. The Council can ask for a new CAP if it thinks the first one is insufficient, and a fine can be imposed via

18 European Commission. *Economic and financial affairs: the MIP framework*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/macroeconomic_imbalance_procedure/mip_framework/index_en.htm, accessed 14 July 2014).

19 European Parliament and Council. *Regulation (EU) No 1176/2011 on the prevention and correction of macroeconomic imbalances*, Article 4(3). Brussels, European Commission, 2011.

20 European Parliament and Council. *Regulation (EU) No 1176/2011 on the prevention and correction of macroeconomic imbalances*, Article 5(13). Brussels, European Commission, 2011.

21 As defined by European Parliament and Council. *Regulation 1174/2011 on enforcement measures to correct excessive macroeconomic imbalances in the euro area*. Brussels, European Commission, 2011.

RQMV for failing to submit an acceptable CAP twice in a row. If a Member State does not move fast enough to implement a CAP once it has been deemed acceptable, the Council can declare that the State is non-compliant. The first non-compliance decision allows the imposition by RQMV of an interest-bearing deposit of 0.1% GDP. After a second non-compliance decision, this deposit can be converted to an annual fine by RQMV.

5.3 Constitutionalizing the rules: the Treaty on Stability, Coordination and Governance

Many of the EU's core policies and principles are subsequently enshrined in treaty law as a way to bolster their legitimacy.[22] In the case of the six-pack, however, the treaty in question is not primary EU law. The Treaty on Stability, Coordination and Governance in the Economic and Monetary Union (TSCG) is a non-EU international treaty signed by 25 Member States in 2012. The TSCG contains the Fiscal Compact and is sometimes referred to as the Fiscal Compact Treaty. The TSCG is binding on Eurozone States, while other Member States can choose to be bound once they adopt the euro or can choose provisions they wish to comply with before euro adoption. The TSCG entered into force in 2013 after 12 States ratified it.[23] It was not signed by the United Kingdom or the Czech Republic and pre-dates Croatia's EU membership. That is why, despite its stated intent to be part of enhanced cooperation under EU law, and to become part of the treaties themselves, it is currently a separate international agreement.

As a result, the six-pack and the TSCG run in parallel, although their main normative elements do closely relate to one another.[24] In some ways, the TSCG mirrors the content of the EU's economic governance. The TSCG requires the contracted States to converge towards the medium-term objectives they have defined under the SGP, and it re-states the SGP's debt rule. The TSCG also mimics RQMV by committing contracting States to vote in support of the Commission when determining excessive deficits. The definitions of what constitutes a significant deviation from the rules and exceptional circumstances are the same.

In other ways, however, the TSCG goes beyond EU law. Contracting States are committed to a lower deficit ceiling than under the SGP: 1% of GDP for States

22 European Commission. *Economic and financial affairs. Six-pack? Two-pack? Fiscal compact? A short guide to the new EU fiscal governance*. Brussels, European Commission, 2012 (http://ec.europa.eu/economy_finance/articles/governance/2012-03-14_six_pack_en.htm, accessed 14 July 2014).

23 At the time of writing, the TSCG had been ratified in the following countries: Austria, Cyprus, Germany, Denmark, Estonia, Spain, France, Greece, Hungary, Italy, Ireland, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Portugal, Poland, Romania, Sweden, Finland, Slovenia and Slovakia.

24 European Commission. *Economic and financial affairs; does the fiscal compact succeed the six-pack or does it run alongside it?* Brussels, European Commission, 2012 (http://ec.europa.eu/economy_finance/articles/governance/2012-03-14_six_pack_en.htm, accessed 14 July 2014).

with debt below 60% of GDP, and 0.5% for those with debt above 60%. States are committed to transposing their commitments, including their medium-term objectives, into national law of a "binding force and permanent character, preferably constitutional". Correction must be put in place to ensure that action is taken when a State deviates from a path that will ensure the achievement of the medium-term objective. Instead of the Council and the Commission, the CJEU can issue a ruling requiring States to implement the new rules and can impose a financial sanction amounting to 0.1% of GDP if the State fails to comply with the ruling. Compliance with the agreement is supposed to be monitored by new independent institutions at the national level, under guidelines issued by the Commission to govern their creation.

The TSCG is not all stick and no carrot, however. The carrot in question is the new European Stability Mechanism, a consolidated, Europe-wide fund that provides financial assistance to signatory States. From March 2013, the TSCG limits access to financial assistance through the European Stability Mechanism (replacing the European Financial Stabilizing Mechanism) to countries that have enacted the TSCG.

5.4 The two-pack reforms

In order to consolidate the six-pack reforms, as well as coordinate them with the TSCG, the Commission proposed two further regulations, now known as the two-pack.[25] The two-pack entered into force in 2013, further expanding upon the six-pack by adding to the European Semester process and the monitoring and surveillance powers of the Commission.

Again, examining the text of the two-pack regulations shows just how much the governance of European economies has changed under crisis conditions. Although the two-pack regulations took longer than usual to pass (15 months) due to a lack of consensus within the European Parliament,[26] the result is still mostly the formalization of the central institutions' ability to shape budgetary agendas and norms for Member States.

Regulation 473/2013 builds on the six-pack by adding a common timeline to the European Semester. Starting in October 2013, Eurozone countries (except

25 The two-pack: European Parliament and Council. *Regulation (EU) No 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, 2013.

26 European Parliament. *Economic governance "two pack" background note*. Luxembourg, Publications Office of the European Union, 2013 (http://www.europarl.europa.eu/news/en/news-room/content/20130304BKG62046/html/Economic-governance-two-pack-background-note, accessed 14 July 2014).

those under Economic Adjustment Programmes (EAPs), the agreements with the Troika, which are also known as Memoranda of Understanding) must submit their draft budget plans[27] to the Commission by October 15th. The draft plans are immediately made public, by the Commission, and must be approved by national parliaments by December 31st. The plans do not just contain information about overall spending projections, they must contain "relevant information on the general government expenditure by function, including on education, healthcare and employment, and, where possible, indications on the expected distributional impact of the main expenditure and revenue measures".

The figures contained in the plan must be justified in terms of any previously issued CSRs, as well as commitments under Europe 2020. Member States' budgetary procedures are required to comply with guidance issued by the Commission and the Council at the beginning of the European Semester cycle. If a draft budgetary plan is seriously non-compliant with SGP, the Commission can request a revision. The Commission then adopts an opinion on the draft budgetary plans by the end of November, and makes an assessment of the budget in the context of the Eurozone as a whole. Independent bodies at the national level, which are required to be created under the TSCG, are supposed to monitor compliance with fiscal rules.

If the Council decides that an excessive deficit exists under the EDP, the two-pack regulations require the Member State to create an economic partnership programme that describes the "policy measures and structural reforms" needed to "ensure an effective and lasting correction of the excessive deficit". Again, these economic partnership programmes are a requirement of the TSCG, with the two-pack bringing this measure under the EU's purview. A CAP, a similar document required under the MIP, can be substituted for the economic partnership programme if necessary, to prevent duplication of effort.

The two-pack introduces more rules about reporting data continuously to the Commission, and gives the Commission the power to adopt delegated acts until May 2016 in order to change the specificities of the required reports. The second part of the two-pack, Regulation 472/2013, is most overtly a formalization of some of the ad hoc procedures adopted during the economic crisis. It applies to Eurozone countries that are in financial distress and receiving financial aid (including precautionary aid designed to fend off the worst) and provides a formal role, defined in legislation, for bodies such as the ECB and the IMF. In other words, it refers to the Member States that have been receiving conditional support from the Troika of IMF, ECB and European Commission: Cyprus, Greece, Portugal and, until recently, Ireland.

27 The 2013 plans are available: European Commission. *Economic and financial affairs: draft budgetary plans of euro area member states*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/sgp/budgetary_plans/index_en.htm, accessed 14 July 2014).

Eurozone States in such situations are subject to "enhanced surveillance", which goes beyond that envisioned for compliant and minimally non-compliant Member States. The MIP's Alert Mechanism and the in-depth reviews created by the Commission during the MIP will be used to determine whether to begin enhanced surveillance. A further decision on whether to continue enhanced surveillance is then made every six months. The State concerned is given the "opportunity to express its views" before the decision is made.

Member States under enhanced surveillance have to take corrective measures "after consulting, and in cooperation with, the Commission, acting in liaison with the ECB, the ESAs [European Supervisory Authorities], the ESRB [European Systematic Risk Board] and, where appropriate, the IMF";[28] this includes the steps recommended under six-pack and SGP procedures and is subject to quarterly reporting.[29]

The Commission can require Member States under enhanced surveillance to submit information to the ECB, to carry out stress tests or sensitivity analyses, to submit to peer review of their financial sector by the ECB or the European Supervisory Authorities (ESAs) and to submit to the Commission information in order to enable it to assess macroeconomic imbalances. For these States, the Commission will carry out regular review missions, which can include members of the ECB, ESAs or IMF.[30]

However, the role of these institutions does not stop there. On the back of stress tests, sensitivity analysis and the MIP scoreboard, the ECB and the ESAs liaise with the European Systematic Risk Board to assess the potential vulnerabilities of the Member State's financial system, which is submitted to the Commission.

Where the Commission is conducting reviews in a State under enhanced surveillance and thinks that more needs to be done, the Council can adopt a decision under QMV recommending that the Member State adopts precautionary corrective measures or prepares a draft Macroeconomic Adjustment Programme.

Since the beginning of the economic crisis, five States (Cyprus, Greece, Ireland, Portugal and Spain) have been asked to formulate EAPs in exchange for receiving emergency financial assistance. The formulation of these EAPs took place rapidly, under a somewhat ad hoc process. That process drew on established policy *aspirations* as expressed in previous dialogue between the Commission and the Member States, incorporating these aspirations into EAPs as more concrete commitments. This process has been widely criticized for subsuming

28 *Regulation 472/2013*, Article 3(1). Bracketed names added to the quote. The European Supervisory Authorities comprise the European Securities and Markets Authority, the European Banking Authority and the European Insurance and Occupational Pensions Authority.

29 *Regulation 472/2013*, Article 3(1).

30 *Regulation 472/2013*, Article 5(5–7).

the definition of social policy goals under the hierarchy of the EU's economic governance.[31]

One of the most important things that Regulation 472/2013 does, therefore, is to formalize and centralize the procedure for Member States to request aid from other states or international organizations. The Commission now has an important formal role in assessing these requests, as does the ECB.[32] Under the two-pack regulations, the Council will act by QMV on a Commission proposal to approve new EAPs. The Commission, in liaison with the ECB and the IMF where appropriate, is responsible for monitoring Member State implementation of the EAP.

There is some hope for Social Europe enthusiasts, however, as the Regulation states that the EAP's budget cuts should "take into account the need to ensure sufficient means for fundamental policies, such as education and health care".[33]

5.5 The European Semester

All of this surveillance, assessment, benchmarking and recommendation is held together by the concept of the European Semester, an annual review cycle that implements the six-pack and two-pack regulations.[34] The European Semester was first introduced in 2011 as part of the six-pack. It is a powerful tool for achieving consistent policy recommendations – not just among Member States, but also horizontally across EU and European programmes as well – as through the Semester the Commission can review a raft of information that is pertinent to the TSCG, Euro Plus Pact and Europe 2020, as well as the SGP and MIP.

As always in politics, timing is everything. The name European Semester refers to the idea that European surveillance of national budgets should come before national surveillance, which occurs during the National Semester in the second half of the year. This process is referred to as "upstream policy coordination" by the Commission[35] but has caused many to question whether the European Semester leaves national parliaments out in the cold.

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31 Examples: Kentikelenis A et al. Greece's health crisis: from austerity to denialism. *Lancet,* 2014, 383(9918):748–753; Karanikolos, M et al. Financial crisis, austerity, and health in Europe. *Lancet,* 2013, 381(9874):1323–1331.

32 *Regulation 472/2013,* Article 7(1).

33 *Regulation 472/2013*, Article 7(6).

34 European Commission. *Press release: the EU's economic governance explained (MEMO/13/318)*. Brussels, European Commission, 2013 (http://europa.eu/rapid/press-release_MEMO-13-318_en.htm, accessed 14 July 2014).

35 European Commission. *Economic and financial affairs: the European Semester*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/the_european_semester/index_en.htm, accessed 14 July 2014).

The European Semester starts in October, when Member States are required to submit their draft budgets to the Commission.[36] These draft budget documents are published. The Commission can ask for redrafts if it considers that a budget plan is out of line with the SGP.

In November, the Commission sets out the EU's budgetary priorities for the next year through a series of reports. The first key report is the Annual Growth Survey, which sets out proposed priorities. It is reminiscent of the state of the global economy reports produced by bodies such as the Organisation for Economic Co-operation and Development and the IMF). The second key report is the Alert Mechanism Report, which flags up macroeconomic imbalances in Member States as required by the MIP and explains which Member States will be subsequently be subject to in-depth review. These recommendations are discussed by the Council and the European Parliament in the following months.

These Commission reports are key agenda-setting documents. In March, the European Council adopts "economic priorities" for the EU, working from the Commission's recommendations in the Annual Growth Survey. And in April, Member States submit the Stability Programmes (fiscal plans drawn up by Eurozone States) or Convergence Programmes (fiscal plans drawn up by non-Eurozone States) required by the SGP, as well as the National Reform Programmes required within the Europe 2020 strategy. The Commission then publishes its in-depth reviews.

From these data and the rest of its ongoing surveillance, the Commission proposes a CSR for each Member State, except those in the most severe trouble – in mid-2014 Greece, Portugal, Ireland and Cyprus. The CSRs are endorsed by the European Council, discussed by the employment, economic and finance, and competitiveness councils, and then adopted by the DG for Economic and Financial Affairs (ECFIN).

The European Semester is a vital link between the soft-law style of target setting often associated with the EU's new governance mechanisms, such as Europe 2020, and the harder structural adjustment politics of the EU's economic crisis. By beginning with budgetary discipline and structural adjustment issues, from the legal basis that these issues have in the TFEU and the normative basis that they have in ECFIN, the European Semester exists as a framework that can

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36 The following text draws heavily on European Commission. *Economic and financial affairs: the European Semester*. Brussels, European Commission, 2013 (http://ec.europa.eu/economy_finance/economic_governance/the_european_semester/index_en.htm, accessed 14 July 2014), *Making it happen: the European Semester.* Brussels, European Commission, 2013 (http://ec.europa.eu/europe2020/making-it-happen/, accessed 14 July 2014); Council of the European Union, and *What is the European Semester?* Brussels, Council of the European Union, 2013 (http://www.consilium.europa.eu/special-reports/european-semester, accessed 14 July 2014).

impose its hierarchy on other, non-economic policy areas. So now it is not just a framework for economic policy governance, it is also a framework for social and environmental policy governance in a way that the Lisbon Agenda never really became. This becomes clear when the relationship between the European Semester and the "soft-law" governance tools such as Europe 2020 and the Euro Plus Pact are considered.

Each Member State's Europe 2020 commitments are articulated via a National Reform Programme, a report stating the policy measures to be adopted by the State and explaining how they meet that State's EU-level targets – both those stemming from the Europe 2020 strategy and other initiatives including the CSRs and Euro Plus Pact commitments. These National Reform Programmes are now reviewed by the Commission during the European Semester, alongside their economic governance equivalents, the Stability and Convergence Programmes.

Commitments made under the Euro Plus Pact are treated in a similar manner. The Euro Plus Pact, also known as the Competitiveness Pact or the Pact for the Euro, is an agreement reached in March 2011 by 23 Member States, as reported in the conclusions of the European Council.[37] Interestingly, as well as the Eurozone countries, the Pact includes six non-Eurozone countries: Bulgaria, Denmark, Latvia, Lithuania, Poland and Romania. These countries agreed to adopt targets in four broad areas of policy, including labour market and employment reforms, competitiveness, fiscal policy and financial stability measures. The Pact is designed to be flexible, and not all Member States have made pledges in each of these areas. Where these pledges do exist, they vary in their specificity: from adopting a fiscal rule to increasing labour participation of certain demographic groups.

Unlike its hard law siblings, the Euro Plus Pact was agreed to under the OMC. There is consequently very little infrastructure supporting it and little public documentation. It also means that the European Parliament has no formal role in scrutinizing activities under the Pact.[38] Like the Europe 2020 targets, pledges made under the Pact are monitored through the European Semester process, with Member States publicly stating that there needed to be consistency rather than overlap between the Euro Plus Pact and the information presented in National Reform, Stability and Convergence Programmes. To that end, Member States urged a focus on fewer, high-impact measures that combine "durable consolidation of public finances with structural reforms".[39]

37 The following draws on European Commission. *Background on the Euro Plus Pact*. Brussels, European Commission, 2011 (http://ec.europa.eu/europe2020/pdf/euro_plus_pact_background_december_2011_en.pdf, accessed 14 July 2014).

38 Library of the European Parliament. *Library Briefing: Parliaments role in anti-crisis decision-making*. Brussels, Library of the European Parliament, 2012.

39 Council of the European Union. *Euro Plus Pact: the way forward – conclusions of member states participating in the Euro Plus Pact.* Brussels, Council of the European Union, 2012.

5.6 Specific recommendations for health systems

In the years since the establishment of these mechanisms, there has been an increasing number of specific recommendations by the EU to countries concerning their health systems, as summarized in Table 5.1.[40] Every EU Member State apart from Denmark, Sweden and the United Kingdom has received a CSR on health or long-term care.

Table 5.1 *CSRs related to health*

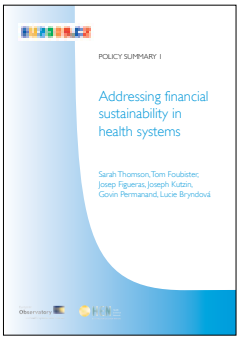
Country	Recommendations
Austria	2011: "Take steps to further strengthen the national budgetary framework by aligning legislative, administrative, revenue-raising and spending responsibilities across the different levels of government, in particular in the area of healthcare" 2012: "Take further steps 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" 2013: "Effectively implement the recent reforms of the healthcare system to make sure that the expected cost efficiency gains materialize. Develop a financially sustainable model for the provision of long-term care and put a stronger focus on prevention, rehabilitation and independent living"
Belgium	2012: "Continue to improve the long-term sustainability of public finances by curbing age-related expenditure, including health expenditure" 2013: "Continue to improve the cost-efficiency of public spending on long term institutional care" and "explore cost-saving measures of health prevention and rehabilitation, and for the creation of better conditions for independent living"
Bulgaria	2012: "Strengthen efforts to enhance the quality of public spending, particularly in the education and health sectors" 2013: "Ensure effective access to healthcare and improve the pricing of healthcare services by linking hospitals' financing to outcomes and developing out-patient care"
Croatia	None (but measures related to health care system reform in the 2013 voluntary economic programme of Croatia related to the European Semester, including centralized hospital procurement, restructuring of hospitals, outsourcing of nonmedical activities in hospitals, increased use of information technology systems, increased controls on sick leave, and new contracting models for health care)
Cyprus	2011: "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" 2012: "Complete and implement the national healthcare system without delay, on the basis of a roadmap, which should ensure its financial sustainability while providing universal coverage" 2013: Recommendations made through the economic adjustment programme rather than through country-specific recommendations (including changes in entitlements, increasing co-payments, restructuring hospital structures, moving towards a payment system based on diagnosis-related groups, and considering establishment of a gatekeeper–general practitioner structure)
Czech Republic	2013: "Take measures to significantly improve cost–effectiveness of healthcare expenditure, in particular for hospital care" (in particular by improving the efficiency of care and reducing "inappropriate" lengths of stay in hospitals)
Denmark	None
Estonia	2012: None, but noted difficulties in local government delivering services including health services because of their small size 2013: "Improve the efficiency of local governments and ensure quality provision of local public services" (including "local support measures necessary to ensure effective health care provision")

40 See European Commission. *European Semester 2014*. Brussels, European Commission, 2014 (http://ec.europa.eu/europe2020/making-it-happen/country-specific-recommendations/index_en.htm, accessed 14 July 2014) for individual country-specific recommendations.

Country	Recommendations
Finland	2013: "Ensure effective implementation of the on-going administrative reforms concerning the municipal structure, in order to deliver productivity gains and cost savings in the provision of public services, including social and healthcare services"
France	2012: None, but noted "barriers to entry and restrictive conduct conditions" in sectors including health 2013: "…increase the cost–effectiveness of healthcare expenditure, including in the areas of pharmaceutical spending"
Germany	2011: "Maintain a growth-friendly consolidation course, in particular by safe guarding adequate expenditure on education and by further enhancing the efficiency of public spending on healthcare and long-term care" 2012: "Continue the growth-friendly consolidation course through additional efforts to enhance the efficiency of public spending on healthcare and long-term care" 2013: "Pursue a growth-friendly fiscal policy through additional efforts to enhance the cost–effectiveness of public spending on healthcare and long-term care through better integration of care delivery and a stronger focus on prevention and rehabilitation and independent living"
Greece	Extensive recommendations through the economic adjustment programmes, focusing in particular on improving the efficiency and management of the health care system
Hungary	None
Ireland	Recommendations in the economic adjustment programme, with ongoing concerns over management of costs and the cost of pharmaceuticals in particular
Italy	None
Latvia	None
Lithuania	None
Luxembourg	None
Malta	2013: "Pursue healthcare reforms to increase the cost–effectiveness of the sector, in particular by strengthening public primary care provision"
Netherlands	2011: None, but noted health care overruns as a particular risk to the overall budgetary strategy
Poland	2012: None, but noted "Existing restrictions on providing professional services are a major obstacle to further growth" in sectors including health 2013: "With a view to improving the quality of public finances minimize cuts in growth-enhancing investment, reassess expenditure policies improving the targeting of social policies and increasing the cost effectiveness and efficiency of spending in the healthcare sector"
Portugal	Recommendations in the economic adjustment programme, including (in 2013) further restructurings of the hospital network to produce additional savings
Romania	2012: None, but noted that "The main risks to the budgetary targets are the arrears of state-owned enterprises, as well as potential re-accumulation of arrears at local government level and in the health sector, even if some measures have been taken in the health sector" 2013: "Pursue health sector reforms to increase its efficiency, quality and accessibility, in particular for disadvantaged people and remote and isolated communities. Reduce the excessive use of hospital care including by strengthening outpatient care"
Slovakia	2013: "…further improve the long term sustainability of public finance by … increasing the cost-effectiveness of the healthcare sector"
Slovenia	2011: None, but "comparatively low spending efficiency" in sectors including health care suggested to imply that "Slovenia may have additional scope for expenditure-based consolidation without compromising the quality of public services"
Spain	2013: "Increase the cost–effectiveness of the healthcare sector, while maintaining accessibility for vulnerable groups, for example by reducing hospital pharmaceutical spending, strengthening coordination across types of care and improving incentives for an efficient use of resources"
Sweden	None
United Kingdom	None

Sustainable finance for health

The question as to whether health systems will be financially sustainable in the future is frequently raised in health policy debate. The problem is often phrased in terms of the ability of governments and others to finance health care adequately in the face of growing cost pressures – with population ageing, new technologies and consumer expectations around health care coverage and quality being the three most commonly cited challenges.



Addressing financial sustainability in health systems

Sarah Thomson, Tom Foubister, Josep Figueras, Joseph Kutzin, Govin Permanand and Lucie Bryndová

European Observatory on Health Systems and Policies, 2009

http://www.euro.who.int/__data/assets/pdf_file/0005/64949/E93058.pdf?ua=1

This policy summary report touches on the myriad elements involved in discussions on financial sustainability and emphasizes the need for a clarification of the key concepts as a prerequisite to understanding both what is at stake and what is involved, in order to then consider potential policy decisions.

How can European states design efficient, equitable and sustainable funding systems for long-term care for older people?

José-Luis Fernández, Julien Forder, Birgit Trukeschitz, Martina Rokosová and David McDaid

European Observatory on Health Systems and Policies, 2009

http://www.euro.who.int/en/health-topics/Life-stages/healthy-ageing/publications/2009/how-can-european-states-design-efficient,-equitable-and-sustainable-funding-systems-for-long-term-care-for-older-people

Across Europe data suggest that an ageing of the population, coupled with changes in the availability of informal family support, increasing costs of care and raised expectations on the quality, intensity and flexibility of services may raise major challenges for policy-makers contending with maintaining or extending coverage and support for long-term care systems.

Assessing different options for the funding of long-term care raises three key issues. First, it requires an assessment of the future need for long-term care services across the population, and of its broader socioeconomic repercussions. Second is the rationale for using public funds for funding long-term care, and how this varies depending on the specific country context. Finally, it begs the question of the way in which funding arrangements can be implemented in order to maximize fairness and efficiency in the system.

The recommendations seem particularly concerned with efficiency and structural issues for health systems (including moving care from inpatient care to outpatient care where possible), and seem to envisage preventive care as holding out the potential to reduce overall costs. Despite the general context of keeping public expenditure under control, issues of equality and coverage are also addressed (e.g. in Cyprus and Romania). These themes broadly correspond with the Commission's approach to health systems set out alongside the Social Investment Package.[41] The recommendations are mostly at a high level of generality (although this is not the case for the EAPs, which are very detailed in their requirements); however, some clear country-specific concerns do emerge, such as the division of responsibilities in Austria, for example.

Other aspects are less clear. It is not immediately obvious why some countries have received recommendations when others have not, for example, given the relative situations of their finances and their health systems, why does Germany have repeated recommendations when Latvia and Lithuania do not? And how has the Netherlands managed to avoid recommendations despite becoming the most costly health system in the EU per person?[42] Or how has the United Kingdom managed to avoid recommendations, given that their Office for Budget Responsibility has identified the health system as one of the principal risks to the long-term sustainability of the United Kingdom's public finances[43] and ECFIN's assessment suggested that it should receive one?[44]

It is also not obvious on what basis the Commission is identifying these issues, although Rita Baeten has suggested that it prefers to focus on countries where it can have more impact.[45] What is clear is that the much strengthened systems of the EU for collective fiscal oversight through the European Semester have fundamentally shifted the role of the EU, and that this is already having an impact on health systems, which is only likely to increase in the future.

41 European Commission. *Staff Working Document SWD(2013)43: investing in health*. Brussels, European Commission, 2013.

42 OECD. *Health at a glance 2013: OECD indicators*. Paris, Organisation for Economic Co-operation and Development, 2013.

43 UK Office for Budget Responsibility. *Fiscal sustainability report*. Norwich, UK, The Stationery Office, 2011.

44 Baeten R. Inside the black box: explaining the EU's economic surveillance of health and long-term care systems. In: *ECPR Standing Group on European Union Politics*, The Hague, 5 June 2014.

45 Baeten R. Inside the black box: explaining the EU's economic surveillance of health and long-term care systems. In: *ECPR Standing Group on European Union Politics*, The Hague, 5 June 2014.

Chapter 6

Conclusions

Looking back at EU action affecting health, both directly and indirectly, this chapter reviews what all this means for health and how it might develop in the future.

6.1 The EU's impact on health

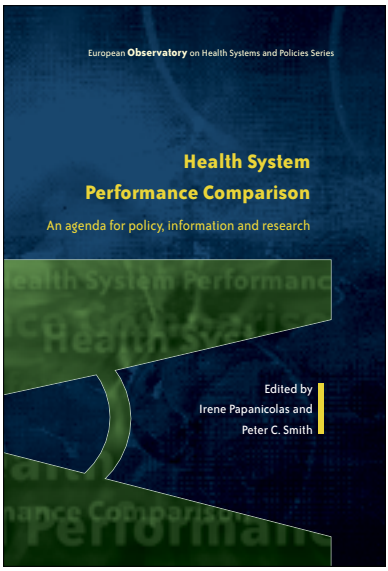
The impact is bigger than you think

The EU has a surprisingly large impact on health, most of which comes from areas beyond the formal health article and that are currently going through the biggest change in decades. This impact on health has been largely a positive one. The EU has clearly helped to improve health by addressing environmental determinants; for example, European citizens are among the best protected in the world in terms of exposure to chemicals or pollution (see section 3.2.3). The EU has made progress in addressing key social determinants such as working conditions (see section 3.2.5), but the impact of wider social inequalities on health remains. This cannot be blamed on a lack of legal powers to act (unlike health, the social powers in the treaties are wide ranging), but rather on a clear preference by national governments to address social issues domestically rather than at European level, and likewise to keep the overwhelming weight of financial tools under national control. The EU has also made some progress in addressing the behavioural determinants of health, but most strongly for smoking (section 3.2.1); by comparison, for diet and exercise and the particularly European issue of alcohol, European action has been broadly limited to providing information and leaving choices to individuals.

… but not where you think

This broadly positive impact is not widely understood, however. The fragmented nature of the EU's action on health – being taken across a wide range of legal bases, many of which do not have health as an objective (section 2.3) – makes it difficult to gain an overall picture. This consequently makes it difficult for health stakeholders to be part of shaping the EU's health-related discussions, when so

Health system performance comparison.
An agenda for policy, information and research



Edited by Irene Papanicolas and Peter C. Smith

Oxford University Press, 2013

http://www.euro.who.int/en/about-us/partners/observatory/studies/health-system-performance-comparison.-an-agenda-for-policy,-information-and-research

International comparisons of health system performance have become increasingly popular, made possible by the rapidly expanding availability of health data. This approach has become one of the most important levers for prompting reform of health systems. Yet, as the demand for transparency and accountability in health care increases, so too does the need to make the comparisons of data from different health systems both accurate and meaningful.

This book offers an important summary of the current efforts and developments in health system performance comparison and identifies and explores the practical and conceptual challenges that arise. It discusses data and methodological challenges, as well as broader issues such as the interface between evidence and practice.

The book outlines the priorities for future work on performance comparison, in the development of data sources and measurement instruments, analytic methodology and assessment of evidence on performance.

much of the discussion and decision-making takes place in forums that are not primarily focused on health. The qualitative nature of much European health cooperation – building networks, providing comparable data for benchmarking, sharing good practice (section 3.3) – means that it works in ways that are hard to quantify and demonstrate.

…and with the financial crisis, its locus and effects are changing

The financial crisis has brought about a fundamental shift in power towards the European level, with major consequences for health systems, as described in Chapter 5. The effect of this third face is difficult to predict, not least

because an evidence base for European analysis of health systems is largely lacking. Historically, national governments have been extremely sensitive about any comparisons of their health systems, but this means that now analysis and recommendations are being made without detailed data to compare and analyse health systems across the EU, although recommendations for how to address this do exist.[1] Similarly, how this shift in power will affect decision-making is unclear; this is a clear example of constitutional asymmetry, with the EU taking decisions with enormous impact on health systems without any major skills or knowledge in the area, and without those who have that knowledge at national level being around the table at the European level (see section 2.2).

6.2 Health is a unique opportunity for the EU

A shared commitment to health is central to Europeans; this provides a way for the EU to make the value of Europe real for its citizens, as well as keeping its economy sustainable and competitive in the coming decades.

A shared commitment to health is a core and distinctively European value

Health has consistently been a central issue for Europeans, and while that might be true of many places, how Europeans have put that value into practice has been unique. While we debate the differences between our health systems, from a global perspective they are remarkably similar and quite distinctive – no other region of the world has such systems for ensuring "universality, access to good quality care, equity, and solidarity"[2] in health.

Health can make the value of European integration real for its citizens

Although these health systems are primarily national, the EU has done an enormous amount for the health of its citizens, as described above. It has made major strides in tackling cancer (see section 3.1) as well as the wider determinants of health (see Chapter 3), making pharmaceuticals both safe and available (see section 4.2.1), and become the major source of capital investment in upgrading the health systems of some EU countries (section 4.5). It enables citizens to be able to travel elsewhere in the EU without worrying about whether they can have health care if they need it (section 4.3), or indeed to be able to go to another country for health care if that better meets their needs.

1 Papanicolas I, Smith P, eds. *Health system performance comparison: an agenda for policy, information and research*. Maidenhead, UK, Open University Press, 2013.

2 Council of the European Union. Council conclusions on common values and principles in European health systems. *Official Journal,* 2006, C 146:1–4.

Yet this contribution is not widely understood, in part because of the fragmented nature of the EU's action on health, as described above. Given how important health is consistently rated by European citizens, this lack of understanding of the EU's contribution is a problem for a system striving for acceptance and approval from its own citizens. There is a risk that only one side of the EU health story is told – the constraints being placed on the health systems of the "bailout" countries, for example, or the transitional costs of environmental improvements – simply because the other side of the story is more complex and harder to present. The European Health Insurance Card was a milestone in making the EU's contribution real; for many EU citizens, it will be the only tangible "piece of Europe" in their pocket. Perhaps this can provide a starting point for showing how the EU contributes to this central priority of people throughout Europe.

For example, the EU already funds the world's largest database on rare diseases, Orphanet,[3] which provides information on the conditions and centres of expertise for them throughout Europe. Although these diseases individually are rare, the thousands of them mean that they affect millions of Europeans – many of them children, given the genetic origins of many rare diseases.[4] This is one of the clearest examples of European added-value; could the EU do more to support the connections between centres and access to care for children with rare conditions, such as through European reference networks (see section 4.3.1)? Or on a wider level, with the greater European oversight of health systems, could the EU provide greater positive support for identifying, sharing and implementing best practice in health care?

Health as a competitive advantage for the EU

There is clearly no future for Europe in trying to become a cheap, low-wage economy; Europe's future lies in adding value through expertise and specialization. To do this with the relatively smaller, older-working-age population that Europe will have in the coming decades depends on people investing in their skills and staying in work; that in turn depends crucially on them staying healthy.[5] So far from being a burden, as sometimes portrayed, Europe's health systems are essential for Europe's future and its ability to sustain its way of life more generally.

Moreover, the health sector itself is one of the strongest economic performers within the European economy. Research in Germany identified that the health

3 See orphanet: the portal for rare diseases and orphan drugs [website]. (www.orpha.net, accessed 14 July 2014).

4 European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Communication on rare diseases: Europe's challenges (COM(2008)679)*. Luxembourg, Publications Office of the European Union, 2008.

5 Suhrcke M et al. *The contribution of health to the economy in the European Union*. Luxembourg, Publications Office of the European Union, 2005.

economy added more value to the German economy than the entire mighty German car industry, and it employed every seventh person in work.[6] In addition, unlike some other areas of major public expenditure (in particular defence), money spent on health stays in the home economy.[7] So investing in health not only improves health and well-being but is also a highly effective way of generating growth and jobs.

One thing is clear. The impact of the EU on health is substantial – it could hardly be otherwise, given how important both health and the EU are within the economies and societies of EU countries – and is only likely to increase. To ensure that this impact is as positive for health and for Europe as possible, it is essential that the contribution of Europe to health is fully understood. That has been the aim of this book.

6 Ostwald DA, Henke K-D, Hesse S. *Das Gesundheitssatellitenkonto: Der zweite Schritt: Wertschöpfungs-und Beschäftigungseffekte der regionalen Gesundheitswirtschaft*. Berlin, Springer, 2013.

7 Reeves A et al. Does investment in the health sector promote or inhibit economic growth? *Global Health*, 2013, 9(1):43.

Appendix

Selected articles relevant to health in the Treaty on the Functioning of the European Union

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; …

1 Council of the European Union. Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal*, 2012,C 326:1–12.

Article 9

In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.

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 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 any 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.

From Title XX, "Environment"

Article 191 (ex Article 174 TEC)

1. Union policy on the environment shall contribute to pursuit of the following objectives:

– preserving, protecting and improving the quality of the environment,

– protecting human health,

– prudent and rational utilisation of natural resources,

– promoting measures at international level to deal with regional or world-wide 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.

Further reading

Baeten R, Thomson S. Health care policies: European debates and national reforms." In: Natali D, Vanhercke B, eds. *Social developments in the European Union 2011.* Brussels, ETUI/OSE, 2012, pp. 187–212.

Baeten R, Vanhercke B, Coucheir M. *The Europeanisation of national health care systems: creative adaptation in the shadow of patient mobility case law.* Brussels, European Observatoire social européen, 2010 [OSE Papers Series].

Greer SL. *The politics of European Union health policies.* Buckingham, UK, Open University Press, 2009.

Greer SL, Jarman H. Managing risks in EU health services policy: spot markets, legal certainty and bureaucratic resistance. *Journal of European Social Policy,* 2012, 22(3):259–272.

Greer SL, Kurzer P, eds. *European Union public health policies: regional and global perspectives*. Abingdon, UK, Routledge, 2013.

Hancher L, Sauter W. *EU competition and internal market law in the health care sector.* Oxford, Oxford University Press, 2012.

Hervey TK, McHale JV. *Health law and the European Union.* Cambridge, UK, Cambridge University Press, 2004.

Krajewski M et al. (eds.). *The changing legal framework for services of general interest in Europe: between competition and solidarity.* The Hague, TMC Asser Press, 2009.

Mossialos E et al. *Health systems governance in Europe: the role of EU law and policy*. Cambridge, UK, Cambridge University Press, 2010.

van de Gronden JW et al. (eds.). *Health care and EU law.* New York, Springer, 2011.

What does the European Union mean for health and health systems? More than one would think. The EU's health mandate allows for a comprehensive set of public health actions. And there are other EU policies which, although not health-related, have important consequences for governing, financing, staffing and delivering health services. In other words: EU actions affect the health of Europe's population and the performance of health systems.

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This book is aimed at policy-makers and students of public health and health systems in the EU who want to understand how the EU can add value in their quest improving population health and the performance of health systems in Member States.

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