

Public health, free movement and  
macroeconomic coordination:  
Mapping the evolving governance of  
European Union health policy

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## **Declaration**

I, the candidate, confirm that this thesis is my own work and that it has not been submitted in substantially the same form for the award of a higher degree elsewhere.

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## List of abbreviations and acronyms

ABPI	Association of the British Pharmaceutical Industry
AGS	Annual Growth Survey
AIDS	Acquired Immunodeficiency Syndrome
ALDE	Group of the Alliance of Liberals and Democrats for Europe
BEPG	Broad Economic Policy Guideline
BSE	Bovine Spongiform Encephalopathy
BTO	Blood, tissue and organ
CANCON	Joint Action on Cancer Control
CAP	Common agricultural policy
CJEU	Court of Justice of the EU
CoEU	Council of the EU
CoFI	Court of First Instance
CoFR	Charter of Fundamental Rights
COPD	Chronic obstructive pulmonary disease
CSR	Country Specific Recommendation
CVM	Cooperation and Verification Mechanism
DCT	Draft Constitutional Treaty
DG	Directorate General
DHSS	Department of Health and Human Services
DTCA-PD	Direct-to-consumer advertising of pharmaceutical drugs
EAC	Europe Against Cancer
EAP	Economic Adjustment Programme
ECAC	European Code Against Cancer
ECB	European Central Bank
ECDC	European Centre for Disease prevention and Control
ECFIN	DG for Economic and Financial Affairs
ECL	European Cancer Leagues
ECPC	European Cancer Patient Coalition
ECSC	European Coal and Steel Community
EDP	Excessive Deficit Procedure
EEC	European Economic Community
EERP	European Economic Recovery Plan
EES	European Employment Strategy

EFSA	European Food Safety Authority
EFSD	European Financial Stability Facility
EFSD	European Financial Stabilisation Mechanism
EGE	European Group on Ethics in Science and New Technologies
EHFG	European Health Forum Gastein
EHIC	European Health Insurance Card
EMA	European Medicines Agency
EMPL	DG for Employment and Social Affairs
EMU	Economic and Monetary Union
ENCR	European Network of Cancer Registries
ENTR	DG for Enterprise and Industry, now DG GROW
EPAAC	European Partnership for Action Against Cancer
EPC	Economic Policy Committee
EPF	European Patients' Forum
EPHA	European Public Health Alliance
EPP	Group of the European People's Party (Christian Democrats)
ESF	European Social Fund
ESIF	European Structural and Investment Funds
ESM	European Stability Mechanism
EU	European Union
Euratom	European Atomic Energy Community
FACT	Fighting Against Cancer Today
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
GDP	Gross domestic product
Green/EFA	Group of the Greens/European Free Alliance
GROW	DG for Internal Market, Industry, Entrepreneurship and SMEs
HAI	Health Action International
HiAP	Health in All Policies
HIV	Human Immunodeficiency Virus
HSPA	Health System Performance Assessment
HTA	Health technology assessment
IARC	International Agency for Research on Cancer
IMF	International Monetary Fund

IR	International Relations
ItP	Information to patients
JHA	Justice and Home Affairs
MAC	MEPs Against Cancer
MARKT	DG for Internal Market and Services
MEP	Member of European Parliament
MIP	Macroeconomic Imbalance Procedure
MLG	Multi-level governance
MoU	Memorandum of Understanding
MTO	Medium Term Objective
NGO	Non-governmental organisation
NMG	New modes of governance
NRP	National Reform Programme
OECD	Organisation for Economic Cooperation and Development
OMC	Open method of coordination
PHAP	Public Health Action Programme
PhRMA	Pharmaceutical Researchers and Manufacturers of America
PICTF	Pharmaceutical Industrial Competitiveness Task Force
PIP	Poly Implant Prothèse
QMV	Qualified Majority Voting
RCI	Rational choice institutionalism
REFIT	Regulatory fitness and performance programme
RTAD	Revised Tobacco Advertising Directive
S&D	Group of the Progressive Alliance of Socialists and Democrats
SANCO	DG for Health and Consumers (now DG Santé)
Santé	DG for Health and Food Safety
SARS	Severe Acute Respiratory Syndrome
SEA	Single European Act
SFE	Smoke-free environment
SGP	Stability and Growth Pact
SLWPPH	Senior Level Working Party on Public Health
SPC	Social Protection Committee
TABD	Transatlantic Business Dialogue
TAD	Tobacco Advertising Directive

TEC	Treaty establishing the European Community
TFEU	Treaty on the Functioning of the EU
TPCD	Tobacco Products Consolidation Directive
TPD	Tobacco Products Directive
TSCG	Treaty on Stability, Coordination and Governance
TWFD	Television Without Frontiers Directive
UK	United Kingdom
US	United States
WHO	World Health Organization
WTD	Working Time Directive

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## **Abstract**

### *Public health, free movement and macroeconomic coordination: Mapping the evolving governance of European Union health policy*

Eleanor Brooks

Health is a unique and intriguing sphere of European Union (EU) policy, not least of all because it has only been recognised as such for the last 15 years. From piecemeal origins in public health and occupational safety it underwent dramatic expansion as a result of exposure to free movement and internal market law in the 1990s. Now, in the aftermath of the economic crisis, it is entering another unprecedented era. As the focus of the European project has turned to fiscal sustainability and the strengthening of collective economic governance, health policy has been swept into frameworks designed for the oversight of macroeconomic policy and national expenditure. Crucially, these frameworks extend EU health influence into areas reserved in the founding treaties for exclusive national control. This thesis seeks to map the changing nature, scope and governance of EU health policy, contributing to the existing patchwork of literature and reviewing the prevailing narrative in light of the critical juncture now being faced. It draws on the theories of European integration, the Europeanisation framework and the more recent governance approaches to assess the continuing relevance of core themes – crisis politics, regulatory policy, the internal market, new modes of governance, and the role of the Court – in health policy development. Using six case studies and data from 41 interviews with experts, policy-makers and officials, it examines the catalysts, drivers and dynamics of health policy integration. It finds that as the actors and interests involved in health policy have proliferated, health issues have become increasingly politicised. Addressing the consequences of this trend, the thesis explores the growing dependence on, and progressive strengthening of, voluntarist governance, as well as the declining scope and influence of EU health policy. Finally, it reflects upon the future of health within a politicised European integration project.

# PART I

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The thesis is divided into three sections. Part I lays the foundations of the study and is comprised of the first five chapters – the introduction, methodology, conceptual and theoretical framework, literature review and history chapter. As such, it outlines the research problem and resulting questions, the methodological tools available for addressing these questions and the conceptual and theoretical approaches which the thesis employs. The literature review and history chapter place the research within its academic and historical context, and allow it to draw on existing work in the field. The typologies and hypotheses developed in Part I are used to structure the empirical research which follows.

Part II contains the six case studies which the thesis uses to explore the research questions and test the hypotheses identified in the earlier chapters. These case studies occupy one chapter each and detail the governance of health in six selected policy areas. They cover EU policy in blood, tissues and organs, cancer prevention, medicines information to patients, tobacco control, patient mobility and health in macroeconomic governance. The policies chosen each embody a particularly unique or important feature of EU health policy and thus offer a valuable insight into the dynamics which have shaped and guided health governance. At the end of each of these chapters, the relevant horizontal theme is examined in more detail.

Part III, comprised of chapters 12 and 13, brings together the previous chapters to analyse the patterns, trends, common factors and defining features of health governance in the EU. It ‘tests’ the hypotheses and typologies identified in Part I against the policy experience described in Part II and examines the implications of more recent developments in EU health policy for the characterisations seen in the existing literature. Finally, it considers the future of health governance in the EU, particularly in light of the economic and financial crises, and discusses the potential further evolution of this unique and important area of EU policy.

## INTRODUCTION

From both an academic and a political perspective, health is a fascinating area of EU policy. It is unpredictable, contentious and often contradictory, yet firmly institutionalised. It is crisis-driven, having been brought onto the agenda and shaped over the years by emergencies such as the thalidomide tragedy, the Bovine Spongiform Encephalopathy (BSE) outbreak, the global blood safety crises and the Poly Implant Prothèse (PIP) breast implant scandal. Yet in periods of calm, it has ‘muddled through’ and woven a steadily expanding web of policy and law. It rests on a fractured legal base and an unwieldy division of mandates which provide at the same time for shared competence and national primacy. It has implications for almost every other policy sector and frequently encroaches, often via non-health policies, upon areas of responsibility reserved exclusively for national governments. Yet, health remains a widely accepted portfolio of EU activity; its logical added value and interaction with the internal market mean that no actor is demanding absolute renationalisation of health policy. It is both a hugely sensitive and an utterly uncontroversial field of supranational politics.

In the post-crisis era, interest in health governance has been reignited. The financial crash, sovereign debt crisis and economic recession have pushed the constituent parts and the sum-whole of the EU to the limit and resulted in a crisis of the European project. Economic and social decline have prompted rising anti-EU sentiment, implicitly curtailing the mandate and ambition of European policy-makers, nowhere more than in health. Furthermore, the mechanisms put in place to manage and avoid repeat of the crisis have ushered in a new era of EU governance. Member states now conduct budgetary and macroeconomic processes at the European level, coordinating national policy with supranational priorities through the ‘European Semester’ framework. This new governance tool enables the European Commission (the Commission) to intervene directly in domestic policy from a financial perspective, to survey and monitor national progress towards economic goals and to impose early warnings and even sanctions where rules are breached. It opens the whole range of national policy to EU involvement but imposes a strict financial lens – only where national policy has an impact upon the economic stability of the region may the EU prescribe specific measures. This means that those policy areas which contribute most to the national debt are exposed to direct intervention – constituting an average expenditure of eight per cent of gross domestic product, health is an unavoidable target (OECD, 2015a).

A recent article celebrating the twentieth anniversary of the Maastricht Treaty reflected upon the development of EU health policy since the ratification of the Treaty, with the aim of identifying concepts which might help to inform the future evolution of the policy area (Stein, 2014). In particular, it was concerned with the nascent economic governance framework and the way in which it was beginning to obtrude upon health policy. A short time later, and in light of the institutionalisation of health within the economic governance framework, this thesis pursues a similar goal. In the broadest sense, it seeks to place the latest ‘chapter’ in EU health policy within the context of what came before. More specifically, it examines the established theoretical perspectives on the governance of health with a view, firstly, to pushing beyond the traditional integration and Europeanisation theory characterisations and, secondly, to employing these perspectives to assess the possible trajectory of health in the post-crisis era.

The rest of this introduction describes the current state of understanding in EU health policy. It reviews the prevailing characterisations of health as an EU portfolio, gives an overview of

the EU's response to the economic crisis and how this has impacted upon health and identifies a number of challenges raised by this latest development. Finally, it lays out the research questions which will guide the study, ahead of an account of the methodological approach in the following chapter.

## The European Union and health

The thesis is concerned with the role of the EU in health systems and how this has changed over time. The World Health Organization (WHO) defines a health system as:

'(i) all the activities whose primary purpose is to promote, restore and/or maintain health; (ii) the people, institutions and resources, arranged together in accordance with established policies, to improve the health of the population they serve, while responding to people's legitimate expectations and protecting them against the cost of ill-health through a variety of activities whose primary intent is to improve health.' (WHO, 2015)

It also identifies six 'building blocks' which make up the health system (WHO, 2007: iv). These are:

1. Health services
2. The health workforce
3. The health information system
4. Medical products, vaccines and technologies
5. The health financing system
6. Leadership and governance ('health stewardship')

These building blocks are helpful in illustrating what EU health policy involves and how this has expanded and developed. The characterisation which follows is purposefully simplified but offers a rudimentary framework for understanding the different strands of EU health policy.

The explicit competence of the EU in health concerns public health, understood as the management of population or collective health. The founding treaties provide a two-fold role – firstly they allow the EU to coordinate and support national public health policies, via the public health programmes and related initiatives, and secondly they require the EU to ensure that all of its other policies work to protect health. As such, the public health 'strand' of EU health policy most directly affects building blocks three and six. In block three, the EU collects, curates and disseminates reliable and timely data on health determinants, system performance and health outcomes for use by member states to inform better public policy. In block six, it coordinates and advises on the creation and leadership of strategic policy frameworks that are supported and informed by the experiences of other member states, via a number of platforms for exchange of best practice and mutual learning.

By contrast, building blocks two and four – concerning the supply, distribution, competency and effectiveness of health professionals and the quality, efficacy, safety and cost-effectiveness of health technologies – represent those areas of the health system most influenced by the EU's internal market competence and law. Here the free movement principles have created a strong role for the EU in the mobility of health professionals and product standards regulation. They have also allowed the EU to encroach into building block one – health services – by requiring the free movement of health services, though responsibility for service delivery has remained at national level.

Until recently, building blocks one and five – the safe, effective and good quality health services provided to individuals and populations and the financing system which ensures that these are adequately funded – were explicitly recognised by the treaties as areas of sole national competence. Some aspects of health services, such as the effectiveness of particular health interventions, are informed by the EU evidence base generated under building block three but responsibility for the choice of interventions delivered, how they are administered and the resources used to provide them lies with national governments. However, since the late 2000s, this ‘final frontier’ of national health competence has been significantly eroded. Though the process was already underway when the financial crisis and economic recession hit Europe, this erosion has been accelerated and institutionalised in the post-crisis era as part of the EU’s strengthened economic governance framework. It is this change, and its contrast to the changes which came before it, that the thesis explores.

Up until the late 2000s, the narrative of EU health policy was relatively well understood. Based on a weak legal mandate and a constitutional asymmetry which favours economic integration over social policy imperatives, health policy was driven forward by health policy actors making creative use of the tools available to them. With the support of the Court of Justice of the EU (CJEU, the Court), a ‘treaty-base game’ was played, stretching the existing mandate and exploiting the strength of internal market law. Where this reached its limits, innovative modes of governance were employed; these were largely based on soft law but wielded surprising power. Health had thus been characterised by a process of creative ‘muddling through’, employing different approaches according to whether the issue stemmed from the public health mandate – encompassing and affecting building blocks three and six – or from the impact of the internal market on health via building blocks two, four and, to some extent, one. The dichotomous nature of EU health policy has been challenged, however, by the EU’s response to the economic crisis and the inclusion of health in the strengthened economic governance framework. Since the late 2000s a third face of EU health policy has emerged, sharing few characteristics with the original two described above, and necessitating a revision of the dominant narrative.

## **Health in EU economic governance**

The aftermath of the financial crisis and resulting economic recession has seen the focus of the European project shift back to economic and fiscal policy. In an attempt to address the weaknesses exposed the EU has sought to strengthen its economic governance framework and to increase the extent to which member states coordinate their macroeconomic and fiscal policies. This has included an overhaul of existing provisions, such as the Stability and Growth Pact (SGP), and the introduction of new instruments, such as the European Semester. It should be emphasised that the inclusion of health and social policies in economic governance mechanisms did not start with the economic crisis – macroeconomic policy tools and instruments began targeting pensions and, with less force, health expenditure in the late 1990s as part of the SGP (Baeten and Thomson, 2012: 188). However, the risk posed to the European economy by instability in any of its 28 member economies was painfully exposed in the aftermath of the crisis, providing ample justification for a tightening of fiscal oversight and coordination.

The EU has pursued a twin-track response to the financial crisis and economic recession. Firstly, it has provided short-term relief to those countries facing immediate financial pressure. This has included the creation of the European Economic Recovery Plan (EERP),

the European Financial Stability Facility (EFSF), the European Financial Stabilisation Mechanism (EFSM) and, more recently, the umbrella European Stability Mechanism (ESM). These vaguely synonymous facilities have provided bail-out funding and loans to member states struggling to keep their economies solvent, thus addressing the apparent symptoms of the crisis. The second track of the EU's response seeks to tackle the longer-term problem and address the causes of instability in order to prevent its repetition. Over a period of five years, the EU has strengthened existing mechanisms and introduced new ones to create an economic governance framework which monitors, coordinates and enforces fiscal and economic policy in the member states.

By contrast to the frameworks put in place to manage future financial crises and the temporary bail-outs being administered to countries under severe pressure, the longer-term strengthening of the economic governance system is serving to institutionalise the routine oversight and coordination of fiscal policy by the EU and, in particular, the European Commission. The European Semester, the annual cycle of economic policy coordination introduced as the central implementing instrument of the new governance system, is especially important in this regard. It allows the Commission to set the economic agenda, to monitor, comment upon and, in some cases, amend national governments' responses to this agenda, and to take measures against member states whose economic situation is deemed to present a threat to the stability of the European economy. First introduced in 2011, the Semester is now in its sixth cycle and is a broadly accepted feature of EU governance – as such, the EU can be understood to have successfully institutionalised the leverage it gained after the economic crisis and to have established a central role for itself in national economic and fiscal policy.

The Semester touches upon almost every field of national policy, including health. It assesses the burden and effectiveness of health expenditure and makes recommendations – which may be binding or not depending upon the status of the country involved – to each member state on how the financial sustainability of their health systems can be improved. The range of topics covered in these country specific recommendations (CSRs) now includes the balance between primary and secondary care, access to and availability of services for different population groups, trends relating to the health workforce and professional migration, provision of prevention and health promotion programmes, the effectiveness and sustainability of specific funding models and the potential gains to be made from implementing eHealth technologies and health-friendly taxation.

In addition to influencing health policy, the crisis and the mechanisms introduced as part of the EU's response to it have had a significant and, in some cases, devastating impact upon health systems and population health. Research in this area is hampered by the inherent time-lag in health data but concerning trends have been identified across the continent. Cuts to health expenditure have resulted in decreased service provision, fewer healthcare professionals, disruption in the supply of medicines and difficulties in accessing care in many regions. In Greece, which has received the greatest attention and suffered the sharpest decline in population health, rates of suicide, homicide, mental disorder, substance abuse and infectious disease prevalence have all increased, whilst the health system has struggled to provide care with the limited resources available to it (Kentikelenis et al., 2014; Kondilis et al., 2013).

The post-crisis acceleration of health's inclusion in the economic governance framework has significantly eroded national autonomy in the organisation and financing of health systems,

bringing EU influence into building block five. As such, it has ushered in a ‘third era’ of EU health policy, where health is understood as an economic sector and the EU’s role, though filtered through a fiscal lens, is extended to areas where supranational intervention was previously unthinkable.

## **Challenges to the established narrative and gaps in the existing research**

The latest era in the evolution of the European project and its implications for health and health policy raise a number of questions and challenge established understandings. EU involvement in national health policy has not only extended into building blocks one and five – those protected in the treaties as national competences – but the nature of its role in those areas where it was already active has changed considerably. Since health is such a significant economic sector, with implications for jobs, growth and fiscal sustainability, there is no longer any area within it which is immune from EU interference. The balance between primary and secondary care, the prescription of generic rather than brand-label drugs, the financing of hospitals rather than care-in-the-community programmes and the provision of universal health insurance rather than out-of-pocket payments all have substantial implications for the cost-effectiveness and sustainability of health systems and thus are now exposed to EU intervention. Furthermore, the economic governance framework operates at an overarching level, setting the parameters of policy before the traditional or established processes formulate policy content. At the most fundamental level, all policy is designed and restricted according to the budget assigned to it – the economic governance framework allows the EU to influence the spending priorities and budgetary plans of member states during their construction, thus delimiting the policy options which might follow at the most upstream point. Strangely, this is generating a dynamic of centralisation – and even federalism – at a time when the discourse surrounding the EU is pulling strongly in the opposite direction.

The EU’s changing role in health has challenged the prevailing narrative. Far from an instance of competence creep, the institutionalisation of new powers under the economic governance framework might better be seen as crisis politics, with justification and support for new powers drawn not from the Court or from the EU’s strong consumer protection mandate, but from the global climate of austerity, fiscal conservatism and the tacit understanding that the continuing rise in health expenditure across the continent threatens stability. The tension between economic and social priorities has been exacerbated by this shift in focus and divisions between national and EU responsibility have been blurred within new governance structures. More fundamentally, such debates have been transcended by discussions of economic significance. Whether the treaties permit a government to unilaterally approve the reimbursement of a new drug or the construction of a new hospital is now of secondary interest – where such decisions have implications for the financial sustainability of the health system, as most do, they are now issues of European concern.

Finally, the governance of health policy at the EU level has undergone unprecedented change. Strengthening of the EU’s hard law competence, contingency in its soft law mechanisms and formalisation of peer review and benchmarking practices in economic governance has meant that the instruments which influence health policy are now more rigid. Whilst the recommendations made under the European Semester are non-binding for most member states, the EU has constructed a continuum of power and interference, ranging from unprecedented binding control over states in receipt of financial assistance to voluntary

guidelines for those with robust economies and low levels of debt. Furthermore, the range of actors, institutions and interests involved in health policy has changed dramatically. Whilst health used only to concern health officials and the public health community, its major policy decisions are now influenced by actors and agendas from the economic and finance sectors. These officials tend to have little experience in health but have been given a central role in the upstream decision-making which shapes eventual health policy content.

The post-crisis development of health policy, understood as the emergence of a ‘third era’, does not fit comfortably with what came before. Almost every aspect of how it was established and how it now operates diverges from the trends and patterns identified in the prevailing literature, not least of all because the changes which are happening were not called for and are not being driven by health actors. Whereas previous extensions of the EU’s role in health – insofar as this latest episode can be considered an example of that – were exploited and pushed forward by the Commission’s health directorate and various other health actors, the influence gained under the economic governance framework has come out of the blue. Furthermore, it can be argued that it does not consistently work to the advantage of health interests or outcomes; though the principle of health in all policies (HiAP) still applies, it is less rigorously enforced here than in the case of health-related policies which originate in the internal market. From a policy output perspective, a cross-section of interviewees describe the EU’s contemporary health activity as in decline; poor leadership, a lack of political will, a restrictive political climate and an increasingly conservative central executive are cited as the primary reasons for stagnation (*European Commission, Health Directorate A; C*). Models of Commission entrepreneurialism and opportunistic expansionism do not, therefore, readily apply and the future direction of this new avenue of health influence is not easily foreseen.

## The research question

The strengthening of the economic governance framework which has taken place in the post-crisis era marks a significant change in how health policy is governed at the European level. The instruments, process, actors and institutions now involved suggest a new direction for EU health policy and test the existing understandings of how health policy has developed. This thesis studies the evolution of EU health governance over time, mapping the changing institutional structures which have emerged and how they have affected the instruments used to pursue health policy. In particular, it focuses on the inclusion of health in the economic governance framework as representing a new and under-researched turning point. It should be noted here that ‘the crisis’ is referred to and used as a chronological marker, rather than a variable of the analysis. The thesis does not seek to examine the micro-level relationship between health policy and the sovereign debt crisis or the economic recession, but rather to explore how the nature of health governance has been affected by changes in the political climate of the EU project since 2008. It aims to put this latest ‘chapter’ into context and explore its implications for the future of EU health policy. As such, the thesis is concerned with three central research questions:

- How did the pre-crisis integration and Europeanisation of health policy unfold?
- What mode(s) of governance dominated in this period?
- How have these characteristics and dynamics changed in the post-crisis period?

These questions – all being concerned with the modes of governance employed by the EU when pursuing its goals in health – are used in the chapters which follow to inform the

methodology and to determine what kind of theoretical framework can best focus the research and provide insight.

## **The structure of the thesis**

The thesis is divided into three parts. Part I (chapters one, two, three, four and five) explains how the research will be conducted, its tools, scope and parameters, and its context within the wider history of health policy in the EU. Part II (chapters six to 11) contains a series of six case studies, each highlighting a different strand of or issue within health policy, as well as a number of ‘horizontal themes’ which explore cross-cutting trends and dynamics. It finishes with an account of the economic crisis, the strengthened economic governance framework which has emerged from it and the impact of this framework upon health policy. Part III (chapters 12 and 13) draws upon the findings of the case studies to discuss post-crisis expectations for EU health policy, bringing the various strands of the analysis together to offer conclusions on the central research questions.

Chapter two outlines how the thesis will explore the research challenge and answer the research questions discussed above. It identifies the central aims of the project – to ‘update the textbook’ on health, to map the modes of governance employed by the EU and to push beyond the traditional theoretical models by applying a governance typology to health – and explains the choice of historical comparative research approach. It introduces the three main tools used to complete the research – literature review, case studies and interview data – and examines what they involve, why they were selected and how they are operationalised. Finally, a brief discussion of limitations is undertaken, in which the constraints and weaknesses of the project are recognised and considerations for future research highlighted.

The third chapter situates the research within a conceptual and theoretical framework which emphasises the institutions and governance of EU health policy. A conceptual exposition explains and defines the core terms used – governance, health policy, integration, Europeanisation – and thus provides parameters for the scope of the study. A review of the mainstream theories of EU studies is then offered, covering integration theory, Europeanisation and the ‘governance turn’, before a more detailed exposition of the latter, as the most suitable framework for reference in the research, is presented. The chapter also introduces the ‘stems’ heuristic, which emerges from the prevailing literature and structures the rest of the thesis. Finally, it operationalises the theoretical framework, adopting a typology of EU governance for application in the case studies and establishing a series of hypotheses to structure the analysis.

Chapter four reviews the EU health policy literature and looks at how the mainstream theories presented in chapter three have been employed in the health policy debate. It is structured according to the stems categorisation and, drawing on the health, social and legal literature, examines the development of the public health, free movement and macroeconomic governance elements of EU health policy. A final section of the chapter summarises the use of the main theoretical frameworks and the dominant narrative of health policy evolution; this understands health to be driven by legal-neofunctional dynamics and governed as part of a multi-level polity, but commonly subject to crisis politics and assertion of subsidiarity.

The fifth chapter provides a brief history and context of EU health policy. It explains how public health came to be an EU policy competence, maps the legal basis of health as it has evolved through the founding treaties, and looks at the models of policy-making and

governance which have developed to exercise the health mandate. It then offers a short chronological overview of the evolution of health policy at European level. This spans the early activity in occupational health safety, through the creation of the public health mandate and the application of free movement law, to the post-crisis climate of contemporary health policy. Finally, the chapter brings together the narrative strands identified across the previous three chapters and presents a characterisation of EU health policy on a ‘bell-curve’ – the latter part of the thesis explores the descending slope of this curve and the possible trajectory of post-crisis health policy.

Chapter six is the first of the six case studies. It examines the development of EU policy on blood, tissue and organ (BTO) products and discusses the specific characteristics of regulatory policy and crisis politics. It explores the role of perceived EU added value and common technical barriers in the success of hard law and binding regulation in this area and notes the more recent introduction of soft law to address issues of ethical standards and cultural practice. The horizontal theme of this case study explores the EU’s regulatory policy-making style and the kind of technical health policy content that it generates, as well as the political leverage produced by crisis situations as a driver of health policy.

Chapter seven, exploring the use of soft law in cancer prevention policy, presents a contrast to the previous case study. It finds that the EU’s activity in cancer prevention is almost entirely based upon soft law and was founded long before the explicit public health mandate in the Maastricht Treaty was introduced. This has not resulted in weak compliance or low participation, however, and the chapter discusses the factors which determine national commitment to non-binding EU governance. The horizontal theme explores the potential strengths and weaknesses of soft law and its value in facilitating genuine health policy, as opposed to health policy constructed around internal market or fiscal goals.

The provision of medicines information to patients (ItP) and the influence of the internal market upon health is examined in chapter eight. Here the use of consultation, the role of interest groups and the balance between the health and market goals of EU legislation are considered as factors which determined the outcome of attempts to overturn the ban on direct-to-consumer advertising of pharmaceutical drugs (DTCA-PD) and set the direction of future developments in the field. The horizontal theme explores the tension between the social and market imperatives of the EU and how these have shaped health policy, particularly via the application of the HiAP principle.

Chapter nine explores the politically-charged history of tobacco control policy and the successful use of binding policy instruments in such a sensitive issue area. It finds a similar but more ‘intensive’ experience as the medicines ItP case; strong interest groups and an entrepreneurial European Commission have resulted in a degree of ‘opening up’ and use of more participatory policy-making modes, but hard law and coercive governance have remained the dominant structures. The horizontal theme draws on the implications for governance of more ‘politicised’ health policy, discussing the open method of coordination (OMC), the ‘new modes of governance’ (NMGs) and the use of comitology in health and what these tools mean for the development of the policy area.

Chapter 10, a case study on patient mobility and the role of the Court in health policy, examines the debate and resulting Directive on patients’ rights in cross-border healthcare. It describes the momentum which built behind the case law of the 1990s and how this facilitated

the design and adoption of binding EU law in this area. It explores the various elements of the Directive and role of the Commission as an ‘opportunistic entrepreneur’ in opening up new avenues for EU activity and involvement. Focusing on the role of the Court, a final section discusses the prevalence of judicial intervention in health policy.

A final case study chapter presents the various tools and instruments of the strengthened economic framework and their impact upon health policy. This chapter is slightly longer than the other case studies, taking account of the departure which this new stem takes from the established models. It reviews the causes, effects and legacy of the economic crisis in relation to the health, wealth and governance of EU member states. It then explores the kind of health policy being made under the EU’s newly strengthened powers, the scale of binding force behind it, the use of sanctions against non-compliance and the varying flexibility of implementation. It focuses particularly on the European Semester and the use of CSRs to guide national policy in the service of EU priorities.

Chapter 12 summarises the findings from the case studies and discusses the trends, patterns and common factors seen. It brings together the theoretical and the empirical elements of the thesis, analysing the latter from the perspectives explored in the former. After a review of the main dynamics and characteristics which arise from the case studies, the hypotheses outlined in chapter three are each examined individually. The changing modes of governance seen in health are thus explored within the context of the dynamics and drivers identified in the literature and case studies.

The final chapter of the thesis offers some preliminary answers to the three central research questions identified in the introduction. To do so, it draws on the analysis conducted in the preceding chapter, linking the politicisation of health and the increasing relevance of soft law to changes in modes of integration, Europeanisation and governance. It goes on to discuss the implications of the project for the EU health studies field and the future development of EU health policy and governance, highlighting potential avenues for future research.

## METHODOLOGY

This chapter explains how the research problem identified in the introduction is translated into a research project. It outlines the design of the project, the tools and methods used and the limitations faced.

### Aims, objectives and research design

The thesis aims to put the most recent developments in EU health policy into context and to examine their implications for future policy development in the field. Beyond this overarching aim, the research objectives can be defined as:

1. To push beyond the dominant theoretical approaches – understood as integration and Europeanisation theory – and focus on changes in health governance
2. To map the modes of governance employed in health at the European level
3. To ‘update the textbook’ on health policy in the EU.

The research takes a qualitative approach and is deductively designed. The observation of changing governance structures in EU health policy, prompted by the particularly significant change occurring under the new economic governance framework, led to a first search for possible explanations within the theoretical literature. Having identified an appropriate field of theoretical literature from which some explanatory propositions could be adopted, the research project was designed so as to allow for empirical testing and identification of causal factors. Pollack (2005: 36) observes that research into governance structures, of which this study is an example, ‘...tend[s] to eschew hypothesis-testing and generalization in favour of thick description and a normative critique’. Though adopting some illustrative hypotheses to structure the research, this project reflects this trend, taking a broadly descriptive approach. It proceeds by applying an adopted governance typology to a number of different health issues and tracing backwards to identify which characteristics determine the type of governance used. The patterns observed are then used to offer propositions about which forms of governance might prevail in the future and what might determine them.

The study takes an historical comparative approach, employing a descriptive and an analytical element. The descriptive element of the research reviews the history of health policy at European level, highlighting relevant changes and interesting features, and providing context for the analysis which follows. It facilitates a temporal dimension in which changes in governance can be considered in light of the ‘maturity’ of the policy area, increasing the potential for application of the results beyond the health sector. The analytical element of the research uses a comparative case study approach to identify patterns and examine the endogenous and exogenous factors which influence them. Applying the typology to a series of case studies allows for analysis and comparison of the role of legal competence, political will, ‘technical’ framing of the issue, perceived crisis or opportunity, political entrepreneurship, institutional barriers and other factors in determining the mode of governance employed. Particular attention is given to the post-crisis governance of health, since this represents a new era in health policy and analysis of how it works and what it means remains limited.

The case studies seek to discover what effect particular characteristics of a given health issue are likely to have on the mode of governance assigned by policy-makers. They do not, however, purport to uncover an ‘X results in Y’ causality. This would be almost impossible, given the complexity of combined factors which play a role in governance design – rather, the

research aims to identify the different factors which can influence the choice of policy instrument and nature of governance and looks at the strength, relevance and outcome of their effect.

The immediate goal within the thesis is internal validity of the research – i.e. ensuring case studies produce results which are comparable enough to facilitate a discussion of the future of health governance. This is achieved by highlighting the variable factors between the cases chosen – the ‘stem’ from which they originate, the role of various actors and institutions, the strength of their legal basis etc. However, the project prioritises a ‘most different system design’ approach, deliberately selecting issues within health which present different dynamics and characteristics to examine how these influence governance (Pennings et al., 2006: 10). As such, it also retains an element of external validity in that other EU policy areas, made up of similarly diverse issues and policy strands, might find the results applicable.

## **Research tools and methods**

Three main tools are used in the research. This section discusses the choice, purpose and design of the literature review, the case studies and the interview data.

### **Literature review methodology**

The main literature review, conducted in chapter four, examines the theoretical and policy debates in the EU health field. Smaller reviews – of the role of the Court, for instance – also inform specific portions of the research and touch upon a broader range of literature. Wherever possible, the literature is restricted to application in the EU setting, though work from other fields is referenced where directly relevant and instructive.

The thesis reviews primary, secondary and tertiary sources. These include primary, secondary and supplementary sources of EU law – founding treaty articles, directives, regulations, communications and other unilateral acts and agreements, and case law – as well as first-hand interview data, academic literature, EU policy literature, newspaper reports, online resources and other grey literature. Literature was restricted to English language sources, except where a specific item was identified in the research or by interviewees, in which instance a generic online translation tool was used. For each topic, broad search terms were used – ‘tobacco policy EU’, ‘austerity health EU’, ‘governance EU’ – and the first 10 pages of results in each catalogue explored. The catalogues used included the British Library catalogue, the Lancaster University catalogue and the Google Scholar search engine; after each search, the bibliographies of relevant sources were combed for additional resources. Interviewees were also asked to identify helpful sources of data.

The main literature review is organised around three ‘stems’ of EU health policy, relating to the legal and political basis of various policy issues. It distinguishes between health issues which are rooted in the explicit public health mandate contained in the treaties, those justified by the EU’s pursuit of a single European market and those emerging from its powers under the recently strengthened economic governance framework. These stems are replicated throughout the thesis, providing a structure for the historical narrative, context for each of the case studies and a framework for the analysis.

## Case study methodology

The historical narrative constructed by the literature review provides a context from which six case studies are drawn to highlight particular features of EU health governance. Figure 1 presents these case studies on a continuum, illustrating the different stems from which they originate and the chronological progression of EU health policy. The stems categorisation is explained in more detail in the next chapter but both it and the chronological framework implied are heuristic devices – they are not purported to be perfect. Cancer prevention policy, for example, was created before the existence of a public health mandate and the inclusion of health in macroeconomic governance began in the 1990s with the SGP, before the patient mobility debate. The stems heuristic and the chronological presentation are used simply as structuring devices, providing a central narrative in which to root the exposition and analysis.

**Figure 1: Continuum of case studies**



When selecting case studies, the need for a range of policies from different stems was the primary consideration, followed by the existence of unique or novel governance models. Beyond this, cases were chosen according to clarity of governance structure, prior knowledge of the policy area, the quality of available literature and the feasibility of access to informed interviewees. Considered but discarded case studies included alcohol, professional qualifications, eHealth and communicable diseases policy.

For each case study, a general literature review was conducted and a background description of the policy's development, within the context of broader health policy, drafted. This was followed by an in-depth exploration of the particular governance measures used, framed by the typology adopted in the theoretical chapter, and the identification of interviewees who might be able to provide further insight. The case studies vary in length according to the complexity of the governance structures involved, with the final case being granted extra space on account of its departure from the established narrative.

## Interview methodology

A review of the health policy literature and an in-depth exploration of selected case studies provides a comprehensive basis for analysis but cannot capture the full spectrum of perspectives. To address the gaps in the literature, clarify any unclear features of the

individual cases studies and inform a discussion of the future prospects for EU health policy, the thesis uses data collected in interviews with professionals and officials from the EU health, social, legal and political affairs fields. References to interview data in the text are denoted using the professional label of the individual concerned, in italic font.

Interview data was collected in two rounds, both during placements at the European Public Health Alliance (EPHA), a health advocacy organisation based in Brussels, Belgium. A first round, comprising 14 interviews, was conducted between October 2012 and June 2013. This early placement, falling in the first nine months of the project, was used to explore the dominant ‘outgoing’ theme of EU health policy, the role of the CJEU in health, and the emerging new theme, the inclusion of health in the economic governance framework. As such, interviews were arranged with officials from the various legal services of the European institutions and actors working with the new economic governance framework. A second placement, in which 27 interviews were conducted, was completed between May and July 2015. This round was more focused, targeting participants with experience in the various case study issues and established policy actors who could discuss and reflect upon the historical evolution and trajectory of health in the EU.

Interviewees were selected according to their particular area of work, with a preference for those who had been involved in relevant fields for longer periods of time, so as to facilitate a historical discussion where possible. Potential participants were first identified from experience gained and discussion with colleagues during a previous internship and an initial fieldwork placement at the EPHA. In each round of fieldwork an initial set of ‘scoping interviews’ were set up with contacts in the field, during which fruitful topics and contacts were discussed. A ‘snowballing’ technique was then employed to gather new contacts from each participant interviewed. Interviewees were given anonymity and are identified in the text only according to the sector or institution in which they are employed (Figure 2).

**Figure 2: Overview of interview participants**

<b>Institution or sector</b>	<b>No. of interviewees</b>
EU Health NGO	9
EU Social NGO	3
EU Environment NGO	2
European Commission Health Directorate	6
World Health Organization	2
Social Protection Committee	1
Member of the European Parliament	3
European Parliament Adviser	4
European Parliament Legal Service	1
Council of the EU Legal Service	1
European Commission Legal Service	1
UK health association, EU Liaison	2
Academic Expert (by speciality)	4
EU Public Affairs Consultant	2
<b>Total</b>	<b>41</b>

The interview data was collected during 39 separate interview sessions. Two interviews were 'joint', meaning two interviewees were in attendance together, and one individual was interviewed twice, on account of the continuing relevance of their work between the two interview rounds. In selecting interviewees an attempt was made to gain a balanced sample from across institutions and sectors. The final composition presented in Figure 2 was influenced in some cases by lack of availability on the part of targeted individuals but is largely deliberate. The higher proportion of non-governmental organisation (NGO) and academic participants was favoured because the research, in examining modes of governance and the historical development of particular health policy issues, does not seek or benefit from a heavy political analysis. Officials from the Council of the EU (CoEU, the Council), Parliament and, to some extent, Commission are more likely to present an ideologically biased perspective. The same reasoning favoured contact with advisors and lower-level officials within the EU institutions, so as to remove some of the political 'coating' that was inherent in interviews with Members of the European Parliament (MEPs), for example. Where MEPs and their advisors were interviewed, a spread of political groups was achieved, with participants from the European People's Party (EPP), the Socialist and Democrats (S&D), the Liberal and Democrats (ALDE) and the Green/European Free Alliance (Greens/EFA) groups.

In each case, a semi-structured approach was taken, with questions emailed ahead of interview where requested – in approximately one quarter of cases – and the topics of discussion kept open. This allowed for flexibility and deviation onto interesting tangents where the opportunity was presented, whilst maintaining cross-case study comparison. A process of triangulation was used to ensure the validity of the data collected. Findings from the literature review and exploration of the case studies were corroborated and elaborated in the interviews and later interviews were used to clarify and expand upon data collected from previous participants (though always anonymously). The latter process was also helpful in highlighting potential cases of bias in accounts received from different actors.

Most interviews were conducted in person in Brussels or London, with a handful conducted via telephone or Skype. The first round was conducted without recording equipment and notes were made by hand during the discussion, whilst second round interviewees all agreed to live recording of the discussion and notes were made afterwards. Full transcripts were not produced but all direct quotations were checked against the original recording. The complete set of interview notes were reviewed shortly after the second round of fieldwork finished, at which point a basic coding process was undertaken. This involved scanning the full data set for common themes and language and then tagging data according to the particular case study to which it applied and to any themes referenced. The notes were then referred to throughout the writing process using keyword searches of the data where necessary.

A full list of interviewees can be found in Annex I and a sample of the questions and logistical information sent to them is given in Annex II.

## **Research limitations**

Though the research was carefully designed a number of flaws remain. Some of these are preventable and might be considered when conducting similar research in the future; others are largely unavoidable but can be managed in different ways.

In the literature review, time and resource constraints impose limits upon what can be included – these relate to language, accessibility of materials, the breadth of the academic

field scanned and the exploration of multi-disciplinary contributions. The thesis is mostly restricted to English language sources which are readily available via the stated library catalogues or online databases. It also stays broadly within the EU studies field of research. These parameters were set in light of resource constraints, but adjusting the focus of the literature review might produce additional or alternative results.

The selection of case studies requires trade-offs and rejection of certain options in favour of others. Adherence to the stems structure, which played an early role in dictating the choice of cases, can be questioned on the basis of its simplistic division of health policy. The structure used is adopted for the purposes of simplicity and operationalisation, but very few policy issues fit neatly into one or the other stem and in most cases, different parts of the same policy belong to different stems. Criticism might also be levelled at the number of case studies used – fewer cases investigated in more depth, or more cases giving a broader sample of health policies, might increase the internal and external validity of the research.

The interview process was limited by language constraints, the availability of participants and the bias or perspective of their accounts. When interviewing actors in the political process the latter problem is magnified, since each is likely either to hold a strong personal viewpoint or feel that they should present the viewpoint of their institution or employer. Conducting anonymous interviews went some way to alleviating this issue but all interview data should be understood within the political context in which the participants operate. Further limits are imposed when the topic of interviews is chosen – since interviews were generally capped at 30 to 40 minutes, a decision had to be made in advance as to what questions and topics to prioritise. In some cases, the scope of an interviewee's relevant knowledge was very broad, or not fully known, meaning that potential data may have been missed. Finally, interviews which seek to gather historical data are automatically limited by bias or human-error in recollection. When examining the evolution of EU health policy from the Community's founding in 1957 through to the present day, interview data is exposed to flaws in memory and recording.

## CONCEPTUAL AND THEORETICAL FRAMEWORK

This chapter presents the main concepts employed in the thesis and the theoretical framework which is used to focus and structure the research. The conceptual exposition explains how the relationship between European integration, Europeanisation and governance is understood and what this means for the parameters of the project. It then defines EU health policy and the activities, instruments and competences which it entails. This is accompanied by a categorisation of health policy issues – into their various legal and political ‘stems’ – which is replicated throughout the thesis to structure the discussion and provide an additional dynamic of analysis. Finally, the distinction between technical and political health policy issues, drawn from the existing literature and interview data, and used in the case studies and analysis, is elaborated.

The second section of the chapter outlines the main theoretical approaches used in EU studies. It briefly reviews the mainstream neofunctional-intergovernmental dichotomy, the impact of the governance turn and the Europeanisation framework, and the more recent wave of constructivist approaches. This overview places the thesis within its academic context and illustrates the toolbox of theoretical approaches available to EU studies research. After explaining why the EU governance theories were selected as the most appropriate in this instance, the section goes on to examine this body of literature in more detail.

A final section links the conceptual and theoretical frameworks with the research problem identified in the introduction and explains how the former aids and structures exploration of the latter. It develops a series of hypotheses which can be tested against the individual case studies and comparatively analysed. As such, this section makes the central question of the thesis – how the governance of health policy has changed and might change further – operational.

### Conceptual exposition

#### Defining integration and Europeanisation

The thesis understands European integration, Europeanisation and the body of EU governance theories to be interested in different phenomena. Their definition and relationship to one another is explained here because numerous understandings have been adopted by various scholars and, consequently, there is a tendency within the EU studies literature for these key terms to be conflated or insufficiently differentiated.

Early literature defined integration as a process whereby political actors ‘...shift their loyalties, expectations and political activities toward a new centre’ and, as a result, forgo their ability to make policy independently (Haas, 1958: 145; Lindberg, 1963: 155). In more recent literature, integration is a process where member states pool sovereignty and establish supranational institutions, themselves being either strengthened or weakened as a result (Radaelli, 2000). The health literature reflects the consensus that integration reduces a state’s ‘capacity to act’ and notes ‘the European Union’s penetration into the national health policy arena’ as evidence of the process (Lamping, 2005: 19). Exploring the potential end-point of integration in the health sector, Steffen (2005: 3) concludes that this would consist of the creation of a true ‘European healthcare system’ where decisions on the financing, organisation and delivery of health services are taken at the EU level. Based on these definitions, the study

of European integration is concerned with why states chose to cooperate in particular areas and to create a European Union. The main schools of thought differ on the driver of such cooperation, usually identifying either supranational entrepreneurialism or the rational self-interest of national governments as responsible for the pace and direction of integration. Consequently, the change examined by integration theory – be it a treaty revision, the creation of a new policy or the veto of a European initiative – is broadly framed as either ‘state strengthening’ or ‘state hollowing out’ (Börzel, 1999). Progress in the European project is understood to be pushed forward by supranational forces and periodically limited by resurgent member state interests.

Four decades after the creation of the European Communities prompted the development of European integration theory the term ‘Europeanisation’ became ‘extremely fashionable in the social science literature on Europe’ (Olsen, 2003: 334). Many variations and dimensions have been extrapolated and their focus and characteristics are examined in the next section, but they have in common their concern with the interaction between the EU and its member states. As such, they are concerned with the impact of integration upon member states. Degrees of Europeanisation are observed in the literature on the EU’s response to the HIV/AIDS (Human immunodeficiency virus, acquired immunodeficiency syndrome) epidemic, pharmaceutical regulation and drug policy (Bergeron, 2005; Permanand and Mossialos, 2005; Steffen, 2012). Within the thesis, Europeanisation is understood as a process in which change in the content of domestic policy and the structures used to govern it is derived from and influenced by European-level developments. Europeanisation theory examines how EU outputs affect domestic systems and how member states work to shape EU policies. As such, Europeanisation is understood as ‘post-ontological’ – it can only occur if the process of integration has already taken place and an EU policy has been constructed (Caporaso, 1996). Once integration has occurred, member states work to affect policy direction and adapt in response to supranational legislation.

A first important point to note about these concepts is that they are used in the extant sense. Health policy, and indeed the European project as a whole, is not considered to be integrated or Europeanised; these processes are understood to be ongoing, perhaps without any end-point at all. Secondly, though concerned with different things, these two concepts are not understood to operate on different ‘levels’. Political theorising is often categorised as being macro-, meso- or micro-focused, referring to whether it studies global interactions between nations, the operation of mid-level state or community units, or local level behaviour amongst individuals. Both integration and Europeanisation are understood here as macro-level theories – the former examines interactions between states and the latter interactions between a supranational state and its constituent members, which are also states<sup>1</sup>.

### **Understanding and observing governance**

A third body of theory, that studying EU governance, is more heavily drawn upon in the thesis. By contrast to integration and Europeanisation, governance theory operates at the meso-level, being concerned with how the EU pursues its objectives. This type of inquiry does not study the EU as a phenomenon in itself, but rather uses it as a case study to test

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<sup>1</sup> It is also possible and valid to assert Europeanisation as a meso-level theory, concerned with intra-state dynamics. However, it is understood as a macro-level theory here to help differentiate it from meso-level governance theory.

existing theories and models of how states govern. For example, EU governance theory might help to identify the range of actors involved in negotiation of the Tobacco Products Directive (TPD, Directive 2001/37/EC) or the impact of the voting procedures in the CoEU on the adoption of the Working Time Directive (WTD, Directive 2003/88/EC). Thus, governance theory treats the EU as a new and emerging polity (Pollack, 2005: 36). Though different definitions are used by different authors, all generally emphasise that governance is broader than government and involves continual exchange of information between networks of non-state actors, conducted through ‘game-like’ interaction and maintaining a significant amount of autonomy from the state (Rhodes, 1996).

The understanding of governance adopted in the thesis can be defined by narrowing first the dimension and second the breadth of the term. Firstly, governance can be framed in the polity, politics or policy dimension (Treib et al., 2005). The polity dimension understands governance as the system of rules which shape the action of social actors, being concerned with institutions, laws and processes, whilst in the politics dimension, governance is about how citizens’ interests are translated into policy via the relationship between public and private actors. The policy dimension, with which the thesis is concerned, understands governance as a mode of political steering, where policies are distinguished according to their steering instruments and where these instruments define how particular policy goals should be achieved.

Within the policy dimension, the understanding of governance can be further refined by the adoption of a broad, rather than a restricted, approach to political steering. Héritier (2002) describes the restricted understanding of governance as one which comprises only non-hierarchical modes of governance, in which both public and private actors engage in persuasion and negotiation – these are the instruments and modes commonly labelled in the literature as the NMGs. By contrast, the broad definition of governance utilised in the thesis encompasses both the ‘new’, non-hierarchical and the traditional, public actor-led modes of government.

Based on this understanding of governance, the thesis is concerned with how the modes of governance in EU health policy have changed over time. This might involve a shift in the balance between legally binding and soft law governance, rigid and flexible approaches to implementation, the use of sanctions, the role of norms or the creation of material, as opposed to procedural, regulation (Treib et al., 2005: 7-8). A typology to classify modes of governance is adopted and explained in the next section but in order to observe or measure which mode is in use a more concrete object of analysis is needed. The thesis mirrors Bähr (2010: 11) in surmising that if governance is understood as political steering, policy instruments are the ‘manifestation of ways of political steering’. Whilst the term governance remains somewhat ‘woolly’, policy instruments are concrete and precise enough objects of analysis to observe modes of governance in different policy areas. Therefore, in order to study the changing governance in EU health policy, the thesis examines the policy instruments used in six specific policy areas and categorises the mode of governance used in each case. A classification of policy instruments is given in the next section.

### **Defining and categorising health policy**

Drawing on the health article in the treaties, European health policy can be defined as all EU activity and legislation which seeks to improve public health, prevent physical and mental

illness and obviate sources of danger to physical and mental health (Art 168(1) TFEU). The Health Programme, the only instrument with which the EU can direct financial resources in pursuit of its health goals, states that these include promoting health, preventing disease, fostering healthy lifestyles, protecting from cross-border health threats, contributing to well-functioning health systems and facilitating access to healthcare (Regulation 282/2014). A vast body of policy and legislation exists within these parameters but for the purposes of the thesis, the scope of EU health policy is limited to those aspects which most affect health systems in Europe, leaving aside the EU's work in global health and those policies that affect health indirectly, such as transport or environmental protection. From this starting point, EU health policy can be divided into two categories: provisions with a direct health objective, rooted in health-related powers conferred by the treaties, and provisions in the treaties which pursue other objectives but have a major impact upon health (Greer et al., 2014: xi). This classification is used by the majority of the literature – commonly referring to the ‘faces’ of health policy (Greer, 2014) – and is adopted in the thesis to structure the discussion and analysis. However, in the post-crisis period, a third ‘face’ has emerged. This new category contains treaty provisions on fiscal governance and budgetary oversight which, whilst not entirely new, are having an increasingly significant impact upon Europe's health systems.

This three-strand classification of health policy is replicated throughout the thesis but the term ‘stems’ is preferred to better reflect the sense of origin. The categories are commonly differentiated by legal base – the public health legal base being used for policy with a direct health objective and the internal market legal base being more useful to achieve health goals in non-health areas – and the various strands of health policy are seen to be rooted in these bases. Though individual elements of health policy can draw on and be shaped by multiple stems during their development, most are rooted in one more than the others.

### **The three stems of EU health policy**

The first stem of EU health policy – the public health stem – concerns those actions which have a direct and explicit health objective. They are generally based either on the health article or on the health-related powers included under the treaty provisions on the environment, health and safety at work and consumer protection. The EU's powers in this first stem are relatively weak but it is the only area where activity is supported by financial resources under the Health Programme. Though it is not exclusively the case, most of these actions target public health; they cover the major determinants of health, such as tobacco, alcohol, diet and nutrition, environmental and social determinants, as well as various disease specific strategies on cancer, communicable diseases, rare diseases and chronic conditions. First stem activity also includes legislation on substances of human origin, the development of data and indicators and some small areas of health systems policy, such as health technology assessment (HTA), quality of care and patient safety. As such, it broadly corresponds to EU action in building blocks three and six of the WHO classification discussed in the introduction.

The second stem of EU health policy – the free movement stem – is comprised of those EU actions which do not have health as a primary objective but which nonetheless have a significant impact on health. Actions in this stem generally seek to facilitate the free movement of goods, services, people and capital and contribute to the creation and functioning of the internal market. The EU's powers are much stronger here but from a health perspective utilisation of this power can be difficult:

‘In practical terms...whilst 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)’ (Greer et al., 2014: 23).

Second stem health policy encompasses action on pharmaceuticals, medical devices, food safety, cross-border healthcare, professional mobility and qualifications, structural and cohesion funds, state aid and competition. Beyond the internal market, it also includes health-related activity under the EU’s research programme and via European social policy, where it targets education, social protection, equal opportunities and employment. It is important to note that this kind of health policy can be both proactive and reactive – the EU’s health agenda has been shaped as much by the application of the free movement principles to the health sector as by the strategic use of the internal market legal base in the pursuit of health goals. This activity corresponds to building blocks two, four and, more recently, one in the WHO classification.

The third and final stem of EU health policy – the macroeconomic governance stem – is born out of the post-crisis strengthening of the EU’s fiscal governance system. Prior to this strengthening, fiscal governance was included in the second category of health policy, affecting health less but doing so in pursuit of economic objectives. Since European leaders voted to increase the EU’s powers in this area, its impact upon health has also magnified and it has been assigned a category of its own in the health literature. Historically it was based upon dialogue about national expenditure, including health expenditure, as part of the SGP and the euro zone convergence criteria. Since the crisis, the health-related action in this stem has expanded to include detailed overviews of national health systems cost-effectiveness and sustainability, sanctions and contingency upon health expenditure, and unprecedented EU oversight of national budgets. Each of the instruments and processes involved has a significant impact upon health systems, creeping into building blocks one and five of the WHO classification.

These three stems are used throughout the thesis to structure the discussion and as a point of analysis when comparing modes of governance. The categorisation is a heuristic device and does not expect to accommodate every strand of health policy comfortably or without overlap. Tobacco policy, for example, has both public health and internal market elements and, if pursued in future macroeconomic policy as a revenue-raising taxable good, might also have claim to inclusion in the third stem. The stems are used to allow a mapping of EU health policy in which the ad hoc development of competences and policy can be clearly demonstrated, and to provide an additional characteristic upon which analysis can be based.

### **Technical versus political health policy**

A final conceptual tool used in the thesis is a distinction between health policy issues which are more technical and those which are more political in nature. Though it is difficult to maintain below surface level – upon closer examination, technical issues commonly become political, political issues have their technical elements annexed and addressed separately, and many issues are labelled differently by different actors – it has proven an enduring, if subconscious, distinction in both the literature and the characterisations described by interviewees. In order to explore the idea that the framing of an issue as technical or political

can affect the mode of governance employed, the parameters of the distinction are outlined below.

Hooghe and Marks (2001) identify two ‘styles’ of decision-making. ‘Politicised’ decision-making, they state, involves contested policy goals, the continual need for political choice and negotiation across interconnected political arenas, whilst ‘technocratic’ decision-making is based on shared policy goals, objectives which can be achieved via problem-solving rather than political choice and issues which are dealt with in compartmentalised policy areas (2001: 121). This distinction builds upon Peterson’s (1995: 74) observation of the sub-systemic level of EU decision-making, in which technical and specialised knowledge dominates the policy process, the administrative capacity to implement decisions is carefully crafted and consensus between predominantly non-political actors is sought ahead of presentation to decision-makers. Radaelli (1999: 4) considers this kind of technocracy to hold the potential for ‘enlightened public policy’ and contrasts it to the ‘logic of politicisation’, where politics play a greater role in decision-making than evidence or expertise.

Technical policy areas are most closely linked to regulatory policy, understood as a primarily technical exercise, devised by epistemic communities of experts and, in the commonly accepted preferable model, conducted by independent bodies and decentralised agencies (Christiansen, 2006: 108; Thatcher, 2006: 314). Wallace (2005: 81) describes regulatory policy as able to ‘escape some of the constraints of politics’ on account of its technical, consensual and rational nature. By contrast, ‘political’ policy issues are those which are particularly sensitive, attract a lot of attention from interest groups, national governments and other stakeholders, and involve disputed policy goals or principles. Expenditure policies, interior policies and foreign policies are all characterised by these kinds of issues and as a result, the EU finds itself both financially and politically limited in these areas (Hix and Høyland, 2011: 3; Majone, 1996: 63).

The core idea within this distinction is that a different kind of policy process tends to apply to health policy issues with high EU-added value, low political or cultural sensitivity and mostly functional content, than to those which are highly sensitive, contested and have a significant impact upon individual interests. The thesis hypothesises that health policy issues are amenable to different modes of governance depending upon the degree of technocracy or politicisation they involve. This is particularly interesting in light of the macroeconomic policies emerging in the third stem, which address political issues within technical instruments and thus further blur the distinction between these concepts. Though the distinction is far from watertight, the technical and political elements of particular policy issues are picked up throughout the thesis and discussed in the analysis.

## **Theoretical framework**

The definitions and understandings outlined above are drawn from the bodies of theoretical literature which accompany the EU studies field. This section reviews these frameworks for understanding the EU and identifies the body of theory most appropriate for exploring the governance of EU health policy. It first presents the mainstream theories of European integration before examining the EU governance literature in more detail and outlining the typology of EU governance which is to be applied to the case studies.

## The theories of European integration

This section reviews the broad range of literature known as the theories of European integration. This label is itself misleading – the literature which falls into this category covers theoretical contributions from the schools of international relations (IR), comparative politics, legal theory, domestic governance, public policy and many more, as well as regional integration. Though only the latter are ‘true’ integration theories – in that they address the process of integration of states – the EU studies field has come to understand all of these sub-disciplines to fall under one broad umbrella. This section reviews the lifespan of EU theorising, from the formation of the central dichotomy, through the comparative, governance and constructivist turns, to the current trends in theorising the unique EU polity.

### Explaining integration

The first era of EU theory, which sought to explain states’ decision to integrate, built upon the dominant IR approaches and treated the early European institutions as traditional international organisations – the frameworks applied to the North Atlantic Treaty Alliance and the Western European Union were replicated and used to explain the creation of the European Coal and Steel Community (ECSC) and its High Authority. The resulting ‘grand theories of integration’ – neofunctionalism and intergovernmentalism – form the central dichotomy of integration theory.

Neofunctional theory holds that functional integration in one area, such as coal production, will overflow into other areas and prompt the creation of supranational institutions, attracting political attention and resulting in the formation of European-level interest groups (Haas, 1958; Lindberg, 1963). As this ‘spillover’ takes place across various sectors, so a centralised EU-level polity will emerge, necessitating further cooperation and making war between member states infeasible. Subsequent variants of neofunctionalism have identified three forms of spillover: functional, where cooperation in one sector requires and results in cooperation in another; political, where national level actors shift their expectations to the European level; and cultivated, where supranational institutions facilitate and manipulate cooperation as a means to furthering their own agendas (Jensen, 2010; Tranholm-Mikkelsen, 1991).

Intergovernmentalism, responding to institutional changes and assertions of national autonomy which challenged the neofunctional model in the early 1960s, represents a revival of IR scholarship (Pollack, 2010). Based on state centrality, zero-sum bargaining and rational self-interest, it posits that integration is not a process, but rather occurs sporadically when the interests of states are directly served by collective action (Cini, 2010; Hoffman, 1964). Cooperation is thus more likely in areas of ‘low’ than ‘high’ politics, and reflects patterns of commercial advantage and bargaining power (Hoffman, 1982; Moravcsik, 1998). Building on Putnam’s two-level game model (1988), liberal intergovernmentalism asserts that states form preferences at the national level, before seeking to maximise them in the European arena; when the credibility or efficiency of interactions can be increased, sovereignty may be delegated (Moravcsik, 1991; 1993; Schimmelfennig, 2004).

The central dichotomy provided by these two schools continues to underpin modern EU studies. The tenets of neofunctionalism have been absorbed into supranational governance frameworks (Niemann, 2006; Sandholtz and Zysman, 1989; Stone Sweet and Brunell, 2004; Stone Sweet and Sandholtz, 1998) and studies of the CJEU (Burley and Mattli, 1993), whilst

intergovernmentalism remains a leading model for assessing the balance of realist factors in EU integration (Moravcsik, 2013; Pollack, 2010).

### **Analysing governance**

With the Single European Act (SEA) and the revival of the ‘grand theories’ in the 1980s, a second era of theorising introduced governance and comparative approaches to EU studies. This move to ‘middle range’ theorising treated the EU not as an international organisation but as a political system, allowing for application of models from the pre-existing toolbox of political science (Bache and George, 2006; Rosamond, 2000). A common feature is its embracing of the ‘deliberative turn’ – moving from the logic of consequences, found in rationalist models, and of appropriateness, found in constructivism, the deliberative turn embodies a ‘logic of arguing’, emphasising the roles of persuasion and dialogue in shaping behaviour and decision-making (Pollack, 2010; Risse, 2000).

Following Hix’s ‘call to arms’ to comparativists, studies of the executive, legislature and judiciary multiplied (Hix 1994; 1999; Pollack, 2010). Federalist research examined the fiscal and regulatory imbalance, whilst the functional allocation of decision-making power was analysed alongside rational-choice and principal-agent models of Commission and Court behaviour. Institutional analyses also proliferated during this period, refuting actor-centred models and instead asserting that ‘institutions matter’ (Hall and Taylor, 1996; Lowndes, 2010). Rational-choice institutionalism (RCI) understands that institutions can produce ‘structure-induced equilibrium’ which frames outcomes and is often combined with principle-agent analysis (Pollack, 2003; Scharpf, 1988; Shepsle, 1979; 1986; Tseblis and Garrett, 1996). Historical institutionalism is concerned with the effect of institutions on actors over time, since sequencing is crucial in determining outcomes, particularly at critical junctures, and early decisions are perpetuated in a cycle of path dependence (Hall, 1986; Pierson, 1996; 2000; Thelen and Steinmo, 1992). Finally sociological institutionalism takes a constructivist approach, asserting that actors behave in accordance with acceptable norms and practices, understanding that the EU shapes behaviour by diffusing such norms (Checkel, 2001; March and Olsen, 1989; 2004; Risse-Kappen, 1996). Multi-level governance (MLG) and networks theory, a central strand of ‘governance turn’ literature, is examined in more detail in the next section but emerged alongside these schools of thought as a meso-level approach to EU studies.

### **Constructing the EU**

Just as the EU’s status as a ‘supplier of authoritative policy outputs’ prompted the application of the political science toolkit in the governance turn, so too its ambiguous non-state characteristics soon led to a reconsideration of what the EU is (Rosamond, 2000). This third era of theorising challenges the assumptions of the ‘old debate’ and brings together a range of critical perspectives on the fundamental nature of the EU’s existence (Bache and George, 2006; Pollack, 2010).

Social constructivism broadly understands that, in addition to formal rules and institutions, actors are constituted of informal norms and their preferences are shaped by, and in turn shape, their social environment (Pollack, 2010). Behaviour is guided by a logic of appropriateness, meaning that EU norms and practices have constitutive effect (Hay and Rosamond, 2002; March and Olsen, 1989; 2004; Risse, 2004). Another critical approach, labelled ‘critical political economy’, examines the link between globalisation and the European project, the model of capitalism likely to emerge in the EU and the role of social

and economic class in integration (Bache and George, 2006; Holland, 1980; Rhodes and van Apeldoorn, 1997). Drawing on ‘new regionalism’ and the EU’s role as a global actor, it critiques the EU’s governance capacity and democratic legitimacy (Pollack, 2010; Rosamond, 2000). Finally, an interdisciplinary body of constructivist approaches is found in the ‘integration through law’ literature (Haltern, 2004). The wide range of contributions to this field examine the EU’s constitutionalism, the judicialisation of policy-making, the integration of Europe’s legal systems and role of the law in the process of integration (de Búrca, 2001; Rasmussen, 1986; Shaw, 1996).

### **Theorising consequences**

A final era of theorising is understood as one which moves beyond the creation, development and functioning of the EU to theorise its outcomes and consequences (Bache and George, 2006). The first major strand of this work is Europeanisation – studying the impact of the EU on member states and vice versa. This literature is reviewed in the following section. A second stream of ‘post-integration’ theorising is concerned with the democratic structure of the EU, in light of its transformation from an elite-governed economic union to a political union governed across multiple levels. On one side of this debate, the need for EU policies to derive from citizens and be made by a popular authority is made difficult by the absence of a coherent ‘demos’ or identity (Scharpf, 1997; van der Eijk and Franklin, 1996). On the other, appeals to a ‘utopian’ standard of deliberative democracy are considered unnecessary, since the EU does not perform the functions of a state and such standards serve only to obscure the practices of the political system (Moravcsik, 2002). This generation of studies accepts the EU as an established entity and seeks to theorise the consequences of its existence for democratic governance and member states.

### **The Europeanisation framework**

Whilst the term Europeanisation is also used to describe the export of the EU’s political model to third countries, changes in its external territorial boundaries and the creation of new EU powers, it is most commonly used to explain the relationship between the EU and its member states (Bache and Jordan, 2004; Buller and Gamble, 2002; Olsen, 2002). As noted in the conceptual exposition, Europeanisation is understood here as a post-ontological concept, in that it presupposes the integration of states and the creation of supranational institutions. Such developments at the EU level form the independent variable; changes in domestic systems are the dependent variable, responding to pressures from above (Olsen, 2003; Radaelli, 2000).

In the early literature on Europeanisation, this top-down model was the most commonly adopted, resulting in an emphasis on ‘downloading’ (Falkner, 2000; Schimmelfennig and Sedelmeier, 2005). Research focused on the effect of EU membership upon domestic political systems in France (Ladrech, 1994), Britain (Bulmer and Burch, 1998; 2005), Scotland (Smith, 2001), Greece (Featherstone, 1998), Germany and Spain (Börzel, 1999) and looked at how member states downloaded EU practices and absorbed them into their national systems (See also Héritier et al., 2001). Subsequently, scholars developed analytic tools to explain observed variations in member state responses to European integration. The ‘goodness of fit’ hypothesis posits that pressure to adapt to European norms and practices will be refracted through institutions – where the difference between existing national systems and imposed European ones is not so large or so small as to cause inertia, change in the domestic structure will occur and the relevant European process or model will be downloaded (Börzel, 1999; Börzel and Risse, 2007; Cowles et al., 2001; Olsen, 2002).

Focus on the downloading of EU inputs was shortly followed by a body of theorising which examined the complementary dynamic of ‘uploading’. This highlights member states’ capacity not only to receive input from the EU, but to upload their interests to the EU level (Börzel, 2002; Bulmer and Burch, 2001). Uploading allows member states to minimise the changes which have to be made at the national level by ensuring that the prescribed European model is as close to their existing system as possible. Most observers now acknowledge that Europeanisation is comprised of both downloading and uploading processes.

As well as distinguishing between downloading and uploading, Europeanisation frameworks identify two types of mechanism through which Europeanisation might occur: vertical and horizontal. Vertical mechanisms operate through positive integration to ‘demarcate clearly the EU level (where policy is defined) and the domestic level, where policy has to be metabolized’ (Radaelli, 2003a). Here, a pressure of adaptation is applied, since member states must change domestic structures in response to the prescribed European model – this is the mechanism used in areas such as health and safety and consumer protection policy (Knill and Lehmkuhl, 2002). Horizontal mechanisms do not involve an EU policy model – instead negative integration utilises mutual recognition and socialisation to trigger adjustment (Radaelli, 2003a). The key mechanism here is change in the domestic opportunity structure, rather than compatibility between EU and national models (Knill and Lehmkuhl, 2002). More recently, Börzel and Risse (2012) have combined this distinction with the literature on diffusion, to identify both direct and soft processes by which common norms and practices are dispersed between and across states. Direct processes, reflecting the vertical mechanism of Europeanisation, involve legal coercion, regulations and harmonisation, whilst soft diffusion, like horizontal Europeanisation, utilises capacity-building and socialisation to promote common adherence to successful policy models. This paradigm has been used widely to assess the importance and effectiveness of the OMC, understood as a crucial soft, horizontal mechanism in the Europeanisation of public policy (Radaelli, 2003b).

The theories of European integration and the Europeanisation framework represent the dominant approaches and the mainstream ‘toolkit’ available to EU studies research. The thesis makes use of both in analysing the changing pattern of health governance but focuses upon the theories of EU governance, commonly considered part of integration theory but concerned with the EU as a polity, as the most appropriate and insightful framework in this instance.

### **Theorising EU governance**

The term governance emerged to reflect the shift towards neo-liberal policies in Europe and the United States (US) in the 1970s and ‘80s. During this time, public sectors shrank and the model of cooperation between state and private actors in the provision of services was replaced by a new dynamic, where governments sought to offload responsibility for policy implementation to networks of private actors which could instead be managed by the state (Pollack, 2005: 37). This prompted an understanding of governance as ‘more than government’ and a will to push beyond the ‘high politics’ relationship between the EU and its member states – the focus of integration and Europeanisation theory – to study day-to-day, ‘mid-range’ processes (Richardson, 1996).

**Figure 3: Levels of analysis, adapted from Peterson (1995)**

Level	Decisive variable	Best model
<b>Super-systemic</b>	Change in wider political or economic environment	‘macro theories’ intergovernmentalism and neofunctionalism
<b>Systemic</b>	Institutional change	New institutionalism
<b>Meso</b>	Resource dependencies	Policy network analysis

Peterson’s classification (Figure 3) is illustrative of the realisation that EU studies could choose from more than one level of analysis. Theories of EU governance can thus be understood as ‘dropping down a level’ from the approaches taken by integration and Europeanisation theory. The research within this field is divided into five main strands – these are briefly reviewed here and elements of each are drawn upon in the construction of the hypotheses and the analysis of the case studies.

### **Multi-level governance**

MLG theory has its roots in Marks’ study of the EU’s Structural Funds, where he identifies two dimensions in the making and implementing of EU policy (Marks, 1992; 1993; Marks et al., 1996; Pollack, 2005: 38). In the vertical dimension, supra- and sub-national actors become more empowered, prompting territorial reform of the power balance. In the horizontal dimension, transnational and transgovernmental actors gain importance and, operating as part of policy communities and expert networks, create informal rules and processes which shape policy-making and implementation. Rosamond (2000: 110) characterises MLG as an approach which seeks to combine ‘a reading of the EU in policy process terms with an acknowledgement of its peculiarities’, moving away from ‘zero-sum’ discourse to depict the complexity of sovereignty transfer.

### **Policy networks and epistemic communities**

For Rosamond, the value of MLG is not as a predictive theory but as a framework for the use of policy network analysis (2000: 111). Policy network analysis starts from the assumption that, in modern governance and particularly in modern European governance, linkages between organisations and actors is more important than the organisations or actors themselves (Peterson, 2004: 117). Policy networks are understood as ‘cluster[s] of actors, each of which has an interest, or ‘stake’ in a given...policy sector and the capacity to determine policy success or failure’ (Peterson and Bomberg, 1999: 8). A related body of literature, focused on epistemic communities, uses a similar network model but concerns a particular sub-group of actors. An epistemic community is a group of experts who share common beliefs and understandings within their field of expertise and supply knowledge to states on technical issues, thus giving them an agenda-setting role (Haas, 1992). For Richardson (2006: 25) the proliferation of these networks has increased the importance of both the ‘politics of expertise’ and the ‘politics of ideas’.

### **Globalisation and legitimacy**

A third major strand of governance theory examines how ‘negative integration’, reflecting broader globalisation dynamics, undermines the governance capacity of member states without providing a legitimate alternative structure at the supranational level (Pollack, 2005: 41). The internal market and the EU ‘regulatory state’, with support from the CJEU, erode

national social regulations, threatening a ‘race to the bottom’ in standards and undermining the social aims of governments (Streeck, 1996). Meanwhile, the EU’s inherent constitutional asymmetry and the absence of a ‘European demos’ throws the legitimacy of compensatory European action into doubt, prompting debate about the ‘input’ and ‘output’ legitimacy of the EU’s institutional structure (Scharpf, 1999). Richardson (2006: 8) finds this crisis of legitimacy to have further fuelled the role of private actors in EU policy-making, since the Commission has responded by introducing more participatory mechanisms.

### **Deliberative democracy**

A fourth strand of governance research has sought to find a solution to the problems highlighted above by framing the EU as a deliberative democracy. Drawing on work by Habermas (1985; 1998) and popularised by Risse (2000) this research embraces the constructivist and, latterly, the deliberative turns in EU studies to suggest that actors do not only bargain and follow institutional rules but also argue, opening their beliefs and positions to persuasion (Pollack, 2005: 42). The deliberative model has found support in the development of mechanisms such as the OMC, which fosters extensive dialogue between stakeholders both to improve problem-solving capabilities and to provide a greater degree of democratic legitimation (Scott and Trubek, 2002: 6). Similar deliberative properties are identified in the comitology procedure, though these discussions are more technical and, occurring behind closed doors, offer less in the way of legitimacy (Joerges and Neyer, 1997).

### **New institutionalism**

New institutionalism, a final branch of governance theory, brings together the concepts and premises above to study the functioning of institutions, based on the premise that these ‘act as intervening variables between actor preferences and policy outputs’ (Rosamond, 2000: 114). Given that the EU is ‘without question the most densely institutionalized international organisation in the world’ it provides a promising testing ground for models which seek to explain how institutions shape preferences and outcomes (Pollack, 2004: 137). The three variants identified above – rational choice, historical and sociological institutionalism – emphasise different aspects of this relationship but are in broad agreement that institutions can be both formal and informal, encompassing both traditional, legalistic rules and the conventions, norms and ‘standard operating procedures’ which structure interaction (Rosamond, 2000: 115; Hall, 1986). As such, policy outcomes are affected as much by non-binding, social factors as by legislative action, and the role of the Commission is determined as much by its various internal working methods as by the rules of procedure laid out in the founding treaties.

## **Making the theoretical framework operational**

The thesis studies the evolution of EU health governance over time, mapping the changing institutional structures which have emerged and how they have affected the instruments used to pursue health policy. Drawing on the prevailing narrative whilst taking account of the newest stem of health policy, it tests the notion that factors such as the technical or political nature of a health issue, the presence of strong interest groups or the onset of a crisis, among others, determine the type of governance which is used to pursue the EU’s goals in a given area. This section uses the conceptual and theoretical framework to identify the premises, tools and heuristic devices upon which the thesis is based. First, it employs a classification by Schimmelfennig and Rittberger (2006) to illustrate the extent of integration in health, as the starting point for the exploration of governance which follows. It

then presents Treib et al.'s (2005) typology of modes of governance and a series of hypotheses – these draw upon the ideas contained in the theories of EU governance and make their explanations ‘testable’ against the health policy experience.

### The state of health policy integration

In accordance with the definition given above, the thesis understands integration as a process rather than an outcome and posits that, whilst integration has clearly reached the health sector, it has not progressed uniformly within it. To illustrate how far health can be considered to be ‘integrated’, three dimensions of integration can be identified: sectoral, vertical and horizontal (Schimmelfennig and Rittberger, 2006: 74; Figure 4). Sectoral integration is a process through which new policy areas or sectors become increasingly regulated at the EU level; exploring it involves asking why and under what conditions new policy sectors become subject to EU regulation. Once sectoral integration has ‘extracted’ a policy area from exclusive national competence, vertical integration refers to the distribution of competences between EU institutions and member states and asks why cooperation at the EU level is stronger in some policy areas than others. Finally, horizontal integration is a process of territorial expansion of the previous dimensions to new member states. This occurs both as part of enlargement and in the creation of different ‘circles’ within the EU structure, such as the euro zone, the European Free Trade Area and the Schengen area.

**Figure 4: Degrees of integration, adapted from Schimmelfennig and Rittberger (2006)**

	<b>Sectoral</b>	<b>Vertical</b>	<b>Horizontal</b>
<b>What is being integrated?</b>	Policy areas or sectors	Decision-making competencies	Territory, borders and boundaries
<b>What is integration?</b>	‘Broadening’: EU regulation of new policy areas and sectors	‘Deepening’: Transfer of domestic competencies	‘Widening’: Extension of geographical territory governed by the EU acquis

In their assessment of vertical integration across the major policy areas, Schimmelfennig and Rittberger (2006: 75) give each sector a numerical grading according to the degree of integration achieved over time; ‘public healthcare’ receives a score of one (all policy decisions taken at national level) for the period 1950 to 1993 and a score of two (some decisions taken at EU level) from 1993 to 2004, where the measurement ends. By comparison, all sectors involving the free movement principles score four (most decisions at EU level) from 1993 onwards.

The thesis takes this classification and assessment as a starting point but offers a refined definition of ‘sectoral’ integration in order to narrow the level of analysis. It works from the premise that, as Schimmelfennig and Rittberger assert, sectoral integration has reached the health sector but notes that it has not progressed at the same rate across all health issues; alcohol policy has not reached the same degree of integration as pharmaceutical policy, for example. As such, the thesis distinguishes between ‘macro-sectoral’ integration, where health has joined energy, environment, trade and a host of other policy areas in becoming subject to EU regulation, and ‘micro-sectoral’ integration, where different issues within health policy

have become integrated to different degrees. Once micro-sectoral integration becomes the focus, vertical integration research can examine the dispersal of competences in different health issues.

### A typology of modes of governance

As noted in the conceptual exposition, the thesis seeks to observe changes in modes of governance, using policy instruments as the main object of analysis. Policy instruments are understood as tools available to policy-makers in the pursuit of policy objectives (Bähr, 2010). The European Commission divides the policy instruments available to it and the other European institutions into four groups: ‘hard’, legally binding rules (regulations, directives and decisions), ‘soft’ regulatory instruments (recommendations, technical standards, self-regulation and the OMC), education and information tools (training, guidelines and campaigns) and economic- or market-based instruments (taxes, subsidies and tradable permits) (European Commission, 2015a).

The modes of governance that these instruments collectively form are also grouped into four categories, by Treib et al. (2005), according to their legal basis and the rigidity of implementation (Figure 5). Modes of governance can be categorised as coercion, voluntarism, targeting or framework regulation.

**Figure 5: Modes of governance, adapted from Treib et al. (2005)**

		Legal instrument	
		Binding	Non-binding
Implementation	Rigid	<b>Coercion</b>	<b>Targeting</b>
	Flexible	<b>Framework regulation</b>	<b>Voluntarism</b>

Coercion is the least flexible and most intrusive form of governance, using binding legal instruments which contain detailed and highly prescriptive standards and leave little room for flexibility or member state leeway. This is the governance approach taken in the authorisation procedures for medicinal products, for example. At the opposite end of the spectrum, voluntarism is based on non-binding instruments and sets out broad goals, allowing member states maximum flexibility in implementation. The OMC is a good example of this kind of governance, setting broad objectives rather than compulsory reforms and providing space for discussion and deliberation. Much of health is governed using a voluntarist approach, as can be seen in the many communications, recommendations and opinions on nutrition and physical activity, patient safety and healthy environments. Targeting uses similar non-binding instruments to voluntarism but is slightly more intrusive – this might be because the recommendations made are more detailed or because a mechanism for reporting or performance measurement is built in which puts pressure on member states to implement in a certain way. The amount of pressure felt by member states is difficult to accurately assess but examples of targeting can be seen in the technical standards on cancer screening and the follow up to Council recommendations on smoke-free environments (SFEs). Finally, framework regulation uses binding instruments but allows member states flexibility in their implementation. Directives are the primary instrument here, setting overarching policy goals but leaving governments to decide how they should be reached. This has been the approach most commonly taken in tobacco policy, as well as BTO policy and cross-border healthcare.

The two sets of categorisations – of policy instruments and of modes of governance – do not overlap or fit together perfectly. Education and information instruments are inherently soft but can be targeted at particular knowledge gaps. Hard law can be used in coercion or framework regulation and economic- or market-based instruments are best used coercively but are commonly part of voluntary co- or self-regulation. Soft instruments are the most complex – a decision might be non-binding and voluntarist but also highly prescriptive or detailed, thus falling into the targeting category, or even contained within a hard law instrument. Thus, whilst the policy instrument categorisation is a useful heuristic device, the instruments within the case study areas are each examined individually to determine their legal basis and approach to implementation.

Within health policy, the EU makes use of all the instruments and modes of governance above, and a single issue might be governed by a number of different instruments simultaneously or sequentially (Hervey and McHale, 2004: 43). The weak competence and limited budget in health has forced the Commission to utilise ‘creative tools’ such as comparable information, benchmarking and multi-stakeholder platforms, becoming a ‘master of ‘soft’ governance and strategic variability’ (Greer et al., 2014: 36; Lamping and Steffen, 2005a: 193). The health agenda has been founded on and underpinned by voluntarist instruments since the early 1990s and contemporary health policy is dominated by mechanisms of ‘Commission-sponsored cooperation’ (Hervey and Vanhercke, 2010: 107; 127). Coercive governance is less common, with binding measures more often taking the form of framework regulation, on account of the sensitivity and disparity in national health systems. The EU has also made good use of market-based instruments, through targeted funding of research projects and policy initiatives via the Health Programmes. In describing the broad trend of health governance, Hervey and Vanhercke (2010: 130) note that the crucial recent innovation has been the linking of voluntarist and coercive modes, using soft instruments as precursors and supplements to hard law.

### **Research hypotheses**

The conceptual exposition clarifies the focus of the thesis and the theoretical framework identifies the primary objects of analysis. In order to apply these tools within the individual case studies, a series of hypotheses are now constructed – these are referred to throughout the analysis and their testing serves to address the research questions identified in the introduction. The first four hypotheses pose questions about the modes of governance identified in the typology above, whilst the last two provide an overall statement on the nature and status of EU health policy. The latter are based on the prevailing narrative of EU health policy found in the literature and described by interviewees. This characterisation provides the context for hypotheses one to four, which should be read in relation to the health sector.

- Hypothesis 1: Crisis politics results in coercive forms of governance.
- Hypothesis 2: Framework regulation, as embodied in the EU regulatory state and the integration of the internal market, is declining in relevance.
- Hypothesis 3: Governing by targeting is more commonly employed where there is strong political will.
- Hypothesis 4: Voluntarist governance is becoming increasingly coercive.
- Hypothesis 5: EU health policy has become increasingly political and, as a result;

- Hypothesis 6: Health policy-makers have increasingly relied on soft policy instruments.

Hypotheses one to four build on the historical role of crisis politics in health policy, the shift away from the internal market as the dominant stem, the increasing sensitivity of detailed and prescriptive policy instruments and the growing use of contingency to make soft instruments harder. The thesis explores these hypotheses through its six case studies and revisits them in the analysis to inform conclusions about the changing nature of EU health governance.

## LITERATURE REVIEW

The literature review examines the body of academic research in EU health policy and how it employs the theoretical approaches reviewed in the previous chapter to explain the evolution and development of this policy area. It is structured according to the three stems of health policy – public health, free movement and macroeconomic governance.

The first section, corresponding to the first stem, reviews the literature concerned with early European action on public and occupational health and safety. It is quite fragmented and is mostly made up of work in tangential areas. For instance, health is referred to in volumes examining social (Geyer, 2000; Hantrias, 2000; Leibfried and Pierson, 1995) and employment (Rhodes, 1995) policy whilst a patchwork of individual articles charts the technical elements of specific initiatives, such as the Europe Against Cancer (EAC) programme (Boyle et al., 1995) and EU action on HIV/AIDS prevention (Dubois-Arber and Paccuad, 1994).

The second section, aligning with the second stem, reviews the proliferation of literature which followed the extension of free movement law into health. In 2001, the Belgian Presidency of the Council instigated the publishing of two books – *The impact of EU law on healthcare systems* (McKee et al., 2002) and *EU law and the social character of health care* (Mossialos and McKee, 2002). These ‘marker’ publications put a spotlight on the impact of recent CJEU rulings on national health services and, most importantly, acknowledged the existence of a collection of coherent ‘health in all policies’ measures at the EU level, if not quite the emergence of a genuine European health policy (Belcher and Berman, 2001). In the decade which followed, the debates raised in these two books were explored and extrapolated in a number of volumes providing comprehensive legal and political overviews of the field (Greer, 2009a; Hervey and McHale, 2004; McKee et al., 2004b; Mossialos et al., 2010; Randall, 2001; Steffen, 2005). These works now exist as a small but well established set of ‘core texts’ in EU health policy.

These two bodies of literature formed the core of health policy research until 2010 when the explicit inclusion of health in macroeconomic policy began to take the policy area in a new direction and reignited academic interest. A foundation for this third strand of research is presented in The Lancet’s ‘Health in Europe’ series, a set of seven articles published in early 2013. The primary focus of this literature is the public and population health impact of the economic crisis and austerity politics (Greer et al., 2013; Mackenbach et al., 2013), but the series also acknowledges the unprecedented level of international intervention now facing European health systems, reflecting a secondary theme of the recent literature (Baeten and Thomson, 2012; Fahy, 2012; Greer, 2014). This research notes that the growing trend for addressing health in the context of macroeconomic policy and structural reform has intensified the impact of the EU upon the organisation, delivery and management of national health systems.

In using this structure, the chapter risks superimposing a chronological template onto the stems heuristic – as noted in the conceptual exposition, this would not be accurate, since EU activity and academic literature within each of the three stems has existed and continues to develop concurrently. However, a loosely chronological approach is taken in order to simplify the literature and draw a clear distinction between different ‘eras’ of EU health policy. As such the chapter highlights the different understandings of health policy prevalent in the early

period of public health activity, in the aftermath of the Court's rulings on free movement law in the health sector, and in the post-crisis period.

## **The EU public health literature: 1957-2000**

The first body of literature spans that written prior to the public health mandate in the Maastricht Treaty and in the early years after its adoption. Since health was not considered a 'European' policy prior to the 2000s, the early literature makes little reference to the theoretical frameworks and models of integration examined in the previous chapter. The measures introduced and processes established in this period, however, set a precedent for the further evolution of health policy. The primary mode of policy-making – leadership by the Commission with qualified majority voting (QMV) in the Council and adjudication by the CJEU – was later to be labelled the 'community method'. It was used in the creation of EU health and safety policy, environmental health policy and the first public health action programme (PHAP). Action in the areas of cancer and AIDS were exceptions to this rule, presenting early examples of soft law and non-binding cooperation. Finally the SEA, in reaffirming political commitment to the single market project, provided the initial catalyst for the spillover of market-building policies into health.

Both the ECSC Treaty and the Rome Treaty laid foundations for a 'social dimension' in Europe and, as such, provided early demonstration of the potential of neofunctional spillover as a driver of health policy.

'The Treaty of Paris gave the ECSC the power to ensure rational use of coal resources (a precursor to environmental policy), to promote improved working conditions (a precursor to social policy) and to promote international trade (a precursor to trade and foreign policy)' (McCormick, 2011: 127).

As coordination between member states increased, the public health research community began to realise the value of this new sample population. The first wave of public health activity thus saw research on the incidence of lung cancer in uranium miners (Wagoner et al., 1965), the public health risks of exposure to asbestos (Zielhuis, 1977) and management of occupational safety and environmental protection (Eichener, 1997). Beyond occupational health and safety, remarkable examples of intergovernmental cooperation were seen in the areas of cancer (Moliner, 2013; see also Thwaites et al., 1995) and HIV/AIDS (Steffen, 2012; See also Pollack, 1994). Some fragmented research was even beginning to look at the operation of public health systems and patterns of health expenditure (Gevers et al., 2000; Hitiris, 1997). Though the literature was more interested in clinical medicine and public health than the application of theoretical frameworks, the common characterisation reflects the neofunctional path that seemed to be emerging, whilst recognising the importance of member states as the gatekeepers of integration.

In contrast to the public health literature, the social policy literature offers a surface-level application of the theoretical frameworks. Most analyses understand social policy to be a primary example of neofunctional dynamics; the development of social regulation is considered to have reduced member state autonomy and to have expanded in scope and content far beyond the wishes of national governments (Rhodes, 1998: 45). Furthermore, the development of occupational health and safety policy is also seen in some accounts as an early instance of the 'treaty-base game' – the Maternity Directive (Council Directive 92/85/EEC), for example, took as its legal basis Article 118A of the Rome Treaty on health and safety at

work, stretching the boundaries of this provision further than had been attempted before (Mazey, 1998: 142).

By contrast, intergovernmentalism better explained the several pieces of legislation which attempted to push social policy further – such as those on part time and temporary work, and parental leave policy – but were opposed by Germany or vetoed by the British government (Majone 1998: 26; Rhodes, 1995: 95). Contesting the neofunctional interpretation, some accounts note that the experience of social policy was narrow and somewhat unique. Streeck (1995: 400) concludes that its expansion in the 1980s was limited to two main areas – gender equality and occupational health and safety – and that ‘...success in these two areas was for very specific reasons that do not apply elsewhere, making spillover to other social policy subjects improbable’. In public health, the marked differences in national health systems were seen as insurmountable barriers to any prospects of European coordination and justifiable reason for recourse to the subsidiarity principle (Hantrias, 1995: 73).

Towards the mid-1990s, hints as to the future direction of health policy began prompting debates about the implications of free movement law and the role of the Court (Pierson and Leibfried, 1995: 66; 433). Hantrias (1995: 74) even makes reference to the growing common problem of health expenditure:

‘In some respects, it seems surprising that the Union has not devoted more attention to standardising public health practices across member states. Intervention could have been justified on both the grounds of ensuring access to a satisfactory level of social protection...and as a means of avoiding distortion of competition, since health care represents the largest proportion of spending on social protection, apart from old age’.

This insightful premonition demonstrates the sense of potential that pervaded early social and health policy. Spillover dynamics were evident in many areas and the ability of the Commission to stretch its official mandate and act as a policy entrepreneur lent promise to the neofunctional model. Whilst the literature on health policy remained limited, the potential for policy activity had grown significantly.

## **The health and free movement literature: 2001-2009**

The two books which emerged from the CoEU conference on the implications of EU law for national health policies marked the beginning of a new era of EU health policy research. At a basic level, the literature of the period concurs that health is an area which uniquely challenges many of the distinctions used by the main theoretical schools. It does not fit neatly, for example, into either of the functionalist categories of ‘technical/functional’ or ‘political/constitutional’ policy; neither does it fall consistently into one or the other of the intergovernmental ‘high-’ or ‘low-politics’ boxes (Mossialos and McKee, 2002: 45; 49). Health is both technical and political and as such can be regarded as a highly sensitive national issue area or a harmless area of functional low politics, depending on the particular policy mechanism. Most importantly, the 1990s had seen a series of legal judgements which forced national governments to empower citizens to seek health care in other member states (Gobrecht, 1999; Greer and Rauscher, 2011; Obermaier, 2008). Consequently the approach taken in the literature is predominantly a neofunctional one, emphasising the role of spillover, via free movement, in the development of health (Greer, 2006; 2008; 2009a: 10; Lamping, 2005: 24; McKee et al., 2004b: 12; Randall, 2001: 8). Furthermore, the arena of health policy is generally understood to be a multi-level one and the interconnection between the legal and

political framework of the EU is almost universally acknowledged (Baeten, 2005; Hervey, 2007; Hervey and McHale, 2004). More broadly, rationalist approaches are used, in conjunction with typologies such as Wilson's (1980), to explain the kind of politics likely to emerge in particular areas of health, whilst constructivist frameworks are employed in analyses of the NMGs (Mossialos et al., 2010: 9; 10).

Taking a bird's eye view, the grand theories of integration are used in this literature to aid understanding of how health policy has integrated (Mossialos and McKee, 2002). Neofunctionalism helps to explain how health became part of the EU agenda; spillover from initial coordination in coal and steel production into harmonisation of occupational health and safety standards, for example, demonstrates the indirect power of single market integration. The BSE crisis, meanwhile, saw spillover from a trade issue to the creation of an EU food safety agency. By contrast, intergovernmentalism is used to understand the limits of health policy integration. The Luxembourg Crisis imposed a provision for use of the national veto where 'very important interests' were at stake – health and welfare decisions fall into this category, meaning that spillover processes did not have unchecked momentum (Mossialos and McKee, 2002: 47). This division is further explored using the liberal intergovernmental framework, which finds that member states can be persuaded that some areas, such as occupational health and safety, are better regulated at the EU level whilst others, including system financing and the prices of pharmaceuticals, will be jealously guarded (Mossialos and McKee, 2002: 50).

The literature of this period embraces two opposing, but not necessarily contradictory, positions. On the one hand, member states are acknowledged to be the most powerful actors in the EU system. Whilst the various interest groups and regional governments are fragmented and hold the power to influence but not to decide, national governments are large and well-resourced actors which have successfully resisted the formal, if not actual, encroachment of the EU into health and have prevented social policy integration from catching up with economic (Greer, 2009a: 3; Lamping, 2005: 20). Lamping goes on to claim that 'European integration does not simply restrict national policy choices; it simultaneously enhances strategic health policy options of governments and private actors' (2005: 37). The main supranational agencies in health – the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) – were originally set up as an alternative to granting the Commission further powers, and have member state representatives on all boards and national regulatory authorities closely involved in the decision-making process (Mossialos et al., 2010: 35). From a legal perspective, whilst the treaty-base for health has slowly expanded in the series of revisions which have taken place, member states have successfully set limits to 'competence creep' in the Maastricht Treaty, secured a strongly worded 'subsidiarity' provision in the Amsterdam Treaty and retain both discretion and the 'benefit of the doubt' in the application of the public health derogation in Article 36 TFEU (Hervey and McHale, 2004: 74; 79; 94).

On the other hand, the same collection of literature is unanimous in its depiction of the constraints put upon member states by internal market law, the European institutions and the EU's wider legal framework. Institutions limit the options for national policy-makers, '...mak[ing] unthinkable forms of Europeanisation seem plausible', whilst the single market limits member state competence to act in areas of health protection (Greer, 2009a: 12; Hervey and McHale, 2004: 90). Though they retain considerable power in the policy-making process, McKee et al. (2004b: 4) note the '...failure of member states to address health issues within

the legislative framework of the EU', instead facilitating a process of case-by-case judicial policy-making. This loss of competence is particularly acute in indirect integration, where Economic and Monetary Union (EMU) and economic integration have '...deprived national policy-makers of many of the policy options that they could and did employ in earlier decades in order to achieve...high levels of social protection' (Lamping, 2005: 24). Whilst some governance innovations, such as independent supranational agencies, have arguably preserved some member state authority (or at least prevented it from migrating to the Commission), others such as the OMC have had the opposite effect (Mossialos et al., 2010: 35). A number of features suggest that national governments originally intended the OMC to be a member state instrument, rather than a platform for an ambitious and entrepreneurial Commission (Greer and Vanhercke, 2010: 204).

## **The health and macroeconomic governance literature: 2010-2015**

By 2007 the health policy literature was relatively well established and its authors were in broad agreement about the dynamics of EU health policy, but the onset of the crisis prompted revised analyses of both public health and health governance narratives.

### **Post-crisis public health literature**

In the early 2010s the public health literature turned to examine the impact of the crisis on public health policies and the health of Europeans. Increasingly negative health trends were soon revealed in Italy, Spain and Portugal, with devolved health powers often exacerbating regional health inequalities as austerity measures were introduced (de Belvis et al., 2012; Gené-Badia et al., 2012; Barros, 2012). By far the greatest attention, however, has been paid to the situation developing in Greece. Both suicide and homicide rates in men increased by over 20 per cent between 2007 and 2009, whilst mental disorders, substance abuse and infectious disease morbidity all show deteriorating trends (Kondilis et al., 2013). The same period has seen dramatic increases in the number of patients not seeking health services on account of the cost involved, as well as a decline in self-rated health status (Kentikelenis et al., 2011; Zavras et al., 2013). Reforms of primary care are lacking, whilst broader health system reforms are focused upon the budget cap, a condition of the Greek bailout package, which requires that health care spending not exceed six per cent of gross domestic product (GDP) (Kentikelenis et al., 2014; Kondilis et al., 2012).

Broader studies of the health impacts of the economic crisis find that the trends seen in Italy, Spain, Portugal and Greece are replicated across member states, particularly in terms of access to care (Eurofound, 2014). A small body of literature charts the threat to health outcomes and equality posed by the recession and accompanying austerity measures (Karanikolos et al., 2013; Mackenbach et al., 2013; McKee et al., 2012; Suhrcke and Stuckler, 2012). Research into policy options for reducing the impact of the crisis on health has shown that investment in active labour market policies can mitigate increases in suicide and homicide rates, whilst a number of commentators have examined the political conditions in which such options are being considered (Stuckler et al., 2009; see also McKee, 2010; 2011, Mladovsky et al., 2012 and Stuckler et al., 2010).

The public health literature, being concerned with the health of populations and the contribution of health systems to the health of individuals, does not discuss in great detail the politics of health, how decisions are made or which institutions govern policy. Nevertheless, it

makes a number of assumptions and highlights a variety of dynamics which portray a specific understanding of health policy. The importance of supranational institutions is evident in almost all public health research but, contrary to traditional, neofunctional understanding, less emphasis is put on the driving role of institutions and more on their value as hubs of expertise, information, shared experience and best practice. The importance and added value of the involvement of the EU and the WHO is understood to be technical and functional, almost above politics, insofar as the value of supranational coordination in public health is undisputed. The literature on tobacco also highlights the power of interest groups and industry, expressing a broad consensus that tobacco companies play a far greater role in the development of EU smoking prevention policy than is appropriate or desirable (Fooks et al., 2011; Fooks et al., 2014; Peeters and Gilmore, 2013; Smith et al., 2010).

### **Post-crisis health governance literature**

Examining the impacts of the economic crisis from a different angle, a second stream of literature is concerned with the way in which the governance of health policy has changed since 2007. The theoretical approaches taken here are more explicit, since research looks at the changing roles of various actors and stakeholders, the development of policy-making processes and the evolution of the EU's health policy mandate.

The central understanding of EU health policy in the contemporary era, broadly agreed and shared by the majority of observers in the field, is most clearly stated in the prolific work of Greer (2009a; 2009b; 2010; 2011; 2014). Reflecting the pre-existing characterisation, the development of health is explained by neofunctional arguments – once coordination in a policy has begun, the development of a given arena generates a momentum of its own, characterised as spillover. The opposing intergovernmental argument is trumped, for Greer, by the emergence of a European health policy despite the absence of an explicit treaty base or competence (2014: 17). The EU is understood to be composed of ‘generally liberalizing, pro-integration...institutions’ which have created an EU health policy without any real demand for it (Greer, 2009a: 3; 2009b: 5). The entrepreneurial Commission, despite its tendency for internal discord, exploits opportunities to increase its own mandate and with support from other actors, creates a complex and prescriptive web of health policies and networks (Greer, 2009b: 6). The precedent set by the application of free movement law to health has opened the door to the extension of public procurement, competition and state aid law, leaving almost no area of health untouched by EU influence (Greer, 2011: 192). Finally interest groups are understood, alongside supranational institutions, to be instrumental in creating a stable health policy (Greer, 2009b: 6). Domestic interest groups appealing to the supranational level and the emergence of new pan-EU alliances in specific issue areas generates further integration and the support of these actors is vital in determining the success of both hard and soft law initiatives (Greer, 2011).

The dominant understanding of member states, by contrast, ascribes formal power to national governments but considers the reality to be one in which member states have no reliable way of controlling the health agenda or avoiding defeats (Greer, 2010: 210). Their involvement in EU health policy is often characterised as reactive, responding to initiatives launched by the Commission or case law passed down by the Court, and whilst they are acknowledged to be more important and powerful than lobbies, regional governments or interest groups, the options from which member states choose are thought to be prepared by the supranational institutions (Greer, 2009a: 3; 11; 13). The weakness of health ministries in comparison to their

counterparts – economy, trade, treasury and foreign policy – creates further problems for member state influence in health policy, since the cooperation and support of non-health departments is often necessary to assert a coherent position in health issues (Greer, 2010: 210). As such the contemporary health policy arena, particularly in the area of internal market and health services, is commonly presented as one in which member states work to oppose the expansionist agenda of the EU institutions.

The ‘member state versus supranational institution’ narrative has been somewhat challenged, however, by the onset of the economic crisis and the acceleration of a reconfiguration of the actors involved in health policy (Baeten and Thomson, 2012). The European Commission remains in the driving seat, as the prevailing neofunctional model anticipates, but has adjusted its strategy in light of the elevation of economic concerns to use economic actors to further its goals (de Ruijter and Hervey, 2012; Fahy, 2012). In this way it is exploiting the constitutional asymmetry as it has historically done in the treaty-base game, assigning constitutionally strong legal bases to health policy legislation disguised as internal market or macroeconomic measures. The power of lobbies and interest groups in determining the degree of integration achieved remains strong and the number of groups involved in health policy has expanded quite considerably (Greer, 2009a; Greer et al., 2013). Though still retaining control through the working parties of the Council, national governments have been forced to change their response and cede further power to the EU in crucial areas (Baeten and Thomson, 2012). National health ministries must now be prepared to discuss and coordinate with their colleagues in the ministries of economy and finance, as well as with their European counterparts and the various departments of the Commission (Fahy, 2012). Crucially, the literature no longer refers to the Court as one of those driving or leading health policy. The importance and relevance of internal market law for health remains a key topic (see Baeten and Palm, 2011; Newdick, 2011; Sauter, 2011 and; van de Gronden and Sauter, 2011) but the role of the Court, not expected to be of particular significance within the economic governance framework, has faded from the literature.

A final focus of the post-crisis literature is the change in processes and policy tools being used in health, in particular the OMC (Vanhercke and Lelie, 2012; Vanhercke and Wegener, 2012). Since its inclusion in the Europe 2020 Strategy, the Social OMC – which embodies the health and long-term care, pensions and social inclusion strands of the original OMC initiative – has enjoyed a modest revival (Barcevičius et al., 2014). Its ability to bridge the constitutional gap by bringing health and social concerns into the economic sphere, where the EU enjoys a stronger mandate and power, is of renewed interest in the post-crisis climate (de Ruijter and Hervey, 2012: 140). The literature revisits the debate about the competing benefits of hard and soft law, with some maintaining that the non-binding nature of the OMC renders it ineffective, whilst others point to its success when sufficiently supported and the seriousness with which it is approached by member states (Brooks, 2012; Greer, 2011). This discussion takes part within the broader dialogue about the place of social policy within Europe 2020 (Armstrong, 2012; Bieling, 2012; Daly, 2012; Vanhercke and Lelie, 2012) and in the EU’s response to the economic crisis (Grahl and Teague, 2013; Vanhercke, 2013). The evolution of the economic crisis into a social emergency in some member states has prompted a reassessment of the EU’s social policies and of the constitutional asymmetry which hinders their development relative to economic issues (Barcevičius et al., 2014).

## Summary

Attempts to explain the evolution of EU health policy have traditionally drawn upon the neofunctional-intergovernmental dichotomy, charting the changing power and importance of supranational institutions and member states as drivers of integration. Later literature, fascinated by the patchwork of competencies which the EU enjoys in health, introduced legalistic and constructivist models to explain the role of soft law and innovative modes of governance. The conclusion of these accounts often mirrored early integration analyses in declaring the role of the state in health policy to be under threat from the EU and its institutions.

In the aftermath of the economic crisis, much of the literature has sought to reapply and expand the dominant narrative, highlighting neofunctional and intergovernmental dynamics in the development of the strengthened economic governance framework. However, a renewed interest in governance has also been sparked – the range of instruments and processes now applicable to health has grown considerably and the nature of pre-existing policies and tools has been altered. Though the traditional integration theories can still offer valuable insight into the ‘high politics’ of integration, the changing approach to health governance in the post-crisis period necessitates analysis at a lower level.

## THE HISTORY AND CONTEXT OF EU HEALTH POLICY

The development of health policy has been influenced and shaped by a variety of factors. Reflecting the common pattern it has, at times, been prompted and pushed forward by functional dynamics, with the introduction of specific health policy initiatives resulting from cooperation and harmonisation in other, non-health areas. At other times, the evolution of health has been steered and scripted by political forces – CoEU leadership in cancer policy and Commission entrepreneurship in the PHAPs illustrate this dynamic well. This predictable evolution has been accompanied, however, by a series of catalysts and developments largely distinct to health policy. Judicial construction of policy frameworks via the application of internal market law, as seen in the rulings and legislation on cross border healthcare, and extension of European competence in response to crisis events, as seen in the BSE outbreak, are two examples of such ‘uniquely health’ characteristics.

This chapter examines the historical evolution of health policy in the EU. It firstly describes the context in which the development of health policy and governance should be understood, reviewing the evolution of the European project, its dominant policy-making models and the changing health provisions of the founding treaties. It then offers a short historical account of health policy at the European level, structured according to the stems heuristic, providing the background from which the six case studies are selected.

### The context of EU health policy

#### The evolution of the European Union

The development of health policy at the European level is inextricably linked to the evolution of the European project as a whole. This section briefly describes how the EU was created, the governing institutions which it has established, the processes of widening and deepening which have shaped its development and the challenges which have been posed by the global financial crisis and economic recession.

The founding treaties of the ECSC and the European Atomic Energy Community (Euratom) were brought together under the treaties of Rome in 1957. This created the European Economic Community (EEC), a supranational organisation based on the economic integration of a common market and political coordination aimed at ‘ever closer union’. The distinction between these economic and political visions has determined the progress of the European project throughout its history. The SEA, the first and arguably most significant treaty revision, introduced QMV into a raft of internal market policy areas and codified the nascent forms of political cooperation, advancing economic and political integration on a relatively equal footing. A few years later, the Maastricht Treaty was forced to acknowledge the limits of political union but did this by formalising them in the three pillar structure, which separated supranational from intergovernmental policy processes. By 1997 a democratic deficit was emerging in the wake of these complex institutional frameworks, challenging the framers of the Amsterdam and Nice treaties to address the efficiency and legitimacy of the EU. Progress towards political union changed form but continued in the adoption of the Charter of Fundamental Rights (CoFR) and strengthened treaty emphasis on citizenship, solidarity and social cohesion.

The peak of integration momentum came in 2004 when European leaders adopted a draft constitutional treaty (DCT) for Europe, enshrining the economic and political union achieved so far and giving the EU legal personality. However, the underdeveloped ‘European polity’ saw the DCT rejected by national populations and established a clear limit for the federalist vision. After a short cooling period, the provisions of the DCT were reframed as amendments and adopted as the Lisbon Treaty in 2007. Thus, whilst expansion and elaboration of the EU’s treaty base has been continuous, it is increasingly constrained and imbalanced, manifesting in a constitutional asymmetry between economic and political integration and social- and market-based competences.

The changing institutional structure described by the EU treaties has resulted in a shifting balance of power between the main EU actors. The European Commission, long-standing executive of the EU, has maintained a relatively autonomous role and has successfully expanded its influence via establishment of numerous decentralised agencies and the creative use of treaty provisions and CJEU support. The Court itself has been elevated to sole arbitrator of the EU treaties, prompting the creation of the Court of First Instance (CoFI) to support its growing role. Responding to the democratic deficit the European Parliament has also seen its powers increase, with direct elections first held in 1979 and strengthening of its legislative role in successive treaty revisions. The Parliament’s rise to co-legislator has occurred at the expense of the Council which, previously a formidable brake on speeding supranationalism, has seen its control moderated under successive expansions of QMV and the evolution of the co-decision procedure. As the scope of EU activity has increased, so too has the vast array of supporting bodies – the European Economic and Social Committee, Committee of the Regions, Social Protection Committee (SPC) and Economic Policy Committee (EPC) play particularly central roles and are indicative of the multi-level structure which now frames the EU’s development. The tension between supranational and intergovernmental cooperation prevails but whilst the scope of intergovernmental control has, at best, remained stable, the institutionalisation of supranationalism has increased continuously.

In terms of scope and content the EU has undergone parallel processes of widening and deepening. From a founding collection of six member states it had expanded to include most of Western Europe by 1995. A watershed was reached in 2004 with the accession of 10 former-communist states from Eastern Europe, posing challenges in light of their collectively lower GDP, weaker economies and greater reliance on EU support. Crucially, this expansion also changed the balance of voting procedures in the Council, shaking up the established power groupings and allegiances. With subsequent accessions in 2007 and 2013 the EU has arrived at a total of 28 member states; appetite for further expansion is markedly lower than at previous points in the project’s history, but seven countries remain engaged in accession negotiations.

The deepening of EU policy has been a less steady process. The spillover from coal and steel sector coordination into related industries and horizontal policies, such as occupational health and safety, provided early momentum and economic integration has historically progressed well. Attempts at a European Defence Community, meanwhile, were thwarted in 1954 and the 1960s saw a resurgence of intergovernmental control and the hampering of plans for political and social union. Against this barrier, attention shifted to monetary union – early failed attempts paved the way for an EMU framework, enshrined in the Maastricht Treaty and introducing a single currency, as well as limits on government debt and deficits. Whilst this

marked a significant step forward for EU integration, the separation of Justice and Home Affairs (JHA) and the Common Foreign and Security Policy as intergovernmental pillars of policy institutionalised the roadblocks to comprehensive integration and neither area has advanced far towards a coordinated EU policy. Outside of these intergovernmental realms, however, the range of EU policy activity has grown substantially. European influence is now felt, albeit to varying degrees, in environment, energy, education, trade, competition, employment, transport and maritime policy, among many others. In 2012, the UK (United Kingdom) government launched a review of the balance of competences between the national and European level which acknowledged the broad scope of EU influence but found no cause for transfer of powers back to national level (UK Government, 2014). Whilst attempts to amalgamate EU policy under centralised banners such as the Lisbon Agenda and the Europe 2020 Strategy have faced difficulties, innovations such as the Citizens' Initiative, the Schengen Agreement, the European Central Bank (ECB), the CoFR and, more recently, the collective awarding of a Nobel Peace Prize, suggest the ongoing relevance of a federalist logic in the development of the EU.

The global financial crisis and economic recession have had two major implications for the evolution of the EU. Firstly, the focus of EU activity has returned to fiscal and monetary integration, whilst policy is guided by principles of budgetary austerity. Secondly, popular support for the EU has declined steeply, with public unrest and Eurosceptic sentiment swelling across the continent. These developments have exacerbated both the constitutional asymmetry and the democratic deficit which have plagued the EU since its creation.

### **Policy-making and governance in the EU**

The changing powers, political climate and goals of the EU have produced, over time, a number of different policy-making types or models. The original form of supranational policy-making, used in the early days of the EEC, became known as the 'community method' and built on experiences with the common agricultural policy (CAP), which dominated the agenda in the 1960s. It provided a central role for the new EU executive with strategic bargaining opportunities for the Council of Ministers, engagement of interest groups and national agencies, and limited involvement of national and European parliamentarians (Wallace, 2010: 94). The community method aimed at positive integration and centralised power and, as such, there are few examples of its more recent use but it remains a point of reference when discussing the evolution of the EU's policy-making processes (Wallace, 2005: 80). Most commonly, it is contrasted to the 'new' modes of governance, in particular the OMC, which take a softer, more deliberative approach designed to circumvent the roadblocks which hinder the established legislative procedures (Armstrong, 2011). Institutionalised in the Amsterdam Treaty, policy-making via the OMC is employed in areas where full harmonisation is not possible, instead facilitating the exchange of information, the sharing of best practice, the establishment of benchmarks and the development of non-binding agreements and guidelines (Trubek and Trubek, 2005).

Wallace (2010) identifies three further models of EU policy-making. Firstly and most prolifically, the regulatory mode of policy-making emerged in the construction of the EU regulatory regime. Given its weakness in distributive and redistributive policies, traditionally used by national executives to exert power, the EU has instead gained influence via the creation, implementation and interpretation of regulatory policy (Eberlein and Grande, 2005: 89; Page, 1998). Utilising the EU's strong mandate in ensuring the smooth functioning of the

internal market, national regulations have increasingly been removed and replaced with harmonising European measures, commonly administered by independent, expert and supranational agencies (Majone, 1996: 2). A second complimentary policy-making type is the distributional model, used in policies which involve the transfer of resources through the EU budget (Hix and Høyland, 2011). This embodies the various socio-economic and regional development policies and the division of funds dedicated to cohesion and solidarity. It is inherently linked to the MLG framework, since it moves away from central control, bringing in a plethora of groups, sectors, regions and countries (Wallace, 2010: 97). Finally, Wallace (2010: 100) identifies ‘intensive transgovernmentalism’, a mode of policy-making which occurs between national policy-makers, with little involvement of EU institutions. Such policy-making excludes the CJEU, the European Parliament and, largely, the European Commission, but is more intensive than the traditional intergovernmental model suggests, involving complex negotiation and cooperation on foreign, external, monetary and JHA policy (Wallace, 2005: 88).

Though the creation of the regulatory state facilitated a process of ‘competence creep’ which enabled the EU to extend its influence into health and social policy, the regulatory policy model is now understood to be declining in relevance (Greer, 2006; Pollack, 2000; Rhodes, 1995; Richardson, 2006). Thus, in light of how politically unpalatable the community method has become, the weakness of distributional policies and the aversion of national governments to engage in transgovernmental health policy-making, the evolution of the sector now rests largely on the softer, more innovative modes of governance.

### **The EU treaties and the legal basis for health**

The early EU treaties did not reference health explicitly but laid some foundations for social policy coordination. The ECSC Treaty, for instance, described the EU’s duty to raise standards of living, whilst the Euratom Treaty was concerned with protecting workers and the general public from the harmful effects of regulation. These provisions were consolidated in the Rome Treaty, which formalised measures on occupational health and safety, permitted restrictions on free movement on the basis of health protection and contained provisions on the right to establishment and the free movement of services, which had an impact upon health professionals. As such, these treaties gave an early indication of the impact of the internal market and free movement principles upon the health sector.

The 1987 SEA sought to speed up the completion of the internal market and was mostly focused on this goal, but provided in Article 100a(3) EC that EU action should take as a basis a high level of health protection, meaning that measures taken to facilitate the internal market should be mindful of their health impacts. Additionally, Article 118a EC provided for the first time that provisions on occupational health and safety, among other issues, could be adopted via QMV. However, it was not until 1992 that the EU gained a legal competence in health.

The Maastricht Treaty introduced co-decision as a legislative procedure and laid down the early provisions of EMU. Article 129(1) EC stated that the EU ‘...shall contribute towards ensuring a high level of human health protection’ and that ‘...health protection requirements shall form a constituent part of the Community’s other policies’. Furthermore, Article 3(o) EC elevated health issues to the status of Community objective, meaning that European action should contribute to ‘...the attainment of a high level of health protection’. Finally, Article 129(4) EC extended QMV to cover an even wider range of health proposals.

The Amsterdam Treaty reformed the institutional structure of the Union but, crucially for health, was being drafted just as the BSE crisis began to affect the Western continent. In light of the need for stronger regulatory control, the health mandate was strengthened under Article 152 EC, elevating the EU's role from 'contributing' to health protection to 'ensuring' health protection in the definition and implementation of all Community policy and action. It also extended the circumstances in which the EU could use the co-decision procedure into BTO policy, whilst offering the first statement of subsidiarity in the health context.

The health provisions of the treaties were not changed again until the Lisbon Treaty of 2007, which sought to resurrect many of the provisions of the abandoned DCT. Article 3 TEU makes 'wellbeing' an objective of the Union whilst a horizontal social clause is inserted in Article 9 TFEU, meaning that the Commission must take greater account of social, health and wellbeing concerns in the legislative process. The newly numbered Article 168 TFEU (previously Article 152 EC) adds Union competence in cross-border threats to health, tobacco use and alcohol abuse, though excluding any harmonisation, and encourages member state cooperation in cross-border health services. It puts greater emphasis on guidelines, indicators, monitoring and evaluation, and adds medicinal products and medical devices as areas of Union competence. However, Article 168(7) TFEU also extends the reference to subsidiarity, reiterating member state responsibility for the definition of their health policy and clarifying that this includes 'the management of health services and medical care and the allocation of the resources assigned to them'. Finally, the Treaty explicitly introduces monitoring and evaluation as an integral part of health policy, seeking to address the lack of comparable data and information collected amongst member states (Tsolova, 2010).

EU health policy thus rests on an imbalanced legal basis. Whilst the protection of health has been raised to the level of 'Union objective', direct EU competence is limited to 'encouraging cooperation' and 'support of national measures' in all but a few, explicitly specified areas. Moreover, the EU's powers to take action in pursuit of health are not neatly collected into one health article but are dispersed amongst provisions on the environment, health and safety at work, consumer protection, the internal market, the coordination of social security systems and fiscal governance. The type of policy pursued, the legal basis on which it rests and the mechanisms put in place to implement it have changed substantially as the EU has grown. The health policy agenda has been shaped by and made use of the evolving institutional structures, as well as the political climate in which they have operated. The rest of the chapter provides a chronological overview of EU health policy before presenting some characterisations of how health as an EU competence has developed.

## **The historical development of EU health policy**

### **The genesis of EU health policy: 1957 to 1992**

The founding treaties of the EU did not make direct provisions for health policy; they were strictly economic in their objectives, reflecting the prevailing *laissez-faire* philosophy. Shaw (2000: 6) notes that 'the dominant ideological premise',

'...was that social progress would be the natural correlative of the economic progress fostered by the benefits of a common market...suggesting that an interventionist social policy...would in fact be counterproductive'.

Health measures were therefore only permitted where they were necessary for the harmonisation of the internal market. For the most part, this meant occupational health and safety and social security arrangements for migrant workers, where the Communities enjoyed extensive competence. However, work also began in this period on the harmonisation of pharmaceutical regulation – based on the inclusion of medical products among the goods subject to internal market rules in the Rome Treaty, this would eventually lead to the creation of the EMA as part of one of the most well-integrated facets of EU health policy, but at the time was undertaken largely as a response to the thalidomide tragedy (Anderson, 2015: 163).

The SEA prompted an acceleration of the European project and a debate about the imbalance between market-orientated and social welfare policies (Leibfried, 2010: 254). The introduction of QMV for legislation in many areas, including occupational health and safety, cleared some of the institutional roadblocks and marked a first important step in the Europeanisation of health and social policy (Falkner et al., 2005). This spawned a mandated ‘rush to the top’ in social policy and the use of the EMU project as a ‘Russian doll’ for the introduction of new initiatives and legislation (Geyer, 2000: 172; Ross, 1995: 368; 371). At the same time and outside of the formal mandate, targeted public health activity was already underway. In 1985 the European Council proposed and adopted an EU programme of action against cancer. The EAC initiative led to the adoption of a string of legislation on dangerous substances, pesticide residues, exposure to carcinogens and tobacco use (Moliner, 2013). Similar programmes were also established to combat HIV infection and AIDS (Steffen, 2012), reduce illicit drug use and coordinate health-related research (Greer et al., 2014: 38).

Health activity to this point was undertaken without a formal mandate. Its development was aided by the trend for re-regulation in the single market and a shift in Community strategy ‘...from adopting directives on specific hazards or sectors to using an overall directive in combination with a series of more specific “daughter directives”’ (Majone, 1996: 95). This new approach enabled the EU to engage in a secondary-law variant of the treaty-base game and meant that the significant impact of the single market project on social policy was achieved ‘...largely through mechanisms operating *outside* the welfare dimension proper’ (Leibfried, 2010: 257).

### **The creation of a public health mandate: 1992 to 1997**

The turning point for health came with the signing of the Maastricht Treaty. It gave the EU a role in coordinating national policies on disease prevention, drug dependence, research and health education, and in adopting recommendations and incentive measures to support these initiatives. It was at this point that the ‘win/win’ nature of public health began to bear fruit – ‘...not politically divisive, not particularly expensive’, public health provided a timely opportunity for the EU to draw attention away from poor economic performance and promote its ‘human face’ (Geyer, 2000: 175; Gold, 1998: 117). Up until the 1990s, legislative reform of social issues was limited to the few areas where the single market or the Rome Treaty allowed latitude – namely gender equality or health and safety (Leibfried, 2010: 268). Armed with an official mandate, the Commission identified eight specific areas for EU-level action in public health – cancer, HIV/AIDS, drugs, rare diseases, accidents and injuries, pollution-related illnesses, health data and health promotion – and built these into the first PHAP.

By the end of the 1990s, public health was a routine feature of all social policy proposals and had issue areas in almost every Directorate General (DG) in the Commission (Abel-Smith et

al., 1995: 127). Crucial to this proliferation was Jacques Delors' identification of the internal market programme as the appropriate platform from which to re-launch the European project whilst tying social policy convergence to economic integration (Noël, 1989: 4). In this strategy, the 'added value' of cooperation in public health was used to help promote the EU's social benefits and to offset concerns about EMU and the effects of economic integration.

### **Crisis, mainstreaming and case law: 1997 to 2008**

The 1990s saw the Court begin to play an important role in the evolution of health policy. The most significant judgements for health were those on the supremacy of EU law and the right to seek reimbursement for medical services received in another member state. Building on the *Costa v ENEL*, *Van Gend en Loos* and *Factortame* cases, the Court ruled in *Kohll* and *Decker* that, since healthcare is a service provided for remuneration, it must be regarded as falling under the scope of the principles of free movement. As a result, EU citizens were granted the right to receive healthcare services in any member state and to be reimbursed by the health system of their home state. The Court refined its judgements in a series of further cases, creating by the mid-2000s a web of jurisprudence on the operation of health services within the EU.

The Amsterdam Treaty, adopted during this steady stream of case law, altered the public health mandate of Article 129 EC, changing the emphasis of existing provisions and adding a mainstreaming element to Union activity in health. Its provisions reflect the political potency of crisis – it is commonly understood that there was originally no intention to amend Article 129 EC, but that the BSE crisis made it clear that some threats warrant European action and spurred member states to better facilitate this (Hervey and McHale, 2004: 76). The mainstreaming provision, in line with the commitments to raising standards of living and the attainment of a high level of health protection, was introduced in response to arguments by the UK government in *UK v Commission* concerning emergency measures in the BSE crisis (Geyer, 2000: 175). This required that all policies take health into consideration and was further emphasised by the Finnish Presidency's commitment to the HiAP approach in 2006 (Puska and Stahl, 2010).

More broadly, the Treaty refocuses EU health policy towards health promotion and the broader determinants of health, expanding Community activities into promotion rather than just prevention, and changing the obligation of institutions from 'requirement to contribute' to 'duty to ensure' a high level of health protection (Hervey and McHale, 2004: 77). The Commission quickly utilised its strengthened mandate and launched a new, simplified PHAP, which streamlined the previous eight-stranded strategy into a three part programme aimed at improving information for the development of public health, reacting rapidly to threats to health and tackling health determinants through health promotion and disease prevention (Decision 1786/2002/EC). This new approach was made possible by the creation of a dedicated DG for health and consumers (SANCO). The establishment of a 'health department' within the Commission was an explicit acknowledgement that a critical mass of health-related issues now existed at the European level and warranted coordination by a dedicated body. It also reflected concern about the range of EU laws and policy areas which now affected health and the potential for this encroachment to continue via litigation and Court judgement.

## **The response to free movement: 2008 to 2011**

Following a series of reflection processes, conclusions and consultations, the European Commission published a proposal for a Directive on patients' rights in cross border healthcare in 2008 (Directive 2011/24/EU). The purpose of the Directive was to codify the case law handed down by the CJEU and to prevent further cases from imposing extra limitations of member states' sovereignty in this area. The negotiations were long and difficult but the adoption of the Directive, with its many provisions to extend the EU's role in health in areas such as eHealth and rare diseases, represented the pinnacle of EU health policy integration.

Around the same time, negotiation began on a series of other internal market-based health policy initiatives, including the revision of legislation on clinical trials, the pharmaceutical package, the action plan on health workforce, the Joint Action on HTA, the directive on human organs for transplantation and others. A third PHAP, running from 2009-2013, expanded EU activity in public health even further, emphasising health inequalities, health security and the need to generate health knowledge (Anderson, 2015: 175). It also shared the objectives of the Europe 2020 Strategy and sought to promote investment in health and measures to address the ageing society.

This policy momentum was somewhat tempered, however, by the adoption of the Lisbon Treaty. Though the changes did not weaken the EU's role in health, they were less ambitious than previous treaty revisions and strongly re-stated the importance of subsidiarity and the autonomy of member states. This provision is particularly interesting in light of the macroeconomic governance reforms which have since taken place and which directly challenge the autonomy of member states in the financing and structuring of their health systems. EU action is focused but remains purely 'complementary' – the monitoring and combating of cross border health threats, for example, is mentioned as an area where the Council and Parliament may adopt incentive measures.

As evidenced by the adoption of the third PHAP and the continuing EU activity in public health areas, the stream of case law handed down by the CJEU did not supplant public health policy, but it did signal the potential of free movement law as a basis and shaping force. The proportion of health policy born out of internal market law increased significantly in the late 1990s and 2000s and it was this new 'face' which ignited a fresh wave of academic interest in health as an EU policy competence.

## **Economic crisis and contemporary health policy: 2011 to 2015**

The onset of the economic crisis did not immediately, significantly or directly affect the content or direction of EU health policy. Rather, it might be more accurate to say that the crisis affected the political climate and priorities of the European project as a whole, which has in turn been reflected in health policy. Most of the legislative projects underway in health at the end of the 2000s were brought to fruition in the aftermath of the crisis and in 2013, a fourth PHAP was adopted. This has four thematic priorities: health promotion and disease prevention; cross border health threats; innovative, efficient and sustainable health systems; and access to high quality and safe healthcare. In addition to maintaining the EU's leading role in public health and health protection, the 2014-2020 PHAP gives the EU a role in 'encouraging' innovation and sustainability in health systems, and in 'identifying and developing' tools to address shortages in human and financial resources.

However, the impact of the crisis on health policy, as described by an official within the renamed DG Santé (DG for Health and Food Safety), was to severely limit the publication of new initiatives (*European Commission, Health Directorate E*). Disquiet about the decline in health and social policy has been widespread since the crisis hit and though some key legislative achievements have been made – the TPD and the Clinical Trials Regulation (Regulation 536/2014), for example, were both adopted in 2014 – the health community remains concerned (Renshaw, 2015; van den Abeele, 2015). This is partly a result of the fact that, more than ever before, EU health policy is determined by policies outside of the health sector. Policies on data protection, trade, research, professional qualifications, the Digital Agenda, environment, agriculture, structural funds, minority rights, Europe 2020 and taxation, among many others, have a significant impact upon health and the attention of the health community is now required in these areas as much as in ‘traditional’ public health fields. As such, conventional health policy ‘output’ is now diluted by the pursuit of health goals within other policy areas.

This is not to say that the perceived decline in health policy described by interviewees is superficial. The conservative, anti-European climate embodied in initiatives such as the Better Regulation initiative and the REFIT (regulatory fitness and performance programme; Commission Decision 3261 final) has caused the Commission not only to block the presentation of too many new policy proposals but also to begin rolling back existing legislation (Schömann, 2015). Furthermore, traditional public health policies have begun to falter – the failure of the Commission to produce a new Alcohol Strategy in 2015 led to the resignation of the twenty NGO participants of the Alcohol and Health Forum, whilst the publication of a new proposal on taxation of tobacco products is now also uncertain (*EU Health NGO I*).

Where policy has expanded, it has been in areas which support health’s inclusion in the strengthened macroeconomic governance framework and DG Santé’s role in assisting DG ECFIN (Economic and Financial Affairs) to monitor, measure and evaluate national health systems. These are mostly soft law, data collection initiatives relating to Health System Performance Assessment (HSPA), which examine the sustainability, effectiveness and cost-efficiency of healthcare. The information gathered is used to inform recommendations on health reform in the European Semester, agreements and expenditure conditions in financial bailouts and broader compliance with the EU’s macroeconomic governance framework.

## **Characterisations of EU health policy development**

Contemporary EU health policy is characterised by involvement of the greatest range of actors, activity in the greatest number of areas and inclusion in the greatest variety of non-health frameworks to date. Policy spans traditional, EU added-value areas such as communicable diseases and action against cancer, second stem free movement areas such as cross border healthcare and healthcare professional migration, and third stem areas such as health expenditure and primary care reform, but is also shaped by initiatives in trade, research, environment and a host of other policy areas. Furthermore, an array of different health policy-making modes and mechanisms are now in day-to-day use, ranging from the community method legislative procedure and intergovernmental agreement to the voluntary OMC and the non-binding recommendations of the European Semester.

## Actors in EU health policy

As health policy has developed, the number of actors involved has increased and academic attention has often turned to examining the impact of these different interests upon health policy outcomes. Essentially, health policy is understood as a ‘public park’, open to access by many actors and consequently at risk of policy being made or constrained by ‘...people who know little, and perhaps care little, about health’ (Greer, 2009a: 3). National governments and the European institutions are broadly understood to be the key players, but they are far from alone in the policy-making arena. Civil society, trade unions, NGOs, national- and EU-level interest groups, industry lobbies, health professionals, patient groups, service providers, social insurers and many others have all invaded the ‘secret garden’ of health policy (Greer, 2009a: 1). Meanwhile, different actors within the national and European institutions have also emerged, sometimes leading to diverging interests within single institutions. Traditionally, Santé, EMPL (DG Employment, Social Affairs and Inclusion) and MARKT (DG Internal Market and Services) were the most common Commission Directorates involved in health, each having their own agenda. Within the institutions, the agency of individual civil servants and officials is also considered by most observers to be of importance, exacerbating issues of poor internal communication, infighting, preferential treatment, overly complex bureaucracy and defence of (supposedly surrendered) national interests, all of which hamper the Commission’s leadership (Greer, 2009a: 12; 26; Lamping, 2005: 20; Randall, 2001: 4; 2002: 18). Further conflict exists between the different committees of the Parliament, between national health ministries and their counterparts in trade, industry and treasury, and between local, regional and international levels of government.

Studies of this complex web of interests and actors emerged alongside the second stem of health policy and the increasing use of the internal market to pursue health objectives.

‘Most single market-related policies, even those relevant to health care, will be initiated by the European Commission’s Directorate General for Internal Market and Services, debated by the member states’ economic or competition ministers at their Council meeting, and in turn examined by the European Parliament’s committees on the internal market or industry, before being forwarded for approval.’ (Mossialos et al., 2010: 16)

The increasing involvement of non-health actors is a core feature of second stem health policy. Greer and Vanhercke (2010: 199) gather the relevant stakeholders into three primary groups, each of which fight to ‘frame’ health policy at the EU level in their own terms. These are the ‘economic’ group, made up of DG MARKT and the internal market jurisprudence of the CJEU, the ‘social’ group, comprised of DG EMPL, the national labour and social affairs ministries and the SPC, and the ‘health’ group, which includes DG Santé and national health ministries. Similarly, Mossialos et al. (2010: 43) label five sets of key players as the ‘public health’, ‘social affairs’, ‘internal market’, ‘enterprise’ and ‘economic’ actors. Since the inclusion of health in the strengthened economic governance framework, a further group, the ‘financial’ group, has entered the health arena. This is comprised of actors from DG ECFIN, national treasuries and macroeconomic advisory bodies, the EPC and, in some cases, the International Monetary Fund (IMF) and the World Bank. In addition to holding different goals and objectives, these actors influence health policy at its most upstream point, defining the financial resources available for use by the ‘traditional’ health policy actors.

## Processes in EU health policy

The literature identifies three defining features of the process by which health policy has emerged and developed at the European level. Firstly, it is understood that the EU's role has expanded via a process of competence creep. Limited by the weak legal basis for health provided in the treaties but aware of the health impact of single market policies, the EU has engaged in a 'treaty-base game' (Rhodes, 1995). Led by the European Commission, this involves stretching the interpretation of explicit health provisions as far as possible whilst 'latching on' to market policies by highlighting the economic element of a health policy proposal to justify action under the single market mandate. Implicit in this strategy is the CJEU, a policy entrepreneur in its own right, which has supported the creative interpretation and gradual expansion of the EU's mandate in health (Burley and Mattli, 1993). This dynamic and its impact upon the evolution of health policy has been described as 'legally-driven neofunctionalism' and 'integration via case law' (Greer, 2006; Steffen et al., 2005: 5).

Secondly, health is understood to be characterised and shaped by a number of interrelated cleavages. At the ideological level, EU health policy is defined by the tension between the market and health priorities of the Union. The creation of a common internal market involves extensive regulation and each piece of legislation adopted for this purpose has an impact upon health. Though the EU is obliged to ensure that its law and policies ensure 'a high level of human health protection' (Article 168(1) TFEU) the trade-off between economic and social imperatives has historically framed the latter as 'market-enabling' and 'market-completing' mechanisms rather than intrinsic goals of the Union in their own right (Lamping, 2005: 21). At a practical level, this tension is enshrined in the 'constitutional asymmetry' which characterises the competences assigned to the EU in the founding treaties (Scharpf, 2002). Whilst a powerful mandate in the creation of the internal market allows the EU to exert significant influence over national economic policy, the weak treaty base ascribed to social protection and equality has meant that integration of the 'economic Union' has moved at a far greater pace than that of the 'social Union'. In health, this constitutional imbalance is mirrored in the division of national responsibility for health service delivery and organisation and the broad EU role in health systems' interaction with people, goods and services (Mossialos and McKee, 2002: 27). This is also reflected at the level of policy integration, where health is defined by a final cleavage between public health – the management of collective health risks – and healthcare – the treatment of individual illness (Steffen et al., 2005: 5). The public health articles of the founding treaties have facilitated an ongoing process of policy-making, establishing a genuine EU policy portfolio. Meanwhile, in the field of healthcare, confrontation between national competence and European law has resulted in a gradual encroachment and patchwork of EU policy and influence.

Finally, health is characterised by the different modes of governance employed to reach its various policy goals. In light of the challenges identified above, health is an area where the EU has had to be particularly creative when designing its governance structure; this has resulted in a diverse range of processes and institutions (Geyer and Lightfoot, 2010; Greer and Vanhercke, 2010; Greer, 2011; Hervey, 2008). Technical agencies such as the European Centre for Disease prevention and Control (ECDC), the EFSA and the EMA offer independent expertise, whilst bodies such as the senior level working party on public health (SLWPPH) and the expert group on effective ways of investing in health provide central leadership and advice. Hard legislation, constructed and adopted via the traditional

‘community method’ of Commission initiative, provides concrete parameters for EU and member state action whilst the various platforms and forums of the OMC bring together a plethora of interest groups and stakeholders to ‘flesh out’ the legislative framework with non-binding policy commitments. The contrast between hard and soft law results in further variation in the flexibility of implementation, with CJEU enforcement playing an important role in binding policy fields and peer review, benchmarking and ‘naming and shaming’ influencing implementation where national action is voluntary.

These commonly identified and understood characteristics have resulted in a narrative of EU health policy which emphasises contradiction and imbalance. Where the legal mandate is strong, hard law and central control have dominated the governance structure; where it is weak, soft law and flexible governance have come to the fore. With the strengthening of the economic governance framework and the inclusion of health in macroeconomic policy-making, these narratives have been challenged – the line between hard and soft law has been further blurred and the distinction between technical and political health issues is addressed differently. Both the actors and the processes have changed, shifting the focus and direction of contemporary health policy.

### **The EU health policy bell-curve**

Triangulating the description gathered from the literature with accounts from interviewees, the narrative of health policy can be expressed as a bell-curve. From small beginnings, momentum began to build through the 1990s and early 2000s, drawing on the internal market mandate, support from the Court and various crisis opportunities to gradually amass a body of law and policy which increasingly impacts upon national health systems. The peak of this integrative momentum is understood to have been reached with the adoption of the Cross Border Healthcare Directive in 2010 – though the body of the Directive addresses a relatively small and distinct set of circumstances, its impact was significantly amplified by the Commission’s capacity to include supplementary provisions. The final text provides for new EU activity in eHealth, HTA and the establishment of reference networks for coordinating expertise in specific disease areas, as well as the strict application of free movement principles in healthcare service delivery. This degree of expansionism in the Directive is largely unprecedented, marking the ‘high water’ point of EU health policy influence and integration.

Essentially, the rest of the thesis explores the evolution and potential projection of this bell-curve. How did its rise, peak and fall come about? What impact has the emergence of the third stem had on the direction, strength, relevance and content of EU health policy? The legal and political potency of macroeconomic governance could lend much-needed weight to health policy initiatives but, if not designed with this in mind, might otherwise undermine health policy efforts and exacerbate the constitutional asymmetry. The potential for a ‘second peak’ and a re-drawing of the bell-curve certainly exists; the thesis’ conclusion draws on the theory, literature and historical understanding of health policy to explore its likely trajectory in the post-crisis era.

# PART II

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The previous five chapters have laid out the research problem, its context within the broader EU and health policy debates and the tools available for addressing the questions it raises. They have identified the prevailing narrative of EU health policy, characterised by gradual expansion and creative ‘muddling through’ in the face of fundamental disjuncture, and the challenge posed to this narrative by the recent evolutions in the EU’s economic governance framework. Part I has thus clarified the aim of thesis – to explore the changing governance of health in the EU with a view to understanding the potential governance models which might come to dominate in the post-crisis era.

Using the hypotheses and typology identified for this purpose in chapter three, the next section of the thesis tests the research questions by mapping the governance modes at various points and in specific instances of EU health policy development. Six case studies, covering EU policy in blood, tissues and organs, cancer prevention, medicines information to patients, tobacco control, patient mobility and health in macroeconomic governance, are presented. As noted in the methodology, each of the case studies exhibits a particularly unique or illustrative feature of EU health policy and, collectively, they provide examples spanning the lifetime of health as an EU policy issue. The specific cross-cutting features of interest – the role of regulatory policy and crisis, the use of soft law, the impact of the internal market, the use of comitology and ‘innovative’ governance models, and the role of the Court – are highlighted and further explored as horizontal themes of each case study. Each chapter ends with a table, used to inform the analysis, summarising the key health policy dynamics seen in the particular case study.

The final case study, which looks at the inclusion of health in the economic governance framework, is longer than the others to give space for a comprehensive review of this latest chapter of health policy. It charts the onset of the financial crisis, the resulting strengthening of the economic governance framework and the inclusion of health within its new structures. Part III brings together the findings from these case studies and considers the research questions posed in the introduction.

## REGULATORY POLICY AND CRISIS POLITICS

### *The case of blood, tissue and organ policy*

Policy in blood, tissues and organs (BTO) intended for transfusion or transplant in humans is a small but central strand of the EU's public health policy. It is not the oldest area of EU activity, nor is it commonly lauded as a ground-breaking or innovative instance of EU policy-making. Yet from initial action to ensure the quality and safety of Europe's blood supply in the late 1990s, legislation has been introduced across other materials of human origin, accompanied by technical directives and action plans which together provide a comprehensive regulatory framework. It is a case which embodies a particular set of health policy characteristics – prompted by crisis and constructed primarily of hard law instruments via the community method of policy-making, it has developed along broadly neofunctional lines but without a role for the Court, the creation of extensive EU bodies or significant influence from market forces. As such, it provides an example of decision-making and governance in an area of almost 'pure' public health policy, where clear EU-added value and the separation of sensitive from technical issues has allowed the development of framework regulation and hard law.

### **What is meant by blood, tissue and organ policy?**

As the title suggests, blood, tissue and organ policy is made up of three strands of legislation and activity concerning blood and blood components for transfusion, human tissues and cells and human organs for transplantation. In each case, EU policy targets safety and quality, focusing on prevention of disease transmission, via a range of regulatory procedures for donor selection, collection, testing, storage, distribution, production of relevant medical device components and processing of the particular material. Within the context of the EU's public health activity, BTO policy is included under the 'health security' strand, along with preparedness and response to serious health threats and policy to combat the threat to health from climate change. This positioning reflects its emphasis on risk management and health protection.

### **The historical evolution of EU policy on blood, tissues and organs**

The evolution of BTO policy is quite linear. Following the adoption of a directive on blood and blood components in 2003 a similar directive was adopted for human tissues and cells in 2004 and, after a brief pause, for human organs for transplantation in 2010. The legislative paths of these framework directives were very similar, constructed using the community method of policy-making and later supplemented with a number of technical and implementing directives. They can also all be attributed to the same catalyst – the blood contamination crises which affected countries around the world during the late 1980s and early 1990s. These resulted in widespread distrust of national safeguards and procedures and, in Europe, prompted the creation of a supranational regulatory framework. The impact of these crises as well as the evolution of the policy which followed them is examined below.

## Blood contamination crises and public trust

In the early 1980s it became apparent that HIV, at this time a little-understood virus which over time results in a collection of symptoms known as AIDS, was being transmitted via blood products. Recent medical advancements had allowed for the production of a clotting agent, Factor VIII, for use in the treatment of haemophilia. In the prevailing manufacturing process, blood components from many donors were pooled and used to make Factor VIII concentrate, injected by haemophiliacs to aid the clotting of their own blood. At this time, however, there was no test for HIV and thus no way to determine whether an individual donor was carrying the infection. Contamination crises soon emerged in several countries, mostly affecting haemophiliacs and those in receipt of regular blood transfusions.

The market for blood products during this period was severely unbalanced. Demand in Europe outstripped supply and as a result European governments became the biggest customers of commercial ‘fractionators’ – manufacturers of blood products – which sourced products primarily from paid American donors (Farrell, 2005: 138). A wealth of research has subsequently been conducted to show that the quality and safety of blood collected commercially is significantly lower than that of blood collected from voluntary, unpaid donations and linking the use of commercial blood supplies to an exacerbation of the contamination crises (Farrell, 2012; Healy, 2000; Hunt and Wallace, 2005; Keown, 1997). It is this debate which has been at the centre of the development of the regulatory framework at EU level.

The French case was particularly destructive in terms of public trust in the healthcare system; haemophiliacs and transfusion recipients continued to receive contaminated blood for two years after officials first gained knowledge of the risks and by the early 1990s, half of all French haemophiliacs were infected with HIV (Bergeron and Nathanson, 2012: 9).. The hierarchical structure of its public administration, the strength of its executive and the faith put in those responsible for protecting the public’s health was such that the scandal shook the foundations of the French health system as a whole and prompted the authorities to review the way in which it approached public health (Steffen, 1999: 96). One account of the period concludes:

‘Whatever may have been the long-term effect on the public at large, the impact on France’s political class was, indeed, of earthquake proportions: innumerable administrative and parliamentary reports testified to the government’s loss of credibility and the public’s loss of trust, and demanded immediate action to “cure” what was diagnosed as a broken public health system. Although the broken-system critique initially focused on the blood system, it rapidly spread to encompass the entire organization of public health in France.’ (Bergeron and Nathanson, 2012: 10)

By the late 1980s, contamination crises had been uncovered in Canada, China, France, Iran, Iraq, Ireland, Italy, Japan and Portugal. Across Europe, trust in the blood supply and confidence in its public regulation was virtually destroyed (Bennett et al., 2011: 269). Seeking to shift this burden and regain some credibility and legitimacy in this most sensitive of public health issues, member states chose to delegate governance to the supranational level (Farrell, 2005: 135).

## **EU policy in blood and blood components for transfusion**

EU policy relating to the blood supply was borne out of the coinciding of the contamination crises and the revived implementation of the single market (Farrell, 2005: 134). The EU adopted a Council Directive on plasma products in 1989 and this was subsequently incorporated into an updated and expanded EU-wide regulatory system for pharmaceuticals. In the early 1990s the differences between national standards of quality, inspection and accreditation, as well as procedures for collection, storage and distribution of blood products, were considerable, making exchange of products and fulfilment of the Community's goal of self-sufficiency difficult (Farrell, 2005). Furthermore, the increasingly global nature of the blood market, in which products were coming from all over the world and risks were inherent at all stages of the supply chain, meant that a common system of regulation seemed to present the safest approach (Adamides and Maniatis, 2001). With the emergence of the blood contamination scandals, the European Parliament and the CoEU passed a series of resolutions calling on the EU to take action and when the Amsterdam Treaty came into force in 1999 it provided a specific competence in the quality and safety of blood products (Article 152(4)(a)).

Utilising its new mandate, the Commission published a proposal for a directive setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (European Commission, 2000). Negotiations on the proposed 'Blood Directive' took over two years to resolve and focused on the preferred procedure for sourcing blood products – paid donation or voluntary, unpaid donation (Farrell, 2012: 464). In the end, the Recital acknowledged the higher levels of safety achieved with voluntary, unpaid donations but the substance of the text required only that member states encourage this method of collection (Farrell, 2012: 465). The Directive was adopted in 2003 and establishes a regulatory framework for each step of the transfusion chain (Hunt and Wallace, 2005: 428). A series of Commission directives and implementing directives has since been issued, revising and supplementing various technical provisions and updating these in response to new health threats, such as the Influenza A (H1N1) pandemic.

## **EU policy in human tissues, cells and organs for transplantation**

Remarkably similar 'legislative stories' can be told in EU policy relating to human tissues and cells, and human organs for transplantation. In the case of tissues a Commission communication, proposing a directive, was published in 2002 (European Commission, 2002). Following amendment by the legislature and the agreement of a common position in 2003 – wherein subsidiarity was again invoked to quell ethical concerns (Kent et al., 2006: 50) – the Directive setting standards for quality and safety in human tissues and cells was adopted in 2004. Since then, a number of Commission directives and decisions have been issued on technical aspects of the policy, such as traceability requirements, adverse reaction reporting and coding of tissues and cells. In the case of organs, a slightly different approach was taken. The catalyst communication from the Commission was accompanied by a series of 'policy actions at EU level' and, following conclusions and a resolution from the legislature, the proposal for a directive was published alongside an Action Plan on organ donation and transplantation (European Commission, 2007b; Council of the EU, 2007; European Parliament, 2008b; European Commission, 2008a). This meant that, as well as the usual implementing directives, the adoption of the 2010 Directive on quality and safety standards

for organs has been followed by council conclusions and a mid-term review of the Action Plan's performance (Council of the EU, 2012; European Commission, 2014a).

## **The integration and Europeanisation of blood, tissue and organ policy**

The sectoral integration of policy on standard-setting for the quality and safety of BTO products is clearly seen in the adoption of the three binding directives. In line with the neofunctional pattern, the contamination crises served as a catalyst for EU action and, in demonstrating the added value of collectively regulating quality and safety issues, prompted spillover into the realms of tissues, cells and organs. As with most policy areas, a level of intergovernmental influence can also be seen. There was a clear choice and political benefit to member states in delegating responsibility to the European level – with confidence in public health systems severely damaged and ongoing dispute about political liability for patient safety, member states engaged in a process of 'burden-shifting', moving responsibility for a sensitive issue to the EU level so as to repair national-level credibility and legitimacy (Farrell, 2005: 135).

With this shift came the establishment and growth of a body of European-level interest groups and epistemic communities. Groups such as the Thalassaemia International Federation and the European Haemophilia Consortium emerged to bring European and international patient organisations together whilst others, such as the European Haemovigilance Network, were established to assist in the implementation of the Blood Directive (Busby et al., 2014: 84). Since 2003, the EU has funded more than 50 projects in the area of transplantation and transfusion and the European Group on Ethics in Science and New Technologies (EGE), originally set up in 1991 to advise on bioethics policy in light of discord over the commercialisation of BTO products, remains one of the central advice committees used by the European institutions (European Commission, 2013: 4; Mohr et al., 2012).

In terms of Europeanisation dynamics, the Directives clearly constrain national policy options in some areas but the ethical debates raised by BTO regulation did not result in the establishment of a European norm. Instead, they were addressed by recourse to subsidiarity and minimum standards. This raises the potential for an unintended Europeanisation effect in that, whilst minimum regulatory standards do not render higher standards unlawful, they may lend justification to the less desirable approach.

‘...the acceptance of these measures and their promulgation in EU-level legal norms may have a destabilizing effect on principles or values in particular Member States...although the Blood Safety Directive mandates unpaid blood donations ‘as far as possible’, it implies that payment for blood donations may be lawful within the EU, a principle that is fundamentally at odds with health care law in Member States such as France’ (Hervey, 2007: 2).

In the creation of minimum standards, a process of uploading can be seen, whilst systems which lag behind commonly engage in downloading of such norms and adjust their structures to accommodate this. Furthermore, higher processes of Europeanisation might be seen in the similarity of the legislative cycle which each successive directive went through – following the precedent set by the Blood Directive, almost identical legislative steps were taken and outcomes reached in tissues and organs policy.

BTO policy has seen a significant degree of integration and the European level is now recognised and accepted as both the *de facto* and the *de jure* locus of activity concerning the quality and safety of BTO products. Threats raised by the H1N1 pandemic and the West Nile Virus were both dealt with, at least in part, within the BTO policy framework. Similarly, the expertise harboured at the ECDC was enlisted during blood safety-related outbreaks in Italy, where chikungunya broke out in 2007, and in the Netherlands during its outbreak of Q Fever in the late 2000s (Bennett et al., 2011: 269). Europeanisation can be seen in the wake of integration, as member states adapt to this transfer of responsibility and adjust their organisational logics according to the binding directives issued by the EU legislature.

## **The governance of blood, tissue and organ policy**

The EU uses a relatively small range of policy instruments in its governance of BTO policy. The backbone of the regulatory framework is formed by the three Directives and these are supplemented and made operational by a number of technical directives and decisions from the Commission. The Directives were often preceded by soft law instruments, such as Council conclusions or European Parliament Resolutions. More recently, in the expansion into organ policy, a non-binding Action Plan forms part of the governance framework. The instruments used are thus mainly hard law, with support and supplementary content offered in softer tools. This choice of instruments reflects the acknowledged EU-added value of centralised regulation and the political will behind the creation of EU policy in this area, prompted by the contamination crises. Meanwhile, the conclusions and resolutions of the legislature can be understood as statements of preferred direction, made in advance of the Commission's proposals to guide their content. The stability of these factors across the three issue areas has resulted in logical expansion from blood into tissue and organ policy, and facilitated policy development along similar lines.

Using the typology by Trieb et al. (2005), the dominant mode of governance employed in BTO policy can thus be characterised as framework regulation. Though the adoption of binding law indicates a ceding of national responsibility, the use of directives rather than regulations puts a limit on the influence of the EU, leaving it up to member states to decide the method of implementation. Some rigidity is introduced via the adoption of technical directives, which provide more detailed guidance on the implementation of certain provisions but, as a whole, BTO policy allows for considerable national flexibility.

The latitude granted is particularly wide for ethical issues, where divergences in cultural approach have presented an insurmountable roadblock to integration, weathered only by recourse to subsidiarity. Moreover, the introduction of the 'softer' Action Plan to support the Organ Directive indicates a possible shift in the balance between hard and soft law. It suggests that the parameters of the EU's mandate may have been reached and that coordination in areas outside of quality and safety standards – such as sources of supply, organ trafficking and broader public awareness – will have to be dealt with using non-binding legal instruments. The Action Plan itself has elements of both voluntarism, in its creation of space for discussion and sharing of policy experience, and targeting, in its identification of specific priority actions. Its mid-term review, an opportunity to encourage more rigid implementation, did not single out poorly performing countries or benchmark member states against each other, suggesting that governance of those issues going beyond quality and safety will remain flexible.

The clearly observed division between the political and the technical elements of BTO policy and the institutionalisation of this division into the policy framework is one of its unique features. The commercial management of BTO products is exceptionally sensitive, pertaining to cultural, social, religious and ethical norms, and the divergence in accepted practices across member states is significant (Busby et al., 2014: 85). As such, it presents a political challenge for EU policy-makers and the frame in which the issue is presented is crucial to determining the parameters of the resulting policy (Farrell, 2012: 468). In her discussion of the Blood Directive, Farrell (2012: 473) concludes that the strategy used and resulting outcome ‘...call[s] into question the general assertions made by the Commission to date about the neutral and technocratic way in which regulation can be used to manage the relationship between risk and innovation’. The approach taken by EU policy-makers was to separate the technical from the political as far as possible; once the debates had been played out and the Directive adopted, the sourcing of blood products was essentially reclassified as a technical issue, enabling further standard-setting within the relevant institutional structures, ‘...far removed from the politics of the Blood Directive’ (Hunt and Wallace, 2005: 435). This practice is common throughout health and wider EU policy-making and involves ‘salami-slicing’ issues into their technical and political components so as to separate sensitive elements from the body of technical, de-politicised policy (*EU Public Affairs Consultant A; European Commission, Health Directorate C*). In the BTO case the areas where political agreement could not be reached, such as the requirement for voluntary, unpaid donation, have been identified and addressed via the subsidiarity principle or, latterly, by use of soft law instruments. The tools used in these more sensitive areas mirror those seen in cancer policy, employing common objectives, agreed indicators, regular benchmarking and identification of best practice, whilst the technical facets of the policy continue to be governed by framework regulation (Canoy et al., 2010: 394). In the case of tissues and cells, Hoeyer (2010) describes the Directive as ‘highly technical’ and devised without political debate despite its significant implications for patients and health systems. He identifies a strategy on the part of the EU institutions, surmising that ‘When regulatory efforts relating to public health and safety are presented as technical matters they rarely cause political or public controversy’ (Hoeyer, 2010: 1873).

A technical framing of BTO issues is also evident in the significant degree of autonomy granted to the Commission via the adoption of technical directives. The tasks assigned to the executive align with Rosamond’s depiction of ‘low politics’, since they pertain to ‘matters of the satisfaction of welfare and material needs’ and are delegated for functional, rational reasons (2000: 57; *European Commission, Health Directorate A*). This element of the policy is also highly technocratic, relying on bodies of experts, such as the EGE, and is necessary for the proper functioning of a governing institution such as the EU (*EU Public Affairs Consultant A*). As such, it is a relatively typical case of regulatory policy – this also reflects the understanding of BTO policy as an example of the type of health issue which is now grouped under the EU’s public health policy, in stem one, but was in fact originally rooted in the internal market and the need for common safety requirements (*European Commission, Health Directorate A; E*).

A final element which has shaped governance in BTO policy is crisis politics. BTO policy is an area founded almost solely on the politics of crisis response – the explicit legal mandate provided in the Amsterdam Treaty was created as a direct result of the contamination crises and perceived threats to the security and legitimacy of national regulation. It is an example of

a policy issue in which consensus around the nature of the problem and the need for an EU response was gained, and the urgency of this response was agreed, thus fulfilling the central conditions for the adoption of hard law (*European Commission, Health Directorate A*). Such political will and legal competence enabled the EU to govern with binding instruments, to delegate significant autonomy to the Commission and to frame the issue as an instance of technical, regulatory policy-making.

## Horizontal themes in EU health policy: Regulatory policy and crisis politics

The BTO case highlights two important dynamics which shape EU health policy – regulatory policy-making and crisis politics<sup>2</sup>. The EU is fundamentally a regulatory state, since it lacks the competence and financial resources necessary to exercise the distributive and redistributive functions of a nation state and so relies on governance-by-regulation (Majone, 1996; Radaelli, 1999). Its exclusive powers over the functioning of the internal market, supported by expansive interpretation by the CJEU and the doctrine of legal supremacy, have facilitated rapid regulatory growth (Thatcher, 2006: 312). The same dynamics mean that the majority of EU activity in health is regulatory; it does not act as a service provider but regulates the activity of other health actors (Lamping and Steffen, 2005a: 189).

Regulation is broadly defined as state control over activity valued by the community and can be pursued via formal legislative rules as well as informal norms and ‘soft’ regulatory influence (Thatcher, 2006: 312). EU action was initially of a deregulatory nature, involving the removal of first tariff and then non-tariff barriers to trade, understood as negative integration (Hix and Høyland, 2011: 192). Deregulatory policy has the advantage of relocating the process of integration from the political arena to the technical/judicial one, focusing on product standards in pharmaceuticals, medical devices, BTO products, tobacco products, food produce and many other areas (Hervey and McHale, 2004: 45). Though it has been used with great success to extend EU activity in health, it also has the potential to make national laws protecting health unlawful, such as those banning certain additives in food stuffs, or imposing a minimum unit price on alcohol (Permanand and Mossialos, 2005: 55; Hervey and McHale, 2004: 46). As the single market project accelerated, EU activity became more re-regulatory, creating minimum standards and common competition rules in a process of positive integration. One of the earliest examples of positive integration in health is the pharmaceutical case – the manufacturing, marketing and sale of pharmaceuticals was progressively harmonised, culminating in the Commission’s nine-volume publication ‘The rules governing medicinal products within the European Union’ (Hervey and McHale, 2004: 49). In health, however, *process* regulation is less common; health actors and policy-makers ‘...know and understand the value of an EU-centred *product* standard for a pharmaceutical drug, for instance, because it stops patients dying...but they don’t attach the same value to coordination in services or systems organisation’ (*UK health association, EU Liaison B*).

Regulatory policy-making has a number of specific characteristics which shape the kind of health policy it produces. Firstly, the regulatory discretion given to the European Commission has enabled it to act as a policy entrepreneur, driving forward the expansion of the EU regulatory state (Majone, 1996). The activism of the Commission, as well as interest groups and the Court, is crucial in the neofunctional model of regulatory growth whereas, by contrast,

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<sup>2</sup> This section is used as the basis for Brooks (2015).

the intergovernmental model emphasises member states' decision to delegate and their acceptance of EU regulation in areas of environmental, competition and social policy (Thatcher, 2006: 315-316; Rhodes, 1995). Both drivers can be seen in health policy, with member states choosing to delegate power in the wake of crises such as the blood contamination scandal and the Commission pushing forward regulation of pharmaceuticals and medical devices.

Another important feature of regulatory policy is its requirement of expertise. Regulatory policy requires little budget but must be founded on a thorough knowledge of the market and subjects to be regulated (Radaelli, 1999: 6). This is made even more important by the speed at which technology and policy options advance (Majone, 1993: 165). The expansion of the 'EU regulatory state' has thus been accompanied by a proliferation of agencies and bodies which advise policy-makers on the technical aspects of policy. In health, the EMA, the ECDC, the EFSA, the SLWPPH and various other bodies play a central role in informing and implementing policy, particularly in 'risk-related sectors' such as medicines, food safety and disease prevention (Kim, 2014: 2; Versluis et al., 2011). Such policy thus elevates the role of epistemic communities and technocratic governance (Richardson, 2006: 6).

Contemporary EU studies is generally agreed that regulatory policy was the motor behind early integration but that its relevance is now declining (Young, 2015: 132; Wallace and Reh, 2015: 104). This trend is attributed to the rise of Euroscepticism and resistance to further integration, the weakening position of the Commission and the increasing use of alternative policy types, such as redistribution through the European Social Fund (ESF) and voluntary coordination through the OMC (Falkner, 2010: 284; Richardson, 2006: 7). As the integration of product standards reaches its limit, the EU has turned to less hierarchical and more decentralised modes of governance to tackle process, services and utilities standards (Wallace and Reh, 2015: 104). However, one circumstance where regulatory policy continues to be the default response is that created by a crisis. In health, crisis situations have periodically destabilised the status quo and altered the shape or direction of the policy area. The thalidomide tragedy in the 1960s led to the creation of a common regulatory framework for pharmaceuticals and the establishment of the EMA, the HIV/AIDS contamination scandal in the 1980s prompted the introduction of new health powers in the Amsterdam Treaty, the BSE crisis in the early 1990s resulted in the creation of the EFSA, the 2003 SARS (Severe Acute Respiratory Syndrome) pandemic led to the establishment of the ECDC and, most recently, the 2010 PIP breast implant scandal has triggered a revision of the regulatory framework for medical devices. Crisis politics are thus considered by most to be an important driver of the evolution of EU health policy competences (Hervey and McHale, 2004: 78; Lamping, 2005: 23; McKee et al., 2004b: 12; Randall, 2002: 9).

The eruption of a crisis opens a window of political opportunity (Nohrstedt, 2008). It increases the political will behind the search for a solution and makes it easier to achieve consensus on a common response, whilst the element of urgency reduces the time made available for debate and obstruction (Boin et al., 2009). In health these factors are amplified by the presence of fear – this is easily generated around issues such as communicable disease and has historically proven a powerful tool for shifting both public opinion and political commitment (*World Health Organization A; UK health association, EU Liaison B*). As a result the introduction of hard law, the creation of new EU competences and the transfer of autonomy are made far easier when undertaken as instances of crisis response. Political commitment to health is not solely witnessed during times of crisis – commitment to

addressing key health concerns has been critical in the creation of EU policy on cancer and patient safety, for example, via the Presidency of the Council – but it is a less reliable driver when crisis politics are not in play (Greer et al., 2014: 35). This power is reflected in the degree of integration and competence transfer experienced in areas such as HIV/AIDS and BSE, as compared to tobacco, alcohol and nutrition policy. Smoking-related disease, alcohol abuse and obesity pose three of the greatest threats to health and health systems but have achieved only marginal centralised policy response when compared to communicable disease control and food safety regulation (Lamping and Steffen, 2005a: 189). This issue exists, according to Leibfried (2010: 279), because the social policy-making capacities of the EU have not been strengthened nearly as much as the capacities of member states have declined; such a stalemate is likely only to be broken through further crisis.

The economic crisis which has enveloped the EU in recent years presents a different kind of opportunity – it is not a traditional crisis of public safety and is thus unlikely to prompt a revival of regulatory policy, except perhaps in the governance of financial markets (Wallace and Reh, 2015: 104). However, it has manifested in a social and health crisis which has prompted calls for greater social and health policy action at European level. It remains to be seen whether policy-makers will respond by recourse to market measures or work to strengthen social policy and integration.

**Figure 6: Summary of health policy dynamics, case study one**

<b>Health policy dynamic</b>	<b>BTO policy</b>
<b>Catalyst and driver</b>	Blood contamination crisis Mandate from member states Driven by Commission/spillover High macro-sectoral & vertical integration
<b>Actors, interests and politicisation</b>	Public health actors, some market Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down & indirect Europeanisation
<b>Policy type and instruments</b>	Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy
<b>Governance mode</b>	Framework regulation (safety) Voluntarism (ethics)

## GOVERNING WITH SOFT LAW

### *The case of cancer prevention policy*

Cancer is one of the oldest areas of EU activity in health. As a case study, it is of particular interest on account of its non-binding nature – it has developed almost entirely, discounting legislative action in tobacco control, via soft law mechanisms and is commonly regarded as one the EU's health policy success stories. An area of clear EU added-value, it received early political support without extensive lobbying or interest group contention, with leading roles being played by individual Council Presidencies and MEPs, as well as technocratic actors from the national and the EU level. Even more so than the BTO policy case, it is characterised as a public health policy, in that it has relatively little connection to the internal market and enjoys a stable legal basis in the public health articles of the founding treaties. It is thus characterised by governance via voluntarism and targeting, enjoying sufficient political will and perceived EU-added value to facilitate a soft law approach.

### **What is meant by EU cancer prevention policy?**

Following from this description, a distinction should be made between the public health stem of cancer policy and the internal market stem of tobacco control policy. The latter has formed a central strand of the former from the outset but can be understood as a separate policy in that it inhabits a different kind of policy space – highly political and subject to the critical cleavage between public health and internal market objectives, tobacco control policy concerns the composition, presentation and sale of tobacco products and is dealt with as a case study in its own right in chapter nine. This chapter, by contrast, explores the development of the 'health promotion' element of cancer policy, covering the creation of the EAC programme and its successors and focusing on EU activity in cancer prevention, screening and early diagnosis, research and data collection, treatment and healthcare professional training.

### **The historical evolution of cancer prevention policy in the EU**

EU activity in cancer policy can be grouped into three periods: the rise of cancer up the EU agenda during the 1987-2002 EAC programme, the absorption and relative weakening of cancer policy under the PHAPs between 2002 and 2007, and the revival of cancer policy, as prompted by the Council and the Parliament and embodied in the 2009-2013 European Partnership for Action Against Cancer (EPAAC).

### **The Europe Against Cancer programme**

At the Milan Summit in June 1985 European Heads of State discussed a report titled 'A People's Europe' which contained a series of measures to better involve citizens in the development of the (then) European Communities. In highlighting one initiative of particular value, the Council pledged its support for the launch of a European action programme against cancer (European Council, 1985: 7). Following the recommendation of the Milan Council, the advice of influential cancer experts, and by way of response to the explosion at the Chernobyl power station, the Council established the EAC programme in 1986 and designated 1989 as the European Cancer Information Year (Gilmore and McKee, 2004: 224; Trubek et al., 2008: 814). The first phase of the EAC ran from 1987 to 1989 and covered prevention, early screening and treatment of cancer, as embodied in the first edition of the European Code Against Cancer (ECAC) (IARC, 2015). It convened a series of advisory committees on

medical, nursing and dental training, which adopted recommendations on how cancer should be taught to the various healthcare professions, and established the European Cancer Registry (Eurocare) project, still running today, which collates data from registries across Europe to provide information on survival rates, prevalence and patterns of care (European Commission, 1989). The EAC thus played a crucial role in raising the profile of health policy at a time when support for the EU project was wavering (*World Health Organization A; European Commission, Health Directorate D*).

Its second phase saw cancer policy become an ongoing part of EU activity in health and be institutionalised within the relevant administrative and legislative structures (Council Decision 90/238/EEC; Hervey and McHale, 2004: 369). The structure and content of the programme were left largely unchanged, but greater emphasis was put upon the tobacco control element of cancer prevention, with initiatives to target particular vulnerable groups, such as young women (Hervey and McHale, 2004: 370). By 1992, changes were afoot – the cancer unit was moved within the Commission’s public health unit in DG Social Affairs (now DG EMPL), constraining its relative independence and prompting several of its senior staff to leave (Trubek et al., 2008: 815). With the public health mandate in the Maastricht Treaty the third phase of the EAC was restructured, with four strands focussing on data collection and research, information and health education, early detection and screening, and training and quality control (Decision 646/96/EC). However, this was the last EAC-specific funding to be provided – from 2002 the EU’s cancer policy was subsumed into the PHAPs, the first running from 2003 to 2008.

### **Cancer policy under the Health Programmes**

With the establishment of the EU’s public health mandate and the launch of the new PHAPs, cancer became ‘only one part of a much larger set of activities’ and a sub-set of the politically-directed nascent EU health policy, thus suffering from deficient long-term planning and commitment (Gilmore and McKee, 2004: 227; Sullivan, 2007: 2). There were fewer specific priorities, targets and assessments, existing projects were renamed and valuable connections with external partners were cut (*European Commission, Health Directorate D*). Having previously enjoyed relative independence and direct access to Heads of State, the EAC lost its earmarked funding and financial support was withdrawn from a number of other cancer programme and projects, including the European Network of Cancer Registries (ENCR) – responding to these drastic cuts, the European Cancer Patient Coalition (ECPC) was formed in 2003 (Trubek et al., 2008: 826; 833). In justifying its decisions the Commission stated that it wanted to extend the successful model used in cancer policy to other areas, requiring the diversion funding, and noted that in light of the many years of dedicated funding cancer policy had received, it should now be able to continue with support from the member states (Trubek et al., 2008: 827). However, national governments rejected this idea and, as described in the next section, were instrumental in reviving cancer policy as a European initiative.

The period from 2002 to 2007 was not entirely without progress or achievement in the fight against cancer. In 2003 the Council published its first recommendation on cancer screening – these recommendations have been continuously revised and supplemented and, though some disparities in implementation remain, EU-level guidelines now exist for the screening of breast, cervical and colorectal cancer and have been endorsed by the WHO (Anttila et al., 2009; Arbyn et al., 2010; Perry et al., 2008). Furthermore, 2005 saw the launch of the

EUROCAN+ Plus project, with the goal of exploring how best to coordinate cancer research in Europe, and the Eurocadet project, which examined the impact of various prevention policies on cancer incidence across the EU. However, activity lacked coherent central leadership and as a result struggled to access funding and resources as successfully as it had in the past (Sullivan, 2007: 3).

### **The revival of cancer policy and the EPAAC**

The revival of cancer as a core area of EU activity was prompted by a confluence of events. The new public health mandate, the growing importance and scope of EU health policy in general, the accession of new member states whose health systems were substantially weaker than those of the EU15<sup>3</sup>, the launch of a dedicated group on cancer issues within the European Parliament, the rise of patient organisations such as the ECPC and the efforts of individual Presidencies of the Council all played a significant role (Trubek et al., 2008: 828). From the mid-2000s the Parliament, latterly led by a group of 44 MEPs under the banner ‘MEPs Against Cancer’ (MAC), pushed cancer policy up the agenda, passing resolutions on breast cancer and ‘combatting cancer in an enlarged EU’ (Andrejevs et al., 2009: 21; European Parliament 2003; 2006; 2008a). Furthermore, between January 2007 and June 2008, the German, Portuguese and Slovenian Presidencies of the Council collaborated on a health policy programme emphasising cancer control. At a high level roundtable in Lisbon, a set of recommendations to inform EU cancer policy was developed and in 2008, the Slovenian Presidency made cancer a main priority and established a new umbrella for action at the EU level, known as FACT (Fighting Against Cancer Today) (Gouveia et al., 2008: 1461). An international collaboration co-funded by the Commission and the Slovenian government, the platform was credited with accelerating and improving Slovenia’s own, as well as a number of other, national cancer plans and is considered one of the most successful projects run by the Commission (Alexe et al., 2008; European Commission, 2012c).

Finally, the work done under FACT led to the establishment of the EPAAC, which ran from 2009 to 2013 and bore many similarities to the original EAC programmes, setting a short-term objective for all member states to have national cancer plans by the end of the Partnership and a long-term goal of reducing cancer incidence by 15 per cent by 2020. It harnessed the provisions of the Cross Border Healthcare Directive relating to reference networks and collaboration, and its final report concluded, similarly to evaluations of the EAC programme, that whilst it had not fully achieved its goal it had made a valuable and significant contribution to furthering member state strategies in the fight against cancer (Ringborg et al., 2008; Boyle et al., 2003: 1322; European Commission, 2014b). In 2014, the EPAAC was replaced by a three year Joint Action on Cancer Control (CANCON), aimed at developing guidelines on quality improvement in cancer care, and the Commission created the Expert Group on Cancer Control, to support and coordinate the exchange of best practice between member states.

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<sup>3</sup> EU15 is the term used by the OECD (2015b) to denote the membership of the EU prior to the 2004 expansion. It includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.

## The integration and Europeanisation of cancer prevention policy

The most significant feature of EU cancer policy is its non-regulatory nature. In contrast to the BTO policy case, it is comprised almost entirely of soft law. Whilst this does not preclude integration or Europeanisation, it implies different forms of these processes.

Little sovereignty or authority has been ceded in cancer policy, even with the introduction of the public health mandate in the Maastricht Treaty. Member states have played the driving role, putting cancer policy on the agenda in the mid-1980s and prompting periodic revivals of activity via Presidency priority-setting (Gouveia et al., 2008; McKee et al., 2010). They have also imposed limits on the far-reaching goals of the European Parliament (*Member of European Parliament A*). Integration has not been entirely intergovernmental, however. Both the European Parliament and the Commission have played central roles and evidence of cultivated spillover can be seen in the proliferation of guidelines to cover different forms of cancer, elements of treatment and the more recent extension from a public health to a ‘quality of care’ agenda (Vollaard et al., 2013). A large and strong group of EU-level cancer organisations has developed, with NGOs such as the European Cancer Leagues (ECL) and the ECPC exploiting gaps in the information network to become key players in the policy-making process (Gilmore and McKee, 2004). In fact, so many European bodies have emerged that, when added to the network of member state actors, the resulting discussions have been described as a ‘Tower of Babel’ (Sullivan, 2007: 3). It remains the case that the EU level does not possess or demand jurisdiction in cancer policy; member states retain responsibility for the design and delivery of national programmes, as well as providing by far the majority of funding (Jungbluth et al., 2007: 15). With the onset of the economic crisis, this control has been reasserted in the cutting of budgets for cancer policy in many member states, highlighting one of the core weaknesses of soft law (Aggarwal et al., 2014: 3). Using the typology by Schimmelfennig and Rittberger (2006) cancer prevention can be described as a policy area of high sectoral integration, meaning that the EU engages in activity in almost every aspect of cancer prevention policy, but almost negligible vertical integration, since no binding transfer of domestic competences has taken place. Thus, a form of quasi-integration might be identified, characterised by a high level of coordination founded on non-regulatory instruments.

Once this distinct form of integration has been acknowledged, a variety of Europeanisation dynamics can be identified. First and foremost, national policy content clearly reflects that designed at the EU level. The recommendations on training of healthcare professionals, the guidelines on cancer screening programmes, the ECAC and benchmarking via the ENCR are all key examples of instruments which have at least contributed to, if not provided the framework for, national policies (Arbyn et al., 2010; Virgo et al., 2013: 2194). This is not to say that coordination is perfect – there is evidence that work is still to be done in ensuring consistent implementation of the screening guidelines, for example (Anttila et al., 2009; Schrijvers et al., 2012). However, whilst the non-binding EU mechanisms in cancer do not constrain member state action, they have been extremely successful in changing behaviour – the creation of the UK’s National Cancer Plan, for instance, is credited to the prior publication of a Eurocare report which found the UK to have some of the poorest cancer survival statistics in Europe (Virgo et al., 2013: 2194). Furthermore, national cancer policy structures have adapted to accommodate EU-level structures. Following the creation of the ENCR, for example, member states which previously did not have registries have been encouraged to

establish them, and existing national bodies have adjusted their operating processes to feed into the European-level (Virgo et al., 2013).

The direction of Europeanisation is a little harder to establish. Since the EU began engaging in cancer policy, its role has been and remained one of support – national actors have retained central control, with the EU facilitating exchange of best practice and shared learning in areas where its competence is strong, thus indicating that cancer policy Europeanisation is not exclusively top-down (Albrecht et al., 2008: 1453). Downloading dynamics can be identified for some individual member states – generally those with weaker or less developed health systems or cancer programmes – whilst uploading can be observed by those with a strong tradition of cancer care and research. Though health promotion and disease prevention policies remain national competences, the extent of the Europeanisation of cancer was demonstrated when the Commission sought to revoke its funding and support of coordination in 2002 and pass responsibility back to the member states. National governments rejected this idea, since ‘...the fight against cancer had been effectively Europeanized and individual states no longer felt it imperative to control the parameters nor take responsibility for the maintenance of registries and research’ (Trubek et al., 2008: 827). Thus, at least in the areas of registration, data collection and research, cancer policy is fully Europeanised, with similar dynamics observed in the setting of guidelines and the benchmarking of national progress.

Cancer policy is a unique case in that EU-level policy content is as important and influential as it is in BTO policy but, unlike in the latter case, such content is non-regulatory. No transfer of competence or formal structural change to the organisational logic of domestic policy-making frameworks has taken place, yet cancer is considered one of the most successful areas of coordination and cooperation in health.

## **The governance of cancer prevention policy**

In 2008 Trubek, Nance and Hervey published an article in which they offered an alternative view of health governance in the EU, using cancer policy as the illustrating case study. The model that they describe – a form of networked governance – is based on the emergence of a policy community ‘coalescing’ around EU action in the fight against cancer. This community, Trubek et al. (2008) assert, has acted over the years as the leading force in shaping and directing EU cancer prevention policy. They identify ‘...a web of doctors’ and patients’ organizations [which] has worked to develop a comprehensive program for cancer control’ by creating an ‘iterative and reflexive system of networked governance’, where the work of physicians, health professionals and cancer experts has been supported by ‘technocrat-driven Commission decisions’ and by a cooperative mode of policy-making (Trubek et al., 2008: 816). Taking a consensus- and evidence-based approach, ‘significant impact [has been] achieved without funding expensive, invasive and unwanted monitoring mechanisms and without extended legal and political battles about competence’ (Trubek et al., 2008: 821).

The policy mechanisms that have been established focus upon knowledge sharing and policy learning, using modest financial incentives to encourage cross-border research projects and multi-country collaborations. In turn, they have led to the creation of indicators, monitoring initiatives and benchmarking, facilitating peer review and targeted guidance without encroaching upon national prerogatives in service delivery or organisation of care. The multi-level networks of experts and activists responsible for these mechanisms and initiatives,

Trubek et al. argue, have been far more significant in the development of EU cancer policy than the Commission or the Court as individual agents.

The characterisation presented by Trubek et al. is a product of the ‘governance turn’ and is also indicative of a shift from principle-agent modes of governance to peer review and dynamic accountability (Sabel and Zeitlin, 2008). It offers an alternative to the dominant ‘institutional expansionism’ narrative of health policy, whereby the Commission and the Court support one another in actively pushing the boundaries of the EU’s mandate and progressively expanding its powers. It also highlights a number of central features of governance in cancer prevention. Firstly, the role and importance of expert groups and policy communities is clear. The original EAC sought to engage as many external experts as possible (*European Commission, Health Directorate D*) and, as a result, cancer experts now wield considerably more influence over EU health policy objectives than, for instance, lung disease experts (*EU Health NGO C*).

Secondly, the governance of cancer prevention is based largely on an understanding that the necessary EU activities are technical in nature. EU action is ‘rational and consensus-based’ (*European Commission, Health Directorate A*), reflected in the assertion that ‘...even the most Eurosceptic of [UK] ministers understands the value of Europe in [cancer] research’ (*EU Health NGO B*). A successful distinction has thus been created between the technical, clinical and added-value goals of cancer prevention policy and the political, cultural and highly sensitive goals of tobacco control. In the former, a vast array of platforms and projects has been established without overt political entrepreneurship, controversy or disagreement. Decision-making follows Hooghe and Marks’ (2001) technocratic model, in that the goals of cancer policy are not commonly contested, since they are largely clinical and evidence-based, and objectives are achieved by problem-solving, rather than by political choice. As such, cancer policy is ‘beyond politics’ in its day-to-day implementation and evolution. Over the longer term, it is broadly majoritarian in its politics – both the costs and benefits of EU coordination are diffuse, presenting a role for an entrepreneurial actor in leading policy change. However, in cancer policy this role has rarely been played by the Commission; its role has historically been a supporting one, ‘creating an environment...where cancer control activities [can] flourish’ (Boyle et al., 2003: 1322). The EU has been instrumental in establishing a comprehensive system of information sharing and financial support – via mechanisms such as the Structural Funds – to help member states reduce inequalities in cancer survival and care (Alexe et al., 2008: 14). When cancer was revived as a European priority in 2007, it was the Council Presidency and the MAC grouping in the European Parliament which led the charge – indeed the Commission had actively tried to reduce its responsibility in cancer policy (Trubek et al., 2008: 828). As such, there is little evidence of an ambitious, self-serving agenda on the behalf of the executive.

Finally, the style of policy instrument established by network governance and evidenced in cancer prevention policy is inherently soft and educational in nature. Recommendations, guidelines, best practice for health professional training, Council conclusions and other such tools lend themselves to governance by voluntarism or targeting. Policy is non-binding but remarkably well adhered to, lending weight to the implementation of targeted governance measures and illustrating the power of political will within this governance mode. Significantly, the creation of a public health base in the treaties did not change the governance style of cancer prevention policy, even in the most recent activities of EPAAC and CANCON, further demonstrating the potency of political will as a lever for implementation (*Member of*

*European Parliament A*). Whilst such commitment can be highly constructive, however, it also places limits on policy activity. EU action has extended to all major forms of cancer but has made little impact on prevention policies, for example, and the recent moves towards a ‘quality of care’ agenda and discussions of palliative care models within the CANCON framework are perceived as an overstepping of the EU’s mandate (*European Commission, Health Directorate D; EU Health NGO B*). Furthermore, whilst the existing guidelines and recommendations are considered largely technical and uncontroversial by national governments, it is likely that any attempt to introduce binding requirements would quickly transform them into highly political dossiers (*European Commission, Health Directorate A*).

Reflecting on the distinction between cancer prevention and tobacco control policy and the limits put on the former in terms of the quality of care and prevention agendas, it might be concluded that EU activity in this area has reached its limit. Most of the areas falling under the ‘public health’ umbrella of cancer prevention now have established EU processes in place, with recommendations and guidelines periodically reviewed in light of new technologies or research findings; activity has not extended beyond these areas in recent years and much contemporary activity serves largely to maintain the status quo. Meanwhile, the focus of the cancer prevention community is increasingly moving outside of the health sector to target policies on data protection, clinical trials, air pollution, the TPD, research funding under Horizon 2020 and tobacco taxation (*EU Health NGO B*). Interestingly, the interest groups now active at European level are no longer the technical or clinical minded stakeholders, such as the oncologist professional associations, but rather the political advocates representing patients in the ECPC, ECL and others (*UK health association, EU Liaison B*). Such trends suggest that those areas where EU-added value was clear and collective action easy to agree have now been exhausted and what is left are those more sensitive areas where consensus is harder to reach (*Academic Expert, EU Health Policy A*).

### **Horizontal themes in EU health policy: The use of soft law**

The most striking difference between cancer prevention policy and the BTO case is the type of legal instruments within which they are contained<sup>4</sup>. From a theoretical perspective, soft law is one half of the answer to the fundamental conundrum of EU health policy (Steffen et al., 2005: 3): how has health continued to integrate in the absence of a legal basis in the treaties? One explanation is the use of non-health treaty articles to expand health policy competence – this is examined in the case studies which follow, in particular chapter eight. Another is the proliferation of soft law instruments. The cancer prevention case is noted as a textbook example of the potential influence and role of soft law in health (Brooks, 2012: 93).

Attempts to define soft law have revealed a number of different interpretations, each trying to untangle the central contradiction of the concept – ‘soft law without legal effects is not law and soft law with legal effects is hard law’ (Senden, 2004: 109). The three main components of soft law – concern for rule of conduct, lack of legally binding force, and an element of practical effect – lead Senden (2004: 112) to define it as:

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<sup>4</sup> This section is based upon the dissertation submitted as part of the candidate’s previous degree of MA/LLM in Internal Relations and International Law in September 2011, and published in Brooks (2012).

‘Rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects.’

Hard law, as the conceptual antonym, is understood as the ‘traditional’ or ‘community’ method of legislating. Regulations, directives and decisions are the binding legal acts which result from the community method, whilst the EU treaties list recommendations and opinions as non-binding, and thus soft, law (Article 288 TFEU). Other non-binding measures, which do not appear in the Treaty texts but which are commonly used and identified by the Court as sources of soft law, include: conclusions, declarations, peer review, monitoring and evaluation mechanisms, Green and White papers, communications, resolutions, codes of conduct, action plans, frameworks and guidelines (Cini, 2001: 195; Di Robilant, 2006: 500; Falkner et al., 2005: 52; Hervey and McHale, 2004: 61). As such, the presence of soft law instruments is a key indicator of the voluntarism and targeting modes of governance<sup>5</sup>.

In health, soft law provides an alternative to the community or regulatory policy-making modes and allows actors to think of health as health, rather than as an element of the internal market or the macroeconomic system (Greer and Vanhercke, 2010: 191). Soft law tools now greatly outnumber hard law instruments and are used to steer or supplement EU activity in almost every area of health. Though seen most prolifically in the 1990s – a period Flynn (cited in Cini, 2001: 193) identifies as the ‘era of soft law’ – voluntary, non-binding instruments were first notably employed in the EU’s activity in cancer in the 1980s. As part of the OMC, soft law is used to encourage upward convergence in hospital waiting times, universal insurance coverage, integrated care pathways, generic medicines use and a variety of other areas (Greer et al., 2014: 31). It is also the approach now taken in organ donation and transplantation policy, nanoscience and nanotechnology, eHealth, obesity and cancer screening (Greer and Vanhercke, 2010: 197). In clinical trials policy, soft law guidelines are made binding by the requirement for compliance when applying for permission to conduct trials or to receive certain EU funding (Hervey and McHale, 2015: 58, footnote 193). Essentially, in addition to offering a framework for activity in the absence of a legal base in the treaties, soft law functions as a supplementary and supporting tool alongside binding health legislation.

The value of soft law has been widely debated in the EU studies and legal theory literature (see, for example, Trubek et al., 2005; Snyder, 1993; Di Robilant, 2006; Falkner et al., 2005 and Senden, 2004) and it is generally recognised as a more influential tool than its non-binding nature suggests. Among the health community, the dominant opinion can be characterised as sceptical, with most considering soft law to be most effective when used as part of ‘hybrid’ strategies (Di Robilant, 2006: 508); one health advocate describes it as ‘all motherhood and apple pie’, citing its value as a tool to target hard law but its inability to induce real change in chronic disease policy (*EU Health NGO G*). Officials from DG Santé perceive a similar role and, during interview, were quick to note that soft law options such as the Alcohol Forum and the Diet Platform are ‘never the Commission’s first choice...you do it because you can’t do hard law’ (*European Commission, Health Directorate A; E*). The European Parliament takes an even stronger view. In a 2007 report, it stated that,

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<sup>5</sup> Soft law received increasing attention in the context of the turn to ‘new’ modes of governance in the late 1990s (Hervey and McHale, 2004: 62) – these instruments are explored in chapter nine. The current section is concerned with the nature of soft law and how it has influenced the development of health policy.

‘...use of soft law is liable to circumvent the influence of the other (democratic) instruments, may flout the principles of democracy and legality and may result in the Commission's acting *ultra vires*’ (European Parliament, 2007: Point N).

On a practical level, Parliamentarians do not see soft law as a sufficient tool for generating change; an MEP remarked during interview ‘Does [soft law] have an impact? It might have, but if I want to change Europe I need [hard] legislation’ (*Member of European Parliament C*).

Though health actors are reluctant to rely on soft law and are sceptical of its capacity to produce change in areas such as alcohol, obesity and tobacco control, there is also a recognition that it is fast becoming the only available tool. Building on the notion that soft law is used where political constraints preclude the use of hard law, and the reality of the conservative political climate currently facing health policy-makers, soft law may increasingly be the tool of recourse (*European Commission, Health Directorate A*). The options under the current assignment of competences have been mostly exhausted; ‘if there were more hard law bases, they’d [health actors in the Commission] have found them by now’ (*UK health association, EU Liaison A*). As soft law instruments proliferate, however, their objective of promoting convergence and coordination at the highest political levels opens them up to the inevitable risk of politicisation (Radaelli, 2003b: 8). As demonstrated in the recent collapse of the Alcohol Forum, when soft mechanisms are the only instruments available to steer a given policy area they acquire a stronger importance, greater sensitivity and closer resemblance to hard law structures.

**Figure 7: Summary of health policy dynamics, case study two**

<b>Health policy dynamic</b>	<b>BTO policy</b>	<b>Cancer prevention policy</b>
<b>Catalyst and driver</b>	Blood contamination crisis Mandate from member states Driven by Commission/spillover High macro-sectoral & vertical integration	Council Presidency Commission/Parliament driver Cultivated spillover High macro-sectoral & low vertical integration
<b>Actors, interests and politicisation</b>	Public health actors, some market Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down & indirect Europeanisation	Public health actors, epistemic communities & experts Mostly clinical actors (beginning) Some political actors (recent) Balance of uploading & downloading Soft/indirect Europeanisation
<b>Policy type and instruments</b>	Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy	Soft regulatory, education & information, market-based Recommendations & resolutions Policy coordination & transgovernmentalism
<b>Governance mode</b>	Framework regulation (safety) Voluntarism (ethics)	Voluntarism Targeting

## HEALTH IN ALL POLICIES AND THE INTERNAL MARKET

### *The case of medicines information to patients policy*

Pharmaceutical policy is a prime example of a strand of health policy which is steered, in large part, by internal market policy. The European institutions and national governments alike have sought to find the appropriate balance between supporting a competitive pharmaceutical industry and ensuring a supply of safe, affordable medicines, under pressure from strong interest groups on both sides. Moreover, much of pharmaceutical regulation was established to facilitate the trade of goods in the single market, rather than in pursuit of specific health objectives. In medicines information to patients (ItP) policy, the ‘market versus health’ dynamic and the diversity of stakeholder interests have required policy-makers to work outside of the health mandate and go beyond pure regulation to embrace more inclusive forms of governance.

### **What is meant by medicines information to patients policy?**

ItP policy refers to a series of legislation and policy which seeks to regulate how and by whom information about medicines is provided to patients. This includes information about ingredients, dosage, therapeutic indications and any possible side effects or interactions. Pharmaceutical companies hold the most comprehensive information about their products but also have an interest in presenting them as positively as possible, creating a conflict of interest. The debate about how best to balance this conflict has historically drawn heavily on the US and, to a lesser extent, New Zealand experiences with DTCA-PD.

DTCA is the promotion of a product, in this case medical devices and pharmaceuticals, to their end-user, in this case the patient or consumer. It can be distinguished from advertising to health professionals, insurance providers or health authorities, for which a separate body of legislation exists. It can also be divided into two categories: direct-to-consumer advertising of prescription drugs, currently prohibited in most countries, and direct-to-consumer advertising of ‘over the counter’ drugs, which is commonly permitted. As such, DTCA-PD can be defined as ‘an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to patients’ (Ventola, 2011: 670). DTCA-PD has never been permitted in the EU but the arguments for and against it have been a central part of the debate on ItP, since they concern the balance between the public health value of informed patients and the commercial value of information provision.

In both the US and New Zealand, DTCA-PD has been permitted in mainstream media outlets since the late 1990s. The Food and Drug Administration (FDA) relaxed the existing US rules in 1997 and again in 2004, following heavy pressure from industry. The law now permits DTCA-PD on the conditions that all information be accurate and not misleading, that it make claims only when supported by substantial evidence, that it reflect the balance between risks and benefits and that it be consistent with FDA-approved labelling (DHHS, 2010). However, implementation and oversight of these provisions has been criticised (Lexchin and Mintzes, 2002). Advertisements do not require prior approval and so are only monitored *ex post facto*, and studies have found that adherence to the voluntary guidelines adopted by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) are routinely violated

(PhRMA, 2008; Arnold and Oakley, 2013: 533; Frosch et al., 2007: 12; Hoek and Gendall, 2002).

Proponents of DTCA-PD commonly state that the provision of information leads to empowerment, strengthening the doctor-patient relationship, improving compliance, reducing the stigma attached to certain conditions and increasing patients' ability to manage their own care (Auton, 2009; Ventola, 2011: 672). Similarly, it has been claimed that creating a health system where health professionals hold all the information creates fear, misunderstanding and drives patients to seek information from unreliable sources, particularly via the internet (UK House of Commons, 2005: 67; Shaw, 2011b; Bonaccorso and Struchio, 2002: 911). Opponents of DTCA-PD note that it has no public health rationale, it is simply a tool for increasing demand and raising pharmaceutical industry profits (Mintzes and Mangin, 2009; Mintzes et al., 2002). The information provided by pharmaceutical companies in their advertisements often 'medicalises' or 'pharmaceuticalises' common, non-essential health issues or 'lifestyle' conditions, considered to be part of the normal range of human experience, such as variation in sexual activity and performance or natural fluctuation of mood (Abraham, 2011; Applbaum, 2006; Mintzes, 2002; 2006; Moynihan and Henry, 2006). As such, DTCA-PD may lead consumers to believe that adopting healthier behaviours is unnecessary and that they can instead rely on a 'pill for every ill' to address their particular concerns (Busfield, 2010; Heath, 2006). This in turn encourages society and industry to misdirect its health expenditure and promotes a belief in new drugs that are much more expensive but no more effective than existing or generic medications (Law, 2006; Medawar, 2008; Vedantam, 2006).

Since 1998 the pharmaceutical industry, with support from various other stakeholders, has sought to overturn or weaken the EU ban on DTCA-PD, via the ItP debate. During this process the rhetoric, strategy and governance approaches employed have evolved to accommodate the broad and forceful interests found in this policy area.

## **The historical evolution of EU medicines information to patients policy**

At the end of the 1990s EU pharmaceutical policy was entering its third phase – having laid down a common framework for authorisation in Directive 65/65/EEC and subsequently developing the multi-state procedure governed by Directives 75/318/EEC and 75/319/EEC, the EU was now focused upon the establishment of the decentralised, centralised and national registration procedures for market authorisation (Matthews and Wilson, 1998; Permanand, 2006). The ban on DTCA-PD was embodied in Directive 92/28/EC, which prohibited advertising of prescription medicines to the general public and stated that any other advertising must not be misleading. However, prompted by the relaxation of the rules on DTCA-PD in the US, two main attempts to circumvent the EU ban have been made and the fundamental issue of providing unbiased, reliable and accessible information about medicines to patients remains a core debate in EU pharmaceutical policy.

### **1998-2002: Attempting to overturn the DTCA-PD ban**

In 1998, the Transatlantic Business Dialogue (TABD) published an assessment criticising the EU ban on DTCA-PD in light of the recent relaxation of US regulation, noting an 'inconsistency in the regulatory treatment of industry in the transatlantic marketplace' and asserting that the existing EU legislation 'deprives EU citizens of the right-to-know compared

to their US counterparts' (TABD 1998 cited in Medawar, 2001). A few months later, the head of the pharmaceuticals unit at DG ENTR (Enterprise and Industry, now DG GROW) raised the possibility of reviewing the ban on DTCA-PD at a meeting of the Internal Federation of Pharmaceutical Manufacturers and Associations – TABD welcomed the statement and invited the Commission to convene a working group on DTCA-PD. Reflecting the interests of the substantial UK pharmaceutical sector, the Pharmaceutical Industrial Competitiveness Task Force (PICTF) was established by British Prime Minister Tony Blair in 1999, paving the way for a series of subsequent 'high level working groups' at the European level. The first of these was the 'G10' – the Medicines High Level Group on Innovation and Provision of Medicines – which was instrumental in pushing the DTCA-PD debate forward in the early 2000s.

The legislative package which sought to consolidate EU regulation of pharmaceuticals for human and animal use, adopted by the Commission in 2001, upheld the DTCA-PD ban (Directive 2001/83/EC, Article 88). However, before the proposal was sent to the legislative institutions, Commissioner for Enterprise and Industry, Erkki Liikanen, inserted an amendment to the text, weakening the legal restriction and suggesting that pharmaceutical companies should be permitted to disseminate information directly to patients on three specific disease groups – asthma, diabetes and HIV/AIDS. The changes were rejected by a ratio of 12:1 in the European Parliament and by majority in the CoEU but, as a compromise, the legislature asked that a report on current practices be published within three years (HAI Europe, 2015). It later became clear that the amendment requiring a report was inserted at the behest of officials in DG ENTR as a strategy to keep the debate on DTCA-PD alive (Baeten, 2010: 177).

### **2006-2009: Shifting the debate to patient information**

Thanks to the reporting requirement the debate on DTCA-PD resurfaced in 2005. The establishment of the Patient Information Network, led by five MEPs in support of renewed efforts to address the provision of ItP, and the creation of the High Level Pharmaceutical Forum, the successor of the G10, were soon announced (HAI Europe, 2015). Chaired jointly by the Commissioners for Enterprise and for Health and Consumers, the Forum hosted a series of debates on 'patient information', as the issue had now come to be known, and a public consultation on its conclusions. These fed into the 2007 DG ENTR report on current practice which noted that 'the pharmaceutical industry has the potential to be an important source of information' (European Commission, 2007a: 14). The final report reaffirmed commitment to the ban on DTCA-PD but emphasised the industry's position as a better-informed supplier of information than member states (European Commission, 2007c: 9).

In December 2008 the Commission presented three formal proposals – collectively known as The Pharmaceutical Package – on ItP, falsified medicines and pharmacovigilance (European Commission, 2008b). The latter two files made their way through the legislative process relatively smoothly, whilst the former, suggesting the creation of a framework within which industry could provide information on its medicines, proved to be much more controversial. The accompanying public consultation on ItP, undertaken by DG ENTR, produced predictable results, finding that 96 per cent of pharmaceutical companies and 72 per cent of media organisations agreed that industry could be a good provider of information, whilst only 7 per cent of healthcare organisations, 11 per cent of regulators, 0 per cent of consumer organisations and 0 per cent of social insurance organisations drew similar conclusions (Geyer, 2011: 596). Furthermore, independent health and consumer organisations campaigned

vigorously against the new proposals, citing conflict of interest, the potential for escalating health costs and the need for comparative and reliable drug information (HAI et al., 2009). These actors were also instrumental in lobbying for the relocation of responsibility for pharmaceutical policy from DG ENTR to DG SANCO (now DG Santé), which finally took place in 2009, greatly reducing the former's role in the legislative process (EPHA, 2008a).

The Rapporteur for the ItP proposal in the European Parliament, MEP Christofer Fjellner (EPP, Sweden), struggled to achieve consensus on the text and when a majority was finally gained in September 2010, it had been modified so significantly and discussion had been so divisive that the Commission opted to re-draft the proposal from scratch rather than proceeding to the Council stage. An amended proposal was adopted in February 2012 but, following indication by the Council that it was not willing to accept the new text and that qualified majority was unlikely to be reached on the issue, this was formally withdrawn in May 2014 (European Commission, 2012a; 2012b)<sup>6</sup>.

### **Literacy, empowerment and contemporary medicines information policy**

With the withdrawal of the Commission's second proposal on ItP the issue once again subsided. However, debate on the appropriate way to inform patients continued, shifting its focus in the late 2000s to 'health information', understood as a more holistic provision of guidance, resources and information to help patients improve and manage their health (Brooks and Geyer, 2012). More recently, the language has evolved again. Discussions of 'health literacy' and 'patient empowerment' seek the creation of informed and autonomous patients via a number of policy initiatives, including the better provision of information on therapeutic treatments and medicines (Baeten, 2010: 191; EHFG, 2013). In May 2015 the European Patients Forum (EPF), a pharma-funded NGO of patients' organisations, launched a campaign to put patient empowerment on the EU health agenda. The pharmaceutical industry is no longer publicly seeking a repeal of the EU's DTCA-PD ban but, aware of the commercial value of reaching consumers with guidance on its products, it continues to advocate itself as the most appropriate provider of clinical and technical information about medicines.

### **The integration and Europeanisation of medicines information to patients**

EU pharmaceutical policy is comprised of intensely integrated areas, such as market authorisation, and fiercely defended national competences, such as pricing and reimbursement; in medicines ItP, the value of coordination at EU level is widely acknowledged and there is a high degree of both sectoral and vertical integration, but balancing the health-promoting and market-based elements of policy has proven difficult. Like all pharmaceutical policy, it is characterised by three competing interests: health care interests, concerned with cost containment and efficiency; industrial interests, concerned with employment, trade and growth; and public health interests, concerned with safe, high quality medicines (Permanand and Altenstetter, 2004: 39). The initial catalyst and on-going basis for EU involvement in pharmaceuticals is the single market. Since the subsidiarity principle puts health- and financing-related policy elements beyond the EU's reach, its goal has been one of deregulating national markets and spillover from this central aim has provided it with a strong regulatory remit in areas including advertising, common packaging, product licensing,

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<sup>6</sup> Withdrawal published in the Official Journal OJ C L153 21.05.2014.

wholesale distribution and patent protection (Baeten, 2010: 173; Permanand and Altenstetter, 2004: 42).

Drug advertising and information policy exhibits many of the traditional characteristics of EU health policy but there are some dissimilarities. There is little role for the Court, for instance, though the CJEU has issued a number of important rulings on the definition of advertising<sup>7</sup>. Crisis events have not played a prominent role in creating or extending powers, though the thalidomide tragedy was a catalyst for the original establishment of broader centralised licensing (Brooks and Geyer, 2012: 1236; Permanand, 2006: 50). However, insofar as there is a ban on DTCA-PD and common EU rules on the content of relevant communications, medicines ItP policy can be considered an integrated area of EU health policy. Prompted by the single market programme and developed via the community method, it quickly produced an established set of EU-level stakeholders and, for the most part, can be understood as a classic example of neofunctional integration, where single market pressures and the passivity of member states have caused stakeholders to shift their attention to the European level.

However, whilst neofunctional spillover goes some way to explaining the market basis of the policy, it does not provide much indication as to why a health basis did not evolve concurrently – here, intergovernmentalism is needed (Permanand, 2006: 56). There is clear added-value for the market in regulating pharmaceutical advertising at EU level and it might therefore be considered in the interest of member states to permit coordination (Brooks and Geyer, 2012: 1236). However, subsidiarity is the primary roadblock to a health-focused drug advertising and information policy and national governments have consistently fought to assert their interests in pharmaceuticals as a component of health systems and a vital industry sector (Hancher, 1990: 13). This reflects the broader division in pharmaceutical policy, whereby industry and market elements are considered ‘low politics’ issues whilst health aspects, along with pricing and reimbursement procedures, remain ‘high politics’ concerns (Permanand, 2006: 56).

Many member states had advertising bans in place well before the introduction of an EU-wide prohibition on DTCA-PD, suggesting a process of uploading. This dynamic is also evident in the most recent legislative developments on ItP, where Sweden successfully utilised the assignment of a Swedish MEP as Rapporteur in the leading Committee to facilitate a proposal which closely resembled the existing national system (Mulinari, 2013: 762; Shaw, 2011a). Though countries with large pharmaceutical industries were periodically vocal in opposition of the DTCA-PD ban – the British government, for instance, set up the PICTF, a stakeholder platform through which national industry representatives could put pressure upon the EU – most had bans in place at national level. This suggests that though policy output was downloaded from the EU, in that it was contrary to what these countries had lobbied for, the ‘goodness of fit’ of the final legislation was strong.

The interaction of trade and industry ministries with health and consumer ministries is a key dynamic in pharmaceutical policy-making, in particular advertising and information policies, and indicates a process of horizontal Europeanisation and diffusion (Börzel and Risse, 2012; Radaelli, 2003a). In the current status quo, national regulatory agencies are well networked, working closely with the EMA and each other, and as a result the differences between national

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<sup>7</sup> See cases C-316/09 *MSD Sharp & Dohme GmbH v Merckle GmbH* [2011] OJ C 186/03; C-249/09 *Novo Nordisk AS v Ravimiamet* [2011] OJ C 186/02 and; C-421/07 *Criminal proceedings against Frede Damgaard*. Reference for a preliminary ruling: *Vestre Landsret – Denmark* [2009] ECR I-2629.

regulatory systems have decreased considerably since the 1990s (Permanand and Altenstetter, 2004: 47). Policy on the advertising and ItP of medicines might therefore be described as integrated and subject to ongoing circular and horizontal Europeanisation dynamics.

Medicines ItP is the issue within pharmaceutical policy where the clash between the EU's market and health competences is most pronounced (Baeten, 2010: 173). An important feature of this conflict, however, is that it is based entirely upon the content and direction of EU policy. It is not a conflict about subsidiarity or competences – medicines ItP is accepted as an integrated and Europeanised policy area.

## **The governance of medicines information to patients policy**

The medicines ItP case offers several insights into the governance of health policy. Firstly, it is an illustrative example of how conflict and politicisation affect the mode of governance employed in a given issue area. The range of actors involved in the ItP policy process is wide and the division between them stark, oftentimes resulting in different positions within single institutions. This is particularly evident in the European Commission – the literature is generally critical of the Commission's approach to the ItP debate but this criticism is aimed primarily at DG ENTR, which was responsible for the file until 2009. The cleavage between the DG for industry and the DG for health is a historic fault line (*European Commission, Health Directorate A*) which had a significant impact upon the way governance developed in medicines ItP policy. Rather than pursuing a strategy of competence expansion, DG ENTR sought to further the interests of its industry stakeholders and raise the profile of its role in ensuring competitiveness in the single market, consistently overruling DG SANCO (Baeten, 2010: 173; 190). An expansionist agenda was not promoted by the latter either; indeed SANCO officials were unaware of the reassignment of the pharmaceutical portfolio until the last minute, the campaign having been quietly driven by an alliance of public health NGOs and senior individuals within the Commission (*World Health Organization B*)<sup>8</sup>.

The political activity of stakeholders also affected the policy instruments selected and their operation. The pharmaceutical industry funded and manipulated patients' organisations, policy networks and MEPs, turning traditionally technical exercises, such as public consultations, into political battles (Baeten, 2010: 175; *EU Health NGO H*). This created rifts within civil society; since this was one issue where industry and patient interests were clearly not aligned, any patient organisation support of information from pharmaceutical companies was likely to have been influenced by pharma-funding, as in the case of EPF (*EU Health NGO D*; Mulinari, 2013: 763). The variety of interests and the difficulty in achieving consensus made adoption of hard law instruments impossible – this was starkly evidenced in the Commission's eventual withdrawal of the ItP proposal in 2012. Instead, softer, more participatory and consultative modes of governance had to be employed, reflecting the broader post-Lisbon trend for experimental governance to accommodate interests beyond those of the Commission and industry alone (Sabel and Zeitlin, 2008: 279). By comparison to cancer and BTO policy, where EU proposals met little opposition, medicines ItP policy is a highly politicised and contested arena where agreement on the fundamental direction of policy and the importance of health as a consideration is difficult to achieve.

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<sup>8</sup> It should be noted that the Juncker Commission attempted to reverse this reassignment in 2014 but was forced to abandon its plans under fierce criticism from the same broad alliance of public health NGOs and experts. See Brooks (2014a; 2014b).

Medicines ItP is also an example of how the use of a market legal base affects the governance of a health policy issue. Both Directive 92/28/EEC and 2001/83/EC rested on the treaty articles providing for approximation of laws in the internal market (Article 100A EEC, later 95 EC). After the first attempt to overturn the DTCA-PD ban on the basis of market and competitiveness arguments failed, the Commission began to employ health arguments (Baeten, 2010: 189). This drew it, however, into an area of far weaker competence, forcing it to utilise different policy mechanisms and governance tools, legitimising its continued action by recourse to questionably-worded public consultations and the conclusions of selective ‘high level working groups’ (Carboni, 2009; Permanand, 2006). Whilst market-based policies are more likely to enjoy hard law support, because of the stronger legal competence here, they are also more likely to favour industry or commercial interests, and thus be presented as framework regulation, or even self- or co-regulation. Though the ban on advertising contained in the Directives is absolute, member states are given latitude in the monitoring and enforcement of the ban and, since the debate turned to information provision, the role of industry guidelines, voluntary self-regulation and governance by targeting has increased (see, for instance, ABPI, 2015).

The division between technical and political issues is harder to identify in the medicines ItP case. Permanand (2006: 55) describes pharmaceuticals as ‘...both a constitutional and a functional matter’ and the logic of coordinating pharmaceutical regulation at EU level is well recognised. However, the medicines ItP case demonstrates a unique level of politicisation within pharmaceutical policy (Brooks and Geyer, 2012). This is reflected in the Commission’s decision to proceed with the falsified medicines and pharmacovigilance strands of the pharmaceutical package, which were recognised as technical and largely uncontroversial, whilst dealing separately with the more sensitive ItP file. Medicines ItP also highlights the impact of internal market influence upon the characterisation of technical or political policy. As one interviewee noted, ‘...the line between technical and political policy began to blur after 1992’ because health was no longer only about health (*UK health association, EU Liaison B*). The increasing involvement of non-health actors and interests in health policies has altered the understanding of health issues; presented as a market issue rather than a simple case of patient safety or consumer protection, medicines ItP policy was not able to enjoy the ‘technical’ label assigned to most elements of the rest of the pharmaceutical package.

The Lisbon Treaty added an explicit competence for the EU in ‘measures setting high standards of quality and safety for medicinal products and devices for medical use’, meaning that, in future, measures such as the DTCA-PD ban could, in theory, be based on a public health mandate (Article 168(4)(c) TFEU; Baeten, 2010: 194). Seen alongside the transfer of responsibilities to DG Santé, this suggests a fundamental shift in the EU’s approach to governing pharmaceutical policy. However, agreement on revised regulation of the provision of information has still not been reached and a concrete distinction between advertising and information, vital to underpin any regulatory effort, has still not been adopted.

## **Horizontal themes in EU health policy: Health in All Policies and the internal market**

The medicines ItP case is an illustrative example of the role of the internal market and of how the location of many determinants of health outside of the health sector affects health policy-making. The internal market has played a central role in furthering the integration and Europeanisation of health policy, as well as shaping its content and governance. Its role

became so important in the late 1990s, in fact, that the Belgian Presidency of the CoEU commissioned two books (McKee et al., 2002; Mossialos and McKee, 2002) to examine its implications. These works and those which followed them identify two primary dimensions of the impact of the internal market on health.

A first dimension involves the application of the free movement principles to the health sector in pursuit of an ‘internal health market’. This might be considered the ‘direct’ impact of the internal market requiring, for instance, that national authorities not discriminate between medicines produced domestically and those imported from other member states, or between nurses of national origin and those trained in other EU countries. Broadly speaking, the creation of an internal market in health goods – meaning pharmaceuticals, medical devices and other health technologies – or in ‘health people’ – understood as health professionals – is not an insurmountable challenge. Difficulties in implementation remain but the structures for these markets have been in place for many years and national health systems have, for the most part, adapted to them (Hancher, 2002; 2010; Peeters et al., 2010). This has enabled the integration of health policy to move far beyond that facilitated by the health articles contained in the treaties. The more problematic issues, which have come to the fore in the last two decades courtesy of the CJEU, concern the creation of internal markets in health services – meaning the provision of treatment and care – and in health consumers or patients (See Greer et al., 2014: 83-95; Gekiere et al., 2010). Opening service tenders to foreign providers and enabling patients to receive care in other EU countries whilst being reimbursed by their domestic insurance package challenges the central structures and financial sustainability of national health systems far beyond what is envisaged in the founding treaties. It moves towards the establishment of a European health system and integration here is patchy, having been driven by a combination of case law and reluctant political initiative (Greer, 2008).

A second dimension concerns the impact of ‘non-health’ internal market policies upon health policies and outcomes. This is the ‘indirect’ effect of free movement on health created by, for instance, the common regulation of tobacco product advertising, limits on emissions from automobiles or rules on maximum daily working hours. Laws which prohibit barriers to free movement also have a health impact by, for example, making unlawful national regulation which imposes minimum unit prices on alcohol. Indirect internal market impact is also felt through the EU competition regime and its rules on state aid and public procurement. These challenge the principle of ‘solidarity’ underpinning European health systems and impose EU law upon the activities of health insurers and providers (Lear et al., 2010; Prosser, 2010). Non-health features of the internal market can thus serve to undermine national or European health policies and are less accessible for health actors or policy-makers seeking to influence them (Hervey and McHale, 2004: 90).

Recognising the health impact of non-health policies and the difficulty of representing health interests within the relevant processes, the EU provided in the Amsterdam Treaty for the mainstreaming of health into all other policy areas. This notion was elaborated by the Finnish Presidency of the CoEU in 2006, which produced a paper on the HiAP principle. HiAP is an approach which acknowledges the need for horizontal, cross-sectoral coordination in order to foster good health and, as such, is closely linked to terms such as ‘healthy public policies’ and ‘intersectoral action for health’ (Ståhl et al., 2006: 4). In the EU context, HiAP has three elements. Firstly, it requires the inclusion of health in headline policies, such as the Europe 2020 Strategy, the Horizon 2020 research framework and the cohesion policy. Secondly, it means ensuring that health policies are designed and coordinated with non-health sectors,

such as taxation, education, environment and research. Finally, it requires that all policies put forward by the European Commission have adequately assessed their impact upon health. The latter objective has traditionally been pursued via impact assessment, though a dedicated health impact assessment does not yet exist and the effectiveness of the 'general' impact assessment in identifying health impacts has been criticised (Ståhl, 2010; EPHA, 2012).

Honouring the HiAP approach and applying internal market law to the health sector have a significant impact upon health policy-making and governance. At the most fundamental level, it increases the number of actors involved in the construction of a health-promoting EU. This has led to the transformation of EU health policy from 'secret garden' to 'public park' (Greer, 2009). Increasing the number of actors in turn increases the diversity of interests and objectives which must be taken into account, often making the achievement of consensus more difficult. This can preclude the use of hard law and coercive governance, instead forcing the EU to employ more innovative, participatory and inclusive mechanisms. However, the power of alternative legal bases also presents opportunities for health policy-makers. So long as health aims are incidental to the primary objective, measures with health implications can be adopted using non-health legal provisions – this strategy has seen utilisation of the treaty provisions on the facilitation of the internal market, the CAP, social policy, environmental policy, the common commercial policy and many others (Hervey and McHale, 2004: 85). The increasing role of non-health sectors and the growing influence of internal market law have thus both expanded and challenged the scope of EU health policy, promoting health interests where they were not previously taken into account but also undermining them in the name of free movement.

**Figure 8: Summary of health policy dynamics, case study three**

<b>Dynamic</b>	<b>Catalyst and driver</b>	<b>Actors, interests and politicisation</b>	<b>Policy type and instruments</b>	<b>Governance mode</b>
<b>BTO policy</b>	<p>Blood contamination crisis set agenda Mandate from member states Driven by Commission, micro-sector spillover to tissues &amp; organs High macro-sectoral &amp; vertical integration</p>	<p>Public health actors, some market relevance but actors less visible Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down &amp; indirect Europeanisation</p>	<p>Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy</p>	<p>Framework regulation (safety) Voluntarism (ethics)</p>
<b>Cancer prevention policy</b>	<p>Council Presidency agenda-setter Commission/Parliament driver thereafter Cultivated spillover across micro-sectors High macro-sect, weak vert integration</p>	<p>Health actors, epist communities &amp; experts Mostly clinical actors (beginning) Some political actors (recent) Balance of uploading &amp; downloading Soft/indirect Europeanisation</p>	<p>Soft regulatory, education, market-based Recom. &amp; resolutions Policy coordination &amp; transgovernmentalism</p>	<p>Voluntarism Targeting</p>
<b>Medicines ItP policy</b>	<p>Completion of the internal market Thalidomide tragedy (crisis) Commission (ENTR) driver, spillover High macro-sect &amp; vert integration</p>	<p>Market, business &amp; health interests Intra-Commission divisions Market v health, little consensus Participatory approach to accommodate</p>	<p>Hard law (regulation) Directives, participatory instruments (consult.) Regulatory policy</p>	<p>Framework regulation (pharmaceuticals) Coercion (DTCA ban)</p>

## COMITOLOGY, THE OMC AND NEW MODES OF GOVERNANCE

### *The case of tobacco control policy*

Tobacco control is part of the EU's health promotion policy and has historically been linked with the EAC programme. However, since the EU is not allowed to harmonise laws for the purpose of public health, measures to control tobacco can only be introduced if they facilitate the functioning of the internal market. Those in place take a hard law form but have been threatened by ongoing legal challenges from industry interests and national governments, giving the Court a pivotal role in the development of the policy framework. Like the medicines ItP case, tobacco control is an example of a policy which has the goal of protecting public health but which utilises the stronger internal market mandate. However, unlike in the ItP case, the EU has managed to adopt binding tobacco control measures in the face of multiple opposing interests and high political sensitivity. In fact, the governance of tobacco advertising and products has made relatively scant use of soft law mechanisms. Furthermore, it is a primary arena for the battle between the EU's social and economic objectives and the judicial rulings it has provoked are considered some of the most important ever on the competence of the EU (Tridimas and Tridimas, 2002).

### **What is meant by tobacco control policy?**

It is helpful to first clarify what is meant by tobacco control and how it can be distinguished from the EU's action against cancer. The two areas are closely interlinked but whereas the earlier case study dealt with activity to combat cancer as a chronic disease, such as prevention, screening, research and training, tobacco control concerns five main strands of policy relating to tobacco as a commercial good and a determinant of health: regulation of tobacco advertising, regulation of tobacco products, the creation of SFEs, the organisation of anti-tobacco campaigns and various other policies concerning taxation, illegal trade and subsidies for tobacco producers. This case study focuses on the first two of these areas – regulation of tobacco advertising and tobacco products – since these are the issues which have generated the most political debate and which present an insight into the role of the Court, the politicisation of health issues and the use of internal market law to govern health.

### **The historical evolution of tobacco control policy in the EU**

Tobacco control policy has its origins in the EAC programme. The preamble to Decision 88/351/EEC, which established the first EAC action plan, stated that 'the fight against cancer' includes 'the fight against tobacco'. Subsequent phases of the EAC strengthened the role of tobacco control as a facet of cancer prevention and it has since become a substantial body of policy in its own right. Unanimous voting initially proved a major hindrance to tobacco control but the extension of QMV under the SEA meant that, so long as a measure was framed in terms of removing barriers to the completion of the market, it could avoid the difficult unanimity framework (Richonnier, 2012: 20). This resulted in the speedy adoption of directives on labelling and maximum tar content in 1989 and 1990 respectively, and even generated enough political momentum to secure adoption of a non-binding resolution on the danger of smoking in public places in 1989. However, whereas legislation adopted unanimously can only be challenged in court by 'interested parties', QMV implies no such

restriction, thus broadening the pool of potential plaintiffs and the risk of legal challenge (Boessen and Maarse, 2008: 83).

Tobacco control policy now uses the co-decision procedure of community method policy-making almost exclusively – only in cases concerning subsidies, which fall under the CAP, is unanimity required (Gilmore and McKee, 2002: 335). The tobacco legislation which has developed from the internal market legal base has followed two main lines – firstly on advertising of tobacco products and secondly on consumer protection via the regulation of health information and lawful composition (Hervey and McHale, 2004: 374). The history of these two areas is interlinked but for clarity is examined separately below.

### **Legislating tobacco advertising**

The advertising of tobacco products on television has historically been prohibited in the EU within the broader regulation of television broadcasts – from 1989 this was found in the Television Without Frontiers Directive (TWFD) and since 2007 has been embodied in the Audiovisual Media Services Directive. Regulation of other kinds of tobacco advertising was proposed soon after the TWFD was adopted but, because of QMV, was blocked by member states until 1997, when government changes in key countries facilitated a break in the deadlock (Gilmore and McKee, 2002: 336). The Commission published a proposal for a Tobacco Advertising Directive (TAD) in 1998. It banned advertising on the radio, internet and print media, in cinemas, on posters and ashtrays, as well as via indirect methods such as logos on clothes and sponsorship of events. The Directive's rationale made reference to the divergence in tobacco advertising restrictions which exist in different member states, forming a barrier to the free movement of tobacco products and distorting competition between advertisers and tobacco companies (Tridimas and Tridimas, 2002: 172). The TAD was adopted by the EU in 1998 but was soon the subject of a series of legal challenges. Many were dismissed by the CoFI but two, brought by the German government and by Imperial Tobacco, were taken before the European Court of Justice (now CJEU).

The two cases dealt with many of the same issues but the ruling handed down in *Germany v Council* (which became known as the *Tobacco Advertising* case) is considered one of the most important ever by the CJEU. The challenges made by the German government and Imperial Tobacco contained many grounds for invalidity of the TAD but focused upon the inappropriate use of Articles 100a, 57(2) and 66 EC (now Articles 114, 53 and 62 TFEU respectively) as legal bases for the Directive. The Court found in favour of these claims, annulling the TAD on the basis that the legislature could not rely on either free movement or distortion of competition arguments to justify the measures it laid out. Fundamentally, this was not an issue of competence, but of overstepping the mark – the ruling was carefully worded to make clear that it was not the banning of tobacco advertising which the Court was opposed to, but rather the sweeping generality of the ban (Tridimas and Tridimas, 2002: 174).

A Revised Tobacco Advertising Directive (RTAD) was adopted in 2003 and is significantly narrower in scope. It prohibits much tobacco advertising, excluding that intended for trade publications, but has been criticised for not going far enough to protect public health. In particular, it fails to regulate indirect advertising via non-tobacco products and it applies only to mediums which are cross-border in nature (Hervey and McHale, 2004: 383). Soon after its adoption another legal challenge was brought, again by the German government, which

sought to annul the Directive. The Court rejected the application and the RTAD remains the governing piece of legislation on tobacco advertising in the EU.

### **Legislating tobacco products**

The packaging, labelling and ingredients of tobacco products have been subject to consumer protection regulation for the same amount of time as tobacco advertising. The 1989 Labelling Directive regulated the health warnings which must appear on the packaging of cigarettes, stating that they must cover at least four per cent of the pack's surface and requiring that the pack display the tar and nicotine yields. In 1992, this was extended to cover all tobacco products and amended to include a list of 17 specific health warnings for use on packages, of which two were mandatory – 'smoking causes cancer' and 'smoking causes heart disease'.

In 2001 the Labelling Directive, along with other directives concerning design and manufacture, was subsumed into the Tobacco Products Consolidation Directive (TPCD), which aimed to provide an overarching approximation of laws on the manufacture, presentation and sale of tobacco products. It was strongly influenced by both the content and political significance of the WHO's Framework Convention on Tobacco Control (FCTC), which was under negotiation at the time, seeking to provide the first legal basis for international cooperation on tobacco control. The original draft of the TPCD, following its predecessors, made recourse to public health objectives in justifying the scope and content of its measures. However, once the *Tobacco Advertising* ruling had been issued and the Court's position on this approach made known, the Commission revised its proposal to remove all references to public health. When the final proposal was published, it was assigned to the European Parliament's internal market committee; the health and environment committee made known its disappointment at the lack of health consideration but acknowledged that, in light of the TAD ruling, the adoption of the TPCD could not take place in a vacuum (Boessen and Maarse, 2008: 84).

The TPCD was adopted in 2001 and was almost immediately challenged in the CJEU. A case referred by the English High Court attempted to replicate the arguments made in *Tobacco Advertising*, adding that the required health warnings distorted brands and infringed upon intellectual property rights. The Court responded by ruling that the use of an internal market legal base does not become inappropriate just because there are public health factors in the regulatory choices made. The TPCD was thus upheld.

### **The revision of the TPCD**

In September 2011 the European Parliament (2011) adopted a resolution on non-communicable diseases which called for an immediate and effective review of the TPCD, which had now been in operation for over 10 years. The review presented the opportunity to bring the tobacco products regulation in line with the FCTC, which had been adopted after the TPCD came into force and which recommended much stricter requirements than existed in EU regulation (Alemmano, 2012: 202). It also allowed the legislative framework to be updated in response to innovations such as electronic cigarettes, oral tobaccos and flavourings (Hiilamo and Glantz, 2015: 58). After 18 months of consultation and discussion the Commission finalised a proposal for a Tobacco Products Directive (TPD) in 2012 but this soon became one of the most politically difficult files in the history of EU health policy. The draft proposal, which had not yet been published, was twice postponed during the inter-

service consultation phase and work was suspended altogether when it was alleged that the Commissioner for Health at the time, John Dalli, had been involved in a deal with manufacturers of oral tobacco to remove the draft provision banning the substance<sup>9</sup>.

With the arrival of a new Health Commissioner the TPD was finally adopted in early 2014. It contains a new article pertaining to e-cigarettes and, crucially, allows member states to go further in their national regulation than EU law requires, which the TPCD did not (*EU Health NGO I*). The industry was again awarded the right to challenge its provisions in Court, but was not successful in delaying the implementation of the Directive, which comes into force in May 2016. Legal challenges are again pending decision by the CJEU – one using the ‘traditional’ arguments about intellectual property and legal basis, one targeting the provisions on menthol cigarettes, which are considered a ‘cultural product’ in Poland, and one seeking to annul the article on e-cigarettes<sup>10</sup>.

### **The integration and Europeanisation of tobacco control policy**

Insofar as tobacco products are understood as goods for trade on the internal market, both sectoral and vertical integration have been achieved and member states acknowledge the necessity and value of EU-level product regulation. The neofunctional model is dominant here, explaining the functional spillover from trade across borders to regulation of advertising, packaging, ingredients and other features. Where moves to harmonise are justified on the basis of health arguments, however, national governments have ferociously resisted EU competence. Neofunctionalism might still offer some insight here, particularly in relation to the cultivated spillover generated by the Commission’s entrepreneurial use of the internal market mandate and its leadership role (Joossens et al., 2004: 102). During the adoption of the early directives, the Commission worked largely on its own; interest groups were small and poorly resourced, leaving them unable to counter industry attacks or take advantage of favourable institutional conditions such as QMV or the role of Presidencies, whilst the CJEU has been less supportive in tobacco control than in other policy areas (Adamini et al., 2011: 50; 80; Duina and Kurzer, 2004: 59). It was thus, particularly in the early stages of EU activity, primarily the Commission which was responsible for pushing the issue up the EU agenda.

The dominant model of integration in tobacco products, however, has been intergovernmentalism. National governments, whilst conceding the logic and rationality of coordinating some elements of tobacco advertising and product standards at the European level, have ceded minimal authority and put constant limits on the extent of integration. Initial advances were made possible only by a change in the institutional environment with the introduction of QMV and the weakening of the Council’s position. Even after QMV was instated, a small group of opposing states was able to block the proposal for a tobacco advertising directive for almost 10 years and when the TAD was finally published, it prompted an ‘intergovernmental battle’ (Duina and Kurzer, 2004: 71). In its seminal *Tobacco Advertising* ruling, the Court set the boundaries of the Commission’s attempts to stretch the treaty base to its advantage, putting the power firmly back into the hands of national governments. As such, in the case of the TAD the Commission ‘...fell into a classic intergovernmental trap: a group of member states offered unwavering support while a second

<sup>9</sup> The Commissioner resigned under pressure, though maintaining his innocence and later unsuccessfully challenging the circumstances of his dismissal.

<sup>10</sup> At the time of writing, the outcome of these cases is unknown.

staged unremitting opposition’ (Duina and Kurzer, 2004: 59). The impact of this deadlock was such that in a study of the factors determining the level of tobacco control in European countries, membership of the EU was found to be an indicator of a weak tobacco regime (Gallet and Catlin, 2009: 144). Thus, like most of health policy, different elements of tobacco control policy are best explained by different schools of integration theory.

Studies of the Europeanisation of tobacco control have focused upon the level of ‘fit’ between national and European policies. Instances of poor implementation or strong opposition are understood to be the result of insufficient fit between the imposed EU policy and the pre-existing status quo in the member state (Duina and Kurzer, 2004: 59). The multi-level nature of tobacco control also plays a key role in determining the extent of Europeanisation – national governments, the Commission, the Parliament, European and national interest groups, the WHO, the United Nations and the World Trade Organisation, among others, all play a role in policy-making and diffusion (Joossens et al., 2004: 99). The primary Europeanisation dynamic in tobacco control policy, identified by Studlar et al. (2011: 728), is top-down. Here ‘vertical policy diffusion through the EU has aided domestic policy adaption [sic]’, but much of this policy learning also comes from the international level, with the FCTC playing a core role in changing national approaches (Bosdriesz et al., 2015: 193). Crucially, Bosdriesz et al. (2015: 194) find that, since the introduction of tobacco control policies at European and international level, ‘the influence of national political factors has decreased’. In addition to EU directives and the FCTC, national governments are strongly influenced by developments in other countries, in particular in relation to legal challenges – many governments are watching the cases currently underway against Australia and Uruguay, both of which introduced tough laws on packaging and health warnings and are being sued by industry consortiums (Mackey et al., 2013). As such, whilst EU directives are generally – though not uniformly – built into the policy structure and organisational logic of national tobacco control frameworks and evidence of policy learning and diffusion can be seen, the process of Europeanisation runs concurrently with a process of ‘internationalisation’ (Princen, 2007).

## **The governance of tobacco control policy**

In terms of the factors which determine the mode of governance used in a given policy area, tobacco control might be understood as a more ‘intense’ example of many of the characteristics exhibited in the medicines ItP case. High political sensitivity, strong lobbies and interest groups, reliance on the internal market legal base and conflict within individual parts of the European Commission are common to both cases but are amplified in the fight to regulate tobacco products.

Tobacco control is governed almost exclusively by European directive. Soft law measures are taken where the issue at hand begins to stray out of the EU’s internal market competence, such as in the case of SFEs, and some market-based instruments are employed in product taxation and for smoking cessation programmes via the PHAP, but binding regulation is used in all other areas (*EU Health NGO I*). Interestingly, the intense political divisions and resulting difficulty in gaining consensus have done little to affect the Commission’s reliance on hard law, or its ability to secure it. Policy-makers have consistently opted for legislative solutions which are developed as ‘escape routes’, designed to overcome the specific roadblocks which have been presented, rather than maintaining the contested provisions in a non-binding instrument (Adamini et al., 2011: 67). A small concession is made in the choice

of framework regulation or ‘new harmonisation’, which sets minimum standards and leaves member states with considerable discretion in implementation, but hard law remains the primary tool (Hervey and McHale, 2004: 379). This may in part be because policy-makers doubt the ability of soft law to ensure implementation in the tobacco sector, but mostly it is indicative of the strength of the EU’s internal market competence. So long as a measure can be justified in terms of its contribution to borderless trade, it can be presented as a binding instrument.

The power at the disposal of the Commission in this area has made ‘expansionism’ a recurring theme in the tobacco control literature. Duina and Kurzer (2004: 57) identify the ‘ambiguous language of the treaties’ as the catalyst for Commission action and surmise that:

‘The European Commission has repeatedly attempted to expand its regulatory authority. Driven, as all bureaucracies, by a natural desire to broaden its sphere of influence and by a vision of an ever more influential European Union, it has mobilized to produce legislative frameworks in areas beyond the mandate set by the founding treaties and their subsequent revisions.’

Similarly, Alemanno and Garde (2013: 3) conclude that:

‘...this field of EU policy has been at the forefront of a ‘federal’ experimentation, helping delineate the limits of EU competences and the relevance of the principles of subsidiarity and proportionality for EU law and policy-making...the EU has not hesitated...to push the EU agenda.’

The use of the internal market article is understood as political strategy on the part of the Commission – the other option at the time, Article 235 EC, reduces the role of the Parliament and requires unanimity, making legislation much harder to pass (Boessen and Maarse, 2008: 5). The historical use of Article 100a (Art 114 TFEU) is understood by many as a ‘creative response’ to the absence of a public health basis, used to frame a market-correcting activity as a market-making one (Boessen and Maarse, 2008: 3; Joossens et al., 2004: 102; *EU Health NGO I*). This playing of the treaty-base game has led some to question the EU’s ‘almost limitless authority to harmonise pursuant to the internal market legal basis’ and demonstrates the ongoing conflict between the expansionist agenda and the limited treaty mandate (Adamini et al., 2011: 73; Alemanno, 2012: 240).

The depiction of an entrepreneurial and expansionist Commission masks the presence of deep internal divisions, however. Tobacco control is a stark example of inconsistency and contradiction in EU policy – in the early 1990s, the EU spent around EUR 1,000 million subsidising tobacco producers whilst dedicating approximately EUR 1.5 million, 0.15 per cent of this amount, to smoking prevention policies (Gilmore and McKee, 2002: 339). The various Commission departments – trade, agriculture, industry, health and finance – each pursue a different objective, seeking conflicting subsidies, taxes, regulations and market freedoms. Direct subsidies for tobacco under the CAP have now been abolished but the new system offers a blanket payment per hectare, maintaining tobacco as a lucrative crop, and use of historic-payment systems in some countries peg subsidies to the higher payments received under previous structures (*EU Health NGO F*). Similar legal and policy inconsistencies exist at national level and, in most member states, health ministers find themselves at odds with their counterparts in the treasury and economic ministries.

Adding intensive and well-funded lobbying to these institutional divisions creates a tobacco control policy which is in constant flux. It has a ‘shifting nature’ (Alemanno, 2012: 240), wherein it tries to balance free trade and public health imperatives, and at any one time it is determined by ‘the balance between the tobacco industry effort to maintain a policy environment that promotes and supports tobacco use and public health authorities seeking policies designed to reduce tobacco consumption’ (Hiilamo and Glantz, 2015:57). Governance is inclusive and participatory, and a large and well-established community of NGOs and interest groups play a significant role in the policy-making process.

The high political sensitivity of tobacco control often takes precedence over the established evidence base. Whilst there are technical aspects to the legislation proposed – such as the need to update in response to developments such as electronic cigarettes, slim-style designs and new flavourings – they take secondary importance to political factors in most cases. This is clearly seen in the rules on nicotine yields – by the time of the drafting of the TPCD research showed that yields were misleading and ineffective indicators of the danger of cigarettes, yet they remained a requirement because the industry favoured their inclusion (McNeill et al., 2012: 2). In this way, tobacco control reflects Radaelli’s ‘logic of politicisation’, whereby politics plays a greater role in decision-making than evidence or expertise (1999: 4). This is partly explained by Toshkov’s assertion that tobacco control ‘does not map well’ on the traditional, left-right, liberal-authoritarian political scale (2013: 448). This implies that, rather than being the result of the will or preference of the executive, the determinants of tobacco control policy-making are found outside of political ideology, in sources such as public opinion, policy diffusion and ‘the fundamental socio-economic characteristics of different polities’ (Toshkov, 2013).

Tobacco control policy is an illustrative example of the power of the internal market legal base and the potential of regulatory policy as a lever for achieving health objectives. Though there are clear limits to the use of the internal market base in pursuing health objectives, potential for tobacco control exists in other areas of EU policy – a new directive on tobacco tax is planned for 2016, for example, though this offers limited health advocacy opportunity and will require unanimity in the legislative process (*EU Health NGO B; D*). By contrast the BTO case, where more recent policy developments in the areas of ethical sourcing and supply have taken a non-binding form on account of their political sensitivity, policy-makers in tobacco control have continued to govern by framework regulation. In fact, use of the internal market base facilitated the introduction of tobacco control measures as a health tool prior to the introduction of a public health mandate. Moreover, according to one interviewee, the achievements made during this period were ‘radical’ and extremely effective by comparison to those secured since 1992 (*European Commission, Health Directorate A*).

## **Horizontal themes in EU health policy: Comitology, the OMC and ‘new’ modes of governance**

As the scope and content of EU policy becomes more complex, policy-makers are forced to innovate, introducing new and creative ways of reaching agreement and maintaining the efficiency of the policy-making process. Both the tobacco control and the medicines ItP cases are illustrative examples of how multiple interests and market dynamics affect the kind of governance which characterises health policy.

The TPD, for instance, provides an insight into the use of the comitology procedure. Comitology is a process which enables the implementation of a particular piece of legislation to be delegated to the Commission<sup>11</sup>. Most governments and constitutions have provisions for the delegation of power to the executive – they exist to speed up the legislative process and remove technical and logistical detail from the already complex process of agreeing and passing a law. They also allow for elements of a law to be updated and amended without re-starting the entire legislative process. As such, delegated powers are a common and, in themselves, uncontroversial feature of government (*EU Public Affairs Consultant A*). In the EU, comitology was first introduced in the 1960s to deal with the more technical aspects of the CAP and agriculture remains one of the most active sectors – in 2011, just one of its 18 new-comitology committees met 76 times (Brandsma, 2013: 33).

In contemporary EU policy-making, new comitology is used in almost every sector; each year the EU produces around 60 to 70 legislative acts, but adopts over 2000 delegated and implementing acts; the content of these acts is theoretically technical, but it is often central to the meaning and effect of the legislation and is commonly quite political in nature (*EU Public Affairs Consultant B*). Delegated acts give the Commission great freedom, preventing the Council or the Parliament from amending its proposals and requiring large majorities to secure a veto. Implementing acts require that proposals are put before and take account of opinions from committees of member state experts. These national representatives commonly come from the civil service or relevant ministries but can come from any background. This creates an immediate geographical imbalance, since larger member states have more experts to choose from, and raises concerns about the independence and vested interests of the representatives present. As such, and particularly in the revised form introduced in the Lisbon Treaty, comitology can be seen to have taken on a new and less benign character.

The TPD contains more than 20 implementing and delegated acts. The implementing acts provide for the use of dedicated committees to decide which additives should be on the priority list for enhanced reporting, what technical specifications should be used for the layout, design, and shape of combined health warnings, and what standards shall be adopted for the establishment and operation of the tracking and tracing system, among other provisions. The delegated acts give the Commission the power to adopt non-legislative acts regulating emissions levels, additive levels and the picture library for use in package health warnings, for example. There is concern among the health community that some of the provisions pushed into delegated and implementing acts significantly affect the functioning of the policy and should have been dealt with in the body of the Directive (*EU Health NGO C*). In the list of diseases mentioned on health warnings, for instance, chronic obstructive pulmonary disease (COPD) has been left out as a result of insufficient expertise in this area on the committee responsible (*EU Health NGO I*). Comitology procedures are also remarkably difficult for civil society groups to influence, raising questions about the accountability of health governance.

Comitology is an early example of a governance tool developed to deal with increasingly complex and prolific EU policy. Similarly, the NMGs emerged during the 1990s in response to the ‘gridlocks’ facing EU policy activity which increasingly encroached upon areas of high

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<sup>11</sup> Officially, the system known as ‘comitology’ no longer exists, having been replaced by delegated and implementing acts in the Lisbon Treaty (Articles 290 and 291 TFEU). However, this article adopts the commonly-used term ‘new comitology’ to refer to post-2010 delegated powers procedures.

political sensitivity, such as health, welfare and education (Héritier, 2002: 187). Emblematic of the ‘...inherent ability of the EU...to constantly reinvent itself as part of an evolutionary process of...survival’, these approaches departed from the traditional community method of policy-making by including private actors in policy formation (Szyszczak, 2006: 487). The group of instruments referred to as the NMGs includes voluntary performance standards, self- and co-regulation mechanisms, social benchmarking, target setting and non-binding agreements, among others. They have in common their emphasis on voluntarism, subsidiarity and inclusion and they seek to influence policy and behaviour through learning, diffusion, persuasion, peer pressure and standardisation of knowledge (Héritier, 2002: 187). The most widely studied of the NMGs is the OMC, designed to facilitate the exchange of information, the establishment of benchmarks of good practice and the development of non-binding policy guidelines in areas where harmonisation is not possible (McKee et al., 2004b).

Since many aspects of health policy are considered national responsibilities and agreement on binding EU regulation is difficult to achieve, the NMGs have been extensively applied in this area. Examples include the networks on rare diseases, eHealth and HTA introduced as part of the Directive on patients’ rights in cross-border healthcare (Greer, 2011), joint actions in the areas of cancer control, health workforce and health inequalities, and the Pharmaceutical Forum, which played a leading role in medicines ItP policy development. Furthermore, the Amsterdam Treaty extended the original employment-focused OMC to cover pensions, social inclusion, health and migration. The SPC, which oversees the health policy strand of the OMC, was established in 2004 to coordinate approaches to a variety of health issues in line with the commitment to the European Social Model outlined in the Lisbon Strategy. Its initial aims were deliberately vague, however, so as to provoke as little opposition as possible and, consequently, it is comparatively less advanced than its equivalents in the social inclusion and pension fields (Mossialos et al., 2010; Steffen, 2005: 40).

Both the comitology procedure and the NMGs play a significant role in contemporary health governance. The use of the former is particularly interesting as an indication of what issues are considered ‘technical’ and how their resolution via a non-legislative procedure affects their content. The latter provides an insight into the creative licence used by the Commission in obfuscating the limits to its legal authority in health and the strength of soft law as an alternative to coercive governance.

**Figure 9: Summary of health policy dynamics, case study four**

<b>Dynamic</b>	<b>Catalyst and driver</b>	<b>Actors, interests and politicisation</b>	<b>Policy type and instruments</b>	<b>Governance mode</b>
<b>BTO policy</b>	Blood contamination crisis set agenda Mandate from member states Driven by Commission, micro-sector spillover to tissues & organs High macro-sectoral & vertical integration	Public health actors, some market relevance but actors less visible Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down & indirect Europeanisation	Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy	Framework regulation (safety) Voluntarism (ethics)
<b>Cancer prevention policy</b>	Council Presidency agenda-setter Commission/Parliament driver thereafter Cultivated spillover across micro-sectors High macro-sect, weak vert integration	Health actors, epist communities & experts Mostly clinical actors (beginning) Some political actors (recent) Balance of uploading & downloading Soft/indirect Europeanisation	Soft regulatory, education, market-based Recom. & resolutions Policy coordination & transgovernmentalism	Voluntarism Targeting
<b>Medicines ItP policy</b>	Completion of the internal market Thalidomide tragedy (crisis) Commission (ENTR) driver, spillover High macro-sect & vert integration	Market, business & health interests Intra-Commission divisions Market v health, little consensus Participatory approach to accommodate	Hard law (regulation) Directives, participatory instruments (consult.) Regulatory policy	Framework regulation (pharmaceuticals) Coercion (DTCA ban)
<b>Tobacco control policy</b>	Completion of the internal market DG Santé driver, cultivated spillover Court role in legal challenges High macro-sect & vert integration (product standards)	Market, business & health interests Strong interest groups & industry lobbies Intra-Commission divisions Int'l level influence important Top-down Europeanisation	Hard law (product standards) Soft law (SFEs etc.) Directives and resolutions Regulatory policy	Framework regulation (product standards) Voluntarism (SFEs etc.)

## THE ROLE OF THE COURT IN HEALTH

### *The case of patient mobility policy*

The development of EU patient mobility legislation – often referred to as cross-border healthcare legislation – has been described by a leading expert in the field as a ‘solution without a problem’<sup>12</sup>. Forced onto the European agenda by a series of judgements handed down by the CJEU, for member states it represented the first major threat to the financing of health systems and the first unanticipated exposure of those systems to free movement principles. Its academic significance is substantial as a case study in judicial activism, legally-driven integration and ‘uninvited Europeanization’ whilst for policy-makers, its implications for national health systems, quality of and access to care offer great potential for policy learning and the improvement of health systems (Baeten, 2012; Fahy, 2010; Greer, 2006). However, the number of patients seeking healthcare abroad is small and, in most cases, those for whom cross-border care holds potential benefit have been accessing such care without the help of an EU legal framework for some years (Footman et al., 2014; McKee et al., 2013).

Whereas the medicines ItP and tobacco control cases illustrate the role of the free movement of *goods* in EU health policy, patient mobility policy has been the battle-ground for the application of free movement of *services* law to national health systems. Furthermore, it is an insightful example of changing health governance, with the Court setting the parameters of policy decisions and forcing a rights-based approach to policy-making. Finally, in terms of competence creep and expanding the EU’s activity in health, the resulting directive introduced a raft of new mechanisms for cooperation and is widely considered to represent the pinnacle of momentum in EU health policy.

### **What is meant by patient mobility policy?**

Discussions of patient mobility generally centre around five ‘categories’ of mobile patient: tourists and those seeking emergency care as temporary visitors abroad; people retiring to other countries and demanding care in their new place of residence; people living in border regions where the nearest or preferable care facility is in a neighbouring state; patients seeking care abroad on their own initiative because of perceived benefits in cost, quality, etc. and; patients sent abroad by their national health systems for specialised care or to serve domestic policy goals (such as challenging care provision monopolies) (Rosenmöller et al., 2006). Provisions for migrant workers are covered by regulation on the coordination of social security systems, which also contains provisions for emergency care, the first category identified above, through the E111 (and more recently the European health insurance card, EHIC) systems. However, the need for a policy framework to coordinate care across the other four categories only emerged on the European agenda with the application of free movement law to the health sector.

### **The historical evolution of EU patient mobility policy**

Provisions to facilitate the receipt of planned or unplanned healthcare in another member state are not new. Based on the free movement of persons provisions in the founding treaties, a mechanism was set up in 1958 to coordinate social security entitlements for migrant workers

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<sup>12</sup> Senior figure quoted by Palm and Wismar (2014) during a workshop on cross-border care, delivered at the European Health Forum Gastein in October 2014.

moving within the European Economic Area (Bertinato et al., 2005: 7). These arrangements were codified in Regulations 1408/71 and 574/72 to ensure that certain groups, under strictly defined circumstances, could access healthcare abroad based on the coordination, rather than the harmonisation of systems (McKee et al., 2004a: 158). The Regulations enabled care to be sought in two specific situations: occasional care arising during a temporary stay, to be addressed with an E111 form, and planned care, arranged with the ‘sending’ member state and requiring prior authorisation via an E112 form. In 1998 a revision of the arrangements for coordinating social security systems was undertaken, the primary outcome of which was the introduction of the EHIC<sup>13</sup>. This replaced the existing E111 form and was designed to foster growth and jobs as part of the Lisbon Agenda, by making cross-border care easier to access and the benefits of the EU more visible to citizens (Bertinato et al., 2005: 8).

Up until this point, the legal basis for cross-border care had drawn upon the principle of free movement of people but, in the 1990s, a series of cases brought before the CJEU began to forge a basis for cross-border care in the provisions on the free movement of services (Footman et al., 2014: 5).

### **The Court of Justice and the legal response**

The transformation of patient mobility policy was prompted, in the first instance, by two court cases in which EU citizens contested the restrictive pre-authorisation requirements of the existing framework (Bertinato et al., 2005: 8). In linked cases, two residents from Luxembourg took their national sickness funds to court for refusing to reimburse treatment received in another member state. Both treatments constituted planned care; neither had obtained the required prior-authorisation from their home institution. In its rulings in *Kohll* and *Decker*, the CJEU found that health is an economic activity provided in exchange for remuneration, irrespective of the type of care or system and that, in most cases, prior authorisation thus constitutes a barrier to free movement. The Court acknowledged that member states should be allowed to require prior authorisation in certain situations where it is necessary to protect the planning and contracting of health systems – this reasoning was termed ‘overriding general interest’. However, in the cases of Mr Kohll and Mr Decker, the Court found no such justification and ruled that the sickness funds issue the reimbursements as requested.

The *Kohll* and *Decker* cases sent waves through the European and national health communities, ‘unleashing a flurry of political and academic discussion about the precise implications of these rulings that...offer[ed] very little detail of what they meant in practice’ (Rosenmöller et al., 2006: 2). The conference organised to address these pressing issues and its resulting publications, noted in chapter four, brought forward for the first time the idea of a coherent ‘EU’ health policy (McKee et al., 2002; Mossialos and McKee, 2002). What followed was more than a decade of case law and a relative explosion of EU health policy literature.

Having established the initial principle, the Court presided over a succession of further cases which refined and further delimited the circumstances under which a patient may expect

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<sup>13</sup> Amendment to Regulations 1408/71 and 574/72 was made in Regulation 883/2004 and again in Regulation 988/2009. Each of these successive revisions has sought to streamline and simplify the coordination of social security systems for migrant workers, temporary workers and students but has not affected the content of health or social security provisions.

reimbursement for care sought abroad<sup>14</sup>. In *Geraets-Smits and Peerbooms*, the Court reiterated its finding that hospital care is an economic service in the sense of the Treaty but clarified that such care, requiring planning in order to guarantee a rationalised, stable, balanced and accessible supply of hospital services, could require prior authorisation so long as this was necessary, proportionate and based on objective criteria (Palm et al., 2011: 27). In *Vanbraekel*, the Court gave further details on reimbursement, ruling that where both the free movement principles and Regulation 1408/71 apply, patients should be reimbursed at the higher level, so as not to discourage them from seeking care abroad. In *Müller-Fauré and Van Riet*, the Court held that the principles elucidated thus far applied to all kinds of health and reimbursement system, whether it be a restitution or a benefits-in-kind system. It was also in this linked case that the concept of ‘undue delay’ was elaborated, meaning that patients could expect to be reimbursed for treatment that was available at home but was subject to an unacceptable waiting time. Finally in *Watts*, a case brought in 2006, the CJEU stated that the obligation to reimburse also applies to health systems which, like the UK National Health Service, provide their services free of charge. The ruling went on to outline a framework process in which the cost of care should be calculated and compared to the objectively quantified cost in the home country.

### **Political negotiation and the legislative response**

As the case law progressed the European Commission, urged by member states keen to adopt a legislative solution that would end the flow of rulings, introduced a number of instruments to construct a political framework. The High Level Reflection Process on Patient Mobility, launched in 2003, created a set of recommendations across the three Commission departments responsible for health, social affairs and the internal market (European Commission, 2003). In 2004 a communication was issued defining the topics on which work would focus and establishing the High Level Group on Health Services and Medical Care to take forward the Reflection Process recommendations (European Commission, 2004; Rosenmöller et al., 2006: 3).

Having collated a clear overview of the areas where solutions were required, the Commission made a first attempt to legislate on the issue of patient mobility in the Services Directive, which sought to create an overarching EU regime for the regulation of services. The Directive was criticised on a number of levels but in particular, the inclusion of health was rebuked and after two years of negotiations, the Parliament agreed to adopt only if health was removed (Palm and Glinos, 2010). When the Directive was approved in 2006 the Commission announced that it would seek to address the health services issue within a dedicated directive and, indicating its tentative support for such a measure, the Council adopted a set of conclusions on common values and principles in EU health systems (Baeten, 2012: 9; Council of the EU, 2006). These conclusions were important because, whilst the Council did not intend for them to become a binding set of minimum standards, they reflected the understanding of the hour, which was that a common market requires health systems to converge on some level, since the presence of weaker and less expensive health systems in some countries creates divergence in costs and distorts competition (*Academic Expert, EU Health Policy B*).

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<sup>14</sup> The summary which follows is abridged from the overview given in Palm et al. (2011).

Soon thereafter the Commission initiated a public consultation, a Eurobarometer survey and a study by the WHO European Observatory on Health Systems and Policies and, in 2008, published its legislative proposal for a directive.

### **The Directive on the application of patients' rights in cross-border healthcare**

The process for adopting the directive was long, since it sought to move the legal basis for action away from the free movement of services and towards a patients' and citizens' rights imperative (Footman et al., 2014: 7). It also sought to take an integrated approach, '...incorporating not only financial elements but also addressing the wider 'flanking' measures' needed to reassure patients and providers (Palm et al., 2011: 32). As such, member states feared it might infringe upon national competence for the planning and contracting of services and were wary of its impact on the provision of rationalised, stable, balanced and accessible hospital care (Bertinato et al., 2005: 9). To address this, the legal base of the proposal was changed from a single reliance on the internal market provisions (Article 114 TFEU) to a split legal base with the public health article (Article 168 TFEU). This also allowed for the inclusion of a number of cooperation and coordination measures and facilitated the expansion of the original scope of the text (Baeten, 2012: 12).

The adopted Directive does not create new patient entitlements but rather clarifies existing ones (Baeten and Palm, 2012)<sup>15</sup>. It states that EU citizens have the right to reimbursement when receiving care in another state and that this reimbursement should be given up to the cost of the same treatment at home, where neither sets of fees can discriminate between domestic and travelling patients. It allows member states to make reimbursement subject to prior authorisation only where the care being received is a) an overnight stay or b) highly-specialised or cost-intensive, and permits refusal of prior application only where there is no undue delay at home or where the cost of reimbursement would threaten the overriding general interest of the health system. These exceptions exist to protect the planning and financing of sustainable health coverage. The quality and safety standards and relevant legislation of the country of treatment apply and a set of minimum patients' rights are enumerated – they include provisions for appeal against decisions of authorisation and reimbursement, redress and compensation, privacy and access to health records and non-discrimination. Finally the Directive requires that member states establish national contact points to provide information to incoming and outgoing patients, encourages them to engage in frameworks for enhanced coordination in eHealth and HTA, and provides for the creation of a European reference network.

The deadline for transposition into national law was set for October 2013 and in 2015 the Commission published its first report on the implementation of the Directive (European Commission, 2015b). The actual impact upon patient consumption of cross-border care and health system financing is acknowledged to have been minimal – of only 560 applications for prior authorisation in 2014, just 360 were granted – but where services are being consumed abroad, problems in the provision of information and continuity of care remain (European Commission, 2015b: 5; EPHA, 2015a; Panteli et al., 2015).

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<sup>15</sup> Overview of the Directive's provisions adapted from Rowan (2014).

## The integration and Europeanisation of patient mobility policy

The cross-border healthcare case is one of the clearest possible examples of both sectoral and vertical integration by neofunctionalism in health. In response to a functional policy problem created by the free movement principles, member states conceded sovereignty in a specific area of policy and created a harmonised policy framework at the European level. Furthermore, evidence of cultivated spillover can be seen in the tactical addition of coordinating and cooperating health measures which were not strictly necessary for the functioning of the policy, such as the networks on HTA and eHealth, but which further expand the EU's activity in health. Finally, during the drafting of the Directive – and the initial attempt to subsume health into the Services Directive – supranational-level interest groups played an active role, calling for an explicit public health basis and greater emphasis on patients' rights (EPHA, 2008b).

Member states were central in granting the Commission a mandate to pursue an EU-level policy framework and the final Directive has maintained significant 'steering capacity' for national governments, but it is difficult to imply an intergovernmental model of integration; Greer (2006: 143) describes patient mobility as 'a dramatic case of neofunctional spillover dynamics, driven by the Court and provoking activity in a policy sector where no member state intended it'. In the marked absence of national demand for an EU health services policy, the Court '...set in motion a dynamic that governments and health policy actors [could] not escape', leaving them with minimal discretion in building a legislative framework around the case law (Lamping, 2005: 30; Baeten, 2012: 6).

Since the Directive came into force in October 2013 national health systems have been required to adapt and comply with the EU framework in a model of top-down Europeanisation. This process has not been seamless – infringement proceedings were opened against 26 member states and four remained open in July 2015, as a result of incomplete transposition of the Directive's measures (European Commission, 2015b: 1). Furthermore, the assumption that fit or misfit dictates the degree or efficiency of transposition is called into question by Austria's rejection of the Directive. Despite being the only country that did not need to change its internal legislation in order to comply with the EU rules – suggesting a strong 'goodness of fit', successful uploading and likely support of the legislation – Austria voted against the Directive in the Council. This decision is attributed to the multi-level nature of hospital funding in the Austrian system and the influence of the regions on the national position (Kostera, 2013).

However, even before the Directive was finalised, adaptation to the principles enunciated in the Court's judgements could be seen. For instance, Baeten (2012: 7) notes evidence of changes in contracting by sickness funds in the Netherlands and the promotion of domestic healthcare facilities for export in Belgium and Poland. Furthermore, it is argued that the Directive might have an impact even in those areas, such as quality and standards of care, which are reserved as national responsibilities. The literature suggest that there is significant potential for the Directive to 'become a lever to change domestic policy and practice beyond the strict legal scope of the Directive', in areas such as transparency of cost calculation and provision of information on quality, safety and health professional records (Baeten and Jelfs, 2012: 26; Rowan, 2014). As such, a form of indirect Europeanisation, top-down in nature but beyond the explicit scope of the Directive, can be seen.

The process of negotiation and litigation which led to the adoption of the patients' rights Directive also contributed to the broader Europeanisation of health. Hervey and McHale (2015: 51) identify the debate, prompted by the Services Directive and embodied in the cross-border healthcare provisions, as the catalyst for the development of a set of 'common values and principles' in EU health systems. The stated values and principles – universality, access, equity, solidarity, quality, safety, evidence-based ethical care, patient involvement, redress, privacy and confidentiality – were adopted by the CoEU in 2006 and subsequently endorsed by the Commission and the European Parliament, and are referenced in the PHAPs and other EU legislation. Though questions remain about the practical realisation of such values, their role in fostering greater coherence in EU health law and further Europeanisation of health policy is significant (Hervey and McHale, 2015: 52).

## The governance of patient mobility policy

The literature on patient mobility concludes unanimously that this is both an integrated and a Europeanised area of health. It emphasises the distinct role of the Court in these processes, describing the evolution of policy as 'legally-driven neofunctionalism' and 'Europeanisation via case law' (Greer, 2006; Steffen et al., 2005: 5), but it also notes the entrepreneurial role of the Commission. Supported by the Court, Commission officials successfully harnessed the political demand for an explicit legal basis for health, as well as the broad concern to avoid a similar framing as the Services Directive, and used this to its advantage. For the Commission the goal of the Directive, in addition to replacing judicial policy-making with executive control, was to 'get a foot in the door' and establish the EU's role in health systems policy (*Academic Expert, EU Health Policy B; UK health association, EU Liaison A*). Some felt that it went too far – an interviewee from the Parliament noted that 'there were genuine issues in [the] cross-border healthcare [debate]...but the Commission response was excessive, expanding specific points to general principles' (*Member of European Parliament B*). Others viewed the legislation as a 'Christmas tree':

'Essentially, the Services Directive made clear that dedicated health legislation was needed but patient mobility, in and of itself, was not sufficiently interesting to warrant attention. Thus an opportunity was presented to add things in. These things weren't drawn from thin air, they were existing projects or ideas, but they were now formalised or made more permanent.' (*European Commission, Health Directorate C*).

Riding on momentum and a sense of optimism from other health policy activity, in areas such as professional qualifications, tobacco control and pharmaceutical policy, the Commission's strategic action might be understood as opportunity politics (*European Commission, Health Directorate C; Academic Expert, EU Health Policy A*). The 'additional' provisions on eHealth, HTA and reference networks 'put in place a new conversation' on the EU's role in health systems, feeding into the discussion of health as an economic sector and eventually resulting in the Communication on effective, accessible and resilient health systems in April 2014 (*European Commission, Health Directorate E*).

The patient mobility case is a good example of the difficulty inherent in attempting to separate technical from political elements of health policy. One interviewee noted that 'patient mobility and health equity *are* the political aspects of health – everything else is technical or clinical' (*EU Health NGO C*, emphasis highlighted). The logistical and legal provisions which needed to be put in place in order to facilitate patient mobility, however, were fairly technical – a loose consensus on the rights and responsibilities involved was in place early in the

drafting process, not least because such rights and responsibilities had already been stipulated by the Court and therefore were not open for negotiation. Even the decision to use a separate directive, rather than incorporating the necessary provisions into the existing regulations on social security coordination, was essentially a technical one, based on whether the scopes and objectives could be sufficiently aligned (*Academic Expert, EU Health Policy B*).

However, during the drafting process, certain and specific technical issues became the cause of political debate – the inclusion of a second legal basis and of reimbursement for non-contracted providers are two such examples (Baeten, 2012). The argument that health could not be considered a service like any other, used to justify exemption from the Services Directive, led to an integrated approach by the Commission which raised opposition in the legislature. The original name for the Directive, for instance, was changed from ‘Directive on safe, high-quality and efficient cross-border health care’ at the insistence of member states wary of its implicit implications for subsidiarity (Palm et al., 2011: 34). Furthermore, whilst cross-border care was a fairly routine notion for countries which share borders, it was inherently more political for the UK and Ireland, for example (*UK health association, EU Liaison A*). As the first explicit measure to address the market’s role in health services and the first explicit statement on the EU’s role in health systems, the Directive was a highly political issue. As a result, the Commission team involved in the drafting and negotiation process, though containing much technical expertise, saw itself at the interface between the technical and political discussions and perceived the process as a political one (*Academic Expert, EU Health Policy B*).

As a result of the political demand for a legislative solution, the relative strength of the Commission as the leader of the legislative process and the careful balance between technical and political considerations, patient mobility policy is now governed by framework regulation. However, the EU institutions have also made use of softer provisions to support and underpin the Directive – targeting via the High Level Reflection Process and its recommendations was key to ‘testing the water’ with potential policy options, whilst Council conclusions were used to guide the draft proposal and the results of Eurobarometer and WHO Observatory research to inform its content. The patient mobility case is also widely recognised as the prime example of health governance via litigation and supplementary law. Case law is not a policy instrument but can be used by the EU institutions, member states and other actors to support, justify or inspire policy positions or proposals. In the patient mobility case, the interpretation of the Court aligned with the desired direction of the Commission, as opposed to that of national governments, and provided the executive with an additional ‘tool’ or ‘lever’ in the policy-making process.

## **Horizontal themes in EU health policy: the role of the Court**

The patient mobility, tobacco control and medicines ItP cases are all examples of the kind of policy which forms at the frontier between health and the free movement principles, as captured in the second stem of EU health policy. In all of these cases, the choice and justification of legal base has been an important determinant of policy instrument and mode of governance; in some instances, as seen in the previous chapter, this has led to an increased role for soft law. Where hard law has prevailed, however, the development of ‘second stem health policy’ has elevated a different actor – the CJEU. As the creativity around the legal base has increased, so too has the prevalence of legal challenge and contestation. This has come firstly from governments and interest groups in the legislative process, as seen in the

tobacco control case and, secondly, from individual citizens, as seen in the development of patient mobility policy. The demand for judicial ruling has given the Court a central role in the development of EU health policy and sparked a debate in the literature on the nature and implication of this role.

Academic interest in the role of the Court ignited in the early 1990s with studies of constitutionalisation and the unique nature of the EU's legal system. For neofunctionalism, the Court is identified as an agent of neofunctional spillover and an 'unsung hero' of revived integration (Burley and Mattli, 1993: 41). For intergovernmentalism, the Court's power is mitigated by the fact that it can only act '...through discreet decisions on concrete issues' and, since national governments control the integration process, its decisions are '...likely to accord with the interests of powerful states' (Moravcsik, 1993: 624; Garrett, 1992: 537). Furthermore, national courts can choose, and in the past have on occasion chosen, to stem the Court's influence by not referring a matter for preliminary ruling and instead interpreting EU law as they see fit, thus exercising a 'gate-keeping' role in the Court-based development of EU jurisprudence (Hervey and McHale, 2015: 56). Both schools now recognise, however, that the doctrines of supremacy, direct effect, state liability and mutual recognition, among other innovations, have fundamentally altered the personality and potential of the European project.

'...it is indisputable that these doctrines, once institutionalised, radically expanded the Court's own zone of discretion and reconstituted the EU as a quasi-federal legal system, comparable to other federal fields...Once constructed as a kind of central nervous system for supranational, and multi-level, governance, the legal system also sustained an ongoing judicialisation of policy-making within many important domains.' (Stone Sweet, 2011: 132)

In health policy the Court has performed two main roles. Firstly, it has supported and facilitated the extension of the health mandate and the increasing impact of EU law on national health systems. Discussing social policy more broadly, Rhodes (2010) notes the importance of the ongoing cycles of the 'treaty-base game', in which the Court supports the Commission in '...stretch[ing] as far as possible the interpretation of "health and safety"'. Duncan (2002: 1029) goes as far as to depict the Court and its generous rulings as the 'wildcard' of EU health policy and the EU's institutional framework. The relevant literature widely concurs that the extension of EU activity into health systems via patient mobility policy, creeping beyond the boundaries of competence envisaged in the treaties, could not have been achieved without the support of the Court or the provisions for state liability and litigation by individual citizens (Greer, 2006; 2008; Lamping, 2005).

The Court's second role in EU health policy stems from its position as protector of the fundamental principles and freedoms enshrined in the founding treaties. Judgements such as *Kohll and Decker*, though considered a turning point, endogenous shock and critical juncture in health policy, did not represent new legal thinking or judicial innovation (Mossialos et al., 2010: 28). Some application of the internal market rules to social security systems had already been explored in the 1981 *Duphar* ruling and the Court was acting within its mandate in interpreting the available law in order to address policy gaps (Mossialos et al., 2010: 29). This ties into a conception of the Court as neither a driver nor an irrelevant bystander in the process of European integration, but rather as an indirect shaper of the broader environment and creator of the necessary conditions for Europeanisation. Hervey (2012) uses the example of communicable diseases policy and the creation of the ECDC, an area without obvious Court intervention or entrepreneurship, to illustrate the Court's role in shaping the institutional

context which facilitated the Europeanisation of a key area of health policy. In particular, the Court's role in designating public health protection as an area of EU responsibility, in affirming the constitutional permissibility of EU agencies, in stating the necessity of legislation to protect public health and in preventing internal market law from undermining such legislation are identified as crucial to the form and substance of contemporary communicable disease policy (Hervey, 2012: 977). A similar characterisation is presented by Martinsen (2005, citing Maduro, 1999):

'That Europe ever came to regulate national healthcare has not occurred as an output of rational political decision-making, but rather as a 'side-effect' of how the European Court of Justice gradually conferred a 'supreme' status to the free movement provisions in the EU legal construct and in this way interfered in virtually all areas of national law and policy.'

Thus the role and influence of the Court in the development of EU health policy, though not always explicit or immediately apparent, should not be underestimated.

**Figure 10: Summary of health policy dynamics, case study five**

<b>Dynamic</b>	<b>Catalyst and driver</b>	<b>Actors, interests and politicisation</b>	<b>Policy type and instruments</b>	<b>Governance mode</b>
<b>BTO policy</b>	Blood contamination crisis set agenda Mandate from member states Driven by Commission, micro-sector spillover to tissues & organs High macro-sectoral & vertical integration	Public health actors, some market relevance but actors less visible Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down & indirect Europeanisation	Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy	Framework regulation (safety) Voluntarism (ethics)
<b>Cancer prevention policy</b>	Council Presidency agenda-setter Commission/Parliament driver thereafter Cultivated spillover across micro-sectors High macro-sect, weak vert integration	Health actors, epist communities & experts Mostly clinical actors (beginning) Some political actors (recent) Balance of uploading & downloading Soft/indirect Europeanisation	Soft regulatory, education, market-based Recom. & resolutions Policy coordination & transgovernmentalism	Voluntarism Targeting
<b>Medicines ItP policy</b>	Completion of the internal market Thalidomide tragedy (crisis) Commission (ENTR) driver, spillover High macro-sect & vert integration	Market, business & health interests Intra-Commission divisions Market v health, little consensus Participatory approach to accommodate	Hard law (regulation) Directives, participatory instruments (consult.) Regulatory policy	Framework regulation (pharmaceuticals) Coercion (DTCA ban)
<b>Tobacco control policy</b>	Completion of the internal market DG Santé driver, cultivated spillover Court role in legal challenges High macro-sect & vert integration (product standards)	Market, business & health interests Strong interest groups & industry lobbies Intra-Commission divisions Int'l level influence important Top-down Europeanisation	Hard law (product standards) Soft law (SFEs etc.) Directives and resolutions Regulatory policy	Framework regulation (product standards) Voluntarism (SFEs etc.)
<b>Patient mobility policy</b>	Case law (Bolkenstein) catalyst Commission driving actor, entrepreneurialism and expansionism Court support crucial factor Micro-sect & some vert integration	Health actors, national governments Mandate expansion, opportunism, some technical aspects Political, defensive line from member states Top-down Europeanisation	Hard law (mobility), soft law (extra provisions) Directive & voluntary, education/info provisions Regulatory policy	Framework regulation (mobility) Voluntarism and targeting (HTAs, eHealth etc.)

## GOVERNING THROUGH A FISCAL LENS

### *Health in the economic governance framework*

The final case study is slightly different in content and structure from those in the previous chapters<sup>16</sup>. The inclusion of health in the EU's strengthened economic governance framework represents the 'cutting edge' of health policy-making and research, having only become a reality in 2010 and evolving almost continually since then. It has significant implications for the actors, processes and fundamental objectives of health policy, introducing a fiscal dimension to existing policies and forging intervention into previously 'off limits' areas of health system organisation and financing.

'Just as the arrival of internal market law incorporated health into the laws and policies of the internal market, the arrival of potent new economic governance in the EU incorporates health into a structure built not to promote health but rather to promote economic stability through austerity.' Greer (2014: 17)

This chapter explores how health came to gain a fiscal dimension and to be included in instruments of economic governance. It first briefly maps the economic crisis, the EU's short- and long-term responses, and how health has been included in the resulting policy frameworks. It then reviews the implications of the 'third stem' of health policy for the integration and Europeanisation of health, focusing on cooperation in health system organisation and reform. Finally, it explores the nature of health governance under these new frameworks, particularly in light of the *de jure* non-binding nature of the European Semester and the increasing use of conditionality as a tool for compliance.

### **Setting the scene: the European 'economic crisis'**

The period described as the 'economic crisis' – beginning with the collapse of some of the world's largest banks at the end of 2008 and continuing to the present tentative recovery period – comprises a series of individual catalysts and consequences<sup>17</sup>. The first, a banking crisis, originated in the US. Encouraged by the strength of the economy and high asset prices, US banks had historically provided extensive credit and made high risk investments, commonly issuing mortgages to individuals not fulfilling standard requirements. When the economy began to slow in 2007, over-extended homeowners were forced to default on their financial commitments, putting pressure on both the American banks which issued the loans and banks all over the world with linked investments. In 2008 Lehman Brothers, the fourth largest investment bank in the US, collapsed under the weight of its high-risk ventures, prompting its investors and trading partners to begin taking precautionary measures and to discontinue lending to one another. European banks with investments in the US market were hit hard, forcing many member states to bail out the worst affected; between 2008 and 2011 national governments spent €1.6 trillion rescuing Europe's banks (European Commission, 2014c).

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<sup>16</sup> It is also an iteration of a working paper presented at the UACES Student Forum Conference 'Evolving Europe: voices of the future', held at Loughborough University, 8-9 July 2013.

<sup>17</sup> This section closely mirrors EPHA (2014), a report written and published by the author during a fieldwork placement, which in turn draws heavily on the overview provided in European Commission (2014c). The term 'economic crisis', preferred in the majority of the literature, is used for ease of reference throughout the thesis.

The expense to governments during a period of poor economic performance caused investors to look more closely at national finances, revealing significant levels of debt and resulting in a dramatic increase in lending rates by markets no longer willing to bear high risk. It was this domino effect which turned the banking crisis into a sovereign debt crisis. When the markets began to scrutinise the health of member states' finances, it became apparent that many governments had, for a number of years, been financing their budgets through unsustainable borrowing, accumulating dangerous levels of public debt. The prevailing economic recession served to exacerbate the problem, leaving member states struggling to maintain their economies with falling revenues, failing national banks and empty coffers. The sovereign debt crisis was met in many member states with programmes to reduce public spending and cut services, resulting in rising unemployment, growing inequality and the emergence of a pan-European social crisis. It is within this difficult context that the EU and its member states have sought to strengthen their economic governance policies, to prevent the recurrence of such a crisis and to secure a European recovery.

## **Economic governance in the EU**

The original structure for the coordination of economic policy between EU member states was set by the Maastricht Treaty in 1991. This introduced a 'triad' of measures, made up of the ECB (Article 105 TEU), the Excessive Deficit Procedure (EDP, Article 104 TEU) and the Broad Economic Policy Guidelines (BEPGs, Article 99 TEU). These structures were supplemented as part of the EMU framework, unique in that it integrated monetary policy whilst leaving fiscal and structural policy under the control of member states. Some 'soft' policy coordination of the latter areas has historically been organised via the BEPGs and the corresponding Employment Guidelines, but this was only formalised in the 2000s.

Two additional, complementary processes were introduced in the late 1990s. On the demand-side, stabilisation policies such as the SGP and the Cologne Process encouraged macroeconomic discipline; on the supply-side, structural reform was prompted by the European Employment Strategy (EES) and the Cardiff Process of capital and market reform. These initiatives were followed in 2000 by the Lisbon Strategy for Growth and Jobs, which institutionalised the regular Spring Councils that had emerged to coordinate decisions and developments within the EMU system and laid the foundations for the Europe 2020 Strategy. Finally the Lisbon Treaty, which came into force in 2010, made a number of changes to the existing framework. In particular, it strengthened the role of the Commission in EMU by enabling it to address warnings to member states whose policies are inconsistent with the BEPGs or jeopardise the stability of the EMU framework.

## **Crisis response: bailout packages and rescue funds**

As noted in chapter one, the short-term dimension of the EU's response to the crisis saw the creation of a variety of financial assistance and rescue funds. The latter include the EERP, the EFSF and the EFSM, which were eventually streamlined under the ESM and which provide an emergency reserve for use in the event of future destabilisation.

The former, commonly termed the 'bailout packages', provide financial assistance to countries under severe and immediate pressure. These are embodied in Memorandums of Understanding (MoUs) and are strongly linked to macroeconomic conditionality; member states must implement the required reforms – commonly laid out in Economic Adjustments

Programmes (EAPs) – in order to receive the agreed funding and this implementation is reviewed regularly by the European Commission, potentially resulting in sanctions for non-compliance (Stamati and Baeten, 2015: 26).

### **Long-term reform: strengthening the economic governance framework**

In addition to these short-term measures, the EU has initiated a series of reforms, significantly altering the pre-existing economic governance architecture. The resulting framework has five pillars: the SGP, the EuroPlus Pact, the Six Pack, the Treaty on Stability, Coordination and Governance (TSCG) and the Two Pack (Figure 11).

**Figure 11: The five pillars of EU economic governance**

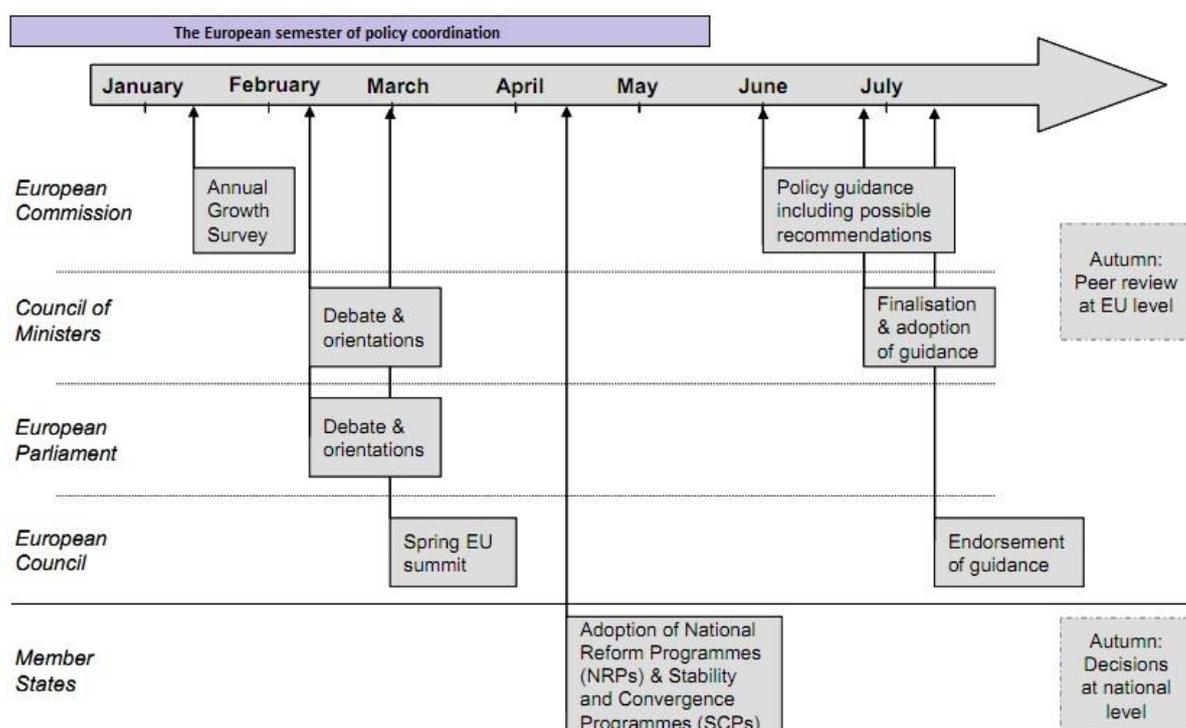
<b>The five pillars of EU economic governance</b>
<p><b>The Stability and Growth Pact</b></p> <p>Originally adopted in 1997, the SGP was reinforced as part of the Six Pack in 2011. Its overarching goal is to maintain budget discipline through a series of preventative and corrective measures which ensure fiscal policy is conducted sustainably and excessive deficits are corrected quickly.</p>
<p><b>The EuroPlus Pact</b></p> <p>Adopted in March 2011 by 23 member states, the EuroPlus Pact commits Treaty parties to closer coordination of economic policy and tighter surveillance at the EU level.</p>
<p><b>The Six Pack</b></p> <p>The Six Pack entered into force in December 2011. Importantly, it codifies the European Semester (see below) and makes a number of changes to the process, such as the introduction of the Macroeconomic Imbalance Procedure (MIP). The Six Pack consists of two regulations addressing macroeconomic imbalance surveillance, and four pieces of legislation – three regulations and a directive – which address fiscal surveillance.</p>
<p><b>The Treaty on Stability, Coordination and Governance</b></p> <p>Incorporating the Fiscal Compact Treaty, the TSCG was finalised in January 2012 and was adopted by all but two member states. Consequently, it is not part of EU law but rather is an international treaty. Its elements of fiscal policy coordination run parallel to the SGP and, as the Lisbon Strategy institutionalised the Spring Council meetings, so the TSCG institutionalises the summits of the euro area leaders. Its other key provisions include the introduction of a ‘balanced budget’ rule, requiring adherence to a medium term objective (MTO) under threat of sanctions.</p>
<p><b>The Two Pack</b></p> <p>Adopted in March 2013, the Two Pack is a pair of regulations, applicable to euro area member states only, which contributes to the further strengthening of budgetary surveillance. The regulations provide for a separate European Semester for euro area member states, with enhanced monitoring and assessment of draft budgetary plans and greater surveillance of member states experiencing or threatened by financial difficulty.</p>

The reform of the EU's economic governance framework is undertaken in the context of the Europe 2020 Strategy. Launched in 2010 to reinvigorate the flagging Lisbon Strategy, the Europe 2020 Strategy mobilises existing EU policies in pursuit of smart, sustainable and inclusive growth (European Commission, 2010a). This pursuit, the Commission noted, must be supported by a strengthening of the economic governance framework and greater economic policy coordination between the national and the European levels (European Commission, 2010a: 6). The mechanism identified for ensuring such coordination is the European Semester of policy coordination.

The Semester synchronises the various reporting and assessment cycles of the economic

**Figure 12: The European Semester of policy coordination**

Source: Eudraconia.org



governance instruments into one coherent process<sup>18</sup>. The Semester is divided into two stages (Figure 12) – the first is dedicated to coordination at the EU level, whilst the second is reserved for the incorporation of EU objectives into national budgets. It begins with the publication of the Commission's 'priorities for Europe' in the Annual Growth Survey (AGS) each November. Governments use the AGS to ensure their National Reform Programmes (NRPs), submitted to the EU in late Spring, are in line with EU objectives. On the basis of the AGS, the NRPs and a vast range of other reports and analysis, the EU then drafts a CSR for each member state, describing the measures which should be taken to ensure healthy public finances. This final adoption signals the end of the first stage of the Semester; member states now take these recommendations back to their national discussions and integrate them into domestic budgets and reform strategies.

<sup>18</sup> Space constraints preclude a detailed exposition of this complex process but the core procedure is briefly outlined – for an excellent overview in the social context see Zeitlin and Vanhercke (2015).

## Health in the economic governance framework

This section examines how health has been included in the EU economic governance framework both historically and, in particular, since the economic crisis. The framing of health as an ‘economic’ sector is not entirely new; the SGP required the European Council to publish the annual BEPGs, which historically included reference to pensions, health and long-term care systems. Whilst the guidance offered on pension reforms became increasingly prescriptive and concrete, the recommendations on health and long-term care remained broad and generic, respecting the role of subsidiarity in the organisation and financing of these sensitive sectors (Baeten and Thomson, 2012: 2). However, the onset of the economic crisis accelerated and intensified the role of health system reform in economic governance, fundamentally altering the actors, processes and objectives of EU health policy.

## Health in the financial assistance mechanisms

The thesis is primarily interested in the governance of health in the long-term macroeconomic instruments but insight from the short-term mechanisms is briefly described first. The MoUs issued to Greece, Cyprus, Ireland, Portugal and Romania all contain detailed instructions for reforming the health care sector (Stamati and Baeten, 2015: 27). In the Portuguese case, savings of EUR 664 million were required and the MoU laid out a number of measures for achieving this reduction, targeting pharmaceuticals, training and retirement of health professionals and stricter exemptions from user charges (Barros, 2012: 17-18). The 2012 Cypriot MoU contained many measures to support the introduction of the delayed Global Health Insurance Scheme but also a number of contradictory requirements. In particular, it sought the removal of the ‘Class B’ category of benefits, which provided subsidised care to those on low incomes, though research indicates that expenditure on this small pool of patients constituted a minimal burden on the health system (Cylus et al., 2013). In Greece, arguably the hardest-hit economy and most heavily-targeted health system, an early MoU stipulation to cap health expenditure at six per cent of GDP – already a low figure by European standards, made worse by the falling value of the national economy – was accompanied by the merger of health insurance schemes, the reform of pharmaceutical policies, reduction of the health workforce, changes in the purchasing of health services and blanket cuts to health sector budgets (Karanikolos et al., 2013; Kentikelenis and Papanicolas, 2011).

The MoUs each seek a reduction in health expenditure as their primary aim, targeting, in the first instance, spending on pharmaceuticals via negotiation of reduced prices, use of electronic prescribing, implementation of prescribing guidelines and increased use of generics (Stamati and Baeten, 2015: 27). Beyond this initial strand of reform, however, the measures required begin to impact upon principles of universal access and high quality care. Restructuring (and, in some instances, closure) of hospitals, changes to payment and reimbursement systems, adjustment of baskets of care and benefits packages, reform of insurance funds and reduction of the health workforce have tangible impacts on the ability of the health system to deliver care and of patients to access it. As such, the increasingly prescriptive nature of EU intervention in health systems has revealed tensions between the goals of reducing public expenditure and maintaining comprehensive access to care (Baeten and Thomson, 2012: 8).

## Health in the European Semester

Whilst the targeting of health policies in the financial assistance programmes represents an unprecedented degree of intervention and prescription, the measures are temporary in nature, tied directly to the receipt of finite loans and bailout packages. By contrast, the European Semester is an institutionalised, ongoing process in which measures are presented as ‘soft’ recommendations from the Commission and tread a fine line between intervention in areas of strict subsidiarity and guidance in areas of common European concern<sup>19</sup>.

The status of health in the documents and recommendations of the European Semester closely mirrors the experience of the Semester itself. Successive iterations have seen the various processes tweaked and adjusted and the volume of targeted recommendations increase. Similarly, from no mention in the first AGS and scant few references in the first round of CSRs, the number of measures featuring health steadily increased, peaking at health-related CSRs for 19 countries in 2014 (EPHA, 2015b: 8). In 2015, the Commission undertook a streamlining exercise, seeking to reduce the scope and number of recommendations made, with references to health moderated to reflect this. At the time of writing, the 2016 AGS has been published but the 2016 CSRs have not; these are thus excluded from the analysis.

### Health in the Annual Growth Survey

Health was first introduced into the AGS in 2012. The 2012, 2013 and 2014 Surveys are roughly similar, all noting the potential of the health sector for providing employment, the role of health in social protection systems, the need to reform health systems to improve cost-efficiency and sustainability, and the importance of the internal market for health services. The 2013 AGS goes a little further, introducing the notion of ‘transparent pricing in healthcare services’ and the need to assess health systems according to ‘the twin aim of a more efficient use of public resources and access to high quality healthcare’ (European Commission, 2012d: 9; 5). In these first three years, health appeared under headings relating to ‘fiscal consolidation’ and ‘addressing the social consequences of the crisis’, framing the targets of Commission guidance as, on the one hand, health expenditure and, on the other, public health policies.

In 2015, despite the broader strategy to reduce the scope of the Semester, health appeared for the first time under the heading ‘structural reforms’. The AGS notes that ‘Healthcare systems need to be reformed to provide quality health care through efficient structures’. It also discusses the use of the SGP and states that ‘Each Member State is assessed individually, taking into account...national challenges posed by ageing, including in the areas of pension and health care policies’ (European Commission, 2014d: 13; 15). This theme of flexibility is further built upon in the 2016 Survey, which addresses health as an investment item for the first time, noting the potential of the Structural Funds for such use (European Commission, 2015c: 9). Somewhat paradoxically, it also contains the most detail on health seen to date:

‘Member States need to introduce measures to ensure a sustainable financing basis, encourage the provision of and access to effective primary health care services, the cost-effective use of medicines, better public procurement, improve integration of care through up to date information channels (such as e-health), assess the relative

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<sup>19</sup> This section reviews the inclusion of health in the European Semester by looking at the AGS and the CSRs. The NRPs and other constituent parts are not reviewed in detail, since the primary interest here is the EU’s intervention, which is most accurately captured in documents drafted at European level.

effectiveness of health technologies and to encourage health promotion and disease prevention.’ (European Commission, 2015c: 15)

### Health in the Country Specific Recommendations

The precise number of ‘health-related CSRs’ issued by the European Commission varies according to the criteria used; for instance, whether mention of health within recommendations which target the innovation sector constitute ‘health-related’ guidance. Adapting data from Azzopardi-Muscat et al. (2015: 379, Table 1), which includes reference to long-term care and mentions of health in other policy sectors, and updating in accordance with EPHA (2015b) and primary research to include the 2015 CSRs, the number of countries receiving health-related CSRs in the Semester to date is summarised in Figure 13.

**Figure 13: Health-related CSRs by country, 2011-2015**

Source: Adapted from Azzopardi-Muscat et al. (2015), EPHA (2015b) and primary research.

EAP/MoU = bailout or adjustment programme requirement.

Year	2015	2014	2013	2012	2011
<b>Austria</b>	Y	Y	Y	Y	Y
<b>Belgium</b>	N	Y	Y	Y	N
<b>Bulgaria</b>	Y	Y	Y	Y	N
<b>Croatia</b>	Y	-	-	-	-
<b>Cyprus</b>	EAP (Y)	EAP (Y)	EAP (Y)	Y	Y
<b>Czech Republic</b>	Y	Y	Y	N	N
<b>Denmark</b>	N	N	N	N	N
<b>Estonia</b>	N	N	N	N	N
<b>Finland</b>	Y	Y	Y	N	N
<b>France</b>	Y	Y	Y	N	N
<b>Germany</b>	N	Y	Y	Y	Y
<b>Greece</b>	MoU (Y)	EAP (Y)	EAP (Y)	EAP (Y)	EAP (Y)
<b>Hungary</b>	N	N	N	N	N
<b>Ireland</b>	Y	Y	EAP (Y)	EAP (Y)	N
<b>Italy</b>	N	N	N	N	N
<b>Latvia</b>	Y	Y	N	N	MoU (Y)
<b>Lithuania</b>	Y	Y	N	N	N
<b>Luxembourg</b>	N	Y	Y	N	N
<b>Malta</b>	N	Y	Y	N	N
<b>Netherlands</b>	N	Y	Y	Y	Y
<b>Poland</b>	N	Y	Y	N	N
<b>Portugal</b>	N	Y	EAP (Y)	EAP (Y)	EAP (Y)
<b>Romania</b>	Y	Y	Y	MoU (Y)	MoU (Y)
<b>Slovakia</b>	Y	Y	Y	N	N
<b>Slovenia</b>	Y	Y	Y	N	N
<b>Spain</b>	Y	Y	Y	N	N
<b>Sweden</b>	N	N	N	N	N
<b>United Kingdom</b>	N	N	N	N	N
<b>Total</b>	<b>15</b>	<b>21</b>	<b>19</b>	<b>10</b>	<b>8</b>
<b>Total (Semester)</b>	<b>13</b>	<b>19</b>	<b>15</b>	<b>6</b>	<b>4</b>

As with the AGS, both the ‘volume’ of health references and the level of detail contained in the CSRs increased to 2014, with a slight decrease seen in response to the Commission’s streamlining efforts in 2015. This evolution can be illustrated by briefly reviewing the CSRs issued to Austria, which is the only country not subject to an MoU or EAP but receiving a health-related CSR every year to date. The 2011 CSR for Austria stated that the government should ‘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 health care’ (European Council, 2011). The 2012 recommendation was virtually identical, but highlighted ‘in particular...concrete reforms aimed at improving the organisation, financing and efficiency of healthcare and education’ (European Council, 2012). In 2013 the detail increased slightly: Austria should take action to, ‘Effectively implement the recent reforms of the healthcare system to make sure that the expected cost efficiency gains materialise. Develop a financially sustainable model for the provision of long-term care and put a stronger focus on prevention, rehabilitation and independent living’ (European Council, 2013). The 2014 and 2015 CSRs have reinforced this message and introduced the long-term care system into Austria’s recommendations, urging the government to ‘improve the cost effectiveness, sustainability and provision of health- and long-term care’ (European Council, 2014; 2015). Austria’s experience reflects the general trend in health-related CSRs, starting with brief references in the frame of fiscal sustainability, developing into more detailed guidance in 2013/14 and returning to vague statements supporting ongoing efforts in the most recent recommendations.

Azzopardi-Muscat et al. (2015: 378) use two different classifications to reveal that the dominant themes of the health-related CSRs are sustainability and financing, with health appearing most frequently under these headings. However, in the 2013 and 2014 CSRs, the guidance branches into the content of healthcare policies, urging reductions in pharmaceutical spending, development of outpatient care, better care integration, removal of barriers in health professional services and improvement of quality of care (Stamati and Baeten, 2015: 25). In the 2015 CSRs, a return is made to the provision of broad recommendations, targeting problems that are common to most health systems and suggesting vague objectives for further or ongoing reform. Absent to date is any reference to investing in health systems, to improving disease prevention and health promotion, to improving health outcomes or to ensuring that other CSRs do not have a negative impact upon health (EPHA, 2015b: 9).

Collectively, the documents of the European Semester comprise the most detailed health system monitoring, assessment and prescription undertaken by the EU to date. Though the origins of this policy extension can be traced before the economic crisis hit, the acceleration of scope and detail since 2010 goes far beyond the ‘natural’ trajectory and has advanced largely without the involvement of health actors.

## **The integration and Europeanisation of ‘third stem’ health policy**

The inclusion of health in the instruments of the economic governance framework, understood as an extension of the EU’s policy affecting health, presents a new challenge for the mainstream EU studies theories. Why have member states chosen to extend coordination into this area and what effect is it having on national health systems?

Utilising integration theory, the emergence of health on the economic agenda can be explained from both a neofunctional and an intergovernmental perspective. 2010 was a pivotal year and the economic crisis played a role in facilitating the introduction of health onto the economic policy agenda by creating a window of opportunity for ‘silent revolution’ (Vanhercke, 2013: 6; Baeten and Vanhercke, forthcoming). Rising health expenditure was a problem for most member states for some years prior to the crisis and efficiency drives, spending cuts and fundamental reforms were obvious policy options to address this issue; with the ‘suspension of normal service’ which accompanied the immediate aftermath of the crisis, the political leverage necessary to overcome opposition to such policies, and the involvement of the EU in their implementation, became available. However, the change was not entirely unprecedented. The foundations for addressing health via fiscal and macroeconomic policy had been laid long before the crisis struck and the European Commission had been gaining momentum in this direction for some time, solidifying its involvement in pension systems and making increasing reference to the financial sustainability of health and long-term care systems. As such, an element of spillover can be identified. This can be understood as both functional and cultivated in nature. The provision of cross-border health services, for instance, would inevitably force transparency, mutual learning and some degree of harmonisation of treatment packages and prices (Baeten et al., 2010: 4), whilst coordination in economic policy, focused on areas of high national expenditure, would naturally require the inclusion of health. Meanwhile, keen to consolidate its creeping competence in health systems, the European Commission – though more notably DG ECFIN than DG Santé – can be seen as an opportunistic driving force. Thus,

‘...the financial crisis created a window of opportunity for the EU to claim greater legitimacy to influence this domain of national competency – something that had been on the Commission’s political agenda for a long time’ (Baeten and Thomson, 2012: 10).

This said, each individual component of the strengthened economic governance framework, including those which impose sanctions and restrictions on non-compliant member states or produce detailed analysis of health system organisation, financing and performance, have been approved and adopted by national governments. Some of the legislation created, such as the TSCG, takes the form of an intergovernmental treaty. In the case of the financial assistance mechanisms, obvious political and material pressures have limited the degree of genuine choice facing governments, but these are less relevant for the creation of the European Semester and the other long-term legislative frameworks. Member states also approve the constituent parts of the Semester cycle – the AGS, CSRs and various national reports – and have successfully limited the force of these documents, which remain non-binding. The weakness of the CSRs was highlighted by one interviewee as representative of the weakness of the EU – the European Semester is a ‘potential superpower for the Commission, but they are missing the opportunity by issuing such weak recommendations’ (*EU Health NGO C*). As such, the relevance of intergovernmentalism remains apparent.

The situation within the Eurozone, where tighter coordination and stricter surveillance is in place, amplifies this trend:

‘...[since the economic crisis] Eurozone decision-making has combined excessive intergovernmentalism (as the overly dominant European Council turned the Commission into a secretariat while sidelining the European Parliament) with growing supranationalism (as the European Central Bank (ECB) ‘saved the euro’ in exchange for

Member State austerity and structural reform while the Commission took on an expanding role in fiscal surveillance).’ (Schmidt, 2015a: 34)

The balanced acceleration of both supranational and intergovernmental integration in the post-crisis period is reflected in the nature of the instruments it produces. The Semester process and the corrective mechanisms of the MIP and MTO were agreed and adopted by national governments, but the European Commission holds responsibility for the management and perpetuation of the former and the application of sanctions in the latter. The CSRs are formally non-binding but have become subject to such a complex web of interlinkage as to acquire genuine significance and agenda-setting capacity (Zeitlin and Vanhercke, 2015). More fundamentally, the inclusion of health in the economic governance framework goes far beyond the mandate intended in the founding treaties (*Academic Expert, EU Health Policy A*). This is perhaps an obvious development – as one interviewee noted, ‘If the area concerned were an EU competence, it wouldn’t feature in [the CSRs] at all, it’d just be done by the Commission’ (*EU Social NGO B*). As such, the inclusion of health in the economic governance framework represents a stark instance of sectoral integration, extending EU health policy activity into a (largely) new area; vertical integration has proceeded with less certainty, as the transfer of competencies remains informal and variable.

As regards the ‘Europeanisation effect’ of health’s economic framing, the degree of influence exerted by the EU varies according to the available leverage, as explored below. At one end of the scale, those countries in receipt of financial assistance, subject to the conditions of their MoU, exhibit clear top-down Europeanisation dynamics and evidence of policy response to EU intervention. At the other end of the scale, those countries not receiving EU funds or undergoing enhanced surveillance by the EU institutions do not display obvious signs of Europeanisation. Interestingly, whilst the precise criteria determining which member states receive health-related CSRs is unknown, these two groups generally overlap – those without financial difficulty, and thus presenting limited EU leverage, tend not to receive health-related CSRs (Azzopardi-Muscat et al., 2015). Complicating the measurement of Europeanisation, most European health systems are in a near-constant state of reform, making assignment of causation difficult, though this has been attempted in some of the literature (see Hassenteufel and Palier, 2015; Pavolini et al., 2015). Furthermore, most research concludes that member states have some opportunity for uploading and participating in feedback loops during the drafting process for the CSRs – data on how this takes place is limited but suggests the potential for circular Europeanisation and utilisation of the third stem by national governments seeking support or justification for national policies (Baeten and Vanhercke, forthcoming).

## **The governance of ‘third stem’ health policy**

As noted, whilst the onset of the crisis accelerated and intensified the inclusion of health within the economic governance framework, a narrative on health as an economic sector and the EU’s role in health systems was already building prior to 2010. The foundation for the relevance of health in the post-crisis period was laid with the creation of the Europe 2020 Strategy. The launch Communication identifies the health sector as a lever for controlling government debt, public expenditure and the sustainability of national finances; specifically, it states that long-term financial sustainability must go ‘...hand in hand with important structural reforms, in particular of...health care [and] social protection’ (European Commission, 2010a: 19; 26). Accordingly, the third multi-annual health programme – the

Health for Growth Programme – ‘...strengthens and emphasises the links between economic growth and a healthy population to a greater extent than previous programmes’ (European Commission, 2011: 2). This link is further embedded in the 2011 Council conclusions on modern, responsive and sustainable health systems, which call for the health sector to play an adequate role in the implementation of the Europe 2020 Strategy (Council of the EU, 2011).

The 2010 Joint Report on Health Systems, the first dedicated health report to be prepared by DG ECFIN, provides a clear outline of the Commission’s intentions and the Council’s understanding (European Commission, 2010b). It explores the drivers of health expenditure but goes beyond the demographic focus of the EPC’s Ageing Working Group and examines organisational factors which affect expenditure and sustainability. It describes good practices in areas ranging from the use of electronic health records for data collection, the reduction of payment differences between medical staff and the use of extended GP office hours, to the improvement of health literacy for self-care, the use of economic (dis)incentives to encourage healthy behaviour and the inclusion of ‘pay for performance’ in hospital budgets. The Report’s central premise – ‘Cost-effectiveness is crucial if countries are to ensure universal access and equity in health, health financing and utilisation’ – is stated alongside the justification for EU involvement, namely that the constraints imposed by the economic crisis make health system reform and EU guidance in support of this more urgent (European Commission, 2010b: 11-12).

The themes emerging in these documents build on a conversation which started with the Directive on patient mobility and continued in the Commission’s communication on effective, accessible and resilient health systems (European Commission, 2014e) and the health agenda set out in the mission letter from the President of the Commission to the Health Commissioner (European Commission, 2014f). They also draw on the discourse rooted in the Council Conclusions on the Joint Report, which grant ‘legitimacy to the finance actors to include health care reform in the European Semester’ (Stamati and Baeten, 2015: 24), to create a narrative on health systems which includes financing, organisation and service delivery. The creation of an explicit common policy in this area remains politically infeasible and the few existing instruments reflect this reality in the ‘softness’ of their approach. However, the acknowledgement of common challenges and the benefits of sharing best practice builds a clear narrative, ‘softening the ground’ for an EU role in health systems and the institutionalisation of a third stem of health policy (*European Commission, Health Directorate E*).

### **Governing health via financial assistance programmes**

Unlike the steady, incremental building of the discourse on cooperation in health systems, the intervention into the health systems of member states receiving financial assistance from the EU has occurred sporadically and rapidly. Drawing legitimacy from the same narrative on the need for cost-effectiveness and sustainability, a framework of highly coercive governance has been put in place, transferring an unprecedented degree of sovereignty from the national to the supranational level, be it for a temporary period. In some instances a form of framework regulation can be seen, in that the methods used to achieve the goals set out by the Troika or relevant European institutions remain at the discretion of the national government – in the Greek case, for instance, the headline cap of six per cent of GDP for health expenditure is binding, but the government faces choices in how it brings about the necessary reduction (Gené-Badia et al., 2012). The objectives and processes involved here, however, are starkly

different from those in first and second stem health policy. Health sector measures which seek to reduce expenditure or increase efficiencies are framed by economic objectives and agreed by financial and economic actors, with minimal involvement of health actors and often at the expense of health goals and progress (Fahy, 2012, see also below).

The governance of health via financial assistance programmes less reflects an instance of crisis politics than an example of a critical juncture. The window of opportunity created by the economic crisis provided the European Commission, along with the ECB and IMF, with the political leverage necessary to choose the policy solution they saw fit to address the problem of unsustainable health expenditure. The Commission was able to tailor the ideas embodied in the early mentions of health in the BEPGs to advocate for coercive governance and a transfer of powers from the national to the supranational level. This supports the first hypothesis in suggesting that crisis politics lead to coercive modes of governance, and might also suggest an entrepreneurial role for the European Commission and its partner institutions in exploiting the opportunity to increase influence and power. More importantly, however, it indicates a path dependency – though the EAPs and MoUs are temporary instruments, historical institutionalism anticipates that the structures adopted in order to fulfil their requirements are likely to endure without substantial modification. As such, the reforms undertaken by governments implementing an EAP will shape the future of national health systems and lend the European institutions a degree of influence previously beyond their reach.

### **Governing health via the European Semester**

The way in which health is governed as part of the European Semester is very different to its treatment under the financial assistance programmes. It is far more nuanced, utilising a complex web of instruments to create a governance framework which has different implications for different member states at different times. Formally, the instruments of the European Semester, most notably the CSRs, are non-binding. They constitute voluntarist governance, setting out guidelines but asserting no obligation on national governments. As such, they might be viewed as a natural extension of the initial groundwork set out above, developing tools for sharing best practice – and to an extent of ‘naming and shaming’ in the annual reviews of implementation – as part of the evolution of the health policy sphere and its gradual encroachment into this new field. In this regard it might be seen as an example of targeted governance, identifying specific policies which member states might revise, reform or study more closely in a forum of collective learning and joint exploration (Sabel and Zeitlin, 2012). However, there are two features which make the Semester a much more significant and influential phenomenon than a natural policy evolution: the actors involved and the increasing use of conditionality.

The literature highlights the imbalance of actors involved in the Semester process as one of its primary flaws. In the early iterations, the Semester and its constituent documents were conceived, researched, drafted and managed by finance actors. This logic was drawn from the objective and context of the Semester as a tool for coordinating macroeconomic policy, an area usually the purview of finance ministries. This raised concern among health and broader social policy actors, who were not involved and who feared that social objectives were being side-lined, or even undermined, by the new framework (*UK health association, EU Liaison B; EU Social NGO C*; Fahy, 2012). More recently, attempts have been made to redress this imbalance – the process behind the CSRs has been made more transparent since 2013 and actively involves other DGs, most commonly DGs EMPL, Santé and REGIO in the case of

the health-related CSRs, as well as other experts (Baeten and Vanhercke, forthcoming). Health ministers began to push for greater involvement in 2011, urging that inclusion of health in the Semester consider more than merely cost-containment, and launching a reflection process to that end (Council of the EU, 2011). The SLWPPH, which has responsibility for the process, maintains a close dialogue with the EPC and the SPC ‘...to ensure that health actors are involved in ongoing debates on health systems by economic and social actors at EU level’ (Baeten and Thomson, 2012: 4). Furthermore DG ECFIN, which still holds overall responsibility for the Semester process, has increased its efforts to involve civil society and broader stakeholders (*EU Social NGO B*). As such, observers have noted ‘...a partial but progressive ‘socialisation’ of the content and procedures of the European Semester’ (Zeitlin and Vanhercke, 2015: 67).

Whilst disquiet about the role of social and health actors – if not the broader imbalance between social and economic objectives – in the Semester is being gradually assuaged, concerning signs of indirect coercion and unanticipated influence are only now becoming apparent. Through the increasing use of conditionality in its existing instruments, mirroring the requirements made of countries receiving financial assistance, the Commission is gradually making implementation of the recommendations of the Semester binding upon certain member states. The European Structural and Investment Funds (ESIF) offer a clear example of this strategy:

‘Although macro-economic conditionality will in principle only apply if the Commission ‘has a strong case’, funding of health related projects is now also one of the domains subject to so-called ‘ex ante conditionality’; this implies that Member States that choose to finance health must submit a ‘health strategy’ for approval by the competent Commission services. For countries with a health related CSR, the Commission can ramp up pressure to include implementation in their strategic plan.’ (Baeten and Vanhercke, forthcoming)

In a similar vein, the EDP has been found to have had an impact on control over health expenditure in France, Spain and Italy, where strengthened enforceability has seen more importance attached to the CSRs (Hassenteufel and Palier, 2015; Pavolini et al., 2015). As one interviewee in recent research by Baeten (2016) noted, ‘...the more you need from Brussels, the more weight the EU prescriptions carry’. This soft but powerful conditionality is similar in nature to that applied to Romania and Bulgaria following their admittance to the EU and is illustrative of the ‘growing use of monitoring reports as instruments for introducing new conditions or threats’ (Gateva, 2010: 14). It is a powerful tool with the potential to turn *de jure* voluntarist governance into *de facto* coercive governance with little member state input.

The Semester encompasses almost every aspect of health systems and policy from a non-health perspective, making it difficult to distinguish between its treatment of technical and political health issues. One interviewee described the Semester as a framework which no longer draws the distinction but rather treats everything as technical (*Academic Expert, EU Health Policy C*). A technical policy issue might be better understood here as a quantifiable issue, an issue which can be expressed, measured and analysed using numbers, where the assessed value of a particular policy or decision overshadows political debate and provides an ‘apolitical’ method for deciding upon the correct course of action. This shift to ‘governing by the rules and ruling by the numbers’ is well documented by Schmidt (2015b) and has led not only to economic problems but also to a crisis in the democratic legitimacy and social solidarity of the Union. It has increased the power of the Commission and replaced the

political process with a technocratic one (*Academic Expert, EU Health Policy C*). The same interviewee noted that, as a result of this technical or quantitative framing, ‘member states are locking themselves into something that they don’t dare decide politically’, drawing comparison between this and the creation of the Court, which locked governments into an inevitable marketisation of health. The idea that the health system issues being explored in the Semester could not feasibly be explored in the ‘traditional’ political context is affirmed by other interviewees, who also note that the status quo works because the governance is formally voluntarist; any introduction of binding law would see strong opposition from member states (*European Commission, Health Directorate A; E; EU Social NGO B*). This raises interesting questions in light of the increasing use of conditionality noted above and the extent to which soft governance can be made coercive without formal agreement.

**Figure 14: Summary of health policy dynamics, case study six**

<b>Dynamic</b>	<b>Catalyst and driver</b>	<b>Actors, interests and politicisation</b>	<b>Policy type and instruments</b>	<b>Governance mode</b>
<b>BTO policy</b>	Blood contamination crisis set agenda Mandate from member states Driven by Commission, micro-sector spillover to tissues & organs High macro-sectoral & vertical integration	Public health actors, some market relevance but actors less visible Burden-shifting, high consensus (safety) Sensitivity, less consensus (ethics) Top-down & indirect Europeanisation	Hard law (safety), soft (ethics) Directives, Action Plan Regulatory policy	Framework regulation (safety) Voluntarism (ethics)
<b>Cancer prevention policy</b>	Council Presidency agenda-setter Commission/Parliament driver thereafter Cultivated spillover across micro-sectors High macro-sect, weak vert integration	Health actors, epist communities & experts Mostly clinical actors (beginning) Some political actors (recent) Balance of uploading & downloading Soft/indirect Europeanisation	Soft regulatory, education, market-based Recom. & resolutions Policy coordination & transgovernmentalism	Voluntarism Targeting
<b>Medicines ItP policy</b>	Completion of the internal market Thalidomide tragedy (crisis) Commission (ENTR) driver, spillover High macro-sect & vert integration	Market, business & health interests Intra-Commission divisions Market v health, little consensus Participatory approach to accommodate	Hard law (regulation) Directives, participatory instruments (consult.) Regulatory policy	Framework regulation (pharmaceuticals) Coercion (DTCA ban)
<b>Tobacco control policy</b>	Completion of the internal market DG Santé driver, cultivated spillover Court role in legal challenges High macro-sect & vert integration (product standards)	Market, business & health interests Strong interest groups & industry lobbies Intra-Commission divisions Int'l level influence important Top-down Europeanisation	Hard law (product standards) Soft law (SFEs etc.) Directives and resolutions Regulatory policy	Framework regulation (product standards) Voluntarism (SFEs etc.)
<b>Patient mobility policy</b>	Case law (Bolkenstein) catalyst Commission driving actor, entrepreneurialism and expansionism Court support crucial factor Micro-sect & some vert integration	Health actors, national governments Mandate expansion, opportunism, some technical aspects Political, defensive line from member states Top-down Europeanisation	Hard law (mobility), soft law (extra provisions) Directive & voluntary, education/info provisions Regulatory policy	Framework regulation (mobility) Voluntarism and targeting (HTAs, eHealth etc.)
<b>Health in economic governance</b>	Opportunity window, pre-existing groundwork, acceleration DG ECFIN entrepreneurialism Council central responsibility and control Sect & vert integration weak (Semester) but strong (MoUs/EAPs)	Initially economic & finance actors at national and EU levels More recently, health/social actors Diverging objectives and interests Intra-Commission divisions Weak top-down Europeanisation	Soft law (Semester), hard law (MoUs/EAPs), sanctions. Recommendations, MoUs, directives & regulations Policy coord, community method, transgovernmentalism	Voluntarism (Semester) Coercion (MoUs/EAPs)

# PART III

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Parts I and II have laid out the research problem, the framework for inquiry and the empirical data, as well as offering some ongoing analysis of the trends which emerge. It is clear from this exposition that EU health policy has developed in a patchwork, oftentimes sporadic or even opportunistic, manner and that its governance framework has evolved to reflect this. The drivers and dynamics of policy in the public health stem differ considerably from those in the free movement stem, and again from those in the economic governance stem. Moreover, the dynamics within the stems are also variable, depending upon the legal mandate, level of politicisation and external climate which prevails during their negotiation.

This section of the thesis brings together the trends, patterns, common factors and individual dynamics seen in the case studies to answer the research questions posed in the introduction. Chapter 12, the analysis chapter, is structured around the theoretical framework and hypotheses outlined in chapter three. It first reviews the perspective on EU health policy evolution taken by the traditional integration and Europeanisation theories, before turning to examine how the governance of health has changed throughout its history. To assess these trends and patterns in more detail, the chapter then takes each hypothesis in turn and explores the empirical evidence which challenges and supports them. A brief summary outlines the main findings ahead of the conclusion.

Chapter 13, the conclusion of the thesis, uses the exposition offered in the analysis to address the research questions posed in the introduction. It takes each question separately and draws on the research conducted in parts I and II, as well as the analysis undertaken in chapter 12, to examine how the pre-crisis integration and Europeanisation of health policy unfolded, what modes of governance accompanied this and how these characteristics and dynamics have changed in the post-crisis period. Finally, it returns to the broader context and identifies the challenges facing health as an EU policy in the contemporary political climate. It explores the potential role of health in the European project and outlines an agenda for further research in the field.

## ANALYSIS

### *The evolving governance of EU health policy*

This chapter captures the trends, patterns and features which run through the case studies, comparing and contrasting their form, relevance and evolution across the different policy areas. In pursuit of the first and second research objectives outlined in the methodology it first reviews the explanations of health policy development offered by the mainstream theories of integration and Europeanisation, drawing on Schimmelfennig and Rittberger's (2006) classification. It then moves beyond the traditional theories to map the modes of governance employed in health, with reference to Trieb et al.'s (2005) typology. It examines each of the hypotheses set out in chapter three individually, exploring the implications of particular modes of governance for the development of the case studies, the relevance of a political/technical policy distinction in health and its relation to the use of hard or soft law policy instruments. As such, this chapter lays the foundations for the conclusion, which addresses the thesis' central research questions and explores the future trajectory of EU health policy.

### **Explaining the development of health policy: the relevance of the integration and Europeanisation frameworks**

As noted in chapter three, the integration theories and Europeanisation framework are concerned with the catalysts and drivers of cooperation at the European level and national level adaptation to the resulting structures. At the broadest level, health supports the neofunctional conception of integration as a process, prompted and propelled along by domestic actors pursuing their interests at the European level. It is less easily explained by the intergovernmental understanding of a series of static decisions to integrate, made in light of external pressures and as part of zero-sum negotiations. The intergovernmental model is lent some support by the response to the global recession and the increased involvement of member states in policy-making and oversight but, as seen in figure 14, each discrete instance of intergovernmental integration in health has led to further expansion of the role and influence of the EU, in line with neofunctional predictions. This has commonly been accompanied by an 'uninvited Europeanisation' of national health policy, either via top-down market regulation or horizontal peer review and learning processes (Greer, 2006).

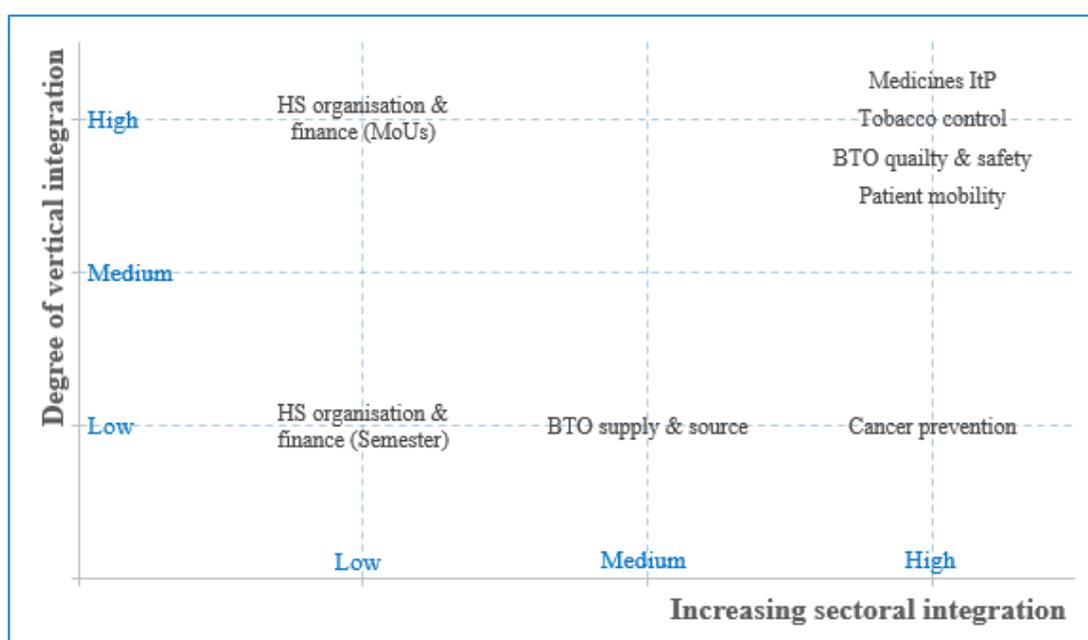
This section examines the dynamics of this evolution and the implications of the health case for the dominant theoretical frameworks. It draws on the main themes reflected in the empirical data, exploring the changing balance between the community and intergovernmental methods of policy-making, the role of crises as integration catalysts and spillover as a perpetuator of the process, and the varying degrees of Europeanisation seen at national level. As with most instances of EU policy development, the different theoretical perspectives have proven to be more or less capable of offering explanation and insight at different periods in time and across different issue areas.

### **The state of health policy integration**

Before exploring the dynamics of health policy integration and the explanations offered by the theoretical frameworks, an overview of the state of health policy integration is offered. Figure 15 plots the case studies on a graphical representation of Schimmelfennig and

Rittberger's (2006) categorisation of integration, according to the degree of sectoral and vertical integration seen in each instance. The figure is not constructed using a complex formula or calculation – the points are roughly plotted according to the extent to which the EU regulates the entirety of policy in the given issue area and the extent to which domestic competencies have been transferred to the national level. Thus, for instance, a high degree of vertical integration indicates strong EU competence and weak national control, whilst a low degree of sectoral integration suggests that the EU has not yet come to regulate the area or sector in question. The figure's purpose is illustrative, providing a comparative overview and an application of the categories identified in chapter three to facilitate analysis.

**Figure 15: Mapping degrees of integration in the case study policy areas**



For clarity, the figure takes the quality and safety aspects of BTO policy, which are based largely on hard law, independently from the supply and sourcing aspects, which are contained in softer instruments. Similarly, it separates the policy on health systems organisation and financing contained in the Semester from that found in the MoUs. The resulting representation illustrates a number of dynamics. Most notably, it shows the high levels of sectoral and vertical integration enjoyed by second stem health policy issues; the contrast between the quality and safety and the supply and sourcing elements of BTO policy further highlights the impact of internal market forces on policy integration. The low levels of vertical integration experienced in cancer prevention, BTO supply and sourcing and the Semester provisions reflect the formal weakness of soft law, but as the issues fall more squarely into the first stem public health mandate, the level of sectoral integration increases. The slightly lower vertical integration in patient mobility policy accounts for the voluntary provisions on eHealth, HTA and reference networks contained in the Directive, whilst the presence of marginal sectoral integration in health system organisation and financing reflects the unprecedented, if limited, encroachment into this realm made in the post-crisis era.

The positioning of the case study policies in figure 15 is not categorical and does not arise from rigorous scientific assessment but provides a helpful basis upon which to explore how and why EU health policy has reached these degrees of integration.

## The community method and Commission expansionism

The early phases of health policy integration are best explained by the neofunctional model. The community method dominated the establishment of EU policy in occupational health and safety, health professional qualifications, pharmaceutical regulation, BTO regulation and a raft of other issues. The European Commission commonly took the lead in these areas, exploiting the potential for spillover from blood to tissue and organ policy, from medicines evaluation to clinical trials regulation, and from free movement of services to patient mobility. It is thus held that the Commission operated, wherever feasible, according to a logic of competence extension (*Academic Expert, EU Health Policy B*). It was supported in this endeavour by the CJEU, which was perceived by health actors as a ‘defender of social solidarity’ (*Academic Expert, EU Health Policy A*) and by a vast network of supranational interest groups, expert communities and regulatory agencies. Crucial stakeholders such as health professional trade unions came to view the EU as a defence against less sympathetic national legislation (*UK health association, EU Liaison A*) whilst technocratic actors harnessed the efficiency gains of cross-border research and knowledge exchange in areas such as cancer, communicable disease and eHealth.

*‘Who else will deal with [health inequalities] other than the EU? It’s just logical; no one wishes to be punished for living in the wrong place.’ (Member of European Parliament A)*

One area where political spillover has been less potent than neofunctional theory might have predicted, however, is in the absence of supranational citizens’ interests. *Patients’* lobbies have become increasingly transnational in structure and have shifted their focus to the EU level in line with neofunctional premises but, as yet, a lobby of European *citizens* has not been established. This is emblematic of the broader failure of European integration to result in a ‘European identity’, a core weakness of the neofunctional argument. Though there has been broad citizen support for European Parliament action in areas such as health inequalities and the social crises affecting Greece, Ireland and other countries in the post-crisis era (*Member of European Parliament B*), the absence of a citizens’ voice in the patient mobility case highlights the extent of the problem. Since the benefits of patient mobility – and access to health services in general – are highly diffuse, and since citizens still consider their health interests to be served at the national level, a crucial stakeholder and potential driver of integration is often missing from the health policy debate.

The intergovernmental model gains support in two instances. Firstly, it has more relevance in explaining the case study on cancer prevention, where initiation by the Presidency of the Council was followed by intergovernmental leadership and soft law cooperation, rather than joint decision-making via the community method. Secondly, the neofunctional depiction is challenged by the role of member states in crafting and delimiting the EU’s formal health competence. National governments have been responsible for each iteration of the EU’s legal mandate in health, leading treaty negotiations which made changes to the wording and content of the health article beyond that seen in other policy areas. However, whether such active engagement was motivated by a desire to promote the non-market values of the Union or to assert formal limits on the EU’s role in health remains open to debate (Merkel, 2015a: 3). It is also likely that the motivation for and perceived purpose of the major treaty revisions varied between governments – for instance, the Finnish government was understood to be excited about the potential expansion of the EU’s health mandate under Maastricht, whilst Dutch and

British officials valued the same process as an opportunity to ‘put a lid on Brussels’ involvement’ (*UK health association, EU Liaison B*). As such, intergovernmental health integration might be more coincidental and less coordinated than it first appears. Moreover, the engagement of health ministers with EU health policy has been far from consistent: ‘The history of EU health policy prior to 2008 was of health ministries being surprised by EU policies hitting them over the back of the head’ (*European Commission, Health Directorate C*). It was only once the momentum began to build that governments became interested in the EU level, making assertions of member state leadership or control difficult to defend.

### **Crisis and opportunity politics**

*‘What drives EU health policy forward? The most obvious driver for action in health is crises’ (Greer et al., 2014: 34).*

Case studies one and five – BTO and patient mobility policy – illustrate the role and power of crises as a catalyst of health policy integration. A crisis, in this understanding, can take one of two forms – it can be a public health emergency, such as the BSE outbreak or the thalidomide tragedy, or it can be an unanticipated political shock to the health system, such as the rulings in *Kohll* and *Decker* and the application of free movement principles to health. In the former, member states have commonly deferred to the European level, keen to shift responsibility to the, comparatively weak, EU institutions and regain legitimacy at the national level (Farrell, 2005: 135; *European Commission, Health Directorate E*). In the latter, a more entrepreneurial approach on the part of the Commission has been required to secure expansion of the health mandate. Here, ‘crisis politics’ might be better described as ‘opportunity politics’, with the Commission reacting quickly and strategically to opportunity for competence extension. The case study on patient mobility policy is an obvious case in point, illustrated by the plethora of tangentially-related instruments which were established alongside the necessary legal framework, but entrepreneurialism on the part of the Commission can also be seen in the case studies on BTO and even tobacco control policy, where the disruption surrounding the resignation of the Commissioner was presented as requiring greater resolve in the passage of the TPD (*EU Health NGO C*).

Considering the broader concept of opportunity windows, figure 14 highlights an event or situation which contributes to EU action and integration in almost every case study. Besides the public health and political crises identified in the BTO and patient mobility cases, the medicines IP case was heavily influenced by changes in US regulation, lending support to the intergovernmental premise that external factors play a part in prompting integration, whilst proponents of early cancer policy harnessed the prevailing political climate and the need for a ‘human face’ of EU policy in pushing their agenda. As such, the health policy experience confirms the importance of windows of opportunity and their successful utilisation, as anticipated by Kingdon (1984).

*‘Health has developed in a de facto rather than a de jure way – it is unintended, uncoordinated and indirect in most cases, and this is what causes the problems.’ (UK health association, EU Liaison B)*

Commission entrepreneurialism has been a crucial driver of EU health policy, as illustrated by its presence in the summary of every case study in figure 14. The opportunism and creative manipulation exercised by committed health actors has been facilitated by spillover from the free movement principles and the primacy of EU internal market law. This has, throughout the

history of health policy, provided entrepreneurs within the Commission with the necessary tools and opportunities to push the boundaries of the EU health mandate. Even before the public health competence was institutionalised in the Maastricht Treaty, the market legal base enabled health measures to be introduced in areas such as occupational safety, recognition of professional qualifications and regulation of television advertising of tobacco products, as noted in case study four. These policies, one interviewee remarked, were 'far more important and radical than what followed under the formal health mandate' (*European Commission, Health Directorate A*).

The Commission has been supported in its entrepreneurial endeavour by the Court. The latter's role has varied across policy areas – in the case study on patient mobility, for instance, its rulings prompted and provided the framework for the development of legislation, whilst in the tobacco control case, legal intervention came after the establishment of the policy. The Court's rulings have had a significant impact upon policy formulation and implementation in both roles but its potential to act as a 'policy-maker' is higher 'when the political institutions are not taking the lead' (*European Parliament Advisor, ALDE Group*).

Though there is little role for the Court, the model of entrepreneurialism continues in the third stem of health policy and the opportunity politics surrounding the inclusion of health in the European Semester framework. The tools for dealing with health as an economic sector existed prior to 2010, as did the will to address health using economic and financial policy; what was lacking was the opportunity (*Academic Expert, EU Health Policy C*). Indeed, research suggests that officials in DG ECFIN were surprised not to receive more opposition from member states to the inclusion of health in the Semester (*Academic Expert, EU Health Policy C*). Though it is difficult to establish how much of the post-2010 integration of health is the result of the crisis and how much is simply a continuation of existing plans, it will certainly prove to be a critical juncture in the development of the EU's competence.

### **Resurgent intergovernmentalism and 'locking in'**

Since the onset of the economic crisis, the climate and focus of the European project has changed significantly, bringing with it a change in the internal dynamics of the European Commission and its approach to health policy.

*'Junker and Timmermans [Commission President and First Vice-President] have effectively left [DG] Santé to play on their own in a room for five years.'* (*European Commission, Health Directorate C*)

The rise of Eurosceptic and nationalist sentiment has prompted the Commission to moderate its activities and move away from the appearance of expansionism and entrepreneurialism. One interviewee went as far as to state that 'the era of the power grab is over' and that whilst the Commission is gaining significant power and influence in certain areas, it is 'too frightened' to use it (*EU Public Affairs Consultant B*). For health policy, this has had a substantial impact. When seeking to initiate new policy, DG Santé now faces considerable hurdles; unless the issue at hand is a health emergency (and falls outside of the jurisdiction of the WHO) or is based on a free movement competence, it has become very difficult to persuade the central pillar – in particular the Secretariat General – of its viability or necessity (*European Commission, Health Directorate A*). The scope for self-motivated individuals to have an impact upon the policy agenda, traditionally a strong dynamic in the Commission's health policy activity, as seen in the case study on cancer prevention, has been curtailed by an

administration which does not see health as a priority (*European Commission, Health Directorate A; D*). What has emerged is a kind of ‘dual speed’ Commission, in which the dominant positions in economy and finance are occupied by the dominant member states and portfolios such as health are swept aside or even undermined by the prevailing advances in fiscal and economic policy (*Academic Expert, EU Health Policy A; Member of European Parliament B*). In place of the kind of DG Santé leadership seen in the case studies on tobacco control and patient mobility, intergovernmental cooperation has begun to dominate; this is evident in areas such as the joint procurement of medicines for the treatment of rare diseases, where the Belgian, Dutch and Luxembourgish governments have established a partnership to secure a better deal from pharmaceutical manufacturers (Chronicle.Lu, 25 September 2015).

The resurgence of intergovernmental decision-making is particularly strong within case study six on the reinforced economic governance framework, but this has not necessarily translated into full engagement by national health actors. Reflecting the intermittent patterns of engagement seen in other areas of health policy national health ministries, initially oblivious or indifferent to the potential health impact, declined to participate in the European Semester and are only now, via the SPC and EPC, registering interest (*EU Social NGO B; European Commission, Health Directorate E*). However, the few actions they have taken, and perhaps more importantly the consequences of those that they have not, have already determined the path of the Semester and its potential future impact upon national policy-making autonomy.

*‘Member states have repeatedly locked themselves in to situations which they dare not decide politically.’ (Academic Expert, EU Health Policy C)*

The concept of ‘locking in’ has commonly been employed in reference to post-communist states and the institutionalisation of democracy and neoliberal political systems (Dimitrova and Toshkov, 2007; Hurt, 2012). It is also identified as a key dynamic in the integration of health and can be observed, in line with the historical intuitionist premise, across the history of health policy development (Pierson, 1996). First seen in the creation of the Court and the inevitable prospect for the application of free movement law to the health sector in case study five, it is now reoccurring in the establishment of stringent rules in the economic governance framework examined in case study six. In describing the catalyst of integrated patient mobility legislation, Greer et al. (2014: 34) note that: ‘Deprived of their historically preferred option of having no EU policy, the second best option [for member states] was an EU policy that they could influence rather than leaving it up to the Courts’. The ‘deprivation’ experienced by member states here is understood as self-inflicted, insofar as they had knowingly created a supranational court and committed themselves to abiding by its judgements many years previously; though it may not have been explicitly stated at the time, it is unlikely that the potential for such an application of the law was not raised (*Academic Expert, EU Health Policy C*). In the case of the Semester a similar evolution is occurring: ‘institutional settings are being put in place to replace the political process with something else’, allowing political issues to be addressed under the Commission’s stronger mandate in technocratic, quantitative decision-making (*Academic Expert, EU Health Policy C*). Having tied themselves into this structure, national governments are now faced with two competing logics in forums such as the SPC – on the one hand, they are reluctant to give power to the EU, but on the other, they acknowledge that if health is in the Semester, the economic and efficiency perspective should be balanced by a quality and access perspective (*Social Protection Committee*). As such, member states have locked themselves in to engaging with the Semester as a tool of health policy and to legitimising EU intervention in health systems.

Neofunctionalism offers little explanation for the contraction of Commission entrepreneurialism and the resurgence of intergovernmentalism seen in the bell-curve described by interviewees. However, its neo-variants, encapsulating reformulations of the traditional framework, may provide some insight. Seeking to address some of the empirical challenges to the neofunctional premises, Schmitter (2004) devises eight new hypotheses about the causes, process and consequences of integration, in line with the traditional model. The final of these, the curvilinearity hypothesis, predicts that when changes become too rapid, ‘actors are liable to react defensively, if not negatively’ (2004: 60). As well as maintaining relevance for neofunctionalism in the broader contemporary era of EU politics, this hypothesis offers some insight into the decline currently facing health policy. If the patient mobility case study represents the pinnacle of EU momentum in health, as interviewees suggest, then it is plausible that, in line with Schmitter’s neo-neofunctional variant, the momentum gathered was too much for national health actors to accommodate, since ‘the whole governing system has a very limited capacity for absorbing change, even “good” change’ (Schmitter, 2004: 60).

### **Resurgent supranationalism and non-health policy**

In light of the political climate which permeates the post-crisis period, the emergence of a multi-speed EU with greater emphasis on intergovernmental decision-making is perhaps logical (*EU Public Affairs Consultant B*). However, it also stands in contrast to the unprecedented level of centralisation and intervention inherent in the Semester and broader economic governance framework (*Academic Expert, EU Health Policy C*). Schmidt (2015a: 42) notes that:

‘As a result of the crisis, the EU’s long-standing ‘democratic settlement’, in which all EU institutional actors were involved in decision-making in their different ways, has become unbalanced. Intergovernmentalism became the primary mode of governance, eclipsing the Community Method.’

However, he goes on in the same passage to add that,

‘Supranationalism has also increased significantly. Even as the Commission was weakened in its traditional role of initiator, it gained greater supranational powers of oversight in the context of the European Semester.’

As such, supranationalism and the role of cultivated spillover might be seen to be relocating, into the realm of fiscal surveillance and economic policy, rather than to be declining across the board (Schmidt, 2015a: 34). As the emphasis on economic integration as the central focus of the European project has increased it has, in turn, pulled the locus of health-related policy into the economic sphere. This change is part of the broader shift in which health is increasingly moving out of the health domain, a dynamic which had taken hold before the crisis struck but has been expanded, accelerated and brought into sharp focus by the increasing role of economic and finance actors in health policy.

*‘Health is no longer just in health; health actors are having to learn about sectors we had no dealings with in the past, because that’s where health is now’ (UK health association, EU Liaison B).*

The encroachment of non-health actors and the proliferation of diverging objectives is one of the defining characteristics of post-crisis health policy and a central determinant of contemporary health integration. In addition to the conservative central bureaucracy of the

Secretariat General, officials in DG Santé and other actors seeking to advance EU health policy now have to consult, negotiate and compromise with actors and interests concerned with trade, development, agriculture, industry, the digital agenda, the environment and, most recently, economic growth and fiscal sustainability. These non-health actors are not making health policy and are not, generally speaking, concerned with health objectives. However, the impact of their actions means that health actors are being forced to pursue their goals and advance health integration down new, non-health paths. Whilst coordination in areas of logical EU-added value and clear national interest – communicable disease monitoring, BTO regulation and rare disease research being obvious examples – will doubtlessly continue these instances of ‘spontaneous’ cooperation in ‘pure health’ areas are likely to become increasingly uncommon (*European Commission, Health Directorate E*). Instead, the majority of health policy – understood as the policy which determines health outcomes – will be contained within non-health policies, such as the CAP, the Transatlantic Trade and Investment Partnership and the European Semester.

### **Free movement, spillover and the future of health policy integration**

Functional spillover from the internal market programme, as evidenced in the case studies on medicines ItP, tobacco control and patient mobility, has been a core driver of EU health policy. In addition to challenging its state-centricity tenet, the impact of free movement law on health integration blurs the distinction that intergovernmentalism draws between high and low politics.

*‘Where it makes sense to harmonise for the benefit of “UK Plc”, as it were, in areas like competition or data across borders, then it’s understood to be fine. But definitely on public health and prevention issues...this is a stumbling block.’ (EU Health NGO B)*

As a sector or single policy portfolio, health occupies a high politics position, since it has ‘...a considerable social-psychological dimension when it comes to establishing bonds of trust between citizens and states and maintaining strong state-society relations’ (Steffen et al., 2005: 2). Divided into individual policies, however, some areas of health – financing, organisation, service delivery – remain highly sensitive, whilst others – research, evaluation of pharmaceuticals, regulation of medical devices – become low politics issues. Case studies five and six illustrate the potential for integration of ‘high politics’ health issues, whilst the approach of the UK, as described by an interviewee above, demonstrates that even technical, ‘low politics’ issues with a firm legal basis are not guaranteed to enjoy consensus among national governments.

*‘In the absence of a better [health] legal basis, what we have to work with is the economic, trade and agriculture angles. There is still a little internal market influence too but less than before. Economy is the main driver now.’ (EU Health NGO C)*

The internal market was the original ‘unknown’ in health policy, providing the potential for spillover and the advancement of integration in the absence of member state demand or willing. As figures 14 and 15 illustrate, it has played a central part in the integration and development of policy in BTO, medicines ItP, tobacco control and patient mobility. In the post-crisis era, however, its relevance is declining. As seen in case study six, health policy is now concerned with ‘making health systems strong and efficient, rather than with the internal market, or competition, or citizens’ (*Academic Expert, EU Health Policy, B*). The tools for addressing efficiency are not located in the internal market or public health, but rather in

performance measurement and transparency, as reflected in the mandate assigned to the new Health Commissioner in 2014 (European Commission, 2014f). This decline is particularly interesting in light of characterisations of ‘tailing off’ in health policy, put forward by a cross-section of interviewees, which might suggest that the main avenues of free movement spillover have been explored and therefore that further momentum is harder to generate. In cancer, for example, ‘limits of integration’ might be identified in the EU’s inability to make progress on prevention or the primary causes of growing cancer prevalence (*Member of European Parliament A*). Moreover, interviewees report a loss of interest in public health, stem one policy and describe its contemporary role as ‘window dressing’ for more sensitive policy in health services and systems (*Academic Expert, EU Health Policy A; European Commission, Health Directorate E*).

A key question is whether the strengthened economic governance framework and the implications of instruments such as the European Semester will replace free movement as the ‘unknown’ of health policy and a catalyst for further integration. A core challenge to the neofunctional narrative is the absence of foreseen anticipated spillover from economic into political integration. Since it became apparent in the late 1980s, the need for political integration to support EMU and the completion of a true internal market has been ‘ignored and underestimated, both politically and technically’ (Delors, 2012: 175). In this sense the very necessity of the strengthened economic governance framework, understood as a response to an economic crisis caused by insufficient political integration, might be viewed as confirmation of the failure of the neofunctional vision. At the level of sectoral integration, however, the evolution of the EU’s strengthened powers in this field can be framed from a neofunctional perspective, emanating from the creation of EMU and spillover into fiscal and macroeconomic policy (*EU Public Affairs Consultant A; EU Social NGO B*). From a similar perspective, the inclusion of health within fiscal and macroeconomic instruments might be seen as spillover from the emerging narrative on health systems (*European Commission, Health Directorate E*). The range of health policy issues covered in the Semester documents and supporting Commission analyses is already considerable, as indicated by its early sectoral integration in figure 15, and there remains plenty of scope for further extension into fields such as health prevention and quality of care. However, there are two main obstacles to the kind of spillover seen in relation to the internal market. Firstly, the degree of intergovernmental control in economic governance is significantly higher than that in free movement law and policy. As a result, attempts by DG Santé or other health actors to ‘use’ the Semester as a health policy instrument, particularly in cases where the guidance issued is non-binding and the Commission has limited leverage over the state concerned, are likely to enjoy less autonomy and automaticity. Secondly, those responsible for inserting health-related provisions and managing the process are not health actors and, as such, have no interest in expanding the EU’s health mandate in this way. The entrepreneurial actors who harnessed the potential of free movement law for health have less access to the European Semester and thus less influence over the process.

### **Unbalanced and indirect Europeanisation**

The impact of EU health activity upon national health systems – the Europeanisation of health – mirrors the changing nature and patterns of integration discussed above. Until the early 2000s, the dominant Europeanisation dynamic was one of vertical, direct diffusion. Policies in stems one and two, based on legal competences in public health or the internal market, often

took regulatory form, as illustrated in figure 14. Action in BTO, pharmaceutical regulation, health professional qualifications, occupational health and safety, patient mobility, medicines ItP and many others was embodied in hard law instruments, generating top-down and direct Europeanisation pressures. In these areas, the Europeanisation of health is well developed – instruments such as the WTD and the Directive on the Recognition of Professional Qualifications are understood to have had a significant impact at national level (*UK health association, EU Liaison A*).

Though less common, some evidence of bottom-up Europeanisation can also be seen in health. However, this process is almost exclusively utilised by the more developed member states, whose health systems, research capacities and related infrastructures are more advanced. The causes and impact of this inherent bias are most stark in the comitology procedure. The committees convened for implementing acts are comprised of an equal number of representatives (usually one or two) from each member state, assumed to be experts in the relevant field – as a general rule, larger member states have bigger pool of experts from which to choose, whereas smaller states have fewer specialists, or even one specialist to cover a range of issues (*EU Public Affairs Consultant B*). Similarly, countries with less advanced health systems or treatment pathways are less able to influence the content of EU policies and increase the ‘goodness of fit’ with their existing structures. Interestingly, in health, this imbalance tends to turn in favour of less developed health systems when engaging in soft, as opposed to direct or binding mechanisms of policy diffusion. Platforms such as CANCON, discussed in case study five, are of less direct benefit to countries such as the UK, which is generally a ‘net contributor’ of best practice in cancer care and research but less developed health systems are likely to gain a great deal in terms of knowledge exchange and mutual learning (*EU Health NGO B*). As the use of comitology and other NMGs proliferates, these imbalances and their relation to the broader issue of health inequality are likely to become a more central feature of EU health policy.

*‘The CSRs dictate more than you think...I’m not sure why, but certainly more than you’d expect given that the sanctions aren’t really there.’ (EU Social NGO C)*

Since the mid-2000s, health has seen a shift towards horizontal Europeanisation and soft diffusion. Whilst circular dynamics could already be seen in the reciprocal uploading and downloading of early policy in the cancer prevention case study, for example, the emphasis has more recently shifted to top-down Europeanisation, as seen in the recommendations of the European Semester in case study six. The impact of the Semester and, in particular, the CSRs on national policy structures is difficult to establish, on account of their non-binding nature, the differing approaches taken by national governments and the obscurity of the drafting process. Many CSRs contain recommendations to continue with or complete initiatives that are or were already underway, indicating potential scope for uploading, but others are so vague that it is difficult to establish what would constitute a direct policy response (*Academic Expert, EU Health Policy B*). However, even in the absence of legal force, the measurement and performance assessment aspect of economic governance is understood to be very powerful. The strengthened framework has effectively granted the EU a mandate in ‘naming and shaming’, which is known to be an influential tool in changing behaviour (*European Commission, Health Directorate A; Merkel, 2015b*).

Some insight might be gained from Lamping and Steffen (2005b: 18), who captured the potential of health Europeanisation via EMU and the SGP in 2005:

‘It is evident that cost containment policies have been or will become more intensive in the healthcare sector than would have been the case in the absence of European integration constraints. Although it is conceivable that most of the health policy reforms...would have emerged anyway, i.e. independently of EU membership, European integration often further strengthens and legitimises such existing initiatives or the consensus for reform.’

This same logic is reflected in early impressions of the European Semester and its likely impact on the Europeanisation of health (*Academic Expert, EU Health Policy C; European Commission, Health Directorate E*). Though assigning causality is fraught with methodological difficulties, the possibility for member states to feed in to the process and the strong roles of the Council and European Council suggest that the scope for uploading and downloading is substantial.

## The governance of EU health policy

This section takes the integration and Europeanisation of the case studies as a point of departure and explores the modes of governance which have characterised the evolution of EU health policy. An introductory section reviews the distinction, elaborated in the conceptual framework and raised by many interviewees, between the technical and political facets of EU health policy. It examines some of the different ways in which this distinction is understood, applied and built into the legislative process, ahead of more detailed analysis under hypothesis five. The rest of the chapter is structured around the six hypotheses outlined in chapter three, which are examined individually in light of the supporting and challenging information gathered from the case studies. Pushing beyond the narrative established by traditional integration and Europeanisation analysis, it explores the roles of coercion, framework regulation, targeting and voluntarism in the case studies and their implications for the development of individual policy areas.

### Mapping modes of governance

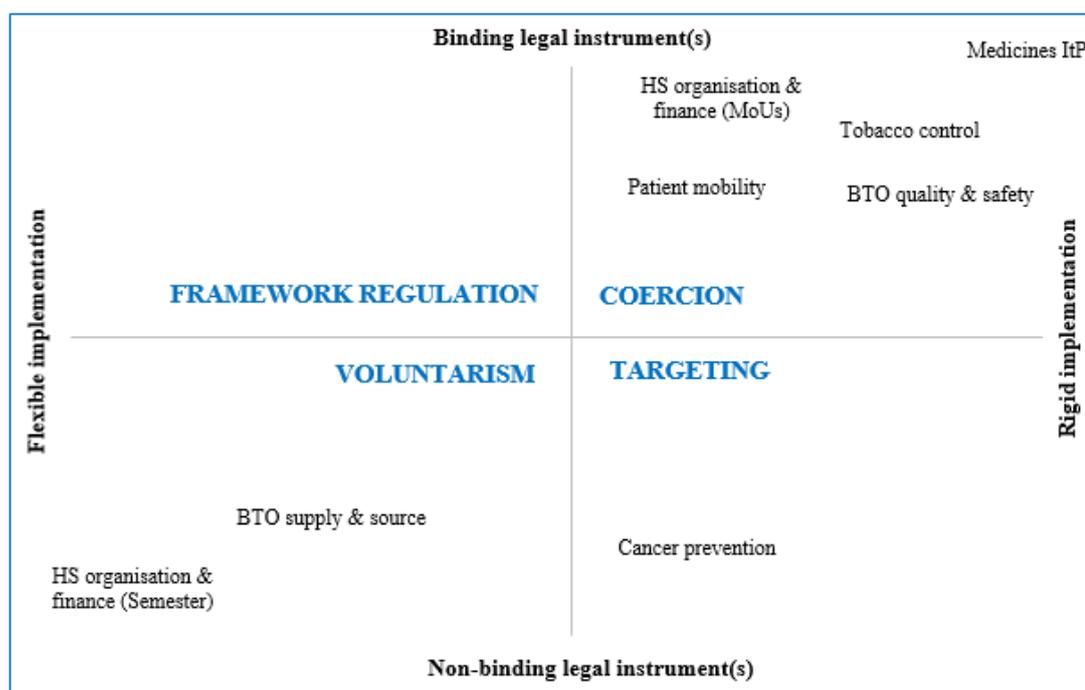
As in the previous section, a visual overview of the modes of governance which dominate in the case study policy areas is presented ahead of closer examination of specific instruments and policies. Figure 16 provides a more literal ‘map’, based on the typology presented by Trieb et al. (2005), of the types of governance which characterise EU health policy.

As in figure 15, mapping the degree of vertical and sectoral integration seen in the case studies, figure 16 separates the quality and safety aspects of BTO policy from the supply and sourcing aspects, and takes the policy on health systems organisation and financing contained in the Semester independently from that found in the MoUs. Further mirroring figure 15, it is not based on complex calculation and does not claim to be infallible. Positioning is based on observation of the dominant instruments in a given policy area, their legal form and approach to implementation, and the relevance of any accompanying or peripheral policy instruments which influence the operation of the policy. As such, figure 15 seeks to provide a visual and comparative overview to guide more detailed analysis through the rest of the chapter. From it, a number of initial points can be drawn.

Firstly, it is clear that the majority of EU health policy is dominated by a coercive mode of governance. Binding legislation is used and implementation is particularly rigid in areas which take as a legal base Article 114 TFEU on the functioning of the internal market,

illustrating the strength of the EU’s mandate in this area. Though they are temporary in nature, coercion is also dominant in the MoUs, on account of their binding conditionality. A second notable point is the absence of framework regulation in health governance – though such regulation is common in second stem health policy, it is often designed to ensure rigid implementation in the face of political sensitivity or strong industry lobbies, as seen in the tobacco control and medicines ItP cases. Voluntarist governance, the figure suggests, is reserved for those areas of weakest formal mandate and highest political sensitivity, where the instruments used are predominantly soft in nature and the policy elaborated provides for considerable national discretion. Finally, the positioning of cancer prevention policy illustrates something of the distinction between technical and political health issues. Though all of cancer prevention policy is embodied in soft instruments and is adopted only voluntarily by national governments, its provisions are more rigid than those of BTO supply and sourcing or the health-related provisions of the European Semester. This is because they are clinical in nature, setting out best practice and technical guidance which allows for less discretion in implementation. As such, technical policy areas enjoy more targeted implementation.

Figure 16: Mapping modes of governance in the case study policy areas



## Politicisation and new modes of governance

*‘Trying to draw a political/technical distinction is a very British approach – it’s about separating economic efficiency from politics, but it doesn’t work like that, the whole system is suffused with politics.’ (Academic Expert, European Parliament)*

The distinction between technical and political aspects of health, or any other, policy is difficult to draw and even more difficult to hold once the legislative process has begun. However, it brings attention to an inherent characteristic which determines the way that a particular policy issue is perceived and treated. It also contributes to the discussion on modes of governance and how they have changed as the scope and depth of EU policy has expanded. At the most fundamental level, technical policy issues, based on an agreed problem and a

common understanding that the solution is best found at the European level, ‘need urgency and consensus’ but can then be addressed using hard law instruments (*European Commission, Health Directorate A*). The degree of urgency and consensus required depends upon the issue but also upon the central bureaucratic pillar of the Commission itself, which makes the final decision on whether a technical, hard law response will be accepted by the legislature and is worth pursuing – if not, it instructs the relevant DG and officials to construct the policy using soft law instruments and NMGs (*European Commission, Health Directorate A*). Therefore, as the central pillar of the executive becomes more conservative and cautious in the face of member state opposition, the use of NMGs is likely to increase.

Illustrating the distinction within the EU policy-making context, the link between the political and technical dimensions of any one policy issue or action becomes clearer:

*‘If you do things in meetings of experts then your arguments are technical, because they’re trying to solve technical problems, whereas if you put [the issues] in the working group, [the process] instantly becomes political and much more problematic.’ (European Commission, Health Directorate C)*

The choice of forum is, to some extent, at the discretion of the Commission, but a mandate is needed from a political grouping to ensure commitment to implementation of the later work agreed at the technical level. This contributes to the strategic agenda-setting of the Commission – an interviewee involved in the ongoing implementation of the patient mobility Directive noted that the issue of prior authorisation had been deliberately assigned only a very short agenda point at an upcoming EPSCO Council meeting, so as to gain the necessary mandate whilst leaving actual discussions to a later technical meeting where political concerns would have less prominence (*European Commission, Health Directorate C*).

Outside of the Commission, the parameters of technical and political health policy might be drawn from the division of responsibilities between the EU and the WHO or the EMA. Both of the latter are technical bodies – they feed technical expertise into the EU, which brings this into its multi-sectoral, political processes (*European Commission, Health Directorate E*). Though the Commission is broadly understood to be a technical executive, by comparison to the EMA or the WHO, it might better be described as quasi-political (*Academic Expert, EU Health Policy A*). Meanwhile, the WHO’s role is delimited by its status as a supranational agency; its constituents are governments, not citizens, meaning that it should not get involved in the political domain. This constrains WHO influence in areas such as air pollution, where there is broad public support for action but governments remain reluctant – in these cases, the WHO has been known to collaborate with the Commission as a channel for expressing its political position (*World Health Organization A*).

These conceptions aid understanding of why some areas of health policy have developed along different paths to others and why the balance of health policy evolution has begun to shift. One interviewee described the distinction by equating ‘regulation’ with technical issues and ‘policy’ with political ones. Another, in assessing the relevance of the distinction in contemporary health policy, noted that in previous decades an assignment of ‘technical’ or ‘political’ was easier to make and the corresponding path of the policy easier to predict, but that more recently it has become less tangible:

*‘Perhaps what is needed now is a two-by-two grid, categorising issues as political, technical, solvable and unsolvable. We’ve done most of the technical things that we can*

*do, but there are many that we can't do because of their path-dependency and starting points. Health issues are never an island unto themselves, they are wrapped up in systems of education and others things, so in cases like health professional training, which should be a technical issue, differences in the prior system of postgraduate training become a barrier.'* (Academic Expert, EU Health Policy A)

This reflects the notion, discussed above, of having reached the limits of integration in some areas of health. The inability of the EU to advance into policy on cancer prevention, for example, indicates that the solvable and technical areas of the current mandate have been explored and exploited as far as is possible and that further action will require either a change in the treaty or a dramatic shift in political will (*Member of European Parliament A*). Whilst treaty change remains an infeasible option, EU activity is pushed into softer, more innovative forms of governance.

The rest of the chapter draws on the dynamics of the technical/political distinction in its evaluation of the hypotheses outlined in part I.

### **Hypothesis one: Crisis politics results in coercive forms of governance**

The role of crisis as an opportunity for non-incremental policy change and as a driver of such change in health policy is well acknowledged in the literature (Greer et al., 2014: 34; Nohrstedt, 2008: 258). Crises 'create political opportunity windows for advocacy groups challenging established policies, newly incumbent office-holders and other potential change agents' (Boin et al., 2009: 82). In health, the changes ushered in by these windows have commonly been binding in nature, creating hard law in areas where no, or less coercive, structures existed previously. Hypothesis one explores this relationship and its relevance in the post-crisis era.

The case studies reveal some differences in the nature of crisis politics and policy-making between 'stem one' and 'stem two' issues. Where the crisis is a public health emergency – in cases such as the thalidomide tragedy, the blood contamination scandal, the BSE outbreak, the SARS pandemic or the PIP breast implant scandal – the response has commonly been one of agency creation and delegation of responsibility to the EU level from governments keen to shift burden and regain legitimacy with their electorate, as seen in the BTO case. Where the crisis is political in nature, affecting citizens and patients indirectly but more immediately requiring negotiation and decision-making between policy-makers, as in the patient mobility case or the political scandal encompassing the latter stages of the TPD, national governments have been more cautious. They are reluctant to part with any more autonomy than is necessary and are more likely to try and shape the outcome in accordance with their interests. However, in both cases the resulting legislation or policy output is likely to be binding and to take the form of, at least, framework regulation, if not coercive governance. First stem crises have resulted in the creation of the EMA, the EFSA, the ECDC, the revised regulatory framework for medical devices and the extension of treaty mandates on food safety, pharmaceuticals and BTO regulation. Second stem crises prompted the establishment of a legal framework for the free movement of patients and the resurrection of the struggling TPD. Though not at the furthest extreme of coercive governance, these instruments all represent hard law, supranational-level responses.

An in-depth survey of the literature of crisis policy-making is beyond the scope of the thesis but the framework put forward by Boin et al. (2009) is helpful in indicating how different

actors approach and utilise crisis situations such as those which have punctuated the development of health policy. Setting aside the option to deny the existence of a crisis, there are two approaches that actors can take. In the first, they might frame the crisis as a threat to the collective good embodied in the status quo and seek to defend it as far as possible; in the second, they might frame the crisis as an opportunity, highlighting the flaws in the status quo and the need for fundamental change (Boin et al., 2009: 84). This distinction aids understanding of the difference between stem one and stem two crises, with the kind of public health emergency which comprises the former being much harder to frame as a threat to the status quo and more likely to result in an overhaul of it. In political crises, it contributes to analysis of the differing approaches taken by national governments and the Commission – the patient mobility case was approached as an opportunity by DG Santé, keen to ‘Europeanise’ the mobility of healthcare services, but as a threat by member states, aware of their legal obligations but reluctant to permit extensive European encroachment.

When looking at crises at the European level, an additional variable is introduced. In the event of a crisis at national level, governments seeking to frame it as a threat and thus to defend the status quo would be expected to acknowledge but not to maximise the significance of the event, so as not to ‘rock the boat’ in a way that might invite criticism, risk or overhaul of the system (Boin et al., 2009: 85). Where the supranational level becomes involved, however, national governments may be able, or indeed may seek, to maximise the significance of the event so as to draw attention to shortcomings or over-reaching by the EU institutions, or to shift blame. The PIP breast implant scandal in 2012, for instance, saw charges brought against the manufacturers but the blame for the regulatory failings was levelled at the EU, thus absolving national governments.

To trace the political rationale behind the framing of a crisis as an opportunity, RCI utilises principle-agent models to examine the delegation of authority to regulatory agencies such as the EMA, ECDC and EFSA and notes the role of functional pressures in prompting this outcome. National governments, RCI holds, make a strategic choice to establish independent agencies and other bodies so as to overcome information asymmetries, ensure commitment from other actors, shift blame and manage complex, technical issues (Thatcher, 2002: 125). The existence of such pressures helps to make evident the logical added-value of cooperation at the EU level and each of them can be identified in the BTO case study and various other public health crisis-response measures, supporting the broader notion that technocratic, regulatory policy is a core foundation of health integration. However, in a review of the literature on delegation Pollack (2008) finds that, in fact, few governments cite Commission expertise or technical capacity as the motivation behind a decision to transfer autonomy. This stands in contrast to the neofunctional assumption, adopted by proponents of supranational governance and other theoretical approaches, that the Commission’s technical capacity is a crucial driver of and incentive for further integration, which seems to be well supported by the health experience and the case studies (Richardson, 2006). As such, health policy challenges the assumptions of the RCI framework and presents an interesting new space for empirical investigation.

The inclusion of health in the economic governance framework represents a similar kind of political, second stem crisis to that seen in the patient mobility case study. It is important to clarify the dependent variable here – the strengthening of the EU’s economic governance powers was itself undertaken in response to an economic crisis, but it is the inclusion of health within this framework which is the focus of this hypothesis and which represents a political

crisis for national governments and a potential opportunity for the Commission. In this case, the diverging approaches taken by different internal divisions of the Commission are as important as those taken by the Commission and national governments. Using Boin et al.'s (2009) categorisation, DG ECFIN has successfully framed unsustainable health expenditure as a facet of the sovereign debt crisis and the fundamental reform of how such expenditure is governed, namely by introducing EU-level coordination, as the necessary solution. What has been crucial is the presentation of both the problem and the solution as technical issues, related to functional coordination, technocratic governance and oversight of quantifiable policy variables, so as to avoid the kind of politicisation seen in stem two crises (*Academic Expert, EU Health Policy C*). DG Santé, meanwhile, initially took the opposite approach to ECFIN, joining NGOs and the broader public health community in drawing attention to the threat posed to health by its inclusion in such structures and calling for a reversion to the previous status quo. More recently, it has shifted to work within the new structure, seeking instead to use it as a vehicle for pursuit of its own goals in improving access and quality of care.

Greater insight may be gathered from re-framing these 'political crises' as windows of opportunity, leading to critical junctures in the development of a given policy. In both the patient mobility and the economic governance case studies an exogenous and unanticipated stimulus – a series of case law in the former, the strengthening of the EU's powers in economic governance in the latter – opened windows of opportunity in which the decisions made and action taken would prove to set the path of further policy development (Pierson, 2000; 2004). Both also support the neofunctional emphasis on continuity and spillover, rather than change or reversal in the face of exogenous pressure (Pollack, 2008). In the patient mobility case, the locking-in of institutional structures was crucial – having subjected other sectors of the health system to free movement law for many years and in light of the earlier attempt to extend this to health services in the Bolkenstein Directive, the fundamental elements of patient mobility policy were already broadly established. Moreover, the case law of the Court served to lock-in these elements from below, granting a set of rights to a constituency of patients which would then fight against losing them (Pierson, 1996). The same path dependence is likely to ensure the duration of the new economic governance framework. Building on the early efforts to address health through macroeconomic instruments, both the Council and the Commission continue to generate 'positive feedback' in their public statements, encouraging utilisation of and adherence to the Semester and its health-related recommendations (Council of the EU, 2016; Pierson, 2000; 2004). It may yet also emerge that, given the capacity for some Semester provisions to undermine health policy objectives, Scharpf's (2006) characterisation of intergovernmental joint-decision mechanisms as rigid and prone to inefficiency is supported by the third stem health policy case.

The pressures facing governments (principals) in the event of a public health crisis make delegation to an independent regulatory agency (agents) and the establishment of coercive governance mechanisms an obvious choice. In the event of a political crisis the inevitability of a coercive response is less clear but, as demonstrated in the patient mobility and TPD cases, hard law has generally been favoured. The economic governance case study challenges these models – the window of opportunity presented to the EU after the economic crash was met with the introduction of non-binding Semester process, whilst the political crisis facing health actors with the inclusion of health in this process has been met with confusion and eventual endorsement. As its implications become apparent, member states may yet be prompted to

frame this latest exercise in Commission – or at least DG ECFIN – expansionism as a threat to national health systems, but unless this happens soon, the prevailing status quo is likely to become entrenched.

### **Hypothesis two: Framework regulation, as embodied in the EU regulatory state and the integration of the internal market, is declining in relevance**

Framework regulation is the default governance mode of the internal market and the EU's regulatory state. As use of alternative modes, such as the OMC and redistribution policies like the ESF, has proliferated and appetite for further integration has decreased, so too the scope and relevance of regulatory policy has declined (Falkner, 2010: 284; Richardson, 2006: 7). This hypothesis examines the implications of this trend for health and its changing relevance in the post-crisis era.

At a fundamental level, the regulatory state is associated with technocratic governance. In health, this is embodied in the work of the EMA, the EFSA, the ECDC and the various other agencies and expert bodies which contribute to and implement health- and consumer-related product regulation. The integration of standards on pharmaceuticals, tobacco, medical devices and BTO products, has now been achieved – divergences in implementation notwithstanding – in most areas, as reflected in the high degree of sectoral integration seen in figure 15. Taking a RCI approach, such agencies and their activities will doubtlessly prevail, in light of their clear added-value and the logic of delegating to reduce transaction costs (Pollack, 2008), but they are unlikely to expand. The technical functions which they were established to fulfil are now in operation and their policy parameters are well defined, meaning that any further regulatory expansion is likely to be related to process, rather than product, standards. The regulation of processes, which targets standardisation of the way in which health services are structured and delivered, is far more political than that of products; integration of this sensitive sphere of national competence is fraught with difficulty and requires more innovative approaches to governance (Wallace and Reh, 2015: 104). Thus, the decline of the regulatory state can be linked to the idea, introduced above, of having reached the limits of 'easy' integration and 'solvable' problems and being forced into the use of voluntarist modes of governance. This trend can be seen in the development of BTO policy – early policy on blood and tissue products was technical and binding upon member states, whereas more recent progression in organ policy has seen framework regulation in the technical, product-based elements of the policy, but recourse to voluntary instruments where extension into the more political issues of supply and ethical sourcing practices has been attempted.

Of particular relevance for the integration of health is the link between the regulatory model of policy-making and the entrepreneurialism of the European Commission. The internal market gave resourceful actors within DG Santé the opportunity to expand their influence into non-health sectors which impact upon health and the determinants of health – as outlined in previous sections and illustrated in figure 14, this strategy has been crucial to the development of EU health policy. However, the scope for entrepreneurialism by DG Santé and other health actors is dependent upon the foundation and composition of the relevant policy network. As the relevance of the internal market regulatory base has receded, the Commission and other health actors have been forced to rely on influencing less amenable structures and networks in agriculture, trade and economic policy instead (*EU Health NGO C*). The decision-making and legislation which has resulted from these 'new-to-health' policy networks has not always promoted health objectives or served health goals – as such it challenges the assumption, held

in most policy network analysis, that interactions between a policy community are generally positive-sum (Rhodes, 2006). As the variety of actors and levels involved in health has increased, securing positive health policy outcomes has become more difficult, as evidenced in cases such as food labelling, reduction of alcohol-related harm and measures targeting the subsidisation of tobacco production. The involvement of non-health actors and interests within the health policy community has commonly served to politicise the issues at hand and often resulted in ‘losses’ for the health agenda.

During this process of politicisation, framework regulation has played a crucial role. Providing enough flexibility to accommodate different interests and approaches whilst maintaining enough binding force to ensure compliance from actors whose main objective might not be the betterment of health, it has enabled policy to be constructed in areas of high political sensitivity, as seen in the case studies on medicines ItP and tobacco control. It also serves to facilitate political agreement between governments in cases such as patient mobility, where member states were reluctant to agree to coercive European governance but willing to accept framework regulation as a compromise. The political potency of the Semester, meanwhile, is embodied in its force, or rather lack of it. If it were to be contained in framework regulation, the politicisation of the process would be intensified dramatically (*EU Social NGO B*). As it stands, the degree of coercion exists on a continuum and the future force of the instruments involved is being ‘locked in’, as anticipated by the historical institutionalist model, whilst the CSRs remain sufficiently vague to minimise member state opposition in the immediate cycle. For those countries whose CSRs are becoming more binding – on account of assessed macroeconomic imbalances or violation of the SGP – the recommendations made have yet to be onerous, objectionable or tangible enough to antagonise national governments.

For the moment, the instruments of the economic governance framework remain at the extremities of the modes of governance mapped in figure 15, taking either a coercive or a voluntarist form. However, in light of the broader emphasis on the EMU-element of European integration, the potential is raised for a resurgence of regulatory policy in the economic and fiscal, as opposed to internal market, sphere. This would likely take a more ‘rules-based’ approach, using indicators to determine progress towards broad policy objectives as part of performance assessment (Schmidt, 2015b) and mirroring DG ECFIN’s attempts to frame the outputs of the Semester as technical, regulatory instruments, rather than policy statements or extensions of integration, so as to avoid political opposition. It would also likely involve a very different set of actors to traditional, market-based EU regulation. Applying policy network analysis an important ‘sub-government’ of actors, responsible for implementing this strategy, can be identified (Saurugger, 2014: 114). DG ECFIN has established a small but dense network of analysts and experts who feed into and enhance the ‘technocratic’ credentials of the CSRs, wielding great influence over the content and nature of the final recommendations (Baeten and Vanhercke, forthcoming). Meanwhile a wider network, more akin to a thematic or issue network, exists outside of this group and includes DG Santé and other health actors, who enjoy more limited access and influence (Saurugger, 2014: 118, figure 5.1). As such, the emergence of a new stream of framework regulation is unlikely to afford health actors the same opportunities as internal market regulation.

The future of regulatory policy within the economic and fiscal fields is, as yet, uncertain. The replacement of the internal market by economic governance as the focus of EU activity has the potential to embody a resurgence of regulation but, whilst its instruments remain (at least

formally) voluntary in nature and whilst the HiAP principle is applied less rigorously here than in internal market policies, such a shift in health policy activity is unlikely.

### **Hypothesis three: Governing by targeting is more commonly employed where there is strong political will**

The targeting mode of governance is the hardest to identify. It has a similar non-binding nature to the voluntarism mode but requires rigid implementation; this is characterised, for instance, by significant detail in EU recommendations or built-in performance monitoring processes which put pressure on member states to comply. It is also the only mode which is commonly embodied in both soft and hard law instruments, and the case studies reveal examples of both forms. This hypothesis explores the relationship between targeted governance and political will, in light of the apparent paradox of achieving agreement on rigid and prescriptive methods of implementation but failing to back this up with binding force. In essence, it asks why targeting is chosen as the appropriate form of governance in certain health policy areas and what advantages it offers over voluntarist or more coercive instruments.

Embodied within a hard law instrument, targeted governance takes the form of a ‘should provision’, usually contained in the preamble or recital of a directive and prescribing specific but voluntary measures which go beyond the required action in the body of the legislation. Examples of the latter can be found in most health legislation, usually as a provision which could not, for political reasons, be agreed as a binding requirement but which appears instead as a suggested method or approach to implementation. For instance, the 2002 Blood Directive states that:

‘Blood establishments *should* establish and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them *by such means as* quality planning, quality control, quality assurance, and quality improvement within the quality system, *taking into account* the principles of good manufacturing practice as well as the EC conformity assessment system’ (Directive 2002/98/EC, paragraph 16, emphasis added)

Similarly, the TPD contains detailed lists of features and characteristics to which the Directive should apply and where implementation should be focused:

‘Tobacco products or their packaging could mislead consumers...This is, *for example*, the case if certain words or features are used, *such as* the words ‘low-tar’, ‘light’, ‘ultra-light’, ‘mild’, ‘natural’, ‘organic’, ‘without additives’, ‘without flavours’ or ‘slim’, or certain names, pictures, and figurative or other signs. Other misleading elements *might include*, but are not limited to, inserts or other additional material *such as* adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself.’ (Directive 2014/40/EU, paragraph 27, emphasis added)

Targeting is thus used to guide or direct implementation in directives where this is formally at the discretion of national governments. It might also be understood as a tool for expressing the intended ‘spirit of the law’ – the Directive which regulates the provision of medicines ItP suggests that the principles which underpin the prohibition on television advertising of prescription drugs should be extended to all other media types, and that regulation of medicines ItP should strive to provide a high level of consumer protection (Directive 2001/83/EC paragraph 44; 40). Whilst political constraints mean that binding agreement of

such values could not be adopted, targeted governance enables legislators to provide guidance, examples and indicators of what the Directive is seeking to achieve.

When embodied in a soft law instrument, targeted governance more closely resembles a voluntarist provision but contains detailed guidance for implementation. For instance, the Council Recommendation on cancer screening (Council of the EU, 2003) sets out a framework for the establishment of cancer screening programmes in member states, noting the various characteristics that these should have in order to be effective, but also including in the annex a list of the screening tests ‘which fulfil the requirements of the recommendation’. The goal here is similar to that pursued via binding instruments – to steer implementation towards an agreed objective in the absence of hard law enforcement – but without reference to an accompanying coercive instrument. As such, it might also be understood as a precursor to hard law. The first report on the implementation of the above cancer screening recommendations noted that ‘The scale of these activities underlines the substantial impact which recommendations of the Council of the European Union can have on the health of the European population’ (European Commission, 2008c: 3), whilst the second detailed the vast array of EU activity in cancer which has emerged as a result of the Recommendation and the later EPAAC programme (European Commission, 2014g). Here, targeted governance demonstrates the power of soft law as a tool for ‘laying the groundwork’, influencing behaviour and bringing about policy harmonisation.

Sociological institutionalism is a particularly relevant approach when considering the role of targeted governance. It holds that the creation of informal institutions, the sharing of experiences and the establishment of common cognitive frameworks, as seen in the case study on cancer prevention and the introduction of the OMC in health, will result in changes in behaviour (Risse, 2004). The way in which these changes occur is labelled isomorphism – this results from ‘social processes of emulation and diffusion...Actors replicate the organizational models collectively sanctioned as appropriate and legitimate’. As a result, the model of best practice in cancer screening, for example, is copied and spreads throughout national health systems (Saurugger, 2014: 94). This process bears comparison to Kingdon’s (1984) multiple streams model, in that the EU provides, via the ongoing ‘primeval soup’ of policy-making, an evidence-based common policy solution, informed by the best practice of member states. Made aware of an issue, such as poor performance in cancer screening, via the problem stream and seeking a policy solution, national governments then look to the European framework to inform their responses and a process of isomorphism begins. The provision of policy solutions is the foundation of the EU’s role in health; collecting and curating data and experiences from across the Union, it establishes a bank of targeted frameworks and best practices and makes them available as a tool of socialisation. The EU’s position as a legitimate and trusted source of expertise in health policy thus facilitates a form of indirect diffusion, where member states emulate EU standards and practices (Börzel and Risse, 2012).

Interestingly, Saurugger (2014: 94) identifies three catalysts of isomorphism – mimesis and normative pressures, both of which involve the migration of professionals between different organisations, and coercion. The latter ‘refers to pressures from other organizations, mostly the government via public subsidies, upon which institutions are dependent’ (Saurugger, 2014: 94). This raises interesting potential for case study six and the influence of the health-related provisions of the European Semester. The value of sociological institutionalism as a framework for analysing voluntarist instruments is explored further in the next section but

bears particular relevance for the CSRs in light of the increasing conditionality being assigned to them.

Drawing on the sociological institutionalist perspective, it is thus perhaps more accurate to surmise that governing by targeting is commonly employed and most likely to be effective where the ‘logic of appropriateness’ is strong (March and Olsen, 1996). Political will is clearly an important element of successful soft law but where targeted governance is used in the absence of political consensus, as in the case study on cancer prevention, for example, sociological approaches might offer a better insight into why such instruments are utilised.

#### **Hypothesis four: Voluntarist governance is becoming increasingly coercive**

EU health policy has been embodied in and has relied upon instruments of voluntarist governance for many decades. As illustrated in figure 14, soft law has played a role in the development of almost every area of health, either as the central pillar of EU activity or as a supporting instrument; in both cases, as the exposition in the case studies has demonstrated, it has considerable strength as a tool for bringing about policy convergence. Extrapolating from the typology presented in chapter three, a shift towards coercion in voluntarist health instruments would be characterised by more rigid implementation and a greater degree of prescription, as well as more binding legal effect and greater leverage or force. Whilst accepting that, by definition, the presence of rigid implementation measures or binding legal effect precludes an instrument from being classed as voluntarist, this hypothesis explores the evolving use of soft law instruments, particularly in light of changes to the use of conditionality in EU policy and the importance of leverage in the strengthened economic governance framework.

A ‘strengthening’ of voluntarist governance in first and second stem health policy is difficult to identify. Taking, for instance, the communication establishing a partnership on cancer in case study two and the Action Plan on organ donation in case study one, both documents set out broad objectives and provide member states with substantial discretion in implementation. The Action Plan goes into a little more detail, identifying priority actions in pursuit of the objectives and introducing common indicators and benchmarks for monitoring progress, but neither instrument can be considered rigid in its approach. Similarly, the patient mobility directive contains voluntarist provisions for the establishment of networks in rare disease research, eHealth and HTA; the relevant articles (12, 13, 14 and 15 of Directive 2011/24/EU) outline the objectives of these bodies and offer some logistical support at the EU level but are otherwise to be interpreted and actioned as member states see fit. Looking at the legal effect of voluntarist governance, however, a shift can be seen in the proliferation of social learning and ‘soft’ Europeanisation tools, which exert considerable pressure on governments. As noted by sociological approaches, practices such as peer review, benchmarking, ranking, common indicators and performance monitoring have significant capacity for changing behaviour via the ‘logic of appropriateness’ and indirect diffusion (March and Olsen, 2004; Börzel and Risse, 2012; Merkel, 2015b). Furthermore, soft law has frequently been invoked by the Court as a source of interpretation, muddying the divide between legally binding force and legal effect (Stefan, 2012), and the OMC is considered to be stronger than traditional soft law, since the higher level of political participation and rigid procedures entail more mutual commitments and exert more forceful peer pressure (Borrás and Jacobsson, 2004: 189). Moreover, understood as forums of ‘deliberative democracy’ and antidotes to the waning legitimacy of EU decision-making, mechanisms such as the OMC and the new comitology

system are likely to be favoured by policy-makers (Richardson, 2006: 8). Thus, whilst accepting that soft law is, by definition, non-binding, its force and effect have increased and its use has proliferated as EU health policy has evolved.

The voluntarist instruments of the strengthened economic governance framework are not only more coercive in their current form, but suggest potential for increased strength in the future. At their ‘peak’ in 2014, the CSRs were highly prescriptive, targeting the content of national healthcare policies on the basis of detailed assessment of health systems. For instance, the Bulgarian government was urged to increase efficiency by ‘improving transparency in hospital financing’ and the Irish CSR recommended ‘more frequent price realignment exercises’ for patented medicines (Council of the EU, 2014a; 2014b). Against an overarching objective of reducing health expenditure, increasing sustainability and improving efficiency, the CSRs and accompanying Country Reports<sup>20</sup> offered detailed guidance on how member states might meet these goals. More significantly, however, the CSRs, MoUs and other instruments of the economic governance framework move beyond urging the achievement of overarching goals and encourage the introduction of specific reforms. The 2013 CSR for Malta recommended that the government ‘Pursue health-care reforms to increase the cost-effectiveness of the sector, in particular by strengthening public primary care provision’, whilst the 2014 CSR for Latvia urged action to ‘Reform social assistance and its financing further to ensure better coverage, adequacy of benefits, strengthened activation and targeted social services’ (Council of the EU, 2013; 2014c). Moreover, the 2015 AGS includes health under the heading ‘structural reforms’. This is a new development and signals institutionalisation and acceptance of the treatment of health as an economic sector. The level of prescriptive detail contained in the CSRs and other instruments of the Semester is not sufficiently onerous as to classify them as forms of targeted governance; they operate at a relatively abstracted level in comparison to, for example, the Council recommendation on breast cancer screening. However, their content clearly indicates a tendency towards prescriptive governance and more rigid implementation mechanisms.

Drawing on the governance literature two perspectives on the future strength of the Semester process can offer insight. Firstly, as seen in the case study on patient mobility, the decision to create a Semester, to engage in its various analyses, benchmarking and collective review exercises and to include health within the outputs of this process is likely to become ‘locked in’, as high institutional thresholds – embodied in the networks established between DG ECFIN and the Council and the binding nature of the legislation establishing the Semester – make overhaul of the system and removal of all references to health infeasible. Positive feedback from the EU institutions will encourage member states to treat the voluntary CSRs as important instruments and implement them fully, whilst national governments, applying a high discount rate to measures which sacrifice long term autonomy but project remedial action against high public debt in the short term, will continue to permit the inclusion of health in macroeconomic instruments (Pierson, 1996). Perhaps most importantly, because of the rigid and inflexible nature of joint decision-making mechanisms, sub-optimal policy results which undermine health objectives – such as CSRs which urge reductions in public spending on social protection systems – are likely to become entrenched.

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<sup>20</sup> The Country Reports, previously known as the staff working documents and published alongside the CSRs, are now published a few months prior to the CSRs. They contain detailed analysis of the situation facing each country and valuable insight into the data and assessments upon which the final CSRs are based.

A second perspective concerns the use of conditionality to increase the force of third stem voluntarist instruments. Within the economic governance framework the EU has created a continuum of leverage in which the degree of force exerted by instruments such as the CSRs depends upon the financial stability of the country to which they are addressed; countries which need more from the EU are under a greater pressure to fulfil the CSR requirements (Baeten, 2016). This is closely linked to the practice of conditionality and reflects the process of isomorphism via coercion anticipated by sociological institutionalism. The EU has applied conditionality to its relations with third countries since the early 1990s and has used it to ease the transition of the Central and Eastern European states which joined the EU in 2004 and 2007 (Smith, 1998; Schimmelfennig and Sedelmeier, 2004). More recently, however, the use of post-accession cooperation and verification mechanisms (CVMs) has highlighted the potential for other uses of conditionality:

‘The increasing application of differentiated and targeted conditionality highlights the evolutionary nature of EU enlargement conditionality. Furthermore, it reflects the Commission’s growing expertise in the candidate countries and new member states. More importantly, by establishing individual country specific benchmarks, the Commission has managed to instrumentalize its knowledge. Benchmarking indicates that the Commission not only can identify a problem but it can provide detailed guidance on how the problem should be addressed.’ (Gateva, 2010: 13)

As a result of their weak incentive structure, the CVMs applied to Romania and Bulgaria have struggled to bring about the intended convergence of judicial reform and anti-corruption measures, but they highlight the power of broad, high-frequency reporting as an instrument for ‘continuous political pressure’ (Gateva, 2010: 15). A similar strategy for indirect Europeanisation and isomorphism via coercion is seen in the structures of the ESF, which has been found to influence domestic policies through leverage, learning and conditionality (Verschraegen et al., 2011). The latter mechanism refers to the requirement that actions funded by the ESF fit the objectives of the EES – crucially, the EES has recently been integrated into the broader Europe 2020 Strategy, of which the European Semester is the implementing arm (van Gerven et al., 2014: 514). Whilst neither of these examples currently applies directly to health, the voluntarist instruments of the strengthened economic governance framework are based upon both an intensified system of reporting, benchmarking and monitoring, and on pursuit of the Europe 2020 objectives. Furthermore, a mechanism of macroeconomic conditionality, creating a link between excessive national public deficits and the management of EU funds, already exists within the ESIF and allows the EU to suspend funding where requirements are not met (Baeten, 2016; Jouen, 2015). In light of this, as well as the emphasis on data collection and HSPA in the Health Commissioner’s latest mandate, it is not difficult to imagine a situation in which fulfilment of the health-related CSRs becomes a condition for access to further EU resources.

### **Hypothesis five: EU health policy has become increasingly political**

In 2005, prior to the economic crisis and the ensuing resurgence of anti-European sentiment, Lamping and Steffen (2005b: 24) predicted a fundamental change in the nature of health policy, noting that ‘From now on health policy integration is set to become a political rather than a simply technocratic process’. This hypothesis draws on the technical/political distinction explored above and examines its relation to the bell curve described by interviewees and the broader evolution of EU health policy.

A shift to more ‘political’ health policy is well reflected in the case studies, with the more recent stem two issue areas requiring continual political choice and negotiation between different stakeholders, interests and divergent policy objectives (Hooghe and Marks, 2001). One implication of this shift is that the style of decision-making required to balance multiple interests involves a more participatory mode of governance on the part of the executive and a more active and visible role for the EU legislature. The Commission, seeking to accommodate an expanding array of interests and stakeholders, has increasingly turned to more consultative and inclusive instruments when designing and proposing policy. Meanwhile, the European Parliament has become an important health actor and its elevation to co-legislator has changed the dynamics of its role – where it previously provided a counterbalance to the Council by supporting the European Commission, it now sees itself as a ‘partner of the 28’ and commonly works with the Council, particularly in the comitology system, to restrict the autonomy of the Commission, as anticipated by RCI analyses (*Academic Expert, European Parliament*; Pollack, 2003). Furthermore, since the crisis, the European Council has taken a leading role in policy-making, moving from a position of guidance and oversight to one of active intervention in the day-to-day politics of the CoEU (Puetter, 2012: 168). This intensified involvement is largely limited to matters within the economic governance framework but it is indicative of a greater political sensitivity in contemporary EU health policy and the rise of high-level political negotiation, rather than technical, knowledge-based pursuit of shared policy goals as the primary mode of policy-making.

The politicisation of health policy has resulted in situation, by contrast to that which prevailed in the earlier case studies, whereby the primary barrier to greater EU involvement in health is political, rather than legal.

*‘If the community and intergovernmental methods don’t work, then we will change the treaties, but even without change in the treaty, we can still do much more than we are doing now’ (Member of European Parliament A).*

To take the example of data collection and comparison across countries, a powerful tool in bringing about policy convergence, there exists scope within the treaties for EU action, ‘...but we don’t do it, because the member states are afraid of it’ (*European Commission, Health Directorate A*). Similarly, the institutionalisation of the HiAP principle provided a legal basis on which to evaluate all EU policies and their impact upon health, but it is not used to its full extent (*Academic Expert, EU Health Policy A*). Thus, the mandate-stretching and treaty-base game strategies which previously shaped the evolution of EU health policy have become less relevant and, ‘Ironically, we have now reached a point where we have maximum legal potential and minimum political will to use it’ (*UK health association, EU Liaison B*).

Health has traditionally been understood as a regulatory policy but in the post-crisis period it has become absorbed into macroeconomic policy and framed as an expenditure policy at national level. This framing changes the nature of policy-making and politics which apply to health, putting greater emphasis on intergovernmental governance and coordinated competences (Hix and Høyland, 2011). The limitations that this imposes are reflected in the efforts of DG ECFIN to present the Semester as a technical instrument and thus maintain a technical policy-making style – the narrative is one of shared policy goals and ‘ruling by the numbers’, where policy-solving is pursued through monitoring and evaluation of common, measurable indicators (Schmidt, 2015a: 34). The process is dominated by a complex, quantitative evidence-base and administered by technocratic actors, as foreseen in Radaelli’s

(1999) model of ‘enlightened public policy’, but is far from apolitical. Though it does not force national level change the issues it touches upon, particularly in the health field, are deeply sensitive and beyond the EU’s formal mandate; as such, ‘[The Semester] is highly political...just without policies’ (*Academic Expert, EU Health Policy C*).

Perversely, the result of increasing politicisation in health is described by some as a proliferation of technical policy activity. Since technical, solvable issues are ‘what DG Santé can do’, interviewees report that there has been a resurgence of effort and activity within technical policy fields (*European Commission, Health Directorate A*). This is occurring even in areas which are perhaps of limited value to member states or do not contribute to a coherent overarching health policy, in line with Scharpf’s model of joint decision-traps (*European Commission, Health Directorate C*; Scharpf, 1988). The effect is perhaps best captured by the term ‘cottage industries’, where strands of work are established and assigned to a given team within DG Santé, which develops policy and resources but does so largely without interaction or dissemination beyond a designated national contact point (*European Commission, Health Directorate C*). The process by which such cottage industries are established can also be somewhat sporadic. Activity is commonly the result of a ‘policy by charter’ process, in which an interest group forms a position, enlists an amenable MEP to gain coverage within the Parliament (often rallying signatories around a charter or resolution) and thus forces the Commission to respond by establishing a strand of work on the issue (*Member of European Parliament B*). Exhibiting strong path dependency dynamics, the work stream established by this process endures long after the publicity and political attention on the issue has waned, with officials in DG Santé continuing to update the relevant resources and ensure implementation and compliance with the growing body of EU health policy; ‘It’s not political, it just happens’ (*European Commission, Health Directorate C*).

### **Hypothesis six: As a result of the above, health policy-makers have increasingly relied on soft policy instruments**

Taking the increased politicisation of health policy as a premise, this hypothesis explores its implications for the governance of health to date and in the future. In particular, it draws a connection between ‘political’ decision-making and soft law, based on the notion that politicisation makes consensus more difficult to achieve and binding EU law more difficult to adopt. Broadly speaking, the EU-wide proliferation of soft law and innovative modes of governance is a reflection of this dynamic – as the scope and depth of EU policy has increased, so too the number of non-binding instruments has multiplied, utilised either in support or anticipation of hard law, or as a way around political gridlock. It is this challenge which now faces health policy – as the agenda becomes increasingly dominated by political and insolvable issues, health actors may find that the only way to avoid stagnation is to encapsulate policy in non-binding governance instruments.

One of the reasons that politicisation results in soft law is that it restricts the entrepreneurialism of the Commission, traditionally a central driver of EU health policy. The increased conservatism of the central Commission bureaucracy is identified by many interviewees as the root of a ‘pulling back’ on the part of the executive, leaving in its wake excess treaty capacity. Whereas, in the past, the Commission might have seized upon any opportunity to exploit such capacity and pushed ahead with hard law solutions, even in political areas like tobacco control and free movement of patients, it is now far less assertive in its approach. This is not to say that soft law was previously irrelevant. As the case studies

demonstrate, it was a central part of policies such as cancer prevention, and it was commonly used in certain areas – SFEs, diet and physical activity, alcohol and health – where the strength of relevant lobbies and the conflicting interests of national ministries made agreement difficult. However, in previous periods hard law was still pursued wherever possible and the dominant ‘issue of the day’ in health policy might as likely have been addressed using a binding as a non-binding instrument. By contrast, in the current climate, the extent of politicisation is such that any DG wishing to pursue a hard law instrument is required to demonstrate an almost unattainable degree of ‘added value’ and necessity before gaining the approval of the Secretariat General (*European Commission, Health Directorate A*). Thus politicisation has two significant outcomes. Firstly, the scope for committed and entrepreneurial individuals to drive policy forward, historically an important feature of the development of health, is greatly reduced (*European Commission, Health Directorate C; EU Social NGO B*). Secondly, the contemporary health agenda and any emerging health policy is likely to be dominated by non-binding instruments.

The inclusion of health in the European Semester holds the potential to exacerbate the latter effect significantly. Not only is it a (formally) non-binding mechanism, but it incorporates the most fundamental elements of national health systems and policies – how they are financed and managed – thus affecting health at the most upstream point and bringing every other aspect of health policy under its umbrella by default. At present, the Semester is not being actively used as an instrument of health policy. Though the recommendations on pharmaceutical expenditure have prompted some interest from the generics industry, health actors are not ‘lobbying’ DG ECFIN as another health legislator; civil society organisations lack the resources to justify engagement with such an abstracted tool and DG Santé recognises the limits to what can be pursued within the Semester’s recommendations (EPHA, 2013; *EU Social NGO B; European Commission, Health Directorate E*). However, the relevance of the Semester for health is becoming more widely recognised, with DG Santé pushing for inclusion of measures on quality and access, and civil society actors calling for greater emphasis on prevention and investment (*Social Protection Committee*). Moreover, there is a fundamental logic in the minds of member states that, whilst the inclusion of health in such an instrument is an undesirable necessity, steps now need to be taken to ensure that a balance between market and social objectives is achieved (*Social Protection Committee*). Thus, as the recommendations made and the analysis which underpins the Semester gets increasingly detailed, greater attention is likely to be focused on its policy-making capacity and greater relevance assigned to its potential as (yet another) soft instrument of health policy.

Two caveats to this trend towards voluntarist and targeted governance should be made. Firstly, as alluded to above, the decline of hard law might best be characterised as a decline in contemporary relevance, rather than a decline in overall volume. Though the politicisation of health, the conservatism of the Commission and the prevailing political climate make the adoption of further binding and expansionist health legislation unlikely, existing health policy remains largely intact and is comprised of a balance of soft coordination and hard regulation. Secondly, should the European Semester and other tools in the economic governance framework continue to ‘strengthen’, arguably the most influential facet of health policy will be one of coercive, rather than voluntarist, governance. As noted in the final case study and subsequent analysis, such a situation is not on the immediate horizon, but is certainly feasible in the longer term. This would significantly alter the balance between soft and hard health policy in favour of the latter.

The increasing reliance on soft law as a tool of EU policy is evident. In the case of health, use of ‘creative tools’ like comparable information, benchmarking and multi-stakeholder platforms is a response to weak powers and small budgets, as well as rising politicisation (Greer et al., 2014: 36). Moreover, this is not a new phenomenon – requirements to report on progress towards healthcare for all legal residents and workers were in place in the early 1990s, prior even to the establishment of the public health mandate (Hervey and Vanhercke, 2010: 107). The introduction of the OMC and its extension into health institutionalised the role of voluntarist governance and also indicated a recognition on the part of the EU institutions that the nature of health policy was beginning to change. As seen, as the EU has extended its influence through technical policies and regulation, the pool of remaining policy problems has become increasingly saturated by political and unsolvable issues. Here, the community method cannot be so readily applied and binding regulation is more difficult to agree. Thus, a new approach to coordination has been required and has taken the form of voluntarist, soft law governance, via mechanisms such as the OMC. Whether this trend will continue depends upon a range of external factors – the political climate, public perception of the European project, the material and political resources afforded to DG Santé and the Commission more broadly, the emergence of new health threats – as well as the trajectory of the European Semester as a tool of contemporary health policy. For the moment, soft law seems likely to remain the primary instrument and voluntarism the dominant mode of governance, but a shift in this status quo in the future is not out of the question.

## Summary

Review of the case studies and analysis of the individual hypotheses reveals a continuous, if not always coherently directed or deliberately undertaken, process of integration, Europeanisation and governance development in health policy. Moreover, it highlights the substantial differences in drivers and dynamics between first, second and third stem health policies. Reflecting the experience of the European project as a whole, early supranational momentum was later moderated by resurgent intergovernmentalism, whilst the proliferation of soft law and NMGs prompted a shift from top-down to more circular and reciprocal Europeanisation. The eruption of crises and the rational-choice politics which surround these situations has played a critical role, oftentimes resulting in the adoption of hard law instruments and delegation of autonomy to supranational agencies, but the economic recession and the inclusion of health in the resulting policy frameworks has presented a new kind of crisis, the political parameters of which are less obvious. Governance by framework regulation appears to be tied to the fate of the single market, which itself might be understood to be declining in relevance as economic governance takes centre stage, but the regulatory potential of the latter is, at least on paper, quite significant. Targeting is a governance approach which has been used in health for some time, either as a precursor to hard law or as a tool for expressing its intended ‘spirit’ and meaning. In line with sociological approaches, it has proven to be an effective change agent and, as the issues on the health agenda have become more sensitive and steadfast political will has become less dependable, its use has increased. Finally, overarching recognition of the power of soft law has led to a perception of strengthening in voluntarist governance, though this is not reflected in the formal construction of policy instruments in stems one or two. Stem three, by contrast, presents a challenge to the form and use of voluntarist governance and the potential, via increasing conditionality and path dependence, for greater coercive force.

More fundamentally, perhaps the central insight from the hypotheses is the importance of politicisation as a determining variable and its relevance for the mode of governance employed in a given policy area. Earlier health policy was dominated by technical issues – either in the form of clinical best practice and advances or of product regulation in the internal market – and governance more commonly took a more binding and rigid approach as a result. However, as the ‘supply’ of technical health issues diminishes and the political climate of the EU intensifies, it is this dynamic which will form the core challenge of contemporary and future health policy.

## CONCLUSION

### *Health policy in the post-crisis era*

In pursuit of the objectives outlined in the methodology, the thesis has explored the integration, Europeanisation and governance of EU health policy, pushing beyond the traditional perspectives to map the changing nature of health policy instruments and steering. The final chapter seeks to satisfy research objective three by using the research and analysis conducted in parts I and II to ‘update the textbook’ on EU health policy. It does this by addressing each of the three research questions identified in the introduction in turn. It first describes the pre-crisis integration, Europeanisation and governance of health, examining the differences between stem one and stem two case studies and the role of politicisation in shaping health policy. Having established the prevailing narrative, it summarises how these dynamics and characteristics have changed in the post-crisis era, noting the paradox of increased intergovernmental policy-making alongside the revival of supranationalism. It discusses the modes of governance seen in the third stem of health policy and their extension into those building blocks of the health system reserved for national control. Finally, the concluding section draws on the concepts and dynamics identified in the case studies to inform reflections on the future development of health, offering an agenda for further research and some preliminary conclusions on the trajectory of contemporary EU health policy.

### **How did the pre-crisis integration and Europeanisation of health policy unfold?**

The case studies have shown health to be a well-established and distinct portfolio of EU activity. Macro-sectoral integration has brought health under the European policy umbrella and micro-sectoral integration has spread, to a greater or lesser extent, across most issue areas and through most building blocks of the health system. For the majority of the time this process has proceeded in a neofunctional manner, the growing interconnectedness of health systems and markets prompting spillover throughout the sector, and has reflected rational actor-based models, the logical added value and political benefits of delegation prompting coordination between states. Underpinning this development, the primary determinant and feature of health policy integration has been its constitutional asymmetry. The imbalance between market and social competences has resulted in a patchwork of micro-sectoral and uneven vertical integration – as seen in figure 15, many issue areas are now integrated to some degree, but the assignment of decision-making competencies within them varies significantly and very few can be considered harmonised policy regimes. The Europeanisation of health has reflected this piecemeal process. For the most part, it has progressed in a top-down manner, as national actors were caught ‘off-guard’ by EU provisions and binding regulatory frameworks proliferated; more recently, the expansion of soft law has facilitated a more indirect, socialisation-based Europeanisation process. As seen in the case studies on BTO and cancer prevention in particular, the presence of technical expertise and EU policy resources, particularly those curated by the public health agencies, is now built into the organisational logic of member states. In other areas, such as the patient mobility case study, Europeanisation continues in a more uneven fashion, caught between oscillating national perceptions of EU health activity as a threat to sovereignty or a valuable facet of social Europe.

As in all EU policies, some elements are best explained by reference to neofunctional assumptions, whilst others fit better with an intergovernmental approach. In line with the neofunctional model, the integration of health has been driven by ‘...extensive political leadership by the Commission, the (self-) interests of actors within...national/transnational interest groups, and the accumulation of logical consistencies’ (Lamping, 2005: 21), as well as the steady progression of legal integration and the support of the Court (Martinsen, 2005). Functional spillover from the internal market project, political spillover from the proliferation of EU-level interest groups and cultivated spillover from entrepreneurial supranational institutions are all evidenced in the case studies and support the neofunctional model. National governments have not been absent from these processes – they fought successfully against the inclusion of health in the Services Directive, took the lead on early cancer policy initiatives and have managed, for the most part, to keep the EU out of the ‘high politics’ realm of health system organisation and financing. Moreover, intergovernmentalism finds support in the dynamics behind formal health integration, and in the role of exogenous factors and domestic interests – such as pandemic outbreaks and protection of national pharmaceutical industries – in determining its pace and extent. However, whilst elements of neofunctional logic can be seen at the centre of each of the case studies, intergovernmentalism remains unable to account for the reality that a European health policy has emerged in the absence of a comprehensive treaty base, explicit mandate or member state demand (Greer, 2006: 135; 2014: 17). Put simply, neofunctionalism is more relevant in more instances.

One crucial factor which both schools of the founding dichotomy recognise, however, is the relevance of a technical-political distinction. Just as neofunctionalism highlights the technocratic capacity of supranational institutions as key to the migration of responsibility to the EU level, so too intergovernmentalism acknowledges the rational added-value of pooling sovereignty in technical, ‘low politics’ issue areas (Rosamond, 2000: 57; 77). The premise that the trajectory of European integration is influenced by the degree of technocracy involved in the particular policy area is strongly supported by the EU health policy experience. The case studies on BTO, cancer prevention and economic governance demonstrate the power of a ‘technical framing’ in health and their respective legislative experiences stand in contrast to those seen in medicines ItP, tobacco control and patient mobility. This dynamic aids understanding of the shifting nature of EU health policy in its second and third stems – as more actors and interests become involved, consensus on the means and ends of health integration become less common and its trajectory is distorted.

### **What mode(s) of governance dominated in this period?**

Health originated as a regulatory policy, drawn together from separate strands of legislation on occupational health and safety, social security coordination and public health. It was immediately multi-level in nature – trade unions, transnational corporations and other sub-national actors played central roles in the development of early health and social policy and various expert networks and communities fed into early public health measures, as seen in the case study on cancer prevention, for example. As a result of these multiple networks, early and first stem health policy privileged the ‘politics of expertise’ and the ‘politics of ideas’ (Richardson, 2006: 25), facilitating a technical policy-making style. Moreover, public health crises, which prompted several of the early steps in EU health policy development, led to the creation of technical agencies, whilst product regulation in the internal market lent further technical framing and legal support to policy integration. As a result, and as illustrated in figure 16, health policy-makers were commonly able to utilise coercive and framework

regulation modes of governance. Voluntarist and targeting instruments were often employed in accompaniment or support of binding legislation but the substance and parameters of health policy were, for the most part, governed with some degree of coercion.

With health's exposure to the full force of free movement law and the expansion into second stem policy areas, health governance underwent a transition. The proliferation of actors and interests involved in the health policy community and the integration of non-health issue networks intensified the multi-level nature of decision-making and prompted a shift in the kind of instruments and approaches employed. In an attempt to accommodate the vast range of perspectives and interests now involved and reflecting the trend of policy-makers faced with a legitimacy crisis, health actors introduced an increasing number of public consultations, reflection processes and multi-stakeholder forums into the governance framework (Richardson, 2006: 8). As seen in the case studies on medicines ItP and tobacco control, the resulting policy-making style was a political one, characterised by continuous negotiation and decision points (Hooghe and Marks, 2001). This politicisation has increased reliance on softer governance, embodied in targeting or voluntarist instruments, so as to accommodate flexibility, preserve political commitment and overcome gridlock. As such, second stem policy represents health's 'constructivist turn', in which integration has been shaped and pushed forward by informal process as much as by formal ones. It has become a testing ground for the power of soft law and innovative modes of governance, displaying great promise in the case of cancer prevention (Trubek et al., 2008), and has challenged the rationalist perspectives which dominated earlier periods.

### **How have these characteristics and dynamics changed in the post-crisis period?**

The strengthening of the EU's economic governance framework and the inclusion of health within the instruments it has established has taken health into a new and unprecedented era, challenging the existing narratives and dynamics of health policy. In essence, what has been presented is a new avenue through which health policy might be integrated, Europeanised and governed. Just as the use of the internal market legal base to protect health allowed a second stem of health policy to emerge, the nascent consensus around addressing health via macroeconomic policy processes presents the potential for a third stem of activity. The early strands of this activity are focused on health system performance and sustainability. They target data collection and the development of detailed, country-specific health system analysis, raising the possibility of extension of EU influence into building blocks one and five of the WHO health system classification, areas long reserved for the exclusive control of national governments. However, the political climate and its impact, particularly on the Commission, mean that the further development and institutionalisation of third stem health policy has an uncertain trajectory.

### **Contemporary EU health policy integration and Europeanisation**

The treaty base and assignment of health competences remain unchanged in the post-crisis period, meaning that the constitutional asymmetry and weak mandate continue to underpin policy development. In reality, if any change has occurred, it has been a reinforcing of these barriers – the former has been exacerbated by the intensification of economic integration and the consequent side-lining of social objectives, whilst the latter forms an even greater hurdle in light of the increasing conservatism of the Commission and its central bureaucratic pillar.

Similarly, the catalysts of health policy remain largely the same – the opportunity window presented by the economic crisis allowed the institutionalisation and acceleration of previous efforts to address health within the macroeconomic framework, confirming the importance of path dependency in dictating policy development. What has changed in the post-crisis period is the process and driving force of health policy integration and Europeanisation. The structures, interests and possibilities facing health actors seeking to advance third stem health policy are significantly different to those available for the utilisation of free movement law and the establishment of second stem health policy.

Firstly, the nature of the legal base is different. The Semester is a voluntarist instrument and the inclusion of health within it is not the result of a formal decision; as such, the legal provisions cannot be so easily manipulated and the ‘treaty-base game’ is not so readily applicable. Secondly, health actors’ position within the policy network which surrounds the Semester is very different to their position in the debates which characterised the tobacco control, medicines ItP and patient mobility case studies. Whilst the latter involved collaborating with corporate and market interests, engagement in the Semester process requires them to seek to influence actors from ministries of economy and finance. Crucially, such cooperation is not conducted between equal partners but rather is structured as health ‘contribution’ to DG ECFIN’s management of the Semester and its analyses, resembling more of an issue network than a policy network or epistemic community. As a consequence, health actors have found themselves on the outside of the Semester. DG Santé has established a dialogue with DG ECFIN and health actors have developed mechanisms for participating in the process where possible but they remain constrained by its economic purpose and parameters, the absence of a formal avenue for engagement and a lack of transparency.

The external constraints imposed by the nature of the Semester are accompanied by a number of internal limitations within the Commission itself, in particular DG Santé. When asked about the prospects of contemporary health policy, interviewees describe a decline in the momentum of DG Santé since the late 2000s, resulting from increasing politicisation and a loss of institutional memory; ‘we’re not being treated like serious policy partners and we don’t deserve to be because we’re not thinking like serious policy partners’ (*European Commission, Health Directorate C*). When combined with the conservatism of the central Commission and the restrictions facing health actors within the economic governance framework, this has significant implications for the development of third stem health policy. Presented with little scope for the kind of opportunism or creative utilisation of available tools seen in second stem health issues, the role of entrepreneurial individuals and health actors is substantially reduced. Health continues to ‘creatively muddle through’ but health actors, and in particular DG Santé, have considerably less control over the process than they enjoyed in the past. As such, one of the primary drivers of first and second stem health policy has been rendered unavailable. This raises the question, for both health policy practitioners and the mainstream EU theories, ‘who or what will now drive health policy?’

This is a difficult question because the common drivers of health policy expansion, which can be traced in figure 14, have less obvious relevance to the economic governance case study. A public health crisis is unlikely to generate the necessary momentum, though the recent focus on anti-microbial resistance suggests that crises will continue to provide stimulus for action in the public health arena. Meanwhile, the economic governance framework lacks the priority and binding force of the internal market as a justification for further policy convergence. The Court’s role has so far been negligible, its ‘enforcing’ role being performed instead by the

imposition or threat of conditionality, and it is not yet clear that member states attach too much importance to the Semester as a process, let alone to its health-related provisions. Thus, it seems likely that the driving force necessary to promote and further develop this third stem is likely to come from the European Commission, either at the behest of member states or via independent entrepreneurialism. This presents three main possibilities.

Firstly, the model of supranational entrepreneurialism could prevail under the stewardship of DG ECFIN and the SPC, as the importance of health system sustainability and the need to balance the Semester's economic objectives with social concerns is increasingly prioritised. This fits well with the historical institutionalist approach, given DG ECFIN's prior advances into pension and long-term care systems, and with experience from the SPC, which suggests that member states are keen to balance the economic perspective of the Semester with a social one (*Social Protection Committee*). A second possibility is that a similar entrepreneurial role might be undertaken by DG Santé, but in an adjacent field – here the confluence of conversations on performance assessment, financial sustainability and access to care might present a window of opportunity for the development of an EU health systems policy, taking DG Santé into a new policy realm and marking a crucial step in the journey towards a European health system. This would more closely mirror the patient mobility case study and would likely involve the use of voluntarist governance to establish supporting policies and complementary initiatives around the central stream of Semester policy output. Finally, member states may, in the face of institutional 'stickiness' and path dependency, choose to fully endorse and engage with the Semester as a tool of economic coordination and a valuable framework for ensuring both sustainability and quality of care in the health system. The case studies suggest that an external catalyst might be required to prompt such a change of approach – it is feasible that the financial failure of one national health system, for instance, with its inevitable ramifications for neighbouring patients and health systems, might be sufficient to revive discussion of more integrated health system financing. This assessment does not seek to offer predictions about the future integration and direction of health policy but rather to highlight the continuing importance of supranational stewardship in its development.

### **Contemporary EU health governance: an agenda for further research**

The mainstream theories face a steep challenge in explaining the development of health's third stem and the extent of health integration to date. The explanatory power of neofunctionalism is limited by the failure of the EU project to result in a common health identity or demos, whilst intergovernmentalism cannot overcome the emergence of a health policy in the absence of demand or its encroachment into 'high politics' realms. Europeanisation offers a valuable framework for analysing the formation and operation of health policy but does not proffer a vision or final goal. As such, whilst acknowledging the value of these frameworks in assessing the catalysts and drivers of policy integration and convergence, the case studies have shown the governance approaches to offer greater potential for insight into contemporary health policy.

As noted by Schmidt (2015a: 42), the post-crisis era has seen an intensification of both intergovernmental and supranational dynamics in EU policy-making. Observing similar trends, Scharpf (2006) adds a new characterisation to his existing joint decision-making and intergovernmental categorisations of EU governance, termed supranational-hierarchical governance. Observing the autonomy and influence of the CJEU and the ECB in the early

2000s, Scharpf identifies a mode of governance in which these institutions are able to exercise policy-making functions without the involvement of politically-accountable actors (2006: 851). Though the Semester retains a significant degree of control for the intergovernmental institutions, the unprecedented powers of intervention wielded by the Troika in the EAPs and MoUs make Scharpf's model relevant to the post-crisis era.

The unbalancing of the democratic settlement in contemporary health policy (Schmidt, 2015a) exacerbates the legitimacy gap facing EU policy-makers and warrants exploration of deliberative democracy and experimental governance models (Scharpf, 1999; Pollack, 2005; Sabel and Zeitlin, 2008). Moreover, insight into the trajectory and influence of the European Semester might be gained from application of the historical and sociological variants of institutional analysis, drawing on dynamics of 'locking in', path dependency and socialisation. Such analysis might address the origin of third stem health policy, identifying how much of it resulted directly from the crisis and how much of it would eventually have emerged anyway, the path it is likely to take and the changes it is likely to experience in the coming Semester cycles, and the mode of governance – be it voluntarist or coercive – which will likely characterise it. It might also offer insight into the fate of the 'pre-existing' health policies, established in the first and second stems, in light of the renewed emphasis on economic integration. A closer examination of the historical circumstances under which health has expanded beyond its official mandate, perhaps through the lens of principle-agent analysis, might inform assessment of the conditions necessary for the further development of a 'health systems' policy. More broadly, institutional analysis of the executive could be crucial in determining the fate of the Commission in the contemporary political climate and implications for its roles as a sponsor of European integration and a health policy entrepreneur.

More fundamentally, the centralisation which accompanies the post-crisis strengthening of economic governance – a paradoxical phenomenon in the prevailing anti-European climate – is generating revived relevance for the 'pre-theories' of European integration. The problems which currently face the EU are generally located in its institutional asymmetry and the absence of a fiscal federalism to accompany economic integration, supporting the federalist assertion that a genuine centre of power is needed in order for a supranational entity to operate efficiently. Similarly, post-crisis developments lend weight to the functionalist notion that member states, on account of the short-termism and desire for power of national governments, are the institutions least suited to addressing the complexities of contemporary public policy and to 'nurturing the fundamental development of their citizens' (Saurugger, 2014: 18-19). These arguments points to a need for 'ever closer union', a path with profound implications for the future of EU health policy.

## **The future of health governance in Europe**

The thesis has described, explored and put into context the latest chapter of EU health policy. Using the stems heuristic, it has illustrated how the window of opportunity provided by the strengthening of the EU's pre-existing roots in macroeconomic coordination has laid the foundations for a third realm of health policy, pushing into the 'final frontiers' of health system organisation, financing and service delivery. It has also identified a trend of politicisation in health and traced its links to the bell-curve of health policy development described by interviewees. As the locus of health policy has expanded beyond the health sector, the policy community has grown, modes of governance have become more participatory and progress towards a coherent and effective EU health policy has faltered.

What might be inferred about the trajectory of the health bell-curve in light of these trends? Exploring the potential for change, a number of possible paths are presented. The external political climate will play a central role in determining whether health enjoys a second expansion as part of an intensified programme of economic coordination, or suffers further stagnation and decline in the face of resurgent subsidiarity and nationalism. Internally, several factors come in to play. Whilst the possibility still remains that the Semester might ‘go the same way as the OMC’ and exist purely as a supporting health policy mechanism (*Social NGO C*), the path dependency and locking-in dynamics observed in case study six support a historical institutionalist understanding of its durability. Moreover, the potential to invoke a sense of technocracy in the European Semester by framing it as an economising process may negate some of its political potency and prompt health and social actors to pursue greater balance within the CSRs – such activity could form the basis of a third stem policy on sustainability and quality of care. Fundamentally, though any revision of formal health integration structures undertaken now would likely be reductionist, informal structures continue to proliferate and supranationalism to prosper within them – the question is therefore whether these voluntarist and targeted governance structures have the potential to spill over and generate an ongoing integrative momentum.

Exploration of these future possibilities is an informative exercise but, from the experience seen in the case studies and the broader policy integration literature, it is most likely a theoretical one. Rather than expansion or retraction of the EU health policy agenda and portfolio, the more probable outcome is an endurance of the status quo. The increasing relevance of non-health determinants and policy processes is unlikely to be reversed and the decline of technical health regulation, resulting in an agenda of unsolvable and political health issues, has already been shown to delimit the further development of health competence. The weakness and conservatism of the Commission, a central and determining feature of the contemporary health policy arena, is continuously exacerbated by the refugee crisis and the faltering of Schengen, the resurgence of populism and the lagging economic recovery. Most fundamentally, those responsible for EU health policy seem to lack the vision and resources necessary to overcome these constraints and initiate change. As such, health policy is likely to continue on a defensive basis, seeking to avoid repeal of first and second stem policies in the face of deregulation, to mitigate the undermining of health objectives in the Semester process and to highlight the value of continued cooperation in technocratic, low politics public health issues.

Reference to the case studies suggests that the way to overcome these suboptimal outcomes is to move from politicised negotiation to a problem-solving approach (Scharpf, 1988) – in essence to make contemporary health policy more technical. As explored in case study six, this is precisely the approach being taken by the actors responsible for the European Semester, evidenced in the quantitative and technical narrative which has accompanied its development; as such, what is occurring in the post-crisis era might better be viewed as an economisation, rather than a politicisation, of health policy. The importance of a technical or political framing for the future of the Semester is emblematic of the broader contradiction facing contemporary EU health policy and the survival of the European project as a whole. In order to address the current political crisis, the EU must increase citizen support and reduce the disconnect between European policy and local outcomes. Within this task, there is a strong role for social and health policy as areas with direct and tangible impact upon individuals and the potential to ‘humanise’ the European project. As seen in the case studies, the necessary expansion of

social and health policy activity can be achieved in one of two ways. The first will require an injection of political will and an extension, either formal or informal, of the existing mandates; an unlikely prospect given the dominant subsidiarity rhetoric from national governments. The remaining option, already underway in some areas, is to deepen social and health policy integration by framing as many elements as possible as technical issues, thus removing them from the political arena. The resulting irony is that the best hope for reconnecting Europe to its citizens and regaining support for the European project lies in removing health and social policy from the democratic arena and putting it in the hands of experts and technocrats. Fundamentally, it is the interaction and balancing of this inherent contradiction which will determine the role played by health in a politicised EU and thus the future development of the policy.

## Appendix I: Full list of interviewees

<b>Interviewee (identifying label)</b>	<b>Date of interview</b>
Academic Expert, EU Health Policy A	9 July 2015
Academic Expert, EU Health Policy B	28 May 2015
Academic Expert, EU Health Policy C	30 June 2015
Academic Expert, European Parliament	22 May 2015
Council of the EU, Legal Service	6 June 2013
EU Public Affairs Consultant A	22 May 2015
EU Public Affairs Consultant B	18 June 2015
EU Environment NGO A	28 March 2013
EU Environment NGO B	18 February 2013
EU Health NGO A	20 November 2012
EU Health NGO B	20 July 2015
EU Health NGO C	21 May 2015
EU Health NGO D	10 July 2015
EU Health NGO E	8 May 2015
EU Health NGO F	2 July 2015
EU Health NGO G	24 June 2015
EU Health NGO H	9 July 2015
EU Health NGO I	2 July 2015
EU Social NGO A	26 March 2013
EU Social NGO B	1 June 2015
EU Social NGO C	21 March 2013; 22 June 2015
European Commission, Health Directorate A	1 June 2015
European Commission, Health Directorate B	25 March 2013
European Commission, Health Directorate C	8 July 2015
European Commission, Health Directorate D	9 June 2015
European Commission, Health Directorate E	12 June 2015
European Commission, Health Directorate F	20 March 2013
European Commission, Legal Affairs Directorate	6 May 2013
European Parliament Advisor, ALDE Group	6 June 2013
European Parliament Advisor, EPP Group	19 June 2013
European Parliament Advisor, S&D Group A	24 May 2013
European Parliament Advisor, S&D Group B	16 July 2015

European Parliament, Legal Service	11 June 2013
Member of European Parliament A	14 July 2015
Member of European Parliament B	25 June 2015
Member of European Parliament C	15 July 2015
UK health association, EU Liaison A	11 June 2015
UK health association, EU Liaison B	11 May 2015
Social Protection Committee	13 July 2015
World Health Organization A	23 June 2015
World Health Organization B	11 June 2013

## Appendix II: Interview discussion topics

This appendix lists the discussion topics sent to each participant in advance of fieldwork interview.

### The rise of EU health policy

- How would you characterise the way in which the EU's health policy has evolved since the EC was created?
- Has it grown too much/not enough/beyond its mandate?
- To what extent do you consider health to be an 'integrated' policy area?
- To what extent do you consider health to be a 'Europeanised' policy area?

### National versus supranational health policy

- In which specific areas of health has the EU been most successful in achieving its stated aims?
- In which areas have member states most successfully retained control?
- How has the balance between national and supranational responsibility in health changed?
- How might it change in the future?

### The governance of EU health policy

- How has the governance of health – broadly understood as the way in which European health actors seek to control policy and change outcomes – changed over time?
- What determines the kind of governance which is likely to be successful in a given health policy area?
- To what extent have regulation and 'hard law' given way to voluntary coordination and 'soft law'?

### The politicisation of EU health policy

- Is there an understood distinction between 'political' and 'technical' health policy issues?
- What determines the 'level of politicisation' in health policy?
- Who is driving health policy at the European level and what opposition do they face?
- How is the governance of health approached differently according to the level of politicisation?
- Is it fair to state that there is now a substantial body of 'technical' health policy, conducted on a day-to-day basis, which is led by the EU?

### Economic governance and the future of EU health policy

- What are the implications of inclusion in the economic governance framework for the scope and governance of health policy?
- Is the inclusion of health in mechanisms such as the European Semester an indication of its institutionalisation as an EU policy area?
- To what extent is it fair to characterise this as a 'new era' of health governance?
- What might be expected from this new chapter in the evolution of EU health policy?

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