I. INTRODUCTION

- What is EU health law and policy?
- How has the scope of EU health law and policy developed within the broader context of EU law/integration?
- What is the direction of travel for EU health law and policy?

These questions introduce EU health law and policy as a discipline in its own right; sketch its historical development; and consider its future. This wide-ranging chapter sets the scene for the in-depth discussions in the chapters which follow.

II. WHAT IS EU HEALTH LAW AND POLICY?

The emergence of EU health law and policy as a discipline has been characterised by discussions of how it is defined, and what it comprises. Perhaps most notably, EU health law and policy has been conceptualised as a ‘patchwork’ made up of various provisions that constitutionally belong to different policy domains, principally those of the internal market, social affairs, public health, enterprise and economic policy. The integration of health policy in particular has further been described as ‘differential, patchy, accidental and discontinuous’.

This fragmented and disparate nature of the framework underpinning EU health law and policy is complicated further by the sheer range of considerations within ‘health’ as a field – from non-communicable diseases to medical devices, to name but two examples.

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1 TK Hervey and B Vanhercke, ‘Health care and the EU: the law and policy patchwork’ in E Mossialos and others (eds), Health Systems Governance in Europe: The Role of European Union Law and Policy (CUP 2010) 85.
The wide-ranging nature of EU health law and policy has led to recognition of the need for different approaches to its interpretation. These are considered below. For example, considerations of EU health law and policy may start with an analysis of EU institutions and processes before examining action taken by the EU regarding health and how other European policies affect health. This suggests that ‘health-specific’ EU policies and legal provisions can be distinguished from those which are incidentally relevant to health. However, a ‘novel taxonomy’ is also beneficial, combining a thematic approach with ‘individual’ and ‘collective’ (or ‘systemic’) perspectives. This volume adopts a development of that taxonomy, comprising history and scope, people, products, systems, public health and the external dimension to examine aspects as diverse as biocitizenship, e-health and m-health, and global health law and policy.

II.i Interpretations of EU Health Law and Policy

II.i.a An ‘interface’ between EU law and health law

This interpretation of EU health law and policy as an interface perhaps suggests an equation whereby EU law + health law = EU health law. Although this would be misleading it nevertheless highlights the limitations of using traditional definitions of both EU law and health law to understand EU health law and policy. Certainly the transversal nature of EU health law and policy is a distinctive feature, with a notable example offered by the change in status of EU tobacco policy from internal market imperative to public health objective.7

The interface approach is concerned with how aspects of EU law such

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3 SL Greer and others, Everything You Always Wanted to Know About European Union Health Policies but Were Afraid to Ask (WHO 2014).

4 TK Hervey and JV McHale, European Union Health Law – Themes and Implications (CUP 2015) 537. In contrast, see Mossialos and others’ (n 1) examination of health systems governance drew on both categories of EU law (such as fundamental rights and competition law) and a thematic approach (for instance in connection with e-health).

5 Aside from acknowledging the scope for different definitions of these branches of law, further discussion is beyond the scope of this chapter.

6 On the relationship between EU health law and medical law more generally, see TK Hervey, ‘The past, present and future of EU health law’ in C Stanton and others (eds), Pioneering Healthcare Law – Essays in Honour of Margaret Brazier (Routledge 2016).

The history and scope of EU health law and policy

as the internal market and competition rules impact health systems in Member States and EU health policy work is considered in a similar manner. While the ‘interface’ approach is now established as an analytical perspective in its own right, different examinations of EU health law and policy are discussed below.

II.i.b Health as an ‘implicit’ or ‘explicit’ characteristic – an ‘all or nothing’ approach?

This interpretation is influenced in part by the apparent paradox of Article 168 TFEU being considered an explicit, yet weak and limited legal basis for EU competence in public health but one which nevertheless incorporates provision for the mainstreaming of health into other policies – ‘A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.’ A consequence of this would seem to be that either EU health policy is non-existent as an autonomous policy area, given that it is mainstreamed in all other policies, or that all EU public policy is also health policy. However, broad conceptions of EU health policy can be more nuanced, and distinguish and describe health policy that is pursued in the context of other European policies, rather than subsuming all EU policy under health policy.

[...] if EU agricultural policy aims to create a European market for milk, it is agricultural policy. However, European Union health policy is adopted when, in the context of creating a market for milk, mandatory testing for bovine tuberculosis is implemented at the European level[...].

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8 Hervey (n 6).
9 See for example, L Hancher and W Sauter, EU Competition and Internal Market Law in the Health Care Sector (OUP 2012), and J van de Gronden and others (eds), Health Care and EU Law (TMC Asser Press 2011).
10 Hervey and McHale acknowledge the significance of the ‘interface’ between EU and health law in their earlier work TK Hervey and JV McHale, Health Law and the European Union (CUP 2004), but their 2015 work (n 4) extends beyond this, reflecting the exponential expansion of the field in the intervening 10 years.
13 ibid 59.
14 ibid.
II.i.c  ‘Constitutional asymmetry’ and EU health law and policy
The ‘constitutional asymmetry’\(^\text{15}\) of EU economic policies assuming greater importance over social ones should not be overlooked in the development of EU health law and policy. On the one hand, it has been suggested that EU health law has moved beyond a tenuous and uncertain position to gain greater coherence from an increasing sense of distance from the internal market rules.\(^\text{16}\) On the other hand, the recent increase in EU powers to intervene in national health policies following the financial crisis has been considered a ‘clear example’\(^\text{17}\) of constitutional asymmetry, yet has significant potential to shape EU health law and policy.

II.i.d  Other interpretations
Two relatively recent approaches are noted here.
First, the use made by the EU of its ‘regulatory toolbox’ in combination with varying degrees of intervention to address differing concerns. Thus the scope for introducing an EU ‘fat tax’ is complicated by the EU’s limited competence to either enact public health measures or introduce tax.\(^\text{18}\) However, the EU has been able to contribute to shaping the emergence of national lifestyle policies regarding tobacco, alcohol and diets through its negative integration provisions in combination with early legislative efforts.\(^\text{19}\)

Second, the development of a ‘rights-based’ approach to EU health law and policy. This draws on the concept of fundamental rights in EU law and recognises the relevance of human rights law in establishing health rights.\(^\text{20}\) Indeed, it has been considered that since 2000, a rights-based focus comprising both the protection of rights with significance for EU health law by the Charter of Fundamental Rights and the language of human rights permeating various aspects of EU health legislation offers a point of coherence for EU health law and policy.\(^\text{21}\)

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\(^{16}\) Hervey and McHale (n 4).

\(^{17}\) Greer and others (n 3) xiii.


\(^{19}\) For a discussion of this, see A Alemanno and A Garde, ‘The Emergence of an EU Lifestyle Policy: The Case of Alcohol, Tobacco and Unhealthy Diets’ (2013) 50 *Common Market Law Review* 1745.

\(^{20}\) See in particular, de Ruijter (n 12).

\(^{21}\) Hervey and McHale (n 4) Chapter 3.
II.ii  Distinguishing Between ‘Public Health’ and ‘Healthcare’ in EU Health Law and Policy

The distinction between ‘public health’ and ‘healthcare’ is a recurrent, even underlying theme of discussions of EU health law and policy.22 In very general terms, ‘public health’ can be defined by reference to collective health, and ‘healthcare’ as a policy regarding the treatment of individuals and the organisational and financing aspects of healthcare provision. However, the two categories effectively combine in concepts of an EU understanding of ‘health’,23 and are seen as differentiated yet overlapping areas of policy within EU health policy,24 hence both are encapsulated in the single word ‘health’ here.25

However, it is recognised that there is potential for varying approaches to defining ‘healthcare’ and ‘public health’.26 The relevance of the distinction between ‘public health’ and ‘healthcare’ appears therefore curious.

On the one hand, it is a notable feature: for instance, the EU’s formal competence in health under Article 168 TFEU is described as a ‘public health’ competence (although ‘healthcare’ is arguably evident in the subsidiarity element of Article 168(7) TFEU). Furthermore, it has been claimed that the CJEU has proved more active in matters connected with ‘healthcare’ (perhaps most notably in considering the application of the internal market rules to patients and practitioners) than ‘public health’, although there is scope for intervention here too.27

On the other hand, the distinction appears less material to certain aspects of EU health law and policy. Thus, insofar as common values can be defined, these may not be influenced solely by ‘public health’ or ‘healthcare’. Furthermore, the starting point for a chronology of EU health law and policy28

23  de Ruijter (n 13) 59.
24  ibid 61.
25  An apparently alternative phrasing of ‘EU health (care) policy’ is used in Mossialos and others (n 1) Chapter I.
26  For a discussion of some of the issues, see Greer and Kurzer (n 2) Chapter 1. Vos draws a further distinction between ‘human health’ and ‘public health’, but this is beyond the scope of this chapter. See E Vos, Institutional Frameworks of Community Health and Safety Regulation: Committees, Agencies and Private Bodies (Hart 1999). For a critical consideration of this view, see de Ruijter (n 12) 51–52.
health law and policy is considered to be the same for both ‘public health’ and ‘healthcare’.

Indeed, as EU health law and policy evolves as a discipline, these two categories – however broadly defined – may no longer prove sufficient. It has already been suggested that EU health policy encompasses ‘three faces’: explicit health policies (relating to public health); health services policies (that is, internal market law, which might be considered to relate to ‘healthcare’); and the much-strengthened fiscal governance system of the European Semester which effectively elevates the EU to supervisor of Member State policy and expenditure decisions, thereby potentially impacting health. This suggests a departure from policies relating to ‘healthcare’ thus far.

Furthermore, the emergence of different categorisations comprising both ‘public health’ and ‘healthcare’ elements arguably undermine a strong sense of distinction. This is evident, for instance, in considerations of the EU’s relationship with international agencies and participation in international agreements – which form a basis for an ‘external’ EU health law related to, but distinct from, the ‘internal’ EU health law considered in this chapter.

Space constraints mean that we have not drawn a strict distinction here between ‘law’ and ‘policy’, but acknowledge the role of the former in the latter. Similarly, we have been unable to explore all the parties involved in this area. However, we nevertheless develop our overview of what EU health law and policy is by reference to its expanding legal basis – from the limitations of the classic Community method in contributing to EU health competence to the use of new governance methods by the EU institutions – against the following chronological framework.

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28 See Hervey and McHale (n 4).
30 See for instance, Greer and Kurzer (n 2) Chapters 7 and 8.
31 On the emergence of ‘external’ EU health law and the distinction between this and its ‘internal’ counterpart, see Hervey and McHale (n 4).
32 For a thorough treatment of the various facets of policy, see de Ruijter (n 12), Chapter 2.
III. HOW HAS THE SCOPE OF EU HEALTH LAW AND POLICY DEVELOPED WITHIN THE BROADER CONTEXT OF EU LAW/INTEGRATION?

We have divided this historical account chronologically into three sections based on those relevant Treaty changes that also involved a change in direction for the EU as a whole: from Rome to Maastricht: 1957–1992; from Maastricht to Lisbon: 1992–2007; and post-Lisbon: 2007–present.33

III.i From Rome to Maastricht: In Pursuit of the Internal Market 1957–1992

The 1957 Rome Treaty contained no explicit references to health, with the exception of public health,34 as a justification for restrictions on free movement. However, the focus on the free movement of goods, services, workers (including establishment) and capital led to incremental legislative actions on health issues.

III.i.a Social security coordination

The earliest provisions of secondary EU law on health are the rules for workers regarding social security coordination. Dating back to Regulations Nos. 3 and 4 of 1958 which included provisions on sickness,35 continuously updated and fundamentally revised in 1971 and 2010, these are set out in fully binding form (as Regulations). Their scope gradually extended to cover all EU citizens and their dependents. Supplementary legislation broadened their scope to legally-resident third-country nationals.36 This

regime includes a system for reimbursement of cross-border treatment, based on the host country level of reimbursement (as opposed to that of the home country in the 2011 Patients’ Rights Directive, discussed below). 37

III.i.b Food law

The first piece of EU legislation pertaining to public health is that on food safety, a form of risk regulation, with a first Directive on colourants in foodstuffs being adopted in 1962. 38 Many principles of EU law were first developed in relation to food (and agricultural production). Here we mainly flag the existence of this extensive area of law but will not go further into it 39 – except to note by way of example that in 2002 a general food safety Regulation was adopted following the food crisis around bovine spongiform encephalopathy/new variant Creuzfeld-Jacob Disease, 40 which involved the creation of the European Food Safety Authority.


37 That is, apart from sickness, it covers maternity and paternity; old-age pensions; preretirement and invalidity pensions; survivors’ benefits and death grants; unemployment; family benefits; and accidents at work and occupational illness.


food are pharmaceuticals and medical devices as well as tobacco (and alcohol).

### III.i.c Pharmaceuticals

Pharmaceuticals have been subject to regulation at EU level, from 1965 onwards. For pharmaceuticals three types of rules are important: the patent rules; rules on admission to market; and price transparency rules. The EU patent rules are general in nature and do not include specific provisions for pharmaceuticals although this is one of the leading sectors in patent applications. Marketing authorisation for pharmaceuticals has been harmonised at EU level. In addition there are rules for special types of medication (orphan drugs, children’s medication and advanced therapy). The most direct EU level intervention is the 1988 Directive on price transparency for pharmaceuticals, which includes time limits and requires decisions to be justified objectively, non-discriminatory and (evidently) transparently. A proposed new...
Directive on this topic was recently withdrawn for lack of political support.46

III.i.d Medical devices
Medical devices have been separately regulated at EU level since 1989,47 as part of the internal market drive to facilitate free movement by means of the ‘new approach’ to standardisation based on the 1979 Cassis de Dijon case law of the CJEU. This assumes identical public interest guarantees are not necessary for free movement across borders to take effect because they are assumed to be equivalent between the Member States. Hence mutual recognition and minimum harmonisation of mandatory requirements suffices.48 Using Directives (which must be implemented in national law) was typical for the ‘new approach’.49


51 Active Implantable Medical Devices Directive (n 47).
devices. At present the three medical devices Directives are being recast and consolidated in the form of two Regulations on Medical Devices.

**III. i.e. Tobacco**

Although classified as a public health concern under Article 168(5) TFEU, tobacco is also a good and accordingly subject to the free movement rules. Tobacco was originally regulated by Directives on tobacco labelling (1989) and on maximum tar yield (1990). The present Tobacco Advertising Directive supersedes a previous version which was annulled by the Tobacco Advertising I case, because the harmonisation prohibition of Article 152(4) EC (now Article 168(7) TFEU) meant other Treaty articles cannot be used as a legal basis in order to circumvent this express harmonisation exclusion. The European legislature subsequently adopted a revised Directive, which survived a further legal challenge. The sector is now governed especially by the 2003 Tobacco Advertising Directive and the 2014 Tobacco Products Directive.
III.i.f Medical qualifications
An early form of EU health legislation regards mutual recognition of medical qualifications. It emerged as part of the 1992 programme of completing the internal market and is necessary to enable free movement of health workers. In line with mutual recognition once a health worker is qualified to practice in a single EU Member State, they are automatically qualified to work elsewhere in the EU, if minimal additional requirements (such as language skills) are met. Originally separate Directives were used for each profession but all health professions are now covered in a general Directive.60

III.i.g Health and safety at work
This branch of EU law and policy also relates to workers but goes beyond free movement.61 It was created in 1989 after the 1987 Single European Act revising the Rome Treaty introduced an EU competence to legislate on this issue in Article 118a EEC (now Article 153 TFEU).62 Relevant EU legislation impacting health is the Working Time Directive.63 This has an exception for doctors in training but is controversial because in effect it regulates the number of staff required for health facilities.

III.i.h Free movement of services
Finally, not only the provision of healthcare but also its consumption was subject to the free movement of services, even the provision of information regarding legal abortions.64 The freedom of services included the freedom to provide as well as to

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61 More generally Vos (n 26).
receive services, in cases where either: the provider; or the recipient; or the service itself crosses a national border within the EU. This led to the patients’ mobility case law and the Patients’ Rights Directive (see below).

III.ii From Maastricht to Lisbon: Expansion and Overreaching 1992–2007

III.ii.a The integration context
Regarding European integration, this period runs from a high point – the 1992 Maastricht Treaty inter alia enhancing the role of the European Parliament and offering a framework for economic and monetary union – to a low point: French and Dutch referenda rejecting a draft constitutional treaty in 2005. The resulting 2007 Lisbon Treaty offered concessions by omitting references to federalism and downplaying the role of competition.

In this period the scope for health rights was significantly expanded. The 1992 Maastricht Treaty introduced an explicit EU competence on health with Article 129 EC. In 2000 the EU adopted its Charter of Fundamental Rights including provisions on the right to the integrity of the person (Article 3), to healthcare (Article 35) and to Services of General Economic Interest (Article 36). These rights under the Charter were subsequently made justiciable by the 2007 Lisbon Treaty, promoting a rights-based approach to EU Health law.65

III.ii.b Public health
From 1993 onwards the EU became involved in public health, with a Commission Communication on public health policy in the European Community.66 This culminated in a programme for 2003–2008 in the field of public health,67 the first in a series initially on public health


65 See de Ruijter (n 12).

66 In the context of the public health framework set out in the Commission communication of 24 November 1993 on the framework for action in the field of public health, eight action programmes were adopted, namely regarding health promotion, information, education and training; on an action plan to combat cancer; on the prevention of AIDS and certain other communicable diseases; on the prevention of drug dependence; on health monitoring; on injury prevention; on rare diseases; and on pollution-related diseases. Commission, ‘The Framework for Action in the Field of Public Health’ (Communication) COM (93) 559 final.

and eventually (the second 68 and the third (current) programme) 69 more broadly on health. During this period the EU’s public health competence was enshrined in the above mentioned Article 129 EEC and its successor Article 152 EC 70 (now Article 168 TFEU). This competence has developed to comprise a mainstreaming element, 71 encourage cooperation not only between the EU and Member States, 72 but also with third countries and international organisations, 73 and outline procedures for EU institutions to take action regarding public health 74 and for the Council and Commission to work together. 75 Perhaps most notably, Article 168 TFEU and its predecessors set out the limitations on harmonisation in connection with health 76 and emphasise Member State competence in connection with health (the subsidiarity clause). 77

III.ii.c The patient mobility case law

This case law regarding restitution-based insurance systems with Kohll and Decker (1998), was extended to benefits in kind systems in Smits Peerbooms (2001) and Müller-Fauré (2003) and finally to taxation-based national health services (NHS) systems in Watts (2006). 78 In each case the Court of Justice of the EU required the home Member State to reimburse costs of cross-border treatment. 79 Once the case law covered all national


70 For an examination of the relationship between these earlier provisions, see Hervey and McHale (2004) (n 10).

71 TFEU, Article 168(1).

72 TFEU, Article 168(2).

73 TFEU, Article 168(3).

74 TFEU, Article 168(4).

75 TFEU, Article 168(6).

76 TFEU, Article 168(5).

77 TFEU, Article 168(7).


systems the Member States came to favour aid rules to apply if an undertaking is granted a (selective) advantage from State resources with an effect on trade, and competition. Where the service offered is simply a quid pro quo the State aid rules do not apply. The Commission elaborated this rule in the so-called Altmark package, published in 2005 and recast in 2012. Part of this package is a Commission Decision of 2012 that works as a block exemption for health providers.

III.ii.d Agencies
The main agencies that are active in the realm of health include the European Medicines Agency (EMA, 1993), the European Monitoring Centre for Drugs and Drug Addiction (1995), the European Environment Agency (1993), the European Agency for Health and Safety at Work (1994) and the European Centre for Disease Control and Prevention (ECDC, 2005).

III.ii.e The Open Method of Coordination (OMC) and health
The OMC was established by the Maastricht Treaty as an instrument for coordinating national economic policies through the use of recommendations and guidelines. The ‘OMC toolbox’ comprises joint (EU)
objectives (political priorities), indicators, guidelines and targets, performance assessment and peer review of national plans.86

A ‘healthcare’ OMC was introduced in 200487 and combined in 2006 with the OMCs for social inclusion and pensions into a single, overarching process – the Social OMC.88 This forms a counterbalance to economic growth as an EU objective under the Lisbon and Europe 2020 strategies. The application of the OMC to health is contentious, especially regarding attempts to measure health systems’ performance.89

III.iii Post-Lisbon: New Methods and Financial Constraints 2007 to Present

The post-Lisbon period combines political malaise with a persistent economic downturn. Nevertheless, the integration of health into EU policies continues.

First, Article 168 TFEU extended Article 152 EC. Whereas the subsidiarity clause for the management and financing of national health systems was retained, the scope for EU activity in health was extended. For example, Article 168 TFEU – jointly with the internal market provision Article 114 TFEU (formerly Article 95 EC and 100a EEC) – became the basis for the Patients’ Rights Directive.

III.iii.a Freedom of services: the Patients’ Rights Directive

The Patients’ Rights Directive forms a codification of the case law of the CJEU on cross-border medical services that had originally been attempted in the Service Directive.90 Although in line with Article 168 TFEU, the

86 Hervey and Vanhercke (n 1).
89 ibid.
organisation and delivery of health services within national health systems were not affected as the Member States were required to reimburse cross-border care based on their domestic reimbursement level subject only to restrictively defined exceptions. In addition, they are to provide information on quality and prices. The Directive also covered enhanced cooperation on rare diseases and e-health.

III.iii.b Freedom of establishment
Regarding the freedom of establishment an increasing number of cases have come before the EU courts during the Post-Lisbon period without however triggering specific EU level legislation.91 The pharmacy sector has seen a large number of cases where the rules governing the spatial distribution of pharmacies and/or licences were contested.92

III.iii.c The third health programme and Europe 2020
A Regulation established the third programme for the EU’s actions in the field of health,93 to be integrated in the Europe 2020 programme.94 The latter is aimed to relaunch the European project and the EU economy with an emphasis on research, growth and jobs (beefing up the earlier Lisbon programme).95 This health programme is largely based on funding the various aspects of health cooperation on the EU agenda. However, a large part of the influence of Europe 2020 on health does not run through the third programme on health but through the European Semester.

III.iii.d The European Semester
The European Semester is an annual review process which implements the 2011 and 2013 reforms of the Stability and Growth Pact (SGP) introduced to address the global financial crisis.96 It forms a powerful tool

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93 Regulation (EU) 282/2014 (n 69).
96 Greer and others (n 3) Chapter 5.
for achieving consistent policy recommendations among Member States as well as across EU programmes.97

While health does not feature explicitly in these mechanisms, country-specific recommendations (CSRs) regarding health have been formulated in the context of the European Semester since 2012. These CSRs have related to the strengthening of national budgetary frameworks and/or improving the long-term sustainability of public finances.98 They have included advice to curb expenditure on, and increase cost-effectiveness of, the health sector.99 Furthermore, they have stressed improvement in cost efficiency and financial sustainability of national health systems to balance public spending.100

III.iii.e The global context

Above we have already mentioned the impact of external economic events. Although the impact of the broader world on EU health law and policy predates the Lisbon Treaty, the external role of the EU in health has been strengthened by the reinforcement of the EU competence in Article 168 TFEU and by the fundamental rights to healthcare in the Charter.101 Health services are also a trade issue, and (public) health is a development issue, so both are on the external health agenda of the EU, which is of growing importance. The EU is active in global institutions such as the World Health Organisation (WHO) and the Food and Agricultural Organisation (FAO). The importance of international collaboration is growing against a background of globalisation and external health threats such as SARS, aggressive new flu variants and multidrug resistant tuberculosis.

97 ibid.
100 ibid.
101 Hervey and McHale (n 4) Chapters 15 and 16.
IV. CONCLUSION: WHAT IS THE DIRECTION OF TRAVEL FOR EU HEALTH LAW AND POLICY?

In conclusion, we agree that EU health law and policy is both a multi-level, multi-tiered and multi-governance system that is unique, and a policy field created by judges and markets rather than politics. In spite of persistent political claims of subsidiarity in the interest of national sovereignty and solidarity, the scope of EU health law and policy has gradually been extended just as the broader process of EU integration itself expanded. This has not however led to a formally coherent body of law and policy so much as a ‘patchwork’ of rules and policies developing in multiple directions. Looking towards the future there are two key related trends: demographic ageing and the shift towards chronic conditions mean problems of controlling costs become acute precisely as there is a shift in power in economic matters to EU institutions in the wake of the financial crisis. Whether this will mainly result in cost cutting or in new and/or common solutions remains to be seen, although recent developments suggest that the direction of travel for EU health law and policy is determined both internally and externally.

102 Lamping (n 2).
104 Greer and others (n 3).