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## *Health care and the EU: the law and policy patchwork*

TAMARA HERVEY AND BART VANHERCKE

### 1. Introduction

Governments of European welfare states face an uncomfortable predicament. To transfer their welfare-state obligations to the EU level would jeopardize the political basis of their legitimacy. However, since at least the mid-1980s, the processes of European integration, to which those governments are irreversibly committed, have become increasingly pervasive.<sup>1</sup> As a result, European integration creates a problem-solving gap in that ‘member governments have lost more control over national welfare policies, in the face of the pressures of integrated markets, than the EU has gained de facto in transferred authority’,<sup>2</sup> substantial though the latter may be.

The research for this chapter benefited from funding by the ‘Shifts in Governance’ programme of the Dutch Science Foundation (NWO) and the ‘Society and Future’ programme, implemented and financed by the Belgian Science Policy Office. We are grateful to Elias Mossialos, Rita Baeten, Govin Permanand, Matthias Wismar, Willy Palm and Szilvia Kalman for their helpful comments on earlier drafts. The usual disclaimer applies.

<sup>1</sup> See F. Scharpf, ‘A new social contract? Negative and positive integration in the political economy of European welfare states’, European University Institute Working Paper RSC 96/44 (1996); R. Dehousse, ‘Integration v regulation? On the dynamics of regulation in the European Community’, *Journal of Common Market Studies* 30 (1992), 383–402; G. Majone, ‘The European Community between social policy and social regulation’, *Journal of Common Market Studies* 31 (1993), 153–70; F. Scharpf, ‘The European social model: coping with the challenges of diversity’, *Journal of Common Market Studies* 40 (2002), 645–70; C. Offe, ‘The European model of “social” capitalism: can it survive European integration?’, *Journal of Political Philosophy* 11 (2003), 437–69; M. Ferrera, *The boundaries of welfare: European integration and the new spatial politics of social protection* (Oxford: Oxford University Press, 2005); L. Moreno and B. Palier, ‘The Europeanisation of welfare: paradigm shifts and social policy reforms’, in P. Taylor-Gooby (ed.), *Ideas and welfare state reform in Western Europe* (Basingstoke: Palgrave Macmillan, 2005), pp. 145–71.

<sup>2</sup> S. Leibfried, ‘Social policy. Left to judges and the markets?’, in H. Wallace, W. Wallace and M. Pollack (eds.), *Policy-making in the European Union* (Oxford: Oxford University Press, 2005), p. 243.

At face value, health care seems to be a case in point to illustrate this predicament. Indeed, generally speaking, with some limited exceptions, the European Union has no legal competence to adopt EU law in the field of health care,<sup>3</sup> this being a matter of national competence according to the EU's founding or 'constitutional' document, the EC Treaty (to be replaced by the Treaty of Lisbon<sup>4</sup> once it has been ratified by all the Member States). Unsurprisingly, both Member States and EU institutions are heavily bound in their ability and willingness (on account of national interests, political sensitivities and the huge diversity of health care systems in an EU of 27) to issue legislation in this area. Those who are (politically) responsible for health care at the domestic level are faced with a second problem: since the very beginnings of what is now the European Union, other areas of EU law have had unintended effects in health care contexts. The second section of this chapter provides an overview of the main examples of this phenomenon. It involves several areas of EU law. Their effects on health care in the Member States form a kind of patchwork, unconnected by legal or policy coherence.

In spite of this predicament, the EU has developed, since the early 1990s, its own health care policies in response to these unintended consequences of the application of EU law in health care settings and their consequent effects on the national health care systems of the Member States. Because the EU has no formal legal powers to develop its own health care law, the EU's emergent health care policy is also something of a patchwork. EU health care law and policy is formed from a variety of provisions that constitutionally 'belong' to different policy domains, principally those of the internal market, social affairs, public health, enterprise and economic policy. The third part

<sup>3</sup> Article 152(5) EC. See, for instance, Case 238/82, *Duphar* [1984] ECR 523, para. 16; Joined Cases C-159/91 and 160/91, *Poucet and Pistre* [1993] ECR I-637, para. 6; Case C-70/95, *Sodemare* [1997] ECR I-3395, para. 27; Case C-120/95, *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR 1831, para. 21; Case C-158/96, *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931, para. 17; Case C-157/99, *Geraets-Smits and Peerbooms* [2001] ECR I-5473, para. 44. See also Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2008 No. C115/1, which, if the Treaty of Lisbon of 17 December 2007, OJ 2007 No. C306/1, is ratified, confirms in a new Title I, Article 6, that the EU has competence to carry out actions to support, coordinate or supplement national actions in the fields, *inter alia*, of 'protection and improvement of human health'.

<sup>4</sup> Treaty of Lisbon, above n.3.

of the chapter explores the processes through which the various sets of actors representing these five policy domains at the EU level have tried to shape the terms of the EU health care debate and expand their influence upon it.

Both the substance of – and the institutional arrangements for – EU health care law and policy-making are therefore highly displaced, in comparison with national health care law and policy-making, which has its own constitutional structures and established mechanisms. While national health care policy tends to be the domain of national (political or administrative) ‘health’ experts, in the EU context most legal measures and policies that have implications for health care are adopted within institutional structures and procedures that were developed for quite different policy domains. Furthermore, EU-level health care law and policy occupies a highly contested space in the EU’s current constitutional settlement. Traditionally understood, EU law and policy-making is legitimated through a constitutional settlement within which powers are formally conferred by the Member States, in a negotiated political settlement represented in legal documents (the EC and EU Treaties) to an institutional triptych of the European Commission, European Parliament and Council of Ministers. In policy areas outside those where the EU has competence to legislate, the Member States enjoy autonomy of action. Recently, however, this binary distinction between EU and national competence has been challenged by the emergence of new governance practices in the EU.<sup>5</sup> By ‘new governance’, we mean ‘a range of processes and practices that have a normative dimension but do not operate primarily or at all through the formal mechanism of traditional command-and-

<sup>5</sup> These include, but are not limited to, the ‘open method of coordination’ (OMC), which was defined by one of its founding fathers in the social field as ‘a mutual feedback process of planning, examination, comparison and adjustment of the policies of Member States, all of this on the basis of common objectives’. See F. Vandebroucke, ‘New policy perspectives for European cooperation in social policy’, Speech at the European Conference ‘Social and Labour Market Policies: Investing in Quality’, Brussels, 22 February 2001. The OMC toolbox typically comprises joint (EU) objectives (political priorities), indicators, guidelines and sometimes targets; national reports or action plans to assess performance against objectives and metrics; peer review of national plans through mutual criticism and exchange of good practices. See also Chapter 4 in this volume.

control-type legal institutions'.<sup>6</sup> These apply in areas from which EU competence is formally excluded. But they involve the EU institutions (and especially the European Commission) in the creation of distinctly normative elements, including non-binding measures such as mutually agreed objectives, indicators and benchmarks, or mandatory reporting mechanisms, which are often embedded in participatory, non-hierarchical and iterative procedures.

Health care law, policy and governance in the EU can thus be understood through a metaphor of a double patchwork. Various parts of long-standing EU law have effects in health care policy settings. The EU institutions, as well as the Member States, have themselves responded to this phenomenon, again using a variety of different policy domains and discourses as their platform. It is our contention that, so far, these patchworks have largely developed in parallel (with governance processes being developed rather defensively in an attempt to soften the consequences of law), but that law and soft modes of health governance are becoming increasingly interwoven, thereby opening the door for hybrid EU policy instruments.

## 2. The EU's public health policy

Before we turn to the examples of ways in which EU law has affected national health care policies through non-health-care policy domains, we must first explore the major exception to the general principle that the EU has no competence in health: the field of public health. Public health and health care are, of course, discrete policy domains. But public health measures have important implications for health care systems, not least because preventative public health measures may reduce burdens on health care systems. The EU institutions – in particular, the Directorate-General for Health and Consumer Protection (DG SANCO) of the Commission – have therefore sought to use public health as one possible platform for health care policy. As we will see in the third section, public health is one of the five main policy domains or discourses that comprise the patchwork of EU health care law, policy and governance.

<sup>6</sup> G. de Búrca and J. Scott, 'Introduction: new governance, law and constitutionalism', in G. de Búrca and J. Scott (eds.), *New governance and constitutionalism in Europe and the US* (Oxford, Portland: Hart, 2006), p. 3.

The EU's public health policy is based on Article 152 EC. This gives the EU a very limited legislative competence to adopt EU-level harmonizing legal instruments such as directives and regulations.<sup>7</sup> However, it does provide an enabling competence to adopt 'incentive measures' – that is to say, programmes that are funded by EU resources and managed by the Commission and its committees or agencies. These general EU public health programmes have been running since 2003, although they have their roots in earlier programmes such as 'Europe against Cancer'<sup>8</sup> and 'Europe against AIDS'.<sup>9</sup> Note that a scientific evaluation concluded in 2003 that the 'Europe against Cancer' Programme (which included the European Code against Cancer) 'appears to have been associated with the avoidance of 92 573 cancer deaths in the year 2000', or a reduction of 10% in the EU overall.<sup>10</sup> Another key tool in this area are the EU Guidelines on Breast and Cervical Cancer Screening,<sup>11</sup> which are extremely influential, as they are being used as a reference manual by cancer professionals and medical practitioners throughout the EU. Furthermore, advocacy groups (such as the German women's associations) use them as leverage to encourage national governments and authorities to improve quality standards.<sup>12</sup>

<sup>7</sup> For instance, this power has been used to adopt EU law on blood safety: Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ 2002 No. L33/30.

<sup>8</sup> See Council and Representatives of the Governments of the Member States Resolution on a programme of action of the European Communities against cancer, OJ 1986 No. C184/19; Council and Representatives of the Governments of the Member States Decision 88/351/EC adopting a 1988 to 1989 plan of action for an information and public awareness campaign in the context of the 'Europe against cancer' programme, OJ 1988 No. L160/52.

<sup>9</sup> Council and Ministers for Health of the Member States Decision 91/317/EEC adopting a plan of action in the framework of the 1991 to 1993 'Europe against AIDS' programme, OJ 1991 No. L175/26.

<sup>10</sup> P. Boyle *et al.*, 'Measuring progress against cancer in Europe: has the 15% decline targeted for 2000 come about?', *Annals of Oncology* 14 (2003), 1312–25.

<sup>11</sup> The latest versions are N. Perry *et al.*, *European guidelines for quality assurance in breast cancer screening and diagnosis* (Brussels: European Commission, 2006); and N. Perry *et al.*, *Guidance for the introduction of HPV vaccines in EU countries* (Stockholm: European Centre for Disease Prevention and Control, 2008). Guidelines for colorectal cancer screening should be produced by 2009, see Europa, Press Release 06/161, 7 April 2006.

<sup>12</sup> Interview with DG SANCO, February 2008.

It will come as no surprise, then, that the 'Europe against Cancer' programme became a template for all future EU health programmes.

The first public health programme (2003–08)<sup>13</sup> addressed three general objectives: improving health information and knowledge; responding rapidly to health threats; and addressing health determinants. These objectives are pursued by specific 'actions'. The programme is managed by the Executive Agency for the Public Health Programme,<sup>14</sup> which launches calls for proposals, negotiates grant agreements, manages projects and organizes conferences and meetings. Details of the more than 300 projects funded are available on the web site of DG SANCO.<sup>15</sup> The detail reflects a reasonably wide range of topical public health concerns of the EU Member States. Note that the Commission's proposals 'to stimulate EU-level action on comparing and assessing health care systems' through the programme were removed during the first reading in the co-decision procedure in 2001, highlighting great reluctance by the Member States to accept interference in this domain, even if it 'merely' implied comparisons of performance.<sup>16</sup>

The second public health programme, which for the first time explicitly deals with health care, will run from 2008–13,<sup>17</sup> with a budget of a similar size. Its objectives are to improve citizens' health security; to promote health; and to generate and disseminate health information and knowledge. Promoting health includes a reduction in health inequalities, which was added by the European Parliament at the second reading of the proposal.<sup>18</sup>

<sup>13</sup> European Parliament and Council Decision 1786/2002/EC adopting a programme of Community action in the field of public health (2003–2008) – Commission Statements, OJ 2002 No. L271/1.

<sup>14</sup> Commission Decision 2004/858/EC setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health – pursuant to Council Regulation 58/2003/EC, OJ 2004 No. L369/73.

<sup>15</sup> [http://ec.europa.eu/health/ph\\_projects/project\\_En.htm](http://ec.europa.eu/health/ph_projects/project_En.htm).

<sup>16</sup> R. Baeten, 'Health care on the European political agenda', in C. Degryse and P. Pochet (eds.), *Social developments in the European Union 2002* (Brussels: ETUI, 2003).

<sup>17</sup> European Parliament and Council Decision 1350/2007/EC establishing a second programme of Community action in the field of health (2008–13), OJ 2007 No. L301/3.

<sup>18</sup> European Commission, European Parliament Legislative Resolution of 10 July 2007, OJ 2005 No. C172.

Although the budget for the EU's public health programmes is modest (as is the EU's budget as a whole), the significance of the programmes lies in the extent to which the EU institutions have used financial incentives to promote particular behaviour. This is governance through 'carrots' rather than 'sticks', and the mechanisms by which EU governance interacts with national health care policy in this domain are quite different from the areas discussed below, where 'direct effect' and 'supremacy' of EU law (at least potentially, where litigation is successful) have immediate implications for national health care systems. It is virtually impossible to determine a clear 'cause and effect' relationship between the EU's public health policies and national health care policies. However, it must be at least conceivable that the availability of funding from the EU for certain activities may encourage certain behaviour. It is also conceivable that the sharing of information and best practices across European networks (which is one of the main types of project funded under the public health programmes) will, over time, feed into national policy-making processes. Cancer screening seems to be a case in point. Furthermore, EU-level financial support may lead to the adoption of principles or values that eventually feed through to EU-level legislation.

If this is the case for EU funding available through the public health programmes, it may also be the case where other EU budget lines are used in areas that could affect national health care policy or practice. For instance, the EU general funding programmes for research and development (the latest of which is known as the 7th Framework Programme or 'FP7')<sup>19</sup> include strands on health. Indeed, under FP7, the first of the ten themes for international research collaboration is 'health'. This includes research on how to optimize the delivery of health care to citizens of the EU and how to promote high quality and efficient health care systems.<sup>20</sup> These could potentially have implications for health care professional practice and for national regulatory structures for health care.

<sup>19</sup> European Parliament and Council Decision 1982/2006/EC concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013), OJ 2006 No. L412/1.

<sup>20</sup> *Ibid.*, p. 12.

Likewise, the EU's Structural Funds,<sup>21</sup> such as the European Social Fund (ESF)<sup>22</sup> and the European Regional Development Fund (ERDF),<sup>23</sup> which aim to reduce disparities in economic development across the EU, are already being used in health care settings. For example, Greece and Portugal have operational programmes exclusively dedicated to health,<sup>24</sup> in spite of the fact that 'health' was not at all central in the 2000–6 programming period (and was mainly linked to health and safety at work and the training of health personnel). Following a consultation,<sup>25</sup> in the new programming period (2007–13), actions such as 'preventing health risks' and 'filling the gaps in health infrastructure and promoting efficient provision of services' can be funded, either through the ERDF or the ESF.<sup>26</sup> The funds can support cross-border cooperation in the field of health care<sup>27</sup> and 'developing collaboration, capacity and joint use of infrastructures, in particular in sectors such as health'.<sup>28</sup> Thus, 'future cohesion policy will provide a broader scope for support in the area of health', even if the Commission finds that 'it must be stressed that the running of the healthcare system is not eligible under the Structural Funds'.<sup>29</sup> Again, the availability of financial support from the EU for such activities may prompt developments in national policy or practice – for example, by supporting '[d]esign, monitoring and evaluation

<sup>21</sup> Council Regulation 1083/2006/EC laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation 1260/1999/EC, OJ 2006 No. L210/25.

<sup>22</sup> European Parliament and Council Regulation 1081/2006/EC on the European Social Fund and repealing Regulation 1784/1999/EC, OJ 2006 No. L210/12.

<sup>23</sup> *Ibid.*

<sup>24</sup> European Commission, *European social fund and health in the 2007–2013 programming period* (Brussels: EMPL A1, 2006), p. 3.

<sup>25</sup> European Commission, 'Working document of Directorate-General Regional Policy summarising the results of the public consultation on the Community Strategic Guidelines for Cohesion 2007–2013', 7 October 2005, pp. 2, 7, [http://ec.europa.eu/regional\\_policy/sources/docoffic/2007/osc/report.pdf](http://ec.europa.eu/regional_policy/sources/docoffic/2007/osc/report.pdf).

<sup>26</sup> Council Decision 2006/702/EC on Community strategic guidelines on cohesion, OJ 2006 No. L291/11.

<sup>27</sup> *Ibid.*, p. 32, para. 2.4.

<sup>28</sup> Article 6(1)(e), European Parliament and Council Regulation 1080/2006 on the European Regional Development Fund and repealing Regulation 1783/1999/EC, OJ 2006 No. L210/1, p. 5.

<sup>29</sup> European Commission, *European social fund*, above n.24, p. 4.



of health policies ... as part of comprehensive reforms in the health system' or '[p]romoting partnership between private bodies and the social sector'. Other examples include 'investment in health information tools' and '[c]ontinuous updating of the skills of training personnel and workers in the health sector'.<sup>30</sup> The operational programmes of some of the central and eastern European Member States (e.g., Poland and Hungary) indicate that health care is indeed a priority for the new programming period. Even though a causal relationship between these funding mechanisms and the outcomes can at most be made 'plausible' (and is virtually impossible to prove), the European Commission will publish, by the end of 2008, an assessment of the impact of the 2000–6 ESF planning period in the area of health.

In sum, through these financial mechanisms, the public health programmes give the EU Commission, especially DG SANCO, a platform from which to engage in the governance of health care, given the connections between public health governance and health care governance. In addition, the unintended effects of other areas of EU law give further platforms or opportunities to develop policy discourse and even legal instruments that have effects on national health care systems. We now turn to the principal examples of these.

### 3. Effects of EU law on national health care systems

What are the main ways in which disparate areas of EU law have had effects on national health care systems? The EU's budget is small and the EU's budgetary powers are distinctly weak.<sup>31</sup> Nevertheless, the EU has used its meagre resources to influence policy discourses and policy learning – for instance, through the public health programmes and their precursors (see section two above). That said, the EU's main influence, in the field of health care, among others, is said to be through regulation, rather than redistribution.<sup>32</sup> One important (although not the only) mechanism by which the EU achieves its goals of (economic) integration is through regulatory activities, in the adoption and implementation of EU law.

<sup>30</sup> *Ibid.*, pp. 6–9.

<sup>31</sup> See B. Laffan and J. Lindner, 'The budget', in Wallace, Wallace and Pollack (eds.), *Policy-making*, above n.2.

<sup>32</sup> See G. Majone, *Regulating Europe* (London: Routledge, 1996).

The regulatory powers of the EU are governed by the Treaties. The legislative and executive institutions of the EU have limited competence and in legal terms may act only where the Treaties give them power to act, according to the principle of ‘conferred powers’.<sup>33</sup> Actions taken outside those powers are unlawful and may be annulled by the European Court of Justice (‘the Court’).<sup>34</sup> In most contexts, including health, competence is shared between the institutions of the EU and those of the Member States.<sup>35</sup>

EU law enjoys unique qualities compared to those of either the national legal systems of its Member States or of traditional international law. EU law enjoys ‘supremacy’ or ‘primacy’ over contradictory national law, requiring national courts to ‘set aside’ any such contradictory national law and apply EU law in its place.<sup>36</sup> Some measures of EU law (regulations and decisions) take effect in the legal systems of Member States without the need for intervening action on the part of national legislatures or executives.<sup>37</sup> Further, the Court has found that certain provisions of EU law, including many key Treaty provisions, such as those establishing the internal market and the rules of competition law, have ‘direct effect’ – that is, they are enforceable at the suit of individuals, before national courts of the Member States.<sup>38</sup>

<sup>33</sup> Article 5(1) EC: ‘the Community shall act within the limits of the powers conferred upon it by this Treaty and the objectives assigned to it therein’. If the Lisbon Treaty is ratified by all the Member States, Article 2 thereof will incorporate a new Title I into what is now the EC Treaty, which elaborates on the EU’s competences.

<sup>34</sup> Under the procedures set out in Article 230 EC or Article 234 EC.

<sup>35</sup> See, for example, P. Craig and G. de Búrca, *EU law* (Oxford: Oxford University Press, 2007), pp. 88–107; S. Weatherill, ‘Competence creep and competence control’, *Yearbook of European Law* 23 (2004), 1–55. See also the Lisbon Treaty, Article 2, which, if ratified, will incorporate a new Title I, Article 2C into what is now the EC Treaty, which enumerates areas of shared competence.

<sup>36</sup> Case 6/64, *Costa v. ENEL* [1964] ECR 585; Case C-213/89, *Factortame* [1990] ECR I-2433.

<sup>37</sup> Article 249 EC.

<sup>38</sup> Case 26/62, *Van Gend en Loos* [1963] ECR 1; Case 43/75, *Defrenne v. SABENA* (No. 2) [1976] ECR 455; Case 39/72, *Commission v. Italy* [1973] ECR 101; Case 9/70, *Grad v. Finanzamt Traunstein* [1970] ECR 825; Case 104/81, *Kupferberg* [1982] ECR 3641; Case 41/74, *Van Duyn v. Home Office* [1974] ECR 1337; Case 148/78, *Ratti* [1979] ECR 1629; Case 152/84, *Marshall* [1986] ECR 723.

It is these two qualities of EU law – its supremacy and direct effect – that have the most wide-ranging implications for national health care systems. Unless a specific exemption is available, where elements of national health care systems fall within the scope of EU law, that law applies in priority over national law and is enforceable by individuals before national courts. Provisions of EU law that may have been adopted without consideration of their application in health care contexts may subsequently turn out to have unforeseen – and perhaps undesirable – implications in those contexts. These implications come to light through the adversarial processes of litigation, where there is a high degree of unpredictability of outcomes. This unpredictability makes it difficult for national health care institutions to respond or plan accordingly, and raises concerns that interests and implications outside those that arise in the particular circumstances of the litigation will not be properly taken into account. Within national constitutional structures, such destabilizing activity by the courts can be smoothed by political processes. In the EU context, as we shall see, although this does take place, it may be more difficult, in part because of the position of health care within the EU's current constitutional settlement – the patchwork noted above. We now explore three areas of that patchwork, where EU law has affected national health care systems: internal market law, competition law and social law.

#### *A. Internal market law: free movement, but not total deregulation*

Already in the 1950s, the EEC Treaty (now the EC Treaty) envisaged the unfettered movement of factors of production within the territory of the EU (the 'internal market'), and put in place legal mechanisms to create that internal market. One such legal mechanism is deregulation. The EC Treaty prohibits all unjustified restrictions on the freedom to provide services,<sup>39</sup> freedom of establishment<sup>40</sup> and free movement of persons,<sup>41</sup> as well as prohibiting measures that have equivalent effect to quantitative restrictions on free movement of goods.<sup>42</sup> The relevant Treaty provisions are directly effective and thus bestow enforceable

<sup>39</sup> Article 49 EC.    <sup>40</sup> Article 43 EC.    <sup>41</sup> Article 39 EC; Article 18 EC.

<sup>42</sup> Article 28 EC.

rights upon individuals.<sup>43</sup> Individuals may therefore bring proceedings before their national courts, to challenge any unjustified restrictions in national laws on freedom of movement. Following the supremacy principle, national courts must apply the Treaty provisions in priority over national law.

In principle, the Treaty provisions on free movement apply to all goods and services that form part of the national economies of the Member States. The fact that provision of a good or service forms part of a national health care system is not sufficient in itself to remove it from the application of EU law.<sup>44</sup> Thus, the Court has applied the Treaty rules on free movement of services to the service of health care given in non-hospital<sup>45</sup> and hospital settings;<sup>46</sup> those on freedom of establishment to third sector providers of health and social care;<sup>47</sup> those on free movement of goods to pharmaceuticals and medical devices;<sup>48</sup> and those on free movement of persons to health care professionals.<sup>49</sup>

The principle that EU internal market law applies to all goods and services is reflected in the significant body of legislation concerning public procurement – the purchase of goods and services by governments and public utilities.<sup>50</sup> The legislation<sup>51</sup> imposes obligations of non-discrimination and transparency upon authorities

<sup>43</sup> Case 74/76, *Iannelli and Volpi* [1977] ECR 557; Case 83/78, *Pigs Marketing Board v. Redmond* [1978] ECR 2347; Case 33/74, *Van Binsbergen* [1974] ECR 1299; Case 41/74, *Van Duyn* [1974] ECR 1337; Case C-413/99, *Baumbast* [2002] ECR I-7091; Case C-200/02, *Zhu and Chen* [2004] ECR I-9925.

<sup>44</sup> See Case C-120/95, *Decker*, above n.3; Case C-158/96, *Kohll*, above n.3; Case C-368/98, *Vanbraekel* [2001] ECR I-5363; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.3.

<sup>45</sup> Case C-158/96, *Kohll*, above n.3.

<sup>46</sup> Case C-368/98, *Vanbraekel*, above n.44.

<sup>47</sup> Case C-70/95, *Sodemare*, above n.3.

<sup>48</sup> For example, Case 15/74, *Centrafarm v. Sterling Drug* [1974] ECR 1147; Case C-322/01, *DocMorris* [2003] ECR I-14887.

<sup>49</sup> Case 96/85, *Commission v. France* [1986] ECR 1475.

<sup>50</sup> See also Chapter 4 in this volume.

<sup>51</sup> European Parliament and Council Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ 2004 No. L134/114, as amended, most recently by European Parliament and Council Directive 2009/81/EC on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts OJ 2009 L216/76.

that enter into public supply or services contracts, where the public contracts meet certain thresholds.<sup>52</sup> Thus, purchasers cannot insulate their national suppliers within national markets, but are obliged to open their contracts to suppliers from anywhere within the internal market.

Given the internal market's underpinning ethos of openness of markets across the EU and efficiency resulting from unfettered competition between suppliers of goods and services within that single market, the application of internal market law to health care settings might be seen as setting in train processes of deregulation and liberalization that are in contradiction to European understandings of health care provision. In European settings, health care is based on principles of equality of access and solidarity in funding arrangements, whether that is primarily through taxation or through regulated social insurance. Generally speaking, European health care is not based on market deregulation or liberalization. However, such a hasty conclusion about the effects of EU law should be tempered by a more considered approach to the operation of internal market law and its detailed provisions. The free movement provisions in the EC Treaty do not operate purely as deregulatory mechanisms, and do not give rights without exceptions. The Court and the Commission have developed this understanding of the internal market since at least the 1970s.<sup>53</sup> It dovetails with the Commission's 'social Europe' discourse, which emerged from the mid-1980s onwards.<sup>54</sup> Unfettered application of deregulatory internal market law might pose significant threats to health (and health care) within the EU, as well as other public interest objectives that are served by national regulatory structures that keep the internal market divided in practice. The structures and details of internal market law, as understood by the Court and Commission, recognize this fact. Broadly speaking, three

<sup>52</sup> The Treaty rules apply to public contracts falling below those thresholds.

<sup>53</sup> Case 120/78, *Cassis de Dijon* [1979] ECR 649; Communication from the Commission concerning the consequences of the judgement given by the Court of Justice on 20 February 1979 in Case 120/78, *Cassis de Dijon*, OJ 1980 No. C256/2.

<sup>54</sup> See T. Hervey, *European social law and policy* (London: Longman, 1998), pp. 20–4; R. Geyer, *Exploring european social policy* (Cambridge: Polity Press, 2000), pp. 40–8; J. Kenner, *EU employment law: from Rome to Amsterdam and beyond* (Oxford: Hart, 2003), pp. 73–8.

types of responses to such potential threats are found within internal market law.<sup>55</sup>

First, the Treaty itself contains some specific exceptions to the general free movement rules. Article 30 EC provides that the Treaty does not preclude restrictions on imports of goods justified on the grounds of the ‘protection of the health and life of humans’. A similar Treaty exemption is available for restrictions on freedom to provide services, freedom of establishment and free movement of persons, on the basis of ‘protection of public health’,<sup>56</sup> although the scope of application of this provision has been interpreted restrictively by the Court.<sup>57</sup>

The second response is a Court-developed exception to the free movement rules. The Court has recognized that non-discriminatory restrictions on freedom to provide services, freedom of establishment and free movement of persons are justified in pursuance of an ‘objective public interest’.<sup>58</sup> The Court has recognized various interests that are directly relevant in health care contexts – for instance, the application of professional rules, including those relating to the organization of professions, qualifications or professional ethics, for the public good,<sup>59</sup> the social protection provided by national social security systems,<sup>60</sup> the financial viability of such social security systems,<sup>61</sup> and consumer protection.<sup>62</sup>

<sup>55</sup> See, further, T. Hervey and J. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004), pp. 46–7.

<sup>56</sup> Article 46(1) EC.

<sup>57</sup> See, for example, Case 36/75, *Rutili* [1975] ECR 1219.

<sup>58</sup> The origins of this approach in the area of services lie in Case 33/74, *Van Binsbergen* [1974] ECR 1299, in which the Court held: ‘taking into account the particular nature of the services to be provided, specific requirements imposed on the person providing the service cannot be considered incompatible with the Treaty where they have as their purpose the application of ... rules justified by the general good ... which are binding upon any person established in the State in which the service is provided’. See also Case 71/76, *Thieffry* [1977] ECR 765, para. 15; Case C-384/93, *Alpine Investments* [1995] ECR I-1141.

<sup>59</sup> Case 33/74, *Van Binsbergen*, above n.58, para. 14; Case 292/86, *Gulling* [1988] ECR 11, para. 29; Case C-106/91, *Ramrath* [1992] ECR I-3351.

<sup>60</sup> Case C-272/94, *Guiot and Climatec* [1996] ECR I-1905.

<sup>61</sup> Case C-120/95, *Decker*, above n.3; Case C-158/96, *Kohll*, above n.3; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.3; Case C-368/86, *Vanbraekel*, above n.44; Case C-8/02, *Leichtle* [2004] ECR I-2641; Case C-372/04, *Watts* [2006] ECR I-4325.

<sup>62</sup> Case 205/84, *Commission v. Germany* [1986] ECR 3755, para. 30; Case C-288/89, *Gouda* [1991] ECR I-4007, para. 27; Case C-76/90, *Säger*

The willingness of the Court to take into account objective public interests and to apply these effectively in order to exempt national laws, policies, practices and structures needs to be taken into account in an assessment of the destabilizing impact of internal market law on national health care systems. It is not the case that the Court simply pursues a deregulatory agenda, to the detriment of national structures designed to protect legitimate objective public interests, such as those of solidarity, equality of access and financial sustainability, which underpin the national health care systems of the Member States. A more nuanced critique takes account of the Court's development and application of objective public interest justifications. The Court is sensitive to the potentially devastating application of internal market law in social contexts, including health care. The 'objective public interest' justification in the Court's jurisprudence allows a balance between the deregulatory impetus of internal market law, and the need to protect public interests that are not well served by EU-level deregulation. Of course, there must *be* a legitimate public interest that can be objectively articulated by the relevant Member State. It must not be disproportionate to the distortion to the internal market involved. It may not be a 'purely economic' aim.<sup>63</sup> If these criteria cannot be met, then without the intervention of the legislature, the consequences of internal market law for national health care systems may be more significant than the handful of cases decided so far suggests. But the structure of the Court's jurisprudence leaves the door open to the justification of national policies and practices.

The third response of EU law to threats to public interests, such as maintaining health protection and national health care systems in the face of the deregulatory impact of internal market law, is to regulate at EU level, in EU legislation such as regulations or directives. Different standards imposed at the national level create barriers to the establishment of the internal market, because goods and services moving across borders have to meet a dual standard, both

[1991] ECR I-4221, para. 15; Case C-275/92, *Schindler* [1994] ECR I-1039, para. 58.

<sup>63</sup> For a less optimistic assessment of the objective public interest justification in this context, see G. Davies, 'The process and side-effects of the harmonisation of European welfare states', Jean Monnet Working Paper No. 02/06 (2006), pp. 27–36.

that of the 'home' and the 'host' state. Harmonized regulatory standards, promulgated at EU level and applicable in all Member States, may achieve the dual objective of protecting public interests – in particular, those of consumers of goods and services – and creating the internal market.<sup>64</sup>

The EC Treaty gives legal power to adopt such measures in Articles 94, 95 and 308 EC. So, for instance, these provisions form the basis of the EU's long-standing and now extensive regulatory measures applicable to the manufacture, marketing and sale of pharmaceuticals and medical devices, designed to protect consumers.<sup>65</sup> The technical requirements for testing new medicinal products are regularly updated, in the light of scientific developments, using powers of delegated legislation, through EU agencies and regulatory or technical committees.<sup>66</sup>

Another example of internal market law with effects on health care is the regulation of tobacco manufacturing, presentation and sale,<sup>67</sup> and the advertising of tobacco in the internal market. Here, the precise scope of the competence provided by Article 95 EC has been the subject of significant litigation. The EU legislative institutions were forced to revise the original Tobacco Advertising Directive,<sup>68</sup> in response to

<sup>64</sup> However, there is a fundamental asymmetry in EU law between deregulation (or 'negative integration') supported by enforceable EU Treaty law, and re-regulation (or 'positive integration'), which is reliant upon the legal competence of the EU institutions to act, and the political will to reach agreement among the governments of the Member States meeting in Council. See J. H. H. Weiler, 'The Community system: the dual character of supranationalism', *Yearbook of European Law* 1 (1982), 267–306; F. Scharpf, *Governing in Europe: effective and democratic?* (Oxford: Oxford University Press, 1999), pp. 51–83; S. Weatherill, *Law and integration in the European Union* (Oxford: Clarendon, 1995); F. Scharpf, 'A new social contract?', above n.1; R. Dehousse, 'Integration v regulation? On the dynamics of regulation in the European Community', *Journal of Common Market Studies* 30 (1992), 383–402.

<sup>65</sup> These have been adopted since the 1960s and are now found in the Commission's (multi-volume) publication, 'The Rules Governing Medicinal Products within the European Union', the 'Eudrallex Collection', <http://ec.europa.eu/enterprise/pharmaceuticals/eudrallex/index.htm>.

<sup>66</sup> For details, see also Chapter 3 in this volume.

<sup>67</sup> European Parliament and Council Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, OJ 2001 No. L194/26.

<sup>68</sup> European Parliament and Council Directive 98/43/EC on the approximation of the laws, regulations and administrative provisions of the Member States



litigation brought by various tobacco companies and by Germany.<sup>69</sup> However, the Court has found the revised version, Directive 2003/33/EC, which prohibits press and radio advertising of tobacco products within the EU, to be valid.<sup>70</sup> More recently, the Commission launched a consultation on freeing Europe from exposure to environmental tobacco smoke (or ‘passive smoking’), which may well lead to binding legislation aimed at banning smoking in work-places, or even in all enclosed public places.<sup>71</sup> Note that European legislation on tobacco has been inspired by – and based on – evidence that was collected through non-binding EU instruments, such as ‘Europe against Cancer’ and the Public Health Programme discussed above. We will return to this kind of cross-fertilization between formal law and governance in section four below.

Specific Treaty provisions, such as Articles 47 and 55 EC on free movement of persons, freedom of establishment and free movement of services, also give the EU power to adopt internal market laws that can have implications for national health care systems. Although the finally adopted version of the Directive on Services in the Internal Market does not apply to health care services,<sup>72</sup> earlier versions of the text did so,<sup>73</sup> and, in principle, such a directive could apply to health care services, so long as health care services meet the definition of ‘services’ for the purposes of EU law.<sup>74</sup> Article 57(2) EC on the free movement of capital is the basis for the Non-life Insurance

relating to the advertising and sponsorship of tobacco products, OJ 1998 No. L213/9.

<sup>69</sup> Case C-376/98, *Germany v. European Parliament and Council (Tobacco Advertising)* [2000] ECR I-8419; Case C-491/01, *R v. Secretary of State for Health, ex parte British American Tobacco and Imperial Tobacco* [2002] ECR I-11453.

<sup>70</sup> Case C-380/03, *Germany v. European Parliament and Council (Tobacco Advertising No. 2)* [2006] ECR I-11573.

<sup>71</sup> European Commission, ‘Towards a Europe free from tobacco smoke: policy options at EU level’, Green Paper, COM (2007) 27 final, 30 January 2007, p. 19.

<sup>72</sup> Article 2(2)(f), European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2006 No. L376/36.

<sup>73</sup> Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on services in the internal market, OJ 2005 No. C221/113.

<sup>74</sup> A ‘service’ in the sense of Article 49 EC must be provided for ‘remuneration’ – that is, consideration for the service in question. See Case 263/86, *Humbel* [1988] ECR 5365. The Commission has now proposed a

Directives, which have had significant implications for health insurance structures in Member States such as Ireland.<sup>75</sup>

The approach of adopting EU level regulatory measures is successful where there is both formal legal power to adopt such EU level standards, through measures of EU law, and the political will to do so. However, where one or both of these factors is missing, EU-level harmonization through law is not feasible. The EU institutions have experimented with different governance approaches in such contexts (see section four).<sup>76</sup>

### B. EU competition law and services of general interest

Alongside the provisions on free movement, the EC Treaty seeks to create a system ensuring that competition within the internal market is not distorted.<sup>77</sup> The legal foundations of EU competition law and policy are found in Articles 81–9 EC, and a significant body of EU legislation, administrative decisions of the Commission, and jurisprudence of the Court. EU law prohibits anti-competitive agreements between firms (Article 81 EC), abuse of a dominant position by monopolies or groups of firms (Article 82 EC), and state aids to industry that distort competition.<sup>78</sup> As with the free movement provisions, in principle, the mere fact that an agreement, or abuse of a dominant position, or provision of a state aid, involves part of a national health care system is not *in itself* sufficient to remove it from the application of EU competition law.<sup>79</sup>

Directive on the application of patients' rights in cross-border health care (not on 'healthcare services in the internal market'). European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare', COM (2008) 414 final, 2 July 2008. See also Chapter 11 in this volume.

<sup>75</sup> See Chapter 10 in this volume. See S. Thomson and E. Mossialos, 'Editorial: EU law and regulation of private health insurance', *Health Economics Policy and Law* 2 (2007), 117–24.

<sup>76</sup> See, further, T. Hervey, 'The European Union and the governance of healthcare', in de Búrca and Scott (eds.), *New governance and constitutionalism*, above n.6, pp. 179–210; T. Hervey, 'New governance responses to healthcare migration in the EU: the EU guidelines on block purchasing', *Maastricht Journal of European and Comparative Law* 14 (2007), 303–33.

<sup>77</sup> Article 3(g) EC. <sup>78</sup> Article 87 EC.

<sup>79</sup> See, for example, Case C-475/99, *Ambulanz Glockner* [2001] ECR I-8089; the UK Competition Appeal Tribunal decision in *Bettercare* [2002] Comp

Both Articles 81 and 82 EC apply only to ‘undertakings’.<sup>80</sup> Where a government department itself provides a service, such as defence or judicial services, it acts purely in the public domain and cannot be said to be an ‘undertaking’. However, since the 1980s, the Member States of the EU have shown an increasing interest in involvement of private actors in the provision of services that were previously provided directly by the state, including in the health care domain. Where public health care provision is provided in this way, EU competition law may apply.

Even if the Treaty rules do apply – again, as is the case with internal market law – the Treaty does not envisage that its competition law rules will apply without exceptions. Values embedded in the constitutional and legal structures of Member States, such as that of solidarity, imply that free competition within markets is not always the optimal mode of delivery of certain types of goods or services, including those provided within public health care settings. These values are reflected in the EU’s constituent Treaties. From the 1950s, the EC Treaty provided a specific legal exemption from competition law for ‘undertakings entrusted with the operation of services of general economic interest’ (such as telecommunications or postal services), to the extent that the application of EU competition law would prevent such firms from carrying out the particular tasks with which they are entrusted (Article 86(2) EC). The concept of ‘services of general economic interest’ has, over time, been developed alongside a related concept, not currently mentioned in the EU’s constituent Treaties,<sup>81</sup> that of ‘services of general interest’.<sup>82</sup> National health care systems within the EU provide services of general interest. It follows that the exception to EU competition law in Article 86(2) EC may apply to national health care systems.

### C. *EU social and employment law*

Another policy domain of EU law that has had unexpected effects when applied within health care settings is that of the EU’s social

AR 226; but contrast Case T-319/99, *FENIN* [2003] ECR II-357; which was upheld in Case C-205/03 P, *FENIN* [2006] ECR I-6295.

<sup>80</sup> For discussion of the definition of ‘undertaking’, see Chapter 8 in this volume.

<sup>81</sup> The Treaty of Lisbon, if ratified, will attach a Protocol on ‘Services of General Interest’ to the Treaties.

<sup>82</sup> ‘Services of general interest’ was used for the first time by the Commission in European Commission, ‘Communication on services of general interest in Europe’, OJ 1996 No. C281/3. Davies suggests that ‘the Commission, and

and employment law. Article 137 EC gives the EU power to adopt directives in various employment-related fields – in particular, health and safety at work and working conditions. These directives only occasionally make special provision for health care professionals, but, provided that health care professionals satisfy the status of ‘employee’ or ‘worker’, simply treat them as all other workers are treated.<sup>83</sup> So, for instance, EU secondary legislation on health and safety at work,<sup>84</sup> employment rights in the event of restructuring of employers’ enterprises,<sup>85</sup> and non-discrimination on grounds of

lawyers, now act as if the phrase “services of general economic interest” meant the same as “economic services of general interest”, which he sees as ‘an act of deliberate misinterpretation as linguistically grotesque as it may be justifiable in terms of policy’. See Davies, ‘Process and side-effects’, above n.63.

<sup>83</sup> Other sectors, such as transport, regularly enjoy special exemptions from measures of EU employment law. For instance, European Parliament and Council Directive 2003/88/EC concerning certain aspects of the organisation of working time, OJ 2003 No. L299/9 (the ‘Working Time Directive’), does not apply to mobile workers engaging in offshore work (Article 20), or to workers on seagoing fishing vessels (Article 21).

<sup>84</sup> See the Council Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ 1989 No. L183/1; as amended by Regulation 1882/2003/EC of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC (Celex No. 31999D0468) the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty, OJ 2003 No. L284/1; Directive 2007/30/EC of 20 June 2007 amending Council Directive 89/391/EEC, its individual Directives and Council Directives 83/477/EEC, 91/383/EEC, 92/29/EEC and 94/33/EC with a view to simplifying and rationalising the reports on practical implementation, OJ 2007 No. L165/21; and Regulation 1137/2008/EC of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny – adaptation to the regulatory procedure with scrutiny, OJ 2008 No. L311/1; and the discussion of the EU’s legal framework on health and safety at work in C. Barnard, *EC employment law* (Oxford: Oxford University Press, 2006), Chapters 11 and 12.

<sup>85</sup> See, for example, Council Directive 77/187/EEC on the approximation of the laws of the Member States relating to the safeguarding of employees’ rights in the event of transfers of undertakings, businesses or parts of businesses, OJ 1977 No. L61/26 (now repealed and replaced by Directive 2001/23/EC of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of employees’ rights in the event of transfers of

sex,<sup>86</sup> racial or ethnic origin, religion or belief, age, disability or sexual orientation<sup>87</sup> applies to employment in the health care field, just as in other fields.

In some circumstances, the fact that the general EU employment law provisions have not been tailored to the health care profession may cause difficulties in a Member State. This is the case with the EU law on working time provisions. The original Working Time Directive was heavily criticized by health care professionals and providers of health care in Member States such as the United Kingdom, Ireland and the Netherlands as being insufficiently sensitive to the traditional practices of their national health systems, and in particular for causing capacity problems, as junior doctors may no longer work the long hours that have historically formed part of their training.<sup>88</sup> Such criticisms led to an ongoing legislative process of amendment of EU working time law.<sup>89</sup>

Working time is an example where activity by the courts – especially the European Court of Justice – that jeopardized elements of national health care systems could be resolved, or at least alleviated, by EU-level political processes. However, in practice, proposals to amend the Working Time Directive are often stalled in the Council.

The elements of EU internal market law, competition law and employment law discussed above all have implications for national health care systems. They also illustrate the multiplicity of institutional and legal settings in which EU law may be important for national health

undertakings, businesses or parts of undertakings or businesses, OJ 2001 No. L82/16); Barnard, *EC employment law*, above n.84, Chapters 13 and 14.

<sup>86</sup> See, for example, Council Directive 76/207/EEC on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions, OJ 1976 No. L39/40 (now repealed and replaced by Directive 2006/54/EC of 5 July 2006 on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation (recast), OJ 2006 No. L204/23); and the discussion of the EU's legal framework on sex equality in employment in Barnard, *EC employment law*, above n.84, Chapters 6–10.

<sup>87</sup> See Council Directive 2000/43/EC implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, OJ 2000 No. L180/22; Council Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation, OJ 2000 No. L303/16, on forbidden grounds of discrimination in the labour market.

<sup>88</sup> See Hervey and McHale, *Health law*, above n.55, pp. 196–7.

<sup>89</sup> For further details, see Chapter 14 in this volume.

care policy, and also the fact that the relevant EU laws and policies are proposed by Directorates-General (DGs) of the Commission, and negotiated and adopted through European Parliamentary committees and meetings of the Council of Ministers, whose members have no specific expertise in health care. Coupled with the EU's public health competence, the EU health care law and policy domain emerges as a patchwork of different measures.

#### 4. The 'governance' of health care in the EU

Section three illustrated that those who are (politically) responsible for health care at the domestic level are faced with a 'double bind'<sup>90</sup> from the EU level. Their freedom to organize their national health care systems is restrained by the important and growing influence of EU law, but the EU has limited specific legal competences, with even less political will to use them in health care fields. Moreover, a patchwork of actors and institutions decides and implements relevant EU legislation. While, in those circumstances, it is difficult to prepare an orchestrated response at the EU level, at the same time 'doing nothing' is not an option, precisely because of the unexpected influences of EU law, especially internal market and competition law, in health care areas, in the context of European solidarity-based models of health care. In this section, we will describe how EU policy-makers have responded to this 'double bind' by establishing various types of EU-level health care governance. These include the (mere) promotion of exchange of information and debate, perhaps feeding into proposals for legislation adopted through traditional hierarchical models ('pre-law'), but also processes of non-hierarchical policy coordination and opportunities for mutual learning within networks, through the use of information gathering, knowledge dissemination, standard setting, benchmarking and monitoring, each of which involves a normative dimension. Governance equally involves the introduction of governance mechanisms within legislative instruments. For example, new governance practices in the field of health care in the United States could lead to the rethinking of three specific legal concepts: that of participation (in relation to social inclusion);

<sup>90</sup> A. Hemerijck, *Revisiting productive welfare for continental Europe* (The Hague: Netherlands Scientific Council for Government Policy, 2007), p. 25.

recalibrated federalism; and the role of government.<sup>91</sup> Others have argued that the practice of new governance could reshape and give renewed meaning to the concept of solidarity, which is also central in the context of health care (litigation).<sup>92</sup> Taken together, this patchwork implies implementation of EU health care policy through a hybrid mechanism of law and governance that mutually influence one another.

### A. *The slow move of health care to the EU agenda*

‘Health care’ as a *sui generis* topic slowly found its way onto the EU agenda between the beginning of the 1990s and the turn of the century. Arguably, the Community Charter of Fundamental Social Rights of Workers constituted the first milestone in raising health care to the European agenda, almost two decades ago.<sup>93</sup> In 1992, within a wider social protection agenda, the Council of the European Union unanimously recommended that Member States should maintain and develop a high-quality health care system, geared to the evolving needs of the population, and ensure for all legal residents access to necessary health care and measures to prevent illness.<sup>94</sup> In order to implement this recommendation, the Council asked the Commission to ‘submit regular reports to the Council on progress achieved in relation to the objectives set out above and to determine and develop, in cooperation with the Member States, the use of appropriate criteria

<sup>91</sup> L. Trubek, ‘New governance practices in US healthcare’, in de Búrca and Scott (eds.), *New governance and constitutionalism*, above n.6. For examples of interactions between governance mechanisms and legislation in the domain of drug authorization and health and safety, see C. Sabel and J. Zeitlin, ‘Learning from difference: the new architecture of experimentalist governance in the European Union’, *European Law Journal* 14 (2008), 271–327.

<sup>92</sup> C. Barnard, ‘Solidarity and new governance in social policy’, in de Búrca and Scott (eds.), *New governance and constitutionalism*, above n.6.

<sup>93</sup> The Community Charter of the Fundamental Social Rights of Workers, Solemn Declaration of the Heads of State or Government of 11 Member States of the EU [the 12 Member States of the time, but not the UK], Strasbourg, 9 December 1989, includes the right of access to preventive healthcare and the right to benefit from medical treatment, to improvement of living and working conditions, health and safety at work, and rights for people with disabilities and elderly people.

<sup>94</sup> Council Recommendation 92/442/EEC on the convergence of social protection objectives and policies, OJ 1992 No. L245/49, p. 51.

for that purpose'.<sup>95</sup> If one replaces the word 'criteria' with 'indicators', the method proposed at the time 'resembles a premature version of the OMC'.<sup>96</sup>

This early Council recommendation was followed by two Commission papers<sup>97</sup> and the 1993 report on social protection in Europe,<sup>98</sup> which 'for the very first time gave a common image of what social protection was in Europe'.<sup>99</sup> In a 1995 Communication, the Commission proposed a wide range of social protection issues for discussion<sup>100</sup> and, more importantly, sent an early warning to the Member States, through the following assessment and (in retrospect, rhetorical) question:

There is a grey area as to the extent to which compulsory affiliation to schemes which are not statutory schemes is compatible with European law. Whilst the European Court of Justice will rule on such questions on a case by case or scheme by scheme basis, is there a need to explore what general principles should be applied with a view to achieving the Community objective of providing a high level of social protection and to avoid unbalancing schemes, and predetermining Member States' choices in this area?<sup>101</sup>

A second Communication, in 1997, on 'modernising and improving social protection' focuses, as regards health care, on reducing costs.<sup>102</sup>

<sup>95</sup> *Ibid.*, p. 52.

<sup>96</sup> C. de la Porte and P. Pochet, 'Supple co-ordination at EU level and key actor's involvement', in C. de la Porte and P. Pochet (eds.), *Building social Europe through the open method of co-ordination* (Brussels: PIE-Peter Lang, 2002), p. 41.

<sup>97</sup> European Commission, 'Options for the Union', Green Paper, European Social Policy, COM (93) 551 final, 17 November 1993; European Commission, 'European social policy. A way forward for the Union', White Paper, COM (94) 333 final, 27 July 1994.

<sup>98</sup> European Commission, 'Social protection in Europe', COM (93) 531 final, 26 April 1994.

<sup>99</sup> Interview with DG Social Affairs, October 2007.

<sup>100</sup> The 1995 Communication suggests, for example, that 'at European level, it would appear useful to analyse whether, as a first step, efficiency gains could be made by improving the complementarity in the supply of specialised health care across borders'. European Commission, 'The future of social protection, framework for a European debate', COM (95) 466 final, 31 October 1995, p. 8.

<sup>101</sup> *Ibid.*, p. 9.

<sup>102</sup> European Commission, 'Modernising and improving social protection in the European Union', COM (97) 102 final, 12 March 1997, pp. 13–4.



But other than keeping the political debate alive, it seems that while the two Council recommendations of the beginning of the 1990s prepared the ground for enhanced EU cooperation based on common objectives and multilateral surveillance, the European level returned, by the end of the decade, to a scenario in which the direct involvement of the EU with social protection was ‘limited to, first, the coordination of social security systems, with the aim of assuring free movement, and, second, to the nurturing of debates through communications (the European level as a platform for the exchange of experience)’.<sup>103</sup>

A number of landmark cases<sup>104</sup> in the Court ‘kick-started’ the political momentum that brought social protection (including health care) more firmly back to the European political agenda. This momentum was obviously strengthened by the entering into the Amsterdam Treaty on 1 May 1999, which confirmed that social policy falls under the joint responsibility of the EU and the Member States. The new Treaty granted the EU explicit competences with regard to combating social exclusion and social security and social protection of workers.<sup>105</sup> The Amsterdam Treaty also constitutionalized the European Employment Strategy,<sup>106</sup> which ‘all of a sudden gave the Directorate-General for Employment, Social Affairs and Equal Opportunities (DG Social Affairs) much more legitimacy towards other DGs, and we felt strong enough to try this for social protection as well’.<sup>107</sup> Importantly, ‘the Commission at that point was still in the post-Delors sort of expansion of competences

<sup>103</sup> B. Vanhercke, ‘The social stakes of economic and monetary union: an overview’, in P. Pochet and B. Vanhercke (eds.), *Social challenges of economic and monetary union*, Work and Society Series No. 18 (Brussels: European Interuniversity Press, 1998), pp. 19–20.

<sup>104</sup> These include Case C-70/95, *Sodemare*, above n.3; Case C-158/96, *Kohll*, above n.3; Case C-120/95, *Decker*, above n.3; and Case C-67/96, *Albany International v. Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751.

<sup>105</sup> The Treaty of Amsterdam incorporated into the EC Treaty the Maastricht ‘Agreement on Social Policy’ (see Chapter 1 of the new Title XI and new Articles 136–145). Under Article 137, the Council may adopt, by qualified majority in co-decision with the Parliament, measures designed to encourage the combating of social exclusion. Unanimity in the Council remains the norm with regard to social security and social protection of workers.

<sup>106</sup> The Treaty of Amsterdam included a new Title (VIII) on employment, thereby giving a specific legal base to the Employment Process.

<sup>107</sup> Interview with DG Social Affairs, October 2007.

perspective, and was still willing to try to push and drag the Member States'.<sup>108</sup>

The resigning Santer Commission, which was still in office until a new Commission was in place, seized the opportunity and published (in July 1999) a Communication in which it proposed a 'concerted strategy for modernising social protection'.<sup>109</sup> What the Commission proposed was to launch a European strategy for social protection systems, which aims at deepening the cooperation between the Member States and the EU, based on common objectives, mechanisms for exchanging experience and monitoring of ongoing political developments in order to identify best practices.<sup>110</sup> Work would be organized around four key objectives, which are key issues of concern to all Member States:

- to make work pay and to provide secure income;
- to make pensions safe and pension systems sustainable;
- to promote social inclusion; and
- to ensure high quality and sustainable health care.<sup>111</sup>

The European Commission proposed that Member States would designate high level senior officials to act as focal points in this process. The result of the work (starting from the four key objectives) would be published by the Commission every year in a 'report on social protection', which would be based on contributions by the Member States and would be submitted to the Council together with the joint employment report.<sup>112</sup> In sum, the European Commission did no less than what the European Parliament had called on the institution to do: 'to set in motion a process of voluntary alignment of objectives and policies in the area of social protection, modelled on the European employment strategy'.<sup>113</sup>

The reason that the Commission could follow this proactive course of action seems to be the fact that, by the time of the publication

<sup>108</sup> Interview with DG SANCO, October 2007.

<sup>109</sup> European Commission, 'A concerted strategy for modernising social protection', COM (99) 347 final, 14 July 1999.

<sup>110</sup> *Ibid.*, p. 12. <sup>111</sup> *Ibid.*, pp. 12–4. <sup>112</sup> *Ibid.*, p. 15.

<sup>113</sup> European Parliament Resolution on the Commission report to the European Parliament, the Economic and Social Committee and the Committee of the Regions on social protection in Europe 1997, A4–0099/99, 25 February 1999, OJ 1999 No. C175/435.

of this Communication in 1999, eleven out of fifteen Member State governments were headed by social democrats, who tend to be more supportive of European social policy initiatives.<sup>114</sup> Consider the contrast with the situation at the beginning of the 1990s (see above), when only two out of twelve Member States were governed by the left.<sup>115</sup> This large support explains: (a) why the resigning Commission (and notably DG Social Affairs) dared to seize the window of opportunity; and (b) why the ‘Social Affairs’ Council of the European Union, merely four months after the publication of the Commission Communication, decided to launch a ‘concerted strategy’ on social protection (to be called ‘OMC’ a few years later, see below). The ministers for social affairs identified ‘high quality and sustainable health care’ as the fourth key objective that should be pursued at the EU level.<sup>116</sup>

Soon after, a so-called ‘High Level Committee on Health’<sup>117</sup> received a strong (parallel) mandate from the Nice European Council to ‘[e]xamine, on the basis of studies undertaken by the Commission, the evolution of the situation with regard to cross-border access to quality health care and health products’.<sup>118</sup> Thus, a second set of players willing to make an issue of health care at the EU level entered the stage (i.e., those responsible for ‘health’).

In mid-March 2001, a third set of actors increased its efforts to influence the European health debate<sup>119</sup> – the ‘enterprise’ players. Our example below focuses upon the pharmaceutical industry: representatives of other industries, including medical devices, or insurance

<sup>114</sup> A. Schäfer, ‘Beyond the community method: why the open method of coordination was introduced to EU policy-making’, *European Integration Online Papers* 8 (2004), 10.

<sup>115</sup> *Ibid.*, 6.

<sup>116</sup> Council Conclusions on the strengthening of cooperation for modernising and improving social protection, OJ 2000 No. C8/7, p. 7.

<sup>117</sup> The High Level Committee on Health is composed of senior civil servants from the health ministries of the Member States. It meets two to three times a year and operates with a number of working groups. See [http://ec.europa.eu/health/ph\\_overview/co\\_operation/high\\_level/high\\_level\\_En.htm](http://ec.europa.eu/health/ph_overview/co_operation/high_level/high_level_En.htm).

<sup>118</sup> European Social Agenda, approved by the Nice European Council, ‘Presidency Conclusions’, Annex 1, OJ 2001 No. C157/4, para. 17.

<sup>119</sup> The G10 on medicines was in fact a follow-up to the ‘Bangemann Roundtables’ (named after Industry Commissioner Martin Bangemann) on the completion of the internal market for pharmaceuticals, held between 1996 and 1998.

might also have similar effects on the debate.<sup>120</sup> Although industry actors may not be interested in the EU health care debate per se, they are concerned where particular sectors are affected – here, the medicines sector – in matters such as industrial competitiveness, direct-to-consumer advertising, transparency of pricing and reimbursement, and the process of authorization for new medicinal products. The ‘High Level Group on Innovation and Provision of Medicines in the EU’ (‘G10’ Medicines Group), was set up by Enterprise Commissioner Erkki Liikanen and Health Commissioner David Byrne to explore ways of improving competitiveness in Europe while encouraging high levels of health protection. The Group consisted of health and industry ministers from five Member States, representation from different sectors of industry, mutual health funds and a specialist in patient issues,<sup>121</sup> and reported to Commission President Romano Prodi after one year.<sup>122</sup> It divided its work into three agenda areas: provision of medicines to patients; single market, competition and regulation; and innovation. The rationale and remit of the Group came in part from DG SANCO’s role as co-initiator.

All of these issues reflect longstanding priorities of the pharmaceutical industry, which were also at stake during the revision of the EU pharmaceutical legislation (the ‘Pharma Review’), launched in 2001,<sup>123</sup> running in parallel to the G10 activities. The Pharma Review, in fact, incorporated crucial G10 recommendations, for example, concerning data protection of innovative medicine.<sup>124</sup> Thus, the pharmaceutical industry (and the Directorate-General for Enterprise and Industry (DG Industry), which held the secretariat) successfully used the

<sup>120</sup> See Chapter 10 in this volume.

<sup>121</sup> The input into this ‘Group of 10’ (which actually consisted of thirteen members) from a wide variety of actors was obtained through a public consultation. The consultation document from DG Industry was issued on 27 September 2007; answers were due within two months.

<sup>122</sup> The G10 Medicines met for the first time on 26 March 2001, followed by meetings in September 2001 and February 2002. See <http://ec.europa.eu/enterprise/phabiocom/g10home.htm>.

<sup>123</sup> The three legislative proposals concerning the review of the Community Pharmaceutical Legislation can be found in European Commission, ‘Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products’, COM (2001) 404 final, 26 November 2001.

<sup>124</sup> European Parliament and Council Regulation 726/2004/EC laying down Community procedures for the authorisation and supervision of medicinal

informal G10 debates to bypass the traditional institutions involved in the Pharma Review, be they political (the Council, the European Parliament) or technical (the European Medicines Agency, whose members are not permitted to have any direct financial or other interests in the pharmaceutical industry). Without a doubt, part of this ‘success’ can be attributed to the fact that the G10, in contrast to its predecessors (such as the Bangemann Rounds), involved ‘stakeholders’, thereby drastically increasing its legitimacy, and thus its ability to exert pressure on decision-makers. The G10 reached agreement on fourteen recommendations,<sup>125</sup> and expressed a wish to continue its exercise. As we will see below, this continuation happened through a ‘Pharmaceutical Forum’.

At the same time, the health care debate, as part of the ‘concerted strategy on social protection’, moved forward, albeit prudently (still, no formal reference was made to an ‘open method of coordination’ (OMC)). The Gothenburg European Council in June 2001 stipulated that further reflections should deal with ‘healthcare and care for the elderly’, which is now considered, together with pensions, to be part of the ‘meeting the challenge of an ageing population’ agenda.<sup>126</sup> Furthermore, the Council mandate makes it clear that another set of players needs to be taken into account in the EU health debate, by stipulating that an initial study on this issue should be prepared by the Social Protection Committee (SPC), an advisory body to the Social Affairs Council, *and* the Economic Policy Committee (EPC), which is the main advisory body to the Economic and Financial Affairs Council (ECOFIN).

The ‘economic’ players thereby strengthened their say in the debate. In fact, in the context of the Broad Economic Policy Guidelines,<sup>127</sup> Member States had already been invited to ‘review pension and

products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 No. L136/1.

<sup>125</sup> High Level Group on Innovation and Provision of Medicines in the EU, ‘Recommendations for action’, Brussels, 7 May 2002, p. 8, <http://ec.europa.eu/enterprise/phabiocom/docs/g10-medicines.pdf>.

<sup>126</sup> Göteborg European Council, ‘Presidency Conclusions’, Doc. No. SN 2001/1/01 REV 1, 15–16 June 2001, para. 43.

<sup>127</sup> The ‘Broad Economic Policy Guidelines’ were introduced by the Treaty of Maastricht (1992) and involve non-binding recommendations from the Council to Member States to monitor the consistency of national economic policies with those of the European Monetary Union.

health care spending in order to be able to cope with the financial burden on welfare spending of the ageing population'.<sup>128</sup> However, until 2001, ministers for finance, who are obviously not in charge of health care policies at the national level, had little legitimacy to discuss these issues. The Gothenburg European Council increased this legitimacy considerably by giving them a place in the health care part of the concerted strategy. Later, in 2001 (November), the ECOFIN Council discussed a report prepared by the EPC on the 'budgetary challenges posed by ageing populations',<sup>129</sup> in which it addressed the expected increase in public spending regarding health care and long-term care up to the year 2050. The ECOFIN Council feared that, regarding health care and long-term care, Member States could face 'increases in expenditure levels over the fifty years to come of around 2 to 4 percentage points of GDP', and underlined in this context that ensuring sustainable public finances 'is a crucial challenge that Member States must address as soon as possible'.<sup>130</sup> ECOFIN also invited the EPC to repeat these projections every three to five years, thereby confirming itself as a regular player on the health care scene.

A few weeks after the EPC report, DG Social Affairs published a short Communication on 'the future of health care and care for the elderly', in which it concluded that health care systems in the EU all face the challenge of attaining simultaneously the threefold objective of access to health care for everyone, a high level of quality in health care and the financial viability of health care.<sup>131</sup> The 'concerted strategy' thus starts to take shape through provisional common objectives, progress towards which should be reported by the Member States in 'preliminary reports' (rather than forward-looking 'action

<sup>128</sup> Draft Report from the Council (ECOFIN) on the broad guidelines of the economic policies of the Member States and the Community, appended to the Presidency Conclusions of the Cologne European Council, Doc. No. 8586/99, 3–4 June 1999.

<sup>129</sup> Economic Policy Committee (EPC), 'Budgetary challenges posed by ageing populations: the impact on public spending on pensions, health and long-term care for the elderly and possible indicators of the long-term sustainability of public finances', Doc. No. EPC/ECFIN/630-EN (2001), p. 113.

<sup>130</sup> ECOFIN Council Conclusions, 'Report on budgetary challenges posed by ageing populations', Doc. No. SN 4406/1/01 REV 1 (2001), p. 2.

<sup>131</sup> European Commission, 'The future of health care and care for the elderly: guaranteeing accessibility, quality and financial viability', COM (2001) 723 final, 5 December 2001, p. 14.

plans’) and all this without a set of commonly agreed indicators. Note that the European Commission reveals itself as a master of timing: the Communication on health care and care for the elderly was published, by no means coincidentally, a week before the Laeken Summit (December 2001) and two days before an international conference organized by the Belgian Presidency in December 2001 on ‘European Integration and National Health Care Systems’.<sup>132</sup>

The Commission’s timing seems to have worked well: the Laeken European Council (December 2001) called on the Council to prepare an initial study on health care and care for the elderly (requested at Gothenburg, see above) ‘in the light of the Commission Communication’ and endorsed, at this early stage, the broadly-based approach taken by the Commission in its Communication on health care and care for the elderly (balancing access, quality and financial sustainability).<sup>133</sup> In other words, the Commission successfully set the terms of the emerging EU health care debate. So, in spite of the fact that there is no legislation involved, the Commission seems to be holding on to its ‘right to initiative’ rather effectively.

Only a few days after the Laeken European Council, the aforementioned report of the High Level Committee on Health was published by Health Commissioner Byrne.<sup>134</sup> This happened rapidly,<sup>135</sup> and even before it was formally adopted.<sup>136</sup> Through this accelerated procedure, the Health Commissioner managed to secure his place in the European debate on health care services, which he was reluctant

<sup>132</sup> ‘European Integration and National Health Care Systems: A Challenge for Social Policy’, International Conference organized by the Belgian Presidency of the EU, Ghent, 7–8 December 2001. Note that the Belgian President of the Council of the EU Frank Vandenbroucke sent the scientific report, which was prepared by Mossialos *et al.* to underpin this conference, to each of his colleagues in the Council, as a preparation for the informal debate that would take place in Malaga (see below).

<sup>133</sup> Laeken European Council, ‘Presidency Conclusions’, Doc. No. SN 300/1/01 REV 1, 14–15 December 2001.

<sup>134</sup> European Commission, ‘The internal market and health services’, Report of the High Level Committee on Health, Brussels, 17 December 2001, p. 30, [http://ec.europa.eu/health/ph\\_overview/Documents/key06\\_En.pdf](http://ec.europa.eu/health/ph_overview/Documents/key06_En.pdf).

<sup>135</sup> The Health Council ‘took note of the Commission’s intention to rapidly submit a report on the impact of the Court’s judgements’. European Council, 2384th Council Meeting on Health, Doc. No. 13826/01 (Press 415), Brussels, 15 November 2001.

<sup>136</sup> The report was agreed by the Working Group in September 2001 and discussed by the Committee in October 2001. Committee members were

to leave to the Social Affairs Commissioner,<sup>137</sup> who was in charge of taking the ‘concerted strategy’ forward.

It seems that the establishment, in early 2001, of the EU Health Policy Forum<sup>138</sup> should be seen in the same light: through this platform of almost fifty umbrella organizations in the health sector, DG SANCO can test new ideas and gather stakeholder support. The recommendations of this Forum<sup>139</sup> (over which DG SANCO presides and provides the secretariat) usually comment on proposals issued by the Directorate-General for the Internal Market and Services (DG MARKT) or the Directorate-General for Employment, Social Affairs and Equal Opportunities.<sup>140</sup> With a view to creating a constituency for itself, DG SANCO also requested the creation of a ‘European Patients Forum’, and sent its officials to the annual European Health Forum in Gastein, which is a significant venue for networking among EU and national administrators and experts within the broader health community.

The Laeken European Council also backed the continuation of the debate desired by the ‘health’ players (mainly ministers for health and DG SANCO) in that it requested that ‘[p]articular attention will have to be given to the impact of European integration on Member States’ health care systems’.<sup>141</sup> On this basis, and strengthened by a first ministerial debate on the issue during the Belgian Presidency,<sup>142</sup>

then asked for their agreement on the draft report in a written procedure.

Eventually, the Committee formally approved the document in the spring of 2002. European Commission, ‘The internal market’, above n.134, p. 2.

<sup>137</sup> Anna Diamantopoulou at the time.

<sup>138</sup> See Chapter 4 in this volume. For further information, see [http://ec.europa.eu/health/ph\\_overview/health\\_forum/health\\_forum\\_En.htm](http://ec.europa.eu/health/ph_overview/health_forum/health_forum_En.htm).

<sup>139</sup> EU Health Policy Forum (EHPF), ‘Recommendations on EU social policy’, Brussels, December 2003, p. 10; EHPF, ‘Recommendations on mobility of health professionals’, Brussels, December 2003, p. 8; EHPF, ‘Recommendations on health services and the internal market’, Brussels, May 2005, p. 17.

<sup>140</sup> S. Greer, ‘Choosing paths in European Union health policy: a political analysis of a critical juncture’, *Journal of European Social Policy* 18 (2008), 219–31.

<sup>141</sup> Laeken European Council, ‘Presidency Conclusions’, above n.133, para. 30.

<sup>142</sup> The Council ‘expressed its wish to hold a detailed discussion on this subject and welcomed the Spanish delegation’s invitation to discuss this topic at the informal meeting scheduled during its Presidency (Malaga, February 2002)’. Council, 2384th Council Meeting on Health, above n.135, p. 8.



as well as new Court judgments,<sup>143</sup> the Spanish Presidency of the EU held an informal ministerial debate in February 2002 in Malaga. The Presidency focused the debate almost completely on patient mobility, afraid as they were of the consequences of large groups of European pensioners residing in the Spanish coastal regions.<sup>144</sup> This was a narrower focus than the Laeken Conclusions suggested. Commissioner Byrne remained remarkably prudent during the debate, as a consequence of a head of cabinet meeting during which it was agreed that, as long as it was unclear which DG within the Commission was to be 'pilot' for the European health care debate, it would adopt a low profile attitude.<sup>145</sup>

The Health Council of 26 June 2002 then endorsed Council Conclusions on patient mobility and health care in the internal market. Recognizing the importance of strengthening cooperation, the Council invited the Commission to launch a 'High Level Process of Reflection' (HLPR) to propose further action so that the Council could 'return to this issue at the next meeting of the Health Council'.<sup>146</sup> The launch of this HLPR was considered a 'milestone', since it recognized 'the potential value of European cooperation in helping Member States to achieve their health objectives'.<sup>147</sup>

Amazing as it may seem, given the increasing awareness that Europe is entering national health care systems by the back door of the internal market (see above), national governments continued to be strongly averse to formalizing the debate about health care at the EU level. Thus, a proposal to investigate the possibility of

<sup>143</sup> Case C-368/98, *Vanbraekel*, above n.44; Case C-157/99, *Geraets Smits and Peerbooms*, above n.3.

<sup>144</sup> The 'questions for debate' were redrafted four times by the Presidency, but remained confusing and lacked focus. A Presidency paper to prepare the debate was withdrawn at the request of a majority of the delegations. See 'The Europe of Health', unpublished paper from the Spanish Presidency of the EU in preparation of the informal ministerial debate in Malaga, 24 January 2002.

<sup>145</sup> Interview with DG SANCO, October 2007.

<sup>146</sup> Council, 2440th Council Meeting on Health, Doc. No. 10090/02 (Press 182), Luxembourg, 26 June 2002, p. 11.

<sup>147</sup> M. Kyprianou, 'The new European healthcare agenda', Speech at the European Voice Conference 'Healthcare: Is Europe Getting Better?', Brussels, 20 January 2005, p. 2; European Commission, 'Follow-up to the High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union', COM (2004) 301 final, 20 April 2004, p. 18.

applying the OMC in this High Level Process was debated, but not accepted, by the Council in June 2002 (a decade, we should recall, after the first Council recommendation calling for coordination in this area). Similarly, the Health Council could not agree on the creation of a formal ‘committee’ to underpin the Health Council. By opting for a High Level ‘Process’ launched and presided over by the Commission, and in which members participated ‘on a personal basis’, the Member States kept all the options open. The same fear that the EU would interfere in national systems, even through a non-binding reflection process, explains why there was considerable resistance (which was eventually overcome) to creating a working group within the High Level Process of Reflection on ‘reconciling national health policy with European obligations’, which would raise issues such as improving legal certainty for health services within the framework of EU law, as well as the need for new institutions or structures. It seems that Member States did not at all perceive this process, formally non-binding, as non-constraining or unimportant.

These topics remained very sensitive for the Member States, despite DG MARKT’s further increase of pressure on the Member States, in the summer of 2002, by launching a consultation process on the follow-up of the Court’s jurisprudence relating to the reimbursement of medical expenses incurred in another Member State.<sup>148</sup>

Thus, while the ministers of health, and especially DG SANCO, struggled with the practical launch of the HLPR on patient mobility, Member States were dragging their feet, in a very similar way, in the ‘concerted strategy’ on health care and care for the elderly. The above-mentioned initial study (requested by the Gothenburg European Council), was drafted by the SPC and the EPC at the beginning of 2002.<sup>149</sup> The Social Affairs Council adopted it, but was extremely prudent concerning the next steps. Whereas it had launched the

<sup>148</sup> European Commission, ‘Report on the application of internal market rules to health services – implementation by the Member States of the Court’s jurisprudence’, Commission Staff Working Paper, SEC (2003) 900, 28 July 2003.

<sup>149</sup> The report recalled that the debate on health care and care for the elderly is still ‘at an early stage’ and that it is ‘even a more complex process’, making it necessary ‘to involve those responsible for health policy’. Economic Policy Committee, Social Protection Committee (Joint EPC/SPC), ‘Draft

OMC in the fields of social inclusion (2000) and pensions (2001), with regard to health care it merely ‘agreed on the need to initiate and to develop cooperation between the Member States over 2002 and 2003’,<sup>150</sup> leaving many doubts over the continuation of the process in the longer term. Nevertheless, both the EU Council<sup>151</sup> and the European Council<sup>152</sup> did confirm the three long-term objectives set out in the afore-mentioned Commission Communication (accessibility, quality and financial sustainability of systems) as a basis for information gathering and exploring possibilities for mutual learning and cooperation. Two examples can further illustrate the steering role of the European Commission in the development of these non-binding governance mechanisms.

First, the European Commission managed to shift the wording of the Council mandate, once again. The Council abandoned the reference to ‘health care and care for the elderly’, and instead referred to ‘health and long-term care for the elderly’.<sup>153</sup> By entirely linking the debate to the ‘elderly’, the Commission succeeded in ‘selling’ the health care OMC as part of the ageing agenda, which was far less contested.

Second, during the first days of 2003, the Commission introduced the vocabulary of the OMC in the slowly emerging concerted strategy on health care and care for the elderly. It was no coincidence that the Commission decided to label a report it issued on this issue<sup>154</sup> a ‘proposal

for a Council Report in the field of health care and care for the elderly’, SPC/2002/Jan./01 en final, p. 3.

<sup>150</sup> Council Meeting on Employment, Social Policy, Health and Consumer Affairs, Doc. No. 14892/02 (Press 376), Brussels, 2–3 December 2002, para. 12.

<sup>151</sup> *Ibid.*

<sup>152</sup> Barcelona European Council, ‘Presidency Conclusions’, Doc. No. SN 100/1/02 REV 1, 15–16 March 2002, para. 25.

<sup>153</sup> The difference is subtle, yet crucial: whereas the former label could be read as a mandate to work on ‘health care’ (in general), on the one hand, and ‘care for the elderly’ (aimed at a specific age group), on the other, the new formulation clearly suggested that work deals with ‘health care and long-term care’, *both* with regard to the elderly. Thus, EU cooperation in this new policy area had moved, at least at the level of discourse, from ‘health care’ (with attention to the challenge of ageing), via ‘health care and long-term care’, to ‘health care of the elderly’ and ‘long-term care’.

<sup>154</sup> The report was in fact a draft analysis of the Member States’ replies to the 2002 questionnaire on health and long-term care for the elderly.

for a joint report'.<sup>155</sup> The 'joint report' had been a cornerstone of the 'up and running' OMCs, such as the employment strategy, for some years, and had already been prepared for more recent OMCs, such as those on social inclusion and pensions. Thus, in terms of wording, the association with an actual OMC became very strong. It is worth noting that an agreement on this joint report (an instrument of 'soft' governance) could only be reached after hard negotiations, and ultimately political compromises, between Member States and the Commission on controversial points such as the relationship between the state and the market as health care provider, and the level of resources 'necessary' for health care funding.<sup>156</sup> This again illustrates how Member States resisted EU involvement in 'their' health care systems, but also that governance is taken seriously (as opposed to being regarded as irrelevant) by Member States.

What happened with the afore-mentioned 'reflection process' of the health players in the meantime? The 'High Level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union' began work at the beginning of 2003. In view of the initial difficulties (see above), there was an unexpected amount of interest from Member States in participating (both in plenary meetings and working groups). All fifteen ministers invited took part from the outset.<sup>157</sup> This may, of course, reflect a fear that issues would be discussed beyond their control, rather than their willingness to take EU initiatives on this subject. The High Level Process of Reflection adopted recommendations for action at EU level by the end of 2003.<sup>158</sup> For the

<sup>155</sup> European Commission, 'Proposal for a Joint Report. Health care and care for the elderly: supporting national strategies for ensuring a high level of social protection', COM (2002) 774 final, 3 January 2003.

<sup>156</sup> These controversies can be seen in the considerable differences between the Commission's draft report, and the Joint Report that was ultimately adopted by the ECOFIN and Social Affairs Council. ECOFIN and Social Affairs Council, 'Joint Report by the Commission and the Council on supporting national strategies for the future of health care and care for the elderly', Doc. No. 7166/03 (SOC 116), 10 March 2003.

<sup>157</sup> Luxembourg participated only in an administrative sense.

<sup>158</sup> These recommendations were structured around five themes: European cooperation to enable better use of resources; information requirements for patients, professionals and policy-makers; access to and quality of care; reconciling national health policy with European obligations; health-related issues and the EU's Cohesion and Structural Funds. European Commission, 'High Level Process on Patient Mobility and Healthcare Developments in

first time, Member States acknowledged that ‘changing the Treaty’ and ‘secondary legislation’ are options to improve legal certainty. The recommendations of the HLPR also invited the Commission to examine how the existing Community financial instruments could be used to facilitate investment in health, health infrastructure and skills development.<sup>159</sup> Crucially, the Commission was asked to propose a permanent mechanism at EU level to support European cooperation in the field of health care (not limited to patient mobility).<sup>160</sup>

Arguably, the HLPR was inspired by the outcome of the above-mentioned consultation process launched by DG MARKT on the application of internal market rules to health services.<sup>161</sup> In short, the Commission concluded that the ‘Internal Market in health services is not functioning satisfactorily and European citizens are encountering unjustified or disproportionate obstacles when they apply for reimbursement’.<sup>162</sup> The Commission reconfirmed its preference for a constructive dialogue with Member States on their responses to the Court’s judgments.<sup>163</sup>

In 2003, the economic players continued their work on the factors driving public expenditures on health care and long-term care, through a report by the EPC working group on ageing populations, adopted by the ECOFIN Council. The report acknowledged that: ‘in practice demographic change has not been a significant driver of increasing levels of health and long-term care expenditures in recent decades, but rather demand and supply factors have prevailed’.<sup>164</sup> Furthermore, the results of a first study examining the impact of non-demographic drivers in shaping future public expenditures on long-term care ‘show for the four Member States covered by the projection

the European Union, outcome of the reflection process’, HLPR/2003/16, 9 December 2003.

<sup>159</sup> *Ibid.*, p. 11.      <sup>160</sup> *Ibid.*

<sup>161</sup> See Chapter 11 in this volume.

<sup>162</sup> European Commission, ‘Report on the application of internal market rules’, above n.148, p. 18.

<sup>163</sup> Among others, in the High Level Process of Reflection on Patient Mobility and the SOLVIT network, which links the national administrations of every Member State. Its task is to find rapid solutions to problems arising from the application by the Member States of the rules governing the internal market. See [http://ec.europa.eu/solvit/site/index\\_En.htm](http://ec.europa.eu/solvit/site/index_En.htm).

<sup>164</sup> The suggestion was therefore made that, in the next round of common projections, an attempt should be made to model these non-demographic factors in a more explicit manner for all Member States. Economic

exercise, spending on long-term care as a share of GDP is projected to more than double between 2000 and 2050'.<sup>165</sup>

In sum, it seems that at least five different sets of actors tried to shape the terms of the EU health care debate, and expand their influence on it, between 2000 and 2003. We have simplified them as the 'social affairs', 'internal market', 'public health', 'economic' and 'enterprise' players. Together, they created, in a remarkably short time span, a very crowded law and policy-making space. Various governance tools began to take shape, but they remained very fragile, involving provisional institutional architectures that left doubts about their longer-term continuation. National governments remained involved, but the different Commission DGs set the pace.

### *B. After the Services Directive: operationalization of the EU health care governance toolbox*

There is abundant evidence that it was the proposal for a services directive of January 2004<sup>166</sup> that boosted the operationalization of governance in the form of policy coordination on health care. There are at least two reasons for this, one substantive, the other procedural. Most obviously, in substantive terms, in its original version the 'Bolkestein Directive' was entirely applicable to health care services. Procedurally, many 'health players' were concerned that:

In spite of the fact that DG MARKT participated in the high level process on patient mobility, it did not at any point reveal its intention to launch the Directive [while this proposal] tackles crucial issues that were discussed during the high level process, such as the reimbursement of costs for care received in another Member State.<sup>167</sup>

Policy Committee (EPC), 'The impact of ageing populations on public finances: overview of analysis carried out at EU Level and proposals for a future work programme', Doc. No. EPC/ECFIN/435/03, 22 October 2003, p. 26.

<sup>165</sup> *Ibid.*, p. 27.

<sup>166</sup> European Commission, 'Proposal for a Directive of the European Parliament and of the Council on services in the internal market', COM (2004) 2 final, 5 March 2004.

<sup>167</sup> R. Baeten, 'Health care: after the Court, the policy-makers get down to work', in C. Degryse and P. Pochet (eds.), *Social developments in the European Union 2004* (Brussels: ETUI, 2005).

The release of the Directive within a few weeks after the final outcome of the High Level Process explains why health players felt that the Bolkestein Directive was deliberately kept in the drawers of DG MARKT until the end of that Process. As a consequence of these substantive as well as procedural factors, the proposal ‘provoked unprecedented reactions from the public authorities responsible for health policy and from the organizations concerned’,<sup>168</sup> in that it ‘opened everyone’s eyes’.<sup>169</sup> The European advisor to the Belgian Minister for Health put it this way: ‘if the Bolkestein Directive had not existed, we would have had to invent it. It was the wake-up call we all desperately needed.’<sup>170</sup>

DG SANCO seized the momentum created by the Bolkestein proposal: the speed with which it decided to create a ‘High Level Group on Health Services and Medical Care’ to take forward the recommendations of the High Level Process of Reflection on Patient Mobility ‘mirrors the competition between the “health” and “social” players at EU level to take the lead in the process of European cooperation on health care’.<sup>171</sup> On 1 July 2004, merely one month after the Group was politically endorsed by the Health Council, the Commission launched the Group through its first plenary meeting. It brings together civil servants from all the Member States<sup>172</sup> and the Commission (which presides over the plenary meetings and holds the secretariat), working in seven priority areas, with the help of working groups.<sup>173</sup> It also contributes to other work relevant to health services, including, on paper, the OMC on health care. In practice, however:

[W]e should have been involved, and to be fair to our colleagues in DG Employment, we have been asked to contribute at every opportunity, but it is physically not possible with the staff we have to do also the analytical work for the OMC. So we decided to drop it, even though we tried to make a contribution when it was absolutely essential.<sup>174</sup>

<sup>168</sup> *Ibid.* <sup>169</sup> Interview with DG Social Affairs, July 2007.

<sup>170</sup> Interview, June 2007. <sup>171</sup> *Ibid.*

<sup>172</sup> The High Level Group is made up of senior Member State representatives (with other stakeholders contributing on relevant subjects).

<sup>173</sup> Cross-border healthcare purchasing and provision; health professionals; centres of reference; health technology assessment; information and e-health; health impact assessment and health systems; and patient safety.

<sup>174</sup> Interview with DG SANCO, October 2007.

The High Level Group reports annually to the Health Council.<sup>175</sup>

As announced in the above-mentioned G10 Medicines Group (see section three), the Commission set up a Pharmaceutical Forum in 2005 to take the process further around three key themes: pricing policy, relative effectiveness and information to patients on pharmaceuticals. The latter issue was one of the most controversial issues in the Pharmaceutical Review, since the Commission wanted to ease existing legislative restrictions on direct-to-consumer advertising.<sup>176</sup> Since this proposal was dropped at the first reading<sup>177</sup> (after having been rejected by a vast majority in the European Parliament), the internal market players brought the discussion back to the EU agenda through the Pharmaceutical Forum in an attempt to influence future legislation. The Forum, which meets annually, brings together health ministers (with all Member States now being invited), representatives of the European Parliament, the pharmaceutical industry and stakeholder organizations (health care professionals, patients and insurance funds). Two of the latter – namely, the European Social Insurance Partners (ESIP) and the Association Internationale de la Mutualité (AIM) – have strong concerns about the lack of transparency in the Forum, and particularly in the Working Group.<sup>178</sup> Other tensions are apparent: even though the Enterprise and Health Commissioners (Günter Verheugen and Markos Kyprianou, respectively) co-chair the Forum, their relationship seems rather tense (for instance, each has

<sup>175</sup> European Council, 'High Level Group on Health Services and Medical Care – information from the Commission', Doc. No. 15190/04, Brussels, 1 December 2004; European Commission, 'Work of the High Level Group on Health Services and Medical Care during 2005', HLG/2005/16, 18 November 2005; European Commission, 'Work of the High Level Group in 2006', HLG/2006/8, 10 October 2006, p. 16.

<sup>176</sup> Articles 86–100, European Parliament and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ 2001 No. L311/67, pp. 91–5; European Commission, 'Proposal for a European Parliament and Council Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use', COM (2001) 404 final, 26 November 2001; OJ 2001 No. C75/216.

<sup>177</sup> European Commission, 'Amended proposal for a European Parliament and Council Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use', COM (2003) 163 final, 3 April 2003.

<sup>178</sup> European Social Insurance Platform and Association Internationale de la Mutualité (Joint ESIP and AIM), 'Position statement on information to patients on diseases and treatment options', Brussels, 20 June 2007, p. 1.



his own Pharmaceutical Forum web site<sup>179</sup> and, more importantly, each held their own public consultation on health-related information to patients). It will come as no surprise, in view of these tensions, that the second Pharmaceutical Forum (26 June 2007) only noted ‘some progress’.<sup>180</sup>

As far as the High Level Group on Health Services and Medical Care is concerned, it was relatively active between 2004 and 2006, but then its work intensity dropped (almost completely) after September 2006. As Greer and Vanhercke note in Chapter 4 of this volume, the Group indicated that the Commission’s intention to bring forward proposals to develop a Community framework for safe, high quality and efficient health services in 2007, on the basis of a consultation beginning in 2006 ‘will have an impact on the future work of the High Level Group’.<sup>181</sup> In retrospect, this sentence seems to have been the announcement of the demise (at least for the time being) of the Group. Arguably, this development is also related to the structural limitations of the Group, which was established by a Commission Decision, and not constitutionalized (in contrast to the Social Protection Committee). As a consequence, it is not accountable to the Council, which obviously limits its capacity to conduct genuine political debates. Also consider that the Commission holds both the presidency of the Group as well as its secretariat, which several Member States, and the Commission, find uncomfortable. Hence, the Council decided to launch a ‘senior level committee’, in which more ‘political debates could take place’ (notably about the proposal for a services directive). And, yet, in practice:

[T]he Group is a very clear example unfortunately of the fact that if you do not have an executive that actually does things, things do not happen. And therefore the Senior Level Group has not followed-up on most of its discussions. There is one important exception: the statement on the core values and shared principles of health systems that was prepared by the

<sup>179</sup> DG Industry’s web site: [http://ec.europa.eu/enterprise/phabiocom/comp\\_pf\\_En.htm](http://ec.europa.eu/enterprise/phabiocom/comp_pf_En.htm); DG SANCO’s web site: [http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharma\\_forum\\_En.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharma_forum_En.htm).

<sup>180</sup> ‘Pharmaceutical Forum Introduction’, DG Health and Consumer Protection web site: [http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharma\\_forum\\_En.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharma_forum_En.htm).

<sup>181</sup> European Commission, ‘Work of the High Level Group’, above n.175, pp. 15–6.

Senior Level Group, and adopted by the Council in 2005, was a genuinely useful exercise.<sup>182</sup>

The European Commission, in September 2006, launched a public consultation on how to ensure legal certainty regarding cross-border health care under Community law, and announced proposals for later in 2007.<sup>183</sup> Questions were asked, for example, about what areas require greater legal certainty and what tools would be appropriate to tackle these different issues at EU level – whether binding legal instruments (a regulation or a directive), ‘soft law’ (e.g., an interpretative communication) or other means. The Commission stated that while ‘[a]ny or all of these different types of instruments could be combined in an overall package of Community action ... ensuring legal certainty seems likely to require at least some elements being dealt with through legislative action’.<sup>184</sup>

Arguably, the increased activities of the Commission – especially DG MARKT, but also ECOFIN, which issued a new report on the impact of ageing populations on public spending<sup>185</sup> – inspired the Member States to try to ‘guide’ the Commission while it was developing its announced framework for safe, high quality and efficient health services. In June 2006, the twenty-five health ministers endorsed a statement on common values (universality, access to good quality care, equity and solidarity) and principles (quality, safety, care that is based on evidence and ethics, patient involvement, redress, and privacy and confidentiality). Crucially, ministers invited the European Commission ‘to ensure that common values and principles contained in the Statement are respected when drafting specific proposals concerning health services’.<sup>186</sup> Since ministers ‘strongly believe that developments in this area should result from political consensus, and not

<sup>182</sup> Interview with DG SANCO, October 2007.

<sup>183</sup> European Commission, ‘Consultation regarding Community action on health services’, SEC (2006) 1195/4, 26 September 2006.

<sup>184</sup> *Ibid.*, p. 11.

<sup>185</sup> Economic Policy Committee, ‘Summary report: impact of ageing populations on public spending on pensions, health and long-term care, education and unemployment benefits for the elderly’, Doc. No. ECFIN/EPC(2006)REP/238, 6 February 2006.

<sup>186</sup> Council Conclusions on common values and principles in EU health systems, Employment, Social Policy, Health and Consumer Affairs Council Meeting, Doc No. 9658/06 (Press 148), Luxembourg, 1–2 June 2006, p. 33.

solely from case law',<sup>187</sup> they invited the institutions of the European Union more generally (read, the European Court of Justice) 'to ensure that common values and principles contained in the Statement are respected in their work'.<sup>188</sup>

Finally, summarizing some 270 responses<sup>189</sup> to the above-mentioned public consultation regarding 'Community action on health services',<sup>190</sup> the Commission concluded in the spring of 2007 that a majority view of contributors felt that 'a combination of both "supportive" tools (such as practical cooperation, or the "open method of coordination") and legally binding measures' (either through changes within the existing regulations on the coordination of social security systems, or by means of a new specific directive on health services) would be best.<sup>191</sup> In other words, law and governance were expected to complement each other. The majority of national governments and many other stakeholders expressed the wish that any Community action should be based on the Council's 'common values and principles of EU health systems'.<sup>192</sup>

Some of the views from the public consultation were taken forward by the (informal meeting of) health ministers in Aachen, which debated cross-border care based on a number of very explicit questions, and even addressed the specific content of a health services directive (including its recitals, objective, definitions and the content of different chapters) and an 'options paper' dealing (very explicitly) with the '[c]onsequences when excluding planned health care services from Regulation 883/04'. In a paper issued after the informal Council meeting, the three successive German, Portuguese and Slovenian Presidencies<sup>193</sup> 'strongly suggest that the Commission presents a broad

<sup>187</sup> *Ibid.*, p. 34.   <sup>188</sup> *Ibid.*, p. 33.

<sup>189</sup> 276 responses were received from national governments, regional authorities, international and national umbrella organizations, social security institutions, universities, industry and individual citizens.

<sup>190</sup> European Commission, 'Summary report of the responses to the consultation regarding "Community action on health services"', SEC (2006) 1195/4, 20 April 2007.

<sup>191</sup> *Ibid.*, p. 34.   <sup>192</sup> *Ibid.*, p. 33.

<sup>193</sup> Germany held the EU Presidency during the first half of 2007. It was followed by Portugal on 1 July 2007 and Slovenia on 1 January 2008. The three successive presidencies have developed a joint 'Trio Presidency' eighteen-month programme of Council activities, which is designed to increase continuity in the Council's work.

framework on all of the above-mentioned issues, not just on patient mobility'.<sup>194</sup>

Was the Commission able and willing to capitalize on this political willingness for a 'broad framework'? It seems not immediately. The Commission proposals on health care services took a long time to appear. A proposal expected at the end of 2007<sup>195</sup> was delayed at the last instant due to protests among Member States and lobbying from MEPs, some of whom feared that the debate about this piece of legislation could undermine the ratification of the EU's new Treaty. Arguably, for the same reason, the publication of a watered-down version of the proposal was delayed, for the second time, in February 2008. The proposal eventually appeared in July 2008, as part of the 'Social Agenda'.<sup>196</sup>

The emerging governance framework of EU-level health care policy described here will be underpinned by its partial 'constitutionalization' in the Lisbon Treaty (if it is ratified by all the Member States). The Lisbon Treaty will amend Article 152 EC, to further enhance (or possibly constrain) the Commission's competence to encourage cooperation between the Member States in the public health field, which will include 'preventing physical and mental illness and diseases'. This Commission-sponsored cooperation is to include, 'in particular, initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation'.<sup>197</sup> The list of areas within which the EU may adopt 'incentive measures' (in other words, financial support through various programmes, particularly the public health programmes

<sup>194</sup> Trio Presidency, 'Health care across Europe: striving for added value', Notes of the Trio Presidency, Aachen, 20 April 2007, p. 5.

<sup>195</sup> In its Annual Policy Strategy for 2007, the Commission announced that it would 'develop a Community framework for safe, high quality and efficient health services, by reinforcing cooperation between Member States and providing certainty over the application of Community law to health services and healthcare'. European Commission, 'Annual policy strategy for 2007: boosting trust through action', COM (2006) 122 final, 14 March 2006, p. 11.

<sup>196</sup> Proposal for a Directive on the application of patients' rights in cross-border healthcare COM (2008) 414 final.

<sup>197</sup> See Article 168(2), Treaty on the Functioning of the European Union, Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, OJ 2008 No. C115/1.

discussed above) also is further specified.<sup>198</sup> Moreover, the role of the European Parliament as a recipient of information is made explicit in the Lisbon revisions.<sup>199</sup>

## 5. Conclusions

Health is and will continue to be an area within which the competence of the EU institutions is highly constrained. This has been reconfirmed by the Treaty of Lisbon.<sup>200</sup> At the same time, however, health is no longer a ‘non-topic’ for the EU, and neither the EU institutions, nor the governments of the Member States, can now retreat from that position, for how could the EU not be ‘for’ health and health care?

We have described EU health care law, policy and governance as a double patchwork. The limitations of: (a) the political incapacity to adopt ‘positive’ legislation; (b) a longstanding but increasing impact of EU law on national health care systems; and (c) a divided policy space, have triggered ‘political spillovers pushing consecutive rounds of EU policy initiatives, pressed for by domestic policy-makers, to deal with the unintended consequences’.<sup>201</sup> More particularly, those responsible for health care at the national levels have responded, feeding into the EU’s use of the ‘governance tool kit’ in health care fields. No less than five sets of actors, which we have labelled as ‘public health’, ‘social affairs’, ‘internal market’, ‘enterprise’ and ‘economic’, have crowded the EU health care governance space and have established different

<sup>198</sup> The revised provision (new Article 152(5)) will give the European Parliament and the Council competence to adopt ‘incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States’.

<sup>199</sup> The new Article 152(2) will state that ‘the European Parliament shall be kept fully informed’ of Commission-sponsored coordination between the Member States.

<sup>200</sup> See Article 168(7), Treaty on the Functioning of the European Union: ‘Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them’.

<sup>201</sup> Hemerijck, *Revisiting productive welfare*, above n.90, p. 25.

(as opposed to integrated) and largely uncoordinated responses, all of which, at least, have the potential to have an impact at the domestic level. So far, law and governance have existed largely in parallel, with governance processes ‘in the shadow’ of legislation.

We have seen that, within each of these sets of players, the European Commission, often from a very early stage, set the terms of the debate, including in processes such as the patient mobility processes and the OMC. In other words, governance does not seem to significantly destabilize the independent agency, or even hegemony, of the Commission as the lynch pin of Community law and policy-making. However, there are strong indications that now that the different health care processes are ‘up and running’, the Commission’s internal divisions may allow the Council and national governments to reassert control. One should recall in this context that, under the United Kingdom Presidency, the Council (daringly) asked for ‘more leadership’ in the European health care debate. A clear message addressed to the Commission, it seems. And yet, one key actor is quite sceptical:

DG Social Affairs has the legal instruments (legal base), but it does not have the legitimate constituency at national level. DG SANCO has privileged relationships with national actors, but it does not have the legal instruments. Result: we have to find a compromise, but for the moment it is a real conflict, a battle for power. Of which we do not see the end yet.<sup>202</sup>

Another clear feature of the double EU health care governance patchwork is that public consultations are increasingly used by the European Commission as a tool to legitimize further initiatives and to create ownership of the final proposal among stakeholders. Examples include consultations on the draft strategic guidelines for the new programming period of the Structural Funds, on freeing Europe from exposure to environmental tobacco smoke, on the follow-up to the Court’s jurisprudence relating to the reimbursement of medical expenses incurred in another Member State, on health-related information for patients, on how to ensure legal certainty regarding cross-border health care, and David Byrne’s electronic Reflection Process in 2004 on the Commission’s new EU health strategy. These consultations seem to help to depoliticize debates (which are sometimes even said to

<sup>202</sup> Interview with DG Social Affairs, July 2007.

be too technical to be discussed among politicians) and thus remain relatively isolated from high profile media or other public scrutiny. And yet, as we have shown, in most cases their effect is significant, as in the case of the Pharmaceutical Forum, which was instrumental in bypassing issues which were rejected in the Pharmaceutical Review.

Another feature of the new EU health care governance patchwork is an increasing interlinking between classical EU law-making and governance processes. Examples of this linkage include the High Level Process of Reflection, which played a key role in pressing the Commission to propose legislation on health services in the internal market. They include the networked governance processes of 'Europe against Cancer' feeding into tobacco legislation. They also include the High Level Group on Health Services and Medical Care, which organized pressure to increase EU funding for health care infrastructure through the Structural Funds, and promoted coordination of national health care policies and adopted soft law measures such as the 2005 'EU Guidelines for Purchase of Treatment Abroad', effectively bypassing the lack of legislative guidance from the EU on this issue. Other examples include the Transparency Committee (set up under Directive 89/105/EEC),<sup>203</sup> which was reactivated because of the information requirements of the Pharmaceutical Forum, and which spilled over into new kinds of cooperation. Thus, new Member States are using the (formal and especially informal) exchanges of information between Committee members (e.g., on the therapeutic value-added of new medicines) 'to arm themselves against the invasion of new pharmaceutical products on their markets'.<sup>204</sup> Another example is the data protection regulation (covered by Directive 95/46/EC),<sup>205</sup> for which the Commission offers 'to work with the Member States ... to raise awareness' of the provisions of the Directive that apply to the health care sector. This governance approach presumably sits alongside more classical modes of implementation and enforcement of EU legislation by the Commission envisaged by the Treaty. Taking all these examples together, it will come

<sup>203</sup> Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ 1989 No. L40/8.

<sup>204</sup> Interview with member of High Level Group, September 2007.

<sup>205</sup> European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281/31.

as no surprise, then, that non-binding measures are far from being perceived as irrelevant by the Member States and that the decision-making process leading to their adoption involves hard politics.

In sum, the cross-fertilization between law and governance seems to point towards the future development of 'hybrid' policy instruments: far from abandoning legislative responses, the EU institutions are keen to pursue them *alongside* the array of governance mechanisms now available to them. A case in point of such 'instrument hybridity'<sup>206</sup> is the interlinking between the OMC and the ESF. The scope of the ESF was redirected in 1999, so that the Fund could support, during the 2000–6 programming period, the newly launched 'European employment strategy', another EU governance process launched in 1997.<sup>207</sup> Even more important in the context of this chapter is that the new ESF Regulation, which determines the tasks of the ESF, the scope of its assistance and the eligibility criteria for the 2007–13 programming period, explicitly refers to the 'open method of coordination on social protection and social inclusion',<sup>208</sup> of which the health care OMC is now one particular strand. Consequently, there is no reason why in the near future certain elements of the health care OMC would not be taken into account by the Commission, *de jure* or *de facto*, to determine whether expenditure is eligible for assistance under the Fund.<sup>209</sup>

What will happen in the future? Most importantly, EU health law and governance will be increasingly interlinked. At first glance, it would seem that we are unlikely to see significant additions to the legislative landscape, in terms of EU law that *directly* treats the provision of health care in the internal market or competition law. Even if the Commission's proposal for a directive on health care services

<sup>206</sup> D. Trubek and L. Trubek, 'New governance and legal regulation: complementarity, rivalry or transformation', *Columbia Journal of European Law* 13 (2007), 539–64. See also T. Hervey and L. Trubek, 'Freedom to provide health care services within the EU: an opportunity for hybrid governance', *Columbia Journal of European Law* 13 (2007), 623–49.

<sup>207</sup> European Parliament and Council Regulation 1784/1999/EC on the European Social Fund, OJ 1999 No. L213/5. More particularly, the Regulation stipulated in Article 1 that 'the Fund shall contribute to the actions undertaken in pursuance of the European Employment Strategy and the Annual Guidelines on Employment'.

<sup>208</sup> Article 4(3), European Parliament and Council Regulation 1081/2006/EC, above n.22, p. 16.

<sup>209</sup> Interview with DG Social Affairs, February 2007.



in the internal market does emerge, it will not significantly change the current position. However, this may be too hasty a conclusion, since support for further legislation may be spurred by the information and new understandings generated through the learning mechanisms of governance procedures, such as the OMC, other forms of policy coordination, and information generation and dissemination drawing on EU funding opportunities. Furthermore, legislation in other fields of EU law that *indirectly* affects health care systems will continue to be adopted, but the ‘health care mainstreaming’ obligation, which will be further embedded in the Treaty following the Lisbon amendments,<sup>210</sup> will be applied more seriously due to the increased visibility of health in the Commission’s vista, and because of Member States’ increased willingness to discuss health care at the EU level, at least in the context of governance processes. Finally, consistent with the ‘constitutional asymmetry’ thesis, the ‘negative integration’ and destabilizing dynamic of litigation before the Court will continue. But this will only be at the margins and, arguably, because the Court is no more blind to governance measures than it is to legislation – and proposed legislation – it will increasingly be inspired by the outcomes of the governance process in its judgements (e.g., perhaps when interpreting ‘undue delays’, ‘solidarity’ or a definition of ‘public interest’ in the context of cross-border health care services; or an agreed list of justifications for non-discriminatory restrictions on the free movement to provide services, freedom of establishment or free movement of persons).

Non-hierarchical, networked methods of governance, based on shared learning, information collection and dissemination, benchmarking, and so on, are likely to continue to be important, since the EU is likely to continue to use information, influence and incentives, rather than hierarchical law-making and regulation in health care fields. The challenges of non-hierarchical governance that apply in any field will apply perforce in the health care governance arena. How will the relevant actors be included, each with an ‘equal voice’ at the table? At present, EU health care governance remains largely a ‘closed shop’ of high level civil servants, EU officials and experts, and many governance practices are particularly poorly integrated into domestic policy processes. Consequently, (European and domestic) parliamentary overview remains poorly developed. What about Member States

<sup>210</sup> See Article 9, Treaty on the Functioning of the European Union.

where human capacity is scarce, so participation in these processes is more limited than in those better endowed with human capacity? How will the processes be protected from ‘capture’ by powerful interests, be they in the pharmaceutical, tobacco or private health insurance industries? These questions are not only questions for non-hierarchical governance structures – they apply equally in the context of more traditional hierarchical law-making and regulatory processes.

Some empirical evidence of longer-standing governance processes suggests that they are being used as an increasingly important trigger for ambitious domestic welfare state reform.<sup>211</sup> It seems that Frank Vandebroucke was right when he said that:

Open co-ordination can and should be a creative process, because it will enable us to translate the much discussed but often unspecified “European social model” into a tangible set of agreed objectives, to be entrenched in European co-operation. ... Efficient EU co-operation can help identify and prepare the legislative work [at] both a national and EU level.<sup>212</sup>

The synergies offered by such an integration of law and governance provide the EU with an opportunity to take health care policy forward, while balancing the interests of the internal market and competition, alongside those of ‘social Europe’.

In the final analysis, neither positive nor negative integration in the classical senses will be the dominant mode for EU law or policy-making in the health care context. Rather, we can expect an interaction, or set of interactions, between legislative and governance processes. And, although the story we tell in this chapter may be read to imply that the law and policy patchwork is becoming increasingly ‘joined up’, for all the reasons explained here, it will never become a single all-encompassing woven tapestry.

<sup>211</sup> M.-P. Hamel and B. Vanhercke, ‘The OMC and domestic social policymaking in Belgium and France: window dressing, one-way impact, or reciprocal influence?’, in M. Heidenreich and J. Zeitlin (eds.), *Changing European employment and welfare regimes: the influence of the open method of coordination on national labour market and social welfare reforms* (London: Routledge, 2009).

<sup>212</sup> F. Vandebroucke, ‘European integration and national health care systems: a challenge for social policy’, Speech at the Ghent Conference on ‘European Integration and National Health Care Systems: a Challenge for Social Policy’, Ghent, 7–8 December 2001, p. 5.