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# 1. The history and scope of EU health law and policy

*Mary Guy and Wolf Sauter*

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## I. INTRODUCTION

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

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

## II. WHAT IS EU HEALTH LAW AND POLICY?

The emergence of EU health law and policy as a discipline has been characterised by discussions of how it is defined, and what it comprises.

Perhaps most notably, EU health law and policy has been conceptualised as a ‘patchwork’ made up of various provisions that constitutionally belong to different policy domains, principally those of the internal market, social affairs, public health, enterprise and economic policy.<sup>1</sup> The integration of health policy in particular has further been described as ‘differential, patchy, accidental and discontinuous’.<sup>2</sup>

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

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<sup>1</sup> TK Hervey and B Vanhercke, ‘Health care and the EU: the law and policy patchwork’ in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 85.

<sup>2</sup> W Lamping, ‘EU health care policy’ in SL Greer and P Kurzer (eds), *European Union Public Health Policy – Regional and Global Trends* (Routledge 2013).

The wide-ranging nature of EU health law and policy has led to recognition of the need for different approaches to its interpretation. These are considered below. For example, considerations of EU health law and policy may start with an analysis of EU institutions and processes before examining action taken by the EU regarding health and how other European policies affect health.<sup>3</sup> This suggests that ‘health-specific’ EU policies and legal provisions can be distinguished from those which are incidentally relevant to health. However, a ‘novel taxonomy’ is also beneficial, combining a thematic approach with ‘individual’ and ‘collective’ (or ‘systemic’) perspectives.<sup>4</sup> This volume adopts a development of that taxonomy, comprising history and scope, people, products, systems, public health and the external dimension to examine aspects as diverse as biocitizenship, e-health and m-health, and global health law and policy.

## II.i Interpretations of EU Health Law and Policy

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

This interpretation of EU health law and policy as an interface perhaps suggests an equation whereby EU law + health law = EU health law. Although this would be misleading it nevertheless highlights the limitations of using traditional definitions of both EU law and health law<sup>5</sup> to understand EU health law and policy.<sup>6</sup> Certainly the transversal nature of EU health law and policy is a distinctive feature, with a notable example offered by the change in status of EU tobacco policy from internal market imperative to public health objective.<sup>7</sup>

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

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

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

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

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

<sup>7</sup> On this point, see, for example, A Alemanno, ‘Out of sight, out of mind: Towards a new EU Tobacco Products Directive’ (2012) 18(2) *Columbia Journal of European Law* 197.

as the internal market and competition rules impact health systems in Member States and EU health policy work is considered in a similar manner.<sup>8</sup> While the ‘interface’ approach is now established as an analytical perspective in its own right,<sup>9</sup> different examinations of EU health law and policy are discussed below.<sup>10</sup>

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

This interpretation is influenced in part by the apparent paradox of Article 168 TFEU being considered an explicit, yet weak and limited legal basis for EU competence in public health but one which nevertheless incorporates provision for the mainstreaming of health into other policies – ‘A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.’<sup>11</sup> A consequence of this would seem to be that either EU health policy is non-existent as an autonomous policy area, given that it is mainstreamed in all other policies, or that all EU public policy is also health policy.<sup>12</sup> However, broad conceptions of EU health policy can be more nuanced, and distinguish and describe health policy that is pursued in the context of other European policies, rather than subsuming all EU policy under health policy.<sup>13</sup> This can be illustrated by the following example:

[. . .] if EU agricultural policy aims to create a European market for milk, it is agricultural policy. However, European Union health policy is adopted when, in the context of creating a market for milk, mandatory testing for bovine tuberculosis is implemented at the European level[. . .].<sup>14</sup>

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<sup>8</sup> Hervey (n 6).

<sup>9</sup> See for example, L Hancher and W Sauter, *EU Competition and Internal Market Law in the Health Care Sector* (OUP 2012), and J van de Gronden and others (eds), *Health Care and EU Law* (TMC Asser Press 2011).

<sup>10</sup> Hervey and McHale acknowledge the significance of the ‘interface’ between EU and health law in their earlier work TK Hervey and JV McHale, *Health Law and the European Union* (CUP 2004), but their 2015 work (n 4) extends beyond this, reflecting the exponential expansion of the field in the intervening 10 years.

<sup>11</sup> Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C326/01 (TFEU), Article 168(1).

<sup>12</sup> A de Ruijter, ‘A silent revolution: the expansion of EU power in the field of human health. A rights-based analysis of EU health law & policy’ (PhD Thesis, University of Amsterdam 2015) 47.

<sup>13</sup> *ibid* 59.

<sup>14</sup> *ibid*.

### **II.i.c ‘Constitutional asymmetry’ and EU health law and policy**

The ‘constitutional asymmetry’<sup>15</sup> of EU economic policies assuming greater importance over social ones should not be overlooked in the development of EU health law and policy. On the one hand, it has been suggested that EU health law has moved beyond a tenuous and uncertain position to gain greater coherence from an increasing sense of distance from the internal market rules.<sup>16</sup> On the other hand, the recent increase in EU powers to intervene in national health policies following the financial crisis has been considered a ‘clear example’<sup>17</sup> of constitutional asymmetry, yet has significant potential to shape EU health law and policy.

### **II.i.d Other interpretations**

Two relatively recent approaches are noted here.

First, the use made by the EU of its ‘regulatory toolbox’ in combination with varying degrees of intervention to address differing concerns. Thus the scope for introducing an EU ‘fat tax’ is complicated by the EU’s limited competence to either enact public health measures or introduce tax.<sup>18</sup> However, the EU has been able to contribute to shaping the emergence of national lifestyle policies regarding tobacco, alcohol and diets through its negative integration provisions in combination with early legislative efforts.<sup>19</sup>

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

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<sup>15</sup> F Scharpf, ‘The European social model: coping with the challenges of diversity’ (2002) 40 *Journal of Common Market Studies* 645.

<sup>16</sup> Hervey and McHale (n 4).

<sup>17</sup> Greer and others (n 3) xiii.

<sup>18</sup> See A Alemanno and I Carreño, ‘Fat Taxes in the EU Between Fiscal Austerity and the Fight Against Obesity’ (2011) 4 *European Journal of Risk Regulation* 571.

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

<sup>20</sup> See in particular, de Ruijter (n 12).

<sup>21</sup> Hervey and McHale (n 4) Chapter 3.

## II.ii Distinguishing Between ‘Public Health’ and ‘Healthcare’ in EU Health Law and Policy

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

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

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

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

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<sup>22</sup> See, inter alia, M Steffen, W Lamping and J Lehto, ‘The Europeanisation of health policies’ in M Steffen (ed), *Health Governance in Europe – Issues, challenges and theories* (Routledge 2005).

<sup>23</sup> de Ruijter (n 13) 59.

<sup>24</sup> *ibid* 61.

<sup>25</sup> An apparently alternative phrasing of ‘EU health (care) policy’ is used in Mossialos and others (n 1) Chapter 1.

<sup>26</sup> For a discussion of some of the issues, see Greer and Kurzer (n 2) Chapter 1. Vos draws a further distinction between ‘human health’ and ‘public health’, but this is beyond the scope of this chapter. See E Vos, *Institutional Frameworks of Community Health and Safety Regulation: Committees, Agencies and Private Bodies* (Hart 1999). For a critical consideration of this view, see de Ruijter (n 12) 51–52.

<sup>27</sup> E Brooks, ‘Crossing borders: A critical review of the role of the European Court of Justice in EU health policy’ (2012) 105 *Health Policy* 33.

health law and policy is considered to be the same<sup>28</sup> for both ‘public health’ and ‘healthcare’.

Indeed, as EU health law and policy evolves as a discipline, these two categories – however broadly defined – may no longer prove sufficient. It has already been suggested that EU health policy encompasses ‘three faces’:<sup>29</sup> explicit health policies (relating to public health); health services policies (that is, internal market law, which might be considered to relate to ‘healthcare’); and the much-strengthened fiscal governance system of the European Semester which effectively elevates the EU to supervisor of Member State policy and expenditure decisions, thereby potentially impacting health. This suggests a departure from policies relating to ‘healthcare’ thus far.

Furthermore, the emergence of different categorisations comprising both ‘public health’ and ‘healthcare’ elements arguably undermine a strong sense of distinction. This is evident, for instance, in considerations of the EU’s relationship with international agencies and participation in international agreements<sup>30</sup> – which form a basis for an ‘external’ EU health law related to, but distinct from, the ‘internal’ EU health law<sup>31</sup> considered in this chapter.

Space constraints mean that we have not drawn a strict distinction here between ‘law’ and ‘policy’,<sup>32</sup> but acknowledge the role of the former in the latter. Similarly, we have been unable to explore all the parties involved in this area. However, we nevertheless develop our overview of what EU health law and policy is by reference to its expanding legal basis – from the limitations of the classic Community method in contributing to EU health competence to the use of new governance methods by the EU institutions – against the following chronological framework.

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<sup>28</sup> See Hervey and McHale (n 4).

<sup>29</sup> SL Greer, ‘The three faces of European Union health policy: Policy, markets and austerity’ (2014) 33 *Policy and Society* 13.

<sup>30</sup> See for instance, Greer and Kurzer (n 2) Chapters 7 and 8.

<sup>31</sup> On the emergence of ‘external’ EU health law and the distinction between this and its ‘internal’ counterpart, see Hervey and McHale (n 4).

<sup>32</sup> For a thorough treatment of the various facets of policy, see de Ruijter (n 12), Chapter 2.

### III. HOW HAS THE SCOPE OF EU HEALTH LAW AND POLICY DEVELOPED WITHIN THE BROADER CONTEXT OF EU LAW/ INTEGRATION?

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

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

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

##### III.i.a Social security coordination

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

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<sup>33</sup> See for instance W Kaiser and A Varsori (eds), *European Union history: themes and debates* (Palgrave Macmillan 2010); D Dinan, *Origins and Evolution of the European Union* (2nd edn, OUP 2014); T Judt, *Postwar: A History of Europe Since 1945* (Penguin 2005); AS Milward, *The European Rescue of the Nation State* (2nd edn, Routledge 2000).

<sup>34</sup> Treaty of Rome, Establishing the European Economic Community (adopted 25 March 1957, entered into force 1 January 1958) 298 UNTS 11 (EEC) Articles 36 (goods), 48 (workers), 56 (establishment) and 134 (association of overseas countries and territories).

<sup>35</sup> Council Regulation (EEC) 3/58 concernant la sécurité sociale des travailleurs migrants [1958] OJ 30 of 16 December 1958; Council Regulation (EEC) 4/58 fixant les modalités d'application et complétant les dispositions du règlement n° 3 [1958] OJ 30 of 16 December 1958.

<sup>36</sup> European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1; Council

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

### **III.i.b Food law**

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

Regarding goods, the main relevant product categories apart from

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Regulation (EEC) 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community [1971] OJ Spec Ed 416; which are applicable by virtue of European Parliament and Council Regulation (EU) 1231/2010 of 24 November 2010 extending Regulation (EC) 883/2004 and Regulation (EC) 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality [2010] OJ L344/1; Council Regulation (EC) 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) 1408/71 and Regulation (EEC) 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality [2003] OJ L124/. F Pennings, *European Social Security Law* (5th edn, Intersentia 2010).

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

<sup>38</sup> Council Directive on the approximation of the laws of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption [1962] OJ Spec Ed 279. Now European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs [1994] OJ L237/13.

<sup>39</sup> See Hervey and McHale (n 4), Chapters 3 and 15; B van der Meulen (ed), *European Food Law Handbook 2014* (Wageningen Academic Publishers 2014); R O'Rourke, *European Food Law* (3rd edn, Sweet & Maxwell 2005).

<sup>40</sup> European Parliament and Council Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1. E Vos, 'EU food safety regulation in the aftermath of the BSE Crisis' (2000) 23 *Journal of Consumer Policy* 227.



food are pharmaceuticals and medical devices as well as tobacco (and alcohol<sup>41</sup>).

### **III.i.c Pharmaceuticals**

Pharmaceuticals have been subject to regulation at EU level, from 1965 onwards.<sup>42</sup> For pharmaceuticals three types of rules are important: the patent rules; rules on admission to market; and price transparency rules. The EU patent rules are general in nature and do not include specific provisions for pharmaceuticals although this is one of the leading sectors in patent applications. Marketing authorisation for pharmaceuticals has been harmonised at EU level.<sup>43</sup> In addition there are rules for special types of medication (orphan drugs, children's medication and advanced therapy).<sup>44</sup> The most direct EU level intervention is the 1988 Directive on price transparency for pharmaceuticals, which includes time limits and requires decisions to be justified objectively, non-discriminatorily and (evidently) transparently.<sup>45</sup> A proposed new

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<sup>41</sup> There has been an EU alcohol strategy since 2006, elements of which are pursued under the general (public) health programmes of the EU (see below). Commission, 'An EU strategy to support Member States in reducing alcohol related harm' (Communication) COM (2006) 625 final.

<sup>42</sup> See eg Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [1965] OJ L22/369; Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products [1975] OJ L147/1; Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1975] OJ L147/13.

<sup>43</sup> European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67; European Parliament and Council Regulation (EC) 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.

<sup>44</sup> European Parliament and Council Regulation (EC) 141/2000 of 16 December 1999 on orphan medicinal products [2000] OJ L18/1; European Parliament and Council Regulation (EC) 1901/2006 of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) 726/2004 [2006] OJ L378/1; European Parliament and Council Regulation (EC) 1394/2007 of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) 726/2004 [2006] OJ L324/121.

<sup>45</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use

Directive on this topic was recently withdrawn for lack of political support.<sup>46</sup>

### III.i.d Medical devices

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

The regulation of medical devices aims to combine market access with guarantees of health and safety (using a conformity assessment and CE marking). The current medical devices regime consists of the 1993 general Directive on medical devices<sup>50</sup> and two specific Directives, the 1990 Directive on implantable devices,<sup>51</sup> and the 1998 Directive on *in vitro* diagnostic

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and their inclusion in the scope of national health insurance systems [1989] OJ L40/8. See Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *Menarini* ECLI:EU:C:2009:217, [2009] ECR I-2495.

<sup>46</sup> Commission, 'Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems' COM (2012) 84 final.

<sup>47</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1990] OJ L189/17 (Active Implantable Medical Devices Directive). C Altenstetter and G Permanand, 'EU regulation of medical devices and pharmaceuticals in comparative perspective' (2007) 24 *Review of Policy Research* 385; C Altenstetter, 'Regulation of medical devices in the EU' in M McKee, E Mossialos and R Baeten (eds), *The Impact of EU law on Health Care Systems* (Peter Lang 2003) 277–303.

<sup>48</sup> Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*) ECLI:EU:C:1979:42, [1979] ECR 649. L Gormley, '*Cassis de Dijon* and the Communication from the Commission' (1981) 5 *European Law Review* 454.

<sup>49</sup> Council, 'Council Resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization' [1985] OJ C136/1. SJ Pelkmans, 'The new approach to technical harmonization and standardization' (1987) 25 *Journal of Common Market Studies* 249.

<sup>50</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169/1.

<sup>51</sup> Active Implantable Medical Devices Directive (n 47).

devices.<sup>52</sup> At present the three medical devices Directives are being recast and consolidated in the form of two Regulations on Medical Devices.<sup>53</sup>

### **III.i.e Tobacco**

Although classified as a public health concern under Article 168(5) TFEU, tobacco is also a good and accordingly subject to the free movement rules. Tobacco was originally regulated by Directives on tobacco labelling (1989) and on maximum tar yield (1990).<sup>54</sup> The present Tobacco Advertising Directive<sup>55</sup> supersedes a previous version<sup>56</sup> which was annulled by the *Tobacco Advertising I* case,<sup>57</sup> because the harmonisation prohibition of Article 152(4) EC (now Article 168(7) TFEU) meant other Treaty articles cannot be used as a legal basis in order to circumvent this express harmonisation exclusion. The European legislature subsequently adopted a revised Directive, which survived a further legal challenge.<sup>58</sup> The sector is now governed especially by the 2003 Tobacco Advertising Directive and the 2014 Tobacco Products Directive.<sup>59</sup>

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<sup>52</sup> European Parliament and Council Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices [1998] OJ L331/1.

<sup>53</sup> See also European Parliament and Council Directive 2007/47/EC of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market [2007] OJ L247/21.

<sup>54</sup> Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products [1989] OJ L359/1; Council Directive 90/239/EEC of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes [1990] OJ L137/36.

<sup>55</sup> European Parliament and Council Directive 2003/33/EC of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products [2003] OJ L152/16.

<sup>56</sup> European Parliament and Council Directive 98/43/EC of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products [1998] OJ L213/9.

<sup>57</sup> Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising I)* ECLI:EU:C:2000:544, [2000] ECR I-8419.

<sup>58</sup> See C Barnard, *The Substantive Law of the EU* (4th edn, OUP 2013) 635–8. Case C-380/03 *Germany v European Parliament and Council (Tobacco Advertising II)* ECLI:EU:C:2006:772, [2006] ECR I-11573.

<sup>59</sup> MJ Elsmore and V Obolevich, 'Thank you for not smoking: the Commission's proposal for a new Tobacco Products Directive – legally sound, but does it hit the spot?' (2013) 4 *European Law Review* 552.

### **III.i.f Medical qualifications**

An early form of EU health legislation regards mutual recognition of medical qualifications. It emerged as part of the 1992 programme of completing the internal market and is necessary to enable free movement of health workers. In line with mutual recognition once a health worker is qualified to practice in a single EU Member State, they are automatically qualified to work elsewhere in the EU, if minimal additional requirements (such as language skills) are met. Originally separate Directives were used for each profession but all health professions are now covered in a general Directive.<sup>60</sup>

### **III.i.g Health and safety at work**

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

### **III.i.h Free movement of services**

Finally, not only the provision of healthcare but also its consumption was subject to the free movement of services, even the provision of information regarding legal abortions.<sup>64</sup>

The freedom of services included the freedom to provide as well as to

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<sup>60</sup> European Parliament and Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22.

<sup>61</sup> More generally Vos (n 26).

<sup>62</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work [1989] OJ L183/1. Related rules were adopted at the time regarding workplaces; work equipment; personal protective equipment; manual handling of loads; and display screen equipment. The subsequent range of legislation under the heading health and safety is vast. A health-specific example is Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU [2010] OJ L134/66.

<sup>63</sup> European Parliament and Council Directive 2003/88/EC of 4 November 2003 concerning certain aspects of the organisation of working time [2003] OJ L299/9. Case C-151/02 *Jaeger* ECLI:EU:C:2003:437, [2003] ECR I-8389.

<sup>64</sup> Joined Cases 286/82 and 26/83 *Luisi and Carbone v Ministero del Tesoro* ECLI:EU:C:1984:35, [1984] ECR 377; Case C-159/90 *Grogan* ECLI:EU:C:1991:378, [1991] ECR I-4685. DR Phelan, 'Right to life of the Unborn v Promotion of Trade

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

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

#### **III.ii.a The integration context**

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

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

#### **III.ii.b Public health**

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

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in Services: the European Court of Justice and the normative shaping of the European Union' (1992) 55 *Modern Law Review* 670.

<sup>65</sup> See de Ruijter (n 12).

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

<sup>67</sup> European Parliament and Council Decision 1786/2002/EC of 23 September 2002 adopting a programme of Community action in the field of public health (2003–2008) [2002] OJ L271/1.

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

### III.ii.c The patient mobility case law

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

<sup>68</sup> European Parliament and Council Decision 1350/2007/EC of 28 October 2007 establishing a second programme of Community action in the field of health (2008–13) [2007] OJ L301/3.

<sup>69</sup> European Parliament and Council Regulation (EU) 282/2014 of 11 March 2014 on the establishment of a third programme for the Union's action in the field of health (2014–2020) and repealing Decision 1350/2007/EC [2014] OJ L86/1.

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

<sup>71</sup> TFEU, Article 168(1).

<sup>72</sup> TFEU, Article 168(2).

<sup>73</sup> TFEU, Article 168(3).

<sup>74</sup> TFEU, Article 168(4).

<sup>75</sup> TFEU, Article 168(6).

<sup>76</sup> TFEU, Article 168(5).

<sup>77</sup> TFEU, Article 168(7).

<sup>78</sup> Case C-158/96 *Kohll v Union des caisses de maladie* ECLI:EU:C:1998:171, [1998] ECR I-1931; Case C-120/95 *Decker v Caisse de maladie des employés privés* ECLI:EU:C:1998:167, [1998] ECR I-1831; Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, [2001] ECR I-5473; Case C-385/99 *Müller-Fauré and van Riet* ECLI:EU:C:2003:270, [2003] ECR I-4509; Case C-372/04 *Watts* ECLI:EU:C:2006:325, [2006] ECR I-4325.

<sup>79</sup> VG Hatzopoulos, 'Killing national health and insurance systems but healing patients? The European market for health care services after the judgments of the ECJ in *Vanbraekel* and *Peerbooms*' (2002) 39 *Common Market Law Review* 683;

systems the Member States came to favour aid rules to apply if an undertaking is granted a (selective) advantage from State resources with an effect on trade,<sup>80</sup> and competition. Where the service offered is simply a *quid pro quo* the State aid rules do not apply.<sup>81</sup> The Commission elaborated this rule in the so-called *Altmark* package, published in 2005 and recast in 2012.<sup>82</sup> Part of this package is a Commission Decision of 2012 that works as a block exemption for health providers.<sup>83</sup>

#### **III.ii.d Agencies**

The main agencies that are active in the realm of health include the European Medicines Agency (EMA, 1993), the European Monitoring Centre for Drugs and Drug Addiction (1995), the European Environment Agency (1993), the European Agency for Health and Safety at Work (1994) and the European Centre for Disease Control and Prevention (ECDC, 2005).<sup>84</sup>

#### **III.ii.e The Open Method of Coordination (OMC) and health**

The OMC was established by the Maastricht Treaty as an instrument for coordinating national economic policies through the use of recommendations and guidelines.<sup>85</sup> The ‘OMC toolbox’ comprises joint (EU)

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A Dawes, “‘Bonjour Herr Doctor’: National Healthcare Systems, the internal Market and cross-border medical care within the European Union” (2006) 33 *Legal Issues of Economic Integration* 167; G Davies, ‘The Community’s internal market-based competence to regulate healthcare: scope, strategies and consequences’ (2007) 14 *Maastricht Journal of European and Comparative Law* 215.

<sup>80</sup> *Ireland – Capital allowances for hospitals Commission* (Case N543/2001) Commission Decision of 27 February 2002.

<sup>81</sup> Case C-280/00 *Altmark* ECLI:EU:C:2003:415, [2003] ECR I-7747.

<sup>82</sup> E Szyszczak and JW van de Gronden (eds), *Financing Services of General Economic Interest: Reform and Modernization* (TMC Asser Press 2013); W Sauter, ‘The Altmark package Mark II: New rules for state aid and the compensation of services of general economic interest’ (2012) 33 *European Competition Law Review* 307.

<sup>83</sup> Commission Decision 2012/21/EU of 20 December 2011 on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest [2012] OJ L7/3.

<sup>84</sup> M Everson, C Monda and E Vos, (eds), *European Agencies in Between Institutions and Member States* (Kluwer Law International 2014); G Permanand and E Vos, ‘EU regulatory agencies and health protection’ in Mossialios and others (n 1) 134–185.

<sup>85</sup> B Kohler-Koch and B Rittberger, ‘Review article: the “governance turn” in EU studies’ (2006) 44 *Journal of Common Market Studies* 27.

objectives (political priorities), indicators, guidelines and targets, performance assessment and peer review of national plans.<sup>86</sup>

A ‘healthcare’ OMC was introduced in 2004<sup>87</sup> and combined in 2006 with the OMCs for social inclusion and pensions into a single, overarching process – the Social OMC.<sup>88</sup> This forms a counterbalance to economic growth as an EU objective under the Lisbon and Europe 2020 strategies. The application of the OMC to health is contentious, especially regarding attempts to measure health systems’ performance.<sup>89</sup>

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

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

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

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

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

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<sup>86</sup> Hervey and Vanhercke (n 1).

<sup>87</sup> Commission, ‘Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of coordination”’ (Communication) COM (2004) 304 final.

<sup>88</sup> For a brief discussion, see J Zeitlin and B Vanhercke, ‘Socializing the European Semester? Economic Governance and Social Policy Coordination in Europe 2020’ (Swedish Institute for European Policy Studies 2014) <[http://sieps.se/sites/default/files/Sieps%202014\\_7%20webb%20NY\\_2.pdf](http://sieps.se/sites/default/files/Sieps%202014_7%20webb%20NY_2.pdf)> accessed 1 June 2016.

<sup>89</sup> *ibid.*

<sup>90</sup> European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45. W Sauter, ‘Harmonization in health care: the EU patients’ rights Directive’ in B Cantillon, H Verschuren and P Ploscar (eds), *Social Inclusion and Social Protection in the EU: Interaction Between Law and Policy* (Intersentia 2012) 105–129.



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

### **III.iii.b Freedom of establishment**

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

### **III.iii.c The third health programme and Europe 2020**

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

### **III.iii.d The European Semester**

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

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<sup>91</sup> L Hancher and W Sauter, 'One step beyond? From Sodemare to Docmorris: The EU's freedom of establishment case law concerning healthcare' (2010) 47 *Common Market Law Review* 117.

<sup>92</sup> Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others (Doc Morris)* ECLI:EU:C:2009:316, [2009] ECR I-4171; Case C-531/06 *Commission v Italy* ECLI:EU:C:2009:315, [2009] ECR I-4103; Joined Cases C-570/07 and 571/07 *Blanco Pérez and Chao Gómez* ECLI:EU:C:2010:300, [2010] ECR I-04629; Case C-84/11 *Susisalo, Tuomaala and Ritala* ECLI:EU:C:2012:374.

<sup>93</sup> Regulation (EU) 282/2014 (n 69).

<sup>94</sup> Commission, 'EUROPE 2020. A Strategy for Smart, Sustainable and Inclusive Growth' (Communication) COM (2010) 2020 final.

<sup>95</sup> Commission, 'Common Actions for Growth and Employment: The Community Lisbon Programme' (Communication) COM (2005) 330 final.

<sup>96</sup> Greer and others (n 3) Chapter 5.

for achieving consistent policy recommendations among Member States as well as across EU programmes.<sup>97</sup>

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

### **III.iii.e The global context**

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

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<sup>97</sup> *ibid.*

<sup>98</sup> Commission, 'European Semester 2014: strengthening the recovery' (*European Commission*, 13 November 2013) <[http://europa.eu/rapid/press-release\\_IP-13-1064\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1064_en.htm)> accessed 1 June 2016. Greer and others (n 3) 124.

<sup>99</sup> For an overview of CSRs made to Member States between 2011–2013, see Greer and others (n 3) 124–5. Baeten and Ghailani include 2014 in their assessment R Baeten and D Ghailani, 'Beleid en recht van de Europese Unie: ontwikkelingen die het nationale gezondheidszorgbeleid beïnvloeden' (Observatoire Social Européen 2015) 11.

<sup>100</sup> *ibid.*

<sup>101</sup> Hervey and McHale (n 4) Chapters 15 and 16.

#### IV. CONCLUSION: WHAT IS THE DIRECTION OF TRAVEL FOR EU HEALTH LAW AND POLICY?

In conclusion, we agree that EU health law and policy is both a multi-level, multi-tiered and multi-governance system that is unique, and a policy field created by judges and markets rather than politics.<sup>102</sup> In spite of persistent political claims of subsidiarity in the interest of national sovereignty and solidarity, the scope of EU health law and policy has gradually been extended just as the broader process of EU integration itself expanded. This has not however<sup>103</sup> led to a formally coherent body of law and policy so much as a 'patchwork' of rules and policies developing in multiple directions. Looking towards the future there are two key related trends: demographic ageing and the shift towards chronic conditions mean problems of controlling costs become acute precisely as there is a shift in power in economic matters to EU institutions in the wake of the financial crisis.<sup>104</sup> Whether this will mainly result in cost cutting or in new and/or common solutions remains to be seen, although recent developments suggest that the direction of travel for EU health law and policy is determined both internally and externally.

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<sup>102</sup> Lamping (n 2).

<sup>103</sup> Contrary to the view of Hervey, see TK Hervey 'Telling stories about European Union Health Law: The emergence of a new field of law' (2016) *Comparative European Politics* DOI: 10.1057/cep.2016.4 <[www.palgrave-journals.com/cep/journal/vaop/ncurrent/full/cep20164a.html](http://www.palgrave-journals.com/cep/journal/vaop/ncurrent/full/cep20164a.html)> accessed 1 June 2016.

<sup>104</sup> Greer and others (n 3).