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978-0-521-74756-1 - Health Systems Governance in Europe: The Role of EU Law and Policy

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

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1 *Health systems governance in Europe: the role of European Union law and policy*

ELIAS MOSSIALOS, GOVIN PERMANAND,
RITA BAETEN AND TAMARA HERVEY

1. The scope and aims of this book

This volume assesses the impact of European Union (EU) policy and law on Member States' health systems and their governance in a number of key areas. In so doing, it builds on two earlier books¹ that sought to assess the changing legal and policy dynamics for health care in the wake of the European Court of Justice's (ECJ) seminal rulings in the *Kohll* and *Decker* cases.² These books showed that, despite widely held views to the contrary, national health care systems in the EU were not as shielded from the influence of EU law as originally thought.³ The explicit stipulations of Article 152 EC (as amended by the Amsterdam Treaty) that health is an area of specific Member State competence, and implicit understanding of the subsidiarity principle where policy is undertaken at the lowest level appropriate to its effective implementation, proved not to be the 'guarantees' of no EU interference in national health care services that they were often held to be. As the raft of legal cases and degree of academic attention that followed have shown, *Kohll* and *Decker* were certainly not the 'one-offs' many policy-makers hoped they would be.⁴ In fact,

¹ M. McKee, E. Mossialos and R. Baeten (eds.), *The impact of EU law on health care systems* (Brussels: PIE-Peter Lang, 2002); E. Mossialos and M. McKee (with W. Palm, B. Karl and F. Marhold), *EU law and the social character of health care* (Brussels: PIE-Peter Lang, 2002).

² Case C-120/95, *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR 1831; Case C-158/96, *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931.

³ T. Hervey and J. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004); M. McKee, E. Mossialos and P. Belcher, 'The influence of European Union law on national health policy', *Journal of European Social Policy* 6 (1996), 263–86.

⁴ K. Lenaerts and T. Heremans, 'Contours of a European social union in the case-law of the European Court of Justice', *European Constitutional*

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they are widely held to have set precedent in terms of the application of market-related rules to health care, which in turn ‘allowed the EU into’ the health care arena. As the growing number of national level analyses of the impact of EU law on health care systems highlight,⁵ it is clear then that careful scrutiny is needed in future in order to ensure the balance between creating and sustaining the internal market and the maintenance of a European social model in health care. So, ten years on from *Kobll* and *Decker*, how has the EU health care landscape changed, and what now are the pressing issues? These are two of the underlying questions with which this book is concerned.

In addressing such questions, and particularly in view of the need to balance the internal market with the European social model in health care, it is worth noting that there are three EU policy types, as discerned by Sbragia and Stolfi.⁶ Market-building policies emphasize liberalization and are generally regulatory, reflecting the ‘Community method’⁷ and with a leading role for the European institutions. These are the typical internal market, trade, competition and commercial policy related rules, including those around economic and monetary union (EMU). Market-correcting policies aim to protect citizens and producers from market forces and tend to be redistributive rather than regulatory, thereby involving intergovernmental bargaining. The Common Agricultural Policy and EU Structural Funds are examples. There are also market-cushioning policies, which are again regulatory in nature, and, as they are intended to mitigate the harm that economic activities can bring to individuals, are shared EU–Member State competences. We see this in the case of environmental policy

Law Review 2 (2006), 101–15; E. Mossialos and W. Palm, ‘The European Court of Justice and the free movement of patients in the European Union’, *International Social Security Review* 56 (2003), 3–29.

⁵ See, for example, D. Martinsen and K. Vrangbaek, ‘The Europeanization of health care governance: implementing the market imperatives of Europe’, *Public Administration* 86 (2007), 169–84.

⁶ A. Sbragia and F. Stolfi, ‘Key policies’, in E. Bomberg, J. Peterson and A. Stubb (eds.), *The European Union: how does it work?* Second edition (Oxford: Oxford University Press, 2008).

⁷ The ‘Community method’ refers to the institutional operating mode for the first pillar of the European Union and follows an integrationist logic with the following key features: the European Commission has the right of initiative; qualified majority voting is generally employed in the Council of Ministers; the European Parliament has a significant role reading and co-legislating with the Council; and where the European Court of Justice ensures the uniform interpretation and application of Community law.

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and occupational health and safety. Economic integration, which began with market-building policies, has, given the pressure it exerts also in other areas, seen the development of market-correcting and, now, market-cushioning policies at EU level. This implies a recognition of the welfare and social policy impacts of policies taken from an otherwise economic perspective.

In view of the *Kohll* and *Decker* ‘fallout’, and given the considerable autonomy exercised by the Commission in this area, our focus in this book is on the first category of policy – market-building – and the effects this has on health policy. We seek to examine these effects, what they mean from the perspective of EU law and the ECJ’s role, and their impact on Member State health care systems. In particular, competition law, which is a core EU policy area (where the Commission can be very active), falls under the market-building category and has a profound impact on EU health policy. Market-correcting and market-cushioning policies are not so relevant to health policy given that the EU has little direct competence here – with some ECJ rulings corresponding to the former, and some aspects of public health falling under the latter.

Involving a cadre of leading experts, this volume thus proposes an interdisciplinary treatment of the subject-matter, drawing primarily from the legal and policy spheres. Aimed at an informed audience, the contributors offer a critical examination in crucial and emerging areas of EU law and health care, as well as assessing potential policy implications given changing governance dynamics⁸ at the EU level. Among the more specific questions and issues addressed are: what are key areas of concern in health care and law at the EU and Member State levels? How is the Court’s role viewed and how has it developed? What do the increasing number of EU soft law instruments and measures

⁸ By ‘governance’, we mean all ‘steering’ carried out by public bodies that seeks to constrain, encourage or otherwise influence acts of private and public parties. We also include structures that ‘delegate’ the steering capacity to non-public bodies (i.e. professional associations). By ‘steering’, we mean to include binding regulatory measures (laws) and other measures that are sometimes called ‘new governance’ measures – that is, ‘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-control-type legal institutions’. See 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: Hart, 2006).

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mean for health care? What challenges and opportunities exist? And what might the future hold in terms of reconciling continued tensions between economic and social imperatives in the health (care) domain? The book thus provides not only a broad understanding of the issues, but also analyses of their specific interpretation and application in practice through the use of issue-specific chapters/case-studies. And while it is clear that such a volume cannot be exhaustive in its coverage, and some issues or policy areas have not been included, each chapter addresses a topical area in which there is considerable debate and potential uncertainty. The chapters thus offer a comprehensive discussion of a number of current and emerging governance issues, including regulatory, legal, ‘new governance’ and policy-making dynamics, and the application of the legal framework in these areas.

The remainder of this chapter is divided into two sections. The first offers an initial snapshot of the current status of health (care) policy in the EU before examining specific challenges facing policy-makers. While the focus of the book is less about theory than about the legal situation and its policy impact, some elements from the relevant theoretical literature are raised in order to help better set the scene. These relate to the different (in part explanatory) perspectives on how policies have developed (why and why not) and where the constraints lie. The second section reflects the structure of the remainder of the volume, providing an introduction to the content of each chapter, as well as an in-depth discussion of the main findings and policy relevance in each case. This opening chapter is therefore written both as an introduction to the book, and as a key contribution to the volume in its own right.

2. EU health policy: contradictions and challenges

Health policy in the European Union (EU) has a fundamental contradiction at its core. On the one hand, the EC Treaty, as the definitive statement on the scope of EU law, states explicitly that health care is the responsibility of the Member States.⁹ On the other hand, as Member State health systems involve interactions with people (e.g. staff and patients), goods (e.g. pharmaceuticals and devices) and services (e.g. provided by health care funders and providers), all of which are granted freedom of movement across

⁹ Article 152(5) EC.

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borders by the same Treaty,¹⁰ many national health activities are in fact subject to EU law and policy.¹¹ For instance, when national health systems seek to purchase medicines or medical equipment, or to recruit health professionals – what would appear to be clear local health care policy choices – we see that their scope to act is now determined largely by EU legislation.¹² Further, when the citizens of a Member State travel outside their national frontiers, they are now often entitled to receive health care should they need it, and have it reimbursed by their home (national) authority. We thus have a situation where national health care systems officially fall outside EU law, but elements relating to their financing, delivery and provision are directly affected by EU law.

In addition to this overarching contradiction, the EU has, since the 1992 Maastricht Treaty, been required to ‘contribute to the attainment of a high level of health protection’ for its citizens.¹³ This is an understandable and important objective in its own right, and there is compelling evidence that access to timely and effective health care makes an important contribution to overall population health – so-called ‘amenable mortality’.¹⁴ But, notwithstanding the EU’s commitment to various important public health programmes and initiatives, how are EU policy-makers to pursue this goal of a high level of health attainment when they lack Treaty-based competences to ensure that national health systems are providing effective care to their populations? How can they ensure that health systems promote a high level of health and, indeed, social cohesion, and that they comply with the single market’s economic rules (particularly regarding the free movement principles) when health care is an explicit Member State competence?

In this regard, EU health (care) policy can be seen to be affected by what Scharpf terms the ‘constitutional asymmetry’ between EU policies to promote market efficiency and those to promote social

¹⁰ Articles 18, 39, 43, 28 and 49 EC.

¹¹ McKee, Mossialos and Baeten (eds.), *The impact of EU law*, above n.1; Mossialos and McKee, *EU law and the social character of health care*, above n.1.

¹² Hervey and McHale, *Health law*, above n.3; McKee, Mossialos and Belcher, ‘The influence of European Union law’, above n.3.

¹³ Article 3(1)(p) EC.

¹⁴ E. Nolte and M. McKee, *Does health care save lives? Avoidable mortality revisited* (London: Nuffield Trust, 2004).

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protection.¹⁵ That is, the EU has a strong regulatory role in respect of the former, but weak redistributive powers as requisite for the latter. This can be ascribed to the Member States' interest in developing a common market while seeking to retain social policy at the national level. More widely, this conforms with Tsoukalis' view that while welfare and solidarity remain national level prerogatives, many issues affecting the daily life and collective prosperity of individuals are dependent on EU level actions, mainly in economic policy spheres.¹⁶ This reflects what he identifies as the 'gap' between politics and economics in the EU system: 'the democratic process of popular participation and accountability has not caught up with this development [an expanding EU policy agenda driven primarily from an economic perspective]'.¹⁷ Rather than a strong political base, therefore, the EU system relies on an increasingly complex institutional arrangement, a growing depoliticization of the issues, and rules set by legislators and experts. This gap is an important reflection on the EU as a whole – in part encompassing what others have identified as the 'democratic deficit' of the EU¹⁸ – and appears of especial relevance to health and social policy where the economic impetus has set much of the path in the absence of a Treaty-based (political) mandate.

In the health (care) arena, we further see that the constitutional asymmetry is exacerbated by a dissonance between the Commission's policy-initiating role in respect of single market free movement concerns and the Member States' right to set their own social priorities. Wismar and colleagues have noted the 'subordinate role' of health within the broader European integration process,¹⁹ and others have highlighted that health policy in the EU has, in large part, evolved within the

¹⁵ F. Scharpf, 'The European social model: coping with the challenges of diversity', *Journal of Common Market Studies* 40 (2002), 645–70.

¹⁶ L. Tsoukalis, *What kind of Europe?* (Oxford: Oxford University Press, 2005).

¹⁷ *Ibid.*, 42.

¹⁸ For a detailed discussion on the merits and failings of the democratic deficit argument in respect of the EU, see A. Follesdal and S. Hix, 'Why there is a democratic deficit in the EU: a response to Majone and Moravcsik', European Governance Papers (EUROGOV) No. C-05–02 (2005), www.connex-network.org/eurogov/pdf/egp-connex-C-05–02.pdf.

¹⁹ M. Wismar, R. Busse and P. Berman, 'The European Union and health services – the context', in R. Busse, M. Wismar and P. Berman (eds.), *The European Union and health services: the impact of the single European market on Member States* (Amsterdam: IOS Press, 2002).

context of the economic aims of the single market programme.²⁰ This has led to a situation in which the Member States have conceded the need for the EU to play a role in health (care), even if only a limited one, and in ill-defined circumstances. As Tsoukalis' view on the politics–economics 'gap' allows us to highlight, this is in part because the EU continues to lack a sufficient political base, not just in health policy but across the board. It has also seen an ad hoc development of measures and, crucially, an ongoing tension between economic and social priorities in the provision of health care. This is in stark contrast to environmental protection, as another area of EU policy, where the EU is given explicit competence under Title XIX of the EC Treaty.²¹ This is not to equate health/social policy and environmental policy. But it is simply to highlight that a greater policy mandate for areas outside (though related to) the single market could be accorded to the EU via the Treaties if desired, and that the asymmetry need not be as clear or as limiting as it appears to be for health. This suggests a redefinition or, at least, a reorganization and re-prioritization of health at the EU level, and one that would change current policy-making dynamics.

A. Constraints and parameters: theoretical perspectives on EU health policy-making

Beyond the constitutional asymmetry, which represents an overarching constraint on the development of health (care) policies, there are other perspectives that are useful in explaining the conditions under which policies can be pursued and implemented. And while a theoretical treatment of the issues or the development of an encompassing conceptual framework²² is not our aim, we can discern three main perspectives that can help us to better understand where policies can or cannot be agreed.

²⁰ See, for instance, W. W. Holland, E. Mossialos and G. Permanand, 'Public health priorities in Europe', in W. W. Holland and E. Mossialos (eds.), *Public health policies in the European Union* (Aldershot: Ashgate, 1999); B. Duncan, 'Health policy in the European Union: how it's made and how to influence it', *British Medical Journal* 324 (2002), 1027–30.

²¹ Articles 174–6 EC.

²² The evolution of the European Community into an organization with supranational qualities has been explored extensively in the academic literature on European integration. For an analysis of the theories and debates that emerged see, for example, B. Rosamond, *Theories of*

The first is a group of rationalist perspectives,²³ where, for instance, Wilson's 'politics of policy' typology²⁴ provides a useful illustrative backdrop.²⁵ Here, policy-making is divided into four categories according to the costs and benefits to the affected stakeholders: majoritarian politics (diffuse/diffuse); client politics (diffuse/concentrated); entrepreneurial politics (concentrated/diffuse); and interest group politics (concentrated/concentrated). In the case of EU health (care) policy, we can define the main stakeholders as the Commission (in some cases, specific Directorates-General), the Member States and, to a degree, the European Court of Justice and industry (in particular, the health-related industries). These actors all have vested interests – often in specific outcomes – and either directly contribute to, or else indirectly affect, policy development. If we are to consider key elements of the EU's current health policies and competences, we see that aspects of public health policy are majoritarian; much pharmaceutical policy is client-based; occupational health and safety or even food safety is entrepreneurial; while the Commission has very little say over those areas that are interest group-oriented and thus fall within the purview of the Member States. It may be the case that aspects of soft law, and the open method of coordination in particular (see below), can play a role in addressing issues within this latter category.

European integration (Basingstoke: Macmillan, 2000); M. Cini and A. Bourne, *European Union studies* (Basingstoke: Palgrave Macmillan, 2006); M. Eilstrup-Sangiovanni, *Debates on European integration* (Basingstoke: Palgrave Macmillan, 2006); I. Bache and S. George, *Politics in the European Union* (Oxford: Oxford University Press, 2006), Chapters 1–4. See also E. Mossialos and G. Permanand, 'Public health in the European Union: making it relevant', LSE Health Discussion Paper No. 17 (2000), for a discussion specific to EU health competencies in respect of theories of European integration.

²³ T. Börzel and T. Risse, 'When Europe hits home. Europeanization and domestic change', *European Integration Online Papers* 4 (2000), <http://eiop.or.at/eiop/texte/2000-015a.htm>; Bache and George, *Politics in the European Union*, above n.22, Chapters 1–2.

²⁴ J. Q. Wilson, *The politics of regulation* (New York: Basic Books, 1980).

²⁵ This is an approach that has already been used to explain the development and orientation of EU public health policy. See Mossialos and Permanand, 'Public health in the European Union', above n.22; G. Permanand and E. Mossialos, 'Constitutional asymmetry and pharmaceutical policy-making in the European Union', *Journal of European Public Policy* 12 (2005), 687–709.

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Given our interest in EU law specifically, as the Court's role in health policy is primarily oriented towards free movement, we see that client-based and entrepreneurial politics are the most feasible avenues of action for the Court (e.g., anti-discrimination or cross-border care). The Court steers clear of majoritarian and interest group politics, such as where financial benefits or other redistributive policies are involved, and where it is for the Member States to agree between themselves. Indeed, the Court may deliver judgements relating to the nature of the Member States' social security systems, but has not sought to rule against them in addressing issues such as reimbursement and pricing, except from an EU-wide free movement perspective.²⁶

A second group of perspectives is oriented around constructivism,²⁷ one where the gradual development and building up of capacity and policies is possible. We see this best reflected in the so-called 'new modes of governance' approaches, where Member States seek mutual learning and progress on sensitive and potentially partisan issues via benchmarking and sharing of best practices. The open method of coordination (OMC) is a clear example, and is in stark contrast to the interest group dynamic under the politics of policy view, where the Member States may engage directly with one another, albeit behind the scenes rather than in a transparent manner, and often without much concrete evidence of change. Issues of entrepreneurial politics, with their concentrated costs but diffuse benefits, may also lend themselves to the OMC.

A third view is the broader one represented by the 'grand' international relations theories of European integration. Inter-governmentalism,²⁸ for instance, which asserts the pre-eminence of the governments of the Member States in the integration process (i.e.,

²⁶ Case C-238/82, *Duphar v. Netherlands* [1994] ECR 523. The *Duphar* case has been widely invoked to support the argument that Community law does not detract from the powers of the Member States to organize their social security systems. See D. Pieters and S. van den Bogaert, *The consequences of European competition law for national health policies* (Antwerp: Maklu Uitgevers, 1997).

²⁷ Börzel and Risse, 'When Europe hits home', above n.23; Bache and George, *Politics in the European Union*, above n.22, pp. 27–8, 43–7.

²⁸ A. Moravcsik, 'Preferences and power in the European Community: a liberal intergovernmentalist approach', *Journal of Common Market Studies* 31 (1993), 473–524.

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that national governments remain very much at the helm in deciding the course of Europeanization), distinguishes between issues deemed to be of high politics (defence, foreign policy) and those of low politics (economic interests, welfare policy). The latter are much easier to secure Member State agreement on than the former. And while the distinction would not appear to hold true for health policy as an ostensibly low politics issue over which agreement should be reachable, it is the case that Member States are more or less agreed on the social welfare underpinnings (low politics) but not so over the health care planning and financing elements (high politics). It is these latter elements that in large part represent the stumbling blocks given the loss of national control and consequent budgetary implications of EU competence here. In the case of neo-functionalism,²⁹ as the other grand international relations theory in respect of the European Union, we see that its central tenet of ‘spillover’ also carries some explanatory value. Spillover asserts that the pressure to integrate or harmonize in one sector can spill over or demand similar integration in another sector; this seems most relevant to the economic and free movement imperatives of the single market programme, which extended into social policy areas as well. For instance, we have seen how, in order to avoid a situation of social and ecological dumping,³⁰ and to establish a level playing field for business, the European Community sought to pre-emptively avoid a weakening of countries’ health and safety legislation by explicitly strengthening such legislation for coal and steel workers under the original European Coal and Steel Community (ECSC) and European Economic Community (EEC) Treaties. This has since evolved to broader health protection for EU citizens more widely. These bird’s eye view perspectives often miss the detail, particularly at the level of policy-making itself, but they do help us to understand the broader roles and interests of different stakeholders – be they those of the European institutions or of stakeholders within the Member States – and they help to establish an overall contextual backdrop to the more immediate political and legal discussions.

²⁹ E. Haas, *The uniting of Europe: political, social and economic forces* (Palo Alto: Stanford University Press, 1968).

³⁰ V. Eichener, ‘Effective European problem-solving: lessons from the regulation of occupational safety and environmental protection’, *Journal of European Public Policy* 4 (1997), 591–608.