

Health Systems Governance in Europe

The Role of European Union Law and Policy

Edited by

Elias Mossialos, Govin Permanand, Rita Baeten and Tamara K. Hervey



HEALTH ECONOMICS,
POLICY AND MANAGEMENT

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Health Systems Governance in Europe

There is a fundamental contradiction at the core of health policy in the European Union (EU) that makes it difficult to draw a line between EU and Member State responsibilities. This raises a number of difficult questions for policy makers and practitioners as they struggle to interpret both ‘hard’ and ‘soft’ laws at EU and Member State level and to reconcile tensions between economic and social imperatives in health care. The book addresses these complex questions by combining analysis of the underlying issues with carefully chosen case studies that illustrate how broader principles are played out in practice. Each chapter addresses a topical area in which there is considerable debate and potential uncertainty.

The book thus offers a comprehensive discussion of a number of current and emerging governance issues in EU health policy, including regulatory, legal, ‘new governance’ and policy-making dynamics, and the application of the legal framework in these areas.

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The Role of European Union Law
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Contents

<i>List of figure</i>	<i>page</i> vii
<i>List of tables</i>	viii
<i>List of boxes</i>	ix
<i>List of contributors</i>	x
<i>Foreword</i>	xii
<i>Acknowledgments</i>	xv
<i>List of abbreviations</i>	xvii
1 Health systems governance in Europe: the role of European Union law and policy Elias Mossialos, Govin Permanand, Rita Baeten and Tamara Hervey	1
2 Health care and the EU: the law and policy patchwork Tamara Hervey and Bart Vanhercke	84
3 EU regulatory agencies and health protection Govin Permanand and Ellen Vos	134
4 The hard politics of soft law: the case of health Scott L. Greer and Bart Vanhercke	186
5 Public health policies Martin McKee, Tamara Hervey and Anna Gilmore	231
6 Fundamental rights and health care Jean McHale	282
7 EU competition law and public services Tony Prosser	315

8	EU competition law and health policy Julia Lear, Elias Mossialos and Beatrix Karl	337
9	Public procurement and state aid in national health care systems Vassilis Hatzopoulos	379
10	Private health insurance and the internal market Sarah Thomson and Elias Mossialos	419
11	Free movement of services in the EU and health care Wouter Gekiere, Rita Baeten and Willy Palm	461
12	Enabling patient mobility in the EU: between free movement and coordination Willy Palm and Irene A. Glinos	509
13	The EU legal framework on e-health Stefaan Callens	561
14	EU law and health professionals Miek Peeters, Martin McKee and Sherry Merkur	589
15	The EU pharmaceuticals market: parameters and pathways Leigh Hancher	635
	<i>Bibliography</i>	683
	<i>Index</i>	745

Figure

3.1 Risk analysis

page 165

Tables

3.1 Agencies of the EU	<i>page</i> 141
5.1 Major EU tobacco control directives	259
10.1 Functional classification of private health insurance markets	422
10.2 Private health insurance in the EU: contribution to total and private expenditure on health, 1996 and 2005	424

Boxes

4.1 Varieties of new governance in health	<i>page</i> 194
4.2 Common objectives with regard to health care	207
4.3 Overarching objectives covering the three strands of the open method of coordination for social protection and social inclusion	208
4.4 Preliminary portfolio of indicators in the health care open method of coordination	210
4.5 Target setting in the framework of the open method of coordination	221
5.1 Resources available under the Public Health Programme 2008–13	245
5.2 European networks involved in surveillance and control of communicable diseases	254
14.1 Experience in implementing the European Working Time Directive in the United Kingdom	626
14.2 Experience in implementing the European Working Time Directive in Hungary	628

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Foreword

It is a great pleasure to introduce this volume edited by Elias Mossialos, Govin Permanand, Rita Baeten and Tamara Hervey. It is a volume which continues the success of two earlier books commissioned by the Belgian government and published by Peter Lang Publishing Group in 2002.¹ The topic of this contribution is a crucial one. Indeed, one can hardly imagine a subject closer to the lives of European Union (EU) citizens than an exploration of how EU law and policy has influenced, and will continue to influence, the health systems of the 27 Member States. This two-dimensional perspective means that this work will certainly be studied with great interest by all concerned with the functioning of the EU as well as by those wanting to discover more about national health systems.

In principle, in light of Article 152 of the EC Treaty, national authorities are solely responsible for health care. Yet, though the Member States are free to decide how to deliver and organize health services, they must do so in compliance with other aspects of the Treaty, in particular with the fundamental freedoms and elements of competition law. Put differently, national health systems are not enclaves of national sovereignty insulated from European market integration. While EU legislators may not regulate health care as a means of promoting social cohesion, they may, however, enact legislation relating to those aspects affecting the establishment and functioning of the internal market. Given that national health systems are deeply rooted in social solidarity and welfare, the “constitutional asymmetry” (to borrow the term used by Fritz Scharpf) laid down in the Treaty gives rise to important tensions.

¹ Mossialos, Elias and McKee, Martin (2002) *The influence of EU law on the social character of health care systems*. P.I.E. – Peter Lang, Brussels; and McKee, M and Mossialos, Elias and Baeten, R (2002) *The impact of EU law on health care systems*. Peter Lang Publishers, Brussels.

Outside the framework of the internal market, not only is EU legislative action to promote social protection founded on a weak Treaty basis, but it is also hard to achieve politically. Taking the view that the Europeanization of health care might be excessively market driven, the Member States fear that transferring too much power to the EU would amount to losing control over welfare entitlements. Besides, due to the large diversity among the different national (and regional) health systems, the significant economic differences among the Member States, and citizens' national allegiances, reaching an EU agreement more ambitious than adopting general guidelines seems a challenging endeavour. Accordingly, it is not surprising that a political deadlock has forced the European Court of Justice (ECJ) to step forward by incorporating social protection considerations when evaluating the validity of limitations on market integration. However, in spite of its best efforts to reconcile the fundamental freedoms and competition provisions with social solidarity, the ECJ may only provide partial answers on a case-by-case basis. Additionally, the ECJ must respect the constitutional settings put in place by the EC Treaty. As a consequence, its capacity to enhance social cohesion at the expense of market integration is somewhat limited.

These constitutional and political restrictions imposed on the "*méthode communautaire*" have given rise to alternative modes of governance at EU level, which are friendlier towards the aspirations of a Social Europe. For instance, the creation of EU agencies, such as the European Medicines Agency (EMA) or the European Food Safety Authority (EFSA), and the adoption of soft law have contributed to bringing clarity into the realm of health care. Because they are less hierarchical, not legally binding, and less focused on attaining uniformity, these new modes of governance encourage the Member States to engage in a constructive dialogue. They are not, however, free from shortcomings. Doubts may arise regarding the normative effectiveness of sharing information, dissemination of best practices, and mutual learning by monitoring. Likewise, these alternatives may not suffice to reduce drastically the economic and political differences between the Member States. Most importantly, these new modes of governance appear to bypass traditional accountability checks which are responsible for ensuring democratic legitimacy.

As a result, when looking at the interaction between the EU and national health systems, the picture that then emerges is that of a

complex patchwork composed of legislation, case-law, differing policy approaches and priorities, and new modes of governance. Additionally, this complexity is further intensified by the current trend towards liberalizing health care as a response to rising costs, greater expectations from civil society, and changes in the population pyramid. Indeed, in the domain of health care there is currently no clear-cut division between activities reserved to the public sphere and activities governed by the market: the vertical (EU versus Member States) and horizontal (regulation versus market) dimensions of national health systems thus become more intertwined.

In a multidisciplinary approach that reflects the operation and governance of national health systems in the EU, this book provides an up-to-date, thorough and innovative insight into how political actors, courts and stakeholders have coped with the challenges of the internal market and social solidarity trade-offs. Owing to the quality of the contributors, this volume offers a critical assessment throughout its 15 chapters which clearly illuminates the virtues and vices of the decisions taken by the EU from both policy and legal angles. Legal arguments are placed in a historical, factual and political context that enables the reader to better understand how law is influenced by politics and vice versa. Very much appreciated is the special attention paid to future developments and proposed strategies to improve the current situation.

On all accounts, legal and policy scholars and practitioners will benefit from this book.

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European Communities

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It remains the case that the views expressed in this book are those of the authors alone and should not be taken as representing those of any of the organizations with which they are affiliated.

Elias Mossialos, Govin Permanand,
Rita Baeten and Tamara Hervey.

Abbreviations

AIM	Association Internationale de la Mutualité
All ER	All England Reports
ASL	Local Health Authority (Italy)
AURE	Alliance of United Kingdom Health Regulators on Europe
BAT	British American Tobacco
BEPA	Bureau of European Policy Advisors
BSE	bovine spongiform encephalopathy
CAT	Competition Appeal Tribunal
CECCM	Confederation of European Community Cigarette Manufacturers
CFI	Court of First Instance
CFT	Commission for Fair Trading (Malta)
CHMP	Committee for Medicinal Products for Human Use
CME	continuing medical education
COMP	Committee for Orphan Medicinal Products
Comp AR	Competition Appeal Reports
CPD	continuing professional development
CPMP	Committee for Proprietary Medicinal Products
CSOPH	Committee of Senior Officials on Public Health
DCA	Dutch Competition Authority
DG	Directorate-General
DG Agriculture	Directorate-General for Agriculture and Rural Development
DG Competition	Directorate-General for Competition
DG Environment	Directorate-General for Environment, Nuclear Safety and Civil Protection
DG Industry	Directorate-General for Enterprise and Industry

DG Internal Policies	Directorate-General for Internal Policies of the Union
DG Justice	Directorate-General for Justice, Freedom and Security
DG MARKT	Directorate-General for the Internal Market and Services
DG Research	Directorate-General for Science, Research and Development
DG SANCO	Directorate-General for Health and Consumer Protection
DG Social Affairs	Directorate-General for Employment, Social Affairs and Equal Opportunities
DHA	Dutch Healthcare Authority
DR	European Commission of Human Rights Decisions and Reports
DRG	diagnosis-related group
EACCME	European Accreditation Council for Continuing Medical Education
EACP	Europe against Cancer Programme
EC	European Community
EC Treaty	Treaty establishing the European Community
ECC	European Commercial Cases
ECDC	European Centre for Disease Prevention and Control
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
ECJ	European Court of Justice
ECN	European Competition Network
ECOFIN	Economic and Financial Affairs Council
ECR	European Court Reports
ECtHR	European Court of Human Rights
EEA	European Economic Area
EEC	European Economic Community
EEC Treaty	Treaty establishing the European Economic Community
EFPIA	European Federation of the Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EGA	European Generics Medicines Association

EHIC	European Health Insurance Card
EHR	electronic health records
EHRR	European Human Rights Reports
EISS	European Influenza Surveillance Scheme
EMA	European Medicines Agency
EMU	Economic and Monetary Union
EPC	Economic Policy Committee
EPC/AWG	Economic Policy Committee/Ageing Working Group
EPHA	European Public Health Alliance
EPIET	European Programme for Intervention Epidemiology Training
EPP	evaluation of professional practices
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EPSU	European Federation of Public Service Unions
ERDF	European Regional Development Fund
ESF	European Social Fund
ESIP	European Social Insurance Partners
ESM	European Social Model
EuroHIV	European Centre for the Epidemiological Monitoring of AIDS
EU-SILC	European Union Statistics on Income and Living Conditions
EWHC (Admin)	England & Wales High Court (Administrative Court)
EWHC (Ch)	England & Wales High Court (Chancery Division)
EWRS	Early Warning and Response System
Fam	Law Reports, Family Division
FCA	Finnish Competition Authority
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration (USA)
FENIN	Federación Española de Empresas de Tecnología Sanitaria
FFSA	French Federation of Insurance Companies
FT	Foundation Trust (United Kingdom)
FVO	Food and Veterinary Office
GCA	German Competition Authority

GM	genetically modified
GMOs	genetically-modified organisms
GP	general practitioner
GSK	GlaxoSmithKline
HCC	Hungarian Competition Council
HFEA	Human Fertilisation and Embryology Authority
HIA	Health Insurance Authority (Ireland)
HLG	High Level Group on Health Services and Medical Care
HLPR	High Level Process of Reflection
HMPC	Committee on Herbal Medicinal Products
HOSPEEM	European Hospital and Healthcare Employers Association
IAA	Italian Antitrust Authority
IARC	International Agency for Research on Cancer
ICT	information and communication technology
IESC	Supreme Court of Ireland
IHR	International Health Regulations
IMS	Intercontinental Marketing Services
IVF	in vitro fertilization
JTI	Japan Tobacco International
MEP	Member of the European Parliament
MRP	mutual recognition procedure
NAP/Inclusion	National Action Plan on Social Inclusion
NBTC	National Blood Transfusion Centre
NCA	national competition authority
NCE	new chemical entity
NHA	National Health Accounts of the World Health Organization
NHS	National Health Service (United Kingdom)
NIHDI	National Institute for Health and Disability Insurance (Belgium)
NMG	new modes of governance
NTPF	National Treatment Purchase Fund (Ireland)
OECD	Organisation for Economic Co-operation and Development
OFT	Office of Fair Trading (United Kingdom)
OJ	Official Journal
OMC	open method of coordination

OTC	over the counter
PASA	Purchasing and Supply Agency (United Kingdom)
PCT	Primary Care Trust (United Kingdom)
PDCO	Paediatric Committee
PFI	Private Funding Initiative
PHEA	Executive Agency for the Public Health Programme
PMI	private medical insurance
PPP	public–private partnership
PPRS	price and profit regulation scheme
QB	Law Reports, Queen’s Bench
R&D	research and development
RMS	reference Member State
SCA	Swedish Competition Authority
SCF	Scientific Committee for Food
SEA	Single European Act
SEM	single European market
SGEI	services of general economic interest
SIGI	services of general interest
SHA	Strategic Health Authority (United Kingdom)
SHA-OECD	System of Health Accounts of the Organisation for Economic Co-operation and Development
SHARE	Supporting and Structuring HealthGrid Activities and Research in Europe
SHI	Social Health Insurance (Germany)
SPC	Social Protection Committee
SPaC	supplementary patent certificate
SSGI	social services of general interest
StCF	Standing Committee on Foodstuffs
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization
WLR	Weekly Law Reports

