

European **Observatory** on Health Systems and Policies Series

Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality

Edited by
Elias Mossialos
Monique Mrazek
Tom Walley

Regulating Pharmaceuticals In Europe

Sally Shorthose



Regulating Pharmaceuticals In Europe:

Regulating Pharmaceuticals In Europe: Striving For Efficiency, Equity And Quality Mossialos, Elias, Mrazek, Monique, Walley, Tom, 2004-06-01 This thoughtful and comprehensive book represents the best work I have seen on the current situation concerning medication policies in the EU. It is not just that this is a very up to date compendium of facts and data across a wide variety of domains that impact on pharmaceutical regulation. The book is also strong on analysis of those facts as well. Jerry Avorn, Harvard Medical School. This book offers a comprehensive examination of approaches to manage pharmaceutical expenditures in Europe. It is a must read for those who seek to understand and navigate the changing regulatory environment for medicines in the European Union. Bernie O'Brien, McMaster University, Canada. The rising cost of pharmaceutical expenditures in many European countries is of concern to governments required to make effective use of health care budgets. Taking a broad perspective that encompasses institutional, political and supranational aspects of pharmaceutical regulation, this book examines approaches used to manage pharmaceutical expenditure across Europe and what impact these strategies have had on efficiency, quality, equity and cost of pharmaceutical care. **Regulating Pharmaceuticals in Europe** is an important book for students of health policy, regulation and management and for health managers and policy makers. The editors: Elias Mossialos is Brian Abel-Smith, Professor of Health Policy at the London School of Economics and Political Science and a Research Director of the European Observatory on Health Systems and Policies; Monique Mrazek is a Health Economist, Europe and Central Asia region for the World Bank and formerly a Research Officer in Health Economics for the European Observatory on Health Systems and Policies; Tom Walley is Professor of Clinical Pharmacology at the University of Liverpool and Director of the UK National Health Technology Assessment Programme. Contributors: Julia Abelson, Christa Altenstetter, Vittorio Bertele, Christine Bond, Marcel L. Bouvy, Colin Bradley, Steve Chapman, Anna Dixon, Michael Drummond, Pierre Durieux, Edzard Ernst, Armin Fidler, Eric Fortess, Richard Frank, Silvio Garattini, Leigh Hancher, Ebba Holme, Hansen, Steve Hudson, Kees de Jonchere, Panos Kanavos, Sjoerd Kooiker, Jean Marc Leder, Graham Lewis, Donald W. Light, Alistair McGuire, Elias Mossialos, Monique Mrazek, Maria Pia Orru, Govin Permanand, Guenka Petrova, Munir Pirmohamed, Dennis Ross, Degnan, Frans Rutten, Steven Soummerai, David Taylor, Sarah Thomson, Tom Walley. **Regulating**

Medicines in Europe John Abraham, Graham Lewis, 2014-04-04 This Book explains and investigates how medicines are controlled in Europe, especially the EU. Based on penetrating documentary and interview research with the pharmaceutical industry, regulators and consumer organisations, it provides the first major critical examination of the new Europeanised systems of medicine regulation. The authors argue that the drive to produce and approve more drugs more quickly for a single European market dominates other considerations such as improvements in democratic accountability, the independence of regulators and scientific expertise from commercial interests and drug safety testing and surveillance.

EU Pharmaceutical Regulation Govin Permanand, 2006-09-05 This book provides an analysis of European Union

pharmaceutical regulation from a policy making perspective The focus is on how the often conflicting agendas of the pharmaceutical industry the EU member states the European Commission and consumer interests are reconciled within the context of regulatory outcomes having to serve public health healthcare and industrial policy needs within the single market In providing a unique perspective on how and why EU pharmaceutical policy is made the book will be of interest to academics students and policy practitioners interested in EU policy making regulation and public policy analysis The Interplay of Global Standards and EU Pharmaceutical Regulation Sabrina Röttger-Wirtz, 2021-08-26 This book analyses the implementation of global pharmaceutical impact standards in the European risk regulation framework for pharmaceuticals and questions its legitimacy Global standards increasingly shape the risk regulation law and policy in the European Union and the area of pharmaceuticals is no exception to this tendency As this book shows global pharmaceutical standards set by the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use ICH after they are adopted through the European Medicines Agency EMA are an important feature of the regulatory framework for pharmaceuticals in the EU In addition to analysing the influence of these global standards in the EU legal and policy framework the book questions the legitimacy of the Union's reliance on global standards in terms of core administrative law principles of participation transparency and independence of expertise It also critically examines the accountability of the European Commission and the European Medicines Agency as participants in the global standard setting and main implementation gateway of the global pharmaceutical standards into the European Union **Guide to EU and UK Pharmaceutical Regulatory Law** Sally Shorthose, 2023-01-10 In the European Union EU its Member States and the United Kingdom UK post Brexit as elsewhere the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but also safe This useful volume lays out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert authors from the law firm Bird and Partners stages and standards for creating a product dossier obtaining a marketing authorisation how and when an abridged marketing authorisation procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials orphan medicinal products biologicals and biosimilars homeopathic herbal and similar medicines medical devices pandemics epidemics and vaccines pharmacovigilance parallel trade advertising and relevant competition law intellectual property rights and data protection regulation In addition sample forms and URLs for the most important reference materials are included Pharmaceutical lawyers and regulatory advisers both in house and in private practice will welcome this unique book It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations Guide to EU Pharmaceutical Regulatory Law Sally Shorthose, 2014 In the European Union and its Member States as elsewhere the marketing of pharmaceuticals has

become subject to an increasingly complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but safe This useful volume lays out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert authors from the law firm Bird Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance offering comprehensive and unambiguous guidance at every stage 00Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe from its underlying rationales to the relevant committees and agencies each of fifteen incisive chapters examines a particular process or subject

Implications of Future EU Policy on the Provision of Medicines and on Actors in the European Pharmaceutical Sector Ewout van Ginneken,2010 *The Autonomy of European Union Agencies* Martijn Groenleer,2009 *Pharmaceutical Regulation in Europe* Panos Kanavos,Christina Golna,2000-05-01 **European Regulation of Medical Devices and**

Pharmaceuticals Nupur Chowdhury,2014-04-29 One of the primary functions of law is to ensure that the legal structure governing all social relations is predictable coherent consistent and applicable Taken together these characteristics of law are referred to as legal certainty In traditional approaches to legal certainty law is regarded as a hierarchical system of rules characterized by stability clarity uniformity calculable enforcement publicity and predictability However the current reality is that national legal systems no longer operate in isolation but within a multilevel legal order wherein norms created at both the international and regional level are directly applicable to national legal systems Also norm creation is no longer the exclusive prerogative of public officials of the state private actors have an increasing influence on norm creation as well Social scientists have referred to this phenomenon of interacting and overlapping competences as multilevel governance Only recently have legal scholars focused attention on the increasing interconnectedness and therefore the concomitant loss of primacy of national legal orders between the global European and national regulatory spheres through the concept of multilevel regulation In this project the author uses multilevel regulation as a term to characterize a regulatory space in which the process of rule making rule enforcement and rule adjudication the regulatory lifecycle is dispersed across more than one administrative or territorial level and amongst several different actors both public and private The author draws on the concept of a regulatory space using it as a framing device to differentiate between specific aspects of policy fields The relationship between actors in such a space is non hierarchical and they may be independent of each other The lack of central ordering of the regulatory lifecycle within this regulatory space is the most important feature of such a space The implications of multilevel regulation for the notion of legal certainty have attracted limited attention from scholars and the demand for legal certainty in regulatory practice is still a puzzle The book explores the idea of legal certainty in terms of the perceptions and expectations of regulatees in the context of medical products specifically pharmaceuticals and medical devices which can be differentiated as two regulatory spaces and therefore form two case studies As an exploratory project

the book necessarily explores new territory in terms of investigating legal certainty first in terms of regulatee perceptions and expectations and second because it studies it in the context of multilevel regulation

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