

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

Ewout van Ginneken



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.

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 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, 2017-02-17 In the European Union EU 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 stages and standards for creating a product dossier clinical trials how and when an abridged procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials biologicals and biosimilars homeopathic and herbal medicines reporting procedures pharmacovigilance parallel trade relevant competition law and intellectual property rights and advertising In addition national variation charts in many of the chapters illustrate eight major jurisdictions Belgium France Germany Italy The Netherlands Spain Sweden and the UK Sample forms and URLs for the most important Directives 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

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 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 *Implications of Future EU Policy on the Provision of Medicines and on Actors in the European Pharmaceutical Sector* Ewout van Ginneken, 2010 *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 **Pharmaceutical Regulation in Europe** Panos Kanavos,2002 **The Autonomy of European Union Agencies** Martijn Groenleer,2009

Pharmaceuticals in the European Union Giuditta Savonitto,2019-04-23 This book offers the first complete and up to date analysis of the European Union s regulation of medicines Through a reasoned description ranging from regulatory developments to the jurisprudence of the Court of Justice of the European Union it delineates the current European pharmaceutical regulation system Moreover the economic and social implications caused by the market fragmentation linked to disparities in national pricing and reimbursement schemes of pharmaceuticals are also explored here In what was theorized to be a patchwork of rules and roles the potential growth of the pharmaceutical industry is hampered and important inequalities in patient access are growing What will be the next moves of European Union legislation to address the aging of the population the higher incidence of some diseases and the growing costs of innovative medicines Answers to such questions are offered in this book **REGULATING PHARMACEUTICALS IN EUROPE: STRIVING FOR**

EFFICIENCY, EQUITY, AND QUALITY; ED. BY ELIAS MOSSIALOS. ,2004 **Medical Product Regulatory Affairs** John J. Tobin,Gary Walsh,2011-08-24 Written in a clear and concise style by an experienced author this attractively priced book covers regulatory affairs in all major global markets for pharmaceuticals and medical devices making it the most comprehensive in its field Following a look at drug development complete sections are devoted to national and EU regulatory issues manufacturing license application and retention and regulation in the USA Other topics dealt with include CDER CBER and marketing and manufacturing licenses the ICH process and Good Laboratory Clinical Manufacturing Practices Everything pharmacologists bioengineers pharma engineers students in pharmacy and those working in the pharmaceutical industry need to know about medical regulatory affairs The Effects of Drug Regulation Graham Dukes,2012-12-06 Most national governments have created agencies with the responsibility for deciding which medicinal drugs should be imported or manufactured and made available through their health systems Many of these agencies were set up some twenty years ago in the wake of the thalidomide disaster Since that time they have developed in quite different ways in response to national cultural and economic influences Their direct cost is very small in comparison to overall health budgets but their indirect effects both in terms of health and the economy can be substantial In 1980 the World Health Organization WHO Regional Office for Europe set up a series of studies of drug evaluation in the European region aimed at determining the

effects of the work of regulatory agencies on the availability of drugs on the pharmaceutical industry and on the health of individuals in the countries concerned This book sets that work in a historical context and describes the sources of the data used by the project team and the methods used by WHO and others in assessing the work of these agencies and its repercussions for the community Finally it presents an analysis of current knowledge and the plans and prospects for future research The first draft of this book was presented to a meeting of experts in the field of drug regulation at Oslo in March 1984 and the present text embodies the views and conclusions of that meeting **Journal of European Integration** ,2007

Health Technology Assessment in Europe ,1999 Recoge 1 Introduction 2 Health Technology Assessment in Europe 3 Conclusions 4 Appendix BMJ ,2007 **Pharmaceutical Patents in Europe** Bengt Domeij,2000 The Effects of Drug Regulation Graham Dukes,2012-03-09 Most national governments have created agencies with the responsibility for deciding which medicinal drugs should be imported or manufactured and made available through their health systems Many of these agencies were set up some twenty years ago in the wake of the thalidomide disaster Since that time they have developed in quite different ways in response to national cultural and economic influences Their direct cost is very small in comparison to overall health budgets but their indirect effects both in terms of health and the economy can be substantial In 1980 the World Health Organization WHO Regional Office for Europe set up a series of studies of drug evaluation in the European region aimed at determining the effects of the work of regulatory agencies on the availability of drugs on the pharmaceutical industry and on the health of individuals in the countries concerned This book sets that work in a historical context and describes the sources of the data used by the project team and the methods used by WHO and others in assessing the work of these agencies and its repercussions for the community Finally it presents an analysis of current knowledge and the plans and prospects for future research The first draft of this book was presented to a meeting of experts in the field of drug regulation at Oslo in March 1984 and the present text embodies the views and conclusions of that meeting

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