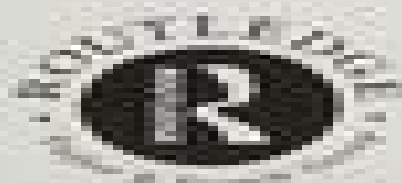

Regulating Medicines in Europe

Competition, expertise and
public health

John Abraham and
Graham Lewis



London and New York

Regulating Medicines In Europe Competition Experts And Public Health

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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

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

Multilevel Regulation and the EU Andreas Follesdal, Ramses A. Wessel, Jan Wouters, 2008-05-31 Rules are no longer merely made by states but increasingly by international organizations and other international bodies At the same time these rules do impact the daily life of citizens and companies as it has become increasingly difficult to draw dividing lines between international EU and domestic law This book introduces the notion of multilevel regulation as a way to study these normative processes and the interplay between different legal orders It indicates that many rules in such areas as trade financial cooperation food safety pharmaceuticals security terrorism civil aviation environmental protection or the internet find their origin in international cooperation Apart from mapping multilevel regulation on the basis of a number of case studies the book analyses its consequences in relation to forms of legal protection and legitimacy In that respect it proposes an agenda for research to study how to cope with multilevel regulation This work offers valuable resources for researchers involved in studying the interplay between international European and domestic law For practitioners it offers background information on the ways in which many international rules come into being

Pharmaceutical Systems John Lilja, Sam Salek, Aldo Alvarez, David Hamilton, 2008-05-27 Offers a social view of the activities leading to the timely patient access to medicines including drug research drug production drug distribution drug prescribing drug information and drug control Provides theoretical models to enable pharmacists to understand the organization of drug systems in their particular global territory Written specifically with the needs of pharmacy students taking Master's degrees in mind

The Law of Off-label Uses of Medicines Andrea Parziale, 2022-08-12 This book examines the regulatory framework for untested and unapproved uses off label uses of medicines in the EU UK and USA Before reaching patients medicines are extensively tested by manufacturers and approved by regulators to minimise the risk of adverse reactions However physicians can prescribe pharmaceuticals for off label uses widespread in paediatrics oncology rare diseases and more recently in treatment for Covid 19 While off label uses may offer hope they may also expose patients to risks and uncertainties Clarification is therefore needed to improve the protection of patients rights while enhancing legal certainty for health actors To this end this work clarifies the regulatory mechanisms and litigation trends concerning off licence prescriptions in these jurisdictions It assesses how traditional prevention driven regulatory and civil liability rules are being adapted to tackle potential risks and scientific uncertainty The book outlines the applicable regulations as well as considering Brexit's impact on off label policies in the UK and EU and national off label policies in the context of the fight against the Covid 19 pandemic It also explores under what conditions

physicians manufacturers or regulators must compensate patients injured by untested prescriptions The book will be an essential resource for researchers academics and policy makers working in the areas of medical law and ethics public health law pharmaceutical law and private comparative law European Union Public Health Policy Scott L. Greer,Paulette Kurzer,2013 Ranging from influence over world trade laws affecting health to population health issues such as obesity to the use of comparative data to affect policy the EU s public health policies are increasingly important visible expensive and effective They also provide an invaluable case study for those who want to understand the growth and impact of the EU as well as how states can affect their populations lives and health European Union Public Health Policy capitalizes on extensive new research providing an introduction to the topic and indicating new intellectual directions surrounding the topic An introductory section and extended conclusion explore the meaning of public health the relationship of EU public health policy to health care policy and the place of public health in the study of European integration and Europeanization Focusing on health system transformation global health governance and population health the chapters address Relevant policy issues and EU policies Effects of the EU policies on practice or outcomes An explanation of the policy trajectory Current issues and likely future directions or conflicts Drawing together an international and multidisciplinary selection of experts this volume is an important contribution for all those interested in public health policy EU health policy and EU governance *The Autonomy of European Union Agencies* Martijn Groenleer,2009 *Health Law and the European Union* Tamara K. Hervey,Jean V. McHale,2004-11-04 How does the law of the European Union affect health law and policy At first sight it seems limited However despite its restricted formal competence the EU has recently become increasingly involved in the health field Litigation based on EU law has resulted in a right to receive health care services across national boundaries which may have huge practical implications for national health systems The EU has promulgated legislation regulating clinical research and the marketing of pharmaceuticals patients rights are affected by EU legislation on data protection and product liability the qualifications of health care professionals are legally recognised across the EU and the EU has acted to promote public health This book explores the various impacts of measures of EU law on national health law and policy Through elaboration of selected examples the authors show that within the EU health law cannot be regarded as a purely national affair European Union Health Law Tamara K. Hervey,Jean V. McHale,2015-11-12 A contextual analysis of the internal logics of EU health law through four themes consumerism human rights interactions between equality solidarity and competition and risk Leading authors in the emergent field explain the interactions and implications of EU health law through thematic reinterpretation of the law in context in key substantive areas such as the regulation of health research access of patients to high quality care health care professional regulation organisation and funding of health care services and public health This book offers a fresh perspective and thorough understanding of EU health law through individual and collective or systemic perspectives and covers health law both within the EU and globally Essential reading for anyone

interested in health law in any EU Member State or in global health law *European Law and New Health Technologies* Mark L Flear, Anne-Maree Farrell, Tamara K Hervey, Thérèse Murphy, 2013-03-14 Health is a matter of fundamental importance in European societies both as a human right in itself and as a factor in a productive workforce and therefore a healthy economy New health technologies promise improved quality of life for patients suffering from a range of diseases and the potential for the prevention of incidence of disease in the future At the same time new health technologies pose significant challenges for governments particularly in relation to ensuring the technologies are safe effective and provide appropriate value for public money To guard against the possible dangers arising from new health technologies and to maximize the benefits all European governments regulate their development marketing and public financing In addition several international institutions operating at European level in particular the European Union the Council of Europe and the European Patent Office have become involved in the regulation of new health technologies They have done so both through traditional command and control legal measures and through other regulatory mechanisms including guidelines soft law steering through redistribution of resources and private or quasi private regulation This collection analyses European law and its relationships with new health technologies It uses interdisciplinary insights particularly from law but also drawing on regulation theory and science and technology studies to shed new light on some of the key defining features of the relationships and especially the roles of risk rights ethics and markets The collection explores the way in which European law s engagement with new health technologies is to be legitimized and discusses the implications for biological or biomedical citizenship **Regulation of the Pharmaceutical Industry** J. Abraham, H. Lawton Smith, 2003-06-10 How are

pharmaceutical technologies developed and controlled in our societies To what extent should the availability of these technologies be determined by scientific experts a democratic state the interests of final users or ethical principles This unique collection brings together the work of social scientists ethicists lawyers and policy analysts on regulation ethics and innovation in the pharmaceutical industry Regulatory systems and their implications for public health in North America Europe and developing countries are discussed including case studies of norplant interferon and anti fertility vaccines

Research Handbook on EU Health Law and Policy Tamara K. Hervey, Calum Alasdair Young, Louise E. Bishop, 2017-03-31 The steady expansion of the European Union s involvement in health over the past 20 years has been accelerated by recent events This handbook offers an up to date analytical overview of the most important topics in EU health law and policy It outlines as far as possible the direction of travel for each topic and suggests research agenda s for the future **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

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

Handbook of Social Policy Evaluation Bent Greve,2017-03-31 This Handbook uses methodologies and cases to discover how and when to evaluate social policy and looks at the possible impacts of evaluation on social policy decisions The contributors present a detailed analysis on how to conduct social policy evaluation how to be aware of pitfalls and dilemmas and how to use evidence effectively

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

New Technologies in Health Care A. Webster, 2006-07-25 The first detailed and comprehensive analysis of the implications of new health technologies for society the delivery of health care and the very meaning of health itself It is based on new critical social science research integrated according to core themes making it accessible and engaging to both students and researchers

Pharmacovigilance in the European Union Michael Kaeding, Julia Schmälder, Christoph Klika, 2017-02-20 This book is open access under a CC BY 4.0 license The book presents the results of an in depth comparative study assessing the implementation of the EU Pharmacovigilance Directive in six EU Member States By going beyond legal transposition and instead focusing on practical implementation this study aims to close a gap in EU compliance research Based on qualitative interviews with relevant actors in Germany Poland Portugal France Finland and the UK the authors identify perceived challenges and best practices issue recommendations and thereby contribute to a better understanding of the factors that incentivize or impede the practical implementation of EU law at the national level

Supplementary Protection Certificates for Medicinal Products Georgia A. Roussou, 2023-01-20 This book explores whether the judicial developments related to the Supplementary Protection Certificate SPC regulation correspond to the objectives of the European legislator Examining the role of SPCs for medicinal products in the European patent system it highlights both the jurisprudence of the Court of Justice of the European Union and the respective judgements of the member states national courts

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