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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

European Ways of Law Volkmar Gessner, David Nelken, 2007-10-30 Can there be such a thing as a European sociology of law The uncertainties which arise when attempting to answer that straightforward question are the subject of this book which also overlaps into comparative law legal history and legal philosophy The richness of approaches reflected in the essays including comparisons with the US makes this volume a courageous attempt to show the present state of socio legal studies in Europe and map directions for its future development Certainly we already know something about the existence of differences in the use and meaning of law within and between the nation states and groups that make up the European Union They concern the role of judges and lawyers the use of courts patterns of delay contrasts in penal sensibilities or the meanings of underlying legal and social concepts Still similarities in legal culture are at least as remarkable in societies at roughly similar levels of political and economic development The volume should serve as a needed stimulus to a research agenda aimed at uncovering commonalities and divergences in European ways of approaching the law

Multilevel Regulation and the EU Andreas Føllesdal, Ramses A. Wessel, Jan Wouters, 2008 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 a multilevel regulationa TM 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

European Law and New Health Technologies Mark L Flear, Anne-Maree Farrell, Tamara K Herve, Thérèse Murphy, 2013-03-14 New health technologies promise great things but they also pose significant challenges for governments particularly around safety concerns effectiveness and value for money This collection analyses the defining features of the relationship between EU law and new technologies and the roles of risk rights ethics and markets

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

Health Governance in Europe Monika Steffen, 2005 Focussing on the health sector this book analyses the closely interwoven relationship between the European Union and Member States

Health Systems Governance in Europe Elias Mossialos, 2010-03-25 Health system governance in Europe the role of European Union law and policy Elias Mossialos et al Health care and the EU the law and policy patchwork Tamara Hervey and Bart Vanhercke EU regulatory agencies and health protection Govin Permanand and Ellen Vos The hard politics of soft law the case of health Scott L Greer and Bart Vanhercke Public health policies Martin McKee Tamara Hervey and Anna Gilmore Fundamental rights and health care Jean McHale EU competition law and public services Tony Prosser EU competition law and health policy Julia Lear Elias Mossialos and Beatrix Karl Public procurement and state aid in national health care systems Vassilis Hatzopoulos Private health insurance and the internal market Sarah Thomson and Elias Mossialos Free movement of services in the EU and health care Wouter Gekiere Rita Baeten and Willy Palm Enabling patient mobility in the EU between free movement and coordination Willy Palm and Irene A Glinos The EU legal network on e health Stefaan Callens EU law and health professionals Miek Peeters Martin McKee and Sherry Merkur

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

Europeanization in Sweden Anna Meeuwisse, Roberto

Scaramuzzino,2018-12-17 Notwithstanding its many successes since 1945 the project of European integration currently faces major difficulties from financial crises and mass immigration to the departure of the UK from the European Union At the same time these challenges have spurred civil society organizations within and across Europe revealing a shared public sphere in which citizens can mobilize around refugee rights opposition to austerity policies and other issues Europeanization in Sweden assembles new empirical research on how these processes have played out in one of the continent s wealthiest nations providing insights into whether and how the Swedish model can guide European integration **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 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 **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

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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 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 **Elgar Encyclopedia of Science and Technology Studies** Ulrike Felt,Alan Irwin,2024-10-03 This Encyclopedia provides a comprehensive overview of the expanding field of science and technology studies STS Covering key frameworks themes and topics Ulrike Felt and Alan Irwin bring together expert contributors to map the development of STS within its historical and intellectual context

Unveiling the Energy of Verbal Artistry: An Emotional Sojourn through **Regulating Medicines In Europe Competition Experts And Public Health**

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