A Guide To European Pharmaceutical Regulations Fo

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WHO Expert Committee on Specifications for Pharmaceutical Preparations National Academies Press
Through the contributions of over 30 global experts, this book meets the growing need to understand the development and implementation of pharmaceutical care. This guide to pharmaceutical Care implementation details the pharmacist's role in providing a broad array of care to various kinds of patients, using strategies that improve humanistic, economic and clinical outcomes. Written with a focus for students, pharmacists and researchers, this book offers multiple scenarios to advance the care of patients. It will enhance the knowledge and skills of the providers. The examples describe the details of the structured processes from pharmacists and researchers who have worked in these fields for many years: detecting drug-related problems, providing pharmaceutical care in different settings (community, nursing homes, hospitals and clinics), evaluating research-indicators and outcomes, and teaching at universities and colleges. Readers will use this book to: Improve their skills to prevent, detect and solve drug-related problems Develop and improve communication skills to establish useful relationships with patients and healthcare professionals. Understand the characteristics of (pharmaceutical) care for patients in different settings Use different tools to showcase pharmaceutical care services Learn the role of standards, guidelines, protocols and indicators to guide and evaluate pharmaceutical care Understand the importance of the documentation of pharmaceutical care practices and create evidence and opportunities for remuneration Consolidate knowledge from different global studies and research outcomes.

Navigating European Pharmaceutical Law **Oxford University Press, USA**
The expanding scope of European law in areas that impinge on health care, coupled with a greater awareness by individuals and organisations within the European Union of the rights that this confers on them, has created new tensions. It throws into relief the challenge of ensuring that progress in developing an internal market enhances rather than undermines consumer safety and social protection. Resolving this challenge has become more important as the social dimension of what was first conceived as primarily an economic union has become more prominent. &ltBR> In December 2001 the Belgian presidency of the European Union convened a conference in Ghent on the implications of European law for the social nature of health care. Two complementary books emerged from this process. This volume provides an in-depth analysis of some of the most important issues facing health policy makers in Europe. Leading commentators present a range of perspectives from the legal profession on the current situation and prospects for the future, providing a detailed map of the often-labyrinthine body of European law and how it impacts on health care.

Guide to EU Pharmaceutical Regulatory Law Kluwer Law International B.V.
New technologies with the potential to improve the health of populations are continuously being introduced. But not every technological development results in clear health gains. Health technology assessment provides evidence-based information on the coverage and usage of health technologies, enabling them to be evaluated properly and applied to health care efficaciously, promoting the most effective ones while also taking into account organizational, societal and ethical issues. This book reviews the relationship between health technology assessment and policy-making, and examines how to increase the contribution such research makes to policy- and decision-making processes. By communicating the value and potential of health technology assessment to a wider audience, both within and beyond decision-making and health care management, it aims ultimately to contribute to improve the health status of the population through the delivery of optimum health services.

Guide to Eu Pharmaceutical Regulatory Law John Wiley & Sons
Publications of the European Communities. Commission - general publications. Commission - non - statistical publications. Eurostat - publications of the statistical office of hte European Communities. Council of ministers. European parliament. Court of justiceof the European Communities. Other bodies. Bibliographic aids. Addresses to which orders for publications should be sent. European documentation centres and depository libraries. Further reading on the European Communities.

EU Law of Competition and Trade in the Pharmaceutical Sector Manhattan Publishing Company
European pharmaceutical law can be a minefield, due to the peculiarities of the European single market, the complexity of contemporary issues, and the rapid pace of scientific advancement. This book offers a comprehensive and in-depth analysis of EU pharmaceutical law, including expert perspectives on the most cutting-edge and contentious legal issues faced by the industry today. It provides analytical and informed discussion of legislation and jurisprudence relevant to the entire lifecycle of pharmaceutical and biopharmaceutical products. This is supported by case studies and incisive commentary to give a full understanding of the controversial policy considerations which shape interpretation of the law in practice. The legislation does not always provide answers, and the book adopts a creative approach which addresses both what the law says and what the law does not say. Written by a team of experts in the field, Navigating European Pharmaceutical Law is an accessible guide for those new to the field, and an invaluable resource for experienced practitioners advising on critical and topical issues.

The Interplay of Global Standards and EU Pharmaceutical Regulation Ashgate Publishing, Ltd.
First multi-year cumulation covers six years: 1965-70.

Guide to EU Pharmaceutical Regulatory Law 4e World Health Organization
Drug Utilization Research (DUR) is an eclectic scientific discipline, integrating descriptive and analytical methods for the quantification, understanding and evaluation of the processes of prescribing, dispensing and consumption of medicines and for the testing of interventions to enhance the quality of these processes. The discipline is closely related and linked mainly to the broader field of pharmacoepidemiology, but also to health outcomes research, pharmacovigilance and health economics. Drug Utilization Research is a unique, practical guide to the assessment and evaluation of prescribing practices and to interventions to improve the use of medicines in populations. Edited by an international expert team from the International Society for Pharmacoepidemiology (ISPE), DUR is the only title to cover both the methodology and applications of drug utilization research and covers areas such as health policy, specific populations, therapeutics and adherence.

The Impact of EU Law on Health Care Systems John Wiley & Sons
"A lot of hard-won knowledge is laid out here in a brief but informative way. Every topic is well referenced, with citations from both the primary literature and relevant resources from the internet." Review from Nature Chemical Biology Written by the founders of the SPARK program at Stanford University, this book is a practical guide designed for professors, students and clinicians at academic research institutions who are interested in learning more about the drug development process and how to help their discoveries become the novel drugs of the future. Often many potentially transformative basic science discoveries are not pursued because they are deemed ‘ too early ’ to attract industry interest. There are simple, relatively cost-effective things that academic researchers can do to advance their findings to the point that they can be tested in the clinic or attract more industry interest. Each chapter broadly discusses an important topic in drug development, from preclinical work in assay design through clinical trial design, regulatory issues and marketing assessments. After the practical overview provided here, the reader is encouraged to consult more detailed texts on specific topics of interest. "I would actually welcome it if this book ’ s intended audience were broadened even more. Younger scientists starting out in the drug industry would benefit from reading it and getting some early exposure to parts of the process that they ’ ll eventually have to understand. Journalists covering the industry (especially the small startup companies) will find this book a good reality check for many an over-hopeful press release. Even advanced investors who might want to know what really happens in the labs will find information here that might otherwise be difficult to track down in such a concentrated form."

National Library of Medicine Current Catalog CRC Press
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 & 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. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following 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. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - 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 Publishers' Trade List Annual Booksurge Publishing
Explains the advantages of herbal remedies, and suggests treatments for ailments affecting each part of the body

Introduction to Market Access for Pharmaceuticals Scarecrow Press
This User ’ s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User ’ s Guide was created by researchers affiliated with AHRQ ’ s Effective Health Care Program, particularly those who participated in AHRQ ’ s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Forensic Chemistry of Substance Misuse: A Guide to Drug Control (2) Academic Press
Healthcare professionals, including doctors, pharmacists and nurses, are often confronted with patients who use over-the-counter (OTC) herbal medicinal products and food supplements. While taking responsibility for one ’ s own health and treatment options is encouraged, many patients use these products based on limited (and sometimes inaccurate) information from non-scientific sources, such as the popular press and internet. There is a clear need to offer balanced, well-informed advice to patients, yet a number of studies have shown that, generally, conventionally trained health practitioners consider their knowledge about herbal medicinal products and supplements to be weak. Phytopharmacy fills this knowledge gap, and is intended for use by the busy pharmacist, nurse, or doctor, as well as the ‘ expert patient ’ and students of pharmacy and herbal medicine. It presents clear, practical and concise monographs on over a hundred popular herbal medicines and plant-based food supplements. Information provided in each monograph includes: • Indications • Summary and appraisal of clinical and pre-clinical evidence • Potential interactions • Contraindications • Possible adverse effects An overview of the current regulatory framework is also outlined, notably the EU Traditional Herbal Medicinal Products Directive. This stipulates that only licensed products or registered traditional herbal medicinal products (THRs), which have assured quality and safety, can now legally be sold OTC. Monographs are included of most of the major herbal ingredients found in THRs, and also some plant-based food supplements, which while not strictly medicines, may also have the potential to exert a physiological effect.

Fundamentals of Pharmaceutical and Biologics Regulations, Third Edition Pangolin Press
This volume, developed by the Observatory together with OECD, provides an overall conceptual framework for understanding and applying strategies aimed at improving quality of care. Crucially, it summarizes available evidence on different quality strategies and provides recommendations for their implementation. This book is intended to help policy-makers to understand concepts of quality and to support them to evaluate single strategies and combinations of strategies.

The Pharmacist Guide to Implementing Pharmaceutical Care London : Mansell ; New York : H.W. Wilson
In recent years, high prices of pharmaceutical products have posed challenges in high- and low-income countries alike. In many instances, high prices of pharmaceutical products have led to significant financial hardship for individuals and negatively impacted on healthcare systems' ability to provide population-wide

access to essential medicines. Pharmaceutical pricing policies need to be carefully planned, carried out, and regularly checked and revised according to changing conditions. Strong, well-thought-out policies can guide well-informed and balanced decisions to achieve affordable access to essential health products. This guideline replaces the 2015 WHO guideline on country pharmaceutical pricing policies, revised to reflect the growing body of literature since the last evidence review in 2010. This update also recognizes country experiences in managing the prices of pharmaceutical products.

Guide to the Preparation, Use and Quality Assurance of Blood Components Academic Press

The second edition of Forecasting for the Pharmaceutical Industry continues to be a definitive guide for forecasters as well as the multitude of decision makers and executives who rely on forecasts in their decision making. The author explores the pharmaceutical forecasting process; the varied tools and methods for new product and in-market forecasting; how they can be used to communicate market dynamics to the various stakeholders; and the strengths and weaknesses of different forecast approaches. The second edition has been updated throughout and includes a brand new chapter focusing on specialized topics such as forecasting for orphan drugs and biosimilars.

European Pharmaceutical Technical and Regulatory Compendium John Wiley & Sons

This is the eBook version of the third edition (October 2016) of the Clinical Manual of Chinese Herbal Medicines. The content is identical except for the use of color in the eVersion. The content describes the actions, indications, dosages and potential combinations of over 330 medicines. Since the first edition, published in 2000, the number of medicines available in the marketplace has expanded considerably. New companies have entered the market, and some previously available medicines have disappeared. Patent medicines are, for many practitioners, the cornerstone of herbal medicine practice. The author believes that patent medicines, carefully and correctly applied, can be as effective as raw herb decoctions for many common conditions. In addition they have numerous advantages, not the least of which are improved compliance, relatively low cost to the patient, and a high degree of quality control. The Clinical Manual of Chinese Herbal Patent Medicines is the most up to date text on what is actually available in the market and what is good and of good quality. It is an essential addition to the desk and bookshelf of all serious practitioners and students of Chinese medicine. In addition to the government registered medicines available in Australia, the details a number of classical prescriptions currently available only in the US and Europe. One of the nicest features of the text is its use of small icons in the left margin to indicate use information. Each formula is discussed in terms of its TCM Actions, Biomedical actions, Indications, Composition, Combinations, Dose and Method of Administration, and Cautions and Contraindications. A specially nice feature are the line drawings of persons illustrating elements of the patterns. These are often expressive of the adittudinal and psychological characteristics of those matching the pattern indicated.

Medicine in Europe Springer Science & Business Media

Updating and expanding the coverage of the first Edition, this book provides a chemical background to domestic and international controls on substances of misuse. In the United Kingdom, structure-specific (generic) controls have been further developed in the past 13 years and now cover 17 groups of compounds. The focus of those controls has been on new psychoactive substances (NPS). Since 1997, over 800 NPS have been reported to the European Monitoring Centre for Drugs and Drugs Addiction. International generic and analogue controls are described together with a critical review of their effectiveness. Other, established, drugs are described as well as a large group of psychoactive substances that are not scheduled by the International Conventions This book has general appeal to those needing information on illicit drugs including forensic scientists, lawyers, law enforcement agencies, drug regulatory authorities as well as graduate and postgraduate students of chemistry and the criminal law. The chapters are supported by chemical structures, numerous tables and charts, appendices, a glossary and a bibliography. This unique book is a valuable addition to the literature in this area and will be of great assistance to those studying this topic.

Health Technology Assessment and Health Policy-making in Europe Kluwer Law International

This online version of this title will be shortly available at www.kluwerlawonline.com. It is written by and for lawyers, both in-house and in private practice, who find themselves having to advise a client or clients on this ever-changing area of law, perhaps on the steps needed to bring a product to market including any supplementary obligations (such as the need to conduct a clinical trial of the product for paediatric use), or perhaps when advising on clinical trial agreements, what “ normal ” rights and obligations of parties should be included in the agreement. We hope the book will also be of interest and assistance to regulatory advisers. Each chapter presents a particular process or subject from a Europe-wide perspective. The chapters take the reader through the life of a medicinal product or medical device, from development to clinical trials to product launch and afterwards, and we provide guidance in matters where regulatory law is used as an instrument of life-cycle management. With the exception of the advertising chapter, this book deals primarily with the European level of legislation. Where there are significant national deviations or differences in interpretation, we have been able to take advantage of the breadth of Bird & Bird experience in a number of major jurisdictions: ;UK, ;France, ;Germany, ;Spain, ;Belgium, ;The Netherlands, ;Italy and ;Sweden to create national variations charts that appear at the end of certain chapters. These charts provide information on how the subject matter of the chapter is implemented in those eight major Member States, and they also serve to illustrate how implementation of the EU regulations varies between Member States. We have only included relevant or significant information so the length of these appendices varies, and for some subjects, such as paediatrics, the legislation is so new and pan-European that we decided that no local variation needed to be included. In addition, at the end of each chapter we have included a list of guidelines/publications which will direct the readers to sources of additional information. European legislation is peppered with acronyms. For help keeping them all straight, we included a list of the most commonly used ones in the pharmaceutical area, in addition to those that appear in each chapter. This online version of this title will be shortly available at www.kluwerlawonline.com.

Guidelines for the Evaluation of Drug Prevention Inner Traditions / Bear & Co

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.

Nonclinical Safety Assessment Government Printing Office

This book provides a systematic analysis of the law and practice of EU competition and trade in the pharmaceutical sector. Authored by leading private practitioners, economists, scholars and high-level officials at competition regulators, this work provides valuable insider knowledge on the application of law and policies to the pharmaceutical industry. The work contains extensive commentary on the legislation and the latest case law and administrative precedents in this sector, at both EU and national level, including certain significant jurisdictions (e.g., the US, China). Coverage of various key developments includes the recent pay-for-delay antitrust investigations, the perennial issues around parallel trade, and an examination of mergers among pharmaceutical companies and medical devices manufacturers. In addition to the legal analysis, it offers vital economic and business perspectives to ensure that the reader has the full range of tools with which to prepare for cases and conduct transactions within the pharmaceutical industry.