Chapter 1 Marketing Authorisation European Commission

This book explores the concept of test data exclusivity protection for pharmaceuticals. Focusing on Art 39(3) of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and relevant provisions in selected free trade agreements (FTA) and national laws, it combines normative, historical, comparative and economic analysis of test data exclusivity protection.At the heart of this book is the novel and original Index of Data Exclusivity and Access (IDEAS), which analyzes the effectiveness of test data exclusivity provisions in FTAs and national laws both on the strength of exclusivity as well as on access to medicine. IDEAS provides a framework for the assessment of current test data exclusivity protection standards on the basis of their proximity to Article 39(3) of the TRIPS Agreement, the scope of exclusivity and the flexibilities in FTAs, and subsequently in national laws. This book aims to broaden national and international policy makers' grasp of the various nuances of test data exclusivity protection. Furthermore, it provides practical recommendations with regard to designing an appropriate legal system with a strong focus on promoting access to medicine for all.

The Rules Governing Medicinal Products in the European UnionUnipub

Herbal medicinal products are becoming more widely accepted as alternatives to medical prescriptions. Many physicians believe that herbal medicinal products are able to beneficially complement or even replace chemical medicines. Recognizing this, European institutions are pushing the harmonization of assessment criteria for herbal medicinal products. However, this kind of reevaluation of herbal medicinal products is combined with increased expectations of physicians, pharmacists, and patients with regard to quality, safety and efficacy. There are often uncertainties about the interpretation of basic terms related to the manufacture and quality of herbal medicinal products. Herbal Medicinal Products clarifies these uncertainties, increasing transparency in the herbal medicinal products market and supporting an adequate scientific discussion related to herbal medicinal products. It offers a complete survey on current scientific knowledge, as well as on legal basic requirements for the development, standardization, and licensing of herbal medicinal products.

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Recoge:1. Regulatory framework for services and networks - 2. Procedural rules - 3. Regulatory framework for terminal equipment - 4. Frequency policy - 5. Data protection - 6. Policy background.

This volume contains EU-related health legislation relevant to legal training programs on EU law and healthcare. Despite the availability of numerous handbooks, a collection of EU legislation on health has been missing. The book includes relevant treaty law provisions and secondary legislation (abridged) on health or health-related norms, clustered as: EU treaty law * human rights and

health * public health * patient safety * consumer protection * patient mobility * mobility of health professionals * pharmaceuticals * medical devices * data protection * insurance * competition law.

This book presents an in-depth analysis of issues in trade law and EU pharmaceutical law concerning market access for traditional Chinese medicinal products. It discusses these issues from the standpoints of fundamental law, international law and EU law, so to offer a comprehensive perspective. Specifically, it points out the core legislative issues for EU policymakers who deal with market access for traditional medicinal products; describes the relation between law and science; and offers essential information on herbal medicinal product registration in the EU. Further, it compares EU law and Chinese law in this regard, which can offer inspirations for readers from other counties that have similar medicinal products. The book uses straightforward, accessible language to break down the key issues involved.

The treatment of children with medicinal products is an important scientific area. It is recognized that many medicines that are used extensively in pediatric patients are either unlicensed or off-label. This textbook will help pediatric health professionals effectively treat children with the most appropriate medicine with minimal side effects.

A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances. This important book: Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation, process control, and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers, solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production.

Although the Bioequivalence (BE) requirements in many global jurisdictions have

much in common, differences in certain approaches and requirements such as definitions and terms, choice of comparator (reference) product, acceptance criteria, fasted and fed studies, single and multi-dose studies, biowaivers and products not intended for absorption into the systemic circulation (locally acting medicines and dosage forms), amongst others, provide food for thought that standardisation should be a high priority objective in order to result in a harmonized international process for the market approval of products using BE. An important objective of Bioequivalence Requirements in Various Global Jurisdictions is to attempt to gather the various BE requirements used in different global jurisdictions to provide a single source of relevant information. This information from, Brazil, Canada, China, European Union, India, Japan, MENA, Russia South Africa, the USA and WHO will be of value to drug manufacturers, regulatory agencies, pharmaceutical scientists and related health organizations and governments around the world in the quest to harmonize regulatory requirements for the market approval of generic products.

The objective of What Went Wrong? Pharma Tech Case Studies is to provide multidisciplinary approaches/guidelines for problem-solving capability. These case studies are based on the actual situation faced by the author in India and overseas and successfully resolved with the back-up of science and technology convincing international regulators/complainants leading to the closing of complaints. The book provides guidelines covering regulatory requirements for documentation. How do you document (format) any complaint? How to investigate a case study, using knowledge of science and technology and method of investigation? How to reproduce the complaint in-house, where ever required? It answers these various questions. The conclusion is with corrective and preventive actions required, submission of the investigation report and assignable reason to the regulatory agency/complainant, getting a response from the complainant and once satisfied, requesting them to close the complaint. Can we integrate regulatory science with other subjects of pharmaceutical sciences to learn ‘What Went Wrong? In Pharma Tech Case Study’. Important regulatory references are provided at the end.

Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

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 pharmaceutical industry and patent legislation are inextricably linked. Pharmaceutical companies could not exist without some guarantee that they can recoup the cost of developing a new product. European patent law offers this opportunity, as it allows companies to exclude competition for a specific product for a fixed time scale. In "Pharmaceutical Patents in Europe" the current legal patent situation is examined by a detailed analysis of case law from the European Patent Office (EPO), the international body created with the signing of the European Patent Convention (EPC). Aspects of European patent law not primarily regulated in the EPC, for example Supplementary Protection Certificates and infringement matters, are examined in the setting provided by EC law and domestic laws of European states. This book is written for the reader who understands the main characteristics of patent law and is looking for a practitioner's text on the European pharmaceutical patent law scene. Moreover, the author's remarks can help all readers to look at the field with fresh eyes.

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Health is becoming increasingly important to the European Union. The EU Court of Justice has also been involved in many health-related issues. The Casebook on European Union Health Law offers practitioners and students an opportunity to discover and understand the Court of Justice’s case law through highlights from health (related) decisions. It presents a range of carefully edited extracts, that clearly illustrate the essence and reasoning behind each decision. Compiled to be used in conjunction with Maklu’s EU Health Law Treaties and Legislation, this book covers an important part of the graduate European health law course in a series of structured chapters dealing with human rights and health, public health, patient safety/consumer protection, safety and health at work, patient mobility, professional mobility, pharmaceuticals, medical devices, privacy and data protection, insurance, competition and public procurement. The book is indispensable for practitioners and students of health law and policy.

Provides a systematic account of the major technical, administrative and legal requirements for registering a product in any of the national markets within the EEC, using the existing procedures, with guidance as to how these procedures are likely to change after 1992.

This book addresses the highly relevant and complex subject of research on drugs from natural products, discussing the current hot topics in the field. It also provides a detailed overview of the strategies used to research and develop these drugs. Respected experts explore issues involved in the production chain and when looking for new medicinal agents, including aspects such as therapeutic potential, functional foods, ethnopharmacology, metabolomics, virtual screening and regulatory scenarios. Further, the book describes strategic methods of isolation and characterization of active principles, biological assays, biotechnology of plants, synthesis, clinical trials and the use of tools to identity active principles.

The Textbook of Pharmaceutical Medicine is the standard reference for everyone working and learning in pharmaceutical medicine. It is a comprehensive resource covering the processes and practices by which medicines are developed, tested and approved, and the recognised text for the Diploma in Pharmaceutical Medicine from the Faculty of Pharmaceutical Medicine. This fully revised Seventh Edition, which includes two new Editors, encompasses current developments within pharmaceutical medicine with new chapters on biological therapeutics, pharmacovigilance, vaccines, drugs for cancer, drug development in paediatrics and neonatalogy, the clinical trials directive, life cycle management of medicines, counterfeit medicines and medical marketing. Also included for easy reference, and referred to throughout the text, are the Declaration of Helsinki, Guidelines and Documentation for Implementation of Clinical Trials, relevant European Directives and the Syllabus for Pharmaceutical Medicine. Written by an international team of leading academics, medical directors and lawyers, The Textbook of Pharmaceutical Medicine, Seventh Edition meets the needs of both those working in pharmaceutical medicine and preparing for the Diploma in Pharmaceutical Medicine. The text breaks down into three core sections: Part I: Research and Development Part II: Regulation Part III: Healthcare marketplace View Table of Contents in detail

'The Complete Guide to Medical Writing' is intended to consider all aspects of medical/scientific writing in one concise introductory text. It explains how to get published, how to write for a particular audience or in a particular media, what the publishing processes are and what the financial rewards might be.

This book describes the authors’ standard or ‘best’ practices used in writing regul- ed clinical documents for the drug and biologics industry. The fundamental premise of this book is that the end (documents submitted to a health authority) is dep- dent on the beginning (the planning and strategy that go into organizing written documentation). Each regulatory document inherently exists within a constellation of related documents. This book attempts to show the relationships between and among these documents and suggests strategies for organizing and writing these documents to maximize ef?ciency while developing clear and concise text. At all times, and irrespective of applicable laws and guidelines, good communication skills and a sense of balance are essential to adequately,

accurately, and clearly describe a product's characteristics. At no time should the reader perceive these suggestions to be the only viable solution to writing regulatory documents nor should the reader expect that these suggestions guarantee product success. The audience for this book is the novice medical writer, or those who would like to explore or enhance regulatory-writing skills. We assume the reader will have a basic understanding of written communication, but little experience in applying this skill to the task of regulatory writing. Extensive knowledge of science, clinical me- cine, mathematics, or regulatory affairs law is not required to use the best practices described in this book.

This book offers a wide-ranging and up-to-date overview of the basic science underlying PET and its preclinical and clinical applications in modern medicine. In addition, it provides the reader with a sound understanding of the scientific principles and use of PET in routine practice and biomedical imaging research. The opening sections address the fundamental physics, radiation safety, CT scanning dosimetry, and dosimetry of PET radiotracers, chemistry and regulation of PET radiopharmaceuticals, with information on labeling strategies, tracer quality control, and regulation of radiopharmaceutical production in Europe and the United States. PET physics and instrumentation are then discussed, covering the basic principles of PET and PET scanning systems, hybrid PET/CT and PET/MR imaging, system calibration, acceptance testing, and quality control. Subsequent sections focus on image reconstruction, processing, and quantitation in PET and hybrid PET and on imaging artifacts and correction techniques, with particular attention to partial volume correction and motion artifacts. The book closes by examining clinical applications of PET and hybrid PET and their physiological and/or molecular basis in conjunction with technical foundations in the disciplines of oncology, cardiology and neurology, PET in pediatric malignancy and its role in radiotherapy treatment planning. Basic Science of PET Imaging will meet the needs of nuclear medicine practitioners, other radiology specialists, and trainees in these fields.

Dementia: New Insights for the Healthcare Professional: 2013 Edition is a ScholarlyEditions™ book that delivers timely, authoritative, and comprehensive information about Diagnosis and Screening. The editors have built Dementia: New Insights for the Healthcare Professional: 2013 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Diagnosis and Screening in this book to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Dementia: New Insights for the Healthcare Professional: 2013 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

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Evidence-Based Validation of Herbal Medicines brings together current thinking and practice in the areas of characterization and validation of natural products. This book reviews all aspects of evaluation and development of medicines from plant sources, including their cultivation, collection, phytochemical and phyto-pharmacological evaluation, and therapeutic potential. Emphasis is placed on describing the full range of evidence-based analytical and bio-analytical techniques used to characterize natural products, including –omic technologies, phyto-chemical analysis, hyphenated techniques, and many more. Includes state-of-the-art methods for detecting, isolating, and performing structure elucidation by degradation and spectroscopic techniques Covers biosynthesis, synthesis, and biological activity related to natural products Consolidates information to save time and money in research Increases confidence levels in quality and validity of natural products

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Pharmaceutical, Biotechnology, and Chemical Inventions: World Protection and Exploitation, This book highlights the special issues arising in obtaining, commercializing, enforcing or attacking intellectual property rights (including

protection of regulatory data) in the pharmaceutical, biotechnology and chemical industries across the world's key jurisdictions. It is unique in presenting topic matter horizontally by subject to facilitate comparison between country practices. The first two chapters give a general introduction to the differences between the jurisdictions and an overview of some of the key concepts in patent law. The remainder of the book is dedicated to a detailed analysis of the major legal issues arising in these areas of technology. Each component chapter has a comparative introduction, looking at the variances in the laws of different domains, followed by side-by-side analysis of the relevant regimes, including tables and flow-charts which summarize and explain the key legal concepts. The jurisdictions covered are the United States, Europe (UK, Germany, Netherlands, France and Italy), Japan, Canada, Australia, India and China.

This Brief describes in three concise chapters one of the newest ‘hot topics’ under EU Food Law and Policy: the new Regulation (EU) No 2015/2283 from the European Parliament and by the Council, November 25, 2015, on novel foods, applicable from January 2018. In this work, the Authors discuss the long-time criticized EU Regulation on novel foods ((EC) No 258/1997) and how it has been significantly altered by the adoption of the new regulation. In the first chapter, the Authors provide a comprehensive analysis of the genesis of the new Regulation, its rationale and the policy’s goals. In particular, they describe what food business operators shall do in order to get a new product allowed on the EU market, providing updated information on the regulatory developments from the European Food Safety Authority in nanofoods, cloned animals and insect foods. The role of the European Food Safety Authority is also discussed. The second Chapter summarizes the current toxicological studies used to evaluate novel foods safety, which are an extremely important pillar when speaking of food safety and commercial introduction of new products. Finally, the third Chapter discusses the ‘history of safe use’ approach to the problem of novel foods, and factors such as consumption period analysis, preparation advices and processes, intake levels, nutritional composition, and results of animal studies. Food lawyers, professionals and auditors working in the area of official inspections, quality assurance, food traceability, and international regulation, both in academia and industry, will find this Brief an important account.

1. Introduction The REACH Regulation entered into force on 1 June 2007 with the aim of improving the protection of human health and the environment from the possible risks posed by chemicals, and their free circulation in the internal EU market, while enhancing the competitiveness and innovation of the EU chemicals industry. For this purpose, two main regulatory risk management measures are available under REACH to address substances that are of the highest concern: authorisation and restriction. Registrants need to prepare chemical safety assessments and demonstrate that the use of their substances is adequately controlled, and that exposure and emissions are minimised. Under REACH, there is an obligation to monitor the progress made in achieving the regulation's objectives every five years. In 2017, as part of this review, the European Commission published a study on the overall impacts of the REACH authorisation process in the EU. The main findings of this study indicated that the

REACH authorisation system had, among other things, promoted the substitution of substances of very high concern (SVHCs) with safer alternatives. This report provides the latest information on this, but also includes the impact of restrictions under REACH as part of its scope, with the goal of understanding the impacts of both processes on the substitution of hazardous chemicals in the EU. It presents the results of a survey sent to more than 500 stakeholders including companies affected by authorisation or restriction as well as industry associations, the conclusions reached concerning drivers for substitution, its costs, the time required to implement substitution, and the challenges and benefits from the companies' perspectives. These findings are illustrated with five case studies. Finally, some recommendations for promoting substitution are presented.

1. Marketing authorisations 2. Mutual recognition 3. Community referral 4. Centralised procedure 5. Variations 6. Community marketing authorisation 7. General information.

Analyzes the practical implications of recent legislative and judicial developments in respect of pharmaceuticals in the EC. The book considers the nature and inherent problems of the pharmaceutical market and the progress of EC harmonization in the light of localized irregularities.

Mononuclear Leukocytes—Advances in Research and Application: 2012 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Mononuclear Leukocytes. The editors have built Mononuclear Leukocytes—Advances in Research and Application: 2012 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Mononuclear Leukocytes in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Mononuclear Leukocytes—Advances in Research and Application: 2012 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

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