Chapter 1 Marketing Authorisation European Commission

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Drug Delivery Trends - Ranjita Shegokar 2020-03-01

Drug Delivery Trends examines a drift in the pharmaceutical field across the wide range of

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dosage forms, drug delivery systems (micro and nanoparticulate), at the regulatory front and on new types of therapies in the market. This volume additionally covers the challenges on drug delivery systems in terms of preclinical and current ways of determining quality and the options to solve the challenges associated with this. Most small-medium scale industries and academics struggle with initial regulatory challenges so a detailed discussion on regulatory trend covers the necessary basic understanding of regulatory procedures and provides the required guidance. The series Expectations and Realities of Multifunctional Drug Delivery Systems examines the fabrication, optimization, biological aspects, regulatory and clinical success of wide range of drug delivery carriers. This series reviews multifunctionality and applications of drug delivery systems, industrial trends, regulatory challenges and in vivo success stories. Throughout the volumes discussions on diverse aspects of drug delivery carriers, such as clinical, engineering, and regulatory, facilitate insight sharing across expertise area and form a link for collaborations between industry-academic scientists and clinical researchers. Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists, regulatory experts, engineers, clinical experts and regulatory stake holders. The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems. Encompasses trends in drug delivery systems and selected dosage forms Illustrates regulatory, preclinical and quality principles Contains in-depth investigation of upcoming types of drug delivery systems

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

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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.

Bioequivalence Requirements in Various Global Jurisdictions - Isadore Kanfer 2017-12-05

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

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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.

Pharmaceutical, Biotechnology, and Chemical Inventions - Duncan Bucknell 2011
Focuses on: Australia, Canada, China, India, Japan, the United States, Europe, France, Germany, Italy, the Netherlands, and the United Kingdom.

Biotechnology and the Law - Hugh B. Wellons 2007
The book is written to help lawyers faced with the challenge of identifying the legal issues and processes that must be faced by their clients in building, marketing, and protecting a biotech business. The contributors are experts in this specialized area and provide thorough, yet accessible, overviews of biotech subspecialties with an eye to practical application. A biotech legal practice involves specialized subject matter and regulatory schemes that, generally, are not part of the business lawyer's repertoire and which can present many hazards for the uninitiated. Because of the expansion in biotech practice beyond the traditional organizations and their representatives, this guide was written to help lawyers find their way through the biotech maze.

Block's Disinfection, Sterilization, and Preservation - Gerald McDonnell 2020-06-26
With more international contributors than ever before, Block's Disinfection, Sterilization, and Preservation, 6th Edition, is the first new edition in nearly 20 years of the definitive technical manual for anyone involved in physical and

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chemical disinfection and sterilization methods. The book focuses on disease prevention—rather than eradication—and has been thoroughly updated with new information based on recent advances in the field and understanding of the risks, the technologies available, and the regulatory environments.

European SPCs Unravelled - Oswin Ridderbusch 2021-06-18

While supplementary protection certificates (SPCs) are governed by the same substantive rules in all Member States of the European Union and the European Economic Area (EEA), they are national intellectual property rights. The formal requirements and procedural practices of the national patent offices granting SPCs still differ significantly, and these divergences can have a substantial impact on the prosecution of SPCs across Europe. This one-of-a-kind handbook provides an in-depth review of SPC law in Europe, covering all substantive and procedural aspects of prosecution, enforcement and invalidation, as well as SPC-related aspects of unfair competition law. Following an overarching European chapter, which addresses general considerations and the relevant European Union law, including the jurisprudence of the Court of Justice (CJEU) and the EFTA Court, this book contains detailed national chapters for all European states that provide SPCs − i.e., the twenty-seven EU Member States (Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden), the EEA/EFTA states Norway and Iceland, as well as the United Kingdom, Switzerland/Liechtenstein, Serbia, Bosnia and Herzegovina, Albania, and North Macedonia. The contributors to this book, all seasoned experts in the field of SPCs in their respective jurisdictions, provide clear and hands-on

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guidance on the most pertinent SPC-related topics of practical and strategic relevance. The considerably expanded second edition of this handbook offers a comprehensive analysis of European SPC law and practice, covering all European states with SPC systems in detailed national chapters. As such, this book provides invaluable assistance to IP practitioners in devising successful pan-European SPC filing and litigation strategies. Its practice-oriented approach, in combination with a country-by-country format where all chapters follow the same structure, makes it easy to compare the national practices and the respective national case law of the different European countries. 'The present work fills a gap and provides, for the first time, an overview of the SPC practice in the EU Member States, which despite the intended harmonization by the respective EU legislation is still decidedly inconsistent in some areas. Altogether, this successful work, with its streamlined structure and clear language that is immediately comprehensible even to non-native speakers, functions not "only" as a source of information for European attorneys, authorities and courts. It also conveys – perhaps not at all intended by the authors – the unique diversity of this European legal regime, which for many exerts a special fascination. The present Practitioner's Guide can be recommended without reservation and should not be missing in any specialist library.' – Jürgen Schell, Judge at the German Federal Patent Court, on the first edition of this book.

Communicating about Risks and Safe Use of Medicines - Priya Bahri 2020-06-17

At the core of this book lies the question how to approach medicines, risks and communication as a researcher - or anybody planning and evaluating a communication intervention, or wanting to understand communication events in private and the media. With a view to tackle current shortcomings of communication systems and processes for improved implementation,

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patient satisfaction and health outcomes, a multilayered approach is presented. This combines multiple data types and methods to obtain a wider and deeper understanding of the major parties and their interactions, as well as the healthcare, social and political contexts of information flows, how they interfere and which impact they have. Illustrated with real life experiences of safety concerns with medicines, worldwide active experts discuss the methods and contributions their disciplines can offer. With considerations on terminologies, tabulated overviews on communication types and outcomes, a patient-centred vision and plain language for non-medical readers, the book creates a platform for multidisciplinary collaborations amongst researchers as well as practitioners from communications, healthcare, the social sciences and pharmacovigilance. Importantly, it advocates for an active role of patients and highlights the achievements and aspirations of patient organisations. Finally, the book suggests establishing an inclusive discipline of humanities and epidemiology of medicinal product risk communication to realise full research potential. The authors are driven by the curiosity for communication as the most human behaviour, and as good health is amongst the basic human needs, medicinal product risk communication is an exciting research field of high global relevance.

Handbook of Bioequivalence Testing, Second Edition - Sarfaraz K. Niazi 2014-10-29

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

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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.

International Intellectual Property in an Integrated World Economy - Frederick M. Abbott 2019-02-07

International Intellectual Property in an Integrated World Economy, Fourth Edition by Frederick M. Abbott, Thomas Cottier, and Francis Gurry, provides a comprehensive treatment of the international intellectual property system across the spectrum of intellectual property rights and interests. It

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introduces the institutional architecture at the multilateral, regional/plurilateral, bilateral and national levels. For each form of IP, it addresses the technical legal rules and illustrative jurisprudence, as well as economic and social welfare implications. Each of the authors has played a role in the development and implementation of the international rules, and they bring their experience to bear in introducing students to the field. New to the Fourth Edition: The latest developments in bilateral and regional agreements regulating intellectual property, including NAFTA 2.0 (USMCA), CPTPP, and CETA Important new judicial decisions, including the U.S. Supreme Court decision adopting international exhaustion of patents and CJEU decisions addressing trademarks, geographical indications, and copyright Developments in IP and human rights; IP and competition law; and IP and health The WTO panel report in the Australia-Tobacco case Professors and students will benefit from: An approach to the international IP system that situates the rules within the broader context of international law and the public policy objectives that governments, industry, and interest groups are seeking to achieve Case law from international dispute settlement bodies, as well as from national and regional courts Discussion of patent, trademark, geographical indication, copyright, design, trade secret, and data protection; as well as plant variety protection, protection of genetic resources and traditional knowledge, and the role of open source An explanation of the new European Union Unitary Patent system Exploration of the increasingly important role of emerging market IP systems Materials to help students understand the disputes between the United States and China involving IP, investment, and transfer of technology Inclusion of important jurisprudential developments

European Union Health Law - André den Exter 2012

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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.

Natural Products as Source of Molecules with Therapeutic Potential - Valdir Cechinel Filho 2018-12-07

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.

Pharmacetical Applications in the European Union - Cheng Yee Lowe 1998-02-28

Written by an expert with twenty years' experience in regulatory affairs in a number of multi-national companies, this book guides readers through the legislative minefield of registering medicinal products in the European Union. Taking a step-by-step approach, the book demystifies all of the regulatory requirements and gives a clear understanding of how to achieve compliance. The author gathers all the relevant requirements, puts them into context,

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and provides regulatory information in an easily accessible format. Headings, subheadings, and key points organized in tabular format make the information easy for readers to find and the book easy for readers to use.

La propriété intellectuelle dans l'industrie pharmaceutique / Intellectual property in the pharmaceutical industry - Jean-Christophe Galloux 2012-01-01
141p

Vaccines - Stanley A. Plotkin 2012-10-01
A guide to the enhancement of the well-being of our world. It offers a coverage of every aspect of vaccination, from the development of each vaccine to its use in reducing disease.

The Life Sciences Law Review - Richard Kingham (Lawyer) 2022

The Rules Governing Medicinal Products in the European Union - Unión Europea 1998

Official Journal of the European Communities - 1999

Practical Aspects of Signal Detection in Pharmacovigilance - 2010
In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences

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of these developments for pharmacovigilance practitioners. The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

The Complete Guide to Medical Writing - Mark C. Stuart 2007

'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.

Dale and Appelbe's Pharmacy and Medicines Law - Gordon E. Appelbe 2013

This text is a comprehensive guide to law and ethics for pharmacy practice in the UK. Since publication of the first edition in 1976, it has become established as the standard student textbook and reference work on this subject in the UK. It includes information on the law that affects the practice of pharmacy in the UK, complete coverage of the pharmacy undergraduate and pre- registration syllabus and British law relating to medicines and poisons. This tenth edition has been

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substantially updated in connection with the advent of the GPhC and the new PLB, and revision of the Medicines Act.

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 & 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,

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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.

Generic Drug Product Development - Isadore Kanfer 2016-04-19

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 therapeutica

Access Delayed, Access Denied: Waiting for New Medicines in Canada - Brett James Skinner 2011

Access Delayed, Access Denied - 1997

Evidence-Based Validation of Herbal Medicine - Pulok K. Mukherjee 2022-07-12

Globalization in the context of drug development has increased the use of natural products worldwide. The trends in use of herbal medicine in therapeutics is becoming more popular and is still open to fascinating realms of research. 'Evidence-Based Validation of Herbal Medicines' brings together current thinking and practice in the areas of characterization and validation of natural products. This book describes different approaches and techniques for evaluating the quality, safety and efficacy of herbal medicine, particularly methods to assess their activity and understand the compounds responsible and their probable underlying mechanisms of action, which improve the level of understanding of various aspects on evaluation of natural products. This book is an effort to bring together the views, expertise and experiences of scientific

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experts in the field of medicinal plant research. This will be useful for the researcher to know more about the natural lead with their validation and also useful to exploit traditional medicines, leading to discovery and development of newer drugs through translational research with cutting edge technologies on natural remedies. This book will be an essential reading for the researchers whose professional life impinges on the use of natural resources. Includes state-of-the-art methods for detecting, isolating, and performing structure elucidation by degradation and spectroscopic techniques Highlights the trends in validation and value addition of herbal medicine with different scientific approaches used in therapeutics Contains several all-new chapters on topics such as traditional-medicine-inspired drug development to treat emerging viral diseases, medicinal plants in antimicrobial resistance, TLC bio profiling, botanicals as medicinal foods, bioprospecting and bioassay-guided isolation of medicinal plants, immunomodulators from medicinal plants, and more

Casebook on European Union Health Law - André den Exter 2014-04-10

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,

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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.

Transparency in Health and Health Care in the United States - Holly Fernandez Lynch 2019-06-06

Examines the impact of increased transparency on the legal, medical, and business structures of the American health care system.

Evergreening Patent Exclusivity in Pharmaceutical Products - Frantzeska Papadopoulou 2021-09-23

This book analyses 4 central pieces of EU pharmaceutical regulation: the Orphan Drugs Regulation, the Paediatric Regulation, the Supplementary Protection Certificate Regulation, and the ATMP (Advanced Therapy Medicinal Products) Regulation. These four regulatory instruments constitute focal points in the pharmaceutical industry's approach to modern business and legal strategy. Their central role is justified by the way these regulatory instruments interact with each other and with the patent system, and by the considerable impact they (as a whole) have for the evergreening of exclusive rights on pharmaceutical products. The book guides the reader through the latest case law and legislative developments and discusses how these influence strategic legal and business choices in the pharmaceutical industry. It brings to the forefront the often-overlooked significance of the legislative architecture of the EU pharmaceutical regulatory framework, and evaluates its results through the lens of the efficiency test. The book is an important resource for academics and practitioners interested in updated case law and an in-depth analysis of these four regulations. It is also important for those interested in legislative studies, evaluation of legislation and a critical approach to legislative architecture.

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Clinical Research in Paediatric Psychopharmacology - Philippe Auby 2019-09-15
Clinical Research in Paediatric Psychopharmacology: An Overview of the Ethical, Scientific and Regulatory Aspects provides a practical guide and overview of the ethical, scientific and regulatory aspects of clinical research in pediatric psychopharmacology, also discussing practical points to consider when developing clinical research in this field. The book is ideal for professionals involved in clinical research in pediatric psychopharmacology, i.e., including, but not limited to pediatricians, health care professionals, researchers, investigators, pharmaceutical company personals and potentially ethics committee members. Topics discussed include the role of patient organization and advocacy groups in research, the role of families and patients: 'should I involve my kid in clinical research, and historical, ethical, regulatory, clinical, scientific, intercultural and practical aspects of clinical research in child and adolescent psychopharmacology. Covers both theoretical and practical aspects of clinical research in paediatric psychopharmacology Approaches the topic from different angles from the regulatory framework to the patient perspective Discusses ethical and safety considerations for research in paediatric psychopharmacology Offers future perspective for paediatric development

Everything You Always Wanted to Know about European Union Health Policies But Were Afraid to Ask - Scott L. Greer 2019
What does the European Union mean for health? What can it mean for health? This comprehensively revised second edition answers these questions. It provides a broad review and analysis of European Union public health policies to mid-2019. It begins by explaining the basic politics of European integration and European policy-making in health, including the basic question of how the European Union (EU)

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came to have a health policy and what that policy does. Thereafter, it moves on to the three faces of European Union health policy. The first face is explicit health policy, both public health policy and policies to strengthen health services and systems in areas such as cancer, and communicable diseases. The second face is internal market building policies, which are often more consequential for health services, but are not made with health as a core objective. These include professional and patient mobility, regulation of insurers and health care providers, and competition in health care. They also include some of the policies through which the EU has had dramatic and positive health effects, namely environmental regulation, consumer protection and labour law. The third face is fiscal governance, in which the EU institutions police member state decisions, including relating to health. Each face has different politics, law, policy, and health effects. The book provides a synthesis of the different faces and the different ways in which they have been used to strengthen or weaken public health and health systems in Europe. It shows the many, often unappreciated, ways that the EU has worked for health, as well as the opportunities to further strengthen the EU's positive impact on health. This book is aimed at policy-makers and students of health systems in the EU who seek to understand how the influence of the EU on health policy affects those systems and their patients. To ensure that the EU's impact on health is wholly positive, the wider health community must understand and engage with the EU in the future - something this book aims to encourage.

Pharmaceutical Medicine and Translational Clinical Research - Divya Vohora 2017-11-14
Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the safety profile of

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medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features. As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine, clinical research, pharmacology and pharmacy, as well as professionals working in the pharmaceutical industry, this book is an ideal resource. Includes detailed coverage of current trends and key topics in pharmaceutical medicine, including biosimilars, biobetters, super generics, and Provides a comprehensive look at current and important aspects of the science and regulation of drug and biologics discovery

Solid State Development and Processing of Pharmaceutical Molecules - Michael Gruss 2021-09-14

Solid State Development and Processing of Pharmaceutical Molecules A guide to the lastest 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

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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.

What Went Wrong? Pharma Tech Case Studies - P G Shrotriya 2020-06-21

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

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Wrong? In Pharma Tech Case Study'. Important regulatory references are provided at the end.

Paediatric Clinical Pharmacology - Evelyne Jacqz-Aigrain 2021-02-25

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.

OECD Competition Assessment Reviews: Greece 2017 - OECD 2017-04-25

This report analyses Greek legislation in a number of sectors and identifies about 350 legal provisions which could be removed or amended to lift regulatory barriers to competition. The work undertaken in the project has involved the review of over 1 200 pieces of legislation in these sectors of ...

Post-Authorization Safety Studies of Medicinal Products - Ayad K. Ali 2018-06-27

Post-Authorization Safety Studies of Medicinal Products: The PASS Book bridges the gap in the literature by providing a complete look at post-authorization safety studies and important pharmacoepidemiology and pharmacovigilance aspects. It covers various types and limitations of active surveillance programs, including the use of large databases and disparate data sources for rapid signal detection, as well as novel and advanced design and analysis approaches for causal interference from observational data. This book serves as an important reference for pharmacovigilance scientists and pharmacoepidemiologists who are searching for the appropriate study design to answer safety research questions. Readers will be able to effectively and efficiently design and interpret findings from post-authorization safety studies with the goal of improving the benefit-risk balance of a drug in order to optimize patient safety. Discusses all types of

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observational studies in post-marketing drug safety assessment, from spontaneous reporting systems, to pragmatic trials, with examples from real-world settings Presents various types of post-authorization safety studies Offers solutions to the common challenges in the design and conduct of these studies Highlights active surveillance programs, including common data models for rapid signal detection of drug safety issues

The Rules Governing Medicinal Products in the European Union - European Commission 1998

The European Union - Kristin Archick 2019-09-15

The European Union (EU) is a political and economic partnership that represents a unique form of cooperation among sovereign countries. The EU is the latest stage in a process of integration begun after World War II, initially by six Western European countries, to foster interdependence and make another war in Europe unthinkable. The EU currently consists of 28 member states, including most of the countries of Central and Eastern Europe, and has helped to promote peace, stability, and economic prosperity throughout the European continent. The EU has been built through a series of binding treaties. Over the years, EU member states have sought to harmonize laws and adopt common policies on an increasing number of economic, social, and political issues. EU member states share a customs union; a single market in which capital, goods, services, and people move freely; a common trade policy; and a common agricultural policy. Nineteen EU member states use a common currency (the euro), and 22 member states participate in the Schengen area of free movement in which internal border controls have been eliminated. In addition, the EU has been developing a Common Foreign and Security Policy (CFSP), which includes a Common Security and Defense Policy

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(CSDP), and pursuing cooperation in the area of Justice and Home Affairs (JHA) to forge common internal security measures. Member states work together through several EU institutions to set policy and to promote their collective interests. In recent years, however, the EU has faced a number of internal and external crises. Most notably, in a June 2016 public referendum, voters in the United Kingdom (UK) backed leaving the EU. The pending British exit from the EU (dubbed "Brexit") comes amid multiple other challenges, including the rise of populist and to some extent anti-EU political parties, concerns about democratic backsliding in some member states (including Poland and Hungary), ongoing pressures related to migration, a heightened terrorism threat, and a resurgent Russia. The United States has supported the European integration project since its inception in the 1950s as a means to prevent another catastrophic conflict on the European continent and foster democratic allies and strong trading partners. Today, the United States and the EU have a dynamic political partnership and share a huge trade and investment relationship. Despite periodic tensions in U.S.-EU relations over the years, U.S. and EU policymakers alike have viewed the partnership as serving both sides' overall strategic and economic interests. EU leaders are anxious about the Trump Administration's commitment to the EU project, the transatlantic partnership, and an open international trading system-especially amid the Administration's imposition of tariffs on EU steel and aluminum products since 2018 and the prospects of future auto tariffs. In July 2018, President Trump reportedly called the EU a "foe" on trade but the Administration subsequently sought to de-escalate U.S.-EU tensions and signaled its intention to launch new U.S.-EU trade negotiations. Concerns also linger in Brussels about the implications of the Trump Administration's "America First" foreign policy and its positions on a range of international

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issues, including Russia, Iran, the Israeli-Palestinian conflict, climate change, and the role of multilateral institutions. This report serves as a primer on the EU. Despite the UK's vote to leave the EU, the UK remains a full member of the bloc until it officially exits the EU (which is scheduled to occur by October 31, 2019, but may be further delayed). As such, this report largely addresses the EU and its institutions as they currently exist. It also briefly describes U.S.-EU political and economic relations that may be of interest.

Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law - Amalia Athanasiadou 2018-08-14

Reverse payment settlements or “pay-for-delay agreements” between originators and generic drug manufacturers create heated debates regarding the balance between competition and intellectual property law. These settlements touch upon sensitive issues such as timely generic entry and access to affordable pharmaceuticals and also the need to preserve innovation incentives for originators and to strengthen the pipeline of life-saving pharmaceuticals. This book is one of the first to critically and comparatively analyse how such patent settlements and various other strategies employed by the pharmaceutical industry are scrutinised by both United States (US) and European courts and enforcement authorities, and to discuss the applicable legal tests and the main criteria used for their assessment. The book’s ultimate objective is to provide guidance to the pharmaceutical industry regarding the types of patent settlements, strategies and conduct which may be problematic from US antitrust and European Union (EU) competition law perspectives and to assist practitioners in structuring settlements which are both efficient and compliant. To this end, an exhaustive legal analysis of some of the most controversial issues regarding pharmaceutical patent settlements is provided, including: – the lengthy split among

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US Circuit Courts on the issue of pay-for-delay settlements, its resolution by the US Supreme Court in FTC v. Actavisand subsequent jurisprudence; – the decision of Lundbeck v. Commissionby the European General Court and the Servier decision of the European Commission; – the Roche/Novartisdecision of the European Court of Justice and the most important decisions by National Competition Authorities on pharma patent settlements in the EU; – an overview of other types of strategies such as product-hopping and product reformulations, no-authorised generic commitments, problematic side-deals, mechanisms affecting generic substitution; – the rejection of the “scope of the patent” test in both the US and the EU and the balancing of patent law and antitrust law considerations in the prevailing applicable tests; – the benefits of settlements and the main criteria for assessing their legitimacy under US antitrust and EU competition law. The analysis provides concrete examples of both illegitimate and legitimate settlements and strategies, emphasising on conduct that falls within a grey zone and on the circumstances and criteria under which such conduct could be deemed problematic from an antitrust perspective. This book will serve as a valuable guide for pharmaceutical companies wishing to minimise the risk of engaging in conduct that could potentially infringe US antitrust and EU competition law. It further aims to save courts and enforcement agencies and also practitioners and academics considerable time and resources by providing an exhaustive analysis of the relevant caselaw, with the ultimate goal to increase legal certainty on the most controversial aspects of patent settlements in the pharmaceutical industry.

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