Chapter 1 Marketing Authorisation European Commission

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, they are national IP 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 in the prosecution of SPCs across Europe. This one-of-a-kind handbook provides an easily accessible overview 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 separate national chapters for eleven key jurisdictions ? i.e., Germany, the United Kingdom, France, the Netherlands, Belgium, Italy, Spain, Portugal, Sweden, Iceland, and Switzerland, as well as a concluding chapter summarizing the fundamentals of SPC law and practice in sixteen further European countries. The contributors to this book, all experts in the field of SPCs in their respective jurisdictions, provide clear and hands-on guidance on a range of specific topics of practical and strategic relevance, including: • What is or is not an ‘active ingredient' amenable to SPC protection? • What is required for an active ingredient to be ‘protected' by a basic patent? • What relevance has the ‘core inventive advance' of the basic patent? • Can SPCs be obtained for ‘loose' combinations of separately formulated active ingredients? • Which basic patent should be chosen for an SPC filing? • Which types of marketing authorizations can be relied upon? • Under which conditions can SPCs be obtained for a new specific salt, ester or other derivative of a previously approved active ingredient, for a new specific enantiomer of a previously approved racemate, and for new therapeutic applications of previously approved active ingredients? • Can affiliated companies obtain several SPCs for the same product? • Does the revocation of an SPC enable the filing of a new SPC for the same product? • What are the limits to the filing of ‘unfriendly' SPCs based on third-party marketing authorizations? • What relevance does the product definition of an SPC have for its scope of protection? • What is the scope of protection of an SPC in relation to derivatives of an active ingredient? • How is the SPC term calculated, and how can an erroneous term be corrected? • How can SPCs and paediatric extensions be invalidated, and which grounds of invalidity can be invoked? • What pitfalls must be avoided in terms of unfair competition law? This book provides invaluable assistance to IP practitioners in devising successful pan-European SPC filing strategies. Its practice-oriented, country-by-country format makes it easy to compare the national practices and the respective national case law of the different European countries.

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.

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

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 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

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.
141p
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 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.
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.
An important reference for researchers in the pharmaceutical industry, environmentalists and policy makers wanting to better understand the impacts of pharmaceuticals on the environment.
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.
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.
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.
The CEFR Companion volume broadens the scope of language education. It reflects academic and societal developments since the publication of the Common European Framework of Reference for Languages (CEFR) and updates the 2001 version. It owes much to the contributions of members of the language teaching profession across Europe and beyond. This volume contains: ? an

explanation of the key aspects of the CEFR for teaching and learning; ? a complete set of updated CEFR descriptors that replaces the 2001 set with: - modality-inclusive and gender-neutral descriptors; - added detail on listening and reading; - a new Pre–A1 level, plus enriched description at A1 and C levels; - a replacement scale for phonological competence; - new scales for mediation, online interaction and plurilingual/pluricultural competence; - new scales for sign language competence; ? a short report on the four-year development, validation and consultation processes. The CEFR Companion volume represents another step in a process of engagement with language education that has been pursued by the Council of Europe since 1971 and which seeks to: ? promote and support the learning and teaching of modern languages; ? enhance intercultural dialogue, and thus mutual understanding, social cohesion and democracy; ? protect linguistic and cultural diversity in Europe; and ? promote the right to quality education for all.

'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.

The Rules Governing Medicinal Products in the European UnionThe rules governing medicinal products for human use in the European UnionThe Rules Governing Medicinal Products in the European UnionUnipub

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.

Written by a team of lawyers with long-standing experience in patent litigation in Europe, this book is a comprehensive and practical guide to European patent law, highlighting the areas of consistency and difference between the most influential European patent law jurisdictions: the European Patent Office (EPO), England & Wales, France, Germany and the Netherlands. It is frequently the case that the decisions and approaches of these courts are cited by European patent lawyers of all jurisdictions when submitting arguments in their own national courts. The book is therefore intended to provide a guide to patent lawyers acting in the national European courts today. The book also looks to the future, by addressing all the areas of patent law for which the proposed Unified Patent Court (UPC) will need to establish a common approach. Uniquely, the book addresses European patent law by subject matter area, assessing the key national and EPO approaches together rather than in nation-by-nation chapters; and provides an outline in each chapter of the common ground between the national approaches, as a guide for the possible application of European patent law in the UPC.

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 ...

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.

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 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

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 report assesses how pharmaceutical pricing and reimbursement policies have contributed to the achievement of certain health policy objectives, and it examines the national and transnational effects of these policies.

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 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.

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.

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

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.

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.

This volume comprises 12 chapters authored by Covington & Burling lawyers. These chapters cover key areas of EU law that impact the life sciences industry, including the specific regulatory obligations that apply to life sciences companies, EU competition rules, EU data protection rules and the laws governing bribery. Each chapter is authored by one or several leading specialists of the subject matter discussed. EU Law and Life Sciences aims at providing in house counsel in life sciences firms, regulators, and lawyers with a comprehensive view of the complex set of rules that affect the business of life sciences companies. It combines theoretical insights with practical advice.

The Cambridge Yearbook of European Legal Studies provides a forum for the scrutiny of significant issues in EU Law, the law of the European Convention on Human Rights, and Comparative Law with a 'European' dimension, and particularly those issues which have come to the fore during the year preceding publication. The contributions appearing in the collection are commissioned by the Centre for European Legal Studies (CELS) Cambridge, a research centre in the Law Faculty of the University of Cambridge specialising in European legal issues. The papers presented are at the cutting edge of the fields which they address, and reflect the views of recognised experts drawn from the University world, legal practice, and the institutions of both the EU and its Member States. Inclusion of the comparative dimension brings a fresh perspective to the study of European law, and highlights the effects of globalisation of the law more generally, and the resulting cross fertilisation of norms and ideas that has occurred among previously sovereign and separate legal orders. The Cambridge Yearbook of European Legal Studies is an invaluable resource for those wishing to keep pace with legal developments in the fast moving world of European integration.

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

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.

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