



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and products
Medicinal products

Revision 5

NOTICE TO APPLICANTS

VOLUME 2A
Procedures for marketing authorisation
CHAPTER 1
MARKETING AUTHORISATION

July 2015

This Chapter 1 Marketing Authorisation will be included in The Rules governing Medicinal Products in the European Union
The Notice to Applicants Volume 2A Procedures for marketing authorisation

Chapter 1 Marketing Authorisation European Commission

European Commission



Chapter 1 Marketing Authorisation European Commission:

Guide to EU and UK Pharmaceutical Regulatory Law Pieter Erasmus, Sally Shorthose, 2025-10-30 In the European Union EU its Member States and the United Kingdom UK post Brexit as elsewhere the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but also safe This useful book lays out this system with extraordinary clarity and logic Adopting a Europe wide perspective on the law governing pharmaceuticals expert contributors from the law firm Bird stages and standards for creating a product dossier obtaining a marketing authorisation how and when an abridged marketing authorisation procedure can be used criteria for conditional marketing authorisations generic products and essential similarity paediatric use and the requisite additional trials orphan medicinal products biologicals and biosimilars homeopathic herbal and similar medicines medical devices pandemics epidemics and vaccines pharmacovigilance parallel trade advertising and relevant competition law intellectual property rights and data protection regulation 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

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 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

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

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 US Circuit Courts on the issue of pay for delay settlements its resolution by the US Supreme Court in *FTC v Actavis* and subsequent jurisprudence the decision of *Lundbeck v Commission* by the European General Court and the *Servier* decision of the European Commission the *Roche Novartis* decision 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 *The Rules Governing Medicinal Products in the European Union* Commission of the European Communities,1998 1 Marketing authorisations 2 Mutual recognition 3 Community referral 4 Centralised procedure 5 Variations 6 Community marketing authorisation 7 General information **Intellectual Property Law and Human Rights** Paul Torremans,2020-06-08 Intellectual Property Law and Human Rights Fourth Edition Edited by Paul L C Torremans Once regarded as a niche topic the nexus of intellectual property and human rights now lies in the eye of the storm that is today s global economy In this expanded new edition of the pre eminent work in this crucial area of legal theory and practice with nine completely new chapters well known authorities in both intellectual property law and human rights law present an in depth analysis and discussion of essential and emerging issues in the convergence of intellectual property law and human rights law The fourth edition is fully updated to address current matters as diverse as artificial intelligence climate change and biotechnological materials all centred on the relations between intellectual property and freedom of expression and the fundamental right to privacy in an intellectual property environment The contributors address such topics as the following and more the status of copyright as a fundamental right fair use transformative use and the US First Amendment intellectual property in the jurisprudence of the European Court of Human Rights freedom to receive and impart information under the EU Charter of Fundamental Rights how to mitigate the risks article 17 of Directive 2019 970 poses to freedom of expression fair dealing defences algorithmic copyright enforcement and free speech developing a right to privacy for corporations expanding the role of morality and public policy in European patent law and ethical and religious concerns over patenting biotechnological inventions As human rights issues continue to arise in an intellectual property context practitioners academics and policymakers in both fields will continue to recognize and use this well established cornerstone work in the debate as a springboard to the future development of the ever more prominent interface of intellectual property and human rights Bio-science Law Review ,2001 **The Rules Governing Medicinal Products in the European Union** European Commission,1998 Examine the rules governing medicinal products for use in Europe in this five volume collection Volume I contains rules governing medicinal products for human use Volume II provides notice to applicants for marketing authorizations and includes 2 disks Volume III presents guidelines on quality safety and efficacy of medicinal products for human use Volume IV is a guide to good manufacturing practices for medicinal products for human and veterinary use Volume V contains rules governing medicinal products for veterinary use Fact Sheets on the European Union ,2009 *Official Journal of the European Communities* ,1998 **California Fruit News** ,1917 *Documents* ,1998 **General and Applied Toxicology** Bryan Ballantyne,Timothy C. Marrs,Tore L. M. Syversen,2009

European Pharmacopoeia Council of Europe, 2010 The 7th edition of the European Pharmacopoeia was published July 15 2010 and consists of a two volume main edition It is complemented by non cumulative supplements that are to be kept for the duration of the 7th Edition Two supplements were published in 2010 and three supplements will be published in each 2011 and 2012 It contains information on all types of active substances used to prepare pharmaceutical products various chemical substances antibiotics biological substances vaccines for human or veterinary use immunosera radiopharmaceutical preparations herbal drugs and homoeopathic preparations Over 1800 specific and general monographs are included

Statutory Instruments Great Britain, 2005 European Access ,1995 **Opinion on the Ethical Aspects of Clinical Research in Developing Countries** European Group on Ethics in Science and New Technologies to the European Commission, 2003 *Reports of Cases Before the Court of Justice and the Court of First Instance* ,2010 *Reports of Cases Before the Court of Justice and the Court of First Instance* Court of Justice of the European Communities, 2007 **Fish Vaccinology** Roar Gudding, 1997 This is the first book to give complete coverage of the field of fish vaccinology Written by acknowledged experts from 15 different countries the reviews in this volume not only provide the theoretical basis for the vaccination of fish but also present a wealth of practical aspects The main topics covered include the immune system of fish methods of vaccine delivery immunization with bacterial viral and parasite antigens antigen production methods of vaccine evaluation regulatory aspects licensing of fish vaccines in Europe and America environmental effects vaccination strategies Compiling the most up to date and comprehensive information on how to protect fish from infectious diseases this book will become the Bible of fish vaccinology It will be of great value to veterinarians fish biologists fish pathologists manufacturers of fish vaccines and anyone concerned with fish health

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