Guide To EU Pharmaceutical Regulatory Law

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In the European Union 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 of the urgent and essential role such products play in human development and welfare worldwide. This incomparably useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, its 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 clear unambiguous guidance in matters of regulatory law at every stage. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe A--- 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; * notification of adverse events; * parallel trade; * relevant competition law and intellectual property rights; and * advertising. Especially useful features include national variation charts in many of the chapters for eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK), sample forms and URLs for the most important Directives, Lawyers, both in-house at pharmaceutical firms and in private practice, will welcome this one-of-a-kind book. Its value for those who find themselves having to advise a client on bringing a medicinal product or medical device to market - and on the relevant continuing rights and obligations - is immeasurable. The book will also be of great interest and assistance to regulatory advisers.

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