# Guide to EU Pharmaceutical Regulatory Law, Fourth Edition

*Sally Shorthose, Bird & Bird LLP*

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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 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.

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.

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