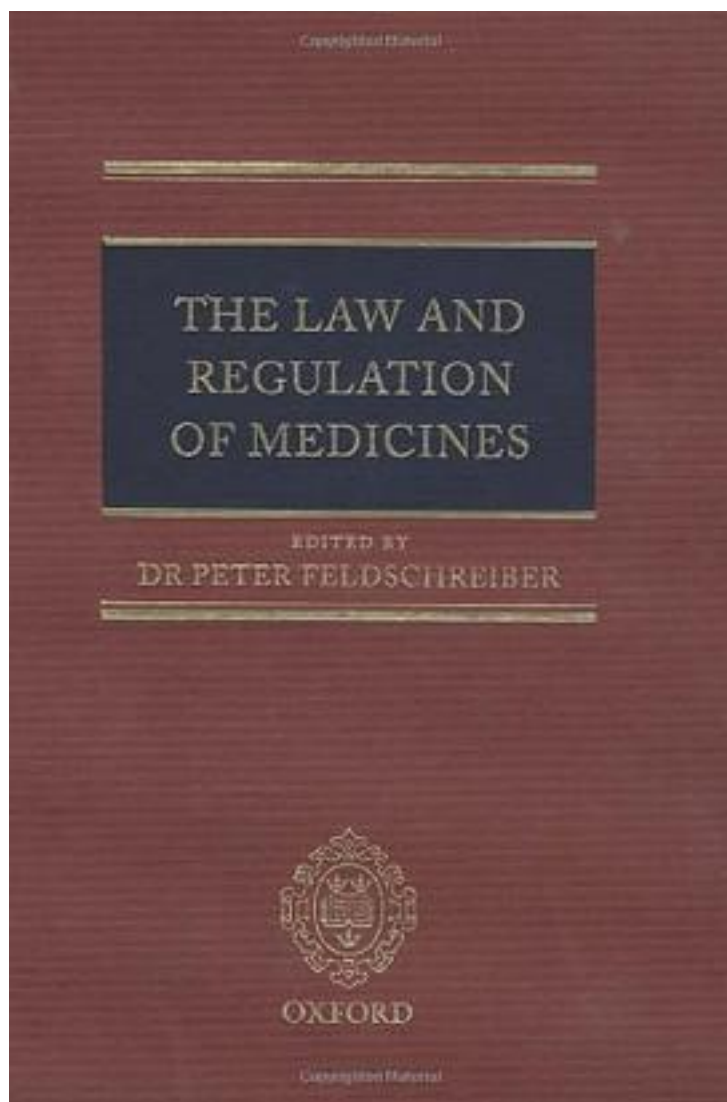


The Law and Regulation of Medicines



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This is a comprehensive textbook on the science, regulatory policy and law surrounding the discovery, development and marketing of new medicines. It is a reference work and source of expertise for legal, medical, and pharmaceutical professionals working in the fields of medicine regulation, medical law and product liability. Written by an author team comprising specialists in pharmaceutical medicine, pharmacology and therapeutics, and lawyers specialising in product liability law and intellectual property, this book reviews all the areas of science, regulatory policy and legislation, together with the consumer protection and intellectual property law as applicable to the development and commercialisation of medicinal products. Serving as a practical introduction for practitioners wishing to undertake work in this highly complex area of law, this book is specifically designed to facilitate deeper mutual understanding of the scientific and technical issues for the lawyer, and the legal issues for those involved with regulatory policy and decision making and senior executives in the pharmaceutical industry. The work covers the European and UK legislation on medicines and healthcare products, including the principal directives and regulations, together with UK implementing legislation and instruments, and the key case law. It covers the structure and function of the regulatory authorities, applications to carry out clinical trials, intellectual property issues, product liability issues and litigation. This book provides practical guidance on drafting regulatory submissions, preparing litigation against decisions of the regulatory authorities; determining appropriate regulatory submission strategies throughout the European Community, and preparing litigation relating to medicinal products liability under the Product Liability Directive and the Consumer Protection Act 1987.

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