Law and the Regulation of Medicines

Emily Jackson

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The principal purpose of this book is to tell the story of a medicine's journey through the regulatory system in the UK, from the definition of a medicine, through clinical trials, licensing, pharmacovigilance, litigation, marketing, and funding. While the UK's regulatory regime is the principal focus, the question of global access to medicines is addressed, not only because of its political importance, but also because it is an issue which places the question of whether medicines are a private or a public good in particularly stark focus. Two specific challenges to the future of medicines regulation are examined separately: pharmacogenetics, or the genetic targeting of medicines to subgroups of patients, and the possibility of using medicines to enhance wellbeing or performance, rather than treat disease. Throughout, the emphasis is upon the role of regulation in shaping and influencing the operation of the medicines industry, an issue which is of central importance to the promotion of public health and the fair and equitable distribution of healthcare resources. The book will be of interest to medical lawyers and scholars interested in medical law, as well as those who deal with the regulation of medicines on a professional basis.

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