



The Law and Ethics of the Pharmaceutical Industry

M.N.G. Dukes

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As one of the most massive and successful business sectors, the pharmaceutical industry is a potent force for good in the community, yet its behaviour is frequently questioned: could it serve society at large better than it has done in the recent past? Its own internal ethics, both in business and science, may need a careful reappraisal, as may the extent to which the law - administrative, civil and criminal - succeeds in guiding (and where necessary constraining) it.

The rules of behavior that may be considered to apply to today's pharmaceutical industry have emerged over a very long period and the process goes on. Even the immensely detailed standards for quality, safety and efficacy laid down in drug law and regulation during the second half of the twentieth century have their limitations as tools for ensuring that the public interest is well served. In particular, national and regional regulatory agencies are heavily dependent on industrial data for their decision-making, their standards and competence vary, and even the existing network of agencies does not cover the entire world. What is more there are many areas of law and regulation affecting the industry, concerning for example the pricing of medicines, the conduct of clinical studies, the health protection of workers and concern for the environment. In some fields it is indeed hardly possible to maintain standards through regulation.

Professor N.M. Graham Dukes, a physician and lawyer with long term experience in industrial research management, academic study and international drug policy, provides here a powerfully documented analysis into the way this industry thinks, acts, and is viewed, and examines the current trends pointing to change.

- *Provides a balanced picture of the current role of the pharmaceutical industry in society
- *Includes indices of conventions, laws, and regulations; as well as judicial and disciplinary cases
- *This is the only book addressing the legal implications of big pharma activities and ethical standards

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