

## BOOK REVIEW

### GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD

*Frederick M Abbott and Graham Dukes*

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How can we ensure that safe and effective pharmaceutical products are available and affordable to those who need them, both in the developed and developing worlds? This is the central research question pursued by the eminent scholars Abbott and Dukes in their timely, ambitious and informative book.

The question posed by the authors is of obvious importance, but is unfortunately difficult to answer. The pharmaceutical industry is complex and subject to regulation from many angles. Tinkering with this regulatory framework could upset the delicate balance of private and public interests that has been forged, bringing adverse consequences for industry and patients alike. Nevertheless, the authors, ably assisted by contributions from expert participants at a roundtable meeting held at Florida State University in 2007, have done a superb job in identifying the weaknesses and tensions in current policies and suggesting practical reforms thereof.

Abbott and Dukes' analysis unfolds over ten chapters, each of which is discrete yet interlinked. In chapter one, the authors provide a helpful summary of the structure of the book and introduce its main arguments. Chapters two and three are closely connected and examine how pharmaceutical innovation is encouraged and new drugs developed and brought to market.

Chapter two ("Promoting innovation: patents, subsidies and prizes") focuses on the role of the patent system in stimulating investment in pharmaceutical research. Patents, and indeed market-based incentives in general, are viewed by Abbott and Dukes in this context as being a double-edged sword. Drug development is an expensive and commercially risky affair. Without the lure of potentially massive profits gathered during the period of patent protection, less money would be invested in the pharmaceutical sector.

Yet, Abbott and Dukes argue, the very same incentive structures can work against the public interest by actually encouraging sub-optimal levels of innovation. For example, rather than following the high risk, high reward strategy of attempting to design truly innovative "blockbuster" drugs, pharmaceutical companies may instead choose to play safe by spending smaller amounts of money to achieve minor improvements to existing drugs. The improved versions can be patented, thereby extending the originator company's monopoly term and restricting competition from generic manufacturers (a practice known as "evergreening"). Market incentives also skew research programmes towards the most profitable markets, such as those for so-called "lifestyle" diseases that affect those in wealthier countries. Diseases such as sleeping sickness that ravage poorer countries are commercially unattractive and therefore largely ignored by the private sector.

Some of the strategies for addressing these problems involve the recalibration of the patent system itself. For example, raising the bar on the inventive step requirement in patent law could incentivise companies to direct their research budgets towards creating truly breakthrough new drugs (rather than modest incremental improvements on existing drugs). The authors also weigh up the possible benefits of creating a “tiered” patent system. Under this regime, small improvements to existing drugs would only be eligible for weaker forms of intellectual property protection through “utility models” or “petty patents”. By contrast, more groundbreaking drugs could receive the full twenty years of strong patent protection. Other proposals include the use of “carrots” other than patents to stimulate pharmaceutical innovation, such as granting subsidies to those prepared to embark on a particular line of research or awarding prizes to those who achieve its successful completion.

In chapter three (“Policies on innovation: past, present and future”), the authors present statistical data which shows a marked decline in rates of pharmaceutical innovation (defined by the numbers of “radical innovations” and “innovations related to existing drugs” entering the market) since the mid-1980s. Abbott and Dukes seek to elucidate the possible reasons behind this trend. They suggest that the rising costs of research and marketing, or the consolidation of industry into a small number of large firms may have played a causal role. Another explanation is the “low hanging fruit” hypothesis. This is the idea that much of what can be achieved through small-molecule chemistry has now already been “picked”. Future innovation may therefore require novel and more complex approaches. Building on this point, the authors discuss the promise of biotechnology to raise levels of innovative output, and consider the regulatory approaches that might best facilitate such progress.

Abbott and Dukes reject the claim that burdensome regulatory requirements, such as the need to assess the effects of a drug through toxicological and clinical studies, have deterred innovation. They go on in chapter four (“The global regulatory environment: quality, safety and efficacy”) to analyse in more detail the system for approval of new drugs. Historical background is provided in relation to the emergence of dedicated drug regulatory agencies, such as the US Food and Drug Administration (FDA), which were set up, despite strong opposition from industry, to protect the public by ensuring that drugs are safe and effective.

What degree of safety and efficacy are people entitled to expect when they take approved medicines? Clearly, absolute standards are unrealistic, as no medicine is entirely safe or 100% effective. Regulatory approval, therefore, signifies that a drug is deemed “sufficiently” or “reasonably” safe and effective, given its known benefits and side-effects and the severity of the condition(s) for which it is indicated. Yet, in addition to these known risks that patients must accept, drugs may carry unforeseen risks that cannot be detected during clinical trials. It is therefore vital that effective systems are put in place to monitor adverse drug reactions. Abbott and Dukes question whether the reporting of adverse reactions to the authorities should be the subject of legal obligation or dependent on the good faith of reporters, and favour the latter approach.

Data confidentiality is a further area of concern in relation to the drug approval process. This privilege may be abused by companies hoping to extend their period of market exclusivity by delaying the entry of generic drugs into the market. More worryingly, control over proprietary data can be used to suppress evidence of adverse

effects revealed during clinical trials. Legal solutions to both of these problems are explored.

Chapter five (“Medicines for the developing world”) provides a systematic discussion of the myriad problems that can limit access to safe and effective medicines in developing countries. The TRIPS Agreement and the restrictive intellectual property clauses in free trade agreements present one set of barriers. Other challenges include patchy infrastructure for the procurement, inspection and distribution of drugs and the lack of R&D targeted towards the health needs of poorer countries. Abbott and Dukes cite the emergence of the “essential drugs” concept (as embodied in the “Model List of Essential Drugs” of the World Health Organization (WHO)) and public-private partnerships (such as the Gates Foundation “Medicine for Malaria” venture) as examples of valuable strategies worthy of further support.

The later chapters of the book examine some of the less frequently discussed but nevertheless important areas of pharmaceutical policy. Chapter six (“The use of medicines: education, information and persuasion”) casts a critical eye over the ways information regarding drug safety and efficacy is conveyed to health professionals and the public. It is in this chapter that the influence of industry perhaps seems most insidious and corrosive. Examples of dubious practices abound. Medical journals that publish articles critical of the exaggerated claims of drug advertisements face punishment in the (somewhat ironic) form of advertising boycotts. Physicians are visited by pharmaceutical representatives (a role which is apparently, in the United States, often filled by attractive young women) who build relationships of trust and employ sales techniques to attempt to influence prescribing practice. Gifts, lunches and even all-expenses paid trips to attend symposia in exotic locations may be offered to doctors as part of the promotional activities of a drug company. Abbott and Dukes do not argue that drug marketing should be halted altogether. They do, however, offer suggestions as to how to counter the industry’s more questionable techniques of persuasion and restore objectivity to the information environment.

Chapter seven (“Regulation and the role of the courts”) discusses, *inter alia*, civil litigation against pharmaceutical companies on the grounds of misleading advertising or drug-related injury. Abbott and Dukes argue that litigation serves a number of useful social functions in this context. It can protect the interests of individual plaintiffs by providing compensation for harm. It can also promote the broader public interest by deterring misconduct and providing a forum in which information on product safety might come to light. The authors are therefore critical of the growing acceptance of the US tort law doctrine of “pre-emption” (whereby approval by a drug regulatory agency shields a manufacturer from civil liability) which they suggest would deprive society of these benefits.

Chapter eight (“Specialized policy areas: vaccines biologicals and blood products; alternative and traditional medicines; self-medication; counterfeit medicines”) provides analysis of various policy sub-fields that merit separate consideration. Chapter nine (“The rich, the poor and the neglected”) highlights the problem of over-subscription of medicines, which raises concerns from the perspectives of public health and economic waste. Abbott and Dukes also survey the measures adopted in France and the United States to encourage research into rare and neglected diseases (also referred to as ‘orphan diseases’). Although these initiatives have yielded some success stories, the authors observe that further fine-tuning may be necessary to prevent abuse in the form of inappropriate profiteering.

In the final chapter (“Global and regional policies: the way ahead”), the various strands of the book are drawn together and suggestions are made for the definition of future policy objectives. The “global” in the title of the book is brought to the fore in discussions of the pros and cons of “global solutions”. One idea floated by Abbott and Dukes is the establishment of a global drug regulatory agency, perhaps operating under the auspices of the WHO, which could maintain uniform standards and avoid the wasteful duplication of effort involved in drug approval on a country-by-country basis. Conceding, however, that this goal may not be achievable in practice, or even wholly desirable, the chapter looks at more feasible alternatives, such as the continuation of international policy-setting by the WHO through consensus-building and the provision of technical support. It also examines the advantages of regional coordination of drugs policy amongst homogenous groups of nations, with examples including the Eastern Caribbean Drug Service (ECDS), the Association of South East Asian Nations (ASEAN) and the European Medicines Evaluatory Agency (EMA). The discussion concludes with reiteration of the core messages from the previous chapters.

Abbott and Dukes have produced a book that is holistic in its approach and forward thinking in its outlook. It is written in a clear and erudite style and manages to provide detailed analysis without ever losing sight of the “big picture”. As the authors themselves point out, there are no magic solutions to the complex problems in this field. Nevertheless, this work provides an excellent framework for thinking about the strengths and deficiencies of the current system and advances powerful arguments in favour of joined-up thinking and smarter regulation. The book is essential reading for students, academics, practitioners and policy-makers interested in the future of pharmaceutical law and policy.

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