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Frederick M. Abbott & Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World*

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The book is divided into neat 10 chapters – starting from the current challenges in Chapter 1[1] to "The Way Ahead in Global and regional policies" in chapter 10. Chapter 2 deals with "Promoting innovation: patents, subsidies, prizes and prices" while chapter 3 focuses on "Policies on Innovation: past, present and future." Chapter 4 elaborates on "The global regulatory environment: quality, safety and efficacy". Chapters 5 and 6 discuss the burning issues relating to "Medicines for the developing world" and "The use of medicines: education, information and persuasion". Chapter 7 spells out the issues relating to "Regulation and the role of courts". Chapters 7 and 8 zoom down to "Specialized policy areas: vaccines, biologicals and blood products; alternative and traditional medicines; self-medication counterfeit medicines". The topic of "The rich, the poor and the neglected" is discussed in chapter 9.The last chapter spells out the "Global and regional policies: the way ahead".

Though the title – Global Pharmaceutical Policy Ensuring Medicines for Tomorrow's World – indicates a futuristic approach, the topic has been analyzed holistically with facts and figures available as on the date of publication (2009) and hence is contemporary. The

[1] Entitled, "The challenges we face"

book gains additional significance in the light of the acrimonious debates and fierce controversy raging in the post-TRIPs regime over the commercial rights of the MNCs to drug patents vis-à-vis the health rights of the patients in the poor and underdeveloped countries of the world.

The authors – Frederick M. Abbott and Graham Dukes are renowned scholars with expertise in the areas of Intellectual Property Rights and the Pharmaceutical sector with personal involvement, at varied levels as advisers to government and international organizations, in the formulation and design of policies relating to innovation, access and affordability of medicines.

The language is crisp and easy, and makes interesting and absorbing reading. The style is elegant and the approach is objective and rational.

In chapter 2 the authors have succinctly discussed "the rights and the wrongs of the patent system" and have also offered some options for reform: tweaking and fine-tuning the criteria for "inventive step"[2]; requiring demonstrable efficacy as condition of patent grant;[3] creation of a tiered patent system (quasi-patents)[4] with term and/or remedy dependent on the level of innovation. Similarly, the authors suggest that the judiciary should shift its focus from traditional remedies of grant of injunction or damages to liability or royalty regime.[5]

While writing on Policies on Innovation[6] the authors have interestingly included a part relating to "The promise – and Problems – of Biotechnology". Several insights into this emerging area of specialization can be obtained – pharming which causes an animal or plant to secrete modified substances which can be used in medicine or health care; pharmacogenomics which determines the adequacy of reaction of all the genes in a patient to a select drug, etc. The box-item dealing with "Fields of Biotechnological Exploration of Known or Possible Relevance to medical Treatment" based on OECD Report of 2007 lists the products that are produced using the new biotechnologies. The authors have expressed their concerns regarding the applicability of "almost any conceivable form of human experimentation" despite the general rules regarding risks to trial subjects and their informed consent, approval and monitoring by an independent and expert body with powers vested in it to terminate the study wherever it might be necessary in public interest.

In this context, it is pertinent to note some of the principles suggested by the authors for policy development in this field. They have suggested, inter alia, the need for some supplementary provisions in law for establishment or modification of regulatory authorities (as has been done in Australia by the setting up of the Office of the Gene

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[2] at 34.
[3] Id at 35.
[4] Id. Where it is suggested that the term of the quasi-patent could be limited (for 8 years or differential terms could be based on innovation/utility criteria) or the rights of the holder could be restricted (to collection of royalty from third-party users rather than exclusion from the market)
[5] Id. at 38
[6] Vide chapter 3

Technology Regulator); need for re-constitution of drug regulatory authorities and bodies such as an Ethical Review Committee and the special need for delegation of decision-making to experts in this new area, especially with special reference to small and developing countries.

Apart from the traditional views on the role of animal studies the authors opine that the very novelty of biotechnological products may warrant priority in the review process besides ensuring adequate precautions in the responsible and safe use of these products. Considering the widespread impact of such products on the entire human population at times with potential to cause irreversible damages and the huge ramifications on the environment it becomes incumbent to have international consensus to avert major risks to human health. Public consultation on these issues, according to the authors, also becomes imperative.

While elaborating on "the global regulatory environment: quality, safety and efficacy" in chapter 4 the figure depicting the Drug Policy Matrix captures the complete dynamics involved in formulation of drug policy and the place of regulation in the matrix to highlight the need for comprehensive and balanced policies. Despite all the pharmacopoeias and the regulatory rules and mechanisms, it is not uncommon for some drug disasters, as has been shown in the Box 4.2 at 95. The essential facts of Thalidomide case have also been provided; the continued marketing by the German drug manufacturer despite troubling medical evidences to the contrary, stands as a gruesome example of the crude profit-driven decision-making in the industry.

At times, it might be several years before the deleterious effect of certain drugs are discovered. The authors point out that only after sixty years of the use of aspirin; it came to be known that its use by children and young people may "precipitate the permanently incapacitating condition known as Reye's syndrome". Hence, it becomes necessary to have adverse reaction reporting system though the extent and efficacy would ultimately depend on the willingness of the prescribers of these medicines to share the information and also on the local legal system.

Yet another aspect which assumes importance in recent times revolves around the confidentiality of data, market and data exclusivity. The authors have cited the case of the attempt by Smith Kline & French Laboratories regarding the patent on cimetidine (which had been marketed in 1976 and was under patent protection until 1992) to prevent registration of generic versions of the drug on the basis of its data. Several cases of protracted litigation have been frequently reported[7]. There is an interesting comment by the authors regarding the decision of the US and EU to grant limited time data exclusivity for orphan drugs.[8]

The incorporation of the figure on WHO Access Framework is both descriptive and self-explanatory in the box item on Pharmaceutical market Development & Challenges in Africa in the chapter on "Medicines for the developing world". The three essential

[7] Vide Syngenta India Ltd vs Union of India (W.P. (C) 8123/2008
[8] At 108

challenges – counterfeiting of drugs, the dilution of flexibilities available under TRIPs by FTAs, the total neglect of "untreated diseases and those for which existing drugs are encountering problems of resistance" require multi-pronged strategies. The historical background of the emergence of essential drugs policies sets the background for proper understanding of its prime importance in drug policies of developing countries. The related topics of Public private Partnerships, Transfers of Technology, the Role of Intellectual Property, the Role of Non-Voluntary Licensing, Role of the WHO, and Transnational R&D collaborations regarding biological resources have been dealt with in a detailed manner. Notwithstanding the fact that appropriate policies for the developing world have been written upon, it would have, indeed, been more useful to the readers if additional information on the changing scenario in the pharmaceutical sector – the increase in the number of patents granted in developing countries and in the US to non-US pharmaceutical organizations, the mergers and acquisitions of generic manufacturing organizations in developing countries by leading pharma MNCs, the international joint ventures between giant pharma companies and smaller pharma start-ups in developing countries, etc. had been provided.

The authors have provided hard evidence to tersely explain their views. For instance, the chapter on "Regulation and the role of courts"[9], specifically mentions several instances to substantiate their assertions: the $80,000 fine imposed on the Richardson-Merrell group in the 1960s for MER-29, Eli Lilly's settlement in June 2005 of nearly 8000 cases regarding the atypical anti-psychotic drug Zyprexa, Merck's agreement to pay $4.85 billion as settlement of 27,000 cases relating to it Vioxx.

The discussion[10] of the classic case Carbolic Smoke Ball (1893) to elaborate the judicial attitude with reference to guarantees of efficacy reveals the comprehensive and in-depth treatment of the topic.

The case of Ms. Ilo Grundberg of Utah[11], who shot her beloved mother under the influence of a prescribed drug triazolam (Halcion) in 1988 even though the product license had been suspended in Netherlands since 1979 and Upjohn, the pharmaceutical company had full knowledge of the data from clinical studies, graphically exposes the callous attitude and the greed of the pharmaceutical companies. Similarly, the importance of judicial intervention (however inadequate the relief or cumbersome the process may be) in obfuscating the ill-effects or adverse impact of drugs has been amply highlighted in the case of the unpatented low-cost estrogenic hormone diethyly-stilbestrol (DES) when due to the inability of the regulatory authorities to make a thorough analysis of drugs, innocent patients suffered[12]. Recourse to criminal prosecution for misleading advertisements and malpractices would be dependant upon the proof of culpability or "wanton disregard for public safety"[13].

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[9] From 193 - 215
[10] at 195
[11] Vide 198
[12] Vide 208
[13] Ibid 211

The value of the book is enriched by the pithy quotes from judicial authorities in small doses, just enough to whet the appetite of the interested and the curious researchers. For instance, at 217:
"…In this situation the interests of the community as a whole may override the interests of the community as a whole. To quote a decision of the US Supreme court dating back to 1905 and bearing on smallpox vaccination at the time when an epidemic was threatening:

> In every well-ordered society charged with the duty of conserving the safety of its members, the rights of the individual in respect of his liberty may at times under the pressure of great dangers be subjected to such restraints, to be enforced by general regulations, as the safety of the general public may demand."

Special topics that deserve discussion are included in the chapter on "Specialized Policy Areas"[14]. Vaccine Liability Issues in the United States is a box-item[15] providing a snapshot of the situation in the US. Although the source is based on a 1998 publication[16] later instances of claims relating to vaccinations have also been included. The reviewer is reminded of another major instance of mishap following the use of Merck's Gardarsil[17].

Similarly, "Alternative and Traditional Medicines" part of the above-cited chapter calls for comment. The approach has been constricted by the "principles of efficacy, quality, safety and truth applicable to Western medicines". One would have expected the authors to seize this opportunity to emphasize the urgent need for Access & Benefit-sharing principle[18] and to expose the bio-piracy by the Pharma MNCs and the greedy commercialization of the indigenous traditional knowledge owned by the aboriginal and primitive communities in the developing and least developed countries[19].

The last chapter encapsulates the policy concerns expressed in the previous 9 chapters with appropriate references. Market responses to bridging the drug-divide between the developed and the LDCs through PPPs – Drugs for Neglected Diseases Initiative (DNDi) and the foundation for Innovative New Diagnostics (FIND), have been mentioned. Health

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[14] From 217 - 255
[15] At 223
[16] G.Evans (1998), "Vaccine liability and safety revisited", Arch Pediatr Adolesc Med, 152, 7-10 cited on page 224
[17] vide http://deathbyvaccination.com visited on 25.08.10.
[18] As propounded in India for the use of Kani tribe's knowledge relating to Arogyapacha, (Trichopus zeylanicus), a herb with tonic qualities. In fact, India has already constituted the national Bio-diversity Authority (vide http://www.nbaindia.org/introduction.htm for further particulars). Attempts are also afoot to negotiate for an International Protocol on Access & Benefit Sharing (vide http://pib.nic.in/release/release.asp?relid=56597 visited on 26.08.10)
[19] Several instances can be cited: For example, the traditional medicinal wisdom of the Shamanic healers from the Amazonian forests leveraged to create a drug, Crofelemer for dehydration; or, the patent granted in 2010 by the USPTO for a medicinal herbal composition derived from Kenyan plants for treatment of HIV or infectious diseases; or the prominent cases relating to grant of patents relating to neem, turmeric, hoodia and other herbal products and associated knowledge that are common in India , Latin America and Africa.

Impact Fund, the "flagship proposal" of Yale University,[20] patent pools of UNIAID[21], Advance Purchase Commitments,[22] Priority Review Voucher[23] are some of the strategies suggested by academicians and researchers for changing the current drug-manufacturing paradigm pivoted around patent protection.

Notwithstanding the above observations, it indeed requires reiteration that the authors have sought to beautifully explain in a coherent manner and with ease of clarity; and, the elegance of expression makes the reading thoroughly enjoyable. To facilitate easy understanding a list of abbreviations is included. Brief "text boxes" have been included containing the presentations made at a spring 2007 meeting held at Florida State University College of Law. The authors have also to be commended for their extensive and comprehensive research. The book will prove a valuable resource for academics, researchers, and definitely for policy makers and a welcome addition to any library. This is an excellent book for any reader interested in IPRs, the pharmaceutical industry, or the health and well being of humanity.

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[20] Vide http://www.yale.edu/macmillan/igh/# for e-book on "The Health Impact Fund: Making New Medicines Accessible for All"

[21] Barring a brief mention at 59 about UNITAID, details of the innovative development financing mechanisms may have been provided in the last chapter. See http://www.diplomatie.gouv.fr/en/IMG/pdf/rapportdugroupequadripartite.pdf

[22] Vide, Kremer and Glennerster "*Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (2004)

[23] Vide Ridley, Grabowski and Moe, *Encouraging Innovative Treatment of Neglected Diseases through Priority Review Vouchers*, (2006) at http://faculty.fuqua.duke.edu/~dbr1/research/priority.pdf (last visited on 27.08.10)