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Choosing health over profit

Sarah Hiddleston

The rollercoaster the Indian pharmaceutical industry has taken this year has revealed much about the challenges and opportunities facing the sector and public health at large. Among them, we have seen the Supreme Court deny the multinational firm Novartis a patent on its cancer drug Gleevec, which paves the way for Indian industry to produce low-cost versions for patients here. But we have also seen one of the leading lights of India's industry, Ranbaxy, fined in the U.S. because its version of the cholesterol drug Lipitor was contaminated with glass.

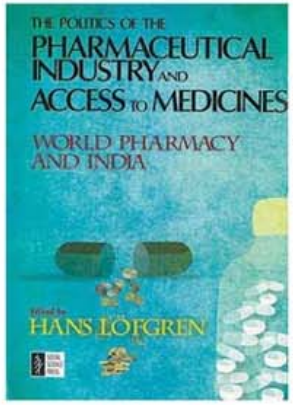
The Politics of the Pharmaceutical Industry and Access to Medicine, a collection of essays examining different aspects of pharmaceutical policymaking and the Indian industry, is therefore timely. It is also useful because it helps to break through a subject often clouded with jargon, obfuscation, intellectual traps and emotion, owing to the high stakes for all involved.

Policy issues

The book lays open the bones of the policy debate, the international treaties and what they contain, what flexibilities are possible and with these how Indian law, regulation and industry has developed. It fleshes out options for policymakers and the industry to galvanise further production, negotiate at international trade fora, and avoid anti-competitive monopolies. It examines the seeping wounds of regulatory incapacity and environmental pollution. It also offers some comparative examples showing how health policy is increasingly interrelated between countries — health policy in India may affect access to medicines in Brazil, Sub-Saharan Africa, Vietnam and Thailand but equally there are lessons in their policy making that India could apply. Finally it asks whether the patent system is the right way of balancing rewards for innovation with medical needs and offers a review of alternatives to run alongside patents or even replace them.

The book is less a comprehensive review than a collection of disparate essays tackling aspects of a vast subject. Its readability suffers somewhat from lack of cohesiveness and some repetition, but the work makes up for this in the details and insights provided in each chapter.

Of particular interest is the information and analysis given by Kajal Bhardwaj about ongoing free trade negotiations between India and the EU, Japan and the U.S. It reveals demands



The Politics of the Pharmaceutical Industry and Access to Medicines

World Pharmacy and India: Edited by Hans Lofgren; Social Science Press, 69, Jor Bagh, New Delhi-110003. Distributed by Orient Blackswan Pvt. Ltd., 1/24, Asaf Ali Road, New Delhi-110002. Rs. 725.

made for intellectual property provisions beyond what is internationally agreed. These would include stringent enforcement provisions normally used in criminal offences that rope in even distributors and providers of medicines, and would change the basis for arbitration of disputes from a transparent multilateral forum (such as the World Trade Organisation) to a private one. All of which, she says, would have a chilling effect on generic production.

The examination of the business activities of three multinational companies in India provides a lesson in what might happen should India rely too heavily on global industry to provide medicines. Christiane Fischer and Claudia Jenkes show through a rigorous methodology that medicines sold by Boehringer Ingelheim, Bayer Healthcare and Baxter, are neither directed at what is needed in India, nor priced at a rate that most people can afford, nor available in the public system. In some cases, they may even have harmful side effects. They conclude that access to medicines is better provided by the generic industry.

The trends laid out by Deepak Kumar Jena and Poduri Balaram show the global potential of India in this regard. Particularly interesting, they point to the future role of biopharmaceuticals in medicine and the role India could play as a supplier. Sales of biologicals are expected to be $150 billion by 2015. Lots of patents have already expired too, creating a gap for biogenerics. This field requires high technology skills but will give high margins.

Lack of technical capability has proven detrimental to Brazil's effort to provide its people with affordable medicines to treat HIV/AIDS, Andre de Mello e Souza explains in another chapter. This serves as a reminder that India should not fall behind the curve with new medicines in the wake of its new patent regime.

Mello e Souza shows how Brazil used the threat of compulsory licensing to force brand name companies to reduce the price of HIV medicines. Interestingly, the Brazilian government also gave its health ministry powers to review patent applications, which resulted in stricter patentability criteria.

Vietnam and Thailand have both used competition law to promote the right environment for access to medicines with mixed results, as Tu Thanh Nguyen explains. Competition law was first used in South Africa to promote access to medicines, and a careful reading of Indian competition law might allow for this in India. It could also apply to mergers and acquisitions of pharmaceutical companies.

The overall impression is one of great prospects for India. But what is the point in putting up a great fight, making investments in production and gaining expertise if slipshod and dangerous work is given the blind eye by regulatory agencies who are ill equipped, or irresponsible, or susceptible to capture by global or local players?

S. Srinivasan and Anant Phadke in chapter 2 and G. Vijay in chapter 4 show how much India has to do to pull itself up by the bootstraps with regard to regulation and monitoring of production and crack the whip on abuses.

Vijay details how pollution in a small area of Andhra Pradesh from pharmaceutical manufacturers is making its way into milk produced by cows affected in the region, which is then redistributed across India. The fact of the pollution is documented by regulatory agencies. Yet they continue to supply environmental clearances. Srinivasan and Phadke compile a long list of musts for an ethical industry that operates rationally in approving drugs including: controlling prices, weeding out irrational drugs, promoting transparency in the regulation process, encouraging a whistleblower scheme, and ensuring that market approval for safety and efficacy is kept separate from considerations of intellectual property. The Central Drugs Standard Control Organisation is, they say, in a "state of regulatory anarchy". A valuable resource for anyone interested in whether we have medicines that are safe and effective.

(Sarah Hiddleston is a journalist who writes on medicine)