

India must protect access to medicine

India needs to safeguard its vital interests in any trade agreement, the way other nations do



The pronouncements by the government, over the last year, that essential drugs would be made available free of cost at public healthcare facilities are now reflected in the 12th Five-Year Plan. Photo: Hemant Mishra/Mint

Is India committed to protecting access to essential medicines for its citizens? Several recent developments have generated national and international debate around this theme. Inevitably, issues related to patent protection and production of generic drugs feature prominently in such debates.

The pronouncements by the government, over the last year, that essential drugs would be made available free of cost at public healthcare facilities are now reflected in the 12th Five-Year Plan. The avowed intent to ensure access to drugs at affordable prices and reduce the inordinately high out-of-pocket expenditure by patients is translating into a scheme to establish Jan Aushadhi stores, which will sell inexpensive generic drugs across the country.

Further interest has been sparked by the recent judgement of the Supreme Court in the **Novartis** case and fanned by concerns about the impact of the proposed free-trade agreement (FTA) between India and the European Union (EU) on access to drugs for Indians. In the Novartis case, stretching of an expired patent, in the absence of genuine innovation or increased therapeutic efficacy, was not permitted by the court. The judgement was seminal in affirming the

principle that “evergreening” attempts cannot thwart the production of cheaper generics.

On the other hand, the draft of the EU-India FTA, as leaked on the Knowledge Ecology International website on 11 March, appears to place a premium on the protection of intellectual property, on terms defined by the commercial interests of multi-national drug companies, the ownership of which lies in high-income countries. Of particular concern are provisions related to data exclusivity, seizure by EU countries of drugs in transit to other countries (on suspicion of intellectual property being violated) and patent linkages that would preclude the registration of generics for product licensing.

It is a generally agreed principle that data related to proof of efficacy of a drug, based on clinical trials, need not be provided afresh when approval is sought for registration of a generic drug after the patent on the original product has expired.

In such cases, the regulatory agency relies on the original evidence of efficacy and safety as well as the evidence of bioequivalence between the generic and original forms. By demanding data exclusivity, large manufacturers deny access to the original evidence of efficacy that can support the claim of the generic and thereby kill competition that can lower drug prices. This is an attempt to effectively extend the patent on the branded drug, even after the patent has legally expired.

The Declaration of Helsinki, a charter of reference on bio-ethics, states that conducting duplicative clinical trials on human subjects is unethical when the question of efficacy has already been settled. Further, denial of original trial data can block a decision by any government to issue a compulsory licence to a generic manufacturer in response to a public health imperative, as permitted by the World Trade Organisation.

Seizure of generic drugs exported by India to another developing country, while in transit through a EU country, can also become an imminent threat under the FTA.

The main argument that is advanced to defend such measures, which restrict treatment access to poor patients across the world, is that protection of intellectual property is the sacred duty of governments. The case is made that large pharmaceutical companies invest a huge amount of money in research and development of new drugs and patent protection offers them the only opportunity to recover those costs.

The response is provided by **Marcia Angell**, former chief editor of the New England Journal of Medicine, the world's leading medical journal published from Boston.

Now a faculty member at Harvard, she exposes the hollowness of the case advanced by Big Pharma in her book *The Truth About the Drug Companies*. It is instructive to directly quote Angell.

“Big Pharma likes to refer to itself as a ‘research-based industry’, but it is hardly that. It could best be described as an idea-licensing, pharmaceutical-formulating and manufacturing, clinical-testing, patenting, and marketing industry. All that takes a lot of money, but the majority of its products are drugs that, in the words of the FDA (Food and Drug Administration), ‘have therapeutic qualities similar to those of one or more already marketed drugs’—in other words, me-too drugs.”

“It claims to be the innovator, as well as the developer and manufacturer of new drugs. It takes credit for the whole shebang. And on that basis it makes the case that it is more than entitled to its gargantuan profits and all the other special favours it receives—the long periods of exclusive marketing rights, freedom from any price regulation, and huge tax breaks. If the much more modest role Big Pharma really plays were widely known, if the public knew where the miracles really come from, people would demand that the industry’s rewards be more commensurate with its contributions and that there be some form of public accountability.”

Finally, it must be remembered that India needs to protect its vital interests in any trade agreement, just as other nations strive to. Our interest lies in protecting the lives and safeguarding the health of Indians, without permitting unreasonable restrictions on our ability to produce, use and even export, generic versions of drugs the patents of which have lapsed (or where compulsory licensing has been invoked to protect public health).

India needs to tread carefully while negotiating the FTA with the EU, so that the health of the Indian people is not compromised through provisions that shackle our generic drug industry.

K. Srinath Reddy is president, Public Health Foundation.