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DP/ DE Deadlock

International standard RDP will provide the correct incentives to innovate

Incentives for investment in research and development are necessary for discovery of new medicines, especially as regulatory regimes around the world require more safety and efficacy data. Pharmaceutical drug development is very expensive and very risky. Countries with strong research based pharmaceutical industries provide about 5 – 11 years of Regulatory Data Protection (RDP). Countries wanting to become centres for innovation need to provide international standard RDP.

"The obligation to ensure that unfair commercial use of data does not occur is distinct from the obligation to not disclose. In India, the reliance on the data submitted by the innovator to a foreign FDA by the DCGI, to grant marketing approval to competitors, amounts to allowing the competitor to make an unfair commercial use of the otherwise proprietary data of the innovator"

- Krishna Sarma,
Managing Partner, Corporate Law Group

The other and more important aspect, often forgotten, is that RDP ensures patient safety as it requires pharmacovigilance under control of one company with all the preclinical and clinical know-how. In fact, countries like Japan do not provide RDP per se but requires a period of post marketing surveillance before a follow on product is allowed in the market. Further, patients benefit through new and better medicines.

Under the Drugs and Cosmetic Act and Rules, 1945, India currently conditions the approval of a new drug, based on the prior approval by a Regulatory Authority in another country like the United States Food and Drug Authority (USFDA) or the European Medicines Agency (EMEA), rather than requiring submission of the entire dossier for review by the Drug Controller General of India (DCGI). A limited bridging study of about 100 patients is all that is required. Interestingly, the new drug applicant may be the innovator company which had done the development of the drug, or it may be a generic company which may have done the limited study alone. The subsequent applicant can obtain a marketing approval with a bioequivalent and toxicity study alone.

Under the WTO Agreement on TRIPS, Members are mandated for a fixed period of time, from relying on or otherwise using the data submitted by the originator for the unauthorised approval of

copies of the drug. There have been varying degrees of assertions in India that TRIPS does not mandate "non-reliance" and that non disclosure of test data submitted to the DCGI is sufficient to fulfill India's obligation under Article 39.3 of TRIPS. Such assertions may not stand the test of correctness on a legal scrutiny. The reason being, that the obligation to ensure that unfair commercial use of data does not occur is distinct from the obligation to not disclose. In India, the reliance on the data submitted by the innovator to a foreign FDA by the DCGI, to grant marketing approval to competitors, amounts to allowing the competitor to make an unfair commercial use of the otherwise proprietary data of the innovator.
The position in India today is such that despite a subsisting valid patent covering a drug product, it is possible for several competitors to obtain marketing approval for the same product, forcing the patent holder to approach the Courts. As it takes years for a case to conclude, and in the absence of an interim injunction, the competitors continue to market the generic products, rendering the granted patents useless.

Among countries at its stage of development, India is unique. Its scientific and cultural endowments have resulted in establishment of a world class IT sector, and is now set to leverage its success into the biotechnology and bio-informatics, other health sector technologies, and agricultural and chemical development. The country is poised to make important contributions to public health through innovation, not only within India, but to become fully integrated into the larger family of scientists around the world working to bring new therapies and cures to patients.

Today, Indian companies are successfully exporting drugs and API to highly regulated markets.

The country would greatly benefit by strengthening its drug regulatory system to match the international best practices, both from the perspective of patient safety and to realise the full potential of value added drug exports. Providing RDP will provide the correct incentives for even small and medium sized companies to innovate and bring better and more effective medicines and therapies to the market.

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