Editorial

Data protection issues in India

As a condition for registering pharmaceutical products, countries normally require applicants to submit (disclose) data relating to quality, safety and efficacy (so called “test data”), as well as all other relevant information on the physical, chemical characteristics and composition of the product for marketing approval. The issue that is currently being debated in India relates to whether such data protection should be introduced in India and whether the drug regulatory authority (the Drug Controller-General of India) can rely on these test data submitted by the applicant company (patent holder or licensee) for market authorization for the product to third party. The original registrant companies claim that significant money is invested in clinical trials for generation of such test data and therefore any use without adequate compensation is unfair exploitation and that the TRIPS Agreement mandates such protection. These companies therefore want ‘data protection’, a system of non-disclosure of trial data to third party by the Drug Regulator for a certain specified period. Through such a protection, registrant companies are ensured of extended monopoly for their product beyond the 20 yr patent life through delaying entry of generics into market. Such data protection and exclusivity are largely provided by developed countries for varying periods.

As a signatory to the World Trade Organization (WTO)'s Trade Related Aspects of Intellectual Property Agreement (TRIPS) agreement, India is legally bound to implement all the provisions of this global treaty from January 1, 2005 including protection of undisclosed information related to test to data submitted to the Government by applicants seeking market approval. But, as is the case with many other clauses of the complex legal text of the TRIPS agreement, the controversy boils down to the interpretation of article 39.3. Drug companies (research-based multinationals which introduce bulk of new drugs) argue that data protection is mandated by the TRIPS agreement. Most domestic drug manufacturers do not think so.

What does Article 39.3 say? “Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use” (emphasis ours). Thus article 39.3 does mandate protection to marketing approval data, but only under certain conditions (italicized above). Member countries, however, have substantial flexibility in determining how such test data should be protected.

Legal opinion both at the national and international level largely does not seem to favour the need for data protection. Experts argue that under Article 39.3 test data must be protected only if national authorities require its submission and that the said article does not require protection be given to already public data. Also, protection is
required only for products that qualify as new chemical entities (NCE) and that member countries have considerable discretion in defining a NCE and thus can exclude new indications, new dosage forms, new combinations, crystalline forms, isomers etc., of existing drugs. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a banned ‘use’ under Article 39.3. The WHO Committee on Intellectual Property Rights, innovation and Public Health in its just published report also opines that article 39.3 does not “…prevent others from relying on data for the marketing approval of the same product by a third party …..” What is more, such interpretations are supported by the Supreme Court decisions of the United States and Canada while interpreting national laws. In addition, prior to consideration of such protection, national regulatory authorities may request the applicant to prove that significant investment and other inputs have been made to collect such data.

Correa further argues that countries can meet their obligations to protect against ‘unfair commercial use’ stipulated by Article 39.3 by barring ‘dishonest’ uses of test data as sovereign nations enjoy considerable discretion to define what is ‘unfair’ in the context of their own national laws and culture. And use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is considered a non-commercial use under 39.3. Countries, for example, may proscribe situations through which a competing party gets clinical trial data through fraud, breach of confidence or other ‘dishonest’ practices, and uses them for the marketing approval of a therapeutically equivalent - a generic. Or, in cases where the government provides access to undisclosed test data to provide unfair advantage to a company that did not generate such data or, if it did, refuse to share the cost of the trial data. WTO member-countries are not obligated under Article 39.3 to confer exclusive rights to the originator of the marketing approval data. MNCs and some countries like the US have argued for much broader coverage of Article 39.3, and that countries confer exclusive protection on originators’ test data. Clearly, these positions are not well grounded in either the text or negotiating history as TRIPS negotiators have specifically considered and rejected language requiring data exclusivity of trial results.

Does such test data constitute new intellectual property that needs protection? There is a clear distinction between patent and test data generated in clinical trials. A patent is granted for a new invention that is novel, non-obvious and has utility. And trial data does not the criteria of patentability. The TRIPS agreement does not consider such data as ‘property’; even the US law does not recognize any IP rights on undisclosed data. But some developed countries offer varying period of data protection (yr): Canada and France, 10; EU, 6-10; Japan, 6; Australia and USA, 5 etc. Developing countries like Brazil, South Africa, however, do not have a data protection system.

There are some gray areas. Like when a generic manufacturer submits an application for marketing approval of an off-patent drug relying of the test data submitted by the originator (patent-holder) company, does it come under ‘unfair practice’? This has been left wide open for debate and countries (developed or developing) have interpreted differently. Another issue being put forward by a section of the industry relates to seeking marketing approval when the patent is about to lapse or already lapsed. Would test data of such products eligible for protection? What about biologicals which are often difficult to IP protect? Such products could often be life saving.

Data protection can seriously impede introduction of generics into the market. In countries where data protection is provided, the only way generics can enter the market is through generation of their own trial data during the period of protection. Repetition of such safety and efficacy trials to generate test data on compounds with
proven efficacy is unethical besides requiring large investments by the company thus adding to the cost of the generic being introduced. Does providing data protection become a barrier to the use of compulsory license by the regulatory authority? We need to be clear on that.

There has also been global concern on the overall secrecy and reluctance of the pharma industry in sharing vital information with the regulators, volunteers who participate in clinical trials, and the public. The International Working Group on Transparency and Accountability in drug regulation has brought out the ‘Statement of Openness of Drug Information’ which strongly argues for the need and importance of access to information. Stating that such secrecy can lead to wasteful and even inhumane scientific work, promote irrational drug use etc. the Working Group underscores the need to put trial data in public domain. The new global standards just announced by the WHO seek 20 key details to be disclosed. There are also attempts at the international level to bring standardization, transparency and public disclosure of trial data. Finally, data protection will adversely impact least developed countries that have no product patent regime as data protection confers monopoly to a company which owns the IP rights. For example, in Guatemala which does not yet have a product patent regime (being a least developed country), generic manufacturers will have to wait for five years to introduce their own version of anti retrovirals. Thus, even where there is no product patent, ‘data exclusivity’ (provided by Guatemala in accordance with the Central America Free Trade Agreement signed with the US in 2003) ensures a five year protection for the US MNCs.

What are the concerns for India? There are a lot of stakeholders - the industry, government, researchers within and outside the government, voluntary agencies that work for affordable medicines for the poor and, most importantly, the patient groups who bear the brunt of cost of medicines. All the three industry groups have diverse views. The Organization of Pharmaceutical Producers of India (OPPI) representing research-based MNCs is for data protection, the Indian Drug Manufacturers Association (IDMA) representing indigenous drug manufacturers, opposes data protection while the Indian Pharmaceutical Alliance (IPA) research -based Indian drug companies prefers limited data protection. The Government of India has taken serious interest and has held wide consultations. An inter-ministerial committee with representatives from major federal Ministries that have stake viz., the Departments of Commerce, Industrial Policy & Promotion, Scientific & Industrial Research, Agriculture & Cooperation, Health & Family Welfare is in the process of finalizing its recommendations on data protection to the government of India.

Meanwhile, we need to redefine NCE by appropriately modifying the definition of ‘investigational new drug (IND) as provided in the Drugs and Cosmetics Act (1940) and the entities exempted from patenting under the Indian Patent Act (1970). A national consensus is broadly on the lines: A new chemical entity for purposes of drug registration will not apply to new indications, new dosage forms, new combinations, salts, esters, polymorphs, metabolites, isomers, and mixture of isomers, complexes, combinations and any other derivatives of known chemical molecules. New also means that the chemical entity has not been approved for marketing in any country including India.

The existing system in India of not providing data protection has been very successful as it has encouraged the timely introduction of generic manufacturers into the market bringing the price of drugs within the reach of poor patients. The Indian model of accessibility of drugs to the poor through generics is widely acknowledged. Thus, while deciding on data protection, the Government should balance the genuine concerns of originator companies with the need to create a competitive environment that promotes increased access to
cheap medicines, especially since the Indian health care system is driven by generics. As the MNCs incur sizable expenditure in introducing a new drug into market, legal systems to protect trial data from disclosure and misuse should be beefed up. But, concern for public health and public health alone should discourage data protection, a TRIPS-plus provision\(^1\). Correa\(^1\) says it all: "In sum, developing countries should carefully consider the scope of regulations on approval of pharmaceutical products. Such regulations should be enacted with a pro-competitive intent, in a manner that maximizes legitimate competition and access to drugs, while respecting the legitimate interests of the originators of data in accordance with the standards of protection established by the TRIPS Agreement".

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References


