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Data protection for agro-chemicals

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Nearly 40 months ago (in February 2004), the Government had set up an Inter-Ministerial Committee under the chairmanship of Secretary, Department of Chemicals and Petrochemicals to "consider the steps to be taken by the Government in the context of the provisions of the Article 39.3 of the TRIPs Agreement for protection of undisclosed test and other data submitted to the Regulator for seeking market approval of agrochemicals and pharmaceuticals." The Committee submitted its report to the Commerce Ministry on May 31. The Committee has recommended three years of Data Protection (DP) for agrochemicals and five years for traditional medicines. It has also suggested protection of information against un-authorised disclosure/use of agrochemicals and pharmaceuticals. The Committee has recommended amendments to the Insecticides Act (1968) and the Drugs and Cosmetics Act (1940) to give effect to the above recommendations.

UNDERSTANDING DP

The Committee has put in much effort/research to untangle one of the most hotly-debated and contentious issue of DP. And, yet, there are misconceptions in certain quarters. It is time to take a critical look at these.

Generation of test and other data to prove the safety and efficacy of a Crop Protection (CP) product is "mandatory" for seeking its registration under the Insecticides Act. This involves huge R&D effort over 8-10 years and investments running into millions of dollars.

The objective of Article 39.3 of the TRIPs Agreement is to ensure that the member concerned (in this case, India) protects the above data against "unauthorised disclosure" and "unfair commercial use". However, there is one school of thought that simply providing for protection against "unauthorised disclosure", the requirement of Article 39.3 would be met; that there is no need to independently address the "unfair commercial use" aspect.

The argument is that a situation of "unfair commercial use" would arise only when the originator's data are acquired fraudulently and submitted for obtaining market approval. If, on the other hand, the government uses the data of the originator for according market approval for the same product to a second and subsequent applicant then that cannot be termed "unfair commercial use".

FLAWED ARGUMENT

This argument is seriously flawed. For, while granting approval to subsequent registrants, the Government does not ask them to generate data but relies on that of the original registrant's. The subsequent applicants do not make any effort or incur costs and yet get the approval to make and sell the product.

This is countered with the view that while processing the application of a subsequent applicant, the regulator does not see the originator's data and, therefore, no reliance is involved. This defies logic. Having scrutinised the data of the original registrant and concluded that the product is safe, where is the need for a re-look at a "me too" application, goes the argument.?

But simply because there is no need to re-look the originator's data, it cannot be concluded that the regulator has not relied on them for granting market approval to the subsequent registrants. Under the Insecticides Act, when a CP product is registered under Section 9 (3), the Government grants registrations to second and subsequent applicants under Section 9 (4) for the same product relying on the first applicant's data.

This then tantamounts to "unfair commercial use". This cannot be addressed merely by providing protection against disclosure. The amendment in the Act must also prohibit grant of registration to "me too" applicants for a certain period. This has been recommended by the Reddy Committee. However, critics argue that DP gives market exclusivity to the holder thereby throttling competition. Consequently, the farmers will be made to pay higher prices. This belies a proper understanding of DP. Unlike patent, which confers exclusivity to the patentee, DP does not prohibit others from launching the same product provided they submit their own data for seeking registration.

Indeed, DP does not allow second and subsequent applicants to enter the market (for a specified period) without submitting their own data. But why repeat studies when the first registrant has already collated them? This is a related argument that is often invoked by critics to oppose DP. The new DP-protected product may also have to compete with possibly dozens already in the market to address a given pest/disease. The former cannot command a price of its choice, and the farmer will buy only if it fetches him more value. Grant of DP for a fixed term is also resisted because this is not provided for by Article 39.3. Unless "me too" registrants are kept out for a certain period, how can the original registrant recover the huge developing expenses? Other similarly placed countries, China and Brazil, provide Data Protection for Crop Protection products for six years and 10 years respectively.

DP is also opposed on the ground that this will result in extension of the patent term. This is based on a flawed notion that patent and DP are synonyms and achieve the same objective. The fact is that they are distinct forms of IPR (intellectual property rights) and covered under different articles of the TRIPs Agreement. While patent rewards the innovator for his "invention," DP protects the data that the applicant must generate to get market approval .

The benefits of granting DP for CP products are as under:

By enabling the originator to recoup the huge expenses of generating registration data and on extension and stewardship, this will help bring new technologies/solutions for increasing yield, crop quality and exports.

The use of new generation CP products is environment-friendly as these are low dose, potent, target-specific and have the capability to degrade fast (persistent use of conventional products puts load on the environment).

R&D bases in India will get a boost. Studies will be conducted here at a much lower cost (due to cheap infrastructure and manpower). India will turn into a hub for data generation and manufacture of CP products.

Farmers often suffer damage to the crop and environment due to indiscriminate/wrong use of a reverse-engineered product supplied by "me too" registrant as this is generally not backed by stewardship. This can be prevented if DP is granted.

In case of medicines, the doctor advises patients to take the correct dose and at the right time. For CP products, only R&D companies are best equipped to perform this function. DP will give them the much needed comfort.

With the high level Inter-Ministerial Committee giving a clear verdict, the Government should take necessary steps for suitable amendment to the Insecticides Act to provide for DP for agrochemicals.

(The author is Resident Director, CropLife India, New Delhi. The views are personal.)