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What is data exclusivity, and how government push may hit availability of cheap, generic drugs

The lack of a data exclusivity provision is what has given India's pharmaceutical industry, which thrives on marketing cheaper generics, its edge in the global market.

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Data exclusivity provisions can delay the entry of generic versions of new drugs. (Wikimedia Commons)

The Indian government appears to be considering implementing "data exclusivity" in the pharmaceutical drugs sector after rejecting demands for the provision during trade deal

negotiations with the UK and the European Free Trade Association (EFTA).

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In recent weeks, government officials have held a flurry of meetings with pharmaceutical industry stakeholders in recent weeks to discuss ways in which data exclusivity may be implemented.

The government's potential change in approach appears to be driven by the expectation that the provision could help bring in additional investment in the country. But at stake is the future of India's pharmaceutical industry.

What is data exclusivity?

When a company develops a new drug, it must submit clinical trial data demonstrating the safety and efficacy of its product to regulators. The regulator may use this data to approve another company's generic version on the basis of much less resource-intensive bio-equivalence studies, which demonstrate that the generic version works as well as the innovator product.

The generic manufacturer can then start marketing its generic drugs on the date the original company's patent ends.

Here's where data exclusivity comes in. This provision grants innovator pharmaceutical companies exclusive rights over the clinical trial data, meaning a regulator cannot use it to grant approvals to subsequent generic versions during this period. So, generic drug companies have to either wait until the exclusivity expires or carry out expensive clinical trials themselves to prove safety and efficacy, just like the innovator company.

Data exclusivity, which protects trial data, works hand-in-hand with patents, which protect the invention itself, to protect the interests of an innovator company.

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What has the Indian government been doing?

Last month, pharmaceutical industry stakeholders took part in meetings involving Union Commerce Minister Piyush Goyal and the Department for Promotion of Industry and Internal

Trade. An inter-departmental meeting between the DPIIT, pharmaceutical department, and the health ministry was also reportedly held to discuss data exclusivity provisions.

The Commerce Ministry did not respond to a request for comment. The Health Ministry said in its response: “There is no such proposal to bring in data exclusivity from this ministry’s end.”

At the centre of the discussions were the ways in which data exclusivity could be implemented, according to industry experts present at some of the meetings.

“The focus of these meetings was not whether to bring in data exclusivity, it was how to do it. If implemented, data exclusivity provisions can delay the entry of generic versions of new drugs beyond their patent expiry — taking away the edge of the Indian generics industry in the global market and also delaying access to cheaper medicines to the people of the country,” said an expert aware of the matter.

“There is no international obligation to implement this as well — it is not specified in any of the trade agreements. The EFTA deal does say that there should be a discussion on data exclusivity after one year but it doesn’t require India to implement such a measure,” said an expert who works on access to affordable medicines.

Commerce Minister Goyal had previously been quoted as saying that implementing data exclusivity provisions in India’s intellectual property laws could bring in another $150 billion in investments under the deal with the EFTA (Iceland, Liechtenstein, Norway and Switzerland).

How data exclusivity affects Indian pharma

If India were to agree to data exclusivity provisions, its generics-focused pharmaceutical industry may lose its edge in international markets.

An industry expert said: “This goes against the Prime Minister’s vision of Atmanirbhar Bharat. It will hamper the industry in the long run. Almost 90% of Indian pharmaceutical companies manufacture generic drugs, they do not invest in developing new ones.”

Countries usually have a data exclusivity period of six or ten years. And patent protections are granted for 20 years. But a key concern is that even off-patent drugs can be protected by data exclusivity.

“Now, in a scenario where the originator company starts marketing its product, say, in the seventh year of the patent, data exclusivity is fine because the patent protection will last beyond that. However, if a company starts marketing the product in the seventeenth year of patent, then the data exclusivity essentially ensures that they are able to exclusively market the product for several years after the patent expiry as well,” the first expert quoted above said.

This expert said: “It also hampers patent challenges. A patent prevents a company from selling a generic version of a drug, but they can get regulatory approval in the meantime. Once that happens, companies can challenge patents and ask the courts to grant them a compulsory license to manufacture the drug. This is exactly what happened with the rare disease medication Risdiplam for Spinal Muscular Atrophy — the court allowed an Indian company to market its cheaper, generic version.”

The courts allowing the generic manufacturer to market its product at nearly a third of the innovator company’s rates have prompted other pharmaceutical giants to further push for more patent protections, the expert said.

The Indian drug regulator’s actions

Before the series of meetings, the country’s apex drug regulator, Central Drugs Standard Control Organization (CDSCO), issued a notice in October that called for initiating discussions to “ensure a level playing field”.

In light of the meetings, activists say the CDSCO notice appears to have been hinting at data exclusivity.

The notice says that for approval of a new drug in India, one company conducts rigorous trials while other companies immediately submit the results of bioequivalence trials and get approval.
“…the subsequent applicants who obtain approval of the same new drug based on bioequivalence study data for whom the cost of regulatory compliance is much lesser as they are not required to conduct the clinical trial… Therefore, there is a lack of level playing field,” it says.

Leena Menghaney, a lawyer who works on IP policies and improving access to medicines, wrote to the drug regulator stating: “We are concerned that the framing of the notice appears to be deliberately vague and non-transparent about the incentives being considered by the

CDSCO. In fact, this will lead to proposals tilted towards data exclusivity driven regulatory approach in the guise of protecting the interests of the first applicant."

These "incentives" for the first applicant could have serious implications such as:

Evergreening of patents (where companies file new patents on minor tweaks to an existing, soon-to-expire patent to prevent entry of generics)

Delaying entry of cheaper generics to the market

Companies conducting questionable, unnecessary clinical trials to get incentives

Monopolies on traditional medicines that may already be in use for certain conditions

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