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Drug ban: EU 'ready' to fast-track clearances for fresh clinical trials

Will mitigate financial impact on exporters, says Pharmexcil

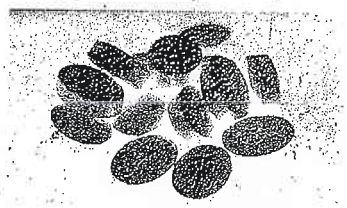
G NAGA SRIDHAR
Hyderabad, September 2

The Commerce Ministry may not have been able to get the EU ban on 700 medicines revoked, but it has managed to convince the European Commission to speed up clearances for new bio-equivalence studies of the affected drugs.

"Based on this, I understand that some drug manufacturers have already commenced the process of getting the trials conducted afresh," PV Appaji, Director-General, Pharmaceutical Export Promotion Council (Pharmexcil), told *BusinessLine* here on Wednesday.

In July, the European Union had announced a ban on marketing of 700 generics on the charge that GVK Biosciences, which had carried out the clinical trials, manipulated the results. The ban came into effect on August 21.

Miffed by the ban, the Commerce Ministry deferred Free Trade Agreement discussions with the EU. Simultaneously, it also tried to get the ban revoked, with ministry officials meeting teams of the European Medical Agency and other regulatory bodies.



However, according to sources, the Commerce Ministry's efforts had resulted in only "limited" success, with the European regulators saying that any dilution of their order would only set a "bad precedent".

However, as a concession, they have agreed to fast-track clearances of new tests.

The industry, too, appears to be wary of a festering confrontation on regulatory aspects with as major a market as Europe. "The government has sent a strong message to the EU on the issue... Further, speedy clearances for products based on new bioequivalence studies can significantly bring down the financial impact," Pharmexcil's Appaji said.

According to initial estimates, the ban is expected to result in a loss of about $1 billion in pharma exports.

Legal tangles

Fresh trials will mean significant financial implications for drug-makers. "But there is no alternative for us other than to get fresh trials done. Our legal teams are exploring contract provisions with GVK Bio, which conducted the tests for us," said a top executive at a pharma firm with a couple of drugs on the banned list.

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