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US FDA may impose huge drug user fee on generic imports soon, India to hit badly

Suja Nair Shirodkar, Mumbai
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The US FDA may introduce a Generic Drug User Fee Act (GDUFA) soon to curb import of cheap generic drugs into that country. The proposed Act empowers the US government to fix an exorbitant fee on the import of each generic product category coming from any overseas sources. The US currently imports about 80 per cent of APIs and 40 per cent of generics made in the overseas locations.

The US Food and Drug Administration (FDA) recently completed and submitted its recommendations for the proposed Generic Drug User Fee Act (GDUFA) to the Congress. The proposed fees could range from $35,000 for API manufacturers to $150,000 for finished drug units.

The move is stated to help fund a portion of FDA's drug review activities while FDA agrees to overall performance goals, such as reviewing a certain percentage of applications within a particular time frame. Indian industry fears that this move is a result of strong lobbying backed by the US generic industry to limit Indian competition from entering the US market.

What is more concerning is that the through the introduction of GDUFA, the US FDA is planning to impose higher fees for non-US facilities despite the fact that about 80 per cent of APIs and 40 per cent of US medicines are made in foreign locations. Expressing their concerns on this move, industry insiders pointed out that US FDA's claim for higher fees from the exporters is highly unwarranted since FDA has offices and staff in countries like India and China now.

An exporter to the US pointed out that this clearly shows that there are greater powers of US generic industry working behind this move so as to stop competition from the Indian generic manufacturers.

Unlike the brand manufacturers who pay fees under Prescription Drug User Fee Act (PDUFA), the generic industry does not pay a user fee to support FDA activities related to its applications. Many industry insiders clarified that the Indian industry is not against GDUFA, which is designed to address the regulatory challenges in an affordable manner. However they pointed out that what they are concerned is about the unreasonable fees that are proposed to be levied from the exporters.

Reports point out that while large generic bodies were involved in discussions with the FDA over GDUFA, Indian industry was not part of these talks, despite the dominant role of Indian firms as suppliers. A reliable source from the industry stressed that the Indian industry, as key stakeholders, should have been given a direct chance to participate in these dialogues, which unfortunately did not happen.

The source implied, “Such increasing regulatory requirements, among others, would only threaten the sustainability of small API's and formulation firms in India. Even leading to many company to increase the price of drugs that are being exported to US leading to difficulty in access to affordable medicines.” It was further suggested that to deal with this access cost the US FDA can carry out joint regulatory inspections to help improve the situation and spare costs.

Other concern that the industry is facing is over whether the gains of faster approvals outweigh the costs and certainty of timelines involved under the GDUFA, since some experts say that while the FDA fees are required to be paid immediately actual commercialization could be years away and comes with inherent risks.