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Govt acts against US body's drug slur

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Mumbai: The government has initiated legal action against a US-based thinktank for "maligning" the domestic pharma industry on quality of medicines manufactured here. Sources said that the action is being initiated by the India Brand Equity Foundation (IBEF), on behalf of the government and domestic industry, which has taken strong objection to the "smear campaign" being orchestrated by the Washington-based American Enterprise Institute (AEI) against domestic companies.

The IBEF, a trust established by the commerce ministry, along with the industry, has strongly disputed a recent study by the US thinktank that claimed domestic pharmaceutical companies cut corners and made substandard drugs for markets with non-existent, under-developed or emerging regulatory oversight, notably Africa. Official sources said "a legal response" is being framed to oppose the study, adding the government was fully in support of the domestic industry, and would like to protect its interests.

TAKING LEGAL RECOURSE

The study — led by research scholar Roger Bate — assessed the quality of 1,470 antibiotic and tuberculosis drug samples that are claimed to be made in India. They were sold in Africa, India, and five mid-income non-African countries, based on samples "from pharmacies in 22 cities of 18 low-to mid-income countries between 2009 and 2012."

It found that nearly 11% of the products failed a basic assessment of active pharmaceutical ingredients (API), and the majority of the failures are substandard (7%) as they contain some correct API but the amount of API is under-dosed.

The conclusions of the study are disputed not only for methodology and ethics, but also for the poor treatment of data sampling used, IBEF said.

Domestic industry body Indian Pharmaceutical Alliance (IPA) told **TOI** that the timing of the study — days before the prime minister's visit to US, was also suspect. "If the researchers' real concern were quality of drugs, they could have approached the drug regulatory authorities (in India) and the importing countries, with full details of products, manufacturers, test methods and results. However, apparently, that is not the intention," IPA secretary general D G Shah said.

Interestingly, the researchers claim that, "Our IRB commitment prevents us from revealing the identity of individual manufacturers as labeled on the package." Thus, they can continue to make allegations against India without even providing an opportunity to investigate their complaints of poor quality of drugs made in India, IPA said. "Earlier this year, the US FDA discredited one such research study that claimed 'impurities in dozens of generic heart drugs made overseas'," Shah added.

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