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Pharma: India seeks review of US whistle blower policy

NEW DELHI, PTI: Taking up the case of domestic pharma sector with the US, India has pitched for review of America's whistle blower policy and lowering of registration charges to help Indian firms seek greater market access.

The concerns over four major issues were raised in a 'non-paper' (a kind of a discussion document) presented to the US authorities by India.

"In our non-paper, we have raised four major issues with the US. Their whistle blower policy needs to be reviewed as the reward under the policy is very high and employees fudge records to take such rewards. The fees for registration is exorbitant and it acts an additional burden for Indian pharma companies," a top official in the commerce ministry said.

The paper follows a meeting in February, between US Food and Drug Administration (USFDA) Commissioner Margaret A Hamburg and Commerce and Industry Minister Anand Sharma.

Sharma has raised concerns over the USFDA's audit inspections of Indian pharma companies and 'disproportionate penalties' in some instances.

Further, the official said that the registration process in the US is also very long and cumbersome.

"They do not follow the time limit for registration process. It becomes very lengthy, sometimes 6-8 months. The fourth matter is about the so-called Form 483, issued when the US regulator has queries regarding some Indian firm," the official said, adding, "we have sought early resolution on these issues."

The USFDA has taken a series of actions against Indian pharmaceutical firms, restricting their shipments to the US, their largest export market.

The US health regulator on January 23 banned the import of products manufactured by Ranbaxy Laboratories at its plant at Toansa. This was the company's fourth plant to face regulatory action from the USFDA, after Mohali, Paonta Sahib and Dewas plants.

In 2013, Ranbaxy had agreed to pay a fine of $500 million to US authorities after pleading guilty to 'felony charges' relating to manufacture and distribution of certain adulterated drugs made at the Paonta Sahib and Dewas units.

Another Indian firm, Wockhardt, had its two plants put under import alert by the USFDA.

Sources said such steps by the USFDA would affect India's pharma exports to the US.

India's pharma exports increased 10 per cent to $14.6 billion during 2012-13, with shipments to the US accounting for about 26 per cent of the total.

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