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Indian companies get US FDA approval for generic versions of four blockbuster drugs: Jena

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During the last two years, the US Food and Drugs Administration (FDA) has given approval to the generic versions of four blockbuster drugs to Indian companies, the Parliament was informed.

"A blockbuster drug is one which has at least drug sale of US$ 1 bn and such drugs becoming off-patent in US market is a continuous process. US drug Authority (US FDA) regularly approves generic versions of such off-patented drugs. As informed by Pharmaceutical Export Promotion Council of India (Pharmexcil), generic version approvals have been given to Indian Companies by US FDA during 2010 and 2011 for four blockbuster drugs," Minister of State for Chemicals and Fertilisers Srikant Kumar Jena told Lok Sabha recently.

The molecules approved thus are Lipitor (Atorvastatin), Plavix (clopidogrel), Seroquel (Quetiapine fumarate), and Zyprexa (olanzapine). "Though the price value of blockbuster drugs significantly decreases as a generic version, there is good opportunity for all generic companies who obtain product approvals and market the product in the US," the Minister said.

In another reply, he said the draft National Pharmaceutical Pricing Policy (NPPP) 2011 was still under the review of the empowered Group of Ministers (GoM).

"The Department of Pharmaceuticals (DoP) has prepared a draft NPPP-2011 based on the criteria of essentiality and requirements as stipulated by the Ministry of Health & Family welfare. The draft NPPP, 2011 was circulated among the concerned Ministries/Stakeholders. The draft policy was also available for comments of any other interested person on the Department's website www.pharmaceuticals.gov.in till 30.11.2011. The view/inputs received on the draft NPPP, 2011 were examined and the matter was placed before the Group of Ministers (GoM) which met on 25.4.2012. Subsequent to this two meeting have been held by the GoM," he said.