**PHARMACEUTICALS EXPORT PROMOTION COUNCILOF INDIA**

(Set up by Ministry of Commerce & Industry, Govt., of India)

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## Generic drug product application to cost Rs 30 lakh in US. The companies would also have to pay about Rs 12 lakh for filing of Drug Master File (DMF) with the FDA

Indian generic drug exporters to US will have to pay about Rs 30 lakh (about $54,700) each as fee for every new product application they file with the US health regulator as per an amended law in that country, Parliament was informed today.

This is as per the Generic Drug User Fee Amendments of 2012 (GDUFA) of the US government, Minister of State for Commerce and Industry D Purandeswari said in a written reply.

She said any company interested in supplying generic drugs with effect from October 1, 2012 have to pay the prescribed fee to the US Food and Drug Administration (FDA) for registering their products in the US.

"There will be financial impact on generic drug exports to USA as the exporters are now required to pay about Rs 30 lakh for registration of each abbreviated new drug application (ANDA)," Purandeswari said.

The companies would also have to pay about Rs 12 lakh for filing of Drug Master File (DMF) with the FDA, she added.

India currently supplies nearly 20% of the generic medicines in global market.

According to Department of Pharmaceuticals, the Indian pharma sector is expected to grow from its current level of Rs 1 lakh crore to Rs 5 lakh crore by 2020.

In 2010, the Indian pharma export business reached $10.3 billion and grew to touch a level of $13.3 billion in 2011. It is targeted to touch $25 billion by 2015.

Source: Business Standard

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