GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:2154
ANSWERED ON:11.03.2013
FEE ON GENERIC DRUGS SALE APPLICATION
Das Shri Khagen

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether the United States of America (USA) has passed the Generic Drugs User Fee Act which makes generic drugs manufacturers to pay an additional fee on generic drugs sale application;

(b) if so, the details thereof;

(c) whether the implementation of the aforesaid act is likely to adversely affect the generic medicine manufacturers and exporters in the country and if so, the details thereof;

(d) whether the Government has taken up the matter with the concerned authorities in the USA; and

(e) if so, the reaction of the Government of the USA in the matter along with the steps being taken by the Government to address the issues of the generic drugs manufacturers in the country?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (DR. D. PURANDESWARI)

a): Yes, Madam.

(b):The Generic Drugs User Fee Act 2012 (GDUFA) enables United States Food and Drug Authority (USFDA) to charge a fee for registration of Generic Drugs. Any company interested in supplying drugs & pharmaceuticals to USA has to pay the prescribed fee to USFDA.

(c): Financial impact on Indian generic drug exporters to USA is reported to be about Rs.30.00 lakhs for registration of each Abbreviated New Drug Application (ANDA) and about Rs.12.00 lakhs for filing of Drug Master File (DMF).

(d)&(e):The Indian office of USFDA have clarified that this enactment has been done to streamline the application review and inspection process and to reduce the review time from an average 31 months to 10 months. This enactment is applicable to both national and international generic industry. No additional fee on Indian pharmaceutical industry is levied.