GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:534
ANSWERED ON:13.08.2012
LEVYING OF ADDITIONAL FEE ON SALE OF GENERIC DRUGS
Vardhan Shri Harsh;Yadav Shri Dinesh Chandra

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

(a) whether the United States of America (USA) has proposed to levy an additional fee on Indian pharmaceutical companies for selling generic drugs;

(b) if so, the details thereof;

(c) the percentage of additional fees imposed by the USA on the Indian pharmaceutical companies on an annual basis;

(d) whether the Government has lodged a protest against the said proposal by the USA; and

(e) if so, the reaction of the Government of USA in the matter?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRI JYOTIRADITYA M. SCINDIA)

(a) and (b): As per the information available in the website of United States Food and Drug Authority (USFDA), Generic Drug User Fee Amendments act of 2012 came into effect on 9.7.2012 enabling USFDA to charge a fee for registration of Generic Drugs.

(c) to (e): A clarification was sought from the Indian office of USFDA, who clarified that the Enactment is intended to streamline the application review and inspection process and to reduce the review time from an average 31 months to 10 months in the next 5 years. It was also clarified that this enactment is applicable to both national and international generic industry. Thus no additional fee from Indian pharmaceutical industry is proposed to be levied.