

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI D. PURANDESWARI): (a) Yes Sir. Government has taken a decision to grant green channel status for DGS&D Rate Contracts to PSUs and firms (Indian as well as foreign) having an average-turnover of Rs. 1000 crore or more during the last three years and making profit in any three years of the last five years.

(b) So far, twenty firms have been given green channel status. The area-wise details of ' these firms are Delhi -04; Mumbai-04; Gurgaon-05; Bangaluru-03; Ahmedabad-01; Vadodara-01; and Noida-02.

(c) More reputed firms in international and national markets would be available on DGS&D/Rate Contracts which will facilitate user departments.

Import of sub-standard cheap products from China

1722. DR. K.V.P. RAMACHANDRA RAO: Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether it is a fact that import of sub-standard cheap products from China have been witnessed in the past by the Customs' Authorities;

(b) if so, the details thereof; and

(c) the steps taken to prevent such imports?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI D. PURANDESWARI): (a) and (b) The details of cases of import of sub-standard cheap products from China detected by the Customs Department for the last three years and current year is as under:

Year	Number of Cases	Value of goods involved (Rs. in Crores)	Duty involved (Rs. in Crores)	Fine/Penalty imposed (Rs. in Crores)
2009-10	49	2.802	0.432	1.0518
2010-11	3	0.746	0.013	0.049
2011-12	-	-	-	-
2012-13 (upto February, 2013)				

(c) Any goods imported into India are subject to domestic laws, rules, orders, regulations, technical specifications, environment and safety norms. These regulations are notified in ITC (HS) classification of export and import items. The Government acts in case goods imported from any source are found to violate these regulations and threaten human, animal or plant life or health. In specific cases where Customs detect import of substandard and hazardous goods, they are empowered to seize the goods and initiate penal action under the provisions of Customs Act, 1962 read with other Allied Acts. In the recent past, the Government has taken steps to prevent/restrict import of toys, milk & milk products (including chocolates and chocolate products and candies/confectionaries/food preparation with milk or milk solids as ingredient) from China.

Effect of Generic Drug User Fee Act of US

1723. SHRI PALVAI GOVARDHAN REDDY: Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether the Ministry is aware that US is very shortly going to pass Generic Drug User Fee Act which makes generic drug manufacturers to pay fee on generic drug sale application;

(b) if so, the details thereof;

(c) whether it is also a fact that the move would cost US \$ 300 million annually to Indian drug players; and

(d) if so, how the Ministry is planning to address this issue?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI D. PURANDESWARI): (a) to (d) A new Act viz. the Generic Drugs User Fee Act 2012 (GDUFA) has been enacted by United States Food and Drug Authority (USFDA) to charge a fee for registration of Generic Drugs. Any company interested in supplying drugs and pharmaceuticals to USA has to pay the prescribed fee to USFDA. 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). The Indian office of USFDA have clarified that the 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.