

**GOVERNMENT OF INDIA  
COMMERCE AND INDUSTRY  
LOK SABHA**

UNSTARRED QUESTION NO:3655

ANSWERED ON:19.04.2010

IMPORT OF OBSOLETE AND DISCARDED MEDICAL DEVICES

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

(a) whether our country is becoming a dumping ground for obsolete and discarded medical, diagnostic, surgical and imaging devices from Europe and United States;

(b) if so, the details thereof and the reasons therefor;

(c) whether there is any regulatory framework in our country for this purpose; and

(d) if so, the steps being taken by the Government to put a check on such imports of obsolete and discarded medical devices from developed world and the outcome thereof?

**Answer**

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

(a) to (d): No specific complaints have been received in Department of Commerce that obsolete and discarded medical, diagnostic, surgical and imaging devices from Europe and United States are being dumped in India.

Under the 'Drug and Cosmetics Act, 1940 and the Rules made thereunder, import of devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, are included under the definition of 'Drug'. Hence, import of such medical devices is subject to compliance requirements under the aforesaid Act and Rules. Further, guidelines prescribed for import of medical devices by the Ministry of Health & Family Welfare specify the procedure for registration and import licence of medical devices under the 'Drugs and Cosmetics Rules, 1945. Further, in case of medical devices, manufactured in USA, USFDA approval for manufacture and free sale in USA in respect of the device is to be submitted. Further, in case of medical devices manufactured in European countries CE certificate along with approval for manufacture and Free Sale Certificate from respective country of origin is to be submitted.