

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:856

ANSWERED ON:26.02.2009

IMPORT OF PHARMACEUTICAL RAW MATERIALS AND VACCINES

Angadi Shri Suresh Chanabasappa

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the norms need to be complied for import of pharmaceutical raw materials and vaccines;

(b) whether the Government has been allowing import of cheap pharmaceutical raw materials and vaccines from some countries without physically verifying the compliance of its regulatory requirement or the equivalent international standards;

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

(d) the steps taken by the Government to ensure transparency in the system of registration of Active Pharmaceutical ingredients and vaccines?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF THE STATE IN THE MINISTRY OF MINES (SHRI B.K.HANDIQUE)

(a): The quality of imported pharmaceutical raw materials and vaccines is regulated through the system of registration and licensing of overseas manufacturer and the drugs manufactured by them as provided under the provisions of Drugs and Cosmetics Act and Rules made thereunder which is administered by the Ministry of Health and Family Welfare in the Government of India.

(b) & (c): The office of Drug Controller General (India) under the Ministry of Health and Family Welfare issues the Registration Certificate after the examination of Drug Master File, Plant Master File, Schedule D-(I) & D-(II) information, Regulatory documents such as manufacturing license, WHO GMP certificate and Free Sale Certificate issued by National Regulatory Authority of exporting country and after testing of the drug at Notified Laboratory. However, whenever considered necessary the manufacturer is also subjected to inspection.

(d) The application received for registration and the Registration Certificate issued are updated regularly on website of the office of Drug Controller General (India) (DCGI) www.cdscsco.nic.in. The turnaround time in respect of each category of drug is displayed. The officials of DCGI office meet with the applicants daily regarding each category of drugs.