

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:4605

ANSWERED ON:21.02.2014

REGISTRATION OF IMPORTED DRUG

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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the provisions/rules formulated by the Government in respect of registration of all the patented pharmaceutical products including new drugs being marketed in India with the Central Drugs Standard Control Organization (CDSCO);
- (b) the mechanism put in place by the Government for proper enforcement/ compliance of the above provisions /rules in the country;
- (c) whether certain instances of registration/marketing approval of imported/new drugs in contravention of the above provisions/rules and also submission of incomplete data by drug companies/ importers have been reported in the country;
- (d) if so, the details thereof and the action taken/proposed by the Government thereon; and
- (e) whether certain multinational drug companies have warned Indian generic drugmanufacturers to stop supplying drugs meant for treating various chronic diseases and if so, the remedial measures taken/proposed by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a)& (b): Drugs, irrespective of their patent status, imported into the country are regulated by the office of Drug Controller General (India) under the provisions of the Drugs and Cosmetics Act, 1940 the Drugs and Cosmetics Rules, 1945 made thereunder, through the system of registration and import licenses.

The criteria and procedure for grant of registration certificate of imported drugs and approval for marketing of new drugs have been prescribed under the Drugs and Cosmetics Rules, 1945.

For the purpose of grant of Registration Certificates, the manufacturer abroad or his agent in India is required to make application to the office of Drug Controller General (India) in Form-40 along with specified fees, Power of Attorney in favour of the agent in India and the information and undertakings as specified in Schedule D(I) and D(II) of the said Rules duly signed by or on behalf of the manufacturer. Thereafter, the importer is required to obtain the import licence from the said authority for the import of the drugs registered for import.

For the purpose of import of newly introduced drugs i.e., new drugs, prior permission is required to be obtained from the office of the Drug Controller General (India) for marketing the drug in the country.

The applicant is required to submit application in form-44 along with specified fees and technical data in respect of safety and efficacy of the drug for grant of permission to import the new drug into the country.

The applicant is then required to get the drug registered for import in to the country.

(c)& (d): The Central Drugs Standard Control Organisation (CDSCO) has detected the following cases of import of drugs from unregistered sources from China, which were handed over to CBI for investigations:

1. M/s. Envee Drugs Pvt. Ltd, Gujarat.
2. M/s. J B. Khokhani & Co, Mumbai.
3. M/s. Sheetal Pharmaceutical, Mumbai
4. M/s. Kwarlal & Co, and Kwarlal & Sons, Chennai
5. M/s. Adcock Ingrahm, Bangalore
6. M/s. Kanwarlal & Co, Chennai
7. General Import Company (I) Pvt. Ltd., Mumbai.
8. M/s. Antonie & Becourel Organic Co., Chennai

Further, Good Manufacturing Practices (GMP) Certificates furnished by the following manufacturers of China were not found to be genuine, whose Registration Certificates and Import Licenses were then cancelled:

1. M/s. Taizhou Waigaoqiao Liantong Pharmaceutical Co. Ltd., China
2. M/s. Zhejiang Materials Industry Chemical Group Co. Ltd., China.
3. M/s. Changshu Nanhu Industrial Chemical Factory, China.

4. M/s. JintanZhongxing Pharmaceutical & Medical Co. Ltd., China.
5. M/s. Suzhou Ausun Chemical Co. Ltd., China.
6. M/s. XianjuHongyan Pharmaceutical Chemicals Co. Ltd., China.
- 7 M/s. YanshiShuda Medicine & Chemical Co. Ltd., China.
8. M/s. Changzhou Kangrui Chemical Co. Ltd., China.
9. M/s. Ningbo Double Sun Pharmaceutical Co. Ltd., China.
10. M/s. ChongqingChunrui Medicine Chemical Co. Ltd., China
11. M/s. Suzhou Dawnray's Pharmaceutical Co. Ltd., China

(e): The Government has not received any such report.