GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1032
ANSWERED ON:05.08.2011
QUALITY OF IMPORTED DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether certain drugs imported particularly from China have been found to be substandard and not in compliance with the requirements of Good Manufacturing Practices (GMP);

(b) if so, the details thereof alongwith the action taken/proposed against the companies found guilty of importing such drugs;

(c) whether some Chinese drug exporters have denied inspection of their respective drug manufacturing units by the Indian Drug Inspectors;

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

(e) the action taken/proposed in the matter and also to ensure the quality and efficacy of imported drugs in the country?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI SUDIP BANDYOPADHYAY)

(a) & (b): Yes. Central Drugs Standard Control Organisation (CDSCO) had detected cases of import of drugs from unregistered sources from China. The following companies were involved in such imports:

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. Kawarlal & Sons, Chennai

5. M/s. Adcock Ingrahm, Bangalore

6. M/s. Kanwarlal & Co, Chennai

7. General Import Company (I) Pvt. Ltd., Mumbai

The cases were handed over to CBI for investigations. The cases have been filed in the Court of law against M/s. Kawarlal & Co, Kawarlal & Sons, Chennai and M/s. General Import Company (I) Pvt. Ltd., Mumbai. In the case of M/s. Adcock Ingrahm, Bangalore a closure report was filed on 30/12/2010 and the same was accepted by the court on 18/02/2011. Further, Good Manufacturing Practices(GMP) Certificates furnished by the applicants were verified by the CDSCO in consultation with State Food and Drugs Administration (SFDA), China. Investigation revealed that the GMP Certificates furnished by some of the manufacturers of China were not genuine. Accordingly, the Registration Certificates and Import Licenses of the 10 Chinese firms were cancelled in 2010. The names of the Chinese manufacturers whose registration certificates were cancelled are given in the annexure.

(c) & (d): Yes. M/s. Chongqing Daxin Pharmaceutical Limited, Chongqing China informed the inspecting team of CDSCO officials, which visited China for the purpose of inspection, that they have stopped manufacturing some of the registered drugs and are not in a position to export other drugs to India. The firm did not agree for inspection. The registration certificate and import licence granted in favour of the firm were therefore, cancelled in June, 2011.

(e)
(i) In order to ensure that drugs imported into the country are from authentic sources and of standard quality, a system of registration and import license for import of drugs was introduced under the Drugs and Cosmetics Rules.

(ii) Random sampling is done at the port at the time of import for monitoring the quality of the drugs imported into the country.

(iii) Inspections of manufacturing sites of the manufacturers abroad have also been initiated in 2011 to assess compliance of Good Manufacturing Practices. Inspections have been carried out in the first instance in China in May 2011.