Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

LOK SABHA

UNSTARRED QUESTION No.2781

TO BE ANSWERED ON THE 15th MARCH, 2016

Violation of Manufacturing Norms

2781. SHRI M.K. RAGHAVAN

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

(a) whether any Indian drug manufacturing pharmaceutical companies have been indicted by the USFDA for violating manufacturing norms ;
(b) if so, the details thereof along with the action taken against these pharmaceutical companies for reduction in export and bringing bad name to the country in international market; and
(c) whether such yardstick is applied for pharmaceutical manufacturers that supply medicine domestically and if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

a) & (b) M/s Ranbaxy USA, Inc. pleaded guilty in the US District Court of Maryland in the year 2013 for manufacture and distribution of certain drugs not in conformity with the Good Manufacturing Practices (GMP) regulation which is considered as adulterated drugs as per US law and agreed to pay USD 500 million. For export, Indian Pharmaceutical Companies are required to comply with the regulatory provisions of the importing country. However, drugs for export are required to be manufactured under the manufacturing license granted by the State Licensing Authority.

c) The Drugs & Cosmetics Act, 1940 provides that drugs are manufactured under a license granted by the concerned State Licensing Authority and comply with the requirements of Good Manufacturing Practices as specified under Schedule M and conditions of the manufacturing License granted under the Drugs & Cosmetics Rules, 1945 for the purpose. However, government has taken the following measures to establish strict enforcement regime for stringent prosecution/penalties in cases of manufacture, supply and sale of drugs as well as non-adherence to the quality norms prescribed:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of

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spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable and setting of special Courts.

2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.

3. A Whistle Blower Scheme was announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country.

4. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs.

5. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

6. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

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