GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:296
ANSWERED ON:06.12.2013
QUALITY OF DRUGS
Sule Supriya ;Viswanathan Shri P.

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

(a) whether the Government has received any report of seizure of drugs manufactured and exported by Indian pharmaceutical companies to European Union, United States of America and some other countries and penalties imposed against them in the recent past;

(b) if so, the details and the facts in this regard along with the reaction of the Government thereto;

(c) whether the Government proposes to put in place a comprehensive mechanism including research laboratories and institutes for better monitoring and quality control of drugs and medical equipment being marketed and also exported in/from the country;

(d) if so, the details thereof and if not, the reasons therefor; and

(e) the other corrective measures taken/ proposed by the Government in this regard?

Answer

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

(a) & (b): No. There has been no such report of seizure. However, as per Justice News dated 13.05.13 released by the Office of Public Affairs, Department of Justice, United States of America, Ranbaxy USA, Inc. pleaded guilty of felony charges relating to the manufacture and distribution of certain drugs. Ranbaxy has also agreed to pay a criminal fine and forfeiture totaling 150 million USD and to settle civil claims for 350 million USD.

(c) to (e): Quality control over the manufacture and sale of drugs is exercised by the State Drugs Control Authorities through the system of licensing and inspection. Random samples of drugs are drawn by the Drugs Inspectors to have a check over the quality of drugs marketed in the country. These are `tested in Central and State drug testing laboratories set up in various parts of the country. Manufacture of drugs is a licensed activity and is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. The manufacturers are required to comply with the Good Manufacturing Practices prescribed under Schedule M of the said Rules and ensure that the drugs manufactured by them are of standard quality. Thus, there is already a comprehensive mechanism in place for monitoring and quality control of drugs and medical equipments.