GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 3778

TO BE ANSWERED ON THE 9TH August, 2016

Regulatory Standard of Pharmaceuticals

3778. SHRI RAGHAV LAKHANPAL:

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

(a) the details of the steps being taken by the Government to improve India's regulatory standard of pharmaceuticals at par with global standards and move beyond being a mere generic player;
(b) whether the Government is aware that recently there have been few cases of warnings being given to leading pharma companies in India with regard to quality and if so, the details thereof;
(c) if so, whether the Government has conducted an independent assessment of the same;
(d) if so, the details and the present status thereof; and
(e) if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): Under Drugs and Cosmetics Act, 1940 and Rules made thereunder, the manufacture, sale and distribution of drugs is regulated by the State Drugs Control Authorities appointed by the State Governments. The regulatory control over the manufacture and sale of the drugs is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the State Governments. Schedule M of the Drugs and Cosmetics Rules provides requirements for Good Manufacturing Practices (GMP) for manufacture of drugs in respect of plant and equipment, personnel, sanitation, storage of raw materials, documentation and records, self-inspections and quality control systems and site master files etc The manufacturer is required to comply with the requirements of Schedule M under the conditions of the licence so as to ensure that the drugs manufacturers in the country conform to the

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standards prescribed for them. In case of contravention of any provisions of the Act or the Rules, the SLAs are empowered to take action against the offender.

(b), (c), (d) & (e) Isolated actions by foreign countries against Indian Pharmaceutical companies involved in export in drugs have been reported from time to time in media, websites of the regulatory authorities of those countries etc. For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country. However, there is no provision under the Drugs & Cosmetics Act and Rules to ensure that Drugs exported from India meet international Standards. For export of drugs, Indian Pharmaceutical companies are required to comply with regulatory provisions of the importing country.

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