Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

LOK SABHA

UNSTARRED QUESTION No. 2609

TO BE ANSWERED ON THE 10th MAY, 2016

Regulatory Standards of Pharmaceuticals

2609. 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 standard to move beyond being a mere producer of generic drugs and focus on innovations;
(b) whether the Government is aware that recently there have been a few cases of giving warnings to leading Pharma companies in India with regard to quality of drugs produced by them if so, whether the Government has conducted an independent assessment of the same, if not, the reasons therefor; and
(c) whether the Government has set up any panel to focus on fixing the compliance issue of Indian pharma products in order to significantly improve the perception of quality of Indian drugs, if so, the details and outcome thereof?

ANSWER

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

(a) M/s IMS Health had been requested to conduct a study on Pharmaceuticals Inspection Convention/Pharmaceuticals Inspection Cooperation and its implication on Indian Pharma Industry (PIC/S) to explore whether India should become member of PIC/S and to assess its likely impact on India's export.

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(b)&(c) 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. There are no provisions under the Drugs and Cosmetics Rules, 1945 which require Central Drugs Standard Control Organisation (CDSCO) to ensure the said compliance by the Indian Pharmaceutical companies.

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