

LOK SABHA

UNSTARRED QUESTION No. 2540

TO BE ANSWERED ON THE 10th MAY, 2016

Pharmaceuticals Inspection Cooperation Scheme

2540. SHRI NANA PATOLE

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

- (a) whether the Government has conducted a study on Pharmaceutical Inspection Cooperation Scheme and if so, the outcome thereof;
- (b) the purpose behind conducting the aforesaid study; and
- (c) the details of further action taken so far/likely to be taken in this regard?

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 to likely impact on India's export.
- (b) Pharmaceutical Industry is a highly regulated sector in every country. While some countries have their own high standards regulations like US FDA, UK MHRA, EDQM etc., some countries follow these standards for regulating the drugs and pharmaceuticals in their countries. Pharmaceutical Inspection Convention/ Pharmaceutical Inspection Cooperation Scheme is a forum where certain standards for drugs and

contd...p/2

pharmaceutical have been adopted. About 47 countries have already joined PICs and more countries are contemplating to join the same. As many countries are requiring the standard of PICs, it was decided by Government to conduct a study to understand the requirements of PICs and the likely implications to Indian Pharma Industry.

- (c) Further action will be taken only after consulting all stakeholders.