

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:293
ANSWERED ON:12.12.2014
PHARMA RULES
Banerjee Shri Kalyan

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

- (a) Whether the Government has taken note of the regulatory actions taken against certain Indian Pharmaceutical companies in some foreign countries and if so, the details thereof;
- (b) Whether the Government has received any complaint from any foreign country on violation/ deviation of pharma rules by the Indian Pharmaceutical companies;
- (c) If so, the details thereof along with the action taken/proposed to be taken by the Government thereon; and
- (d) The measures taken/proposed to be taken by the Government to ensure compliance of pharma rules and regulations by the Indian Pharmaceutical companies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI SHRIPAD YESSO NAIK)

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 293 FOR 12TH DECEMBER, 2014

(a) Isolated cases of action taken by foreign countries against Indian Pharmaceutical companies exporting drugs to such countries have been reported in the media and also on the websites of the regulatory authorities of those countries in the recent past. Details of some of the major regulatory actions taken in some foreign countries in the recent past are given in Annexure-I.

(b) to (d) All Indian Pharmaceutical companies are required to manufacture drugs under license as per the Drugs and Cosmetic Rules. In addition, the companies are also required to comply with the requirements relating to regulatory provisions of the importing countries. Details of Complaints received from the foreign countries on quality related issues of drugs exported by the Indian Pharmaceutical companies and action taken by the State Licensing Authorities thereon are given in Annexure-II.