

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

UNSTARRED QUESTION NO:3301

ANSWERED ON:30.08.2013

REGULATORY ACTIONS AGAINST INDIAN DRUG COMPANIES

Bapurao Shri Khatgaonkar Patil Bhaskarrao;Chitthan Shri N.S.V.;Gaikwad Shri Eknath Mahadeo

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

- (a) whether a number of instances of Indian pharmaceutical companies facing regulatory actions like drug recalls, warning letters and penalties from the US Food and Drug Administration (FDA) have been reported in the recent past;
- (b) if so, the details thereof and the reaction of the Government thereto;
- (c) whether the Government/Drug Controller General of India (DCGI) has examined the matter;
- (d) if so, the details thereof and if not, the reasons therefor; and
- (e) the corrective measures taken/ proposed by the Government in this regard?

Answer

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

(a) & (b): Yes. US Food and Drug Administration (FDA) has taken certain regulatory actions in respect of violations or deviations of US FDA regulations applicable in that country in the cases of the following Indian Pharmaceutical companies:-

1. M/s Ranbaxy Laboratories Ltd.,
2. M/s Wockhardt Ltd.,
3. M/s Hospira Healthcare India Pvt. Ltd.,
4. M/s RPG Life Sciences Ltd.,

(c) to (e): The Drugs Controller General (India) [DCG(I)] has taken appropriate measures to ensure that the said firms manufacture drugs in compliance with the standards and Good Manufacturing Practices prescribed for them under the Drugs and Cosmetics Rules, 1945 through the system of inspections and testing of drugs.