

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

UNSTARRED QUESTION NO:1074

ANSWERED ON:21.07.2017

Violation of Manufacturing Rules by Pharma Companies

Chavan Shri Harishchandra Deoram;Giluwa Shri Laxman

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

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

- (a) whether certain pharmaceutical companies have violated drug manufacturing rules;
- (b) if so, the details thereof during the last three years;
- (c) the action taken by the Government against the pharmaceutical companies found guilty and the outcomes of the action taken; and
- (d) the reaction of the Government towards the above said outcome?

**Answer**

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE

(SHRI FAGGAN SINGH KULASTE)

(a) to (d): The manufacturing of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take action against violation of any provision of the Act and Rules. However, the data regarding such violations noticed by the SLAs and action taken by them is not maintained centrally. Further, the pharmaceutical companies that manufacture drugs are required to comply with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and Good Storage and Distribution Practices (GSP) as per the provision of the said Rules.