

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO. 4401  
TO BE ANSWERED ON 12<sup>TH</sup> AUGUST, 2016**

**ADVERSE DRUG REACTION MONITORING CENTRES**

**4401. SHRI PASHUPATI NATH SINGH:**

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

- (a) the number of Adverse Drug Reaction monitoring centres working at present in the country;
- (b) whether the cases of adverse drug reaction have come to the notice of the Government during the last three years and the current year and if so, the details thereof and the action taken by the Government thereon;
- (c) whether the Government has formulated any scheme to withdraw the drugs from the market, impose regulatory ban on them due to the problem of drug reaction; and
- (d) if so, the details thereof during the said period and if not, the reasons therefor?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI FAGGAN SINGH KULASTE)**

- (a): At present, there are 202 Adverse Drug Reaction Monitoring Centers (AMCs) in the country under the Pharmacovigilance Programme of India (PvPI).
- (b): No drug is 100% safe and all drugs are allowed to be marketed based on risk-benefit assessment. The Government of India has started the PvPI with a view to gather information / data about Adverse Drug Reactions (ADR). Such data is used to develop effective, safe medications and doses and provide specific information to the end users, doctors, regulators and also industry. During 2013 to 2015, as many as 1,18,182 ADRs have been reported under the PvPI.
- (c) & (d): The Central Government prohibits manufacture, sale and distribution of drugs that are not found to be safe or rational. The Government of India has so far prohibited/restricted/suspended 439 drugs for manufacture for sale, sale and distribution in the country. However, no drugs have been banned based on ADRs received under PvPI.

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