

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

STARRED QUESTION NO:62  
ANSWERED ON:25.02.2011  
ADVERSE DRUG REACTION  
Mani Shri Jose K.

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

- (a) whether the Government has set up any mechanism to monitor, record and report Adverse Drug Reaction (ADR) in the country;
- (b) if so, the details thereof alongwith the number of ADR monitoring centres in the country, State/UT-wise;
- (c) the number of ADR cases reported during the last three years and the current year;
- (d) whether the Drugs Controller General (India) has imposed any market withdrawal, regulatory restrictions or cancellation of authorization of medicines and drug formulations due to ADR problems; and
- (e) if so, the details thereof indicating the list of medicines withdrawn from the market or regulated with restrictions or cancelled authorization during the said period?

**Answer**

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRVEDI)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 62 FOR 25TH FEBRUARY, 2011

(a) A National Pharmacovigilance Programme (NPVP) was undertaken on project basis in 2004 which came to an end in June, 2008. A revised pharmacovigilance programme was initiated on 14.7.2010 under the nomenclature Pharmacovigilance Programme of India (PvPI) with the All India Institute of Medical Sciences (AIIMS), New Delhi, as the National Coordination Centre for monitoring adverse drug reactions (ADR) in the country.

(b) Currently there are 22 ADR monitoring centres including AIIMS, New Delhi, under this Programme, the details of which are annexed.

(c) Under the earlier National Pharmacovigilance Programme, 11633 cases of ADRs were reported during the period 2006 to 2008. Under the new Pharmacovigilance Programme of India, 1394 number of ADRs have been reported since September, 2010.

(d) None of the ADRs as in (c) above has led to any restriction/prohibition on any drug in the country so far.

(e) Does not arise.