GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:156
ANSWERED ON:23.03.2012
ADVERSE DRUG REACTION
Dutt Smt. Priya Sunil;Thakor Shri Jagdish

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

(a) whether the Government has put in place any mechanism to monitor, record and report Adverse Drug Reaction (ADR) in the country;

(b) if so, the details thereof indicating 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 so far, State/UT-wise;

(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(e) if so, the details thereof indicating the list of drug withdrawn from the market or regulated with restrictions or cancelled authorization during the said period?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 GHULAM NABI AZAD)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 156 FOR 23RD MARCH, 2012

(a)&(b): The Pharmacovigilance Programme of India (PvPI) to monitor, record and report Adverse Drug Reactions (ADRs) in the country was started by the Government on 14.7.2010. Currently, 60 ADR Monitoring centres including AIIMS, New Delhi, are functioning under this Programme. The details of these 60 ADR Monitoring Centres are given in Annexure A.

(c) So far 21696 cases of ADRs have been reported by the ADR Monitoring Centres, the details of which are given in Annexure B.

(d) The ADRs reported so far have not led to any restriction/prohibition on any drug in the country.

(e) Does not arise.