GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:422
ANSWERED ON:18.12.2009
ADVERSE DRUG REACTION MONITORING CENTRES
Mani Shri Jose K.

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

(a) whether the Government has set up adverse Drug Reaction (ADR) Monitoring Centres in the country;

(b) if so, the details thereof, State-wise;

(c) the number of ADR cases reported during the last three years and the current year;

(d) whether the Government has imposed any market withdrawal, regulatory restrictions or cancellation of authorization of medicines on account of ADR problems; and

(e) if so, the details thereof during the said period?

Answer

THE MINISTER 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. 422 FOR 18TH DECEMBER, 2009

Yes, Madam.Government had started a National Pharmacovigilance Programme (NPVP) for monitoring Adverse drug reaction in the country w.e.f. 23rd November, 2004, under a World Bank assisted Capacity Building Project. The NPVP had two Zonal, Five Regional and Twenty Four Peripheral Centres throughout the country.The Programmes ended with the closure of the Capacity Building Project on 30.6.2008.During the duration of the programme, about 12000 Adverse Drug Reactions (ADR) were received by Zonal, Regional and Peripheral Centres across the country. A list of all the Zonal, Regional and Peripheral Centres is annexed.

Seventy-eight categories of drug formulations have so far been prohibited in the country by the Central Government, which are considered irrational or harmful due to ADR problem. These include the drug Diclofenac and its formulations which have been banned since year 2006 for animal use under section 26A of Drugs and Cosmetics Act, 1940. Apart from these, based on the recommendations of the expert committee, the office of Drugs Controller General (India) has asked State Licencing Authorities (SLA) and manufacturers/importers to withdraw/discontinue the marketing authorisation of Lumiracoxib and Rimonabant. Further, the State Drug Controllers have also been requested to incorporate box warning on safety issues of the drugs Rosiglitazone and Pioglitazone.