GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5263
ANSWERED ON:24.04.2015
REPORTING OF SIDE EFFECTS OF DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the existing laws and infrastructure put in place by the Government for constant monitoring of side effects of drugs in the country, State/UT-wise;

(b) the present status of operationalisation of indigenous pharmacovigilance system in the country;

(c) the number of cases of drags` side effects reported along with the action taken/ proposed to be taken by the Government thereon in the country during each of the last three years and the current year, State/ UT-wise;

(d) whether the Government proposes to make it mandatory for the pharmaceutical companies to report side effects of drags to the drag regulator, if so, the details thereof and the mechanism put in place by the Government to ensure its compliance; and

(e) the other measures being taken by the Government to strengthen the pharma co-vigilance reporting system in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a)to (c): A nationwide Pharmacovigilance Programme of India (PvPI) has been launched by the Central Drags Standard Control Organization (CDSCO) in 2010 to monitor the Adverse Drus Reactions (ATOO Commission (IPC) functions as National Coordination Centre (NCC) for PvPI. At present, 150 ADR Monitoring Centres (AMCs) monitor and report ADR across the country. The details of AMCs are at Annexure A and the number of ADRs reported to PvPI State/UT wise during the last three years and the current year (till March) are at Annexure B.

(d): Till date, the Government has not decided to make it mandatory for the pharmaceutical companies to report side effects of drugs to the drug regulator.

(e): To facilitate the process of ADR reporting under PvPI following measures have been taken:

NCC launched the toll free helpline facility for the healthcare professionals and patients.

The reporting forms have been made available in Hindi and other languages also to empower patients for direct reporting of ADRs.

PvPI is coordinating with Revised National TB Control Program; National AIDS Control Program and Adverse Events Following Immunization Programme to ensure the safety of drugs used in the National Health Programs.

Several Continuing Medical Education (CME) on Pharmacovigilance have been organized for the healthcare professionals across the country.