GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3179
ANSWERED ON:19.08.2011
ADVERSE SIDE EFFECTS OF DRUGS
Panda Shri Baijayant;Pradhan Shri Nityananda;Yadav Shri Ranjan Prasad

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

(a) whether the Government has set up any mechanism and launched any project with All India Institute of Medical Sciences (AIIMS) as co-coordinating agency to monitor and combat the side/adverse effects of various drugs in the country;

(b) if so, the details thereof;

(c) the details of the drugs detected having adverse side effects in the country during each of the last three years and the current year; and

(d) the steps taken/proposed to ban the drugs having adverse side effects on human health?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): The Pharmacovigilance Programme of India (PvPI) was started by the Government on 14.7.2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC) for monitoring adverse drug reactions (ADRs) in the country. The NCC has now been shifted from AIIMS to Indian Pharmacopoeia Commission (IPC), Ghaziabad on 15.04.2011.

(c): The NCC under AIIMS had reported about 8000 ADRs upto April, 2011. The NCC under IPC has collected 2442 ADRs so far.

(d): The decision to ban or withdraw a drug by the regulatory authorities is normally based on the risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safer substitutes and overall safety profile of the drug. These conditions are different for different countries. It is for this reason that a drug banned / restricted in one country may continue to be marketed in other countries. There is a well laid mechanism in India to review the status of the drug formulations as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been banned / withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the expert committees set up for the purpose, based on available technical information, benefit-risk ratio, local needs and availability of safer alternatives etc. Based on the recommendations of the expert committee, the Central Government prohibits manufacture and sale of drugs in the country through a Gazette Notification.

None of the ADRs reported under the pharmacovigilance programme have led to any restriction / prohibition of any drug in the country. However, because of safety issues and / or restrictions / bans imposed in other countries several drug formulations have been prohibited in the country.