GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA UNSTARRED QUESTION NO.1781 TO BE ANSWERED ON 16th DECEMBER, 2022

SIDE-EFFECTS OF BANNED MEDICINES

1781: SHRIMATI SANGEETA AZAD:

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

- (a) whether the Government has made any assessment regarding the side-effects of medicines on the human body;
- (b) if so, the details of such medicines and their reported side-effects;
- (c) whether the Government is aware that the medicines which are banned in the developed countries including Europe and America are allowed/being sold in the country; and
- (d) if so, the details thereof?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) to (d): Before approval of any drug for marketing first time and during drug development, side effects of the drugs are assessed through non clinical animal studies and clinical studies. During such studies, side effects of the drug on various systems/organs like Cardiovascular, CNS, Respiratory, etc. are reported and assessed depending on nature of the drug.

Safety issues of marketed drugs reported in any published literature/journal are examined by Central Drugs Standard Control Organization (CDSCO) in consultation with Subject Expert Committees (SEC)/ Drug Technical Advisory Board (DTAB), based on whose recommendations such drugs are prohibited for manufacture, sale and distribution in the country. Moreover, Indian Pharmacopoeia Commission (IPC) as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) collates and analyses, Individual Case Safety Reports (ICSRs) related to adverse drug reactions.

A drug banned/ restricted in one country may be marketed in other countries as the respective Governments examine the usage, doses, indications permitted, etc. along with the overall risk-benefit ratio and take decisions on marketing of any drug in the Country. A list of drugs prohibited in India is available on CDSCO's website.

(https://cdsco.gov.in/opencms/opencms/en/consumer/List-Of-Banned-Drugs/)
