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

## LOK SABHA UNSTARRED QUESTION NO.†5054 TO BE ANSWERED ON 01<sup>st</sup> APRIL, 2022

## SIDE-EFFECTS OF MEDICINES

†5054: SHRI HANUMAN BENIWAL:

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 side-effects reported thereon;
- (c) whether the Government is aware that the medicines which are banned in the developed countries including Europe and America are allowed for sale 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.

Any safety issues of marketed drugs reported in any published literature/journal are examined by Central Drugs Standard Control Organization (CDSCO) in consultation with expert committees/ Drug Technical Advisory Board (DTAB), based on whose recommendations such drugs are prohibited for manufacture, sale and distribution in the country.

A drug banned/ restricted in one country may continue to 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 the continued 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/)

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