

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

**LOK SABHA
UNSTARRED QUESTION NO.1961
TO BE ANSWERED ON 06TH DECEMBER, 2024**

SALE OF FIXED DOSE COMBINATION DRUGS

1961: SHRI HIBI EDEN:

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

- (a) the details of the procedure for banning of pharmaceutical drugs in the market, including Fixed Dose Combination (FDCs) drugs;
- (b) whether the already produced drugs falling within the banned list continue to be sold in the market from the existing stock, if so, the details thereof and if not, the reasons therefor;
- (c) the steps taken/proposed to be taken by the Government to stop the sale of such drugs in the country;
- (d) whether the sale of combination drugs that have been banned in August 2024 is continuing in the commercial market from the stock already produced before the ban and if so, the details thereof; and
- (e) the steps taken/proposed to be taken by the Government to stop such sale in the country?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (e): There are provisions under the Drugs and Cosmetics Act, 1940, under which Central Government may regulate, restrict or prohibit manufacture, etc of any drug including Fixed Dose Combination (FDCs) drugs in public interest if the use of drugs is likely to involve any risk to human beings or animals or there is no therapeutic justification for the ingredients contained in FDCs.

Whenever, any such concerns on any drug including FDCs are reported, the matter is examined in consultation with expert committee/ Drugs Technical Advisory Board (DTAB) and appropriate action is taken for prohibition of such drugs.

Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under Section 18 of the Drugs and Cosmetics Act and the State Licensing Authorities are empowered to take action in this regard.

In August 2024, the Central Government issued gazette notifications prohibiting the manufacture for sale, sale and distribution of certain FDCs for human use on the basis of recommendations of Expert Committee/DTAB. List of such banned FDCs is available on the website of CDSCO i.e www.cdsc.gov.in.

However, many a times after issuance of prohibition notification, stakeholders have challenged them in the Courts and Courts have granted interim protection for the drugs already in the distribution network.

Earlier, Government also has filed application in Hon'ble Supreme Court against such stay order of the Court in respect of banned drugs.
