

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

**LOK SABHA
UNSTARRED QUESTION NO. 2289
TO BE ANSWERED ON 01ST AUGUST, 2025**

BAN ON FIXED DOSE COMBINATIONS

2289. DR. THIRUMAAVALAVAN THOLKAPPIYAN:

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

(a) whether the Government has banned any medicine, irrational fixed dose combinations in the country during the last three years, if so, the details thereof, year-wise; and

(b) whether the Government has any data of the medicine and its treatment category along with the names of the companies producing it and if so, the details thereof?

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

(a) & (b) : 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 under the provisions of Section 26A of the Drugs and Cosmetics Act, 1940.

The Central Government has prohibited number of drugs including FDCs for manufacture, sale or distribution. Through notification issued on 07.09.2018, the Central Government prohibited 328 FDCs for manufacture, sale or distribution. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions. Subsequently, Central Government vide notifications S.O. 180 (E) to S.O.259 (E), dated 11.01.2019, prohibited 80 FDCs for manufacture, sale or distribution. Further, Central Government vide notification S.O. 2394 (E) to S.O. 2407 (E) dated 02.06.2023 prohibited 14 FDCs for manufacture, sale or distribution. Recently, Central Government vide notification S.O. 3285 (E) to S.O. 3440 (E) dated 02.08.2024 prohibited 156 FDCs for manufacture, sale or distribution.

The Central Government also prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of S(+) Etodolac + Paracetamol vide S.O. 3284(E) dated 12.08.2024.

List of banned FDCs is available on the website of CDSCO i.e. www.cdsc.gov.in
