

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

**LOK SABHA
UNSTARRED QUESTION NO. 930
TO BE ANSWERED ON 24TH JULY, 2026**

BAN ON FIXED DOSE COMBINATIONS (FDCs)

**930: THIRU THANGA TAMILSELVAN:
DR. GANAPATHY RAJKUMAR P:**

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

- (a) whether the Government has recently issued notifications under Section 26A of the Drugs and Cosmetics Act, 1940, prohibiting sixteen more Fixed Dose Combinations (FDCs), including dermatological preparations, painkillers, antispasmodics and antibiotics;
- (b) if so, the details thereof, along with the specific reasons, expert evaluations and the objective behind banning these sixteen FDCs;
- (c) the total number of FDCs banned by the Union Government during the last three years, year-wise;
- (d) the exact date on which these prohibition notifications came into force across the country;
- (e) the supervisory and regulatory mechanisms established by the Central and State drug regulatory authorities to enforce the ban and monitor the manufacture, distribution and retail sale of these 16 FDCs; and
- (f) whether the Government proposes to review more existing FDCs in the near future, if so, the details and timeframe thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE**

(SMT. ANUPRIYA PATEL)

(a) to (f): There are provisions under the Drugs and Cosmetics Act, 1940, under which Central Government may regulate, restrict or prohibit manufacture, 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.

The Central Government has prohibited manufacture, sale or distribution of 16 FDCs vide gazette notification dated 11.06.2026 vide S.O No. 3068(E) to 3083(E) with immediate effect in public interest under section 26A of Drugs and Cosmetics Act 1940 in the country.

The details thereof, along with the specific reasons are available on the website of CDSCO i.e. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQzOTc=

The details of the FDCs prohibited during the last three years are as under.

- (i) 14 FDCs vide gazette notification SO no. 2394(E) to 2407(E) dated 02.06.2023,
- (ii) 156 FDCs vide gazette notification S.O No. 3285(E) to 3440(E) dated 02.08.2024,
- (iii) The fixed dose combination of S(+) Etodolac + Paracetamol vide gazette notification S.O. 3284(E) dated 12.08.2024.

The prohibitions become effective across the country from the date of publication of the respective notifications in the Official Gazette.

Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under Section 18 of the Drugs and Cosmetics Act, 1940 and the State Licensing Authorities are empowered to take action in this regard. As and when any such complaints/issues is received, the matter is taken up with the concerned State Licensing Authority for necessary action including the cancellation of the manufacturing licenses.

The meetings of Drugs Consultative Committee (DCC), a statutory committee under the said Act, comprising of all States /UTs Drugs Controllers as members, are held and various issues related manufacturing, sale and distribution of drugs are discussed/deliberated and decisions are taken for effective & uniform implementation of the various provisions of said Act & Rules.
