

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

**RAJYA SABHA
UNSTARRED QUESTION NO.1406
TO BE ANSWERED ON 11TH MARCH, 2025**

UNAPPROVED FDC OF ANTIBIOTICS

1406: DR. KANIMOZHI NVN SOMU:

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

- (a) whether Government has taken any steps to ban unapproved Fixed Dose Combination (FDC) antibiotics in the country;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether Government has prosecuted drug manufacturers for selling FDCs that have not been approved by Drug Controller General of India (DCGI); and
- (d) if so, the details of action taken against such drug manufacturers?

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

(a) to (d): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Under the said rules, Fixed Dose Combination (FDC) is a new drug. For manufacture of any FDC falling under the definition of new drug, permission is required from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license from the concerned State Licensing Authority.

Some cases of grant of manufacturing license of new drugs including FDCs by some of the State Licensing Authorities without due approval of the Drugs Controller (India) came to the notice of the Government.

The Central Government, vide notifications dated 07.09.2018, prohibited 328 FDCs including 63 antibiotic combinations 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 including 12 antibiotic combinations 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 including 01 antibiotic 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 including 14 antibiotics for manufacture, sale or distribution. List of banned FDCs is available on the website of CDSCO i.e. www.cdsc.gov.in

Under the Drugs & Cosmetics Act, 1940, manufacture, sale and distribution of any prohibited/banned drug is a punishable offence and State Licensing Authorities are empowered to take action in this regard
