

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

**LOK SABHA
STARRED QUESTION NO. 120
TO BE ANSWERED ON THE 9TH FEBRUARY, 2024**

BANNING OF FDC DRUGS

†*120. DR. SANJAY JAISWAL:

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

- (a) whether the Government has taken any steps to ban unapproved Fixed Dose Combinations (FDCs) of antibiotics in the country;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether the 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 thereof and if not, the reasons therefor?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR MANSUKH MANDAVIYA)**

(a) to (d) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 120 FOR 9TH FEBRUARY, 2024**

(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 Combinations is a new Drug. For the 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 for the New Drug from the concerned State Licensing Authority.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

The Central Government vide notifications dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution. It also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications dated 07.09.2018. Subsequently, Central Government, vide notifications 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. List of banned FDCs is available on the website of CDSCO i.e. www.cdsc.gov.in.

Under the provision of Drugs & Cosmetics Act and Rules, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in case of manufacture, sale of such unapproved FDCs.
