

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
STARRED QUESTION No. *373
TO BE ANSWERED ON THE 20th DECEMBER, 2024

Ban on FDC Medicines

***373. Shri S Venkatesan:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the Government has banned 156 Fixed Dose Combination (FDC) medicines which included commonly used antibiotics, painkillers and multivitamins;
- (b) if so, the details thereof;
- (c) the number of FDCs identified by the Kokate Committee as irrational and under production without licences; and
- (d) the measures taken/proposed to be taken by the Government to protect people from risks associated with these irrational drugs?

ANSWER

**THE MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)**

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

STATEMENT REFERRED TO IN REPLY TO THE LOK SABHA STARRED QUESTION NO. *373 (13TH POSITION) FOR ANSWER ON 20.12.2024 RAISED BY SHRI S VENKATESAN REGARDING “BAN ON FDC MEDICINES”.

(a) to (d): As per the information provided by M/o Health & Family Welfare, 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.

Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, Central Government prohibited several FDCs. List of such banned FDCs including 156 banned FDCs in the month of August, 2024 is available on the website of Central Drugs Standard Control Organisation (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 Licencing Authorities are empowered to take action in case of manufacture, sale of such unapproved FDCs.
