

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

LOK SABHA  
UNSTARRED QUESTION No. 1726  
TO BE ANSWERED ON THE 16<sup>th</sup> DECEMBER, 2022

**Usage of FDC Drugs**

**1726. SHRI VINOD KUMAR SONKAR:  
DR. SUKANTA MAJUMDAR:**

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

- (a) whether the Government has any plan to increase monitoring of the usage of Fixed Dose Combinations (FDCs) drugs in the country and if so, the details thereof;
- (b) whether the Government has asked National Pharmaceuticals Pricing Authority (NPPA) and Indian Council of Medical Research (ICMR) to study the usage and prescription of FDCs medicines in the country and if so, the details thereof;
- (c) whether the Government has banned some FDC medicines on recommendations of experts;
- (d) if so, the details thereof along with the list of such FDC medicines, banned during last five years; and
- (e) the steps taken/proposed to be taken by the Government so far to ensure marketing of FDC medicines to public?

**ANSWER**

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS  
(SHRI BHAGWANTH KHUBA)**

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(a): Manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection.

(b): As per the available information with the Department, both National Pharmaceuticals Pricing Authority (NPPA) and Indian Council of Medical Research (ICMR) have not been asked to study the usage and prescription of FDC medicines in the country.

(c) & (d): List of FDC medicines banned during last five years is available on the website of Central Drugs Standard Control Organisation (CDSCO) [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MzIIMQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzIIMQ==)

(e): Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. For the manufacture of any Fixed Dose Combination (FDC) falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organization (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority

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