

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

**LOK SABHA  
UNSTARRED QUESTION NO.1872  
TO BE ANSWERED ON 06<sup>TH</sup> DECEMBER, 2024**

**QUALITY OF FIXED DOSE COMBINATION DRUGS**

**1872: MS SAYANI GHOSH:**

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

- (a) whether it is a fact that 53 medicines have failed the quality checks conducted by Central Drugs Standard Control Organisation (CDSCO) and if so, the details thereof;
- (b) whether there is any mechanism put in place to inform consumers about potential risks if a drug fails testing and is not recalled by the manufacturer and if so, the details thereof;
- (c) the number of instances in which CDSCO has asked companies to recall drugs, and the number of drugs recalled by companies during the last five years, year-wise; and
- (d) whether there is a mechanism put in place to test the quality of fixed-dose combination drugs before permitting their manufacturing and if so, the details thereof?

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

(a) & (b): List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert ([www.cdsc.gov.in](http://www.cdsc.gov.in)). In the cases concerning quality or safety of drugs as and when reported, action is taken by the licensing authorities concerned under the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

(c): The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. The data regarding drugs recalled after failing quality tests is not maintained centrally by CDSCO.

However, as per information received from various States/U.Ts Drugs Controllers, the details of number of batches recalled during the last five years are as under.

| S.No. | Year (April to March) | Number of Batches Recalled |
|-------|-----------------------|----------------------------|
| 1     | 2019-2020             | 950                        |
| 2     | 2020-2021             | 1091                       |
| 3     | 2021-2022             | 1153                       |

|   |            |      |
|---|------------|------|
| 4 | 2022-2023  | 1171 |
| 5 | 2023-2024* | 1394 |

\* Provisional figure

(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 New Drugs Clinical trial Rules 2019, Fixed Dose Combinations is categorized as “New Drugs”. 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. Before a ‘New Drug’ is approved by CDSCO, it goes through the rigorous process of evaluation of submitted data and Subject expert committee (SEC) recommendation for safety and efficacy of the drugs and quality of the drug is also tested at Indian Pharmacopoeia Commission/Central Drugs Testing Laboratory, Mumbai before grant of the permission. Further, as per conditions of manufacturing license, the licensee is required to test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product.

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