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

LOK SABHA
UNSTARRED QUESTION No. **1179**
TO BE ANSWERED ON THE **6th FEBRUARY, 2026**

**Sale of Banned Medicines**

**†1179. Dr. Anand Kumar:**

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

(a) the number of medicines banned by the Government during the last five years, year-wise and category-wise;
(b) whether the Government is aware of the fact that such medicines despite being banned, continue to be sold and purchased in the market;
(c) if so, the details thereof along with the corrective steps being taken by the Government in this regard;
(d) the action taken by the Government against such drug manufacturing companies and vendors during the last five years;
(e) whether new medicines under different name have been manufactured by the drug manufacturing companies by making minor changes in the composition of the medicines and sold in the market; and
(f) if so, the details thereof along with the action taken by the Government in this regard?

**ANSWER**

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

(a) to (d): As per the information provided by Department of Health & Family Welfare, number of drugs banned by Central Government under the provisions of Drugs & Cosmetics Act, year wise is as follows:

| Year | No. of Drugs Banned |
|---|---|
| 2021 | NIL |
| 2022 | NIL |
| 2023 | 14 for human use and 02 drugs for animal use |
| 2024 | 157 for human use and 01 drug for animal use |
| 2025 | 01 human use and 36 drugs for animal use |

However, several writ petitions were filed in various High Courts across the country challenging the ban of the Fixed Dose Combinations (FDCs) and the Court granted interim protection for the drugs already in the distribution network.

Manufacture, sale and distribution of Banned Drug in the country is a punishable offence as per Drugs & Cosmetics Act, 1940 and State Licensing Authorities (SLAs) appointed by respective State Governments are empowered to take action against such offences.

As and when any such complaints/issues are received in Central Drugs Standard Control Organisation (CDSCO) on selling of banned drugs, the matter is taken up with State Drugs Controller for necessary action.

(e) to (f): Department of Health & Family Welfare has informed that manufacture, sale and distribution of drugs are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

Any change in composition in respect of active ingredients of medicines require New drug permission from CDSCO before obtaining the manufacturing licence from SLA. Such applications are reviewed based on the provisions under New Drugs and Clinical Trial Rules, 2019.

Further, Drugs and Cosmetics Rules, 1945 was amended vide GSR no. 828(E) dated 06.11.2019, providing that in case an applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trademarks registry, central data base for brand name or trade name of drugs maintained by CDSCO, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

As and when any such complaints/issues regarding manufacturing/ marketing of any medicine with change in composition of active ingredients without CDSCO approval are taken up the matter with the concerned State Drugs Controller for necessary action under provision of Drugs Act and Rules.

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