



Sale of Spurious Drugs

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As per the information provided by Department of Health and Family Welfare manufacture/sales/distribution of Spurious/ Adulterated/Not of Standard Quality drugs etc. is a punishable offence under the Drugs & Cosmetics Act, 1940 and the Drugs Rules, 1945 and concerned licensing authorities are empowered to take action in such cases.

As per the information provided by Department of Health and Family Welfare, Central Drugs Standard Control Organization (CDSCO) as well as State Drugs Control Authorities draw samples of drugs for test and analysis from supply chain under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder. All the drug samples found not of standard quality/spurious/ adulterated by the Central Govt. Laboratory and reports of Not of Standard Quality (NSQ)/spurious /adulterated forwarded by the State Drugs Controllers to CDSCO are uploaded on the website of CDSCO as part of the monthly drug alerts to make it available publicly.

In such cases, the manufacturers (as per the label claim) are directed to recall such drugs and based on investigation outcomes, actions are taken by the concerned licensing authorities under the provisions of Drugs & Cosmetics Act & rules made thereunder.

The 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	

Further, under the Drugs and Cosmetics Act, 1940, the manufacture, sale, or distribution of spurious drugs is strictly prohibited. According to Section 17B, a drug is considered spurious if it is manufactured under the name of another drug, is an imitation intended to deceive, bears a false manufacturer's name, claims to be produced by a non-existent manufacturer, or has been wholly or partly substituted with another

substance. Section 18 prohibits the manufacture, sale, stocking, or distribution of such drugs without proper authorization. The Drugs and Cosmetics Rules, 1945 support these provisions by regulating licensing, labeling, inspection, and manufacturing standards to prevent the production of counterfeit medicines.

Punishment for manufacturing or selling spurious drugs is provided under Section 27 of the Act. If the spurious drug causes death or grievous hurt, the offender may face imprisonment of not less than 10 years, which may extend to life imprisonment, along with a fine of at least ₹10 lakh or three times the value of the drugs confiscated. In other cases, the punishment includes imprisonment of not less than 7 years, which may extend to life imprisonment, along with a minimum fine of ₹3 lakh or three times the value of the drugs. Additionally, under Sections 31 and 34, the drugs and related materials may be confiscated, and company officials responsible for the offence may also be held liable. Offences relating to spurious drugs are cognizable and non-bailable, ensuring strict enforcement against manufacturers of fake medicines.

This information was given by Minister of State for Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in the Lok Sabha today.

PC/PM

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