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

RAJYA SABHA
UNSTARRED QUESTION NO. 280
TO BE ANSWERED ON 21ST JULY, 2026

MEASURES TO PREVENT COUNTERFEIT DRUGS AND STRENGTHEN DRUG QUALITY ENFORCEMENT

280. SMT. JEBI MATHER HISHAM:

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

(a) the number of cases, convictions and rate of conviction against counterfeit drug manufacturers and sellers during the last five years, State/UT-wise;
(b) the action taken against wholesalers and retailers violating profit margin caps on scheduled drugs during the last five years, State/UT-wise;
(c) whether Government proposes to amend the law to provide stricter punishment and prevent easy bail for counterfeit drug offenders, the details thereof;
(d) whether any study has been conducted on public health risks from counterfeit medicines, if so, the findings and action taken and if not, the reasons therefor; and
(e) the budget allocation and expenditure on drug quality enforcement during the last five years?

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

(a) to (e): The terminology “Counterfeit Medicines” is not defined under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, the Drugs and Cosmetics Act defines spurious, adulterated and misbranded drugs which includes counterfeit drugs. Presently, there is no specific study conducted to assess the current volume and estimated market size of counterfeit medicines.

As per information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last five years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	Number of prosecution cases for manufacturing, sale and distribution of spurious/adulterated drugs
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961
2025-26	1,41,322	3,012	283	779*

* Provisional figure

As informed by Department of Pharmaceuticals (DoP), The National Pharmaceutical Pricing Authority (NPPA) implements the provisions of the Drugs (Prices Control) Order (DPCO), 2013. Under DPCO, 2013, NPPA fixes the ceiling prices of scheduled drugs based on market data, and no manufacturer of scheduled medicines can sell such medicines above the ceiling price (plus applicable GST) notified by NPPA.

As per the present price fixation methodology provided in DPCO, 2013 ceiling prices of scheduled drugs are fixed by adding 16% margin to the average price to retailer (PTR) of all brands having a market share of more than 1% of the specified medicine. However, no such margin cap for wholesalers is specified in DPCO, 2013 for the purpose of fixing of ceiling prices.

The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

Further, for strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 24 New Drug Testing Labs have been constructed and 32 existing labs have been up-graded in various States/UTs. Additionally, the Central Drugs Standard Control Organisation (CDSCO) has been allocated ₹1019.8 crores over the last five years.

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