

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 436
TO BE ANSWERED ON 03RD FEBRUARY, 2026**

DRUG QUALITY TESTING UNDER CDSCO

436. DR. VIKRAMJIT SINGH SAHNEY:

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

- (a) the details of mechanisms and frequency of drug quality testing under Central Drugs Standard Control Organization (CDSCO) random sampling processes;
- (b) the details of any updates on plans to strengthen real-time tracking of drug quality issues using digital technologies;
- (c) the protocols in place for ensuring quick recalls of drugs found to be substandard; and
- (d) whether the Ministry is planning to bring a national standard norm for manufacturing of the medicines, so that the quality of the drugs should not vary State to State?

ANSWER

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

- (a): Under the Drug and Cosmetics Act 1940, Drugs Inspector randomly draws drug samples from the supply chain for quality checks. Also, list of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsc.gov.in).
- (b): An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.
- (c): Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country. In case of drug samples declared as Not of Standard Quality by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the Not of standard quality Drugs in the market. One of the conditions for licensing is regarding withdrawal/recall/take back of drugs which is reproduced below:

“the licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch of the drug has been found by the Licensing Authority or the Controlling Authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch.”

Further, CDSCO has issued guidelines on “Recall and Rapid Alert System for Drugs” (including Biologicals & Vaccines). Further, draft Guidelines on Good Distribution Practices for Pharmaceutical Products is also published for ensuring quality of Drugs in the supply chain. These guidelines are available on website of CDSCO (www.cdsc.gov.in).

(d) Manufacture of drugs is regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules made thereunder which is applicable to all the States and UTs. Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in implementation of the Drugs and Cosmetics Act.
