

CDSCO revises guideline for sampling of drugs, cosmetics and medical devices

The Central Drugs Standard Control Organisation (CDSCO) has revised the regulatory guidelines for sampling of drugs, cosmetics and medical devices, by the Drugs Inspectors of the Central and state drug authorities, which has been in prevalence from the year 2024, with updated formats for reporting of Not of Standard Quality (NSQ) and spurious drugs.

The updated format for monthly reporting of NSQs seek the drugs inspectors to specify the product type, name of the product and the brand name separately, the dosage form, route, manufacturer name, details of the firm where it has been manufactured by, manufacturing state, manufacturing date, expiry date, reporting source, reporting month and year, batch number, NSQ result, and the details of the modified dosage form, if applicable.

This is an expansion from the existing format in which seeks the drugs inspectors to furnish the product and drug name, batch number, manufacturing date and expiry date, details of the unit where the product has been manufactured by, NSQ results, and the details of the CDSCO or State Laboratory which has reported the result.

"The NSQ reports received from state and central laboratories shall be reported in excel sheet format as per Annexure-6 with copy of test report preferably before 10th of every month for uploading at CDSCO website under Drug/Device/Cosmetic NSQ Alert for wide public awareness," said the amended regulatory guidelines issued by the Enforcement Division of the CDSCO.

Similarly, the format for reporting of spurious alerts has also been revised with the latest format which is being followed by the central drug regulator. While in the previous format under the guidelines, there was a provision to report the details of the firm which manufactured the product as per label, it has now been changed to "manufactured by" which may exempt the regulator from mentioning the firm which manufacture the genuine or original product as per the label. The column will now mention that the name of the manufacturer of the spurious drug is under investigation.

The revised format also has the provision to mention the reason for failure, the name of the authority which drew the sample, the firms reply and remarks. The previous format had a provision to mention the sales outlets involved in distribution of the spurious drug, including the name and address of the outlet and the pharmacist name with registration number, which has been omitted in the revised format.

The revision also defines that a drug shall be deemed to be spurious if it is manufactured under a name which belongs to another drug, or if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug.

Besides, a drug shall be deemed as spurious if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or if it has been substituted wholly or in part by another drug or substance; or if it purports to be the product of a manufacturer of whom it is not truly a product.

As part of the continuous regulatory surveillance, drugs samples are picked from sales or distribution point, analysed and list of spurious drugs are displayed on CDSCO portal on monthly basis. The purpose of displaying the spurious drugs list is to make stakeholders aware about the spurious drug batches identified in the market.

"The samples identified as Spurious due to distribution chain breakage or reported by the manufacturer as spurious shall be reported in excel sheet format as per Annexure-7 with copy of drugs inspector report indicating distribution chain break with manufacturer response indicating how to identify original product from reported Spurious," said the revised guidelines.

As reported earlier, the number of NSQs reported monthly by the central drug regulator has gone up significantly after the state drug regulators started actively participating in the reporting process in the year 2024.

The number of drug samples declared as Not of Standard Quality (NSQ) by the drug regulators in the country has registered over two fold growth during the 12 months of the year 2025, primarily owing to the increased participation from the States and Union Territories, as compared to the previous year.

The NSQ reported by the CDSCO, with the data collected from both the States and the Central drug testing laboratories across the country, was 1,879 samples during the year 2025, as compared to a total of 877 samples during the year 2024. Out of the 1,879 samples reported as NSQs during the year, 1,163 samples (almost 62%) were from the States. This is compared to the 339 samples (almost 39%) reported by the states during the year 2024.

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