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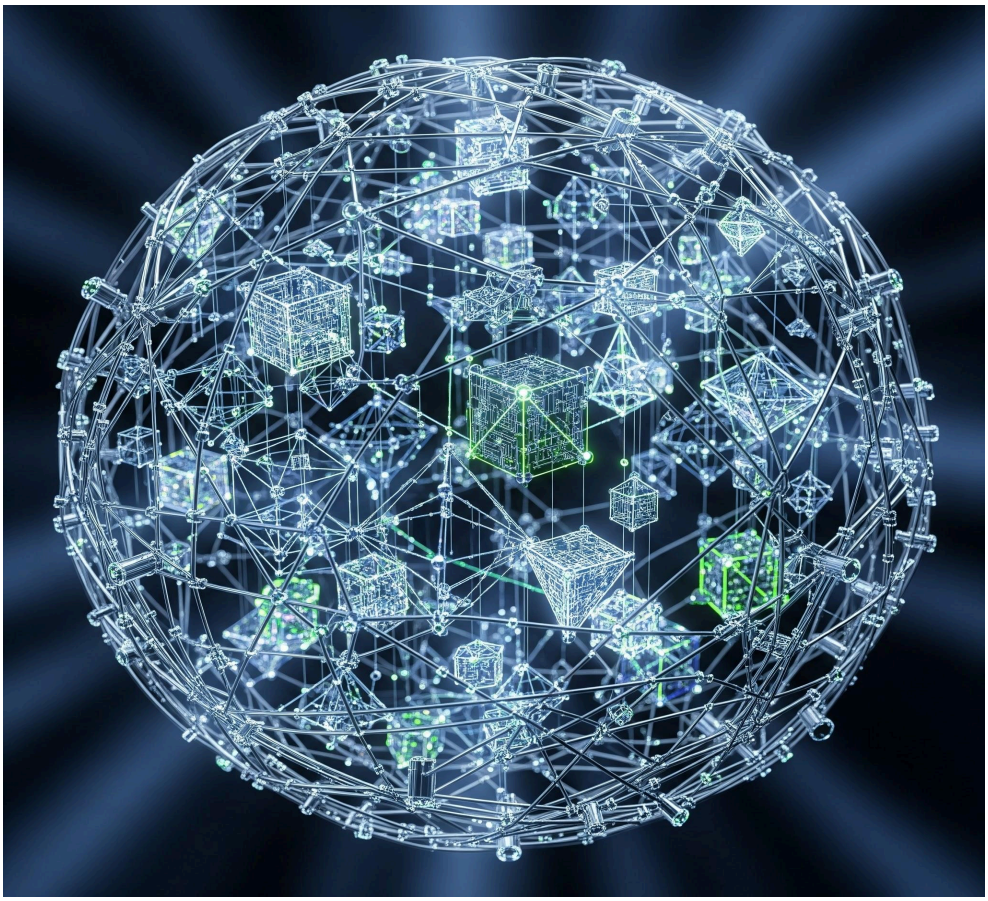
Central Drugs Standard Control Organization (CDSCO) Regulatory Updates – May 2025:

Key Compliance Requirements and Legal Implications



The Central Drugs Standard Control Organization (CDSCO) issued a regulatory framework in May 2025 for the safe disposal of expired and unused drugs. It is a significant step addressing the challenges of environmental contamination, public health risk, and antimicrobial resistance (AMR) caused due to unchecked pharmaceutical waste. These guidelines change the operational, financial and legal framework within which pharmaceutical companies must operate introducing Extended Producer Responsibility that extend the manufacturer accountability from production through the final disposal of expired and unused medications. The guidelines operate under the Drugs and Cosmetics Act, 1940.Section 3 of the Act

empowers the Central Government to regulate the manufacture, sale and distribution of drugs and Section 26 addresses the control of manufacturing processes to ensure public safety.

Disposal Method and Stakeholders Responsibility

The guidelines define “expired drugs” as medications that have crossed the expiry date mentioned in their labels, while “unused drugs “refer to medications not consumed by the individuals for whom they were prescribed or purchased. There are disposal methods for both expired drugs and unused drugs. The scientifically approved methods include landfilling were drugs are sealed and placed in engineered landfill facilities to prevent harmful substances from contaminating soil and groundwater. The other method is waste immobilization which involves mixing the drugs with binding agents such as cement or lime to neutralize potential environment hazards. For liquid pharmaceutical wastes, controlled disposal through sewage systems is permitted under stringent conditions designed to avoid contamination of natural water bodies.

The guidelines establish reverse logistics were expired or unused drugs move backward in the supply chain. The unused or expired drugs from the retailer must be send back to the wholesaler or the distributor who would further send it back to the manufacturer. The containers or bags containing the expired or unused drugs are transported from the premises of the manufacturer to any bio-medical waste treatment facility in the vehicles having label as provided in part ‘A’ of the Schedule IV along with necessary information as specified in part ‘B’ of the" Schedule IV of Bio-Medical Waste (Management and Handling) Rules, 2016. The manufacturer must dispose off all the expired drugs both in the site and received from the retailers/wholesalers within 6 months of the expiry. The retailers/wholesalers/distributors can also dispose the drug themselves in compliance with the BMW Rules. For hospitals and clinics the guidelines permit them to dispose off the drug on their own in accordance with the BMW Rules. For the consumers, they are encouraged to participate in drug take back programmes established by state governments in coordination with local bodies. It also includes a “Flush List” of 17 specific high-risk medications, including fentanyl, tramadol and diazepam which must be safely flushed on their expiry to prevent accidental exposure or misuse.

Compliance Requirements & Legal Implications

Under the Drugs and Cosmetics Act,1940, manufacturers are required to obtain license for drug manufacturing and ensure compliance with good manufacturing practices including waste management protocols.

All the stakeholders must maintain a detailed record of expired/unused drugs, proper disposal methods, transportation details and final disposal confirmation.The records must be available for verification by the regulatory authorities and during inspections and audits.All the stakeholders must maintain a detailed records of disposal as per the formats mentioned under Annexure-A and Annexure-B of the guidelines.

Enforcement and Penalties

For the safety of the consumers health and a successful market the authority enforces strict regulations.Non compliance with the rules can lead to legal consequences for the business operators.Under Drugs and Cosmetics Act,1940 includes penalties of imprisonment and fines upto Rs. 10 lakhs or three times the value of confiscated goods, whichever is greater.

Recently, the Central Drugs Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare with the state regulators have undertaken strict enforcement actions inspecting 905 drug units, resulting in 694 actions taken.The actions include Stop Production Orders(SPO),Stop Testing Orders(STO),license suspensions/cancellations,warning letters and show cause notices depending on the severity of non-compliance.

The CDSCO guidelines are responsible steps for safe drug disposal, protection of the environment and fair market practices. For the businesses, they require a structured approach towards managing compliance. A minor pitfall can lead to losing the trust of the consumers.The ban on products may erupt the businesses significantly causing a lost of revenue and legal consequences. A clear understanding and implementation of the guidelines would ensure fair practices, thereby protecting the business, consumers and the environment.

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