

CDSCO Issues Guidelines for Disposing Expired, Unused Medicines

The guidance has been prepared by a subject expert committee under the Drugs Consultative Committee of CDSCO and was recommended to be publicly notified by the Drugs Technical Advisory Board (DTAB) in April this year.



New Delhi: The Central Drugs Standard Control Organisation (CDSCO) has issued a detailed guidance document for disposing of expired and unused medicines for the "general public" and other stakeholders.

Issuing a public notice, the Drugs Controller General of India (DCGI) noted that expired and unused drugs have emerged as one of the key factors contributing to growing antimicrobial resistance (AMR), and that proper disposal of such medicines is crucial for protecting the environment and public health.

The guidance has been prepared by a subject expert committee under the Drugs Consultative Committee (DCC) of the CDSCO and was recommended to be publicly notified by the Drugs Technical Advisory Board (DTAB) in April this year.

Under the issued guidance framework, “the licensee (retailer) is responsible for returning the stock to the supplier or manufacturer within 30 days after its expiry, from whom it was purchased, and shall maintain a register or record of expired/unused drugs.”

“If multiple wholesalers/stockists are involved in the supply chain, each level should ensure the return of such drugs to the next level within 30 days,” the document reads.

Additionally, the document has listed 17 active-ingredient-based drugs that may be disposed of by flushing by the general public, excluding retailers, wholesalers, and manufacturers.

The list includes drugs containing Fentanyl, Tapentadol, Oxycodone, Buprenorphine, Diazepam, and several other active ingredients.

The notified guidance draws references from the WHO Guidelines for the Safe Disposal of Expired Drugs and Unwanted Pharmaceuticals, the US FDA guidelines, and various existing laws and regulations in the country.

The move to formulate formal guidelines was initiated after CDSCO received a letter from AIIMS Delhi, referring to a study reporting the presence of antimicrobial agents and other active pharmaceutical compounds (APCs) in the hydrologic cycle in and around New Delhi.

The study identified the disposal of unused and expired pharmaceutical compounds into landfills as the second leading cause of this contamination.

As per details from the 58th DCC meeting, the study analyzed the presence of 28 drugs from different classes in surface water and reported the existence of antimicrobial agents and other APCs in the aquifers of Delhi, with levels exceeding 0.1 µg/L (micrograms per liter).

Currently, in India, units under the revised Schedule M (GMP) norms enforced in 2024 only mandate that drugmakers ensure the proper and safe storage of waste material awaiting disposal.

The latest document issued by CDSCO provides guidance to other stakeholders : including retailers, wholesalers, and stockists, along with the general public.

News Source:

<https://pharma.economictimes.indiatimes.com/news/policy-and-regulations/cdsc-releases-essential-guidelines-for-safe-disposal-of-expired-and-unused-medicines-to-curb-antimicrobial-resistance/121477021>