New Regulation of unused drugs by Central Drugs Standard Control Organization (CDSCO

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Why in News?

The CDSCO circulated the guidelines on the disposal of expired and unused drugs to all state and Union Territory drug controllers, urging them to encourage wider adoption by relevant stakeholders.

- It outlines methods for the disposal of ***expired or unused drugs,*** existing policies, procedures to be followed by stakeholders, and processes for the collection, storage, and transportation of drugs before disposal.
- They also include a list of 17 drugs under a ***'Flush List',*** which may be safely flushed down the sink or toilet to prevent harm.
- The guidelines were developed following a 2018 study by the All-India Institute of Medical Sciences, New Delhi.
    - It highlighted the ecological risks posed by the disposal of expired or unused drugs in landfills.
- CSE recommended introducing an extended producer responsibility (EPR) provision, making drug manufacturers, both branded and generic, accountable for the disposal of unused medicines.

Extended Producer Responsibility (EPR) *is a concept under which manufacturers are held responsible for the entire lifecycle of a product, including its take-back and disposal.*

- The current guidelines suggest that drugs should move back through the supply chain, meaning from retailer to supplier to manufacturer for disposal.
- For instance, a retailer should return expired stock to the supplier or manufacturer.
- A wholesaler, distributor or stockist should accept expired or unused drugs from those to whom they have been supplied, and ensure segregation and return.
- Manufacturers, in turn, are to accept all expired or unused drugs from retailers and wholesalers.
- Procurement agencies, including government and private hospitals, may dispose of expired or unused medicines directly under the ***Biomedical Waste Management Rules, 2016***, or return them to suppliers.
- However, the responsibility is not fully placed on manufacturers.
- Moreover, *consumers are not included in the reverse supply chain* process, unlike drug take-back programmes in Europe and the United States, where consumer participation is central under EPR mandates.
- The guidelines, however, place strong emphasis on record-keeping and verification by regulatory authorities when required.

- For public disposal of expired or unused drugs, state drug control departments and chemists' and druggists' associations are encouraged to jointly launch drug take-back sites or programmes at designated locations.
- Citizens can drop off unused or expired medicines from home, which will then be appropriately disposed of by the associations.
- Kerala already has an operational drug take-back initiative, the *New Programme on Removal of Unused Drugs or nPROUD,* launched in December 2024 by the state drug control department.

Reference

Down to Earth | Guidelines on disposal of expired and unused medicines

