CDSCO’s guidance document specifies disposal methods of expired & unused drugs

The Central Drugs Standard Control Organisation (CDSCO) has asked the manufacturers to ensure appropriate sorting of various categories of drugs that require different disposal methods, systematically, without mixing hazardous drugs with the others.

In its latest guidance document on disposal of expired or unused drugs, the central drug regulator also listed specific disposal methods with appropriate restrictions in terms of landfill, disposal of antineoplastics, among others.

"It should be ensured that appropriate sorting is done to separate the pharmaceuticals into categories that require different disposal methods. Controlled substances (e.g. narcotics), antineoplastics (cytotoxic) drugs, Anti-infective drugs and other hazardous drugs shall be separated and not to be mixed among the other pharmaceuticals," said the guidance document, while elaborating the systems for collection, storage and transportation of such drugs.

Expired or unused drugs should be collected in yellow coloured non-chlorinated plastic bags or containers, and should be stored in a separate area or room which is appropriate to the quantities of such drugs and frequency of collection.

Cytotoxic drugs which are expired or unused are stored separately from others in a designated secure location.

Radioactive drugs which are expired or unused are stored in containers that prevent dispersion, behind lead shielding and should be strictly in accordance with the AERB guidelines. Controlled substances which are expired or unused are treated as normal solids and stored in yellow coloured non-chlorinated plastic bags or containers and stored separately in a designated secure location to prevent it from coming out into public domain as they may be abused. 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 vehicles used for transportation of such drugs shall comply with the conditions, if any, stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988.

If the disposal is to be carried out at the manufacturer’s site itself, then the bags or containers containing the expired or unused drugs are transported by means of wheeled trolleys, containers, or carts that are dedicated for such purpose or not used for any other purpose. "Such equipment should either be autoclaved before using it or disposed of as per the Bio-Medical Waste (Management and Handling) Rules, 2016 as amended from time to time," it added.

The guidance document also stipulates clear handling methods, method of disposals and things to be noted during disposal, for various categories and dosage forms, such as solids, semisolids, and powders except biological wastes; liquids except biological wastes; ampoules; aerosol canisters; PVC plastic, and glass packages; anti infective drugs; antineoplastics, controlled drugs; disinfectants; and radioactive drugs.

Solids, semisolids, and powders except biological wastes should be disposed through landfill, waste encapsulation, waste inertisation, or medium and high temperature incineration. However, not more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilised) to a landfill.

Liquids except biological waste should be disposed of through sewer, high-temperature incineration such as cement kiln incinerator, though antineoplastics should not be sent to sewer. Ampoules should be crushed and the diluted fluid should be flushed to the sewer, and should not burnt or incinerated. However, antineoplastics should not be disposed of into the sewer.

Aerosol canisters should not be burnt, and should be disposed of through landfill and waste encapsulation, PVC plastic and glass through landfill and paper and cardboard to be recycled, burned or disposed of in the landfill.

Anti-infective drugs should be disposed of after waste encapsulation and waste inertisation, and through medium and high temperature incinerators such as cement kiln incinerators. Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer.

Anti-neoplastic materials should be returned to the donor or manufacturer, and disposed of using waste encapsulation, waste inertisation and high temperature incineration. It should not be disposed of through landfill unless it is encapsulated. It also should not be disposed of through sewer or through low or medium temperature incineration.

Controlled drugs should be disposed of after waste encapsulation, waste inertisation, through medium and high temperature incineration such as cement kiln incinerators. Provisions of NDPS Rules, 1985 should be followed in these cases and the controlled drugs should not be used for land filling unless encapsulated, it added.

Disinfectants should be disposed of through sewer or fast flowing water course, in small quantities of diluted form, which should be a maximum of 50 liters per day under supervision.

Radioactive drugs should be subjected to deep geological disposal or methods as per the AERB guidelines, it added.

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