ADEQ Arizona Department of Environmental Quality

FACT SHEET

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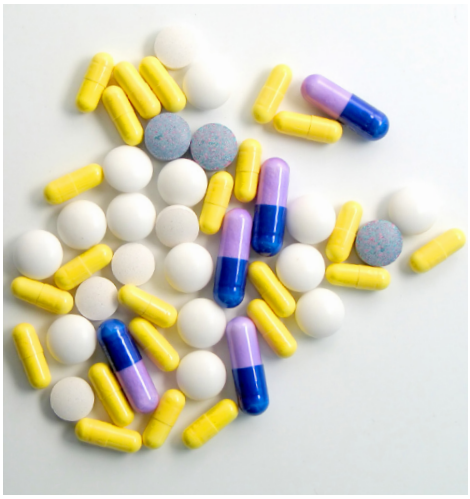
Managing Pharmaceutical Wastes



What are pharmaceuticals?

Pharmaceuticals are a diverse group of chemicals including, but not limited to, pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compound solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics, medicinal dermal patches, and any delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic. They are obtained via prescription or purchased over the counter. Pharmaceuticals are swallowed, rubbed onto the skin, and injected or otherwise administered to pets.

How are pharmaceutical wastes generated?

Pharmaceutical wastes are generated by a variety of facilities including pharmacies, hospitals, physicians' offices, dentists' offices, other health care practitioners, outpatient care centers, ambulatory health care services, residential care facilities, veterinary clinics and reverse distributors. Wastes from these facilities can be generated through a wide variety of activities including, but not limited to, intravenous (IV) preparation, general compounding, discontinued items, unused items, spills and breakage, and reverse distribution. Reverse distribution companies enable pharmacies to ship outdated products back to their manufacturers for credit. Any outdated items that do not meet the manufacturer's return policy become waste at the reverse distributor, which then becomes the waste generator.

What are some of the ways through which pharmaceuticals enter the environment?

Pharmaceuticals and their metabolites can enter the environment through many routes, including but not limited to, treated and untreated domestic sewage; leaching from landfills following disposal of expired and unused products; disposal of expired and unused prescriptions in the toilet; release of unabsorbed externally applied products such as lotions to surface waters from activities such as swimming; excreta from animals including pets and other domestic animals; use of sewage solids and manure for soil amendment and fertilization; improper incineration; and industrial manufacturing waste streams.

Why is it important to manage pharmaceutical wastes?

Pharmaceuticals generally dissolve easily but do not easily break down into common elements once discharged into the environment. They usually remain intact allowing them to be consumed by plants, animals, and humans. Therefore, the improper disposal of pharmaceutical waste can have adverse impacts on human health and the environment. Potential adverse consequences include water quality degradation, endocrine disruption (interference with physical, mental, and sexual development) in humans, and negative public perceptions regarding water cleanliness. Additionally, aquatic organisms and other ecological receptors could be continually exposed to pharmaceutical wastes on a multi-generational level causing respiratory, reproductive and other harmful effects.

What makes a pharmaceutical waste a "hazardous waste" and subject to RCRA regulation?

In order for materials to be hazardous wastes and therefore subject to the Resource Conservation and Recovery Act (RCRA) regulations, they must first meet the definition of solid waste at A.R.S. 49 § 49-701(01) / 40 CFR § 261.2. Such materials must be discarded or are intended for discard. Solid wastes become hazardous wastes if they are listed in 40 CFR § 261, Subpart D (F-, K-, P-, and U-listed wastes), or exhibit one or more of the hazardous waste characteristics (ignitability, corrosivity, reactivity, or toxicity) provided at 40 CFR § 261.20 -261.24. Thus, there are three main ways a discarded pharmaceutical waste or one intended for discard can be identified as a hazardous waste:

- It exhibits one or more characteristics of a hazardous waste as described in 40 CFR 261.24,
- It is specifically identified as a P-listed hazardous waste in 40 CFR § 261.33.

This document is not a substitute for the regulations. To legally manage pharmaceutical wastes that meet the definition of hazardous wastes, generators must comply with all applicable provisions in A.A.C. R18-8 et al and the 40 CFR Subtitle C. This fact sheet is intended solely to provide basic guidance.

- It is specifically identified as a U-listed hazardous waste in 40 CFR § 261.33.

P-listed hazardous wastes are acutely toxic commercial chemical products that have been or identified to be discarded. Their effects can be fatal or extremely harmful in low doses. U-listed hazardous wastes include commercial chemical products that have been or intend to be discarded. Though toxic, their effects are less harmful than P-listed hazardous wastes.

To qualify as a U- or P-listed hazardous waste, the waste must meet the following criteria:

1) It must be a commercial chemical product. Commercial chemical products are unused chemicals, manufacturing intermediates of a chemical, off-specification variations of a chemical, residues in containers that are not "RCRA, empty" or cleanup residue or debris of any chemical named on the U or P list.

2) The commercial chemical product's sole active ingredient must be specifically listed on the U or P list. Sole active ingredient is interpreted as the ingredient that performs the main function of the product. Fillers, colorants, carriers or the like are not considered active ingredients. The commercial chemical product is not a U- or P-listed hazardous waste if it has two or more active ingredients, even if all the ingredients are listed on the U or P list.

What are some of the steps to necessary to manage pharmaceutical wastes?

Ownership or management should commit to addressing compliance by providing the necessary financial and suitably qualified/experienced human resources. Staff should conduct a thorough audit of all waste streams generated by the facility including a waste characterization for every waste type – including each drug at each dose – either through analysis of the waste, review of material safety data sheets, or checking with suppliers and/or manufacturers of products. (See correspondence from Region 1, EPA: *http://www.epa.gov/region1/healthcare/pdfs/AcadiaHospResponse12-30-08.pdf)*.

The completed characterization should identify which wastes are hazardous waste (listed or characteristic), non-hazardous solid waste, or liquid industrial waste. Once all waste streams have been defined, staff should determine the level at which the hazardous waste should be managed. Under RCRA, there are three hazardous waste generator levels: 1) Large Quantity Generator (LQG); 2) Small Quantity Generator (SQG), and 3) Conditionally Exempt Small Quantity Generator (CESQG), pursuant to 40 CFR § 262 . The generator status is established by determining the amount of all non-acute and acute hazardous waste generated at the facility in one month as follows:

- An LQG generates more than 1,000 kg/month of hazardous waste, more than 1kg/month of acute hazardous waste, or an LQG generates more than 1,000 kg/month of hazardous waste, more than 1kg/month of acute hazardous waste, or more than 100 kg/month of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill of any acute hazardous waste, into, or on any land or water.
- An SQG generates more than 100 kg/month but less than 1,000 kg/month of hazardous waste.
- A CESQG generates less than 100 kg/month of hazardous waste, less than 1kg/month of acute hazardous waste, or less than 100 kg/month of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill of any acute hazardous waste, into, or on any land or water .

While determining generator status, the facility should pay special attention to containers that once held pharmaceuticals that are on the P-list of commercial chemical products, because consideration must be given to the amount of residue remaining in such containers and assessing whether they are "empty" as defined by RCRA. See the "Memo" from EPA's Office of Resource Conservation and Recovery for more detailed information on this subject.

After establishing the generator status, the facility must follow the applicable regulations, including storage, reporting and transportation, for the waste generated. Since the three generator status levels have storage time limits and specific requirements for handling and disposal, a monthly inventory should be developed, maintained, and made available for inspection, to verify the level of management required for the hazardous pharmaceutical waste.

Please refer to "Managing Pharmaceutical Waste – A 10 Step Blueprint for Healthcare Facilities in the United States," a project initially funded by the EPA for more detailed guidance on managing pharmaceutical wastes.

For more information

For more information regarding this subject, please contact ADEQ**.**

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Arizona Emergency Response Commission
www.azserc.org/AZSERCHome/tabid/36/Default.aspx

A.R.S. § 49 Chapter 5
A.A.C. R18 Chapter 8
Code of Federal Regulations
(40 CFR 260-273):
www.gpoaccess.gov/cfr/index.html