Gigi Davidson April 9, 2018

Chair, Compounding Expert Committee.

United States Pharmacopeia

12601 Twinbrook Parkway

Rockville, MD 20852

RE: USP 800 and Unassimilated Hazardous Drugs

Dear Gigi:

Chapter 800, hazardous drug handling in healthcare settings does actually identify contact with unassimilated hazardous drugs in body fluids as potential opportunities of exposure to hazardous drugs in healthcare settings. This is defined in section 3, table 1.

This would define unassimilated drugs from certain treatments as hazardous drugs. In some cases, up to 90% of the drug is in the bodily fluids. I have attached a list of hazardous drugs that are excreted heavily in the urine and feces as well as the sweat and saliva, they all happen to be chemotherapy drugs. [See attachment 1.]

This would put human waste contaminated with cytotoxic chemotherapy drugs under regulation by USP 800, and would also apply to a patients clothing, bedding and anything the patient came in contact with during the excretion time. Due to the amount of unassimilated drug in the urine and feces the bodily fluids should be collected during the excretion time and disposed of as bulk chemotherapy waste and the contaminated clothing and bedding should be disposed of as trace chemotherapy waste.

Human waste contaminated with certain cytotoxic chemotherapy drugs are covered in the following manner in USP 800 in various sections;

1. **Introduction and scope**. This section applies to hazardous drug handling including unassimilated drugs in human waste and includes home healthcare workers. It is important to note that most cytotoxic drugs are administered in the hospital on an outpatient basis or administered in the patient’s home. It is still the responsibility of the administrator to control the human waste excreting from the patient for 24 to 48 hours as also stated by the World Health Organization.
2. **List of hazardous drugs.** This list constantly changing and is currently adding 20 or so new hazardous drugs. It is the responsibility of the administrator to know which of these drugs are a hazard post patient and to apply necessary containment.
3. **Types of exposure.** Under this section handling bodily fluids (e.g., urine, feces, sweat and vomit) or body fluid contaminated clothing, dressing, linens and other materials are a source of exposure and therefore are considered hazardous drugs and are regulated under USP 800.
4. **Responsibilities of personnel handling hazardous drugs.** The World Health Organization places the responsibility of controlling hazardous drugs including human waste containing cytotoxic chemotherapy drugs on the chief pharmacist. It also states that the control of cytotoxic waste should be paid for by the entities that pay for healthcare
5. **facilities and engineering controls.** As we agree that certain contaminated human wastes are still hazardous drugs, engineering controls should be put in place to protect the workers and the environment including containment of the urine and feces as well as the linens and the patients clothing.
6. **Environmental quality and control.** The same controls apply to the unassimilated chemotherapy drugs and many wipe samples have been taken around toilets and bathrooms clearly showing the need for control. The hazardous drugs referenced in this section are all cytotoxic chemotherapy drugs that are heavily excreted. Data on the excretion rates and times can be found in attachment 1. Cyclophosphamide, ifosfamide, methotrexate, fluorouracil and platinum containing drugs are all heavily excreted with methotrexate estimated at 90%. This information is readily available from the drug package insert and from the Food and Drug Administration.
7. **Personal protective equipment.** This section would apply to personnel handling the patient, the linens and all human waste containing unassimilated hazardous drugs. All PPE should be treated as trace chemotherapy waste and as stated by the World Health Organization. The human waste from certain unassimilated cytotoxic chemotherapy drugs must be collected and disposed of to prevent potential environmental disaster. The human waste collected would not be considered trace chemotherapy waste as some of the drugs are concentrated in the urine and feces. Please see attachment 2, a review of the World Health Organization’s Blue Book on Healthcare waste management as it pertains to Hazardous Drugs.



1. **Hazard communication program.** The section would apply to unassimilated hazardous drugs that are excreted by the patient and the information must be communicated to personnel handling the patient, linens and clothing as well as collecting the human waste.
2. **Personnel training.** The section would apply to unassimilated hazardous drugs as well.
3. **Receiving.** The section would not apply to post patient hazardous drugs.
4. **Labeling, packaging, transport and disposal.** Unassimilated cytotoxic chemotherapy drugs are covered under this section. It should be notedthat used personal protective equipment should be considered trace chemotherapy waste and the collected urine, feces and vomit should be considered bulk chemotherapy waste and handled under strict Department of Transportation regulations as well as OSHA guidelines.
5. **Dispensing final dosage forms.** This section would not apply to unassimilated hazardous drugs.
6. **Compounding.** This section would not apply to Unassimilated hazardous drugs.
7. **Administering.** Under this section used PPE should be handled as trace chemotherapy waste and unused IV bags should be considered bulk chemotherapy waste and handled appropriately.
8. **Deactivating, decontaminating, cleaning and disinfecting.** This section would apply to unassimilated cytotoxic chemotherapy drugs and areas where the patient is after infusion for 24 to 48 hours. In most cases this is the patient’s home. Contaminated clothing and linens are treated as trace chemotherapy waste and collected urine and feces are treated as bulk chemotherapy waste and handled under OSHA and department transportation regulations.
9. **Spill control.** Release of bodily fluids containing cytotoxic chemotherapy drugs would be considered under this section and appropriately all spill materials must be disposed of as a hazardous waste.
10. **Documentation and standard operating procedures.** All SOP’s must take into consideration the unassimilated drugs that pass through the patient’s body. This section applies to unassimilated cytotoxic chemotherapy drugs.
11. **Medical surveillance.** Healthcare workers that handle unassimilated hazardous drugs would fall into this category and would include nurses collecting the unassimilated drugs contained in the urine and feces of the patient as well as home health care providers.

In summary I would like to see a clarification by the United States pharmacopeia that takes into consideration the 27 unassimilated hazardous drugs. I would be happy to go over this with the Compounding Expert Committee.

Sincerely

Jim Mullowney

Sr. Chemist

Pharma-Cycle, LLC.

55 John Clarke Ln.’

Middletown, RI 02840

617-755-0883

[jmullowney@pharma-cycle.com](mailto:jmullowney@pharma-cycle.com)

TED Talk <https://youtu.be/zX6OsvzZdOw?t=4>