



SAFE HANDLING Q&A

HOW TO DETERMINE IF A DRUG IS HAZARDOUS

BY PHILIP SCHWIETERMAN, PHARM D, MHA, & CORBIN BENNETT, PHARM D, MPH

USP<800> refers to the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* as the official reference for identifying hazardous drugs (HDs) (National Institute for Occupational Safety and Health [NIOSH], 2016; U.S. Pharmacopeial Convention, 2016). NIOSH (2016) considers six primary characteristics of a drug that could lead to it being considered hazardous:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structures and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the previously mentioned criteria

The NIOSH (2016) HD list uses these criteria to group each drug as one of the following:

- Antineoplastic (see Group 1/Table 1 in the NIOSH list)
- Non-antineoplastic drugs that meet one or more of the NIOSH criteria for an HD (see Group 2/Table 2 in the NIOSH list)
- Drugs that primarily pose a reproductive risk to men and women (see Group 3/Table 3 in the NIOSH list)

Facilities and practices should cross-reference their current medication formulary against the NIOSH list and then create standard handling protocols for each HD or category of HD. It is important to remember that USP<800> requires all antineoplastic HDs to be handled as defined within the chapter, but it does allow for drugs in Tables 2 and 3 in the NIOSH list to be handled differently, as defined by a drug-specific assessment of risk, which can be unique to each facility.

Categorizing drugs that were approved by the U.S. Food and Drug Administration after the most recent NIOSH list was published can be complicated. One potential pathway to complete this assessment includes the following:

- Referring to a drug information source, such as Lexicomp. These references may use drug-information specialists to complete this review as new drugs come into the market.
- Considering the formulation and risk for exposure
- Reviewing the six characteristics using the following:
 - Drug package insert or safety data sheet to identify any of the previously mentioned HD characteristics

- International Agency for Research on Cancer to identify carcinogenicity
- Published studies in humans or animals

If these sources do not provide enough evidence to ensure that the drug is nonhazardous, the drug should be considered hazardous until NIOSH reviews it or additional literature is available. A similar method should be used for drugs in clinical trials prior to approval by the U.S. Food and Drug Administration.

Package inserts include safety information in several sections, including the following:

- 1: Box warnings
- 5: Warnings and precautions, including data on organ toxicity, carcinogenicity, or embryo-fetal toxicity
- 6: Adverse reactions, including reactions postmarket
- 8: Use in specific populations, including information on pregnancy and human or animal development
- 13: Nonclinical toxicology, including animal studies with information on carcinogenesis, mutagenesis, and fertility impairment
- 16: Storage and handling, including information on special handling or disposal

According to the 2016 NIOSH list, many biologics and monoclonal antibodies are considered nonhazardous to individuals handling them. One rationale for this is that the drug size is too large to have any appreciable penetration through the skin. However, some biologics are conjugated with HDs and would need to be handled accordingly. The NIOSH list is updated periodically, with interim changes noted on their website. Healthcare workers are encouraged to monitor the NIOSH website for changes.

REFERENCES

- National Institute for Occupational Safety and Health. (2016). *NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016*. <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>
- U.S. Pharmacopeial Convention. (2016). General chapter <800> hazardous drugs—Handling in healthcare settings. <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>

COPYRIGHT 2020 ONS AND HOPA. ALL RIGHTS RESERVED.