

# Drug Products, Labeling, and Packaging

## Unit Dose Packaging Availability (1801)

*Source: Council on Pharmacy Management*

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that reduces medication waste; further,

To urge the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

*This policy supersedes ASHP policy 0309.*

## Availability and Use of Appropriate Vial Sizes (1812)

*Source: Council on Pharmacy Practice*

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste and enhance safety; further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the safe and appropriate use of single-dose, single-use, and multiple-dose vials.

## Ensuring Effectiveness, Safety, and Access to Orphan Drug Products (1821)

*Source: Council on Therapeutics*

To encourage continued awareness of, research on, and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of orphan drug products for approved and off-label indications; further,

To advocate that health policymakers, payers, and pharmaceutical manufacturers ensure continuity of care and patient access to orphan drug products; further,

To advocate federal review to evaluate whether orphan drug designation is being used inappropriately to receive FDA approval, extend patents, decrease competition, or limit discounts, thereby reducing patient access.

*This policy supersedes ASHP policy 1413.*

## Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use (1711)

*Source: Council on Pharmacy Practice*

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacies repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

## Expiration Dating of Pharmaceutical Products (1712)

*Source: Council on Pharmacy Practice*

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures to encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

*This policy supersedes ASHP policy 9309.*

## Protecting Workers from Exposure to Hazardous Drugs (1615)

*Source: Council on Pharmacy Management*

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs; further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of hazardous drugs; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for hazardous drugs that would alert handlers to the potential presence of surface contamination; further,

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations, such as ASHP guidelines and United States Pharmacopeia Chapter 800, to protect workers from undue exposure to hazardous drugs.

*This policy supersedes ASHP policy 0618.*

## Excipients in Drug Products (1528)

*Source: Council on Pharmacy Practice*

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

*This policy supersedes ASHP policy 0808.*

**Nonproprietary Naming of Biological Products (1535)**

Source: Council on Public Policy

To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,

To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.

**Standardized Clinical Drug Nomenclature (0920)**

Source: Council on Pharmacy Management

To encourage federal agencies, the pharmaceutical industry, pharmacy and medical software providers, and purveyors of clinical data repositories and drug databases to explore the potential benefits of supplementing or modifying the National Drug Code with a coding system that can be used effectively to support patient care, research, and financial management; further,

To encourage that such a coding system encompass prescription drug products, nonprescription medications, and dietary supplements and include both active and inactive ingredients.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Standardizing Prefixes and Suffixes in Drug Product Names (0720)**

Source: Council on Public Policy

To collaborate with others, including the United States Pharmacopeia and the Food and Drug Administration, in standardizing and defining the meaning of prefixes and suffixes for prescription and nonprescription drugs to prevent medication errors and ensure patient safety.

*This policy was reviewed in 2016 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**Mandatory Labeling of the Presence of Latex (0501)**

Source: Section of Inpatient Care Practitioners

To urge the Food and Drug Administration to mandate that manufacturers of medications and medication-device combination products include labeling information on whether any component of the product, including its packaging, contains natural rubber latex.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Ready-to-Use Packaging for All Settings (0402)**

Source: Council on Professional Affairs

To advocate that pharmaceutical manufacturers provide all medications used in ambulatory care settings in unit-of-use packages; further,

To urge the Food and Drug Administration to support this goal; further,

To encourage pharmacists to adopt unit-of-use packaging for dispensing prescription medications to ambulatory patients; further,

To support continued research on the safety benefits and patient adherence associated with unit-of-use packaging and other dispensing technologies.

*(Note: A unit-of-use package is a container–closure system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling.)*

*This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Drug Shortages (0002)**

Source: Council on Administrative Affairs

To declare that pharmaceutical manufacturers, distributors, group purchasing organizations, and regulatory bodies, when making decisions that may create drug product shortages, should strive to prevent those decisions from compromising the quality and safety of patient care.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Pediatric Dosage Forms (9707)**

Source: Council on Professional Affairs

To support efforts that stimulate development of pediatric dosage forms of drug products.

*This policy was reviewed in 2016 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Use of Color to Identify Drug Products (9608)**

Source: Council on Professional Affairs

To support the reading of drug product labels as the most important means of identifying drug products; further,

To oppose reliance on color by health professionals and others to identify drug products; further,

To oppose actions by manufacturers of drug products and others to promulgate reliance on color to identify drug products.

*This policy was reviewed in 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Tamper-Evident Packaging on Topical Products (9211)**

Source: House of Delegates Resolution

ASHP should support the standardization and requirement of tamper-evident packaging on all topical products, including all dermatologicals and nonprescription products.

*This policy was reviewed in 2016 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Drug Nomenclature (9011)**

Source: House of Delegates Resolution

To work with the FDA, USP, and pharmaceutical industry to assure that drug products are named in a manner that clearly and without confusion permits identification of ingredients' strengths and changes.

*This policy was reviewed in 2019 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**Elimination of Apothecary System (8613)**

*Source: Council on Professional Affairs*

To recommend to all health professions and to the Pharmaceutical Manufacturers Association (PMA) [now the Pharmaceutical Research and Manufacturers of America (PhRMA)] that the apothecary system be eliminated in referring to dosage quantities and strengths.

*This policy was reviewed in 2016 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

## ASHP Policy Positions 2009–2019 (with Rationales) Pharmaceutical Industry: Drug Products, Labeling, and Packaging

**1801**

### **Unit Dose Packaging Availability**

*Source: Council on Pharmacy Management*

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that reduces medication waste; further,

To urge the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

*This policy supersedes ASHP policy 0309.*

### ***Rationale***

The benefits of unit dose drug administration were well established in the 1960s. Despite these benefits, some drugs are not available from manufacturers in unit dose packages. One reason sometimes cited for this lack of availability is that because unit dose packages make up a relatively small portion of business for many manufacturers, some manufacturers are making a business decision to discontinue this form of packaging. When manufacturers do not provide drugs in unit dose form, the pharmacy must repackage them, introducing opportunities for error. Although it may not be practical for FDA to mandate unit dose packaging to improve public health and patient safety, FDA could encourage such packaging in other ways, such as by developing packaging guidelines for the pharmaceutical industry. In cases in which unit dose packaging is not practical, manufacturers should at a minimum provide package sizes that reduce medication waste.

**1812**

### **Availability and Use of Appropriate Vial Sizes**

*Source: Council on Pharmacy Practice*

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste and enhance safety; further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the safe and appropriate use of single-dose, single-use, and multiple-dose vials.

### ***Rationale***

A [2016 study](#) estimated that the U.S. may spend close to \$2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Since that landmark study, policymakers, healthcare providers, and payers have been calling for action on vial sizes. The Centers for Medicare & Medicaid

Services (CMS) has begun to require that billing for Part B drug products distinguish between claims for those received by a patient and those for discarded drug product, and the Office of the Inspector General (OIG) of the Department of Health and Human Services has initiated a study to determine the cost of such waste. Considerable savings could be gained if vial sizes more closely matched doses, and one of the goals of the OIG study is to determine how much could be saved by using vial sizes available overseas that more closely match doses. As [one analysis](#) has pointed out, pharmacoeconomic analyses done in the U.S. typically do not incorporate leftover drug product in cost calculations, which may inflate cost-effectiveness ratios, and drug manufacturers may be exploiting that omission. In contrast, the United Kingdom National Institute for Clinical Excellence [requires](#) manufacturers to include the cost of leftover drug in manufacturers' submissions, and vials of two cancer drugs studied (bortezomib and pembrolizumab) contain 1 mg and 50 mg, respectively, in the U.K., and 3.5 mg and 100 mg in the U.S. Further, the availability of different vial sizes can enhance patient and worker safety. Vial sizes that more closely match doses can minimize preparation time and steps, reducing employee fatigue and the number of opportunities for error.

ASHP advocates that pharmaceutical manufacturers provide drug products in vial sizes that reduce drug waste (e.g., multiple-dose vials or single-dose vials of differing doses), and that regulators, manufacturers, and healthcare providers cooperate to develop and implement best practices for drug vial optimization.

## **1821**

### **Ensuring Effectiveness, Safety, and Access to Orphan Drug Products**

*Source: Council on Therapeutics*

To encourage continued awareness of, research on, and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of orphan drug products for approved and off-label indications; further,

To advocate that health policymakers, payers, and pharmaceutical manufacturers ensure continuity of care and patient access to orphan drug products; further,

To advocate federal review to evaluate whether orphan drug designation is being used inappropriately to receive FDA approval, extend patents, decrease competition, or limit discounts, thereby reducing patient access.

*This policy supersedes ASHP policy 1413.*

### **Rationale**

The U.S. Orphan Drug Act of 1983 and similar programs in other countries have greatly expanded the number of therapies available to treat rare diseases through the use of financial

and other incentives that encourage drug manufacturers to develop medications for limited patient populations. Despite the overall success of orphan drug programs, concerns have been raised about the breadth of drugs approved through these mechanisms. Although there are more than 7,000 designated orphan diseases in the United States, oncology drugs represent approximately 33 percent of all orphan drug approvals. ASHP believes that there is a significant need to develop a more comprehensive approach to orphan drug development in order to encourage drug manufacturers to expand the breadth of rare conditions treated by these therapies.

Once an orphan drug is approved, it may be used without restrictions, and these therapies are frequently used to treat patients and conditions that were not assessed during pre-approval clinical studies. While this use can spur innovation and lead to advances in the treatment of common diseases, ASHP believes that this use is also associated with the potential for increased patient harm, given the small patient populations and other characteristics common to studies used to support orphan drug approval. Research is necessary to evaluate the safety and effectiveness of these therapies under real-use conditions. In addition to manufacturer-conducted research, ASHP encourages private and public sector research in order to provide sufficient evidence to support off-label use.

ASHP is concerned about the high cost of these therapies, which contributes to increased healthcare costs and potentially decreases patient access, especially among those who are under- or uninsured. Further, some orphan drugs have later been discontinued by the drug manufacturer—an occurrence that often leaves patients with rare conditions without a treatment alternative. It is essential that stakeholders (e.g., health policymakers, payers, and pharmaceutical manufacturers) continue efforts to provide patient access to these therapies, including developing strategies to ensure that the cost of these therapies does not create an unreasonable barrier to patient access.

There are additional challenges regarding patient access to orphan drugs. There is a need for more emphasis on increasing patient access and addressing 340B issues, especially with critical access facilities. Orphan drug development and marketing in the U.S. is concentrated in a few therapeutic areas. Despite the increase in the number of orphan drugs approved by the Food and Drug Administration, the unmet needs of patients with rare diseases provide evidence that the current incentives are not efficiently stimulating orphan drug development. There is need to balance economic incentives to stimulate the development and marketing of orphan drugs without jeopardizing patients' access to treatment.

## **1711**

### **Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use**

*Source: Council on Pharmacy Practice*

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacies repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

### ***Rationale***

Home use of oral chemotherapy increases patient convenience and lowers healthcare costs, but it presents [unique safety risks](#). In a hospital or clinic setting, healthcare professionals manage the risks posed by hazardous drugs, defined as any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity ([NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings](#)). In the home environment, however, patients and caregivers must be prepared to fill that role. Ready-to-administer packaging of hazardous drugs minimizes patient, caregiver, and family exposure to hazardous drugs, promotes patient adherence, and enhances safe medication use. Ready-to-administer packaging is defined as packaging that provides the product in a way that requires no manipulation before that patient or caregiver can administer the medication. In contrast, ready-to-use packaging may require a small amount of manipulation (e.g., reconstitution). These definitions are consistent with United States Pharmacopeia and Institute for Safe Medication Practices terminology. ASHP advocates that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging, and that regulators have the authority to require manufacturers to (1) provide hazardous drug products intended for home use in ready-to-administer packaging, and (2) label hazardous drug products intended for home use to warn that special handling is required to ensure safety. ASHP further advocates that when hazardous drug products intended for home use are not available in ready-to-administer packaging, pharmacies repackage those drug products to minimize exposure risk for caregivers and others in the patient’s household. For example, intravenous drug products should be dispensed in a container designed so the patient or caregiver does not have to puncture a vial; tablets are split or crushed prior to dispensing; compounding of liquid medications is done by the pharmacy, if stability information for the drug product supports advanced compounding and transport; and all liquid medications are dispensed with a dispensing cap that can accommodate attachment of an oral syringe. Finally, ASHP advocates that patients and caregivers be provided education regarding safe handling of hazardous drug products from a qualified healthcare professional, preferably a pharmacist experienced in managing the risks of hazardous drug products.

**1712**

**Expiration Dating of Pharmaceutical Products**

*Source: Council on Pharmacy Practice*

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures to encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

*This policy supersedes ASHP policy 9309.*

**Rationale**

Extending the expiration date of commercially available pharmaceutical products for as long as possible, while maintaining drug potency and safety, reduces healthcare costs and increases access. ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. However, the current process for updating expiration dates in drug product labeling presents barriers to timely revision and should be streamlined to allow for timely updates. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

**1615**

**Protecting Workers from Exposure to Hazardous Drugs**

*Source: Council on Pharmacy Management*

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs; further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of hazardous drugs; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for hazardous drugs that would alert handlers to the potential presence of surface contamination; further,

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations, such as ASHP guidelines and United States Pharmacopeia Chapter 800, to protect workers from undue exposure to hazardous drugs.

*This policy supersedes ASHP policy 0618.*

**Rationale**

The outer surfaces of vials of hazardous drugs have been shown to be contaminated with hazardous substances, and pharmacy and other personnel handling those vials may unknowingly be exposed. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines, including ASHP guidelines and United States Pharmacopeia Chapter 800, to avoid undue exposure to hazardous substances but recognizes the limits of these best practices. Pharmaceutical manufacturers have a responsibility to provide vials that are devoid of surface contamination due to inadequate vial-cleaning procedures, and can reduce contamination by using decontamination equipment and protective sleeves during the manufacturing process.

The purpose of United States Pharmacopeia (USP) Chapter 800 is to establish standards for protecting personnel and the environment when handling hazardous drugs. Each year, approximately 8 million U.S. healthcare workers are potentially exposed to hazardous drugs, according to the Centers for Disease Control and Prevention. USP Chapter 800 includes definitions, processes, and worker responsibilities that enhance understanding of risk and limit exposure. To support workers in protecting their patients, themselves, and the environment, the FDA and manufacturers will need to develop new production and processing standards to mitigate exposures, including labeling and package design that alerts handlers to the possibility of contamination.

**1528**

**EXCIPIENTS IN DRUG PRODUCTS**

*Source: Council on Pharmacy Practice*

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

*This policy supersedes ASHP policy 0808.*

**Rationale**

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. In some patients, however, excipients cause allergic responses or aggravate medical conditions. Examples include patients with celiac disease reacting to gluten

in a drug product or pediatric patients with a red-dye allergy reacting to a suspension containing red dye. Inclusion of excipients in drug product labeling, including their derivative source (the botanical, animal, or other source from which the excipient is originally derived), would allow substitution of nonallergenic alternative, but in many cases patients may not be aware of the allergy or it may not be documented in the patient medical record. Manufacturers are therefore encouraged to avoid putting allergenic excipients (e.g., red or yellow dye, gluten) in drug products when possible.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the allergenicity of excipients will be required. Medication-related databases will need to be configured to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients.

### **1535**

#### **Nonproprietary Naming of Biological Products**

*Source: Council on Public Policy*

To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,

To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.

### **0920**

#### **STANDARDIZED CLINICAL DRUG NOMENCLATURE**

*Source: Council on Pharmacy Management*

To encourage federal agencies, the pharmaceutical industry, pharmacy and medical software providers, and purveyors of clinical data repositories and drug databases to explore the potential benefits of supplementing or modifying the National Drug Code with a coding system that can be used effectively to support patient care, research, and financial management; further,

To encourage that such a coding system encompass prescription drug products, nonprescription medications, and dietary supplements and include both active and inactive ingredients.

*This policy supersedes ASHP policy 0801.*

#### **Rationale**

Clinical decision support systems (CDSS) in computerized provider order entry (CPOE) and pharmacy information systems have been widely used for screening drug interactions and patient allergies. For this screening to be effective, a baseline coding structure for medications

must be available, and the coding system needs to include prescription and nonprescription medications, dietary supplements, and drug excipients.

The National Committee on Vital and Health Statistics (NCVHS) has recommended regulatory changes to give the Food and Drug Administration (FDA) full control over the National Drug Code (NDC). Currently, FDA controls only a portion, and manufacturers control the remainder. FDA has made recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. During the past several years, NCVHS has focused considerable attention on the feasibility and desirability of standards to support e-prescribing and the need for standard terminology for clinical drugs to facilitate automated drug-use review and decision support for patient safety. In previous reports, NCVHS documented NDC shortcomings, most notably concern about perceived weaknesses of the current NDC database and linkage of the NDC to RxNorm concepts. NCVHS expressed the need for harmonization of terminologies to eliminate incompatibilities that impair drug utilization studies and may negatively affect patient safety. RxNorm, a standardized nomenclature for clinical drugs, is produced by the National Library of Medicine. In RxNorm, the name of a clinical drug combines its ingredients, strengths, and form. RxNorm has limitations, however; it does not identify a product's excipients, and it does not include herbal products or nonprescription medications.