

Drug Products, Labeling, and Packaging

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.

Ensuring Effectiveness, Safety, and Access to Orphan Drug Products (1413)

Source: Council on Therapeutics

To encourage continued 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 these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products.

This policy supersedes ASHP policy 0715.

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 2013 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 2011 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.

Unit Dose Packaging Availability (0309)

Source: Council on Administrative Affairs

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages; further,

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

This policy was reviewed in 2012 by the Council on Pharmacy Management 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 2012 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 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Expiration Dating of Pharmaceutical Products (9309)

Source: House of Delegates Resolution

To support and actively promote the maximal extension of expiration dates of pharmaceutical products as a means of reducing health care costs and to recommend that pharmaceutical manufacturers review their procedures to accomplish this end.

This policy was reviewed in 2011 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 2011 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 2013 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Codes on Solid Dosage Forms of Prescription Drug Products (8709)

Source: Council on Legal and Public Affairs

To support efforts requiring manufacturers of solid dosage form prescription drug products to imprint a readily identifiable code indicating the manufacturer of the drug product and the product's ingredients; further,

To make information on transition of the codes readily available.

This policy was reviewed in 2011 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 2011 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Size, Color, and Shape of Drug Products (8310)

Source: Council on Legal and Public Affairs

To approve the authority of manufacturers to copy the size, shape, and color of generically equivalent drug products as a means of promoting better patient compliance (rational drug therapy), but only when the source and identity of the product are readily ascertainable from a uniform mark or symbol on the product.

This policy was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2016 (with Rationales) Pharmaceutical Industry: Drug Products, Labeling, and Packaging

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,

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1413

ENSURING EFFECTIVENESS, SAFETY, AND ACCESS TO ORPHAN DRUG PRODUCTS

Source: Council on Therapeutics

To encourage continued 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 these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products.

This policy supersedes ASHP policy 0715.

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 7000 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 health care 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.

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.