

Drug Products, Labeling, and Packaging

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 supersedes ASHP policy 0801.

Disclosure of Excipients in Drug Products (0808)

Source: *Council on Pharmacy Practice*

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

(Note: *Derivative source* means the botanical, animal, or other source from which the excipient is originally derived.)

Patient Access to Orphan Drug Products (0715)

Source: *Council on Public Policy*

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

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

To support public policies that ensure that the cost of orphan drug products does not preclude reasonable patient access to these agents.

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.

Elimination of Surface Contamination on Vials of Hazardous Drugs (0618)

Source: *Council on Professional Affairs*

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

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

To encourage health care organizations to adhere to published standards and regulations to protect workers from undue exposure to hazardous drugs.

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.

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 2008 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs (0404)

Source: *Council on Administrative Affairs*

To advocate standardization of application criteria, processes, and forms for manufacturer-sponsored patient assistance programs (PAP); further,

To advocate the automation of PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings.

This policy was reviewed in 2008 by the Council on Pharmacy Management 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 2007 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 2004 by the Council on Administrative Affairs 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 2006 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; and 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 2008 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 2006 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 2006 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 2008 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 2006 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

International System of Units (8612)

Source: Council on Professional Affairs

To not advocate, at this time, adoption of the International System of Units (SI units) as the exclusive labeling for drug dosages and concentrations; further,

To urge labelers to include: (1) units of mass, volume, or percentage concentrations and (2) moles or millimoles in labeling until the health professions and the public can be educated and be comfortable with use of SI units in prescribing and labeling drug products.

This policy was reviewed in 2008 by the Council on Pharmacy Practice 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 2006 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 2006 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.