



USP STATEMENT
General Chapter <1> *Injections*, Section on Labeling of Ferrules and Cap Overseals
August 4, 2010

The 2005-2010 United States Pharmacopeial Convention (USP) Nomenclature Expert Committee has approved a standard for labeling of injectable products to reduce the likelihood of death and disability from misadministration of these products. The standard states that only cautionary statements (those intended to prevent an imminent life-threatening situation) may appear on the top (circle) surface of the ferrule and/or cap overseal of a vial containing an injectable product. If no cautionary statement is necessary, the top surface of the vial, including the ferrule and cap overseal, must remain blank. Other statements or features (e.g., identifying numbers or letters, such as code numbers, lot numbers, company names, logos, or product names, etc.) may appear on the side surface of the ferrule on vials containing injectable products but not on the top surface of the ferrule or cap overseal.

The standard is intended to make it more likely that healthcare practitioners using injectable products will be able to better see and act on labeling statements that convey important safety messages critical for the prevention of imminent life-threatening situations resulting from misadministration of injectable products.

Reports from the Institute of Medicine (*To Err is Human: Building a Safer Health System*), the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), the Institute for Safe Medication Practices (ISMP) and others have indicated that labeling of injectable products may be linked to medication errors in the administration of these products. Patient safety data from U.S. hospitals collected through the USP MEDMARX program (1998-2008) indicated that the most severe medication errors for injectable products were predominantly related to human performance deficits, occurring most often at the time of administration, with environmental distractions as the major contributing factor. Specific examples of death and disability have arisen with misadministration of potassium chloride for injection concentrate, neuromuscular blocking agents, and vincristine sulfate injectable products.

Over the past decade, four USP Expert Committees (Nomenclature, Packaging and Storage, Parenteral Products—Industrial, and Safe Medication Use) have evaluated the evolving scientific literature, reviewed data from medication error reporting databases, facilitated stakeholder meetings, and routinely consulted with the Food and Drug Administration (FDA) regarding labeling of injectable products. These Expert Committees already have established several specific labeling standards (for the aforementioned products that have caused death and disability—potassium chloride for injection concentrate, neuromuscular blocking agents, and vincristine sulfate injectable products) to reduce the likelihood of serious medication errors.

This new standard will be published in *USP 34-NF 29* (November 1, 2010), in the General Chapter <1> *Injections*, Labeling of Ferrules and Cap Overseals section, and will become official on December 1, 2013.

USP is a scientific, nonprofit organization that for nearly 200 years has advanced public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. In the United States, drugs must comply with USP standards for identity, quality, strength and purity, packaging, and labeling, or be deemed adulterated, misbranded, or both by FDA.

USP's independent volunteer experts are elected to serve on various topic-specific Expert Committees, and work under USP's strict conflict-of-interest rules to establish public standards for medicines, excipients, dietary supplements, and food ingredients. These expert volunteers have diverse healthcare backgrounds such as pharmacy, nursing and medical practitioners, or experience in academia, health plans, consumer organizations, and/or the pharmaceutical, excipient, dietary supplement, and food industries. Expert Committee members serve as individual experts, and do not represent any outside interest. USP Expert Committees publish proposed standards for public comment, then review public comments related to the draft standards. The standards are adjusted based on Expert Committee consideration of the public comments, and then are adopted by those USP expert volunteers by a majority vote.

USP standards are in a process of continuous review and revision based upon new evidence, emerging public health concerns, and public requests for revision. The ongoing role of USP Expert Committees is to evaluate new data and to shape standards based upon the available evidence, public input, and the Expert Committee's expertise.

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