



FOR IMMEDIATE RELEASE

CONTACT: Francine Pierson
301/816-8588; fp@usp.org

First Universal Standards Guiding Content, Appearance of Prescription Container Labels to Promote Patient Understanding of Medication Instructions

*Nearly Half of Patients Misunderstand One or More Dosage Instructions
Pharmacies Across the Country Urged to Adopt “Patient-Centered” Labels*

Rockville, Md., October 9, 2012 — With medication misuse resulting in more than one million adverse drug events per year in the United States, new standards released today by the U.S. Pharmacopeial Convention (USP) for the first time provide a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists. Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a “patient-centered” manner that best reflects how most patients seek out and understand medication instructions.

“Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, non-adherence and medication errors,” said Joanne G. Schwartzberg, M.D., director, aging and community health for the American Medical Association and a member of the USP Nomenclature, Safety and Labeling Expert Committee, the group of independent experts responsible for the new standard. “With an aging and increasingly diverse population, and people utilizing a growing number of medications, the risks are more pronounced today than ever. These USP standards will promote patient understanding of their medication instructions, which is absolutely essential to preventing potentially dangerous mistakes and helping to ensure patient health and safety.”

Studies have found that 46 percent of patients misunderstood one or more dosage instructions on prescription labels. The problem is particularly troublesome in patients with low or marginal literacy (one study showed patients with low literacy were 34 times more likely to misinterpret prescription warning labels), and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, non-standardized time periods. However, even patients with adequate literacy often misunderstand common prescription directions and warnings.

The USP effort to create these new standards developed from an Institute of Medicine (IOM)-led initiative to improve health literacy, which is defined as the degree to which people can obtain, process and understand the basic health information and services they need to make appropriate health decisions. According to IOM, 77 million Americans have limited health literacy, and a majority of Americans have difficulty understanding and using currently available health information and services.

Elements of the new USP standards, contained in General Chapter <17> *Prescription Container Labeling*, of the *United States Pharmacopeia* and the *National Formulary*, include:

- **Emphasize instructions and other information important to patients.** Prominently display information that is critical for patients’ safe and effective use of the medicine. At the top of the

USP Headquarters
12601 Twinbrook Parkway
Rockville, Maryland
20852-1790, USA
+1-301-881-0666

Europe/Middle East/Africa
Münchensteinerstrasse 41
CH-4052 Basel, Switzerland
+41 (0)61 316 30 10

USP-India Private Limited
IKP Knowledge Park
Turkapally Village, Genome Valley
Shameerpet, Ranga Reddy District
Hyderabad 500 078, A.P., India
+91-40-4448-8888

USP-China
Building 11
Lane 67 Libing Road
Zhangjiang Hi-Tech Park
201203, Shanghai, China
+86-21-51370600

USP-Brazil
Avenida Ceci, 1600-Tamboré
Barueri-SP
06460-120
Brazil
+55-11-3245-6400



label specify patient name, drug name (spell out full nonproprietary and brand name) and strength, and clear directions for use in simple language. Less critical information (e.g., pharmacy name, drug quantity) should not supersede critical information and should be placed away from dosing instructions.

- **Improve readability.** Labels should be designed and formatted so they are easy to read. Typography should be optimized by using high contrast print; adequate white space between lines of text (i.e., 25-30 percent of the point size); simple uncondensed familiar fonts (Times Roman or Arial are specifically recommended); and large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Older adults, in particular, have difficulty reading small print.
- **Give explicit instructions.** Instructions for use should clearly separate the dose itself from the timing of each dose. Do not use alphabetic characters for numbers. For example, write, “Take 2 tablets in the morning and 2 tablets in the evening” rather than “Take 2 tablets twice daily.” Dosing intervals such as “twice daily,” “3 times daily,” or hourly intervals such as “every 12 hours” should be avoided because such instructions are implicit rather than explicit, may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions worded in terms of specific hourly times (e.g., 8 a.m. and 10 p.m.) may be assumed to be more easily understood, in actual use they are less readily understood and may present greater adherence issues due to individual lifestyle patterns (e.g., shift work) than general timeframes such as “in the morning” or “after breakfast.” Ambiguous directions such as “take as directed” should be avoided without clear supplemental information.
- **Include purpose for use.** If the purpose of the medication is included on the prescription, it should be included on the label unless a patient prefers that it not appear. Confidentiality and FDA approval for intended use (i.e., labeled vs. off-label use) may cause some to constrain its inclusion on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms, e.g., “for high blood pressure” rather than “for hypertension.”
- **Address limited English proficiency.** Whenever possible, the directions for use on a prescription container label should be provided in the patient’s preferred language. The drug name shall be in English as well so that emergency personnel can have quick access to the information. Translations should be produced using a high-quality translation process; an example is provided in the standard.
- **Address visual impairment.** Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics or assistive technology).

“Patients’ best—and often only—source of information regarding the medications they have been prescribed is on the prescription container label,” Dr. Schwartzberg noted. Although other written information and oral counseling may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

USP issued a draft version of this standard for public review and comment by all interested stakeholders—including healthcare practitioners, retailers, software vendors, consumers and others—in December 2011. The final standard will be published in November 2012, and incorporates multiple additions based on comments received, including more detail on producing high-quality translations,



the visual impairment section, and the direction to include both brand and nonproprietary names on labels.

Enforcement of the standard will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations—similar to USP standards for sterile and nonsterile pharmaceutical compounding, both of which are widely recognized by states. At its 2012 annual meeting, the National Association of Boards of Pharmacy passed a resolution supporting state boards in requiring a standardized prescription container label.

Examples of prescription container labels that comply with the new USP standard are available at <http://uspgo.to/prescription-container-labeling>. Media inquiries may be directed to mediarelations@usp.org.

###

USP – Advancing Public Health Since 1820

The United States Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are relied upon and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1317**

