

## Withdrawal of Dextropropoxyphene

Finalizing a review of the safety and efficacy of dextropropoxyphene-containing medicines, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) concluded that the risks, particularly the risk of potentially fatal overdose, are greater than the benefits. The committee therefore recommended that the marketing authorizations for these medicines be withdrawn across the European Union. The withdrawal will be gradual to allow time for the transfer of patients to appropriate alternative therapies, in line with national recommendations. Dextropropoxyphene is a painkiller used to treat acute and chronic pain. It has been available as a prescription-only medicine for about 40 years, either on its own or in combination primarily with paracetamol, as tablets, capsules, suppositories and solutions for injection. The Agency's recommendation has been forwarded to the European Commission for the adoption of a legally binding decision.

*Reference:* Press Release, Doc. Ref. EMEA/401062/2009. 25 June 2009 at <http://www.emea.europa.eu/pdfs/human/opinion>

## USP 33- NF 28 Recall

*IDMA have received a communication from Dr. Scott Sutton, Microbiology Network on USP 33-NF 28 Recall -Second Public Notice (as reproduced below)*

**Rockville, Md., January 12, 2010- USP Provides Additional Information on Recall and Reissuance of USP 33-NF 28.** With this second notice following the first notice of January 8, 2010, The United States Pharmacopeial Convention (USP) provides additional information about its recall of the United States Pharmacopeia 33-National Formulary 28 (USP 33-NF 28) and its plans to reissue the publication.

### Official Text

USP 32-NF 27 is official at this time and remains official until further notice. USP 33-NF 28, which was released on November 1, 2009 and recalled on January 8, 2010, was not scheduled to become official until May 1, 2010 and should not be used. The current official standards in USP 32-NF 27 can be used with confidence.

### Reason for Recall

USP recalled USP 33-NF 28 because of errors that occurred when monographs

were redesigned into a new format. The redesign was intended to improve ease of use, streamline presentation, and update and harmonize terminology, but was not intended to change any of the monograph requirements. The effort was comprehensive all of the ~4000 monographs in the USP 33-NF 28 were redesigned, encompassing more than 4100 pages, over 4 million words, and many figures and tables. While many of the monographs were successfully redesigned, a significant number contained errors.

While USP has an Errata process for issuing corrections to USP-NF on an ongoing basis, this process was inadequate to address the number of errors resulting from the redesign. Because maintaining the integrity and accuracy of its standards is of paramount importance, USP recalled USP 33-NF 28 in its entirety.

Official text in USP-NF evolves through continuous revision and appears in several publications. While USP 33-NF 28 is being recalled as a publication, other official text related to the publication remain available and may be used with confidence, as follows:

### Accelerated Revisions

Accelerated Revisions posted on the New Official Text section of the USP Web site are not affected by the recall and are official as of the dates indicated on the Web site. See: <http://www.usp.org/USPNF/newOfficialText>.

### Other USP Publications

Other USP publications related to USP-NF are not affected by the recall because their content comes from USP 32-NF 27 and additional sources. Thus, official and authorized text in the following publications can be used with confidence:

USP Dietary Supplements Compendium

Food Chemicals Codex, Sixth Edition, and its Supplements

USP Pharmacists' Pharmacopeia, Second Edition, and its Supplements

The 2009 USP Dictionary

### Reissuance of USP 33-NF 28

#### Electronic

USP plans to reissue the online and a CD version of USP 33-NF 28 in March 2010 with an official date six months after reissue. Only new and revised monographs available since the Second Supplement to USP 32-NF 27 will be in the redesigned format.

### Print

Coincident with release of the electronic forms of the publication, USP intends to reissue a print volume of new and revised monographs and other official text available since the Second Supplement to USP 32-NF 27. The monographs will appear in the redesigned format. This smaller volume, combined with official text in USP 32-NF 27 and its Supplements without redesign will be the print version of USP 33-NF 28. Its official date will be the same as the official date of the electronic versions.

### First Supplement to USP 33-NF 28

USP plans to release the First Supplement to USP 33-NF 28 at the same time as the reissued USP 33-NF 28 and with the same official date.

### Further Information

USP's notices to the public about the recall and reissue of USP 33-NF 28 can be found on USP's Web site: <http://www.usp.org/USPNF/reprint.html>.

### 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 recognized and used worldwide. For more information about USP visit <http://www.usp.org>.

## India and USP Strengthen Partnership

As part of its mission to help ensure the quality, safety, and benefit of medicines and foods worldwide, the U.S. Pharmacopeial Convention (USP) held a groundbreaking ceremony for a planned expansion of its USP-India Private Limited facility in Hyderabad. Headquartered outside of Washington, DC, USP is a nonprofit scientific organization that sets standards for the quality, purity, strength and identity of drugs, food ingredients and dietary supplements. USP's drug standards are legally enforceable in the United States, and all three types of standards are used in more than 130 countries.

For more information, contact [mediarelations@usp.org](mailto:mediarelations@usp.org)