

U.S. Pharmacopeia
The Standard of QualitySM

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U.S., Russian Organizations Team to Improve the Quality of Medicines

Russian Language Version of U.S. Standards Compendia Announced

Rockville, Md., April 7, 2009 — Aiming to improve the quality of medicines in the Russian Federation and the United States, two leading drug quality organizations in those countries today announced plans to work together on standards-related activities for drugs and their ingredients. These include efforts to reduce the availability of counterfeit and substandard medicines.

The agreement was captured in a Memorandum of Understanding (MOU) signed in Moscow by the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (Roszdravnadzor) and the United States Pharmacopeial (USP) Convention. Roszdravnadzor is the surveillance agency for medicines and medical supplies within Russia's Ministry of Healthcare and Social Development. USP is an independent, non-profit organization that sets federally recognized quality standards in the United States for prescription and over-the-counter medications. It also sets widely recognized standards for food ingredients and dietary supplements.

"Access to good quality medicines is of critical importance to the public health, given the role that medicines play in saving lives, restoring health, and treating and preventing diseases," said Roger L. Williams, M.D., chief executive officer of USP. "Through a number of potential activities detailed in this agreement, Roszdravnadzor and USP will work to improve the quality of medicines that patients receive in Russia and the United States. This includes reducing the availability of counterfeit and substandard medicines, which pose a substantial threat to citizens of both countries and globally."

"With medicines and their ingredients coming from all over the world, international collaboration is a key part of protecting and enhancing the health of patients," said N.V. Yurgel, head of Roszdravnadzor. "We look forward to a productive relationship with USP that ultimately results in a safer drug supply."

Among the potential areas of collaboration is utilization of the first Russian translation of USP's internationally recognized book of drug standards, the *United States Pharmacopeia–National Formulary (USP–NF)*, which USP is introducing this week at the XVI Russian Man and Drug National Congress. Through these compendia, USP provides scientifically based standards that help ensure the identity, quality, purity and strength of more than 4,000 medicines, drug substances, dosage forms, excipients (inactive substances such as binders, coatings, colorings, flavorings, preservatives and sweeteners), and dietary supplements. The Russian version of the compendia was translated and published by GEOTAR-MEDIA, one of the leading publishing companies in the Russian Federation and well known internationally for

its translations of major medical works. USP plans to publish a supplement to the book in 2010. At this time the translation is current through *USP* 29 and *NF* 24, with plans on-going to make the translation current.

"As *USP–NF* is the world's most complete collection of quality standards for medicines, I believe that its translation into Russian will promote further enhancement of Russia's regulatory system for medicines, harmonization of Russian pharmacopeial standards with those of the world's leading pharmacopeias and improvement of drug quality in Russia as a whole," said Yurgel.

Other potential areas of collaboration between the two groups as detailed in the MOU include:

- Working Relationships. Activities such as organizing joint annual scientific
 meetings, exchanging scientific staff, promoting pharmacopeial
 harmonization, promoting the use of modern laboratory standards and
 application of modern metrologic principles, and facilitating exchange of
 information and taking action in cases of emergency arising from accidental
 contamination or intentional adulteration of medicines and their ingredients
 will be considered.
- **Reference Materials.** Development and use of reference materials, which are essential for assuring compliance to procedures described in compendia including the *USP-NF*, is another possible activity.
- Third-Party Certification (Verification). Establishment of programs that allow review, testing and auditing of manufacturers of pharmaceutical ingredients available in either the United States or the Russian markets will be considered.

For more information about the MOU, please email <u>mediarelations@usp.org</u>. For more information on the Russian translation of *USP–NF*, visit GEOTAR-MEDIA's Web site at www.geotar.ru.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention is a private, non-profit, 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/newscenter. **FY0937**