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PhRMA Urges Support for International Standards in Russian Medicines Law

Washington, D.C. (March 4, 2010) — As Russia embarks on legislative reforms to strengthen pharmaceutical regulation, the Pharmaceutical Research and Manufacturers of America's (PhRMA) President of International Affairs Christopher A. Singer called on the Russian government to use the opportunity to align with international standards and obligations on clinical trial regulation and intellectual property rights.

"With its strong scientific background and long-term commitment to innovation, Russia is uniquely positioned to become a leader in bio-pharmaceutical development," Mr. Singer said. "Right now, Russian legislators have the chance to make key improvements that will improve their investment climate and speed access to innovative medicines for Russian patients."

The current draft of the Law on the Circulation of Medicines, which has passed its first reading in the Duma, contains provisions that could greatly delay access to new medicines for patients in Russia. As mentioned in a joint letter signed by PhRMA and eight other associations, "The Draft Law currently could require the applicant to re-conduct locally the full cycle of clinical studies, regardless of whether there are existing results from clinical trials that have already taken place elsewhere." Local estimates envision delays of three to ten years resulting from these unneeded trials.

In addition, the draft Law should incorporate language to provide regulatory data protection in Russia that would meet its commitments to the US and EU. "Regulatory data protection will be a key issue for Russia's development as an innovative pharmaceutical leader," said Singer. "Regulatory data protection helps create the certainty necessary for life sciences companies to thrive and support innovation. Russian enterprises should reap the benefits of this policy as well."

Singer noted that Duma officials are actively considering amendments to the Law on the Circulation of Medicines in the period before the second reading. "We hope Duma officials will use this opportunity to strengthen Russia's investment climate and remove barriers to access for Russian patients. We will continue to support stronger Russia-U.S. ties in the sphere of innovation and pharmaceutical development."

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$50.3 billion in 2008 in discovering and developing new medicines. Industry-wide research and investment reached a record \$65.2 billion in 2008.

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