

# Medicine Makers Warned to Prepare for WTO

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February 13, 2012

**The  Moscow Times**

New regulations are needed on the pharmaceuticals market before Russia enters the World Trade Organization, the head of the Association of International Pharmaceutical Manufacturers said Monday.

"The Health and Social Development Ministry needs to develop new regulation in the pharmaceuticals market now. These steps are not being taken, [and] we only have a law on the distribution of medicines, which was adopted without consideration of WTO entry," Vladimir Shipkov told The Moscow Times.

Russia has problems meeting international quality standards for medicine, Shipkov said.

Vladimir Dorofeyev, a scientific adviser to the group, said the problem stems from the dissolution of the government Pharmacopoeia Committee in 2004.

"You never know who is responsible for medicines' quality," Dorofeyev said. "Some of [the committee's] functions went to the Federal Health and Social Development Inspection Service, but we still have no uniform state quality standards."

Industry publication The Pharmaletter noted Sunday that new regulations are slowing the development of clinical trials in Russia. It estimated the clinical trials market in the CIS would be worth 940 euros (\$1.25 billion) by 2014.

Nonetheless, "[for the government] the main thing is not the effectiveness and safety of medicines, only budget savings. This is unacceptable," Shipkov said. "We are entering the WTO now, which means equal rights, equal terms and healthy competition among market participants."

Market players will be informed of changes in regulation well in advance after Russia enters the WTO, as is rarely done now, Shipkov added.

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