## KING & SPALDING Client Alert

nternational Trade & Litigation Practice Group

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#### WTO Accession of the Russian Federation

#### Implications for Pharmaceuticals and Medical Devices

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Russia's accession to the World Trade Organization (WTO) will create opportunities to increase exports of pharmaceutical products and medical devices. On 16 December 2011, WTO Members accepted the terms of the Russian Federation's accession. Russia will officially become a WTO Member 30 days following the ratification of its Protocol of Accession, which will take place before 15 June 2012.

As part of its WTO accession agreement, Russia has commitment to reduce and "legally bind" import tariffs on pharmaceuticals and medical devices. Russia must also follow WTO rules on non-tariff barriers, particularly under the WTO Agreement on Technical Barriers to Trade (TBT Agreement), and on the protection of intellectual property, under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

#### **Lower Import Tariffs**

Russia's tariffs on pharmaceuticals will be significantly reduced and will be "bound" at a maximum level of 6.5% by 2016, at the latest. Tariffs on medical devices will also be reduced and bound at an average of 5%.

#### **Non-Tariff Barriers**

Quantitative restrictions on imports, such as quotas, bans, permits, prior authorization requirements or other requirements or restrictions that cannot be justified under WTO provisions will be removed with Russia's accession to the WTO. Importers of pharmaceuticals will no longer need specific import licenses. However, foreign legal persons intending to import pharmaceuticals, including veterinary drugs, into Russian territory will be required to register and hold a license to engage in the production or distribution of pharmaceuticals.

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All technical regulations and conformity assessment procedures will have to be developed and applied in accordance with the relevant WTO agreements and in particular with the TBT Agreement. Under the TBT Agreement, international standards should be followed and Russia may only apply technical regulations to the extent that they are not more trade restrictive than necessary to fulfill legitimate objectives.

#### **Protection of Intellectual Property**

Upon accession, Russia must protect intellectual property, including patents and trademarks, in accordance with the TRIPS Agreement. Furthermore, data protection rules will enter into force to protect the data related to pre-clinical and clinical trials of innovative drugs.

#### **Price Control Rules**

Russia will continue to apply price controls on certain products and services, including medical goods, but these controls must be applied in manner consistent with WTO standards. Russia will not be entitled to use price controls for the purposes of protecting domestic products or services. A comprehensive list of goods and services subject to State price controls will be published in the Rossiiyskaya Gazeta.

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King & Spalding's specialized international trade lawyers have been working on the Russian accession since 1995 and have assisted many clients in connection with accession negotiations. Our international legal team assists clients in taking advantage of trade and investment opportunities in Russia and in connection with the implementation of Russia's WTO commitments.

This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

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