



**RUSSIAN
PHARMALICENSING
GROUP**

BD&L | International Regulatory Affairs

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Create a safer environment by bridging business culture gaps

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For Immediate Dissemination

To: All Partners of the Russian Pharmalicensing Group Ltd. (RPG) Company.

According to confirmed reports from the Ministry of Health, the Federal Service for Surveillance in Health Care (Roszdravnadzor) plans to alter the existing procedure of medicinal products registration in the territory of the Russian Federation starting from 2013.

Change in the procedure of registration is intended to optimize the registration procedure per se, and it features the development of new requirements for Technical Regulations, control over the circulation and proper use of medicinal products, and gradual harmonization with EC benchmark instructions as well as WTO standards upon ascension to this organization in 2012.

In RPG's view, changes in the procedure of registration will lead to a more complex registration procedure with extended requirements for a list of regulatory and legal documentation to be rendered, labeling, and a more complicated procedure of mandatory testing, its timeframe and cost within mandatory payments. On the other hand, in a short term perspective, changes in the procedure of medical devices registration shall foster the procedure of mutual recognition of medicinal products registration certificates in countries of the Customs Union.

Reference Information from RPG.

The Customs Union in the framework of the Eurasian Economic Community— is a form of trade and economic integration of Byelorussia, Kazakhstan and Russia implying the unified customs territory where mutual trade of goods is not subject to customs duties and a protectionist policy, except special protective anti-dumping and compensation measures. Further, member-countries apply a universal customs tariff and other universal measures of trade regulations for the trade of goods with third countries.

At present, the Federal Service for Surveillance in Consumer Affairs and Human Safety (Rospotrebnadzor) issues a universal certificate of state registration for food supplements, disinfectants and selected types of goods, which is valid on the territory of the Customs Union.

The RPG company points out that earlier prepared commercial proposals for the registration of medical devices will become invalid in 2013.

You are welcome to ask for further information on the terms of medical devices registration procedure and the amount of mandatory payments and the cost of RPG's services, upon additional request.

About Russian Pharmalicensing Group Ltd.

*Russian Pharmalicensing Group (RPG) specializes in licensing, business development and the registration of pharmaceutical and VMPs including pharmacovigilance, biotec, APIs, medical devices, food supplements and life science with high regional prevalence in Russia, Ukraine and ex-USSR countries. RPG is headquartered in Moscow, Russia.
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