EU – RUSSIA INDUSTRIALISTS' ROUND TABLE

Conclusions from the Project Workshop "Modern pharma policy: Collaboration between Business and Authorities for new Quality of Life"
(Yaroslavl, September 5-6, 2011)

The biopharmaceutical sector is one of the most dynamic hi-tech industries in the world economy. Cooperation between Russian and European pharmaceutical companies can make a significant contribution to achieving the goals of the EU-Russia Partnership for Modernization, as well as increasing competitiveness and the technological level of manufactured goods. The Development Strategy for Pharmaceutical Industry of the Russian Federation for the period until 2020 adopted in 2009 (Pharma-2020 Strategy) constitutes a solid foundation for such cooperation. Building on the results achieved at the Project Workshop, its participants – representatives of Russian and European pharmaceutical companies, authorities and expert organizations – have worked out the following agreed recommendations with the view to improve development conditions for the pharmaceutical industry in Russia.

1. Support for Russia's pharmaceutical industry in order to achieve comprehensive solutions aimed at improving healthcare and quality of life. Modern trends in industrial development encourage full integration of pharmaceutical production, production of medical goods and equipment, R&D in medical technologies, and interaction with medical institutions on issues of treatment and prevention of diseases. Therefore, support should be provided not only for the development and production of pharmaceutical products, but also for the implementation of projects by pharmaceutical companies in healthcare-related fields, including projects of long-term cooperation with leading scientific centres.

2. It is necessary to give a strict legal definition of the term "medical drug produced in Russia" that would be confirmed by law or a decision of the Government. This term is critically important for implementing support measures under the Pharma-2020 Strategy. A failure to provide an unambiguous definition leaves pharmaceutical companies with uncertainty in their business planning process. Precise criteria for localization of manufacturing would allow companies producing medications on the territory of the Russian Federation to claim eligibility for state support. These criteria should cover all stages of production localization starting from packaging as the first step to the full cycle production.

3. Priorities should be determined regarding the range of products that will be supported during localization of their complete production cycle on the territory of Russia. Global experience proves that on the territory of one country it is possible to organize complete cycle of competitive production only for a limited range of pharmaceutical products. Pharmaceutical companies need certainty whether products that they manufacture meet the complete cycle localization requirements to develop long-term business plans.

4. It is critically important for the development of investment and technological cooperation to ensure access for European pharmaceuticals to the Russian market

and Russian pharmaceuticals to the European market. This issue should be addressed by concluding an agreement between Russia and the EU on mutual acceptance of clinical trials results on the basis of European norms and principles of good clinical practice (ICH GCP). Elaboration of standards for pharmaceuticals in the Customs Union of Russia, Belarus and Kazakhstan should also be based on EU standards.

5. Given the significant role of public procurement in the pharmaceutical market, it is necessary to take into account specific characteristics of the pharmaceutical industry when elaborating a new public contracting system. Current Federal law №94 prioritizes cost, resulting in the purchase of cheap, sometimes low-quality medicines. As purchased medicines have a direct impact on the health and quality of life of patients, priority should be given to product quality and safety. A relevant rule should be either recorded in a new law on the public contracting system, or be introduced by a special by-law.

6. The high level of administrative costs and barriers remains a serious obstacle for investment projects on the territory of the Russian Federation. The share of overhead costs for foreign investors that have located their factories on the territory of Russia can be three times higher than for the factories based in the EU. Lower administrative barriers and effective protection of intellectual property rights (primarily, fight against counterfeit medicines) are a prerequisite for locating competitive hi-tech pharmaceutical factories in Russia. An effective mechanism to tackle this problem could be cooperation with self-regulating business organizations that monitor administrative barriers and come up with proposals to remove them.

A better investment climate and a high-quality, predictable legal framework for Russian-European business cooperation in the pharmaceutical field are critically important for both achieving the goals of commercial efficiency of pharmaceutical production and increasing the contribution of corporations to improving provision of healthcare services for the people. The participants in the Workshop hope that their recommendations, critical for the development of the industry, can be implemented soon.