Russian pharmaceutical market today and tomorrow – legal overview

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21-11-2016

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The Russian pharmaceutical market is one of the fastest growing in the world, and it has always been attractive for foreign pharmaceutical manufacturers. However, a policy on import substitution, defined in the State Program "Development of Pharmaceutical and Medical Industry for 2013-2020," resulted in elaboration of several restrictive initiatives. At the same time, certain new regulatory instruments were introduced to create additional incentives for localization and investments. Therefore, the key purpose of this overview is to describe the main regulatory trends, associated legal risks and opportunities for pharmaceutical manufacturers in 2016-2017 in Russia.

INTRODUCTION

It has been four years since Russia joined the World Trade Organization (WTO) and implemented the basic international principles and standards to the national legislation. Further, in 2015 Russia, Belarus, Kazakhstan, Armenia, and Kyrgyzstan created the Eurasian Economic Union (EAEU) which envisages the gradual integration of the former Soviet countries'

economies, establishing free trade, unbarred financial interaction and unhindered labor migration. Although the EAEU is just gaining strength as an institution, the pharmaceutical sector is planned to become the first point of integration through the creation of a common pharmaceutical market. Therefore, the national Russian policy in the pharmaceutical sector must fall within the rules of the WTO and the EAEU.

INTELLECTUAL PROPERTY REGULATIONS

Compulsory licensing

For the last two years, compulsory licensing (CL) in relation to patents for medicines became one of the most debated issues in Russia, which raises big concerns of innovative pharmaceutical manufacturers. Notwithstanding the Russian Government's goal to stimulate the development of an innovative pharmaceutical industry, the Federal Antimonopoly Service of Russia (FAS) sequentially insists on amending the existing concept of compulsory licensing.

The FAS suggests two basic scenarios for CL implementation:

(a) through a government decision (by amending the provision on "government use of an invention" in the Russian Civil Code); and

(b) through a court decision (by enabling the FAS to apply to the court for CL issue).

The concept and the exact wording of the CL initiative are subject to further discussions between governmental stakeholders (the Ministry on Economic Development, the Ministry of Health, the Ministry of Justice, etc) and may be changed significantly or even abolished as has happened several times before. The timelines of work on the CL draft law largely depend on the results of such discussions.

Data protection

Russia's commitments on regulatory data protection (RDP) are an integral part of Russia's WTO obligations and came into force on the date of Russia's accession to the WTO. When entering the WTO, Russia provided a six-year period of RDP for undisclosed information, submitted to obtain marketing approval for pharmaceuticals, in accordance with Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

However, the industry has significant concerns related to the recent court decision on RDP, holding that RDP regime should not protect the originator clinical trials data available in the open domain.

The whole story started at the end of 2014 when the originator applied to the court claiming that the local generic manufacturer had infringed the originator's data exclusivity. On December 17, 2015, the IP Court resolved the case in favor of a generic manufacturer. Inter alia, the IP court stated that data exclusivity protection is applicable only to closed data, contained in the registration dossier. In 2016, the Russian Supreme Court confirmed the findings of the IP Court that the data exclusivity regime is not applicable to open information.

Following the path, highlighted by the above precedent, in September 2016 Arkadiy Dvorkovich, Vice Prime Minister, instructed the Ministry of Health and other responsible stakeholders to elaborate a draft law, which should directly enable the manufacturers of follow-on products to rely on originator clinical trial data published in the open domain for the purposes of follow-on

product registration. On October 27, 2016, the relevant draft law was made available for public discussions, which must continue until December 29, 2016.

Parallel Imports

Parallel Imports (PI) authorization is another controversial law-making initiative, which is discussed at the EAEU level. Currently, PI is prohibited from countries outside the EAEU, based on the regional principle of exhaustion of trademark rights, laid out in the EAEU Treaty. At the same time, the possibility to authorize PI from outside the EAEU for certain product groups (eg, pharmaceuticals and medical devices) has been actively discussed since 2015.

On April 13, 2016, the EAEU Interstate Council adopted a specific Resolution, which directly assigns work on the Protocol amending the EAEU Treaty to the Eurasian Economic Commission. Inter alia, such a Protocol must enable the Interstate Council to make exceptions from the regional principle of exhaustion of trademark rights, ie, authorize PI in certain industries.

However, the positions of EAEU member states differ on this issue and thus the negotiation process may take significant time. Timur Suleymenov, EEC Minister of Economy and Financial Policy commented that the republic of Belarus is strictly against parallel imports piloting based on the necessity to protect the investments and local market.

Conclusions and recommendations

Despite the fact that the Russian Federation has outlined a strategy for long-term innovation development as part of its policy, the Russian Government is considering measures that do not adequately protect intellectual property, or reward the value of innovation and the benefits it brings to Russian patients.

At the same time, the adoption of amendments to the Russian federal legislation is quite a complex process and the decision-makers are usually ready to open a dialog with the industry and patients to find a suitable regulatory compromise.

PRICING REGULATIONS

Maximum sale prices

Selling prices are subject to state control only if they apply to medicines included on the Essential Drug List (EDL), annually approved by the Russian Government. The Ministry of Health (MoH) approves the maximum drug prices that a foreign supplier (for imported drugs) or domestic manufacturer (for locally produced drugs) may charge.

Since July 2015, the FAS has been actively involved in setting of prices for EDL medicines together with the MoH. As a result, the FAS significantly changed previously existing pricing approaches.

In October 2016, the FAS announced its plans to change the pricing regulations and associated practice by 2018. In particular, it has been proposed that the maximum sale price will be determined not by the manufacturer, but by the FAS itself. The FAS currently works on the exact mechanisms for determining the price for grams, milligrams, and other dosages. At the same time, no draft amendments have been made available for public discussions yet.

Pricing in State tenders

In August 2016 the Health Minister informed on plans to implement reference pricing in state procurement of medicines, which is aimed at decreasing budgetary spending. For these purposes, in 2017 the new pricing monitoring system will start functioning. It is supposed to be an automatic platform, which collects information on state pharmaceutical tenders from each Russian region (starting from tender planning and ending up with information on the concluded supply agreements), and calculates a reference market price for every INN and trade name of a medicine. In a forward thinking approach, the use of the new method may lead to decrease of the initial tender price significantly below the registered sale price level.

Conclusions and recommendations

Existing Russian pricing policy is far from being perfect. At the same time, inclusion of a medicine on the EDL provides access to the state tenders. Even the existing single-molecule tenders may create significant incentives for the unique patented products and other medicines included on the EDL.

ACCESS BARRIERS TO STATE PROCUREMENT

Three's a crowd

On November 30, 2015, the Russian Government adopted Resolution No 1289 "On Restrictions and Conditions of Access of Foreign EDL Medicines to State and Municipal Tenders" (further the "Resolution No 1289"), which codifies the so-called "three's a crowd" approach in relation to the EDL medicines. According to Resolution No 1289, if two or more EAEU pharmaceutical manufacturers are bidding on a tender for an EDL product, any foreign bid for that same tender must be rejected. At the same time, "three's a crowd" is not applicable for patented medicines and unique products.

However, in November 2016 the Draft Resolution of the Russian Government amending the "three's a crowd" rule was made available for public discussions. The Draft Resolution suggests adopting the so-called "three-tier preference" system and sets forth that the state contract must be exclusively granted to a tender participant, who manufactures the EDL medicine in Russia, starting from the active substance phase. If no such companies participate in the tender, then the "three's a crowd" rule should apply. Tender participants not falling within the first two "filters" remain subject to 15% pricing preference for local products.

The "three-tier preference" system is widely viewed as excessive and unnecessary regulation. The public discussions of this initiative will continue until 29 November 2016.

New investment options

In 2015 Russia adopted the new investment mechanism – special investment contracts (SPICs), called to create incentives to invest in Russian industry.The SPIC is an agreement under which an investor undertakes to upgrade and/or develop manufacturing of an industrial product in Russia, and the other party (Russia or the Russian region) undertakes to provide incentives for industrial activities, specified by legislation (ie, tax preferences, state support measures, non-application of new restrictions, etc. during the term of the SPIC).

From September 1, 2016, investors under the SPIC, as well as regional investors may benefit from additional preferences during the procurement of various types of product for state and municipal needs. The Federal Law 365-FZ dated July 3, 2016 (further the "Law 365-FZ") provides the following new procurement options:

(a) direct purchases of products manufactured under the SPIC for state and municipal needs;

(b) direct purchases of products manufactured under a regional investment contract with an investor who creates or upgrades and/or sets up the production of certain goods in a Russian region (further the "Regional Investment Contract" or "RIC").

At the same time, rules for SPIC/RIC in the pharmaceutical sector remain unclear. Law 365-FZ does not directly provide exclusivity for an investor who manufactures a product under a SPIC or under a RIC. Additionally, there are a number of legal gaps, which require additional clarifications (eg, when a product manufactured under SPIC/RIC acquires local status).

Introduction of such an incentive in theory may create auxiliary localization opportunities. However, it seems that the implementation of a SPIC/RIC in the pharmaceutical sector will not be that simple.

Conclusions and recommendations

The on-going initiatives may represent critical challenges for companies focused on the Russian market. While the positive expectations for business development prevail among manufacturers of generics and local companies, global players operating in Russia are not that optimistic.

At the same time, creation of a common pharmaceutical market of the EAEU is being awaited by various companies with inspiration. The new system based on the compromises between different EAEU economies may bring balance to the existing controversies.