



Russia: Key concerns of the pharmaceutical industry

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Background

Russia remains a key market for the European pharmaceutical industry, maintaining its place as the 5th largest export market for European pharmaceuticals (following US, Switzerland, Japan and China), covering a total of 4.3% of total EU pharmaceutical exports. In 2016, EU exports to Russia amounted to €72.3 billion, and pharmaceuticals made up 8.6% of these exports, representing an increase of 0,3% compared to 2015, and an amount of ca. €6.2 billion. In the past years, exports fell significantly, although in 2016 the sector registered a positive growth rate of 1,8%.

However, the investment climate and market access environment in Russia continues to be challenging for the industry, as the Russian Government continues to focus on a protectionist agenda, with increased localisation efforts such as discriminatory tendering procedures and proposed compulsory licenses, in order to support domestic manufacturing.

Overview of key trade barriers

This briefing provides an overview of some of the key trade barriers currently experienced in Russia by the pharmaceutical industry and related topics, which include:

- Intellectual Property
- Regulatory
- Market access, localisation and pricing
- Eurasian Economic Union

Intellectual Property (IP) - Regulatory Data Protection (RDP) and Compulsory licensing (CLs)

RDP: As part of its WTO accession, Russia committed to provide an effective period of six years of regulatory data protection (RDP). However starting from 2016, amendments to the Federal Law on Circulation of Medicines (FL-61) entered into force, effectively shortening the overall RDP period by allowing generics to apply for market authorization 4 years after the original medicine has been registered and after 3 years for a biosimilar product.



Draft amendments to FL 61 were published in October 2016 stating that the data exclusivity regime does not apply to publicly available information. This allows (pre)-clinical data available in the public domain, such as in clinical trial databases and scientific journals, to be relied upon by a generic company for registration of its products before the expiry of the originator's RDP term and without requiring the written consent of the rights owner. In 2016, the Supreme Court of Russia further supported this notion by allowing local generic companies to rely on partial clinical data sets published in scientific journals abroad to seek marketing approval in Russia. The Ministry of Health is currently seeking to codify that ruling. This is of significant concern to the innovative pharmaceutical industry and such practices further weaken the RDP regime in Russia and are entirely at odds with established international practices on the use of disclosed clinical data published in scientific journals.

Compulsory licensing¹: The Federal Anti-Monopoly Service (FAS) continues to strongly support the expanded use of compulsory licenses and expresses its intent to adopt restrictive patentability criteria for pharmaceuticals. Since 2016, FAS released several draft amendments to the anti-competitive regulation and Civil Code in order to exclude IP immunity from anti-competitive regulation. In December 2017, the Russian President approved the Competition Development Plan for the Russian Federation for 2018-2020 which was introduced by FAS. According to the Plan, a draft law is to be submitted to the Duma by January 2019 clarifying the procedure of issuance by the Government of a CL in the interests of defense and security. The Plan indicates that the expected result is oriented towards lowering high medicine prices intended for epidemics threatening national security. Even though the law provides for notification of the patent holder in due time with payment of an adequate compensation, the proposals threaten to weaken the already low IP protection in Russia as the definition of national security is very vague and the system as proposed could easily be misused in order to provide preferences for local manufacturing of patented medicines or as a non-competitive leverage to achieve cost-containment objectives.

Patents: Currently, there is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. The Russian courts were not only reluctant to issue court injunctions in patent infringement cases related to pharmaceuticals but had previously decided that marketing authorization of generics did not constitute an infringement of the patent unless the infringing product was sold to the customer. This is leading to the approval and marketing of follow-on products in Russia, despite the fact that a patent for the original drug is still in force. The Russian regulation is then compounding this injury by permitting prematurely launched generics to participate in state procurement tenders.

Regulatory – Good Manufacturing Practices (GMP)

Russia does not recognize GMP certificates issued by regulatory authorities of other countries and regions, e.g. EU. Since January 2016, Russia has required local GMP certificates for foreign producers as part of the marketing authorization application as well as for any other regulatory action, such as authorization renewals, variations related to changes in the product information, safety etc. This requirement was introduced without any transition period and foreign manufacturers were not given sufficient time to obtain a GMP certificate before entry into force of the new rules. The long timelines of the GMP inspection procedure and inspection capacity constraints, aggravated by the lack of transition period, has effectively hindered access to the Russian market for foreign producers. The measure has a

¹ Compulsory licensing is when a government allows a generic manufacturer to produce the patented product without the



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clear discriminatory element, as products manufactured by Russian manufacturing sites are not affected, as in lieu of a Russian GMP certificate, authorities accept the copy of the already issued manufacturing license. As a consequence, there have been very few new drug registration applications filed by foreign companies in Russia in 2016 and 2017, i.e. in 2017 only 35 new marketing authorization applications took place, which is about 1/10 of the usual figure. Another serious concern is that variations to change the safety information of the product information require a Russian GMP certificate. According to a survey of AIPM member companies more than 300 such safety variations cannot be submitted, as GMP certificates are not available yet.

EFPIA has been actively engaging with the European Commission to repeal the discriminatory GMP measures. The EC has raised this issue in several bilateral discussions with Russian counterparts and it has remained a standing complaint at the WTO TBT committee. Moreover, the industry's concerns were elevated to Commissioner-level as the EU Commissioner for Trade sent a letter to her Russian counterparts denouncing the GMP measures as actively discriminating EU producers. In June 2017, EFPIA and AIPM co-organised a GMP roundtable with the support of the Russian GMP inspectorate. The workshop included participation of Eurasian Economic Union (EAEU) Member States authorities and representatives of the Ministry of Industry and Trade and the Ministry of Health as well as EFPIA and international experts. The workshop focused on key aspects of GMP inspection trends, ways of cooperation, modern challenges for industry and regulators as well as possible solutions for the further development and alignment of the Russian GMP system.

At the end of last year, the government finally put forward a set of proposed amendments to the State Duma, with active input by industry, which allows for some flexibility in the GMP inspection process, whereby foreign manufacturers will be able to apply for marketing authorization while the GMP process is ongoing. However, the final decision on marketing authorization depends on the outcome of this GMP inspection, and would not require a GMP certificate for a safety variation. The first hearing of the Duma on this matter took place in January. It is of key importance to expedite the amendments approval in view of the current grave situation with regards to registration of medicines in Russia.

Market access, localisation and pricing

As part of the Government's policy to support domestic manufacturing, Russia continues to enforce discriminatory practices in public procurement, which effectively hinders access of foreign producers to state procurement of medicines. A regulation with a three-tier preference system, the so-called "three is a crowd rule", stipulates priority in tenders for the supply of medicines listed in the Essential Medicines List to local producers where at least two companies from Member States of the EAEU are participating with the subsequent exclusion of the foreign product. If no such product exists, the tenders will be based on current regulations, i.e. a 15% price preference to local products (the latter rule is not specific to pharmaceutical products). A recent draft proposal establishes a new preference of a 25% price reduction for domestic producers that conduct full-cycle production (including active pharmaceutical ingredient) in Russia or the Eurasian Union as of 1 January 2019.

EFPIA has raised this discriminatory practice on numerous occasions with EC and Member States, and the issue was duly included in the update of the EC Key Barriers list for Russia in November 2017. However, although part of the WTO commitments and started in 2016, Russia has not yet taken any formal steps to accede to the WTO Government Procurement Agreement (GPA). Furthermore, the Ministry of Industry and Trade has stated that there is no intention to revise the rule, as support to local manufacturing remains a key priority for the Government.



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Moreover, local generics have been able to apply for marketing authorisation before the RDP term expiration (see above), allowing them to register an EDL (Essential Drug List) price that is 20% lower than the original for tendering purposes, as price registration for these generics is possible even if they are not yet on the market. Additionally, there were situations when offers made by local generics were submitted to the Ministry of Health (MoH) for public tenders, even though the product was not yet registered. This was used by the MoH to exert unjustified pressure on international producers to submit lower prices. A number of companies have taken local legal action against this infringement, however the shortcomings of the judicial system in terms of pharmaceutical companies being able to pursue effective court injunctions limits the possibility for any enforcement.

In May 2017, Russia issued a new draft methodology for calculating maximum manufacturers prices for the medicines in the essential drug list and in addition proposing forced downward re-registration of all registered prices within 2018. The industry submitted comments on the new methodology in June 2017 but the draft document had been significantly modified since then and the development continues in the closed format. While some of industry's concerns are reflected in the amended methodology, several harmful elements remain. For instance, the requirement for constant downward price review in case of change of prices in any of the reference countries may lead to difficulties in the drug distribution chain as medicines are not allowed to be sold above currently registered price and the price will be revised on the constant basis, which may ultimately lead to drug shortages for Russian patients.

Eurasian Economic Union – implementation of the common medicines market

Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan are members of the Eurasian Economic Union (EAEU), an economic integration platform launched in January 2015. The Eurasian Economic Commission (EEC) is the executive body of the EAEU. An agreement was signed in 2014 to establish a common pharmaceutical market, which aims to harmonise key regulatory aspects across Member States. In November 2016, EAEU Member States signed the entry into force of the common pharmaceutical market the common medicines market was launched in May 2017.

The common medicines market provides an opportunity to deal with some of the regulatory challenges in the region via stronger harmonisation with international best practices (EU, ICH, PIC/S, FDA etc). But there are also potential challenges as some countries forming the Union, notably Russia, currently have protectionist policies in place which could spill over to other EAEU MSs, as not all EAEU MS are members/observers of the WTO and ICH (International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use). In addition, there are technical implementation challenges such as delays in full implementation of EAEU regulations and marketing authorization procedures. However, it is noteworthy that the Eurasian Economic Commission filed an application for observer status at ICH in 2017, which is an encouraging signal that there is an opportunity to fully align the EAEU with EU and ICH standards. It will be important to monitor the transposition and implementation of the EAEU legislation on national level throughout the operation of the new common pharmaceutical market and the pharmaceutical industry aims to support the EAEU in ensuring the proper regulatory and scientific support needed to fully and properly implement the EAEU common pharmaceutical market.



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Conclusion

The pharmaceutical industry continues to be impacted by market access barriers in Russia and the increasingly protectionist policies of the Russian Government, with a strong focus on localisation. Nevertheless, Russia remains a very important market for European pharmaceutical manufacturers and our industry is committed to continue to export to and invest in Russia in order to ensure continued access to medical treatments for Russian patients. To that end, the support of the European Commission and the EU Member States in raising the key concerns of the European pharmaceutical industry in bilateral exchanges will be crucial in order to improve the operating environment for foreign producers in Russia.



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