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Russia

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Trends and Developments

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2020 was a challenging and dynamic year for the life sciences industry. The COVID-19 pandemic prompted changes in the regulatory landscapes of many countries and Russia is no exception.

Stimulation of local production of medicines and medical devices remains high on the agenda of the Russian healthcare regulator. In 2020, however, the limitations of the approach focused on import substitution have become obvious, which has resulted in a new trend to soften restrictions relating to state procurement of foreign medicines. Much has yet to be done in this direction, but the first step is always the hardest.

Measures in the Field of the Sale of Medicines and Medical Devices Taken in Response to the COVID-19 Outbreak

Many of the COVID-19 measures were of a temporary nature. For example, Russia established a zero rate of import duty on medicines and medical devices and prohibited the export of several medical devices in Spring 2020.

Some other measures, however, have had a long-term effect and remain available in 2021.

New powers of the Russian government to set maximum selling prices

On 26 March 2020, a new law empowered the Russian government to set maximum selling prices, and wholesale and retail increments for medicines and medical devices.

The Russian government will be entitled to regulate prices in the following cases:

- if there is a threat of the spread of a disease that constitutes a threat to others;
- if it has been revealed during the monitoring of prices that prices have increased unreasonably in several regions by more than 30% within 30 days;
- in an emergency situation.

Such restrictions may last for a period up to 90 days.

Previously, it was possible to set maximum selling prices, wholesale and retail increments only for drugs included in the List of Vital and Essential drugs and only for certain types of medical devices.

Simplified procedures for obtaining marketing authorisations for medical devices and medicines

Any such simplified procedure for obtaining marketing authorisation extends to 36 types of medical devices, including medical masks and respirators. The simplified procedure allows the obtaining of marketing authorisation without submitting results of any trials and tests, which had been required before. If no request is issued by the regulator, the marketing authorisation will be issued within five business days after the receipt of application and supporting documents. The applicant for marketing authorisation must complete technical tests, toxicological studies and clinical trials of the medical devices for which marketing authorisations have been obtained under the simplified procedure, after receipt of the marketing authorisation.

The Russian government has also established a simplified procedure for obtaining marketing authorisations for medicines that are, for instance, intended for the prevention and treatment of diseases that pose a danger to others. This procedure remains in force until 1 January 2022.

Online Sale of Over-the-Counter Medicines

Online sale of over-the-counter medicines has been legalised in Russia. In order to sell such medicines online, the pharmacy must have:

- a licence for pharmaceutical activity;
- special permission of *Roszdravnadzor* (ie, the Federal Service for Surveillance in Healthcare).

A pharmacy selling medicines online should use its own courier service or may engage a third-party courier service.

Also, there is an initiative to allow the selling of prescription drugs online. Currently, the respective draft law is pending.

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Tightening Administrative and Criminal Liability for the Sale of Counterfeit and Sub-standard Medicines

Administrative and criminal liability established for sales of counterfeit, sub-standard or unapproved medicines or counterfeit or sub-standard medical devices, or counterfeit dietary supplements, as well as sales of biologically active additives containing pharmaceutical substances not declared during the process of obtaining marketing authorisation, has been tightened.

The liability now includes an administrative fine in the amount of up to RUB6 million (approximately EUR65,000) or administrative suspension of the company's activity for up to 90 days. Criminal liability is envisaged in the form of a fine, imprisonment of up to 12 years or compulsory labour of up to five years, with the deprivation of the right to occupy certain positions or engage in certain activities for a period of up to ten years.

This more severe administrative and criminal liability is envisaged in order to mitigate the risks caused by the newly introduced online sale of over-the-counter medicines.

Telemedicine Initiatives

Back in 2018, the Russian Law on Telemedicine granted medical organisations (which had obtained a licence for rendering medical services) the right to provide several medical services online, in particular to conduct consultations and monitor the patient's health status. However, the Law on Telemedicine does not allow the diagnosing of patients based on online communication only. The COVID-19 pandemic has resulted in some initiatives to expand the area of telemedicine and steps are being taken to extend the availability of telemedicine in Russia.

Track and Trace System

In July 2020, the track and trace marking of medicines became obligatory in Russia. All medicines imported into Russia or produced in Russia (with limited exceptions) should bear a track and trace mark. Information on each transaction with a particular medicine should be entered into the system for monitoring the circulation of medicines and will be available through mark-scanning.

Also, the transfer of data to the system for monitoring the circulation of medicines became a mandatory licence requirement for obtaining licences for the production of medicines, pharmaceutical and medical activities.

Compulsory Licensing

Compulsory licence claims by generic companies remain a reality in Russia. On 31 December 2020, the Russian government confirmed a grant of compulsory licence for remdesivir for one year to the Russian generic producer and this has already triggered an enormous controversy. Still, the practitioners hope that the aforementioned precedent is COVID-19 pandemic-related and thus exceptional.

Patent Linkage

The Russian Patent and Trade Mark Office (the Federal Service for Intellectual Property) (*Rospatent*) promises a prompt launch of the Unified Register of Pharmacologically Active Substances Protected by Invention Patents. This register is supposed to include information on:

- inventions protected by patents and used in drugs (namely, the numbers of the relevant patents, international non-proprietary names (INN), patents' validity periods, patent-holders, type of patent). This information is to be entered into the register by *Rospatent* upon a patent-holder's motion;
- marketing authorisations' details and dates of introduction of such drugs into civil circulation in Russia. This information is to be entered into the register by the Russian Ministry of Healthcare.

Simultaneously, the current procedure for obtaining marketing authorisations provides the requirement to indicate in applications for obtaining marketing authorisations the information on patents and trade marks which are used in the respective medicines and are valid in Russia. This requirement applies to all medicines for which marketing authorisations are sought from 1 January 2021. For all medicines approved under the old rules, new marketing authorisations must be obtained before 1 January 2026.

Patent Litigation

In Russia, the IP Court continues to take an important role in pharma patent litigation. In 2020, the IP Court operated efficiently despite the pandemic: where necessary, the parties were given the opportunity to attend the hearing online, while in on-site hearings the number of representatives was limited. The pharma patent cases dealt by the IP Court include appeals against the Russian PTO (*Rospatent*) rulings in patent-opposition proceedings and second appeals against the rulings of lower courts in patent-infringement cases. The complexity of cases brought to the IP Court increased and, therefore, the specialists with a technical background from the IP Court's administration were involved in proceedings more frequently. The IP Court dealt equally efficiently with more straightforward compound patent disputes and with fewer trivial-use patent cases. While the quality of pharma patent dispute resolution before the lower courts and the Chamber for Patent Disputes under *Rospat-*

ent is inconsistent, the IP Court as a forum has the trust of patent rights-holders.

Positively, in 2020 permanent injunctions based on the mere threat of patent infringement and patent-infringement claims were granted by Russian courts. Moreover, the Russian courts imposed an *astreinte,* or penalty, for non-compliance with the court's effective ruling in a patent-infringement case against a major Russian generic producer in a cumulative amount per each week of non-compliance. The outcome is precedential as it is the first case where *astreinte* was granted in a patent-infringement case and in a cumulative amount.

Softening Restrictions of State Procurement of Foreign Medicines

In 2020, Russia was confronted with a deficit of many medicines, including not only the medicines used for COVID-19 treatment but also many other vital medicines, such as antineoplastic drugs and drugs used for treatment of rheumatoid diseases.

Many experts consider this problem to be a result of the "third extra" rule application, under which state procurement of medicines produced abroad is restricted if there are at least two producers of the medicine in the Eurasian Economic Union. Since, during 2020, the limitations of the approach focused on import substitution have become obvious, the Russian government proposed abolishing the "third extra" rule for public procurement of some vital and essential medicines. In August 2020, the Russian government issued a resolution introducing exceptions to the "third extra" rule for some onco-haematological medicines until the end of 2021. The discussion related to some other medicines is still ongoing.

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Hogan Lovells (CIS) is a global law firm with over 500 life sciences and healthcare practitioners worldwide, spanning government regulatory, corporate, finance, intellectual property, and litigation. The Moscow office was established in 1994 and has been helping clients to resolve the most complicated legal matters for more than 25 years across Russia and the Commonwealth of Independent States (CIS). The team delivers a world-class level of service to start-ups and multinational enterprises by providing them with increasingly creative strategies and integrated solutions that protect and support their business, day in and day out. With a strong client base of pharmaceutical, biotech, and medical device clients, Hogan Lovells advises companies at every stage of their journey from creation to commercialisation of a life-saving therapy, regulatory compliance to domestic and international patent disputes, and the formation of a strategic alliance to a complex, global merger.

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