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2022: Legislative developments impacting the pharmaceutical and medical device industries

Overview by the Life Sciences & Healthcare sector group at SEAMLESS Legal

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Since February 2022 business in Russia has been affected by dramatic political and economic events. Military action and sanctions have given rise to logistical, manufacturing and reputational challenges that have not spared the pharmaceutical and medical device industries.

On the one hand, only a few foreign companies have left the Russian market entirely. On the other hand, many of them have limited or completely stopped supplying certain products, suspended investment in Russian projects, curtailed clinical trials, and frozen marketing activities.

Against this background, the Russian authorities have sought to prevent the medical product market from collapsing. To this end, the available levers of influence on the industry had to be used and various legislative changes had to be made.

Although almost all of 2022 was characterised by legal uncertainty, some conclusions can be drawn.

Termination and suspension of supplies

One of the first things companies did in response to the situation was to restrict the supply of certain drugs / products and scale back their business in a number of nosologies. As early as March 2022 this prompted the Russian Ministry of Industry and Trade ("**Minpromtorg**") to send out queries to companies in the industry, asking about their future plans in Russia.

In this context, many companies had to refresh their knowledge of what had been a rarely used legal provision, namely Article 52.1(6) of the Federal Law "On the Circulation of Medicines" ("**FZ-61**"): Minpromtorg and the Federal Service for Healthcare Supervision ("**Roszdravnadzor**") must be notified at least one year in advance of the suspension or cessation of production / import of drugs to Russia.

At the same time, amendments were quickly made to the Federal Law "On the Fundamentals of Public Health Protection", imposing a similar requirement with respect to medical devices: Roszdravnadzor must be notified at least six months before the suspension / discontinuation of supplies and production.

Just how these rules are applied in practice has raised many questions, including:

What are the penalties for failing to give notice of suspension or discontinuation of supplies / production?

First of all, a company can be fined under Article 19.7.8 of the Russian Code of Administrative Offences, which envisages a fine of up to RUB 70,000 on the company and up to RUB 15,000 on its officers.

In addition, if a company has a dominant position on the market for a drug /product, its refusal to supply it in the absence of timely notification can be deemed unjustified. This is a form of abuse of dominance.

Some have even noted a theoretical risk of criminal liability under Article 237(1) of the Criminal Code for concealing information endangering human life and health. Formally, the absence of a warning that an important drug / product will no longer be on the market could trigger such liability. But we are not aware of any such cases to date.

Is there a difference between suspension and discontinuation of supplies / production?

On the one hand, any interruption in supplies / production can be regarded as both suspension and discontinuation.

On the other hand, dictionary definitions of the word "suspend" tend to use, among other things, the verb "delay". In theory, this means that the regulatory authorities could treat even a temporary decrease in previous volumes of supply / production as a violation.

Initially it was widely believed that, strategically speaking, it would be better to serve notice of suspension (rather than complete cessation) of supplies or production. This position was based on the assumption that the potential sanctions the Russian state authorities could impose on companies that announced "temporary suspension" would be milder than on companies that were permanently withdrawing from the market. However, this assumption, as we can now see, did not materialise in practice.

Is a company required to continue importing or manufacturing its products after notice has been given?

Neither the law nor the competent authorities provide an answer to this question.

The most balanced position seems to be that it is not required to continue importation or production if the company has sufficient stock to meet market needs during the notice period (one year or six months). In that case, there is no risk of a sudden shortage of the product, and there is no point in requiring the company to continue importing or manufacturing products that it does not plan to sell after the notice period ends.

What happens if a company decides to resume supplies / production after notice has been given?

There is no specific procedure for resuming supplies / production. The company can resume discontinued business processes at any time before or after the notice period ends. However, any further suspension / cessation will only be possible after new notice is given and the appropriate period of time has elapsed.

Combating inventory shortage

The cessation or curtailment of business in Russia by many companies, the scaling back of supplies, and logistical difficulties have forced the Russian authorities to implement a number of additional measures to deal with the resultant or potential shortages of drugs and medical devices.

Fast-track registration of analogue drugs

In the event of [a risk of] inventory shortage due to sanctions, an analogue drug may be registered under the fast-track procedure approved by Russian Government Decree No. 593 dated 5 April 2022. Once the fast-track registration is completed, the marketing authorisation will be issued, valid until the end of 2023 and extendible up to the end of 2025.

Fast-track registration of certain types of medical devices

Certain types of medical devices can also be registered under a fast-track procedure if there is a shortage of such devices. According to the specifics of circulation approved by Russian Government Decree No. 552 dated 1 April 2022, the list of types of medical devices eligible for fast-track registration is to be drawn up by a special multi-authority commission.

Re-registration of prices for VED medicines

If there is [a risk of] inventory shortage of a medicine from the List of Vital and Essential Drugs (VED) in connection with pricing, the holder of the marketing authorisation for the medicine that is in short supply will receive a proposal to re-register the maximum ex-factory price.

The holder of the marketing authorisation does not have to do anything to receive such a proposal. The Russian Ministry of Health and Roszdravnadzor establish any inventory shortage on their own.

The calculation of the new price may be based on the average exchange rate of the producer's national currency against the rouble in the month preceding the application for re-registration. That exchange rate must be more than 10% higher than the average exchange rate of the producer's national currency over the three months prior to the filing of the application.

Threat of compulsory licensing

Following announcements by foreign companies that they are scaling back their business in Russia, government officials have repeatedly reminded that there is a compulsory licensing mechanism. By this they mean the right of the Russian Government to decide, in case of emergency (a shortage of a drug can be deemed as such), to use a patent without the patentee's consent. This allows a government-appointed Russian company to use another party's patent and produce the drug without the patent owner's permission.

What is more, the legislators have even obviated the payment of compensation to patent holders from "unfriendly" countries (for right holders from "friendly" countries, it amounts to 0.5% of the proceeds from sales of the product made using another party's patent).

Despite this, the events of 2022 have not led to a significant increase in the number of compulsory licences. This is probably due to the fact that the reduction in the supply of drugs and products has not been as sharp as expected. However, we believe there remains a risk that the compulsory licensing mechanism could become "popular".

Parallel imports

Parallel imports are where goods lawfully marketed in country A are imported to country B without the right holder's consent. Partial legalisation of this model has been Russia's vociferous response to the exit of foreign companies.

Goods for which parallel imports are not officially considered a violation are specified in a special list approved by Minpromtorg Order No. 1532 dated 19 April 2022. To date, we are not aware of any drugs or medical devices on Minpromtorg's list, but in theory this is a possibility for certain types of medical products.

Importing drugs in foreign packaging

As a further measure to ensure the availability of essential foreign drugs on the market, the legislators have allowed them to be imported in foreign packaging (Article 47(3.2) of FZ-61), subject to the following conditions:

- the drug imported in foreign packaging meets the applicable requirements for its registration in Russia, save for the requirements on primary and secondary packaging;
- the drug is in short supply or there is a risk of a shortage;
- the multi-authority commission has issued an opinion that a particular series (batch) of the drug can be marketed in foreign packaging (we have written about the commission's work earlier);
- a self-adhesive label containing information about the drug in the Russian language is affixed to the consumer packaging of the imported drug.

Importantly, this does not constitute legalisation of parallel imports of drugs. When a drug is imported in foreign packaging, public-law liability for the circulation of substandard products should be excluded, but the importer is not exempt from private-law liability (e.g., compensation) to the right holder.

New export restrictions

In March 2022, the Russian Government imposed broad export restrictions. The measures in question are set out in Decrees Nos. 311, 312 and 313 dated 9 March 2022 and affect, among other things, laboratory, medical and industrial equipment.

Depending on the type of goods and the country of destination, the decrees either establish a blanket ban on exports or require that a special permit be obtained from the Russian Government or a regulatory or supervisory authority.

Importantly, for certain types of products export authorisation may need to be obtained from more than one governmental authority. In our practice we encountered a case where the export of a medical device required two permits: one from Minpromtorg and the other from the Russian Ministry of Natural Resources and the Environment.

Such export restrictions not only hamper companies' general commercial activity but also complicate their plans to exit the Russian market. For example, many companies leaving the country would like to remove equipment from their Russian offices / warehouses and send it to third countries, because the equipment uses the company's intellectual property. But in the current environment, obtaining export authorisations is a time-consuming process with a high risk of rejection for formalistic reasons.

Curtailment of clinical trials

In 2022, many foreign companies decided not to conduct new clinical trials in Russia and stopped enrolling Russian participants in existing programmes. In addition to the main reasons (sanctions and response to the military conflict), there were additional factors that made it difficult to conduct trials in Russia:

- The import and export of many biological materials for clinical trials requires a special permit. In the current environment, to our knowledge, obtaining permits has become a more time-consuming process.

- As mentioned above, the Russian Government has restricted the export of a wide range of equipment, including, for example, equipment used for physical or chemical analysis.

- Many sponsors and contract research organisations (CROs) take the view that paying for the services of Russian research centres is a transaction potentially subject to secondary sanctions. This is due to the fact that many such centres are publicly funded institutions (i.e., established by the state), hence they are suspected of being associated with sanctioned governmental authorities / officials.

All this has made it difficult to deliver samples on time, equip laboratories, and perform agreements between sponsors, CROs and research centres.

However, despite the general tension around clinical trials in Russia, far from all market players have drastically scaled back their activity in this area. Many companies are continuing and completing trials as planned and are even continuing to provide the necessary treatment to patients before the drug / product is registered.

Corporate restrictions upon exit

Many companies that have not left the market are not ruling out deciding to leave in the future. Even more companies are considering restructuring their Russian assets (e.g., by selling parts of their business to local players).

Since March 2022, corporate restrictions have successively been introduced into Russian law which make it more difficult to scale back operations in Russia. The restrictions include a requirement to obtain approval from the Government Commission for Control over Foreign Investment in the Russian Federation (the "**Commission**") for certain transactions and operations involving shares in limited liability companies ("**LLCs**") and joint-stock companies ("**JSCs**").

The Commission's approval must be obtained for transactions that concurrently:

a) are entered into by persons associated with states that commit "unfriendly acts" against Russia or by persons under their control ("**Restricted Persons**"):

   - with Russian residents;
   - between themselves; and
   - with foreign persons who are not Restricted Persons.

   However, Russian or foreign persons that are controlled by Russian persons (the ultimate beneficiaries) are not deemed Restricted Persons if such control has been disclosed to the Russian tax authorities.

b) entail the possibility of determining the terms on which a company does business.

   In theory, this wording applies not only to transfers of rights to shares but also to other transactions through which a person gains the ability to determine the terms on which a company does business. For example, entering into a corporate agreement also formally falls under the restriction.

The lack of practice and guidance regarding the new restrictions has led many notaries to refuse to certify signatures on filings for the liquidation of companies associated with Restricted Persons, even though there are no formal obstacles preventing this.

Notably, the restrictions are silent on the consequences of failure to comply with the procedure for obtaining the Commission's approval of transactions. We assume that transactions that are subject to the restrictions but are made without the Commission's approval may be rejected by the Federal Tax Service or the administrators of the JSC

registers at the stage of execution or may be challenged in court by governmental authorities immediately after execution. If, however, transactions falling under the restrictions are nevertheless performed, the persons involved may be fined in accordance with administrative law.

At this stage it is difficult to predict whether any new restrictions will be introduced. The requirement to obtain the Commission's approval could well become just one of a number of measures to ensure that foreign companies maintain a presence on the local market.

Partial mobilisation

The partial mobilisation carried out in autumn 2022 has had a significant impact on the Russian economy. Expedited implementation of military registration at companies, cooperation with military enlistment offices, and mass relocation of employees are just the main consequences of mobilisation. The legislation has rapidly been amended to introduce a number of changes.

Suspension of contract

If an employee is mobilised, their employment contract is suspended for the duration of their military service (effectively for an indefinite period). In this case, all amounts owed to the employee must be paid by the employer before the date of suspension of the employment contract.

During the period of suspension of the employment contract:

- the employer can enter into a fixed-term employment contract with another employee to perform the missing employee's duties;
- no salary is paid to the mobilised employee, nor are their average earnings maintained;
- the mobilised employee retains their job / position and benefits, if any (voluntary medical insurance, company car, etc.);
- the mobilised employee's length of employment is not interrupted.

Resumption of work

The employment contract resumes on the day the employee returns to work. The employee may do so on any day up to three months after finishing military service, subject to three business days' notice to the employer.

Conclusions

Looking back on 2022, straightforward conclusions are elusive. The healthcare industry and economic reality in general were plunged into an atmosphere of tension and legal uncertainty.

At the same time, many fears and suspicions, as is now evident in hindsight, did not materialise. Most importantly, European and US businesses have not completely left Russia. As for the companies that did quit the Russian market, no cases intended to make an example of them by holding them liable or nationalising their Russian assets have been initiated.

In 2023, it will be important to maintain dialogue with the regulatory authorities and insist on the need for positive (rather than negative) incentives for the pharmaceutical and medical device industries. Companies should take advantage of the opportunities for business development and continuation offered by the current regulatory environment but be mindful to rely on a comprehensive legal risk assessment.

Our team is always ready to provide full legal support on any issues associated with doing business in Russia.

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