CLIENT UPDATE

RECENT DEVELOPMENTS IN THE RUSSIAN PHARMACEUTICAL INDUSTRY

NEW YORK
Andrew L. Bab
albab@debevoise.com

Kevin A. Rinker
karinker@debevoise.com

Dmitriy A. Tartakovskiy
datartak@debevoise.com

MOSCOW
Anna V. Maximenko
avmaximenko@debevoise.com

During the first few months of 2013, the Russian government has proposed, and in some cases adopted, new legislation that introduces a number of significant changes to the regulation of (1) the procurement of pharmaceuticals[1] by Russian state-owned clinics, the Ministry of Health and other Russian federal, regional and local governmental authorities and financed from the federal, regional or municipal budgets ("Government Procurement") and (2) the advertisement of biologically active substances and pharmaceuticals in Russia.

The new legislation is aimed at:

- counteracting corruption in Government Procurement by increasing transparency and improving the monitoring, auditing and public oversight over the Government Procurement process;
- protecting competition by providing access to Government Procurement tenders for a greater number of participants and preventing discrimination in selecting suppliers of pharmaceuticals;
- supporting Russian and Belarusian manufacturers of pharmaceuticals by providing them with certain price and selection preferences in Government Procurement; and

[1] The new legislation applies to both prescription and OTC pharmaceuticals, unless specifically indicated otherwise.

- protecting patients by establishing stricter rules for the advertisement of bioactive supplements (and possibly imposing a complete ban on all advertising of pharmaceuticals in the mass media).

The new legislation impacts or, in the case of pending legislation, would impact pharmaceutical companies (including foreign companies) doing business in Russia in a number of different ways.

First, the new legislation should improve access to Government Procurement for manufacturers and distributors of pharmaceutical products operating in Russia, which is one of their most important sources of revenue due to the dominance of state-owned clinics on Russia's medical services market.[2]

Second, because pharmaceuticals qualifying as products of Russian or Belarusian origin will continue to have preferential access to Government Procurement under the new rules, foreign pharmaceutical companies should consider whether their business strategy in Russia should be adjusted to meet the qualification requirements (e.g., by moving manufacturing operations into Russia).

Third, the new legislation would impose additional restrictions on (or even ban outright) the advertisement of pharmaceuticals, which would require manufacturers and distributors of pharmaceuticals to adjust their strategies for the promotion of their products in the Russian market.

GOVERNMENT PROCUREMENT OF PHARMACEUTICALS

New Government Procurement Law

On April 5, 2013, the legislature adopted Federal Law No. 44-FZ on the Contract System of Procurement of Goods, Works and Services for State and Municipal Needs (the "Government Procurement Law"), the majority of the provisions of which will become effective as of January 1, 2014. The Government Procurement Law introduces:

- a system of planned procurement based on annual and three-year procurement plans;

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[2] According to expert reports, private clinics account for as little as 5% of the total number of Russian clinics. See http://www.mhg.ru/publications/3E8A150. Unlike private clinics, state-owned clinics may procure pharmaceuticals only through the Government Procurement process. As a result, the pharmaceutical industry is one of the leaders in Government Procurement. According to some experts, it currently ranks second (after the construction industry) in terms of volume of Government Procurement contracts. See http://pharmapractice.ru/64809; http://gmpnews.ru/2012/03/eksperty-protiv-izmeneniya-zakona-o-goszakupkax-lekarstv/.

- additional methods of selecting a provider, including rules relating to requests for proposal, tenders with limited participation and two-step tenders;
- monitoring, auditing and public oversight of procurement; and
- anti-dumping measures intended to ensure that participants in the procurement process comply with their price undertakings and select suppliers based on other important criteria, such as corruption potential.

Among other things, the anti-dumping measures require suppliers of goods deemed to be basic necessities (which include pharmaceuticals) to offer a price that is at least 25% below the initial (maximum) contract price for the applicable goods[3] and to provide the customer with evidence of the supplier's ability to furnish the goods at the price offered. Failure to meet these requirements results in the exclusion of the supplier from the public tender or auction process.

In addition, the Government Procurement Law contains the following regulations:

- Protection of the rights of suppliers of essential and vital pharmaceuticals. Under the new law, a supplier of essential and vital pharmaceuticals for which no maximum sales price is registered in the register maintained by the Russian government[4] may be excluded from the Government Procurement process only if the supplier has not complied with all applicable requirements or has provided false information with respect to its compliance with those requirements. By contrast, if there is a maximum registered sales price for such pharmaceuticals, the supplier can be excluded from the Government Procurement process if the sales price offered by the supplier exceeds the maximum sales price and the supplier refuses to reduce the offered price.
- Promotion of competition by expanding pharmaceuticals eligible for the participation in Government Procurement. Under the new law, documentation with respect to the procurement of pharmaceuticals must specify their international nonproprietary name (commonly referred to as a "generic name") or, if there is no generic name, their chemical and group names. The procuring entity may indicate the brand name of the pharmaceuticals sought to be purchased only if the pharmaceuticals are included in a list approved by the Russian government. This rule promotes competition and directly impacts the accessibility of the Government Procurement process. For example, if the

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3 Depending on whether the procurement contract is awarded in a tender (i.e., the winner offers the best contract terms) or auction (i.e., the winner offers the lowest price), this requirement may apply to the initial (tender) or maximum (auction) price, which is to be determined, in either case, by the procuring entity (customer) in accordance with the guidelines provided in Article 22 of the Government Procurement Law.

4 The register of maximum sales prices is available at http://grls.rosminzdrav.ru/PriceLims.aspx.

terms of a Government Procurement tender are defined based on brand names, pharmaceuticals with the same characteristics but different brand names may not participate in the tender. As a result, more participants should be able to participate in a tender to purchase pharmaceuticals defined by generic names rather than by one of the brand names in such pharmaceuticals' generic name groups.

- Promotion of competition by encouraging purchasing from multiple bidders. Government Order No. 301, dated April 6, 2013, establishes the maximum initial offer price[5] at which a procuring entity may offer to purchase a single lot of pharmaceuticals with different generic names in a Government Procurement auction.[6] If the procuring entity wishes to purchase pharmaceuticals with different generic names for a total price exceeding the prescribed maximum initial offer price, the procuring entity must offer to purchase multiple lots. This rule is designed to make Government Procurement auctions more competitive by allowing more bidders to participate in the auction and avoiding the situation where the procuring entity contracts with a single bidder for the entire quantity of pharmaceuticals sought to be purchased.
- Counteracting corruption and promoting competition by defining exceptional cases when pharmaceuticals can be procured without a tender or auction. Under the new law, a customer may procure pharmaceuticals by way of a request for proposals, rather than through a tender or auction, if a medical commission deems the pharmaceuticals medically necessary for a particular patient and the quantity of pharmaceuticals so purchased does not exceed the amount required for the treatment of the patient. A customer may also procure pharmaceuticals by way of a purchase from a sole supplier, rather than through a tender or auction, if a medical commission deems the pharmaceuticals medically necessary for a particular patient, the contract price does not exceed RUB 200,000 (approximately US$6,600) and the quantity of pharmaceuticals so purchased does not exceed the amount required for the treatment of the patient.

Preferences for Russian and Belarusian Producers

On April 17, 2013, the Russian Ministry of Economic Development adopted Order No. 211 on Procedures for Admitting Goods Originating from Foreign Countries for the Procurement of Goods for Public Needs (the "Order").[7] The Order establishes preferences

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5 Such maximum initial price is generally RUB 1.0 million (approximately US$32,000) and, for Moscow and Saint-Petersburg, RUB 5.0 million (approximately US$161,000).

6 In an auction, the procuring entity offers the maximum initial price for the pharmaceuticals that it wishes to purchase. To win the auction, bidders have to offer prices below the maximum initial price.

7 The Order was registered with the Ministry of Justice on May 28, 2013.

in Government Procurement for products (including pharmaceuticals) of Russian or Belarusian origin. These preferences include:

- Price preferences: In an auction, if a supplier submitting the lowest bid offers to supply products that are not of Russian or Belarusian origin, the final contract price paid to the supplier will be reduced by 15%. Similarly, in a tender, if the winner offers products of Russian or Belarusian origin, the final contract price paid to the winner will be increased by 15%.
- Selection preferences: Where the same terms and conditions are offered by two or more suppliers in a state tender, the government will be required to award the contract to the supplier that offered products of Russian or Belarusian origin.[8]

Under the Order, these preferences will not apply if:

- the tender also includes goods to which preferences do not apply;
- the tender has failed and the purchaser places an order with a single supplier;
- none of the tender applications includes goods of Russian or Belarusian origin;
- none of the tender applications includes goods of foreign origin; or
- the winner of the tender offers goods of both Russian or Belarusian and foreign origin, and the goods of Russian and Belarusian origin comprise at least 50% of the offered goods.

Pharmaceuticals qualify as being of Russian or Belarusian origin if:

- the manufacturer has rights to intellectual property in respect of the final product and/or the method of production in the territory of the Russian Federation, as evidenced by the patent;
- technologically significant components[9] are produced in Russia from a list approved by the Russian government and/or are used in the production of the pharmaceutical in accordance with procedures established by the Russian government;

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8 The same preferences were previously established by Order No. 120 of the Ministry of Economic Development on Procedures for Admitting Goods Originating from Foreign Countries for the Procurement of Goods, dated March 12, 2012, which expired on January 1, 2013.

9 Technologically significant components are components the production of which is extremely important for the development of the Russian medical and pharmaceutical industry and allows the commencement of production of high-technology equipment and pharmaceuticals without the localization of production in Russia, where, in Russia, it is not possible to reach the goals set in the programs for the development of the medical and pharmaceutical industry reflecting the priorities for its development.

- production of pharmaceuticals is related to a transfer for value of technological solutions from a list approved by the Russian government and/or in accordance with procedures established by the Russian government; or
- production of pharmaceuticals at all stages of the production process (production of an active pharmaceutical ingredient and/or drug form) takes place in Russia.[10]

A pharmaceutical would qualify as a product of Russian or Belarusian origin if any one of these criteria is satisfied. The Order will be in effect until December 31, 2013.

These rules will continue to make it difficult for manufacturers and distributors of pharmaceuticals that do not qualify as being of Russian or Belarusian origin to compete in the Government Procurement process with manufacturers and distributors of pharmaceuticals that do so qualify. However, because the Order will remain in effect only until December 31, 2013, it is not entirely clear to what extent these criteria for qualifying pharmaceuticals as products of Russian origin should be taken into account by foreign pharmaceutical companies in determining their long-term strategy in the Russian market.

PROMOTION OF PHARMACEUTICALS

Strategy for the Provision of Pharmaceuticals

On February 28, 2013, the Strategy for the Provision of Pharmaceuticals to the Russian Public through 2025[11] (the "Strategy") was adopted by the Ministry of Healthcare. The Strategy provides an analysis of the current situation with respect to the provision of pharmaceuticals in Russia[12] and declares goals for fostering and measuring improvement in this process, including legislative changes. The main goal of the Strategy is to improve access to high-quality, effective and safe pharmaceuticals. To achieve this goal, the Strategy, among other things, declares the need for:

- improvements to the process of compiling lists of pharmaceuticals made available to the public through the program of state guarantees of free medical care and social security assistance;

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10 Russian law does not provide a definition of a pharmaceutical product of Russian origin. The criteria for determining whether a pharmaceutical product is of Russian origin have been under continuing discussion since the adoption of the preferences described above.

11 A Strategy is a policy announced by the Russian government. It typically includes guidelines and conceptual proposals that require further development and implementation through specific measures, including, among other things, the adoption of new rules and regulations.

12 According to the Strategy, the Russian pharmaceutical market has increased four-fold during the last 15 years and totaled RUB 768.5 billion (approximately US$25.6 billion) in 2012.

- improvements to state regulation of pricing for pharmaceuticals made available to the public through the program of state guarantees of free medical care and social security assistance;
- the establishment of a unified register of persons entitled to free or discounted pharmaceuticals while undergoing outpatient treatment;
- the creation of a list of pharmaceuticals that can be used for the treatment of the same illness (so-called "interchangeable" pharmaceuticals);
- improvements to the system of state registration of pharmaceuticals used for the treatment of rare illnesses (so-called "orphan" pharmaceuticals);
- the launch of pharmaceutical procurement projects, including procurement at the expense of the obligatory medical insurance fund;
- the introduction of co-payments by patients for pharmaceuticals, as well as cumulative payments from the obligatory medical insurance fund;[13]
- improvements in the availability of qualified healthcare and pharmaceutical professionals; and
- the establishment of a system of so-called "reference prices" for pharmaceutical products.[14]

The Strategy has already been criticized for not being sufficiently concrete. The success of its implementation will depend in large measure on exactly what specific actions will be undertaken by the Russian government and other stakeholders to actually achieve the goals identified by the Strategy.

Advertising

On March 15, 2013, the Government of the Russian Federation approved a bill amending the Federal Law on Advertising. If passed, the bill would provide, among other things, for

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13 The obligatory medical insurance fund is one of Russia's social security funds (which also include pension and employment funds).

14 Currently, the Russian government regulates prices for vital and essential pharmaceuticals through a system of state registration of the maximum sale prices for various pharmaceutical producers (both Russian and foreign) and establishing maximum wholesale and retail price mark-ups for these pharmaceuticals (based on the manufacturer's maximum price, development costs, etc.). The Ministry of Health approves and registers the maximum sale prices. The Strategy contemplates the creation of a system of reference prices for all interchangeable pharmaceuticals. Although the Strategy does not provide details of such a system, indicating only that the system needs to be developed and tested, if properly implemented, such a system could better align state regulated sales prices for pharmaceutical products with their market prices, which would improve the system of state reimbursement of expenses for pharmaceutical products in the cases provided by law and would better protect the interests of both pharmaceutical companies and consumers.

mandatory notices in advertisements of bio-active supplements indicating that they are not pharmaceuticals, as well as for the extension of liability for improper advertising not only to the advertiser, but also to any distributor. On May 14, 2013, the bill was adopted by the State Duma in the first reading and is currently scheduled to be considered in the second reading on June 21, 2013.

The Bill would also add to the Code on Administrative Offenses a new provision prohibiting the improper advertisement of pharmaceuticals, medical goods, medical services and bio-active supplements, with penalties for such violations consisting of a fine in the amount of up to RUB 500,000 (approximately US$16,000) for legal entities and up to RUB 20,000 (approximately US$650) for individuals.

In addition, quite remarkably, the Government has asked the Ministry of Health and the Federal Antimonopoly Service to study the impact of simply prohibiting advertising of any pharmaceuticals in the mass media all together. A report was due by May 20, 2013. As of today, it has not been officially published.[15]

CLINICAL TRIALS

On March 20, 2013, the EU Commission released a report on cooperation in clinical trials.[16] The report provides a comparative analysis of the regulatory regime for conducting clinical trials in Russia and the European Union, indicating the similarities in the regulation and noting the existing administrative barriers for conducting clinical trials in Russia.

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Please do not hesitate to contact us with any questions.

May 31, 2013

[15] According to the most recent media reports, the Minister of Healthcare supports prohibiting advertising of any pharmaceuticals in the mass media. See http://www.newsfiber.com/p/s/h?v=E2XvscaLnQKs%3D+qiGgfwsrnaQ%3D.

[16] The report can be found at http://ec.europa.eu/health/files/international/report_clinical-trials__sept2012.pdf.