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New Federal Law ‘On the Circulation of Pharmaceuticals’: Quo Vadis?

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The Russian pharmaceutical market has undergone significant changes in the past couple of

years, and these changes are set to continue with the introduction of new Federal Law No. 61-FZ of April 12, 2010, "On the Circulation of Pharmaceuticals" (the "Law"). The Law is aimed at improving legislation regulating the circulation of pharmaceuticals, taking into account the development priorities for the pharmaceutical industry in Russia.

Despite the efforts of the Russian Federal Anti-Monopoly Service, the Law does not contain provisions developed by this agency aimed at restricting the promotion of pharmaceuticals by pharmaceutical companies through medical representatives. Further, despite foreign pharmaceutical manufacturers' expectations, the Law also does not establish any special regulations for the importers of pharmaceuticals that are the subsidiaries of foreign companies.

In our view, the most important provisions of the Law are as follows.

The Law focuses on establishing a precise and transparent process for registering medicines and strengthening the anti-corruption element in the circulation of pharmaceuticals. Currently, open-ended registration certificates for pharmaceuticals are issued. Under the new Law, registration certificates will be limited to a validity period of five years for their first registration. An open-ended registration certificate for pharmaceuticals will only be issued in the event of subsequent re-registration (confirmation of state registration). It is important to note that, under the new Law, medicines designated exclusively for export will not be subject to state registration.

The Law clarifies the provisions that regulate the clinical trials of medicines and introduces provisions that regulate the procedure for international clinical multicenter trials. As was the case previously, the Law requires that clinical trials of medicines are held only in medical institutions that have been accredited under the procedure established by the Russian government. It is expected that such research centers will have to meet the Good Clinical Practice (GCP) standard approved by Russian National Standard GOST R 52379-2005 "Good Clinical Practice" (this standard is a translation of the Consolidated Guideline for Good Clinical Practice of the International Conference on Harmonizing the Technical Requirements for Registering Pharmaceuticals for Human Use). The Law also raises the qualification level required by the researcher responsible for the relevant trial.

As far as the production of pharmaceuticals is concerned, the Law establishes a deadline of Jan. 1, 2014, for the transition by domestic pharmaceutical manufacturers to the new rules for the manufacture and quality control of pharmaceuticals. It is intended that the new rules will be stipulated in legal acts adopted by the Russian government and will comply with National Standard GOST R 52249-2009 "Good Manufacturing Practice" (this standard is a translation of the EU Guide to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, except for Annex 20).

Pharmaceutical production licenses issued before Jan. 1, 2014, will only be valid after the above date (until they expire) if the licensee meets the requirements for the new rules concerning good manufacturing practice.

In terms of pricing regulation, the Law repeats and for the first time introduces at the federal legislative level the main price regulation rules for vital and essential medicines ("Essential Medicines"), effective from Jan. 1, 2010, and introduced earlier by Russian Government

Resolution No. 654 of Aug. 8, 2009, "On Improving the State Regulation of Prices for Vital and Essential Pharmaceuticals."

The above rules can be summarized through the following main provisions. The Law requires that manufacturers register maximum selling prices for Essential Medicines. The list of Essential Medicines will be approved annually by the Russian government. Manufacturers will have to justify their maximum selling prices for Essential Medicines under the prescribed procedure and methodology for determining the maximum manufacturer's selling price for Essential Medicines.

Maximum wholesale and retail markups will be established in accordance with the respective methodology to be used by the executive bodies of Russian constituent regions for defining maximum wholesale and retail markups applicable to manufacturers' actual selling prices for Essential Medicines.

Maximum markups (both wholesale and retail) will only be established for the manufacturer's actual selling price (not exceeding the registered maximum manufacturer's selling price) and not for the selling price of the wholesale trader of the pharmaceuticals. The Law prohibits the sale of Essential Medicines whose maximum manufacturers' selling price has not been registered.

Importantly, the Law does not contain provisions that establish the state regulation of prices for medicines that are not Essential Medicines.

With the exception of certain provisions, the Federal Law will take effect on Sept. 1, 2010. From that date, the current Federal Law No. 86-FZ of June 22, 1998, "On Pharmaceuticals" will cease to be in effect. Pharmaceuticals registered before Sept. 1, 2010, will be included in state pharmaceutical registers without having to go through the state medicine registration process again.

It should also be noted that for the effective application of the Law, a range of subordinate legal acts need to be adopted (for example, rules concerning good manufacturing practice and the procedure for disposing of inferior and fake pharmaceuticals). We understand that such legal acts are currently being elaborated.

Overall, the Law was adopted to improve the provisions of the Development Strategy for the Russian Pharmaceutical Industry up to 2020, the main goals of which are to improve the competitiveness of the Russian pharmaceutical industry and import substitution. We hope that the provisions set out in the Law will help achieve these goals.

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