

Legal Alert

December 2009

Revised Draft of the Law on Circulation of Medicines Prepared

An amended version of the draft Federal Law “On Circulation of Medicines” (the “Draft Law”) was placed on the website of the Russian Ministry of Healthcare and Social Development on December 3, 2009. The initial Draft Law was published on the same website on July 8, 2009, attracting much attention and criticism. Many suggestions were made to improve the initial Draft Law so as to ensure the effective functioning of the Russian pharmaceutical market. In this Legal Alert we discuss only the most important aspects of the newly revised Draft Law as compared with its initial version.

1. Data Exclusivity Issue

In its Article 40, the initial Draft Law contained an attempt to introduce data exclusivity protection in Russia. Despite discussions regarding the exact language of Article 40, this was one of the most important developments in the initial Draft Law. For some reason, the new Draft Law completely removes Article 40 from its text, together with any traces of data exclusivity protection.

2. Introduced Improvements

The new Draft Law contains several improvements as compared with the initial draft:

- the list of grounds for cancellation of the state registration of medicines has been extended to include two new grounds: (i) an application to cancel the registration of a medicine by the initial applicant due to health risks related to the administration of the medicine; and (ii) the absence of a registered medicine in commercial circulation in Russia for more than five years;
- the prohibition against registering different medicines under the same trade names, and the same medicines under different names has been enhanced, and the second part of this rule now prohibits registration of a medicinal preparation manufactured by a manufacturer under different trade names;
- a reference to the right of the Russian Government to establish special types of customs duties applicable to foreign medicines has been removed;

- the pharmacovigilance rules have been made less stringent, and now use an “adverse reaction” as the main term instead of an “adverse event”. The new Draft Law demands that the following be reported: (i) side effects of medicines, and information on interactions with other medicines, which do not correspond to the information on these medicines contained in the instructions for their medical use; and (ii) adverse reactions. At the same time the new Draft Law does not contain a specific definition of “adverse reaction” (the definitions of “serious” and “unexpected” adverse reactions are based on the term “adverse event” and therefore provide no guidance);
- new separate provisions as to the destruction of medicines have been introduced;
- not only are veterinary medicines expressly covered, but the new Draft Law also establishes clearer distinctions between them and medicines for human use;
- the pricing regulations with respect to medicines apply to “medicinal preparations” (lekarstvennyi preparat) and not to “medicines” (lekarstvennoye sredstvo), in general, thus excluding active pharmaceutical substances and bulk medicines from the regulations’ application.

3. Suggestions not Reflected

The following suggestions with regard to the Draft Law were not taken into account in the preparation of the revised draft:

- the removal of the separation of the expert examination function from related state procedures (e.g., state registration of a medicine);
- express reference to the phases of clinical trials was removed, as suggested by experts; however, a classification of clinical trials as per their aims – identical to the classification of clinical trials as per phases – still remains;
- despite a suggestion to the contrary, the Draft Law still contains stricter requirements for clinical trials in Russia than those currently in force, making clinical trials generally less accessible in Russia;
- the suggestion to define and separate expedited and simplified procedures for the state registration of medicines, and to establish clear rules for each of them, was also not implemented in the revised Draft Law.

The revised Draft Law omits a definition of an orphan medicinal product and any special rules reflecting the particularities of this type of medicine (for example, application of an expedited procedure of registration), which were introduced in its initial version.

As of today the website of the Russian Ministry of Healthcare and Social Development invites comments to be submitted to the Draft Law

(including via the website itself). As of the date of this Legal Alert, the Draft Law has not yet appeared on the open electronic system of the Russian State Duma (lower chamber of the Russian Parliament) as introduced for its consideration.

Additional Notes

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