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B2B: New Registration Rules and Calculation Methodology for Vital and Essential Drugs

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On October 1, 2015, the new versions of the following regulations will come into legal force and effect:

The Rules for the state registration and re-registration of maximum sale prices set by pharmaceutical manufacturers for medicines on the list of vital and essential drugs ("EDL") (the EDL Price Registration Rules); and

The Methodology for calculating maximum sale prices set by pharmaceutical manufacturers for medicines on the list of vital and essential drugs (the EDL Price Calculation Methodology).

These new versions of the EDL Price Registration Rules and EDL Price Calculation Methodology were approved by the RF Government Decree No. 979 of September 15, 2015 (the Decree 979).

Decree 979 also clarifies the procedure for the maintenance of the state register of maximum manufacturers' sale prices for medicines (the EDL Price Register).

Decree 979 introduces a large number of changes that are nonetheless mainly supplementary in nature. The new versions of the EDL Price Registration Rules and EDL Price Calculation Methodology detail and formalize many issues concerning calculations of the maximum manufacturer's sale price for an EDL drug (the Maximum Price) and the grounds for changing it.

Integration of the Eurasian Economic Community (the EAEC) is reflected in the EDL Price Calculation Methodology by setting out special provisions applicable to manufacturers from EAEC states. Some of the rules contain specific provisions applicable to pharmaceutical manufacturers whose products fall within a specific price segment or to manufacturers

intending to package medicines in the Russian Federation, etc.

Acording to the new EDL Price Registration Rules, in order to register or re-register a Maximum Price for a medicine which is on the EDL (the EDL Drug) an applicant will have to provide more information than previously was required. For example, it will be necessary, inter alia, to provide information about the volumes and manufacturer's sale/import price of the EDL Drug in question and a justification for and calculations of the Maximum Price.

The amount of information needed to register the Maximum Price for an EDL Drug that have not yet entered into the Russian market has been considerably expanded. Manufacturers from EAEC member states will be required to provide information about the entity's accounting policy, a breakdown of expenses and costs, documentation of amounts of certain types of expenses, etc. Foreign manufacturers will be required to provide data supporting information about the foreign manufacturer's minimum sale price for such EDL Drug.

A manufacturer from any EAEC member state planning to package an EDL Drug in the Russian Federation, as well as a holder of a marketing authorization for an EDL Drug will be required to submit a similar set of information if there is no registered Maximum Price of the foreign manufacturer for that medicine.

A number of limits have been set for Maximum Prices. For example, if an application is being filed to register a Maximum Price within the three years from the date the Maximum Price for the same Medicine has been excluded from the EDL Price Register on the basis of an application from the same marketing authorization holder, the new Maximum Price applied for cannot be more than the price previously excluded. The Maximum Price of a generic (a medicine that has the same quality and quantity of active ingredients in the same pharmaceutical form as the reference drug and the bioequivalence or therapeutic equivalence of which to the reference drug has been confirmed by the relevant trials. Federal Law No. 61-FZ on the Circulation of Medicines of April 12, 2010)1 EDL Drug that is not in circulation cannot exceed 80% of the Maximum Price of the reference drug or its analog. The threshold for a biosimilar (a biological medicine similar in terms of quality, efficacy and safety parameters to the reference biological medicine in the same pharmaceutical form and having an identical mode of administration. Ibid.) drug is 90%. Limits on the Maximum Price are set for the second and subsequent foreign manufactured generic/biosimilar drugs (5% lower than the most recent registered Maximum Price for the similar drug), and also for cases of a significant decrease from the maximum registered Maximum Price for reference/similar drugs.

In addition, the new version of the EDL Price Registration Rules sets forth in much greater detail the grounds for re-registration of a Maximum Price. Among the reasons for re-registering a Maximum Price are change in prices for raw materials and supplies and overhead expenses, currency exchange rate fluctuations (for a foreign manufacturer's medicines), however, those are taken into account only if certain additional parameters are observed. The grounds for re-registration of Maximum Prices for EDL Drugs in the lower and average price segment of up to and including 500 rubles are set out separately.

A number of amplifying rules are also introduced to the EDL Price Calculation Methodology. The algorithm for recalculating prices for EDL Drugs of the lower and average price segment

of up to 500 rubles is set out in detail. Potential limits on the Maximum Price are clarified, for example, for medicines manufactured within an EAEC member state the price cannot be more than the minimum manufacturer's sale price in the countries for which the information about minimum manufacturer's sale prices for medicines (including customs duties and costs) is being provided.

At the same time, the list of those countries has changed. The "manufacturer's country" continues to be indicated in the list, but the vague wording "other countries" has been removed, Germany was deleted from the list, but Hungary was added.

Attention of manufacturers from EAEC member states planning to do primary and/or secondary packaging of Medicines in the Russian Federation is drawn to the fact that the Maximum Price proposed for registration cannot exceed the maximum registered foreign manufacturer's maximum sale price for that medicine. Furthermore, when calculating the Maximum Price for a different quantity of EDL Drug in the secondary (consumer) packaging, the price for a single pharmaceutical unit cannot increase.

The new version of the EDL Price Calculation Methodology generally corresponds to, and is largely consistent with, the new version of the EDL Price Registration Rules.

Manufacturers and developers of essential medicines should take into account that, according to the statements of the governmental officials (Interview with Timofey Nizhegorodtsev, Head of the Department for the Protection of Competition in the Social Sphere and Trade of the Federal Antimonopoly Service of Russia — in Russian), the new versions of the EDL Price Registration Rules and EDL Price Calculation Methodology are only the first stage in making changes to EDL pricing regulation, and other amendments are expected to be adopted by 2016.

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