FROM 1 OCTOBER, NEW RULES HAVE BEEN IN FORCE FOR REGISTERING (RE-REGISTERING) THE MAXIMUM SELLING PRICES OF MEDICINES INCLUDED IN THE LIST OF VITAL AND ESSENTIAL MEDICINES

For the attention of Russian and foreign manufacturers and developers of medicines included in the List of Vital and Essential Medicines.

Pepeliaev Group advises that the Russian Government has adopted a Resolution (the "Resolution"[1]) which has amended the rules for registering and re-registering the maximum selling prices for manufacturers of medicines included in the List of Vital and Essential Medicines ("VEM"). The Resolution also provides for a new method for calculating such prices[2].

The Resolution came into effect on 1 October 2015.

Main New Developments

The holder or owner of a registration certificate for a medicine[3] or any person authorised by such holder or owner may file an application for the maximum selling price of a medicine to be registered.

The fact that this approach is becoming entrenched may be interpreted as a very positive trend. The previous version of the document stated that an application may be filed by the manufacturer or a person authorised by it, although in practice the registering authority met the holders of a registration certificate halfway. However, the resulting situation was ambiguous, for example, for contractual manufacturing. It is obvious that the developer should determine the pricing policy for the medicine; however, the developer thought that it had the power to file an application to have the maximum selling price of a medicine registered. Sometimes it used its status as leverage during negotiations[4]. As a result, differences emerged between the contract manufacturers and the developers of a medicine.

The new Resolution takes into account the prospects of a single EEU market. The general rule is that the maximum selling prices of medicines *manufactured in EEU member states* (not only produced by Russian manufacturers, as was previously the case) and circulating in Russia are calculated based on the actual weighted average selling price of the medicine for one calendar year according to information about the volumes and selling prices of the medicines.

[1] Resolution No. 979 of the Russian Government dated 15 September 2015 "On amending Resolution of the Russian Government No. 865 dated 29 October 2010 and approving the method for calculating the maximum selling prices of medicines set by the manufacturers of medicines included in the list of vital and essential medicines and applied when such prices are registered and re-registered".

[2] Before, these guidelines represented a separate document, which was not quite correct, either from the legal perspective, or in terms of user-friendliness.

[3] The developer or the manufacturer of a medicine, or any other legal entity having the right of ownership to the registration certificate, who is responsible for the quality, efficiency and safety of a medicine, is deemed to be the holder or owner of a registration certificate for a medicine (article 4(26.1) of Federal Law No. 61-FZ "On the circulation of medicines" dated 12 April 2010).

[4] However, regardless of the new features established by the Resolution, article 61(2) of the current version of Federal Law No. 61-FZ "On the circulation of medicines" dated 12 April 2010 still stipulates that an application to have the maximum selling price registered should be filed by the manufacturer of the relevant medicine. It can be only hoped that the relevant amendments will soon be made to that Federal Law.

The maximum selling prices of medicines *produced by foreign manufacturers* are determined based on (1) the actual weighted average price of the relevant medicine imported into Russia for one year, taking into account customs payments, which is determined according to information about the volumes and selling prices of the medicines, and (2) the minimum selling price of the relevant medicine (disregarding production sites) in foreign countries in relation to which information is provided about the minimum selling prices of medicines[5] ("foreign countries"), taking into account any customs payments.

While we consider each new aspect to be very important, the following should be emphasised.

1.1. The list of documents and information has been extended which should be submitted to have the manufacturer's maximum selling price registered

(1) The Resolution has significantly extended the existing list of documents and information to be submitted to have the maximum selling price of a medicine registered.

For instance, the application to have the maximum selling price registered/re-registered should contain, among other things, the following:

- the name of the holder or owner of the registration certificate for the relevant medicine, the email address and the name of the manufacturer, and the location of the production sites involved in manufacturing the medicine, indicating the stage of the production process;
- the number of the registration certificate for the medicine;
- the package contents of the medicine;
- the code of the medicine according to the anatomic, therapeutic and chemical classification recommended by the World Health Organisation;
- the code of the medicine according to the All-Russian Classifier of Products and/or the unified Commodity Classification for Foreign Trade of the EEU; and
- the signature and printed name of the authorised person, as well as his/her position and phone numbers.

The application must be accompanied by the information about the selling prices of medicines manufactured in EEU member states/import prices of medicines manufactured abroad that are in circulation in Russia. Previously, only information about the selling volumes/import volumes of medicines had to be attached to the application, along with the calculation of the maximum selling price and a substantiation of it.

(2) The Resolution establishes special requirements for the package of documents to be provided by a manufacturer. These requirements relate to registering the maximum prices of medicines which are for the first time put into circulation in Russia.

Thus, manufacturers from EEU member states should submit the following:

- a calculation of costs that relate to the development, manufacture and sale of a medicine, and costs relating to the necessary documents being provided;
- information about the entity's accounting policy regarding the way in which the general production costs and general business expenses are accounted for and allocated over the costs of medicines;
- documentary support for the amount of the general production costs and general business expenses;
- information about how the general production costs and general business expenses are recorded in the cost of a specific medicine;
- information about the output of the medicine and its share in the overall amount of medicines manufactured;
- documentary support for and a breakdown of expenses that constitute the largest proportion of the cost of the goods[6]; and
- a breakdown of costs incurred on manufacturing the relevant medicine and booked in the lines 'Raw materials' and 'Materials', as well as documentary support for the costs under the above categories.

[5] The list of foreign countries is set out in Appendix 4 to the Guidelines for Calculating Maximum Selling Prices Set by the Manufacturers of Medicines as approved by the Resolution.

[6] It should be noted that no such information was required before.

For their part, manufacturers from EEU member states who are planning to carry out primary and/or secondary packaging of the medicine in Russia (if there is no maximum selling price of this medicine for a foreign manufacturer), and also foreign manufacturers should provide the following:

- information about the minimum selling price set by an EEU/foreign manufacturer (without taking into account the production sites) for the medicine abroad, taking into consideration any customs payments; and
- information supporting the minimum selling price set by an EEU/foreign manufacturer for the medicine.

The Resolution stipulates that the above information should be provided specifically by the manufacturer of the relevant medicine. This raises fears concerning how this provision will in future tie in with the provision of the Resolution that the holder or owner of the registration certificate for the medicine (or a person authorised by such holder or owner) should file an application for the maximum selling price to be registered/re-registered. Moreover, as was mentioned above, it is the developer who may determine the price of the medicine; consequently, the developer should provide to the authorised body all the documents necessary for such price to be set.

It is obvious that the Resolution does not consider partial localisation (related to primary and/or secondary packaging the medicine being carried out) to be a ground for treating the medicine as having been manufactured in an EEU member state. At the same time, it directly follows from the document that localising production at the stage of primary and secondary packaging does not require the price to be registered again if the foreign medicine has already been registered.

1.2. Restrictions on the maximum prices of generics and biosimilars which are not in circulation in Russia

The Resolution provides for restrictions on the maximum prices of generics and biosimilars which are not in circulation in Russia. For instance, the price of generics may not exceed 80% of the registered average maximum selling price of the reference medicine and, should there be no reference medicine, of the registered maximum selling price of a similar medicine.

The maximum selling price of biosimilars may not exceed 90% of the registered average maximum selling price of the reference medicine and, should there be no reference medicine, of the highest figure for the registered maximum selling price of a similar medicine.

For second and subsequent generics/biosimilars manufactured abroad the price to be registered should be 5% lower than the highest figure for the latest registered maximum selling price of a similar medicine.

The Resolution interprets similar medicines as medicines having one international non-proprietary name or, if there is no such name, having the same chemical or generic name, and the same pharmaceutical form and dosage. However, this approach to the definition of 'similarity' of biomedicines may hardly be justified owing to the specific nature of the latter.

1.3. Having the manufacturer's maximum selling prices re-registered

Changes have also affected aspects of having the maximum selling prices of medicines re-registered.

(1) Specifications and additions have been made to the grounds for adjusting the maximum selling prices for medicines manufactured in an EEU member state.

(2) The ground has been established for adjusting the maximum selling price of a foreign manufacturer's medicine. This price may be re-registered if the exchange rate of the national currency of the manufacturing state to the Russian Ruble has risen starting from the day when the maximum selling price was registered (or re-registered for the last time) with the state authorities before the day when the documents were submitted to have the price re-registered again, and if this growth exceeds the inflation forecast for the current year set out in the federal law on the federal budget for the relevant financial year and target period.

(3) The Resolution also provides for the maximum selling price to be reduced on grounds of an application filed by the holder or owner of the registration certificate for the relevant medicine (or any person authorised by such holder or owner).

Another new change is a 30% restriction (based on various grounds) on the profitability of manufacturers from EEU member states when the maximum selling price is re-registered.

There are no similar restrictions in relation to foreign manufacturers. This, in our opinion, may create unequal conditions for manufacturers.

The Resolution does not give an answer regarding the procedure and rules for re-registering the maximum selling price when the entire production of a medicine has been localised. The solution offered by the Resolution concerns only the packaging stage being localised. It does not substantially look into the status of the price of a medicine when the country of origin is changed. The ultimate solution to this issue is especially important in connection with the idea, which has been actively discussed and incorporated into legislation, that production should be localised and preference should be given to manufacturers from EEU member states.

1.4. Changes made to the register entry about the manufacturer's maximum selling price being registered with state authorities

An important new feature is that no consent of the anti-monopoly authority is needed when a register entry is made about the state registration of the manufacturer's maximum selling price and changes in the name of the medicine, the formulation of the pharmaceutical form, the dosage, changes of the holder or owner of the registration certificate, manufacturer, changes in the names of the production sites, the number of the registration certificate of the medicine, the bar code applied to the secondary (consumer) package, and the package contents of the medicine (provided there are no changes in its amount in the secondary (consumer) package). At the same time, the latest registered price of the medicine remains in force.

What to think about and what to do

Russian and foreign manufacturers, as well as manufacturers from EEU member states (especially those who plan to localise packaging stages) should bear in mind that from 1 October 2015 the maximum selling prices of medicines included in the List of Vital and Essential Medicines must be registered and re-registered in accordance with the new rules set by the Resolution at hand.

Help from your adviser

Pepeliaev Group experts will readily provide advice on any issues concerning having the maximum selling prices of medicines included in the List of Vital and Essential Medicines registered and re-registered, as well as any issues of how to calculate such prices.

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