

# Tax Flash Report

Russia, Issue No 11 (209), August 2009

PRICEWATERHOUSECOOPERS 

## Price regulation changes for vital and essential pharmaceuticals

*Comment by Alina Lavrenteva and Yana Zoloeva*

### Price regulation changes for vital and essential pharmaceuticals

This flash report deals with Russian Government Regulation No.654 of 8 August 2009 "On Improving the State Regulation of Prices for Vital and Essential Pharmaceuticals" (hereinafter, the "Regulation").

The Regulation introduces amendments to existing price regulation acts related to vital and essential pharmaceuticals (hereinafter, the "Essential Pharmaceuticals"). The Regulation introduces the form of the protocol for approving prices for the Essential Pharmaceuticals (hereinafter, the "Price Approval Protocol"). The Regulation also defines organisational steps to be taken by federal executive bodies and executive bodies of Russian constituent regions for applying the amended rules.

The Regulation takes effect from 14 August 2009. The amended rules for regulating Essential Pharmaceuticals' prices will take effect from 1 January 2010.

The most important changes introduced by the Regulation are as follows:

### The system of state executive bodies in regulating prices for Essential Pharmaceuticals

When the Regulation and the respective amendments take effect, the competency of government agencies will be defined as follows:

- The RF Government shall approve the list of Essential Pharmaceuticals;
- The RF Ministry of Health and Social Development shall submit to the Government a draft list of Essential Pharmaceuticals and develop and approve the methodology for defining the maximum manufacturer's selling price for Essential Pharmaceuticals (hereinafter, the "Price Definition Methodology");
- The RF Federal Tariff Service (hereinafter, the "FTS") shall develop and approve the methodology to be used by executive bodies of Russian constituent regions for defining maximum wholesale and retail mark-ups applicable to manufacturers' actual selling prices for Essential Pharmaceuticals (hereinafter, the "Mark-ups Definition Methodology") and shall approve maximum selling prices of Russian and foreign manufactures of Essential Pharmaceuticals;

- The Federal Service for Health and Social Development Supervision (hereinafter, "Roszdravnadzor") shall perform the state registration of maximum selling prices of Russian and foreign manufactures of Essential Pharmaceuticals approved by the FTS, maintain the state register of the registered maximum selling prices of Russian and foreign manufactures of Essential Pharmaceuticals and monitor the product range of Essential Pharmaceuticals and their prices;

- The Federal Customs Service shall on a monthly basis provide the Russian Ministry of Health and Social Development and Roszdravnadzor with information on the actual prices for Essential Pharmaceuticals imported into Russia and in what volumes they are imported;

- The executive bodies of Russian constituent regions shall set maximum wholesale and retail mark-ups applicable to the actual selling prices of manufacturers of Essential Pharmaceuticals, in accordance with the Mark-ups Definition Methodology.

Thus, the power of the federal executive bodies to regulate prices on Essential Pharmaceuticals shall be extended and additional regulatory acts for price regulation will be developed and approved, including the Price Definition Methodology and Mark-ups Definition Methodology aimed at harmonising the system of price regulation. In addition, the monitoring of prices for Essential Pharmaceuticals is to be increased.

### Mandatory state registration of maximum selling prices

The manufacturers of Essential Pharmaceuticals (or legal entities acting on their behalf) are required to register/re-register before 1 March 2010 the maximum selling prices for Essential Pharmaceuticals in accordance with the Price Definition Methodology.

Mandatory registration/re-registration of maximum selling prices shall apply to Essential Pharmaceuticals regardless of whether or not their maximum selling prices have been registered before 1 January 2010.

Since the Price Definition Methodology is expected to be approved by the end of 2009, in practice the statutory deadline for registration/re-registration may be difficult to meet. Therefore, the manufacturers of Essential Pharmaceuticals (companies representing their interests in Russia) should monitor



the process of adopting the Price Definition Methodology and begin preparing documents for registering/re-registering prices for Essential Pharmaceuticals immediately after the respective document is approved.

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### Definition and registration of maximum selling prices

A manufacturer will be required to justify the maximum selling prices for Essential Pharmaceuticals as required under the Price Definition Methodology,

The maximum selling price of a Russian manufacturer will be based on prices for **similar** (according to international unpatented name, form and dosage) pharmaceuticals in Russia.

The maximum selling price of a foreign manufacturer will be based on the minimum price for the pharmaceutical applicable in the country of the manufacturer and other states where such pharmaceutical is registered, and taking into account associated transportation costs.

The Regulation does not provide for the list of states where the prices for Essential Pharmaceuticals should be taken into account when setting maximum selling prices. Nor does it entitle a foreign manufacturer to include any expenses other than transportation costs in the calculation of the maximum selling price. The approach towards determining the maximum selling prices for Essential Pharmaceuticals may give rise to disputes between federal executive bodies and manufacturers, given a potential mismatch between pharmaceutical markets in other countries and the Russian pharmaceutical market, in terms of regulating rules, the length of time of a medicine on the market, supply volumes and additional payments necessary for selling a medicine (for example, marketing expenses, product storage expenses, tax liabilities of pharmaceutical market players, etc.).

The Regulation provides that a decision to refuse the registration of a maximum selling price by Roszdravnadzor can be appealed to a special commission for settling disputes arising in connection with the state registration of maximum selling prices for Essential Pharmaceuticals, and/or to a court.

The Regulation also provides for a transfer from the state registration of maximum selling prices of foreign manufacturers in a foreign currency to their registration in roubles:

- Before 1 January 2010: in a foreign currency **and** in roubles at the RF Central Bank exchange rate as of the date of state registration, the maximum rouble price shall be re-calculated when the state register of pharmaceutical prices is updated;

- In 2010: in roubles or a foreign currency. If the price is registered in a foreign currency, it shall be re-calculated in roubles at the RF Central Bank exchange rate as of the date of state registration and when the state register of pharmaceutical prices is updated;

- From 1 January 2011: in roubles.

### Maximum wholesale and retail mark-ups

Maximum wholesale and retail mark-ups will be established by the executive bodies of Russian constituent regions as a percentage and may differ *depending on the cost of pharmaceuticals* and geographical position, available transportation facilities and other specific aspects. Currently, the law does not directly allow a differentiation in mark-ups.

As is presently the case, the maximum selling price for pharmaceuticals should be based on the manufacturer's actual price (not exceeding the maximum registered selling price) and the wholesale and/or retail mark-ups within the respective maximum mark-ups established in a Russian constituent region.

In contrast to the current regulation procedure, the Regulation and the applicable amendments require that the maximum mark-ups (both wholesale and retail) should be applied to the actual selling price of the manufacturer (which should not exceed the maximum registered selling price of the manufacturer), and not the selling price of a wholesale trading company.

For pharmaceuticals produced outside Russia, the maximum selling price should be determined based on the actual selling price of foreign manufacturers (not exceeding the maximum registered selling price) which is declared at Russian customs, including customs duties and the custom clearance fee. The maximum selling price registered in a foreign currency shall be recalculated in roubles at the RF Central Bank exchange rate as of the date of the cargo customs declaration.

Wholesale companies will be allowed to sell pharmaceuticals only if the Price Approval Protocol is completed. Pharmacies will have the right to sell pharmaceuticals provided the Price Approval Protocol is available.

It should be mentioned that, at present, the requirement to complete the Price Approval Protocol is established only at Russian constituent region level and not federal level; in practice, market players often do not comply with the above requirement. With the introduction of the Regulation and related amendments, the execution of the Price Approval Protocols will become mandatory in Russia, and is expected to become the focus of close scrutiny by the government. Non-compliance with the Price Approval Protocol requirement may entail negative consequences for market players, including suspension and revocation of their licenses.



### Change of license requirements

License requirements related to the production of pharmaceuticals approved by RF Government Regulation No. 415 of 6 July 2006 have been amended, to include a provision regarding the mandatory state registration of maximum selling prices of manufacturers for Essential Pharmaceuticals.

License requirements for pharmaceutical activity approved by RF Government Regulation No. 416 of 6 July 2006 have been added with the requirement for licensees to comply with statutory maximum wholesale and retail mark-ups applicable to the actual selling prices of the manufacturers of Essential Pharmaceuticals.

Failure to meet the above license requirements shall be considered a gross violation and, if from 1 January 2010 a licensee is held administratively liable for violation of the above requirements, a license can be suspended or revoked by judicial procedure.

### Changes in rules of importation and exportation of Essential Pharmaceuticals

The rules for importing and exporting pharmaceuticals, approved by RF Government Resolution No. 438 of 16 July 2005, have been amended to include the following provisions.

In order to obtain a decision from Roszdravnadzor regarding the issuance of a license for importing pharmaceuticals, the applicant is required to provide additional data on the actual prices for imported Essential Pharmaceuticals and documents on the state registration of the maximum selling prices of the manufacturer for the imported Essential Pharmaceuticals.

Thus, from 1 January 2010, failure to meet the above requirements may result in a negative decision from Roszdravnadzor regarding the issuance of a license for importing Essential Pharmaceuticals, the absence of such license and, as a consequence, the inability to import Essential Pharmaceuticals into Russia.

When pharmaceuticals are imported into Russia, customs authorities should be provided with data on the actual prices of imported Essential Pharmaceuticals and their import volumes.

### Gaps in the Regulation

We believe that the new rules contain a number of gaps related to price regulation for Essential Pharmaceuticals. In particular, there are still no grounds for revising the maximum registered selling prices for Essential Pharmaceuticals and no established revision procedures. The limits of powers of Russian constituent regions bodies for establishing maximum wholesale and retail mark-ups (namely, the minimum level of statutory mark-ups) have not been introduced. These gaps may potentially be addressed in the Price Definition Methodology and Mark-ups Definition Methodology, which are expected to be approved by the end of 2009.

What also remains insufficiently regulated is the application during the transition period (i.e., from 1 January 2010 to the date of registering the maximum selling prices of manufacturers of Essential Pharmaceuticals) of the provisions related to liability, suspension/revocation of licenses and the rules for importation. We understand that the absence of mandatory registration may also be due to reasons outside the control of the manufacturers of Essential Pharmaceuticals, for example: a delay in approving the Price Definition Methodology or a delay on the part of government authorities in registering maximum selling prices for Essential Pharmaceuticals.



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