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On 1 October 2015 the rules for registering ED prices and the methodology for calculating them were amended

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Government Resolution No.979 dated 15 September 2015 introduced changes to Government Resolution No.865 dated 29 October 2010 "On the State Pricing Regulation for Essential Drugs"; in particular, it:

- **§ 1. Extended the list of documents and information provided for the registration and re-registration of Essential Drugs (ED)**
- **§ 2. Introduced an option to change the state registration record without FAS approval and without a change in the registered selling price**
- **§ 3. Introduced an improved selling price calculation methodology for ED produced in the Eurasian Economic Community (EEC) and by foreign manufacturers**
- **§ 4. Envisaged selling price restrictions for generic and biosimilar ED not previously sold in Russia**
- **§ 5. Specified the procedures and grounds for re-registration, also applicable to foreign RD producers**

Registration of maximum ED selling prices

§ 1. The government resolution **extends the list of documents and information to be submitted for the registration and re-registration of maximum ED selling prices**; in particular, the following data should be submitted:

- information on the sale and import prices of ED in circulation in Russia
- a calculation of expenses related to the development, production and sale of ED produced by EEC manufacturers, and respective supporting documents
- the accounting policy of a company in relation to the procedure for accounting and allocating general and administrative expenses related to ED

§ 2. The resolution prescribes that **register entry changes** on maximum ED selling prices should be performed by the Ministry of Health, based on the application of a registration certificate holder or owner, **without the consent of the antimonopoly authorities**. Specifically, changes related to:

- the ED name, dosage form, dosage strength
- the ED registration certificate holder or owner
- the manufacturer or the name of the production site
- the ED registration certificate number
- the barcode on the secondary package
- the completeness of ED (provided there were no ED quantity changes in the secondary package).

The most recently registered ED price **remains unchanged** in the event of the above register entry changes.

§ 3. The resolution introduces an **updated methodology for calculating maximum ED selling prices.**

ED produced by EEC manufacturers:

- **ED previously in circulation in Russia:**
  - the maximum selling price of ED **produced by an EEC manufacturer and in circulation in Russia** should be calculated based on the **weighted average actual selling price** for such ED per one calendar year, using data on the volume and selling prices of such ED
  - the maximum selling price of ED **should not exceed the weighted average actual selling price of ED for the previous (in certain cases current) calendar year** (the procedure was not significantly changed in comparison with the previous methodology).
- **ED not previously in circulation in Russia:**
  - the maximum selling price of ED **produced by an EEC manufacturer** (including primary and (or) secondary packaging) which were **not in circulation in Russia for one year** should be calculated based on the amount of **expenses to develop, produce and sell such ED**
  - in the event that the EEC manufacturer is planning to carry out primary and secondary packaging on the territory of the Russian Federation, the maximum selling price subject to registration **should not exceed the maximum registered selling price of the foreign manufacturer for such ED**, and in the event of the absence of such a price, the **minimum selling price for such ED in a selected list of foreign countries**, including customs charges.

ED produced by foreign manufacturers:

- **ED previously in circulation in Russia:**
  - the maximum selling price of ED **produced by a foreign manufacturer and in circulation in Russia** should be calculated based on the **weighted average actual import price** of such ED for one calendar year, using data on the volume and import prices of such ED, including customs charges
  - the maximum selling price of ED **should not exceed the weighted average actual selling price** of such ED for the previous (in certain cases current) calendar year
- **ED not previously in circulation in Russia:**
  - the maximum selling price of ED **produced by a foreign manufacturer which were not in circulation in Russia** should be calculated based on the **minimum selling price for such ED in a selected list of foreign countries**, including customs charges, and **should not exceed such minimum selling price of the foreign manufacturer**

The methodology also prohibits an increase in the price of one dose in a secondary package in the event of a change in the quantity of ED in the package

Pricing specifics of generic and biosimilar drugs

§ 4. The resolution introduces a special pricing **procedure for generic and biosimilar drugs, which involves the application of decelerating factors** to the maximum selling prices for reference[1] and similar drugs.

Thus, the maximum **selling price for generic and biosimilar drugs** should not exceed the average maximum ex-factory price for the reference drug for three years, and in the event of an absence of the reference drug, the maximum registered selling price for the biosimilar drug, subject to the following **decelerating factors:**

Generic

- for registering the **first** ED produced in the EEC and by foreign manufacturers a **decelerating factor of 80%** to the maximum selling price of the reference or similar drug has been established
- for registering the **second and further** ED produced in the EEC and by foreign manufacturers a schedule of a **decelerating factor from 80% to 60%**, with a further decrease of 5% for each additional generic, has been established.

Biosimilar drugs

- for registering the **first** ED produced in the EEC and by foreign manufactures a **decelerating factor of 90%** to the maximum selling price of the reference or similar drug has been established
- for registering the **second and further** ED produced in the EEC and by foreign manufacturers a schedule of a **decelerating factor from 90% to 60%**, with a further decrease of 5% for each additional generic, has been established.

Re-registration of maximum ED selling prices

§ 5. The resolution specifies the **grounds and procedure for the re-registration of maximum selling prices of ED produced by EEC and foreign manufacturers upwards**

ED produced by EEC manufactures:

1. For ED whose price is less than or equal to RUB500, re-registration can be performed if the cost of **raw materials and components or overheads increases**. In such a case the **increase** in the maximum ED selling price **shall not exceed the actual inflation rate for the previous year, taking into consideration the forecast inflation rate of the current year**[2], as follows:

$$\Delta P^{*} = \frac{CPI \times (100 + i_f)}{100} - 100\%$$

where:

ΔP^{*} – the index of the ED maximum selling price increase

CPI – the previous year's consumer price index for goods and services (as a percentage)

i_f – the current year's forecast inflation rate established by the Federal Law "On Federal Budgets" for the respective financial year and planning period (as a percentage)[3]

[1] In accordance with Federal Law N 61-FZ of 12.04.2010 "On the Circulation of Pharmaceuticals", up until 1 January 2016 reference drug is defined as an original drug which is registered in Russia for the first time and used for assessing bioequivalence or therapeutic efficiency, quality, efficiency and safety of generic or biosimilar pharmaceuticals.

[2] Inflation rate is defined in accordance with the Federal Law "On Federal Budgets" for the year under consideration. The Federal Law is subject to publication at the Russian Newspaper website, http://www.rg.ru, or on an official internet-portal for legal information, www.pravo.gov.ru.

[3] Under recent legislative changes the federal budget for a three-year planning period will not be prepared from 2016, hence data is available for the next financial year only.

Furthermore, the **ED margin shall not exceed 30%:**

$$R = \frac{\text{Forecasted profit}}{\text{Cost}} \times 100\%$$

where:

R – the margin of the ED

Forecated profit – profit from the sale of ED

Cost – the amount of direct, general and administrative costs.

2. If the cost of **raw materials and components or overheads increases**. In such a case, the increase in the maximum ED selling price **shall not exceed the forecast inflation rate of the current year, and the ED margin shall not exceed 30%**

The procedure for the re-registration of maximum selling prices stipulated in points 1 and 2 above can be applied by EEC manufactures performing primary and (or) secondary ED packaging in Russia

3. If the **weighted average actual selling price** for the period (that expired after the date of the most recent price state registration (re-registration)) was **lower** than the respective registered selling price **by no more than the forecast inflation rate of the current year**. In such a case, the **increase** in the maximum selling price **shall not exceed the difference between the forecast inflation rate for the current year and the difference between the registered maximum selling price and the weighted average actual selling price calculated** as a percentage, as follows:

$$\Delta P^* \le i_f - \frac{P^* - WAAP}{P^*} \times 100\%$$

where:

ΔP^* – the index of the ED maximum selling price increase

i_f – the current year forecast inflation rate established by the Federal Law "On Federal Budgets" for the respective financial year and planning period (as a percentage)

P^* – the registered maximum selling price

$WAAP$ – the weighted average actual selling price

ED produced by foreign manufacturers:

The re-registration of the maximum selling price for **ED produced by foreign manufacturers** can be performed **if the following conditions are met:**

1. **any growth in the manufacturer's national currency** against the Russian rouble for the period from the date of the ED price state registration (the most recent re-registration) to the date of filing documents for the next re-registration **exceeds the forecast inflation rate for the current period**
2. **the weighted average actual import price** for the period, which has expired since the date of the ED price state registration (the most recent re-registration), was **lower** than the registered ED selling price for this period by no more than the **forecast inflation rate for the current year**
3. **the maximum selling price** proposed for re-registration, net of customs charges, **does not exceed the minimum selling price for such ED in a selected list of foreign countries**, based on the price of one dose

Should the above conditions be met, the **increase** in maximum selling price in the course of re-registration **shall not exceed the difference between the forecast inflation rate for the current year and the difference between the registered maximum selling price and the weighted average actual import price**, calculated at present as follows:

$$\Delta P^* \le i_f - \frac{P^* - WAIP}{P^*} \times 100\%$$

where:

ΔP^* – the index of the ED maximum selling price increase

i_f – the current year's forecast inflation rate established by the Federal Law "On Federal Budgets" for the respective financial year and planning period (as a percentage)

P^* – the registered maximum selling price

$WAIP$ – the weighted average actual import price

The following grounds for **rejecting the registration or re-registration of the maximum ED selling price** have been adduced: the submission of unreliable information, an incomplete package of documents/information, the price proposed for re-registration exceeding the price calculated in accordance with the methodology.

Re-registration of the maximum ED selling prices should be performed in the event of application and document submission **before October 1 each year** and **no more than once in a calendar year.**

Based on statements from the state authorities, both the new version of the rules on the state registration and re-registration of maximum ED selling prices and the methodology for calculating maximum ED selling prices is transitional. It is planned that an updated document, regulating the procedure of ED pricing, will be submitted to the Federal Antimonopoly Service by 2016.