

## **1.1. Regulatory mechanisms**

The state regulation of prices for medicines included in the list of vital and essential medicines has been carried out since 2010, the basic requirements and principles of which are established by the Federal Law “On Circulation of Medicines”<sup>1</sup>.

One of the main requirements that has been in force since 2010 is setting prices in Russia in accordance with the minimum price level for the same drugs being set in reference countries for Russia.

Moreover, the list of countries in accordance with which information is provided by drug manufacturers has been established by the Government of the Russian Federation and has been in effect since 2010.

The FAS Russia in pursuance of the instructions of the President of the Russian Federation V. Putin conducted an international comparative analysis of prices and found a significant excess of prices for a part of drugs in Russia compared to the minimum selling prices in many countries around the world, including those that are reference for Russia.

According to the results of the set of measures undertaken by the FAS Russia to reduce the maximum selling prices of drug manufacturers registered in Russia to the minimum prices in reference countries for Russia, as of October 15, 2018, prices of 1043 previously registered expensive vital and essential medicines were reduced. The average price reduction was 43%, and the largest decline in monetary terms was 240 000 rubles (\$3 650) for one consumer package, which led to significant budget savings (according to calculations, only for the federal budget, savings were more than 5 billion rubles (\$76 080 340) per year).

In addition, as a result of the research conducted by the FAS Russia, countries were identified with persistently high or consistently low prices for medicines.

In this regard, as well as in order to reduce the time and increase the effectiveness of the work carried out by the FAS Russia concerning the reduction of prices for medicines, the Russian Ministry of Health, together with interested federal executive bodies, have developed a draft Decree of the Government of the Russian Federation “On the state registration and re-registration of maximum sale prices for medicines included in the list of vital and essential medicines ”(hereinafter - the draft Decree),

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<sup>1</sup> Federal Law of 12.04.2010 No. 61-FZ “On Circulation of Medicines”

which establishes obligation to owners or holders of medicines registration certificates to revise registered prices of medicines in the event of their reduction in the reference countries.

The practice of using pricing information in other countries is widespread in the world.

The FAS Russia analyzed the European experience in applying external price regulation using the example of the European Union countries<sup>2</sup>. Further, tab. 1 presents information on those countries that, along with Russia, use prices in the reference countries for the Russian Federation:

*Table 1*

<b>Reference countries for the Russian Federation</b>	<b>Countries that use price information in price regulation in each of the reference countries for Russia (presented in column 1)</b>
1	2
Hungary	Austria, Belgium, the Czech Republic, Estonia, Greece, Italy, Lithuania, Latvia, Malta, Poland, Romania, Slovakia
Greece	Austria, Belgium, the Czech Republic, Cyprus, Germany, Spain, Finland, Hungary, Italy, Poland, Romania, Slovakia
Belgium	Austria, the Czech Republic, Germany, Denmark, Greece, Spain, Finland, Hungary, Ireland
Spain	Austria, Belgium, Bulgaria, the Czech Republic, Germany, Greece, Finland, France, Hungary, Ireland, Malta, Italy, Poland, Portugal, Romania, Slovakia
Netherlands	Austria, Belgium, Switzerland, the Czech Republic, Germany, Denmark, Greece, Spain, Finland, Hungary, Ireland, Norway, Poland, Portugal, Romania, Slovakia
Bulgaria	Belgium, Greece, Finland, Hungary, Italy, Lithuania,

<sup>2</sup> European Commission report “External reference pricing of medicinal products: simulation-based considerations for cross-country coordination”:  
[https://ec.europa.eu/health/sites/health/files/systems\\_performance\\_assessment/docs/erp\\_reimbursement\\_medicinal\\_products\\_en.pdf](https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/erp_reimbursement_medicinal_products_en.pdf)

	Poland, Romania, Slovakia
Poland	Austria, Belgium, the Czech Republic, Greece, Spain, Finland, Hungary, Ireland, Norway, Poland, Portugal, Romania, Slovakia
Croatia	Hungary, Italy, Poland, Slovakia, the Czech Republic,
Romania	Belgium, Bulgaria, Greece, Finland, Hungary, Italy, Latvia, Poland, Slovakia
Slovakia	Austria, Belgium, Bulgaria, the Czech Republic, Germany, Greece, Spain, Finland, Hungary, Italy, Lithuania, Latvia, Malta, Poland, Portugal, Romania
France	Austria, Belgium, Bulgaria, Switzerland, Cyprus, the Czech Republic, Germany, Greece, Spain, Finland, Croatia, Ireland, Italy, Holland, Poland, Portugal, Slovenia, Slovakia
Czech Republic	Austria, Belgium, Germany, Greece, Finland, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, Slovakia

Thus, the principle of using prices in reference countries in the Russian Federation corresponds both to the European practice of price regulation and to the positive experience of a significant reduction in prices for expensive medicines in the Russian Federation.

At the same time, at present, the Russian Ministry of Health, together with the FAS Russia, has developed a draft Decree of the Government of the Russian Federation, providing for changes to the current price registration rules.

The draft laid down the principles of price regulation proposed by the FAS Russia with due regard for law enforcement practice from 2015, including:

1. The transition for domestic medicines from the “costly” method of price registration to the “indicative” one, which will simplify the price registration process, as well as eliminate discrimination of domestic producers in comparison with foreign ones.
2. Introduction of the formula-dependent decrease of the coefficient for generic medicines from the price group of the reference medicine.

It provides for the dependence of the decreasing coefficient on the price of the reference medicine (the higher the price, the greater the coefficient). The size of the decreasing coefficients corresponds to international practice and make up to 60% for foreign and up to 45% for domestic medicines while canceling the use of coefficients for cheap medicines.

3. The necessity for manufacturers of vital and essential medicines to revise the registered prices in case of their reduction in the reference countries.

Such measure will contribute to the pricing of vital and essential medicines in the Russian Federation in accordance with prices in reference countries for Russia and eliminate the situation in which registered prices in Russia significantly exceed the prices of such medicines in most European countries.

4. Optimization of the list of reference countries with the exclusion of countries with persistently high prices, as well as countries with unstable price regulation systems.

5. Implementation of the revision of previously registered prices in accordance with the proposed approaches, which will result in the synchronization of prices in the Russian Federation with prices in the reference countries for Russia.

## **1.2. Antitrust mechanisms**

In 2017, the Federal Antimonopoly Service initiated a case<sup>3</sup> on the grounds of violation by Novartis Pharma LLC of Clause 1, Part 1, Article 10 of the Federal Law of 26.07.2006 No.135-FZ “On Protection of Competition” (hereinafter - the Law on Protection of Competition).

In accordance with Clause 1, Part 1 of the Article 10 of the Law on Protection of Competition, actions (lack of action) of an economic entity occupying a dominant position, which result or can result in prevention, restriction or elimination of competition and (or) infringement of the interests of other persons (economic entities) in the sphere of entrepreneurship activity or indefinite range of consumers are prohibited, including establishment and maintaining of monopolistically high price for a commodity.

The case was initiated because of the claim of the Moscow Government, which is the buyer of the "Tyverb" medicine (the “Lapatinib” International Non-Proprietary Name) for patients under the programme of government guarantees of free medical aid to the population.

The FAS Russia conducted an analysis of the state of competition in the commodity market of the "Lapatinib" medicine in accordance with the order of the FAS Russia of 28.04.2010 No. 220 "On establishment of the procedure for analyzing the state of

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<sup>3</sup> The FAS Press-release of 20.04.2017 "FAS opened a case against Novartis Pharma LLC": <http://en.fas.gov.ru/press-center/news/detail.html?id=49825>

competition in the commodity market" and found that Novartis Pharma LLC occupies a dominant position in the specified commodity market within the geographical borders of the Russian Federation.

As part of the investigation, Novartis Pharma LLC had to justify an increase in the price of the oncological medicine Tyverb (Lapatinib), which is under patent protection, by 35% in January 2016.

Having reviewed the case, the FAS Russia's Commission concluded that Novartis Pharma LLC, occupying a dominant position in the commodity market of the Lapatinib medicine in the Russian Federation, established a monopolistically high price for the medicine. The Commission made a decision on issuing a prescription to eliminate the revealed violation<sup>4</sup>.

On April 9, 2018, Novartis Pharma LLC was brought to administrative responsibility<sup>5</sup> for the sale in the territory of the Russian Federation of a medicinal product with the trade name "Tyverb" ("Lapatinib") at a monopolistically high price<sup>6</sup>.

The violator of the antimonopoly law is imposed an administrative fine: 912,500 RUB (\$13 884).

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<sup>4</sup> The FAS Press-release of 15.01.2018 «FAS: "Novartis Pharma" fixed monopolistically high price for "Tyverb"»: <http://en.fas.gov.ru/press-center/news/detail.html?id=52712>

<sup>5</sup> The FAS Press-release of 12.04.2018 «"Novartis" must return around a million rubles to the state for abusing dominance»: <https://fas.gov.ru/news/24746>

<sup>6</sup> The FAS Decision of 24.01.2018 on the case No. 1-10-30/00-18-17 on violation by Novartis Pharma LLC of the antimonopoly legislation (Russian version only): <http://solutions.fas.gov.ru/ca/upravlenie-kontrolya-sotsialnoy-sfery-i-torgovli/ak-4735-18-ak-4737-18>