



Federal Antimonopoly Service

Expensive Drugs Price Reduction

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Introduction

In 2016 the FAS Russia conducted a research in fulfillment of:

–The Instruction of Vladimir Putin, the President of the Russian Federation, dated 27.07.2016 No.Пр-1452 (Clause 3)

» **The information was gathered:**

- ❖ From Governing bodies in the sphere of healthcare and economy of the corresponding countries;
- ❖ From the Association of the Pharmaceutical Manufacturers, distributors and pharmacy chains of the corresponding countries;
- ❖ From open Internet sources;
- ❖ As a result of actual supervision in pharmaceutical organizations of the corresponding countries.

Participating Countries

43 countries took part in the research:

CIS

1. Austria 
 2. Belgium 
 3. Bulgaria 
 4. UK 
 5. Hungary 
 6. Germany 
 7. Greece 
 8. Denmark 
 9. Spain 
 10. Italy 
 11. Ireland 
 12. Lithuania 
 13. Netherlands 
 14. Portugal 
1. Poland 
 2. Rumania 
 3. Slovakia 
 4. Finland 
 5. France 
 6. Croatia 
 7. Czech Republic 
 8. Sweden 

OTHER

1. Azerbaijan 
 2. Moldavia 
 3. Russia 
 4. Uzbekistan 
 5. Ukraine 
- ### BRICS
1. Brazil 
 2. India 
 3. China 
1. Abkhazia 
 2. Australia 
 3. Argentina 
 4. Egypt 
 5. Canada 
 6. Korea 
 7. Morocco 
 8. Norway 
 9. Serbia 
 10. USA 
 11. Turkey 
 12. Switzerland 
 13. Japan 

Searching for opportunities for reduction of prices on expensive drugs (their procurement demands the largest part of the budget), increasing of efficiency of the budget expenses on medical supply

Stages of the Research

• **Stage 1. List 1 – “7 ICDs” program**

• This list includes **24** international non-proprietary names of the drugs, within the frameworks of which there are **292** registered drugs of different manufacturers in concrete packages (with consideration of different formulations, dosage forms and packages). In accordance with the auctions' results, in 2016 the Ministry of Health of the Russian Federation purchased **78** positions of the drugs.

• **Stage 2. List 2 – “HIV and Hepatitis” program 2**

• This list includes **43** international non-proprietary names of the drugs, within the frameworks of which there are **852** registered drugs of different manufacturers in concrete packages (with consideration of different formulations, dosage forms and packages). In accordance with the auctions' results, in 2016 the Ministry of Health of the Russian Federation purchased **107** positions of the drugs.

• **Stage 3. List 3 – “Tuberculosis and Vaccines” program 3 этап.**

• This list includes **19** international non-proprietary names of the drugs, within the frameworks of which there are **80** registered drugs of different manufacturers in concrete packages (with consideration of different formulations, dosage forms and packages). In accordance with the auctions' results, in 2016 the Ministry of Health of the Russian Federation purchased **18** positions of the drugs.

Brief Methodology

- Bringing prices received by FAS Russia to a comparable level is difficult due to the fact that different countries use different amounts of medicines from the selected lists with different trade names, dosages and packages.
- This study used data on producer prices, government procurement prices, and wholesale prices for medicines (excluding VAT).
- The prices are set for different dates and in different currencies.



To compare prices, each national currency was converted into US dollars at a weighted average rate of **12 months. 2016**

Research Results

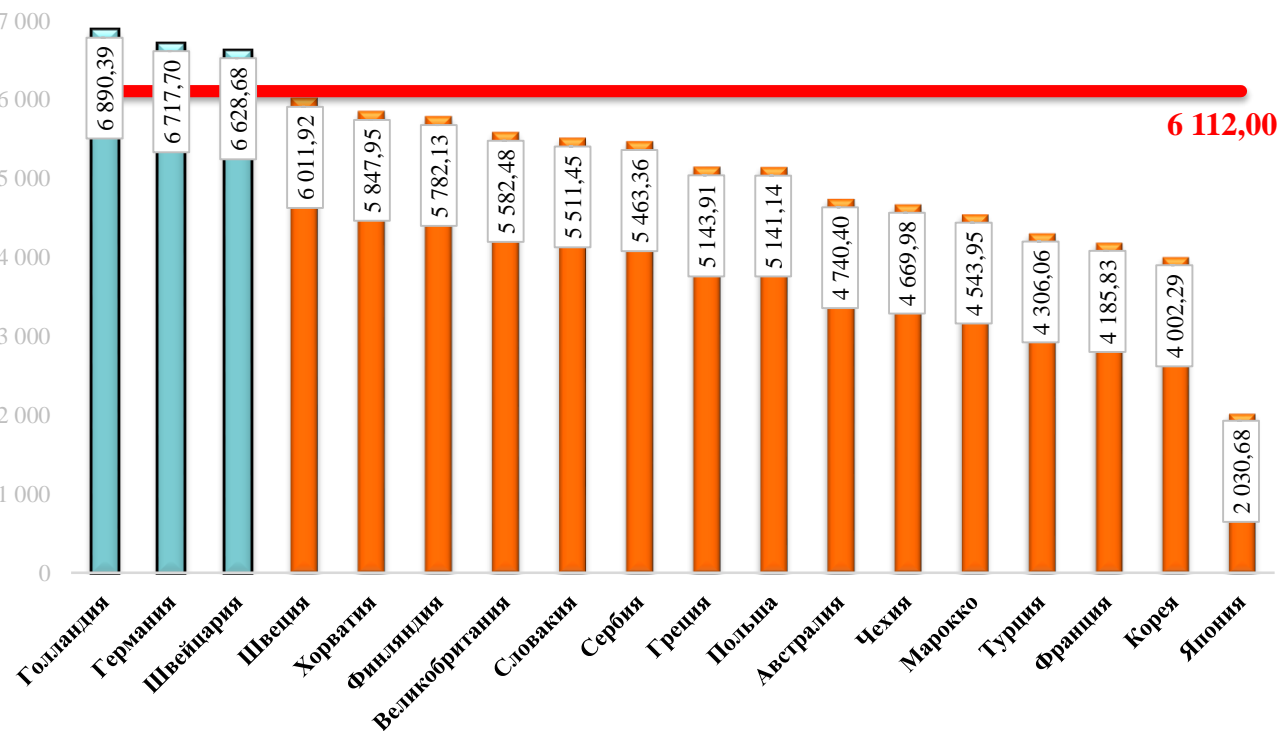
The results of the conducted research on this group of drugs showed that, in general, prices for them in Russia were lower than the prices revealed in the countries of the world examined. For 100 drugs, prices in Russia were the lowest among the countries surveyed.

168 positions of medicines were revealed, according to which the maximum selling prices of producers registered in Russia were significantly higher than the prices found in several countries of the world, including in countries that are reference for Russia. In Russia, the registration of prices for imported drugs is carried out at a level that does not exceed the minimum prices in the reference countries.

For all the cases of excess of prices registered in Russia over prices in reference countries, an analysis of the reasons for their overstatement was carried out and violations were detected during registration of prices, including the provision of incomplete or unreliable price information in the reference countries when registering prices.

Examples of **over-pricing** in Russia

Maximum prices in Russia and in other countries on Revlimid
(Lenalidomid), capsules 5 mg No.21, US \$ (VAT exc.)



On different dosage
of this drug the
situation is the same

Among 15 countries with the
lowest prices there are cases
when the marginal price in
Russia appeared to be higher
than retail prices in, for e.g. in
Australia

**7 countries with the lowest
prices** are included in the list
of referential countries

FAS Russia's actions on reducing prices

In order to prevent a possible shortage of medicines, the FAS Russia did not start the procedure for the abolition of price registration, but suggested that manufacturers of appropriate medicines voluntarily reduce the inflated prices

(an ad was posted on the official website of the FAS Russia, and letters were sent to each producer).

Negotiations were held with individual producers, which resulted in the companies agreeing to reduce prices to the minimum values.

In addition, the FAS Russia offered to voluntarily reduce prices for reproducible generic drugs manufacturers (generics), taking into account the reduced prices for reference medications.

FAS Russia's actions on reducing prices

For drugs whose manufacturers refused to reduce prices, the FAS Russia canceled earlier decisions on price harmonization (due to violations detected during their registration).

In particular, registered prices for medicines were abolished:



"Akineton"
(INN "Biperiden")
produced by Sirton
Pharmaceutical Sp. (Italy)



Imatinib
(INN Imatinib)
Produced by Biosintez Laboratories
Private Limited (India)

Reduction Results

As a result of the measures taken, FAS Russia succeeded in a short time without prejudice to patients and government customers

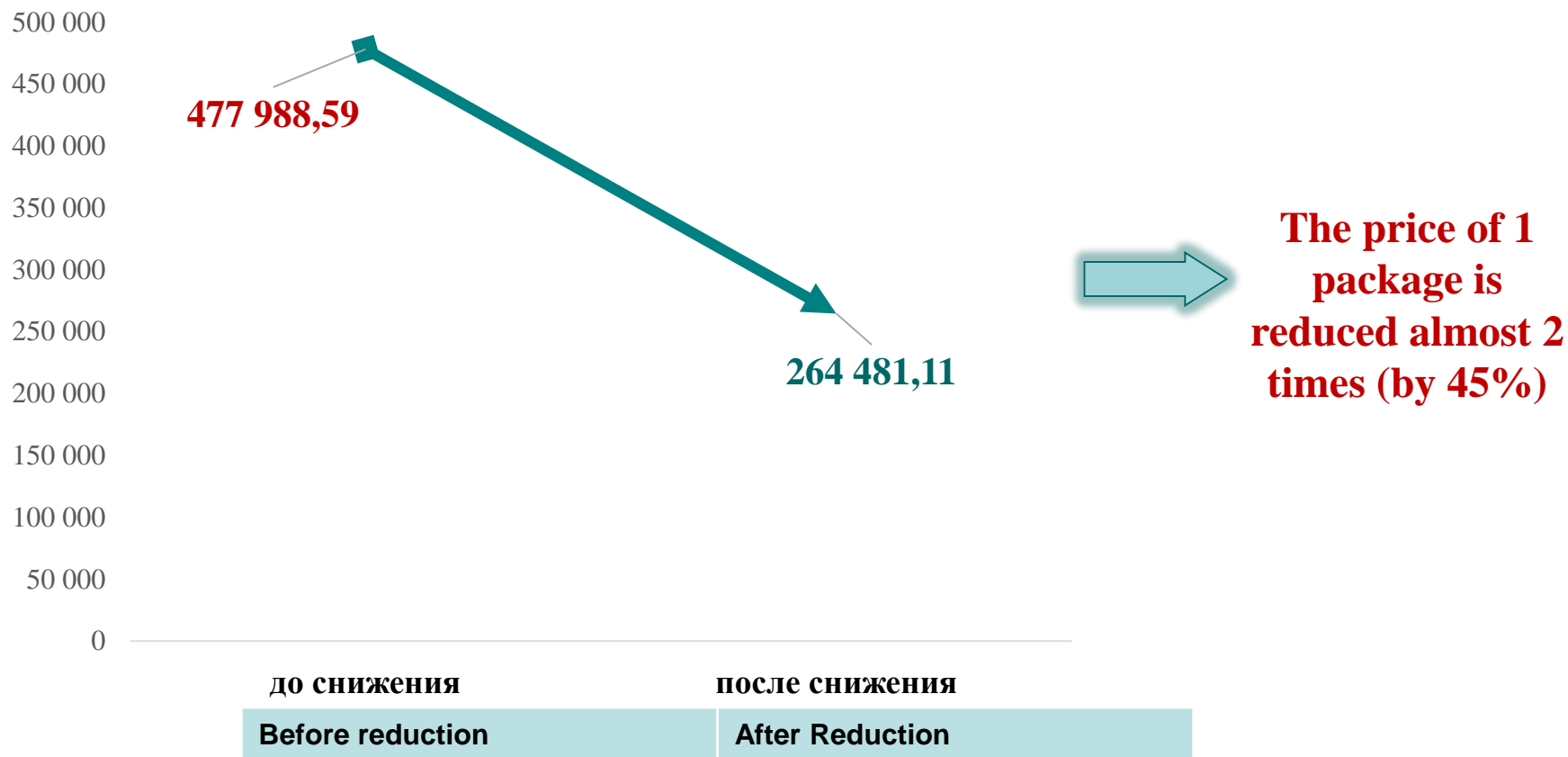
to achieve a significant reduction in the registered maximum selling prices of producers for **451 items** of expensive and essential medicines.

On average, the price reduction was 50%.

The measures taken by FAS Russia served as an incentive for lowering prices for other medicines, including Russian manufacturers.

Price Reduction Example

Reduction of the manufacturer's limit selling price for the Revlimid preparation (INN "Lenalidomide"), capsules 25 mg No. 21, rubles. without VAT for 1 packing



Results

- The revision of the registered marginal producer prices for medicinal products leads to **significant savings in budgetary funds**, which can be additionally directed to drug provision.
- According to calculations, the annual savings from the price reduction only for the Ministry of Health of Russia (excluding regional purchases) in 2017 will be more than **5 billion rubles**.
- Based on the results of the survey, the FAS Russia sent proposals to the President of the Russian Federation on improvement of procedure for registering the maximum selling prices for medicines. Currently, the Ministry of Health of Russia, in cooperation with the Federal Antimonopoly Service, is preparing the relevant amendments to the Order of the Government of the Russian Federation No. 865 dated October 29, 2010.
- Presently, the FAS Russia continues the analysis and work on reduction of prices for other, primarily expensive vital medicines.

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