



FEDERAL ANTIMONOPOLY SERVICE
Department of Control over Social Sphere and Commerce

RESULTS

**of the assessment of pharmaceuticals affordability
on basis of the analysis of consumer prices and
price setting for pharmaceuticals in the Russian
Federation (Federal subjects included) and on
comparable markets of other countries, comprising
the CIS, European Union and BRICS**

2013

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GENERAL STATEMENTS

In accordance with Minute 3 of the Meeting Held by I.I. Shuvalov, First Vice-Prime Minister of the Russian Federation on January 18, 2013 №ISH-P12-6pr, named “Concerning Measures, Aimed at Developing Competition on the Pharmaceuticals Market”, there it is entrusted to the FAS of Russia, the FTS of Russia, Public Health Ministry of Russia, the Ministry of Economic Development of Russia and the Russian Statistics Committee, together with the interested executive power bodies of Federal subjects as well as organizations, to undertake the assessment of pharmaceuticals affordability on basis of retail prices analysis and drugs price setting in the Russian Federation (Federal subjects included) and on comparable markets of other countries, including member-countries of the European Union and BRICS. They are also entrusted to organize field checks on the given matter in Federal subjects and report their results to the Government of the Russian Federation (hereafter – I.I. Shuvalov’s instruction, the instruction).

The Drafting of the report was conducted in fulfillment of:

- Minute 3 of the meeting held by I.I. Shuvalov, First Vice Prime Minister of the Russian Federation on January, 18, 2013 №ISH-P12-6pr “Concerning measures, aimed at developing competition on the pharmaceuticals market”.

During the drafting of the report there was used information of:

- The Ministry of Public Health of the Russian Federation;
- The Ministry of Economic Development of the Russian Federation;
- The Federal Tariff Service;
- The Federal Service of Health Care Control;
- The Federal Service for National Statistics;
- Commercial missions of the Russian Federation in countries of the European Union, BRICS and CIS;
- Antimonopoly bodies of the CIS’s state-members;
- The Government of the city of Moscow;
- 14 territorial departments of Russia’s FAS.

1. ACTUALITY OF THE STUDY UNDERTAKEN

The actuality of studying problems of pharmaceuticals price setting as well as of those of analyzing drugs affordability for the population is related to a steady increase of budget expenses for drug coverage. The actuality of this study is also related to gap in the population's coverage by state programs, including patients suffering from special illnesses, and to the ongoing growth of pharmaceutical prices against the backdrop of increase in volumes of drugs needed, due to the ageing of population and growth of chronic illnesses.

Owing to limited budgets of public health services all the countries undertake measures, aimed at streamlining expenses for pharmaceuticals and reducing drug prices.

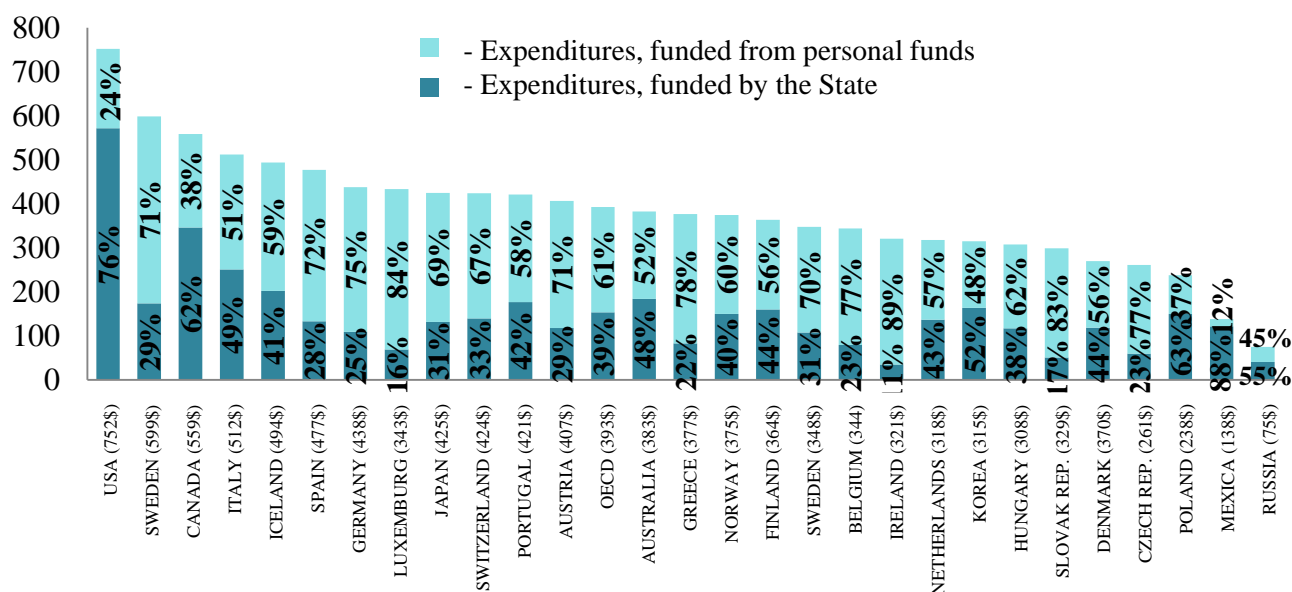
Thus wise, there it is necessary to search for opportunities to improve the efficiency of current expenses for drug provision, by means of reducing prices and bettering forms of accomplishing state programs of pharmaceutical provision. It's also necessary to search for ways of securing equal and universal medicine access for all the citizens, without increasing spending on public health services.

In the opinion of Russia's FAS, in Russia retail drug prices should be "fair" both in the state segment, and on the commercial market. It is necessary, in the first place, to undertake measures to lower prices for monopoly expensive pharmaceuticals.

2. COMPARATIVE ANALYSIS OF PHARMACEUTICALS AFFORDABILITY

According to the data by the OECD, presented by the Trade Mission of the Russian Federation in France, average per capita spending for pharmaceuticals in the EU countries amount to \$US 400 (producers' price). By experts estimates, in the Russian Federation this spending amounts to, approximately, \$US 75, what is, at the average, in 5,3 times less, than in the EU countries. In those countries spending on pharmaceuticals from state and public funds amounts, at the average, to more than 60% of total spending on pharmaceuticals, while in Russia – not more than to 45%.

Comparison of expenditure on pharmaceuticals per inhabitant in 2008, as reported by the OECD

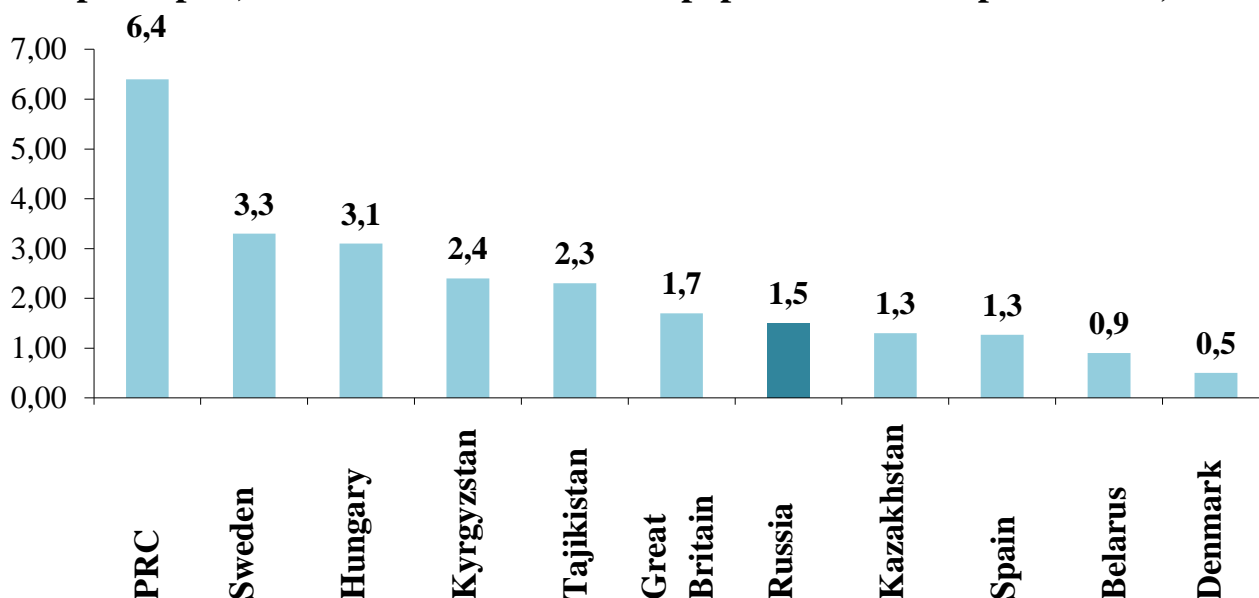


By estimates, in Europe average expenditure on pharmaceuticals comes up to, approximately, 17% of total expenditures on health care (from 7% in Norway up to 32% in Slovakia). In the EU countries the share of pharmaceuticals expenditures in the Gross Domestic Product (GDP) comes up, approximately, to 1,5% - producers' price- (from 0,5% in Luxemburg to 2,3% in Hungary) and in the Russian Federation – up to 0,43% - producers' price.

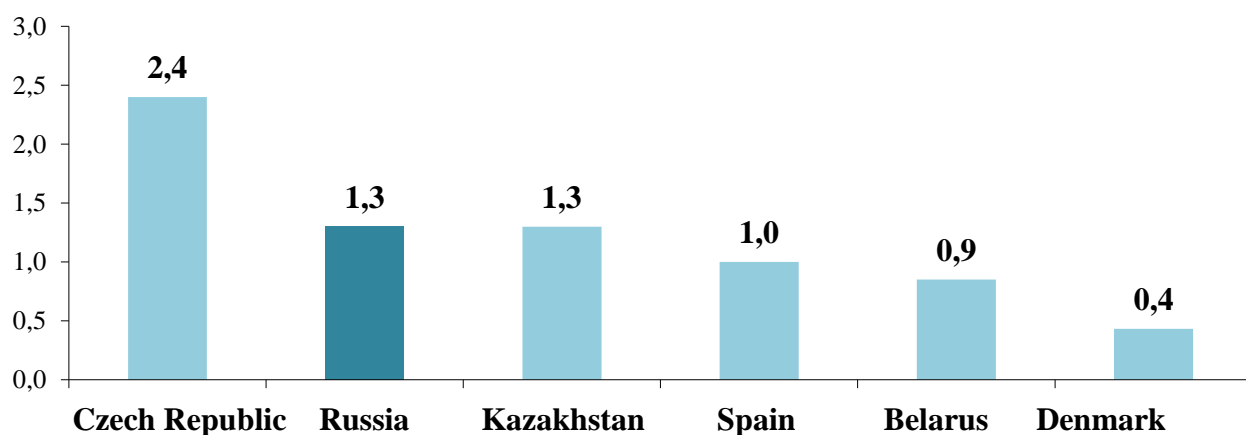
The problem of pharmaceuticals affordability in developed economies is related, first of all, to increasing expenditures on their acquisition. Galloping growth of health care costing is a global trend, which has recently turned into one of the leading factors contributing to economic growth retardation and development of crisis phenomena as well. Growth rates of state expenditure on health care services often exceed growth rates of the GDP and price index for consumer goods. Difficulties of advanced economies in given sphere are related to wide coverage and high level of state-subsidized expenditures on pharmaceuticals.

According to the official data, per capita expenditures of Russia's population on pharmaceuticals do not exceed their average level in the countries considered. However, it should be taken into account that the official data may considerably differ downward from the factual ones.

Approximate share of the population expenditure on pharmaceuticals (average per capita) in the total amount of the population cash expenditures¹, %



Approximate share of the population expenditures on pharmaceuticals (average per capita) relative to disposable population income, %



Drugs physical accessibility, not only their price, is an important factor in the population provision with drugs.

In Russia, due to the minimum distribution margin for pharmaceuticals of low price bracket, which does not guarantee a sufficient profit level, low-priced medications continue vanishing from pharmacies assortment.

¹ In Sweden the population expenditures on health care as a whole, including expenses on pharmaceuticals, come up to 3,3%.

In Great Britain expenditures on medical services, including those on medications, amount to 1,7%.

In China expenditures on pharmaceuticals come up to 6,4%. in town, and still more in the country – up to 8,4%.

The level of expenditures of medications in Russia has been calculated by Russia's FAS, based on the data, provided by the Statistics Service.

Moreover, many citizens, entitled to preferential provision with pharmaceuticals, don't get required medicines on account of their absence in corresponding lists.

In advanced economies, partial reimbursement of monetary means, spent on the drugs, prescribed by medical doctor, to the patient, when ambulatory, is a common denominator of the systems of pharmaceutical provision. The systems of reimbursement of monetary means for medicines, known as prescription drug insurance, operating in these countries, have a substantial impact on drug prices and on their affordability and accessibility for the population.

Besides the schemes of co-payment, there exist other schemes of motivation both for patients, and for pharmacies. In the majority of advanced economies the part of patients' expenditures on purchasing pharmaceuticals changes depending from a type of medication. If a medication is prescribed for treating a chronic illness or possesses a life-saving therapeutic endpoint, the share of co-payment by the patient may be inconsiderable.

There exist different forms of co-payments: fixed co-pay for a drug, prescription or package and co-pay of a certain percentage of the drug price. This percentage may vary in dependence from population groups. Moreover, the most socially vulnerable categories of population are exempt from co-payments. In France, in dependence from a type of illness, different population groups co-pay 0%, 35% or 65%. In the UK the co-payment is fixed and comes up to €6,1 (12,2 US\$), at that 80% of the population are exempt from co-payment. In Germany fixed co-payments are from 2 up to 10 Euros. The introduction of co-payments gives patients reasons to take generics (cheaper duplicated drugs).

In order to limit drug prescriptions by doctors, in a number of countries (Germany, France, UK) there exist budget limits for family doctors and medical specialists, working at outpatient-and-policlinic institutions. When and if they exceed those limits, they incur penal sanctions. In Great Britain, for instance, in the doctor's contract it is stipulated that out of pharmaceutical budget approved the doctor must spend not less 15% on the cheapest medications, including no less than 5% on generics. In different countries generics constitute various shares in general pharmaceutical expenditures: from 5% in Austria (it's related to low prices for original medications), 22% - in UK, and up to 40% in Germany and Sweden.

Country	Brief description of operational systems of pharmaceutical reimbursement/insurance
In the UE countries	
Austria	Fixed reimbursement for medication of any price
Bulgaria	75% of drug cost is reimbursed (in some cases – 100%)
Great Britain	Co-payment and 100% payment of prescription drugs
Hungary	Up to 10% of the cost is reimbursed

Germany	90% of the cost is reimbursed. The cost of cheap medications (which price is less than 5 Euro) is not reimbursed. The reimbursement of expensive drugs cost (which price is more than 100 Euros) is 100%.
Denmark	There is reimbursed only the cost of its cheapest equivalent
Spain	40-90% of drug cost is reimbursed
Lithuania	Partial and total reimbursement
Netherlands	There it is reimbursed up to 100% of cost of drugs which are on the basic insurance list
Poland	According to the corresponding drug list, there are reimbursed 100%, 70% and 50%.
Finland	There are reimbursed 35-100% of drug cost. Moreover, in case any citizen's yearly expenditures on drugs exceed 670 Euros, the surplus expenses are reimbursed.
France	40% of all pharmaceuticals costs are reimbursed in the amount of 15 to 100%.
Sweden	$\frac{3}{4}$ of prescription medicine costs (of around 2, 5 thousand medications) are reimbursed. Furthermore, in case any person's annual expenditures on pharmaceuticals exceed 162 US\$, there are granted discounts, amounting to 50% of the drug cost.
In the BRICS countries	
PRC	Reimbursement covers only a part of medications according to the insurance list.
In the CIS countries	
Armenia	A part of pharmaceuticals is granted preferential terms or 100% - reimbursed.
Kazakhstan	Up to 2012 there was reimbursed a half of medication costs for 7 types of illnesses. Since 2012 100% reimbursement is determined for certain illnesses.
Kyrgyzstan	There exist 50% cost reimbursements for 77 medications.
Moldavia	The National Company of Medical Insurance grants a partial or total cost reimbursement for a part of prescription medicines.
Russia	The population categories, entitled to benefits, get pharmaceuticals free on the programs of provision of necessary pharmaceuticals and that of additional provision of pharmaceuticals (pharmaceutical costs are not reimbursed, but given free on prescriptions).
Turkmenistan	Reimbursement of up 90% is provided for the cost of a part of locally produced medications.

As it can be seen from the above, practically, in all the countries, including the CIS ones, there operate state programs of providing the population with pharmaceuticals. In the Republic of Moldova there are introduced elements of pharmaceutical costs reimbursement (a partial or complete reimbursement of costs of a part of prescription medications by the National Company of Medical Insurance). In

the Kyrgyz Republic, within the framework of the CHI additional program, the CHI Fund reimburses around 50% of the cost of 77 medications. In the Russian Federation there are still being elaborated models of pharmaceutical costs reimbursement.

The FAS of Russia considers the following problems of pharmaceutical affordability for the population as the main ones:

1. Difficulties in getting reimbursable drug prescriptions as well as prescriptions for medications in commercial sale due to:

1.1. Prolonged procedure of filling out prescriptions (necessity to visit a doctor by appointment, long stay in the doctor's waiting room and prolonged filling out a prescription, doctors' redirection of the patient from one to another).

To solve this problem, it's necessary to simplify the procedure of receiving prescriptions, in the first place, for chronic patients and disabled persons, recipients of prescription medications free of charge or at their own expense from the medication list specified by the doctor.

1.2. Availability of reimbursable pharmaceuticals in quantity required at pharmacies (their deficiency, interruptions in their delivery, flooding of regional warehouses).

To solve this problem the FAS of Russia considers necessary to move from state procurement of medications, to be provided to citizens, entitled to benefits, to the system of pharmaceutical costs reimbursement to them.

2. The situation in rural and remote localities, where medication affordability is unsatisfactory, because of a low profitableness of pharmacies opened on such territories, reduction of the number of pharmacies, making up medications as well as of pharmacies, rendering a full variety of socially desirable services (namely, individual making up pharmaceuticals, night service, dispensing oxygen and narcotics, etc.), shortage of personnel there. The FAS of Russia believes that it is possible to promote the expansion of a network of pharmacies in small, remote or hard-to-reach municipal formations and on territories, inhabited by low-income population, through granting state and municipal preferences, inclusive reduced rate and long-term rentals of premises, alleviation from tax burden for such pharmacies.
3. Low level of financing pharmaceutical provision of the population, insufficient coverage of the population by state medication costs subsidizing and small amounts of reimbursement.

The FAS of Russia considers possible to solve this problem through a system of measures, aimed at enhancing the efficiency of using budgeting funds, among those: 1) incentive to generics production, 2) introduction of system of reimbursing the cheapest medication costs within interchangeable groups, 3) monitoring filling out prescriptions for generics, 4) procurements of innovative monopoly medications directly from the producers by negotiated price.

4. Absence of patient records on all the illnesses falling under the systems of medication provision, what results in insufficient effectiveness of mechanisms of control over expenses and in difficulties of planning expenditures on pharmaceutical provision in accordance with real needs of public health and the population.

It's necessary to set up a common federal and regional format for keeping patient records on all the illnesses, as well as to determine the order of their keeping compulsorily providing the confidentiality and safety of personal data. There should be set up a format of patient records on the illnesses, potentially falling into the systems of medication provision, as well as sub formats of records of patients /resistant to basis therapy.

3. SURVEY OF PROBLEMS OF PRICE REGULATION IN THE COUNTRIES OF EU, BRICS AND CIS.

Since pharmaceuticals are socially significant products, paid, to a great extent, by the state itself, all the countries seek to reduce their expenses; moreover, some of them seek to control markups of all the participants of sales process.

The system of regulation of pricing on pharmaceuticals in the CIS, CC and BRICS countries comprises a complex of different measures. They are aimed at creating conditions for patients for receiving necessary pharmaceuticals, over the corresponding time, in accordance with their clinic needs, both patients themselves and the state bearing minimum expenses.

It is ascertained by the FAS of Russia that in majority of the countries considered medication prices are regulated to any extent. The necessity to regulate medication prices is related to a continuing and anticipated increase of expenditures on public health, while possessing limited resources.

In the European Union the sphere, regulating medication pricing and medication costs reimbursement by state funds, is referred to the exclusive jurisdiction of the member-states. It means that the main requirements to pricing and reimbursement of medication costs, concrete sums of reimbursement, etc. is a prerogative right of the member-states. As a result, in the EU pricing and medication costs reimbursement there exist different national systems, based on diverse requirements, criteria and methods.

At present in some countries there are employed no restrictions on medication prices, including those, financed from public funds. Among such countries, for example, out of the CIS member-states, it is Kyrgyzstan (though in Kyrgyzstan there is employed a requirement to grant retail discounts - from 5 to 10% - to citizens entitled to them), as well as Tajikistan and Armenia; out of the EU countries – Great Britain (in Great Britain there is regulated the level of company incomes).

In the majority of countries considered cost regulation covers only a part of pharmaceuticals – most often those reimbursed and included into state programs of medication provision. The drugs, not financed at taxpayers' expense and accessible on the market, are not subject to the rules of pricing and their prices are freely determined by the ration of demand and supply. In other countries pharmaceuticals regulated range from prescription drugs (in Germany) or non-prescription ones (in the PRC) to the most expensive ones (in Austria) or most frequently sold ones, which price growth has got high dynamics (in India). There are other examples (Belgium, Austria, Lithuania), when, though a part of pharmaceuticals has got regulated prices, mark-ups and extra charges by wholesale and retail vendors are determined for all the drugs.

In certain countries there are employed mechanisms of indirect control over drugs offering. They include: control over producer's profits and incomes in given country (Spain, Portugal, Great Britain), fixing the maximum profit for wholesale

vendors and pharmacists (Poland, Denmark), compulsory discounts (France, Germany, Italy, Netherlands, Hungary), reduction of marketing expenses (Germany, France).

In the controlled price system different countries use diverse mechanisms. Reduction or freezing of medication prices (Italy, France, Germany, Spain, and Great Britain), centralized procurements and auction by tender are some of the most frequently used mechanisms of direct control over medication prices and, thus, of control over cumulative expenditures for pharmacotherapy. As to types of drug price regulation, all the countries can be divided into 3 main groups: heavy regulation of prescription drug prices (Belgium and Spain); regulation of pharma producers' profits (Great Britain); fixation of maximum retail drug prices, based on special formula (Greece, Netherlands, Portugal, Italy).

Regulation of medication prices comprises a system of the following interrelated functions:

- determination of pharmaceuticals, subject to price regulation;
- determination of concrete price components, subject to price regulation;
- determination of the method by which concrete price components are to be regulated;
- determination of concrete size of the price regulated.

In a number of countries there are separately fixed maximum wholesale and maximum retail mark-ups, sometimes –a common trade mark-up, that constitutes from 8% (Switzerland) up to 20% (Germany) and 37% (Czech Republic). Most often there is fixed a progressive mark-up scale depending from producers' pharmaceutical cost.

Proceeding from the lowest or one of the lowest prices on the market, there are determined fixed (reference) prices for the pharmaceuticals, which costs are reimbursed from state or public funds. Mechanisms for determining a reference price may differ. The system of reference prices (determination of a price by way of comparing drug prices on different markets with those on the domestic market) is widely used almost in the countries of the European Union.

The comparison of pharmaceutical prices on different markets is a direct method to determine the price, by which vendors can sell drugs on given market. It involves the determination of prices based on the drug price on a different market or fixed by other payers. For the first time external reference prices were brought into use in Canada in 1987. Since then they are most widely employed for determining drug prices in the OECD countries (in 24 of 30 countries, members of the Organization for Economic Cooperation and Development). Out of 25 EU countries surveyed the comparison of pharmaceutical prices on different markets is not employed only in 7 countries: Denmark, Latvia, Malta, Germany, Italy, Sweden and Great Britain.

The principle dissimilarities in attitudes to drug prices comparison on different markets deal with the following:

- criteria for choosing countries, where reference prices are taken into account;
- number of so called "reference" countries to be considered;

- formula, used for determining price in given state regarding “reference” countries;
- legal basis for solutions referring prices on the ground of prices in ‘reference’ countries.

The criteria for choosing “reference” countries can relate to the following:

- 1) pharmaceutical prices in neighboring countries (in the European Union countries);
- 2) drug price level in similarly economically developed countries (for instance, such criteria were approved of in Norway and considered earlier than 2008 reform; The Czech Republic simultaneously surveys prices in the equally GDP leveled countries and in not geographically remote ones);
- 3) drug price level in the countries, which are close economic partners (for example, Austria compares drug prices in 24 European Union countries, in other words, in all, with exception of Bulgaria and Romania; Luxemburg , that imports 99% of medications, uses the prices of the state which the medication was brought from, France and Germany, for instance).

Some countries have developed their own criteria, not used anywhere else. For example, in Canada the price is compared to the prices in France, Germany, USA, Switzerland, Sweden, Great Britain and Italy. These countries are chosen, because they facilitate innovations. In its turn, Mexico, after determining maximum price for certain drug, compares this drug price of the 6 countries, where the drug has become very popular(it means that for each drug there can chosen its own group of countries, and the choice of countries may change as time passes, because the list is changed once per year. It should also be noted that not in all the countries there is determined a clear cut basis for choosing “reference” countries; sometimes this choice is pre-conditioned by historic reasons.

The quantity of “reference” countries, which are taken into account, while determining drug prices, is very variable too. In the majority of cases there are chosen from 2 to 7 “reference” countries, but in Austria there are 24 of them.

The formula, used for determining pharmaceutical prices, based on the information from “reference” countries, is wrongful too. It can be based on the following principles:

- drug price is determined as average price from the chosen basket of countries (this approach is used, in particular, in Austria, Greece, Canada and Netherlands; in 1993-2001 in Italy prices for new drugs were calculated as average-weighted one in 13 out of 15 countries of the European Union);
- drug price cannot exceed the top price in the “reference” countries (for instance, Iceland);
- drug price cannot exceed the lowest prices in ‘reference’ countries (in New Zealand and Hungary, for example);
- others (Slovakia admits the price calculated on the basis of average one out of 3 lowest prices in “reference” countries and increased by 10%. Turkey determines drug prices on level of the lowest price and increased by 22%).

The comparison of drug prices on different markets, taking place during the process

of drug price determining and control over them, has got its merits and demerits. Easiness of drawing comparisons, transparency of this process, low cost of simple risks and relative feeling of fairness are regarded as its merits. However, there appear publications about a negative impact of drug price comparison on different markets. To diminish it, it's recommended to:

- use external reference prices in combination with other methods;
- choose a bigger number of countries for comparison, so that evade an inproportionally major influence of just one country's price on end price;
- avoid using the countries, that also apply price comparison on different markets, when choosing 'reference' countries;
- keep account of sales volume, when calculating prices in different countries.

For example, in the Czech Republic there is set up a more complicated system of pharmaceutical pricing. There maximum price is the average price, calculated on the basis of prices in 7 'reference' countries (Estonia, France, Greece, Hungary, Lithuania, Portugal and Italy). If any medication is not on sale in, at least, 3 EU countries, its maximum price is determined based on the price of similar medication on sale in the Czech Republic.

The inclusion of medication into the list of the ones on reimbursement (included into the system of medication reimbursement) and the determination of its official price according to certain rules of payments by patients and payers result in obtaining by given medication a privileged position on the market in comparison with other drugs not sold on reimbursement. The higher level of reimbursement and lower level of patient copayment, the higher is drug affordability (if there are no more additional limitations, but purchase price).

Reimbursement is a system instrument, rendering considerable influence on pharmaceutical prices. The medication, not sold on reimbursement, is supposed not to reach such sales volume as those included into the list of medications sold on reimbursement. Therefore all over the world manufacturers are interested in obtaining status of drug sold on reimbursement for his drugs. In connection with this, the inclusion of a medication into the list of those on reimbursement presents wide possibilities for price negotiations and deriving additional benefits for state economy and citizens.

In regard to monopoly medications, there is no sense to apply the system of tenders which requires no less than two proposals to be made by two competing manufacturers. Therefore holding auctions to purchase monopoly medications is not rational and results in additional expenditures and drug growing prices.

The majority of countries determine official, fixed or maximum prices for monopoly drugs after considering the results of negotiations with their manufacturers or in the framework of the system of reference prices that is by way of comparing prices in different countries. In the course of negotiations in the system of prices regulated price is determined with due regard to medication therapeutic efficiency, comparative economic study, total of expenditures on traditional and alternative treatment, plans of sale volume and price level in other countries.

For a number of small-market countries the principle problem is the fact, that during negotiations public payer's positions are much weaker than those of a monopoly drug manufacturer. The risk of public payer's refusal to reimburse concrete medications may influence on their price only in major countries and on the biggest pharmaceutical markets, such as Russia.

Negotiations regarding medication prices are usually held in two forms: 1) so called individual ones – between a payer and a pharmaceutical company concerning prices for certain medication (they are held by most countries) and 2) general ones (in the industry as a whole) – between the payer and branch organizations, uniting drug manufacturers. General negotiations are held in Great Britain, Spain, Portugal and Hungary.

The parallel import, taking place only between countries of the European economic zone and based on the principle of free merchandise movement, contributes, to a great extent, to increase in medication affordability and accessibility to the population of the EU countries. In the opinion of the European Court, any pharmaceutical company, manufacturing innovative medications on given territory and restricting parallel export by refusing to meet ordinary orders, made by wholesale buyers, abuses its dominating position and violates the principles of competition, acting in the European Union. Parallel trade results in the following: while the same standards of medication safety are kept, consumer-patients have possibilities to purchase the same products by lower prices.

The study by York, conducted in 2003, covered 5 countries: Great Britain, Germany, Sweden, Netherland and Denmark. It was established that in these countries the total saving from parallel trade made up 635 million Euros, including: 342 million Euros in Great Britain, 194 million Euros in Germany, 47 million Euros in Sweden in 2002 and 32 million in Denmark in 2001. The drug prices in parallel import were lower for 1,6 – 23% than prices for the same drugs in the countries, where they had been imported to.

In 2006 another study was conducted by Denmark. It was calculated that in these countries in 2004, thanks to parallel trade, the total direct saving by national public health systems made up 441,5 million Euros, including 237 million Euros in Great Britain, 145 million Euros in Germany, 45,3 million Euros in Sweden and 14,2 million Euros in Denmark. Moreover, saving was also reached in connection with decrease of prices for drugs, imported by official distributors.

The influence of parallel import on drug prices in any country-importer can be seen on the example of Poland:

- up to September 2006 medication A was brought into Poland exclusively by its manufacturer – company X. The average price was 40 PLN;
- in November 2007 a parallel importer imported medication A for the price of 30 PLN to the Polish market;
- in response to this, company X cut the cost of medication A;
- in January 2008 the parallel importer brought medication A for the price of 25 PLN to the territory of Poland ;

- in March company X cut the cost of medication A up to 24 PLN, and medication A stopped being profitable for parallel importers.

In accordance with the German legislation, it is required that every pharmacy have 5% of its stock medications from parallel import.

Here are some examples of methods of regulating pharmaceutical prices in different countries:

1. On the European pharmaceutical markets:

Austrian Republic. According to the legislation on price regulation, in case the price claim is too high for the Austrian economy, the Federal Government of the Austrian Republic can start an official process of regulation. If the regulation process has not been launched during 6 weeks, the price claim is automatically considered as medication maximum price approved. Therewith in the Austrian Republic there is comparatively widely applied so called individual cost reimbursement. That is: when certain medication to treat one or another illness is registered in the country and there is no alternative to it, its cost is reimbursed.

Republic of Bulgaria. In dependence from illness, to treat which the medication is put on, there are determined 3 categories of medication costs reimbursement. The cost of drugs, falling under the first 2 categories, is reimbursed in full, and medications of the third category – by 75%. Reference groups are formed on the basis of medications producing the same effect and having the same form of issue.

United Kingdom of Great Britain and Northern Ireland (Great Britain). The basic principle of the National Public Health System of Great Britain, set up in 1948, is free-of-charge basis of medical aid for all the legal residents of the country. This principle is also applied to the medication provision of the population, some inconsiderable payments are made for prescription drugs, though. All non-prescription medications are paid by citizens themselves. At that, in Great Britain there is no state regulation of medication prices, and the level of companies' incomes only is regulated.

Peculiarities of the systems of medication price regulation in different countries of the EU

State	Medications, subject to price regulation	Rules of medication price regulation	Rate of maximum mark-ups
<u>Austria</u>	part of reimbursable medications, part of expensive medications; as to the rest of them, only mark-ups are regulated	producers' price claims, mark-ups for all medications	
<u>Belgium</u>	the most needed medications; as to others, mark-ups	price and mark-up regulation	

	only are regulated		
<u>Bulgaria</u>	all the medications	regulation of manufacturers' prices (average price makes 3 minimum prices in the EU countries), regulation of wholesale and retail mark-ups	wholesale – up to 7-10%/ retail – up to 20-28%
<u>Hungary</u>	part of medications	regulation of manufacturers' prices, as well as of mark-ups and discounts	wholesale – 4,4 – 8%, additional wholesale – 5-20%, retail – 17-27%
<u>Germany</u>	prescription medications	regulation of wholesale and retail mark-ups	wholesale – up to 3-21%, retail – up to 8-68%
<u>Denmark</u>		prices of procurements to pharmacies on the results of trading, fixed mark-ups, regulation of pharmacies' profit	retail – 1,5 US\$ per package
<u>Spain</u>	reimbursable medications	price fixation for medications to be reimbursed	
<u>Lithuania</u>	reimbursable medications, mark-ups to all the medications	regulation of manufacturers' prices, establishment of different-level mark-ups for reimbursable and non-reimbursable medications	reimbursable medications: wholesale – 5,5 -14%, retail – 4-22%; non-reimbursable medications: wholesale – 5-18%, retail – 15-30%
<u>Netherlands</u>		there are established maximum prices (average one makes one out of minimum prices in 4 neighboring countries), discounts are regulated	
<u>Poland</u>	reimbursable medications	regulation of wholesale and retail mark-ups	wholesale – up to 5%, retail – up to 40%
<u>Finland</u>	reimbursable medications	wholesale prices are fixed, retail prices for prescription medications are determined equal for all national pharmacies	wholesale – up to 7%
<u>France</u>	reimbursable medications	manufacturers' price regulation, determined by agreement between the manufacturer and the responsible authority, regulation of wholesale and retail mark-ups	wholesale – up to 6,68% retail – up to 6,68-26,1%
<u>Czech Republic</u>	reimbursable medications (4,5 thousand ones)	regulation of prices for medications, having less than 4 analogues registered (not higher than average price out of 3 minimum ones in	common trade mark-up, in dependence from drug price – from 4% up to 37%

		reference countries), establishment of cumulative mark-ups for all the chain of distributors	
<u>Sweden</u>	subsidized medications	wholesale price regulation for all the pharmacies	

3. CIS Pharmaceutical Markets:

In the Republic of Armenia, Tajikistan and Kyrgyz Republic, drug prices are not regulated by the state; on the other side, Russia, Ukraine, Kazakhstan, Belarus, Moldova and Uzbekistan employ various government controlling tools.

Republic of Uzbekistan - On February 1, 1999, there was introduced a unified pricing system for medicines and medical devices in hospitals and health retail pharmacy network as well as for the system of drug reimbursement and insurance.

Turkmenistan - Differentiated minimum trade markups are envisaged for the retail prices of the most essential drugs so as to make them accessible to the public. Most of the medicines manufactured by the local industry are dispensed by insurance prescriptions. In some cases, the discount can be up to 90 percent of their value, with account to the benefits granted to certain categories of citizens, as well as under valid medical insurance policy.

Specific Features of Regulatory Systems for Medicines in Selected CIS Countries

Country	Medicines subject to price regulation	Regulation procedure for medicine prices	Ceiling markups
<u>Russia</u>	EDL	Registration of ceiling factory EDL prices, limiting wholesale and retail markups.	Wholesale – from 5% (Belgorod region) to 43% (Sakhalin Region). Retail – from 10% (Belgorod, Orel, Altai Republic, Altai Region) to 159% (Chukotka).
<u>Belorussia</u>	Home-made medicines	Ministry of Health establishes the ceiling factory prices for national producers for 138 INN names (637 medicines with account to pharmaceutical forms & dosages).	Wholesale - from 2 to 11%, retail - from 2 to 30% of the producer price.
<u>Kazakhstan</u>	State purchased medicines	Annual approval of the ceiling purchase price at the auctions and in the commercial market; Memorandums to restrain the price rise are executed between the Ministry of Health of the Republic of Kazakhstan and pharmaceutical associations.	Wholesale markups - up to 15%; retail - 25%
<u>Moldavia</u>		Registration of ceiling	Wholesale - 15%,

		factory prices, limiting of wholesale and retail markups.	Retail - 25%
<u>Uzbekistan</u>		Wholesale and retail markups are regulated	Wholesale - 20%, Retail - 25%

On the whole, the analysis of the international practice demonstrate the diversity of models of drug supply and pricing control, which factors must be considered when comparing prices for medicines and relevant decision-making for modification of existing systems.

4. PROBLEMS OF PRICING REGULATION FOR PHARMACEUTICALS

Since 2010, the behavior of price growth in the pharmaceutical market has been affected by the state regulation of prices for pharmaceuticals covered by the list of vital and essential drugs (hereafter – “EDL”).

The list of vital and essential drugs for 2012 was approved by the Federal Government Resolution of 07.12.2011 № 2199-p that includes 567 international nonproprietary names, of which 267 are produced in Russia and abroad; 207 – abroad only and 93 - in Russia only.

Vitally important and essential drugs that have passed a complex process of state registration; they may not circulate in the market without registering of ceiling factory prices in accordance with the Russian Ministry of Health and the policies of Russian Federal Tariff Service (FTS). Procedures for the establishment of wholesale/retail trade markups and their maximum rate are strictly regulated, and trade organizations may not violate the requirements established by both federal and regional legislations.

According to analyst agencies data, in 2011, average prices for medical use drugs rose by 8.8%, while the for drugs not covered by EDL - by 10.8%, for EDL-listed drugs for medical use - 3,3%. Since early 2012, the price upturn for EDL-listed medical use drugs equaled 3.2% and for medical use drugs not covered by EDL 7.05%.

At the same time, it was revealed that a stronger government regulation of drug prices has failed to eliminate the causes of high prices and has not created any conditions for their reduction. Rigid and not always efficient administrative regulation of prices in Russia has accelerated the leaching of cheap drugs from pharmacy product ranges, as manufacturers have reduced the sales of unprofitable cheap products, whereby, the wholesalers and retailers are interested in most expensive drugs given the policy of limited markups.

Moreover, the manufacturers and retailers began to shift their lost profit resulted from operations with drugs whose prices are regulated to other medicines, triggering an accelerated price growth in the unregulated segment.

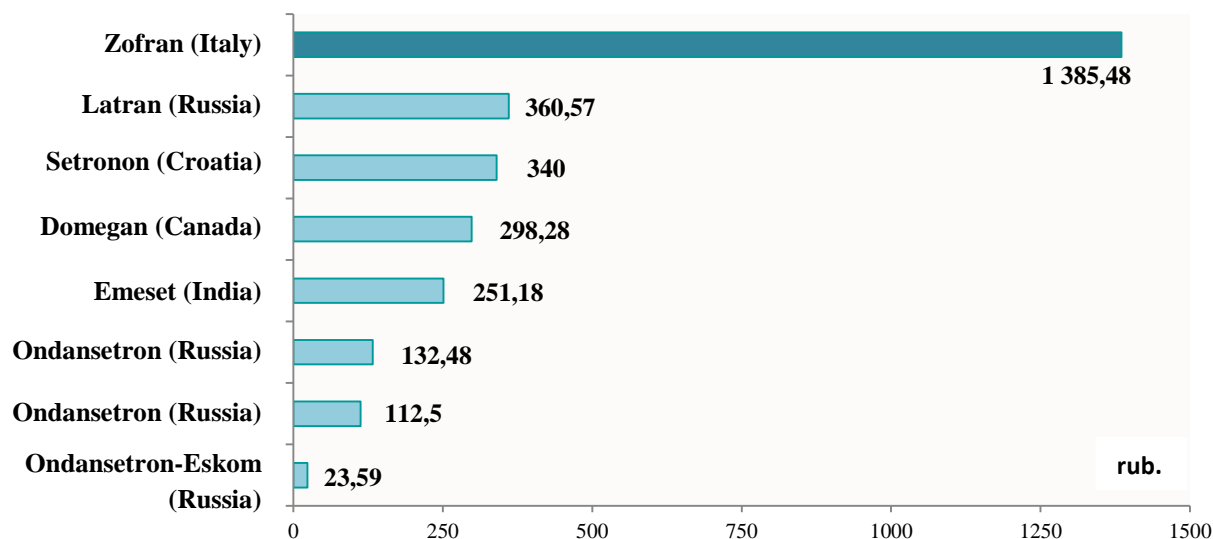
Thus, although the government regulation of medicines pricing tends to control the prices, and prices for certain EDL drugs are almost stable, on the whole, the market demonstrates a price rise in public spending on pharmaceuticals, in particular, due to a reduced range of drugs and disappearance of cheap medicines from the commodity chain.

Competition-related challenges have a more substantial impact on drug prices than the administrative regulation of the same. A price upturn in competitive environment becomes possible when doctors prescribe, and consumers buy expensive drugs, despite the availability of cheaper products. Basically, this is due to subjective reasons related to the buyer’s price perception, who distinguishes the drugs in terms of brands instead of International Nonproprietary Names. On top of that, the competition

development in Russia for interchangeable drugs is supported by a wide-spread paradigm that good preparations cannot be cheap, and expensive original drugs have better quality versus cheap generics.

For example, only in the environment of unresolved problems of competition development, including those associated with the uncertainty of drugs interchangeability under single INN; despite the price controls on EDL there can be a disparity in the prices of identical drugs with "Ondansetron" INN in one pharmaceutical form or dosage:

Scattering values of ceiling sale prices of different trade names of drugs within "Ondansetron" INN; solution for intravenous and intramuscular injection, 2 mg/ml, 2 ml - ampoules (5)



The price spread for absolutely identical drugs is 5873%, i.e., the price of the most expensive drug is 59 times higher versus the cheapest product. Wholesalers and retailers bear the same costs while selling these drugs and receive a fundamentally different level of profit.

The governments of all developed countries take care of lower prices in the market. This goal is being realized in different ways; however the main path is outside the mainstream of administrative restrictions but in the creation of competition environment instead. High dynamics of drug prices is directly attributed to the competition status in the pharmaceutical market. State regulation of prices is only effective for the segment of drugs with a lower competition (first and foremost, these are original drugs before the expiry of patent protection).

5. COMPARATIVE ANALYSIS OF PRICES FOR PHARMACEUTICALS

5.1. Selection Criteria for Pharmaceuticals, whose Prices are Subject to Investigation

In pursuance of Mr. Shuvalov's order, the FAS of Russia has performed a pricing investigation for several lists of drugs selected according to certain criteria.

1. Monopoly Pharmaceuticals

The first list of drugs that the FAS of Russia has investigated in terms of prices contained 24 drugs that simultaneously satisfy the below criteria:

- the only medicines registered on the territory of the Russian Federation without registered analogues under one international nonproprietary name;
- strategically important drugs for the treatment of widespread and complex diseases covered by the appropriate government lists of essential drugs:
 - in the List of products procured by the federal budget allocations for diagnostic tools to detect and monitor the treatment of persons infected with human immunodeficiency virus and hepatitis B/C, as well as antiviral drugs for the prevention of diseases and treatment of said persons, approved by the Decree of the Government of the Russian Federation of 27.12.2012 № 1438;
- the most expensive drugs requiring the largest volumes of budget funds for purchase (average registered ceiling factory price of one package of surveyed drug equals to approx. RUB 8 thousand without VAT).

The investigation of prices for these drugs is feasible because the reduced prices can significantly affect the budget savings and push up the affordability of such drugs for the public enjoying special benefits.

The data on actual wholesale prices of medicines in respective countries was used in the comparative study²; in some cases registered ceiling factory prices (with VAT for Russia) were given for comparison purpose.

2. Public's Best Buyable Medicines

The second list of drugs, which the FAS of Russia used for pricing analysis, covered 44 medicines, including 21 EDL-listed products, which simultaneously satisfy the below criteria:

- drugs on the highest public demand in retail segment selected by the highest retail sales value in Russia by the end of 2012³, implying the highest public expenses for the purchase of such drugs;
- prescription drugs (implies that the public demand and selection of these drugs are generated non-independently and that the exchange of such drugs is difficult);

² Regretfully, FAS of Russia has obtained data on the wholesale prices for CIS countries only.

³ The list of these drugs was served to the FAS of Russia by IMS Health information & analytical company.

- some of them are included in EDL, and others are not, implying an alternate pricing criteria.

The pricing survey for the most popular medications is feasible, because lower prices for the same can trigger a significant reduction of public spending on medicines.

The comparative study used the actual VAT inclusive retail prices for medicines in pharmacy organizations in various regions both in the independent entities of the Russian Federation and in other countries that provided information for the survey.

3. Medicines Used for Cardiology

The third list used by the Federal Antimonopoly Service covered five drugs used for heart disease treatment. All five products are prescription drugs; two of them are EDL-listed, the rest are not, i.e. their prices are not regulated. One of the examined drugs (TN - Teveten, INN - Eprosartan) has no analogues in the framework of INN.

For the comparative survey, were used VAT inclusive actual retail prices for these drugs in the pharmacy organizations in various regions of the Russian Federation and in other countries that provided information for the Study.

5.2. Complexities and Limitations for Comparing Prices for Pharmaceuticals in Various Countries

The supply & demand system would not always work at the drug markets since the pricing is affected by many economic drivers and market players.

In drug pricing process, the pharmaceutical companies generally seek to resolve the below objectives:

- set the optimal exchange value, so as to sell the product;
- set a price allowing to get the absolute maximum profit;
- reduce the production costs; to this end, the companies move their pharmaceutical production to the countries with lower production cost (thanks to cheap labor, raw materials, infrastructure or lower taxes), such as India or China;
- ensure the maximum protection for the drugs from possible competition by virtue of patent cover for various components of the drug (i.e. composition, mechanism of action, production method) and brand, as well as special consumer properties enabling to distinguish the pharmaceutical from its analogues.

Experts estimate that **about 80 % of the final cost of the drug may account for the value of trade name, i.e. the brand**. Actively promoted brands are much easier to perceive and remember, so the drugs with one and the same active ingredient but with different trade names may be sold with a significant price margin (for example, in Russia the price spread for different trade names of EDL-listed drugs with INN name "Ondansetron" makes 59 times).

The price of branded medicines is generated not just by the cost of production and sale but rather on the basis of market conditions. Thereby, the ceiling prices for medicines are not known, partly because of significant discounts and bonuses that manufacturers provide to distributors. Manufacturer's discounts can reach 50% or more, and their particular feature is that the producing company provide relevant discount budget at the maximum in advance, but in reality the amount of discounts is almost always somewhat lower because not all conditions are satisfied.

According to estimates, the drug price at the stage "from manufacturer to end-user" increases by two fold approximately. In the end-price, the manufacturer's margin is around 50%, the distributor's margin - 15%; another 15% account for state taxes and fees and 20% - for the pharmacies.

Pharmaceutical pricing proves to be a very complicated process. Pricing decisions are often made by virtue of various methods and take into account a wide range of factors. Each pricing solution is unique, depends on the company, its situation, characteristics and specifics of a particular. These drivers complicate the feasibility investigation of the established drug prices and comparative analysis of the same in various markets.

The comparability of medicine prices in various countries is limited for the following reasons:

- different drugs list circulated in various countries (for example, India virtually lacks patented drugs in circulation);
- differences in drug names, as well as differences of production forms/dosages;
- different release dates from the drug patent protection;
- different consumption volumes of specific drugs in various countries;
- different regulatory systems (tax, customs and medicine circulation schemes);
- different state regulation of pricing;
- different structure and level of public income and expenditures;
- in the government sector of many countries, producer prices for drugs result from agreements between payers (budget system, insurance funds, etc.) and producers;
- differences in drugs interchangeability options, different ways for prescribing and the practice of transferring patients from one drug to another;
- many countries employ refund systems for drugs in the form of discount; in this context, prices with account to discounts in some countries and without account of the same in other countries, can be incomparable and deviate considerably;
- in one country, some drugs can be the most expensive compared to other countries, while other drugs - the cheapest. So the comparison of one-day treatment cost in different countries is preferable for analysis rather than a direct price comparison.

Moreover, the complexity of pricing comparing is associated with insufficient information on the impact degree of each of these factors on the price.

In this regard, within the framework of initial pricing research, the FAS of Russia has performed a simple comparison only. But even this comparison appeared difficult because:

- various countries has their own quantities of selected drugs with different dosages and packages in circulation;
- not every data was presented correctly, i.e. in different units, not always with indicated currency; with/without VAT; per 1 primary package; per 1 secondary package; per 1 unit of active substance (tablets, capsules or bottles) without indication to price calculation method;
- various countries have provided different price values (actual producer prices, import, wholesale/retail prices, ceiling prices (maximum possible rates), prices from price registers, average/minimum/maximum prices, etc.), which sometimes simply cannot be compared.

Hence, while generalizing the analysis deliverables or simply comparing prices, we should remember that the price in a country may often reflect the value after a series of discounts or markups, as well as exchange rates, taxes, purchase volume, shelf life or other drivers. Given the complexity and heterogeneous nature of available data, international comparisons are not always objective; in other words, we cannot

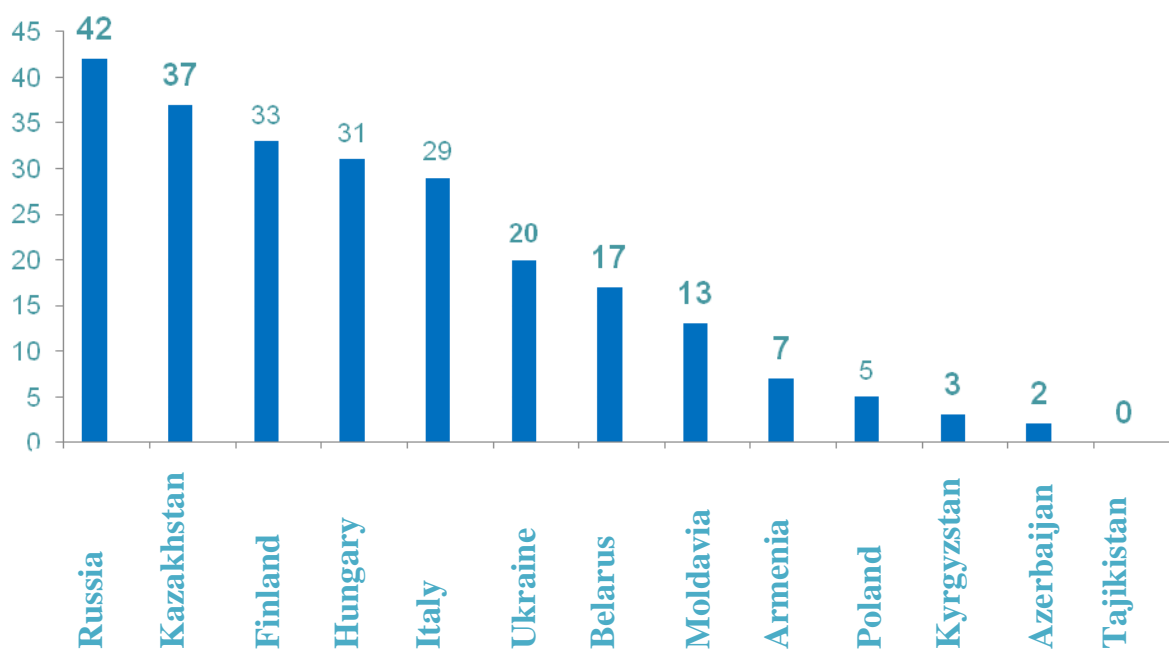
use them in full for the purpose of pricing government regulation, and the conclusions from such comparisons should be done very carefully.

5.3. Comparison of Prices for Expensive Monopoly Pharmaceuticals in the Russian Federation and Other Countries

The survey on expensive monopoly pharmaceuticals covered by the Essential Drug List (EDL) has compared VAT net wholesale prices in the corresponding countries. Thereby, since the Federal Antimonopoly Service lacks data reflecting the actual wholesale prices for the list of medicines concerned, for comparison purpose, it has provided the manufacturers' marginal selling prices with VAT registered in Russia.

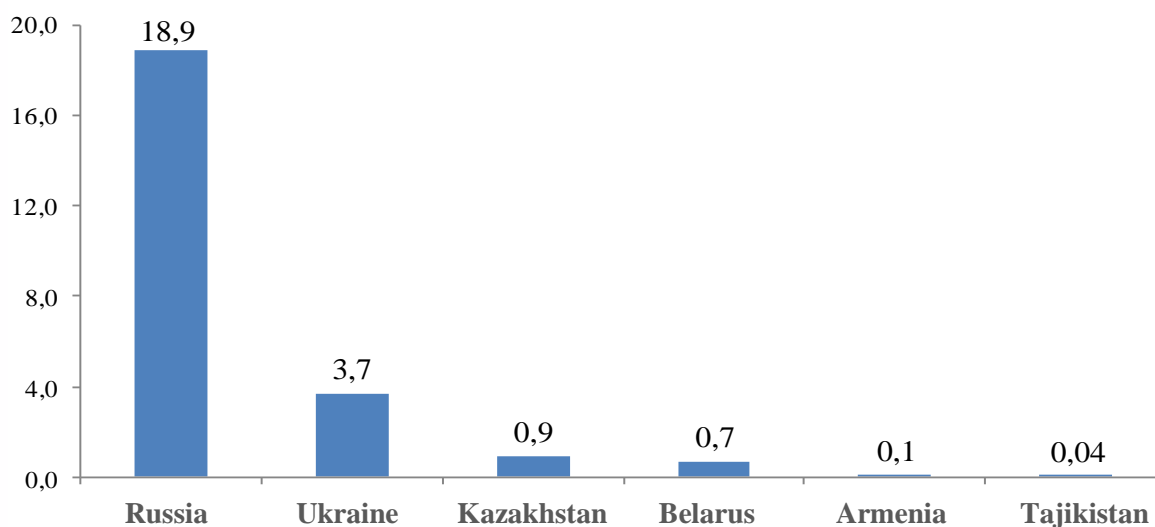
On the grounds of survey deliverables, the FAS of Russia intends to file requests on prices for relevant drugs and reasons where the same exceed the wholesale prices in other countries directly to manufacturers/holders of Registration Certificates.

**Number of matches of selected drugs available in circulation
(Excluding pharmaceutical forms)**



According to this graph, the largest overseas pharmaceutical companies are not interested to supply expensive drugs to the territory of countries with low medicine market capacity.

Comparison of approximate volumes of pharmaceutical market in the CIS as per 2011 bottom line (in retail prices), USD billion



The monopoly status of medicines concerned prompts a conclusion that necessary treatment is unaffordable to people suffering from certain expensive nosologies. At the same time, it is worth noting that in accordance with information served by relevant CIS countries, expensive drugs are imported in the form of humanitarian aid.

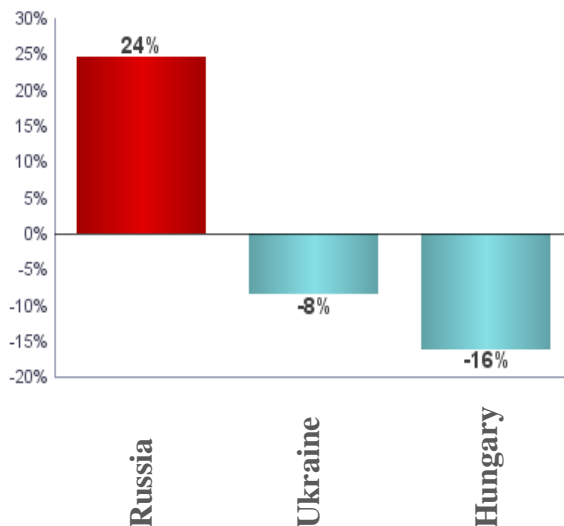
Comparative examples of wholesale prices for expensive drugs, USD⁴:

Copaxone-Teva (International Non-proprietary Name [INN] - Glatiramer Acetate), solution for subcutaneous injection, 20 mg/ml, 1 ml, 28 syringes

Comparison of
wholesale prices
for expensive
drugs, USD

⁴ The average price is computed as the arithmetic average of wholesale prices among the countries affected by the survey. For comparison purpose, in Russia, registered, ceiling selling prices of manufacturers with VAT were used as the wholesale prices.

Deviation of
wholesale prices
from the average
value, %



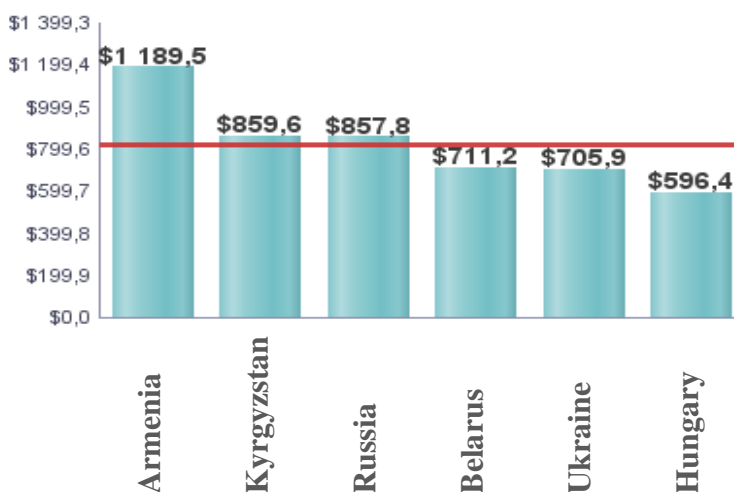
Copaxone-Teva is listed as a medicine of strategic importance being the most marketable product in Additional Pharmacological Support segment (APS) and is purchased under “7 Nosologies” Program. Registered ceiling price of one package in Russia equals to RUB 37.7 thousand with VAT.

According to DSM Group data, as at July 1, 2013, in Russia, the actual average wholesale price per one package totaled to USD 1173.35 with VAT or USD 1066.7 VAT net, i.e. the price in Russia has topped the counterpart values in Ukraine or Hungary as well.

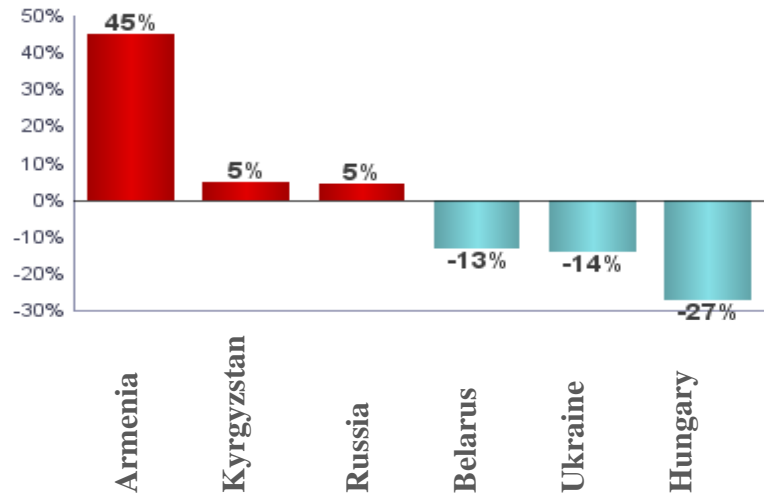
The letter received by the FAS of Russia from TEVA PHARMACEUTICAL INDUSTRIES LIMITED № 1/06-12-2013 dated 06.12.2013 reads that as a result of presentation «Preliminary Outcomes of CIS Medicine Pricing Monitoring», published on FAS website, TEVA PHARMACEUTICAL INDUSTRIES LIMITED referring to the presentation assumptions has voluntarily reduced the supply price for Copaxone-Teva to the Russian Ministry for Health by 10% and by 25% - for regional government customers. As per November 2013 Federal Auction for this medicine supply for 1H 2014, the Russian Ministry for Health has saved RUB 282 million of the budget funds.

***Mabthera (INN - Rituximab), concentrate for infusion solution,
100 mg/10 ml, 10 ml, 2 bottles***

Comparison of
wholesale prices
for expensive
drugs, USD

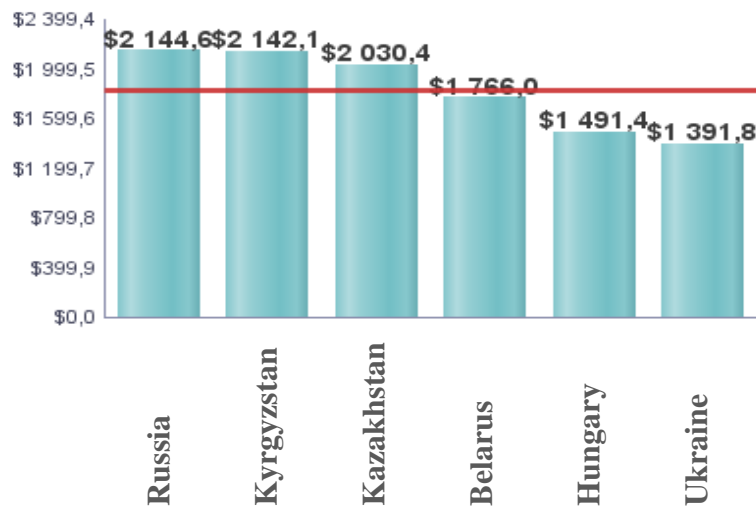


Deviation of wholesale prices from the average value, %

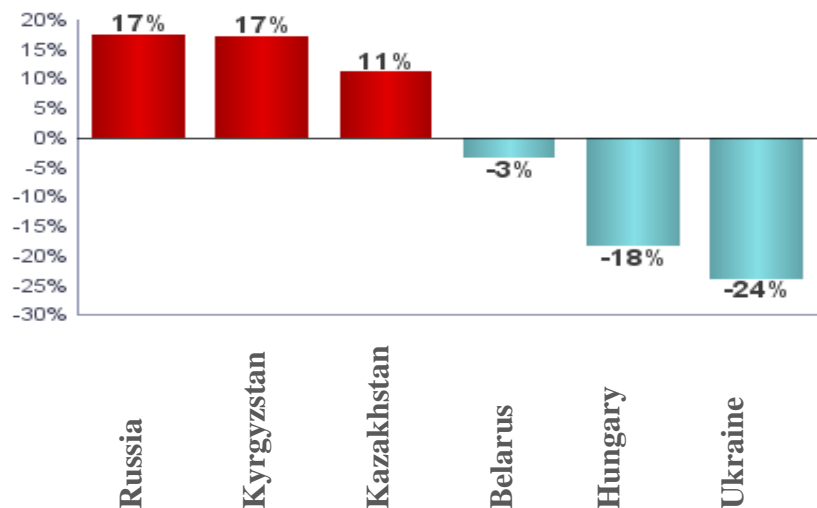


... 500 mg/50 ml, 50 ml, 1 bottle

Comparison of wholesale prices for expensive drugs, USD



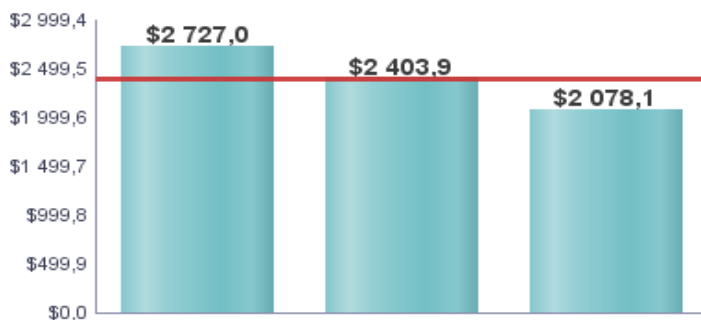
Deviation of wholesale prices from the average value, %



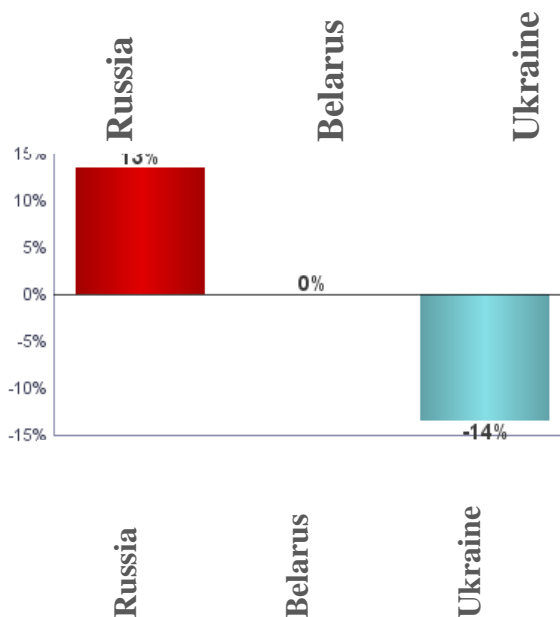
Mabthera has no registered analogues and is listed as a strategically important medicines; purchased under «7 Nosologies» program; ceiling price for one package with 500 mg/50 ml dosage, 5 ml in Russia – RUB 63.2 thousand with VAT.

Cerezyme (INN - Imiglyutseraza), lyophilized for infusion solution, 400 units, 1 bottle

Comparison of wholesale prices for expensive drugs, USD



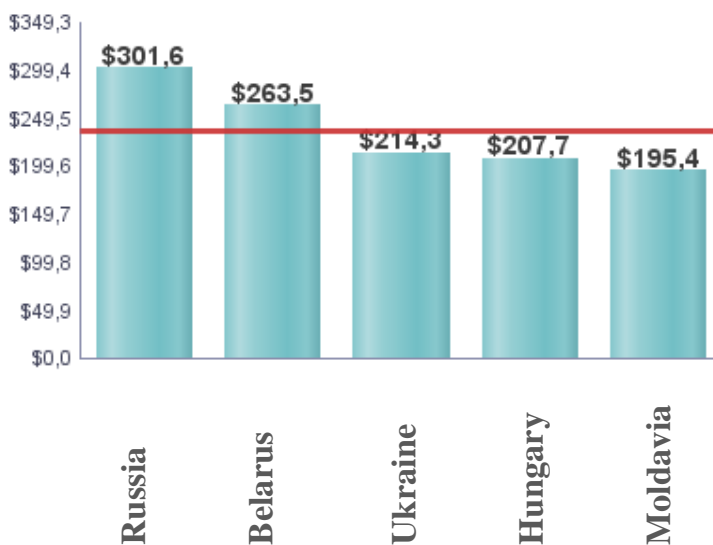
Deviation of wholesale prices from the average value, %



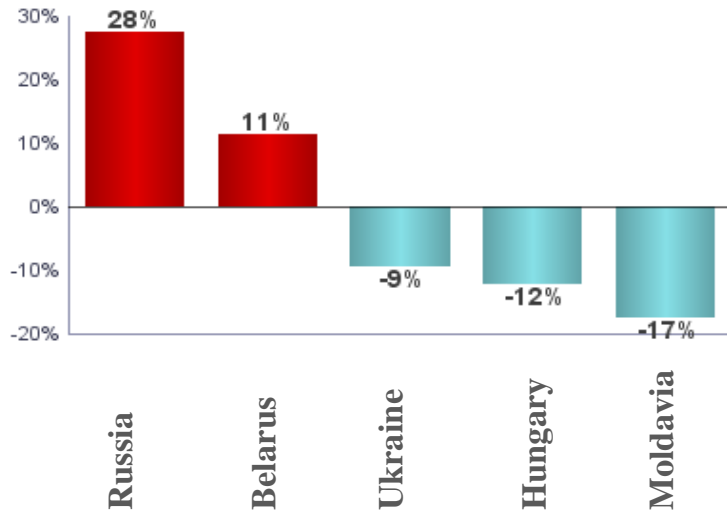
Cerezyme has no registered analogues and is listed as a strategically important drug; purchased under «7 Nosologies» program; ceiling price for one package in Russia in dosage 400 units – RUB 84.8 thousand with VAT.

Pegasys (INN- Peginterferon Alfa-2a), solution for subcutaneous injection, 0.27 mg/l (135 mkg/0.5 ml), 0.5 ml, 1 unit-dose syringe

Comparison of wholesale prices for expensive drugs, USD

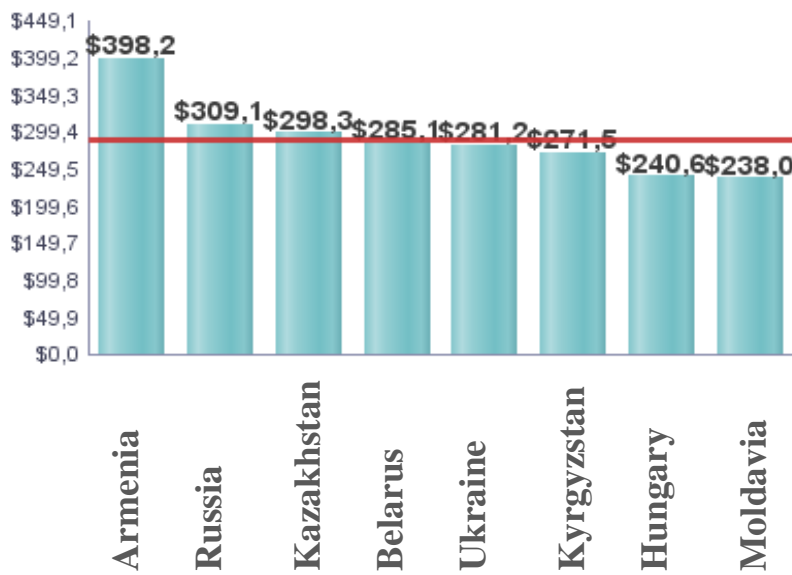


Deviation of wholesale prices from the average value, %

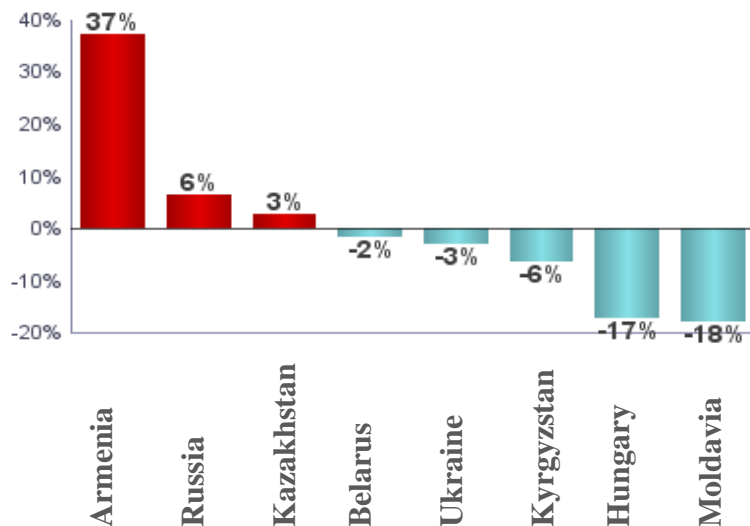


0.36 mg/ml (18 mkg/0.5 ml), 0.5 ml, 1 init-dose syringe

Comparison of wholesale prices for expensive drugs, USD



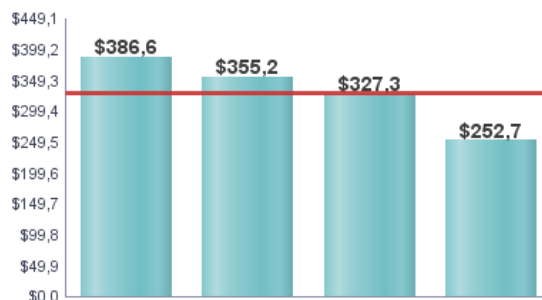
Deviation of wholesale prices from the average, %



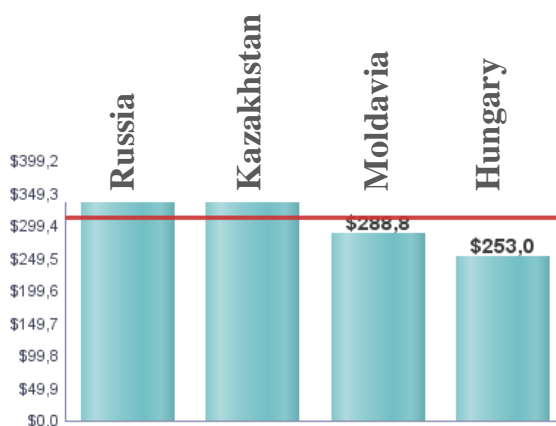
Pegasys drug has no registered analogues and is listed as a strategically important drug; purchased under «HIV» Program, ceiling price for one package in Russia in dosage 0,27 mg/ml – RUB 9,4 thousand with VAT.

Pegintron (INN - Peginterferon Alfa-2b), Lyophilisate for subcutaneous injection solution

0.1 mg, 1 bottle



0.1 mg, 1 prefilled syringe



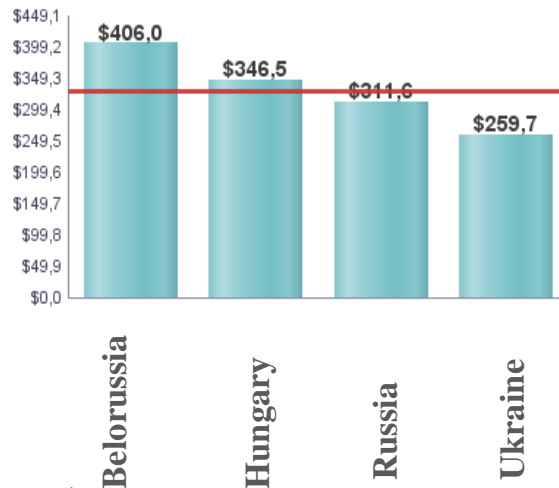
0.12 mg, 1 bottle



0.12 mg, 1
prefilled syringe



0.15 mg, 1
prefilled syringe



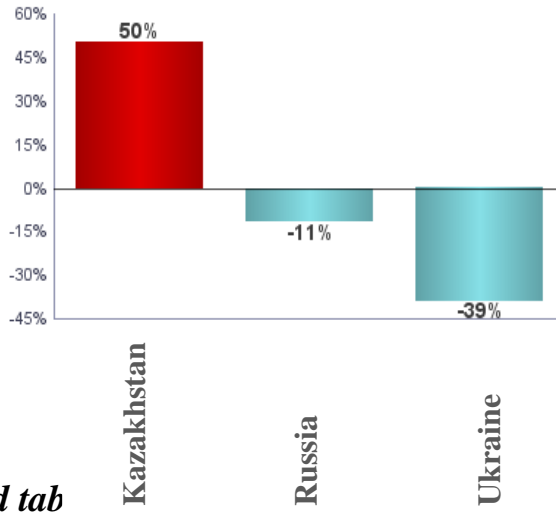
Pegintron drug has no registered analogues and is listed as a strategically important drug; purchased under «HIV» Program, ceiling price for one package in Russia in dosage 0,1 mg, 1 bottle – RUB 12 thousand with VAT.

Ziagen (Abacavir INN)
Oral solution, 20 mg/ml, 240 ml, 1 bottle

Comparison of
wholesale prices
for expensive
drugs, USD

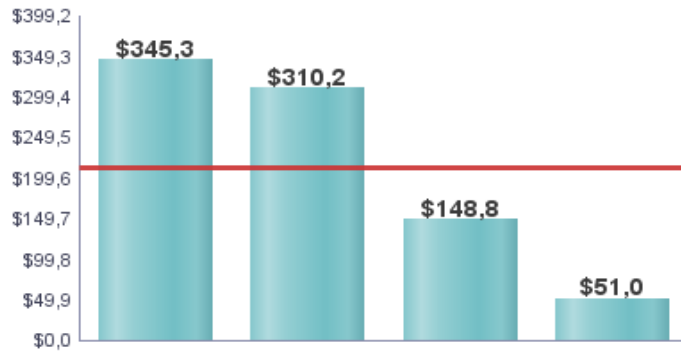


Deviation of wholesale prices from the average value, %

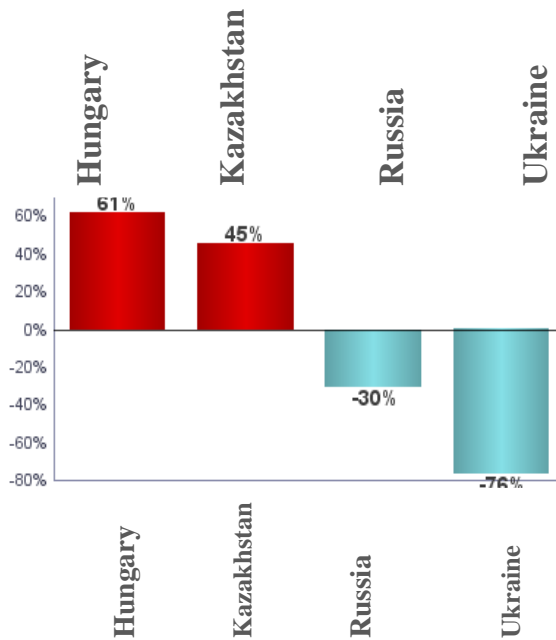


Coated tab

Comparison of wholesale prices for expensive drugs, USD



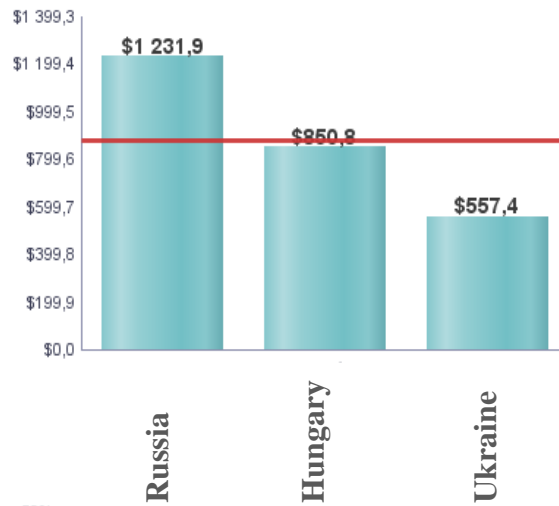
Deviation of wholesale prices from the average, %



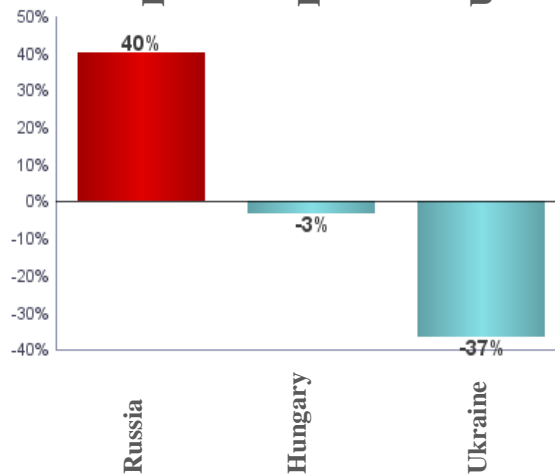
Ziagen drug has no registered analogues and is listed as a strategically important drug; purchased under «HIV» Program; ceiling price for one package in Russia in dosage 300 mg, 60 tablets – RUB 4.6 thousand with VAT.

Isentress (INN - Raltegravir), film-coated tablets, 400 mg, 60 tablets

Comparison of
wholesale prices for
expensive drugs,
USD



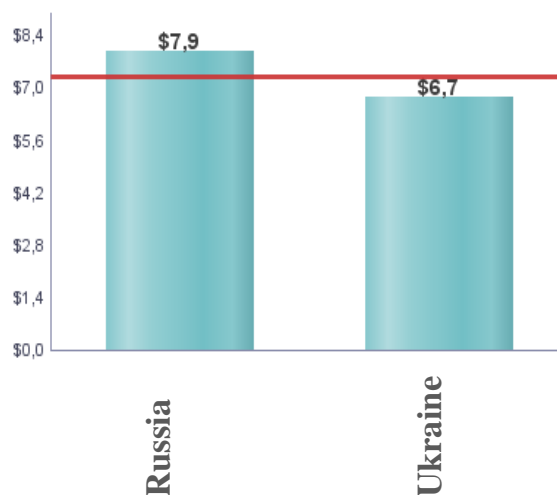
Deviation of
wholesale prices
from the average
value, %



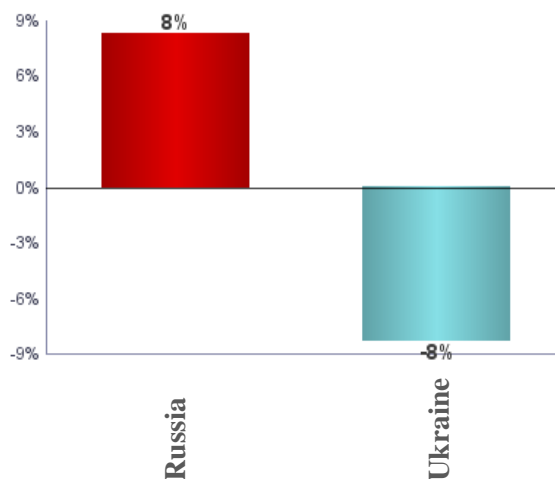
Isentress has no registered analogues and is purchased under «HIV» Program; ceiling price for one package in Russia in dosage 400 mg, 60 tablets – RUB 38.3 thousand with VAT.

Sparflo (INN - Sparfloxacin), coated tablets, 200 mg, 6 tablets

Comparison of
wholesale prices
for expensive
drugs, USD



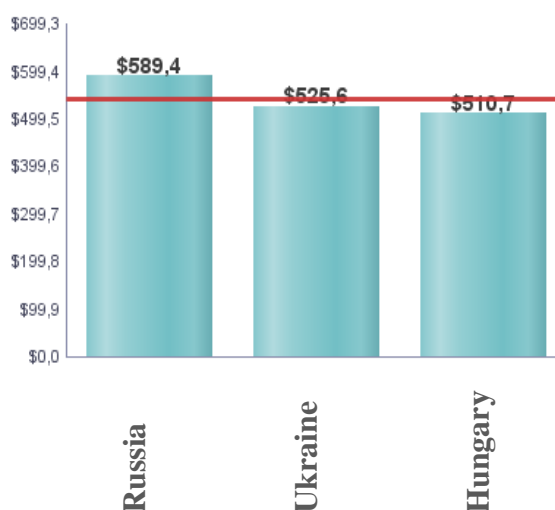
Deviation of wholesale prices from the average value, %



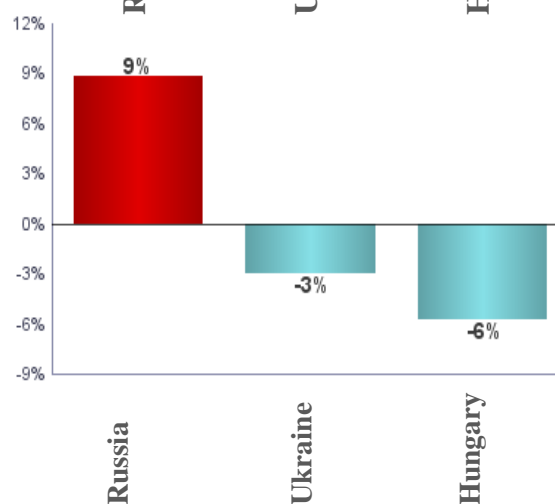
Sparflo belongs to EDL category, has no registered analogues and is purchased under «Tuberculosis» Program; ceiling price of 1 package in Russia in dosage 200 mg, 6 tablets – RUB 247 with VAT.

Intence (INN - Etravirine INN), 100 mg 120 tablets

Comparison of wholesale prices for expensive drugs, USD



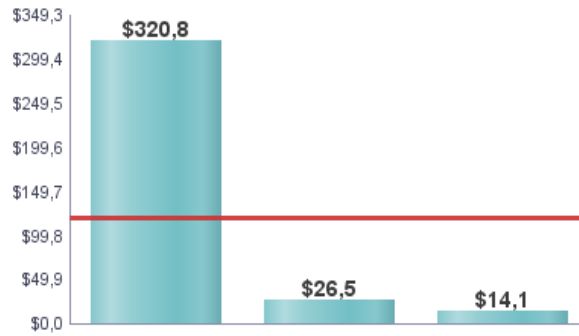
Deviation of wholesale prices from the average value, %



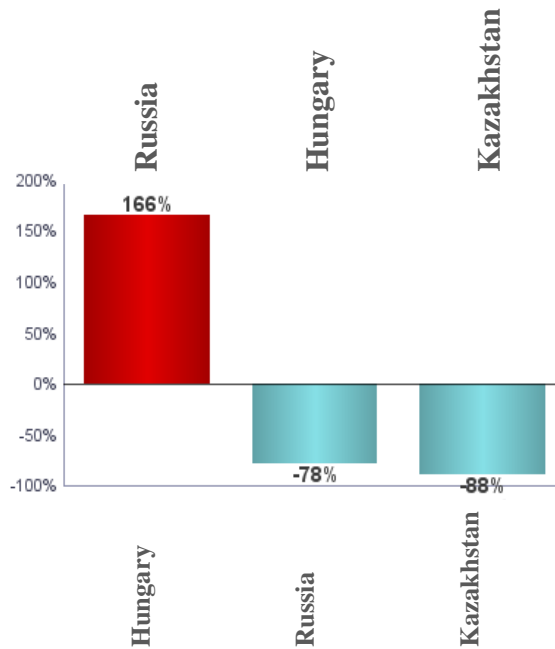
Intence has no registered analogues and is purchased under «HIV» Program; ceiling price for one package in Russia in dosage 100 mg, 120 tablets – RUB 18,3 thousand with VAT.

Sustiva (INN - Efavirenz), film-coated tablets 600 mg, 30 tablets

Comparison of wholesale prices for expensive drugs, USD



Deviation of wholesale prices from the average value, %



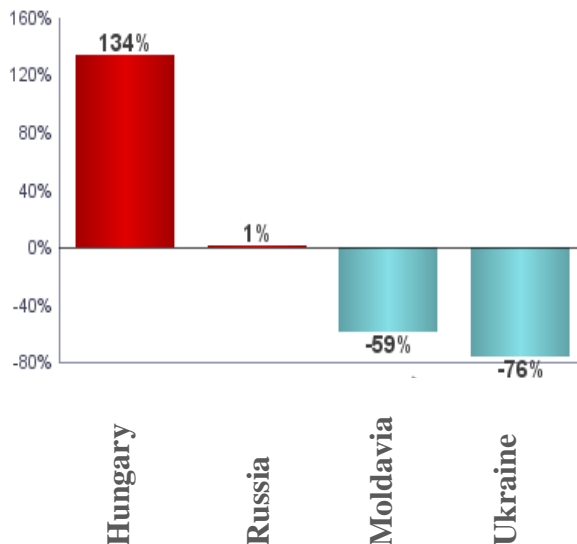
Stocrin has no registered analogues, is listed as a strategically important drug and is purchased under «HIV» Program; ceiling price for one package in Russia in dosage 600 mg, 30 tablets – RUB 825 with VAT.

Kaletra (INN – Lopinavir + Ritonavir) film-coated tablets 200 mg + 50 mg, 120 tablets

Comparison of wholesale prices for expensive drugs, USD

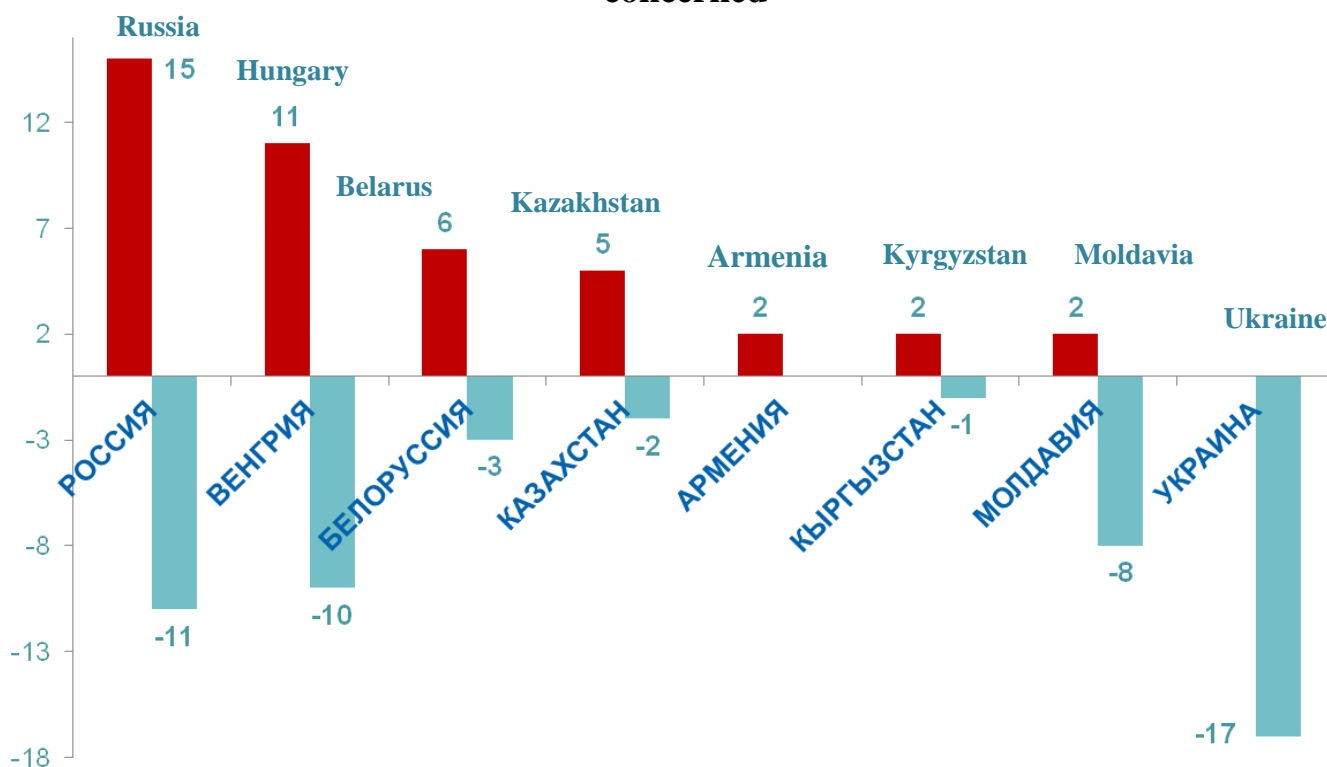


Deviation of wholesale prices from the average value, %



Kaletra has no registered analogues and is listed as a strategically important drug; purchased under «7 Nosologies» Program; ceiling price for one package in Russia in dosage 200 mg +50 mg, 120 tablets – RUB 8 thousand with VAT.

The number of positive (higher prices) and negative (lower prices) deviations of the wholesale prices for the surveyed medicines from the average values in the countries concerned



Therefore, Ukraine has demonstrated the lowest prices for the overall list of drugs surveyed. In Russia, over one half of the surveyed expensive drugs is imported at higher prices than in other CIS countries. According to the FAS of Russia, price downturn for these drugs will bring a significant savings for the budget.

In some countries, including CIS states, the pricing is made on the basis of the supplies from the Global Fund. The Global Fund buys expensive drugs, including HIV pharmaceuticals for the developing economies at highly favorable terms in most cases. As a result, in international comparison of prices for drugs in individual countries supported by the Global Fund financially in terms of drug purchases, the prices for such medicines are underestimated.

The same trend is pronounced in Ukraine, where the prices of the surveyed drugs are very low. The Global Fund against AIDS, tuberculosis and malaria co-finances the budget, aimed to fight HIV in Ukraine. In particular, almost half of the financing intended to oppose HIV/AIDS in Ukraine in 2009-2010 accounts for the Global Fund.

December 15, 2011 in Geneva (Switzerland), a Grant Agreement was signed between Ukraine and the Global Fund to finance the program against HIV/AIDS. The Board of the Global Fund has supported the measures proposed by Ukraine to prevent and fight HIV/AIDS that will be implemented within 2012-2013. The budget of two-year Grant Program of the Global Fund totals to USD 86 million.

As per data provided by the Trade Mission of the Russian Federation in the Republic of Tajikistan (Letter № 289 dated 16.04.2013), around 30% of the drugs volume for the treatment of cancer, tuberculosis, HIV, immunization, etc. come in the Republic as humanitarian aid, as well as under projects of international financial institutions, governments of some countries, the UN Children's Fund (UNICEF) and the World Health Organization (WHO).

Based on the Analysis, the FAS of Russia intends to investigate the reasons for significant differences in the prices of monopoly expensive drugs that have been revealed.

5.4. Comparison of Retail Prices for the Pharmaceuticals Most Popular among the Russian Population

5.4.1. Comparison of Retail Prices for the Most Popular Pharmaceuticals not Included into the EDL in the Russian Federation, CIS, EU and BRICS

Information on the retail prices for the most popular drugs distributed on prescription in Russia not covered by the EDL was received by the Russian Ministry of Economic Development from the Russian Federation Trade Missions in a number of CIS, EU and BRICS countries. IMS Health data on the weighted average prices of these drugs in the Russian Federation were used as the retail prices across Russia.

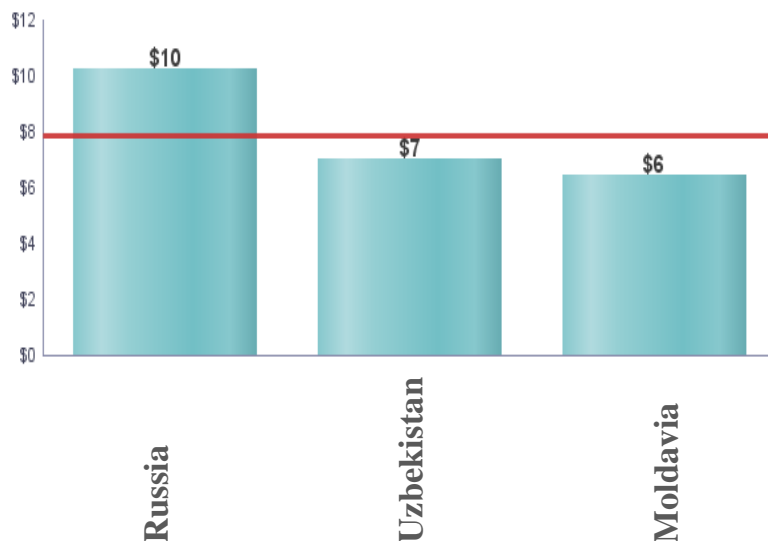
According to the drug list selected by the FAS of Russia, less than one half of medicines with the same trade name, manufacturer, pharmaceutical form, dosage or package circulate in the markets of most surveyed countries.

Number of exact matches of selected drugs available in circulation

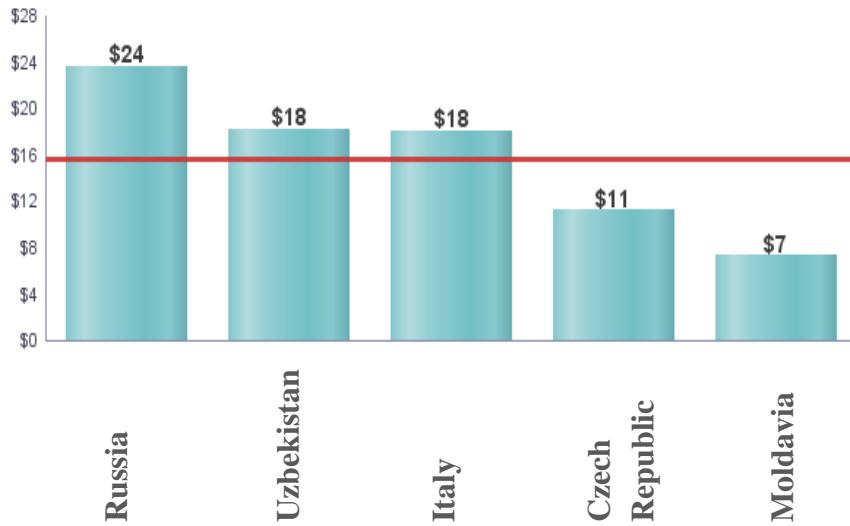


Below follow comparison examples of the retail prices for specific medicines from the List in USD.

Comparison of retail prices for Kvinaks (INN - Azapentatsen), eye drops, 0.015%, 15 ml bottle, USD



Comparison of retail prices for Detraleks (INN - Diosmin Hesperidin), tablets, 500 mg, # 30, USD



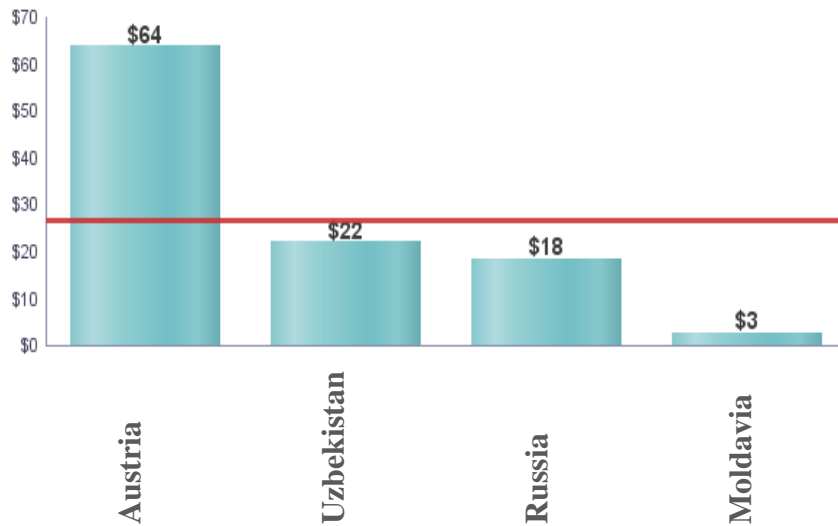
Comparison of retail prices for the Losap Plus (INN – Hydrochlorothiazide + Losartan), tablets 50 mg + 12.5 mg, # 30, USD



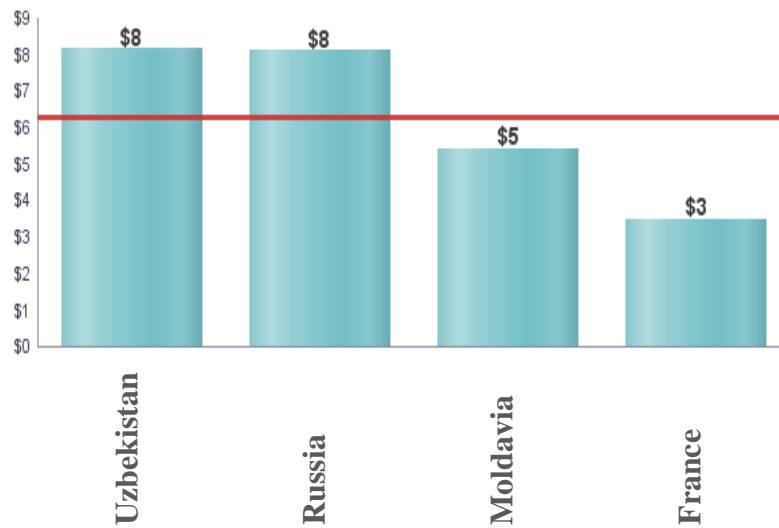
Comparison of retail prices for Diabeton MV (INN - Gliclazide), tablets with modified release, 60 mg, # 30, USD



Comparison of retail prices for Actovegin (INN - Gemoderivat Deproteinized from calf blood), ampoules, 200 mg, 5 ml, # 5, USD



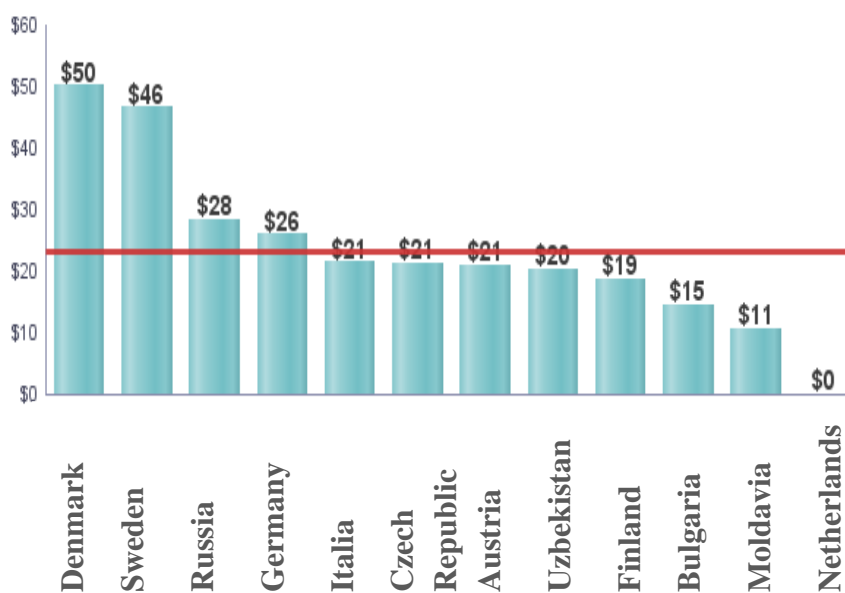
Comparison of retail prices for Donormil (INN - Doxylamine), tablets, 15 mg, № 30, USD



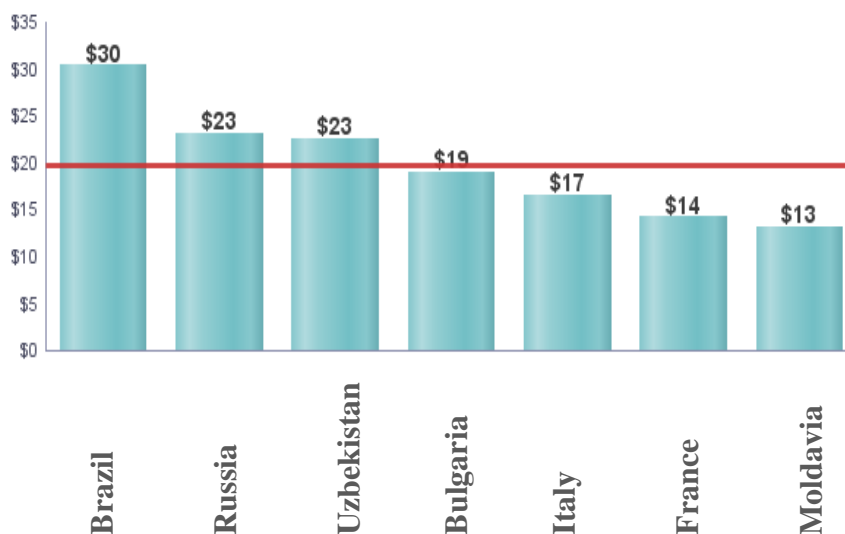
Comparison of retail prices for the drug Yarina (INN - Drospirenone + Ethinylestradiol), tablets, # 21, USD



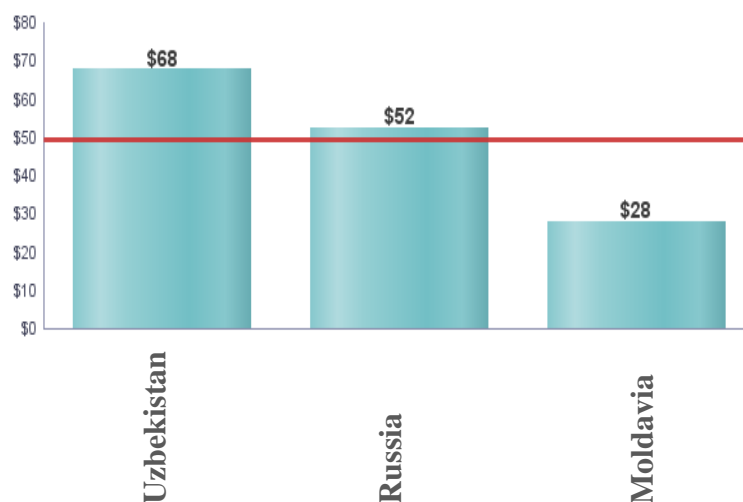
Comparison of retail prices for Yaz (INN- Drospirenone + Ethinylestradiol + [Calcium Levomefolinat]), tablets, # 28 USD



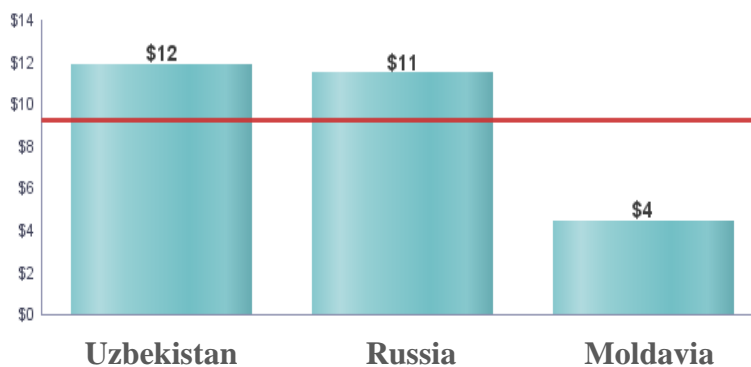
Comparison of retail prices for Noliprel bi-forte (INN - Indapamide Perindopril), tablets forte 5 mg/1.25 mg, # 30, USD



Comparison of retail prices for Alflutop (INN - concentrate of marine fish), injection solution, 10 mg, 1 ml, # 10, USD

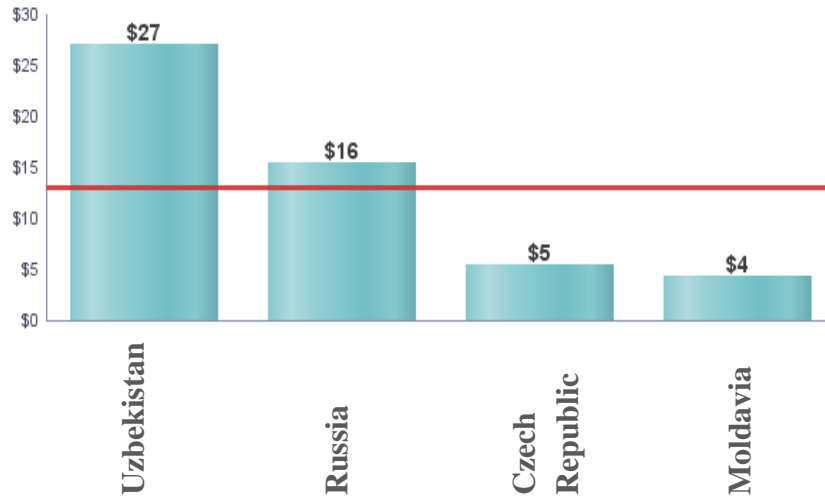


Comparison of retail prices for Mydocalm-Richter (INN – Lidocaine + Tolperisone), ampoules, 100 mg, 5, 1 ml, USD



Comparison of retail prices for Movalis (INN - Meloxicam), injection solution, 15 mg, 1.5 ml ampoules, # 3, USD

Comparison of retail prices for Exoderil (INN - Naftifine), outward solution, 1%, 10 ml bottle, USD



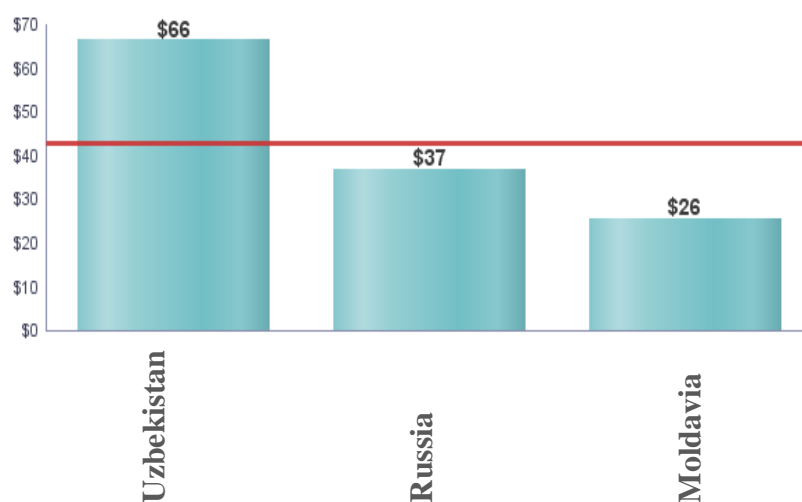
Comparison of retail prices for Nise (INN - Nimesulide), tablets, 100 mg, # 20, USD



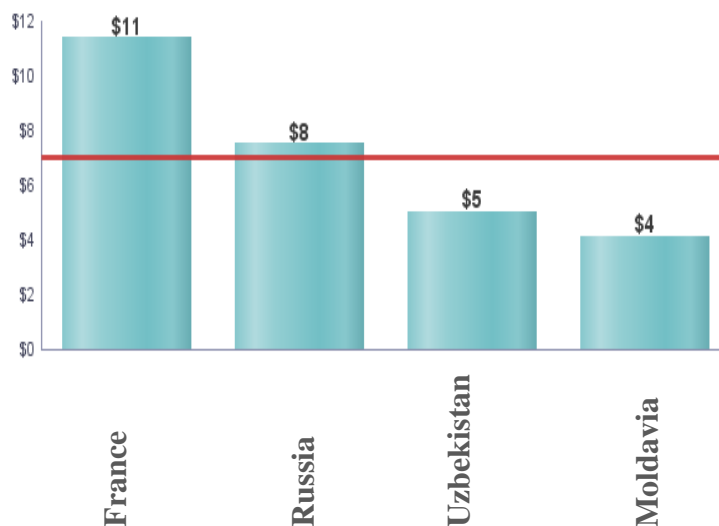
Comparison of retail prices for Nimesil (INN - Nimesulide), gran/for suspension, package 100 mg/2 g, # 30, USD



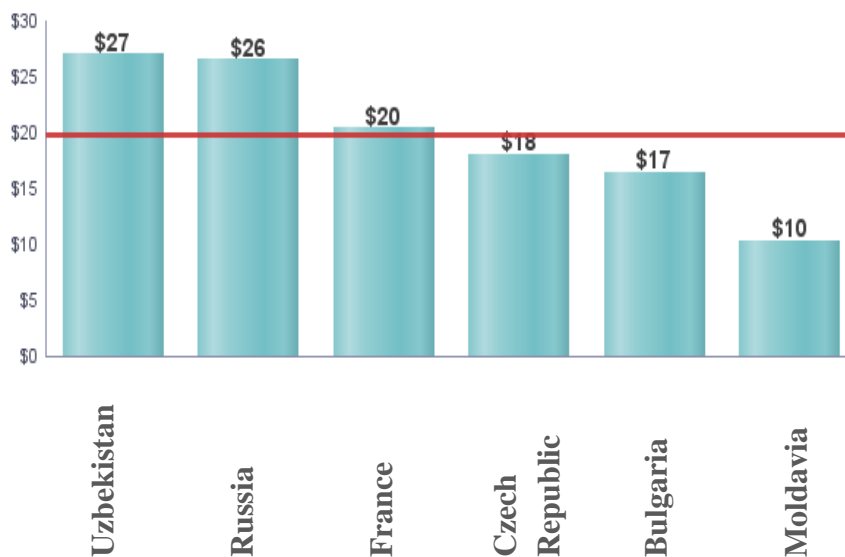
Comparison of retail prices for Cortexin (INN – Polypeptides of cattle cortex), Lyophilisate for intramuscular injection solution, 10 mg, bottle # 10, USD



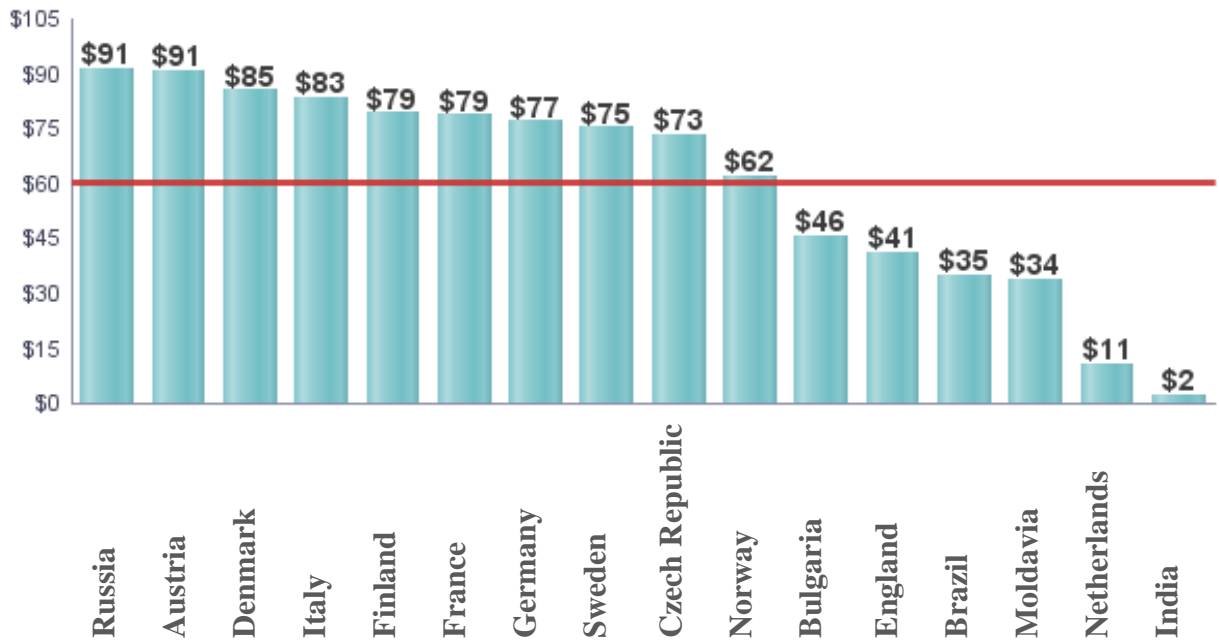
Comparison of retail prices for Karsil (INN - milk thistle fruit extract), pills, 35 mg, # 80, USD



Comparison of retail prices for Preductal MR (INN - Trimetazidine), tablets, 35 mg, # 60, USD



Comparison of retail prices for Viagra (INN – Sildenafil), tablets, 100 mg. # 4, USD



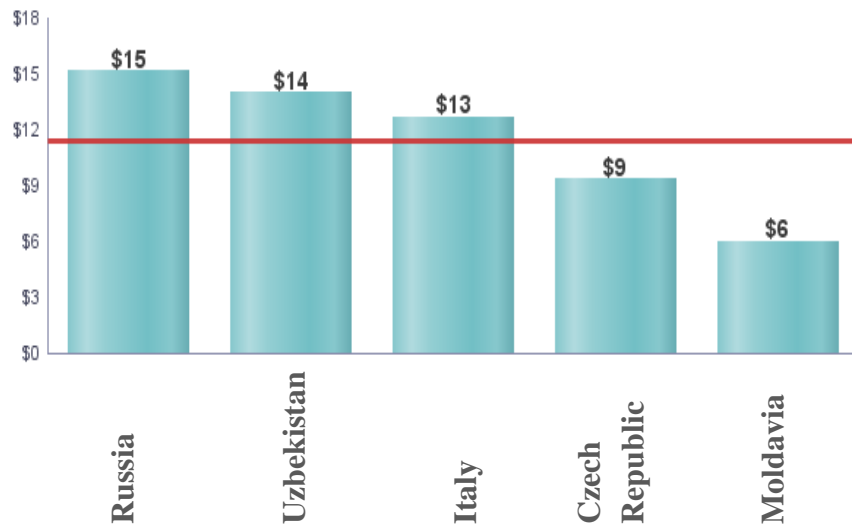
Comparison of retail prices for Milgamma (INN - Thiamine Chloride Hydrochloride; Pyridoxine Hydrochloride; Cyanocobalamin; Lidocaine Hydrochloride), injection solution, 2 ml, # 5, USD



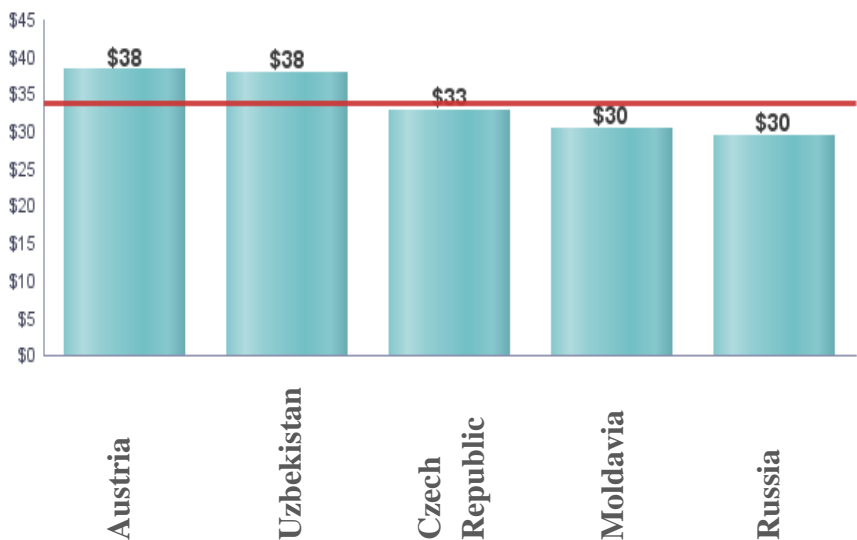
Comparison of retail prices for Crestor (INN- Rosuvastatin), tablets, 10 mg, # 28, USD



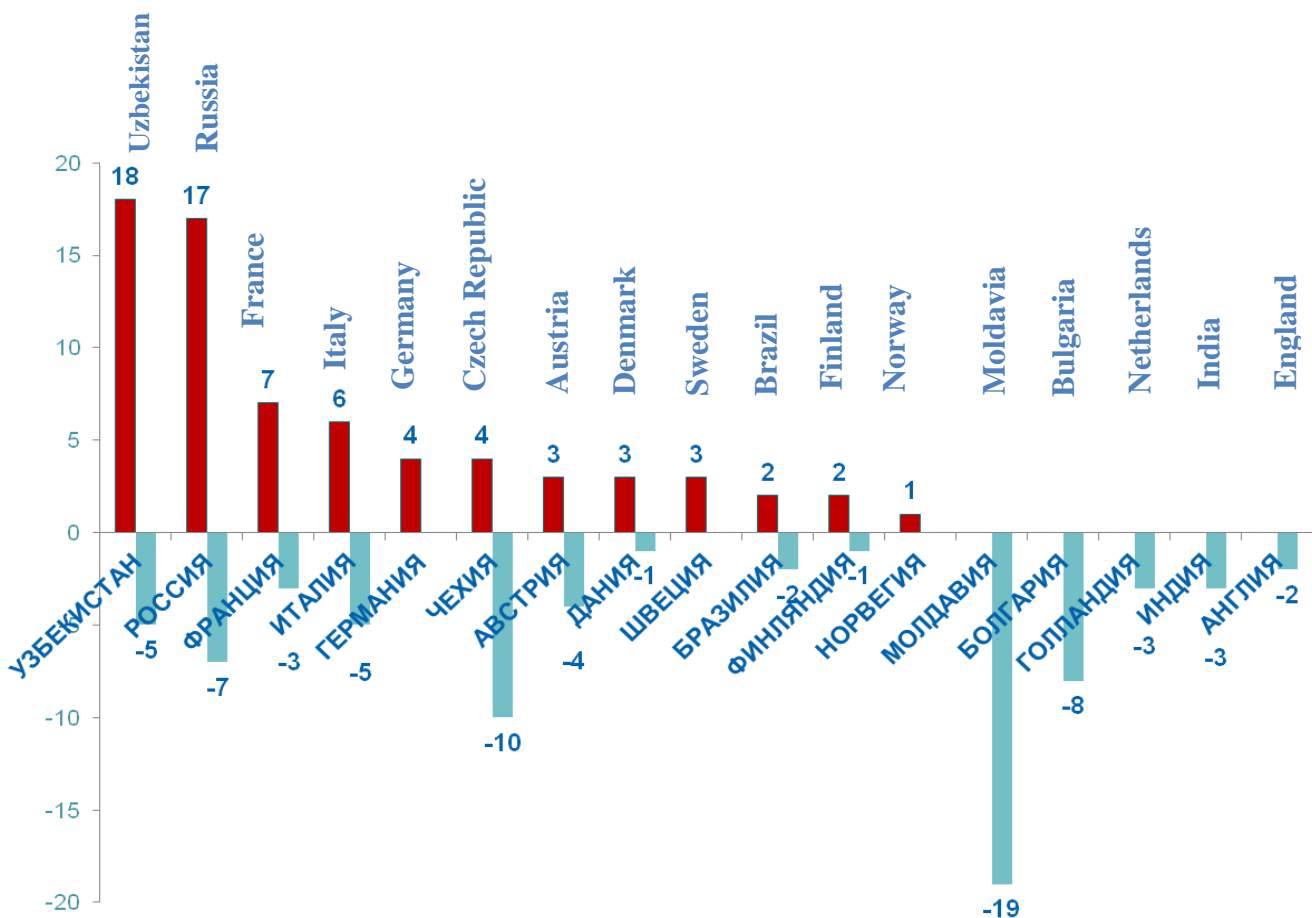
Comparison of retail prices for Bioparox (INN - Fusafungine), 125 mkg/dose, 400 doses, spray, 10 ml, USD



Comparison of retail prices for Cerebrolysin (INN- Cerebrolysin), injection solution, ampoules, 5 ml, # 5, USD



Number of positive (higher prices) and negative (lower prices) deviations of the retail prices for popular drugs on prescription from average values in the surveyed countries



The survey showed that in Russia, from 24 most popular retailed drugs on prescription, the prices for 17 (71%) pharmaceuticals exceed the average level in the surveyed countries and only prices for 7 (29%) are behind the average values.

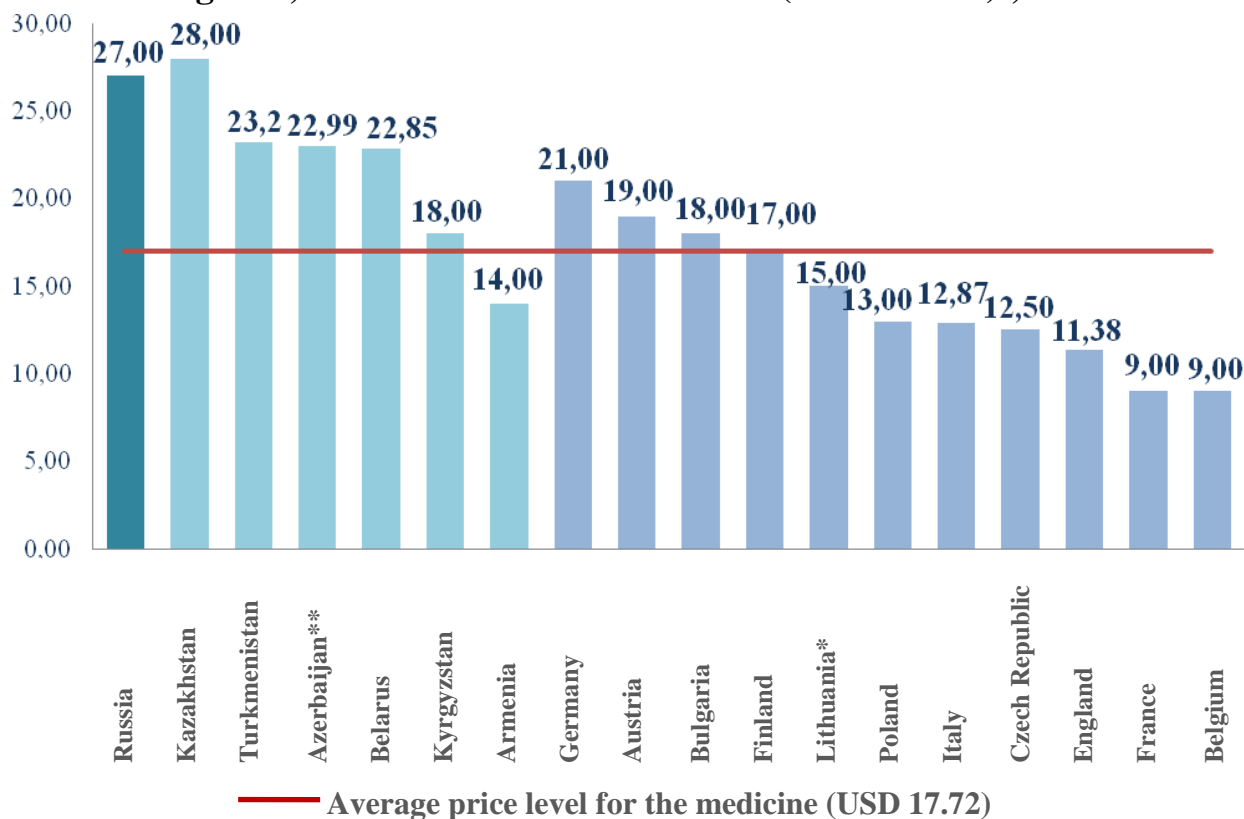
Moreover, Russia has the highest prices of the analyzed countries in CIS, EU and BRICS for the following 10 products: Kvinaks (INN - Azapentatsen), Detraleks (INN – Hesperidin + Diosmin), Donormil (INN - Doxylamine), Yarina (INN – Drospirenone + Ethinylestradiol), Movalis (INN - Meloxicam), Nimesil (INN - Nimesulide), Preductal MV (INN - Trimetazidine), Viagra (INN - Sildenafil), Crestor (INN- Rosuvastatin) and Bioparox (INN - Fusafungine).

It should be noted that all surveyed drugs have their registered counterparts; hence their prices should be formed in terms of pricing competition. Thus, generally, the retail prices for the surveyed drugs in Russia prove to be high versus other countries. Downward prices for such drugs can save a good deal on medicine spending for the people.

5.5. Comparison of retail prices for cardiac medicines in the Russian Federation and in other countries

The Federal Antimonopoly Service has also investigated the prices for certain medicines in circulation in Russia. These are prescription products; two of them are EDL-listed (Isoptin SR 240 and Plavix), and the rest - are not, i.e. the prices are not regulated, thereby one of them (TN - Teveten, INN - Eprosartan) has no registered counterparts under INN.

Comparison of retail prices for Teveten (INN - Eprosartan) film-coated tablets, 600 mg # 14, Abbott Helskea Products BV (Netherlands)⁵, USD



** - minimal retail price,

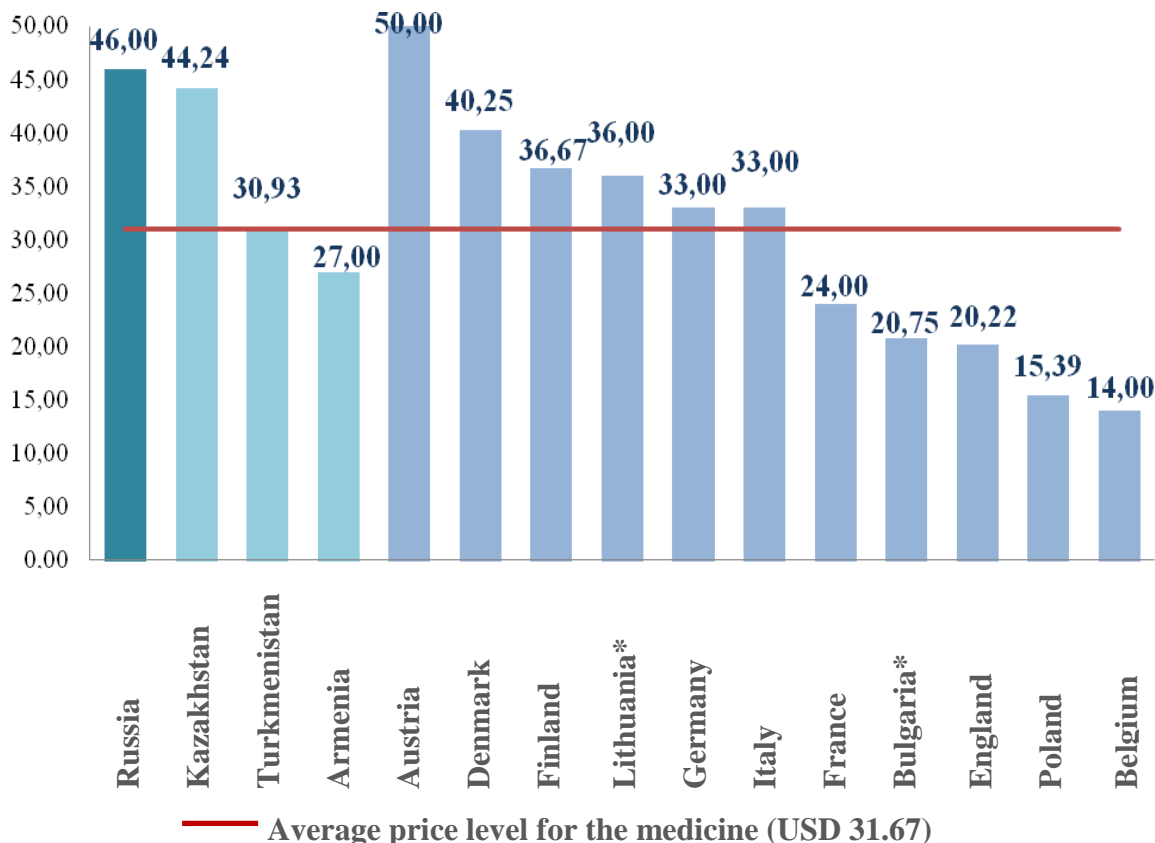
* - ceiling retail price.

The retail price for the Russian monopoly prescription medicine Teveten (Eprosartan INN), whose price is not regulated, totals to RUB 856.3 or USD 27.3 in this country, i.e. almost the highest among the CIS and EU countries; it is 54.1% higher versus the calculated average level of retail prices. The highest price was found in Kazakhstan – USD 28.4.

Similar situation was revealed with the price for the prescription medicine Atacand (INN - Candesartan INN), whose price is under Government control as well.

⁵ For Russia, the average price is given as computed by the FAS of Russia on the basis of quotations shown at reference websites. Information sources: <http://www.pharminindex.ru/>, <http://amt.allergist.ru/>, <http://medbrowse.ru/>, <http://health.mail.ru/drug/list/abc/%D0%9F/>.

Comparison of retail prices for Atacand (INN - Candesartan), tablets, 16 mg, # 28, AstraZeneca AB (Sweden)⁶, USD

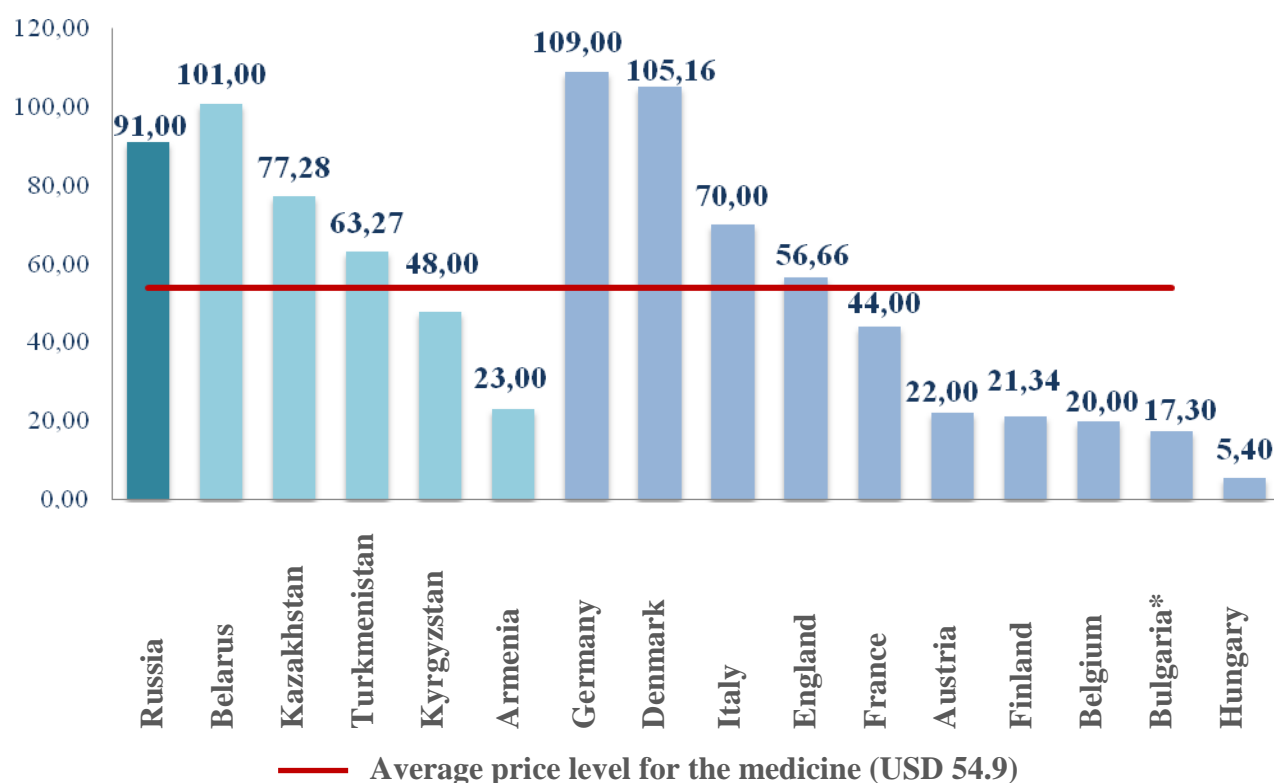


* - minimal retail price.

For example, Atacand retail price in Russia equals to RUB 1453 or USD 46.3, that is 45.2% higher versus the average price level in the surveyed countries. The highest retail price of USD 50.8 was registered in Austria, and the lowest in Belgium – USD 14.00.

⁶ Same

Comparison of retail prices for Plavix (INN – Clopidogrel), film-coated tablets, 75 mg, # 28, Sanofi Pharma Bristol-Myers Squibb SNC (France)⁷, USD

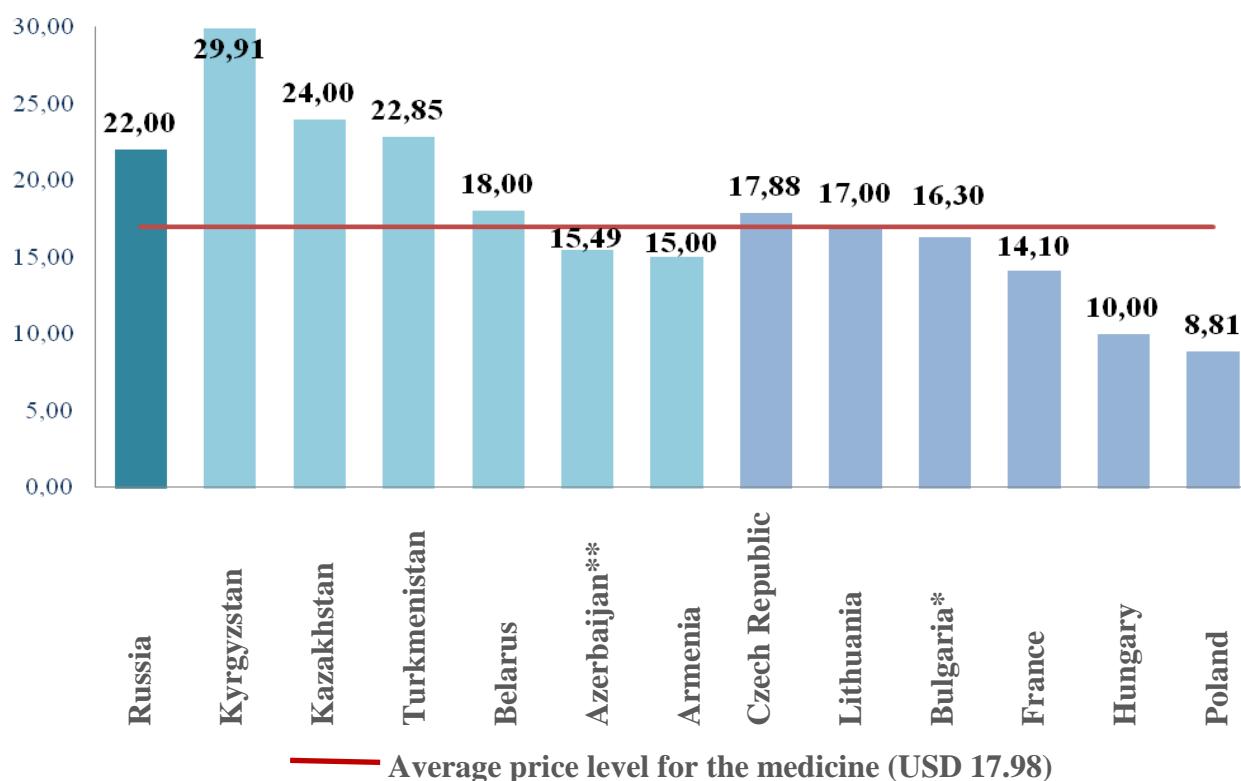


* - ceiling retail price.

The highest price for Plavix (INN - Clopidogrel) among the EU countries was found in Germany (USD 109.4) and Denmark (USD 105.2) and among CIS countries – in the Republic of Belarus (USD 101). Although the price for this prescription medicine, which is listed in TOP-100 popular products, is regulated in this country, Russia proves to be a top-price leader – the retail price for this drug totaled to RUB 2860 or USD 91.2 that is 66.1% higher as compared to the average price.

⁷ For Russia, the actual 2013 average weighted retail price is shown per one package of the medicine in the country (according to IMS Health data).

Comparison of retail prices for Preductal MR (INN - Trimetazidine), film-coated tablets, 35 mg, # 60⁸, USD



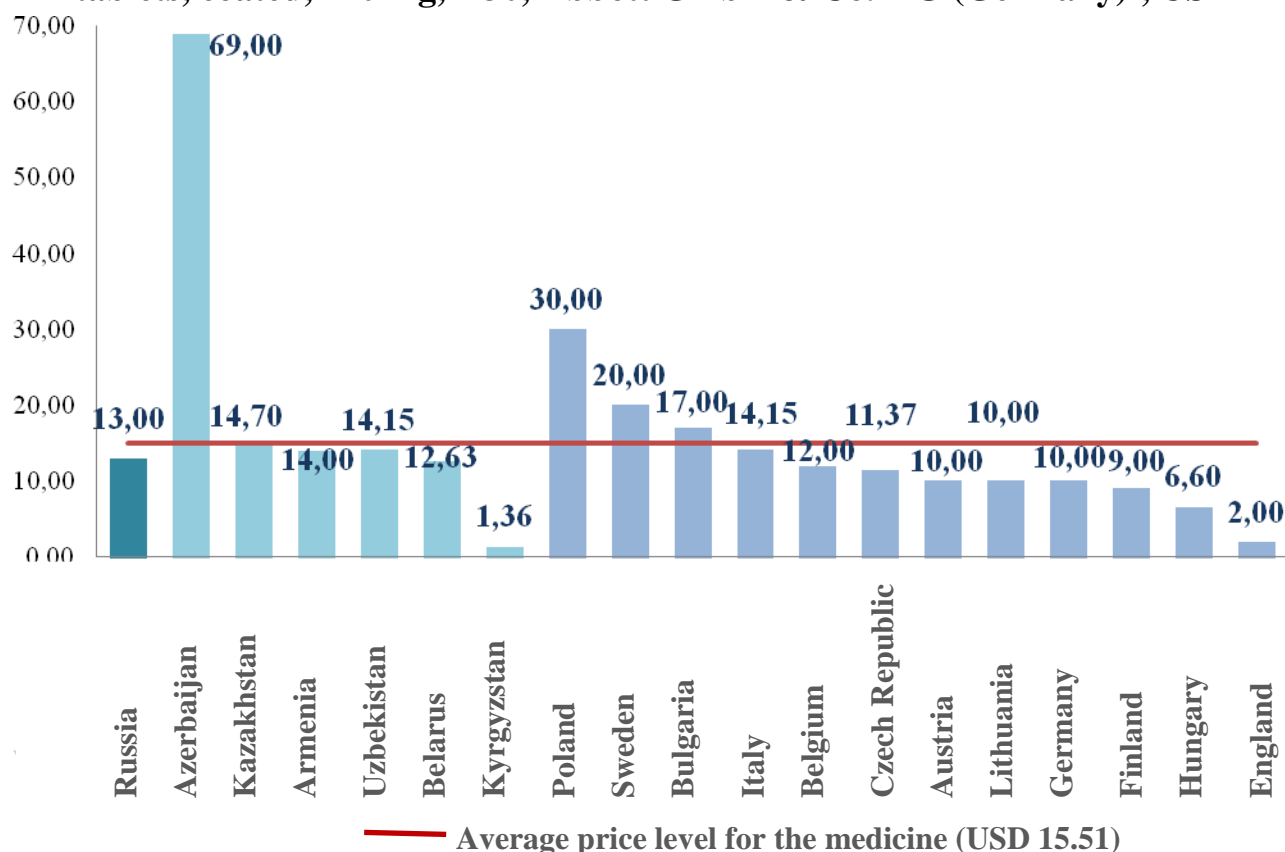
** - minimal retail price,

* - ceiling retail price.

Russia ranks the third among the countries with the highest retail prices for Preductal MR (INN - Trimetazidine). Virtually all surveyed CIS countries are among the leaders in this ranking: Kyrgyz Republic (USD 29.91), Republic of Kazakhstan (USD 24.6), Russia (RUB 719.4 / USD 22.93), Turkmenistan (USD 22.85) and the Republic of Belarus (USD 18.33). Thereby, in Russia this medicine belongs to TOP-100 list of the drugs on highest demand.

⁸ For Russia, the actual 2013 average weighted retail price is shown per one package of the medicine in the country (according to IMS Health data).

Comparison of retail prices for Isoptin SR 240 (INN - Verapamil), prolonged action tablets, coated, 240 mg, # 30, Abbott GmbH & Co. KG (Germany)⁹, USD



The price for the prescription medicine Isoptin SR 240 (INN - Verapamil) in Russia is subject to state regulation and does not exceed the average level of prices among the countries surveyed. Such price is also associated with many counterpart medicine traded in the country with same dosage form and INN identification.

Thus, the only medicine of the five selected drugs used in cardiology whose weighted average retail price in Russia (i.e. TN - Isoptin SR 240, INN - Verapamil) with Government controlled price is behind the average price among the countries surveyed. In terms of remaining four drugs, Russia is among the leaders of the countries where the highest prices were found.

⁹ For Russia, the average price is given as computed by the FAS of Russia on the basis of quotations shown at reference websites.

CONCLUSIONS & SUGGESTIONS

Based on primary research of medicines affordability in the Russian Federation and their prices, the following conclusions can be drawn.

The problem of medicines affordability in Russia and in the majority of surveyed countries is primarily associated with their rising purchase costs for certain individuals and public payers.

In Russia, the problem of medicines affordability is rooted both in the drugs price and their physical accessibility. In the regions, it is still difficult to get discounted prescriptions for medicines; many prescription drugs are provided with delay. Most citizens' claims concerning medicine support are filed to "Roszdravnadzor" when pharmacy organizations lack essential drugs or doctors refuse to prescribe this or that medicine. On top of that, many people entitled to preferential drug coverage, would not receive necessary pharmaceuticals because they have not been incorporated in the respective lists.

Lack of patient registries for all diseases related to drug supply system entails poor efficiency of cost control and planning difficulties of drug coverage expenses in accordance with the actual needs of health protection system and population.

Insufficient coverage of drug programs for the population coupled with persisting affordability challenges eventually lead to self-medication, self-diagnosis and self-selection of drugs instead of visits to the doctor.

Effective medicine support schemes (drug insurance) for the people are seen as a significant driver for the price and physical availability of drugs. Once implemented, the scheme for medicines reimbursement in Russia can significantly reduce drug prices and the cost of medic programs, as well as expand the coverage and the amount of financing for medicine support through possible use of co-payments to increase the physical and price affordability of drugs for the people on the outpatient level.

The performed comparative investigation of prices for monopoly expensive drugs has shown that over one half of surveyed drugs are imported in Russia at higher prices than to other CIS countries. In order to reduce the price for such products and to attain a significant budget savings, it is essential to develop a package of measures including the speediest market launch of generics, modification of registration procedure for manufacturers' ceiling sale prices based on comparison with reference countries, as well as addressing issues of long-term pricing agreements and procurement of such medicines directly from the manufacturers.

The analysis of retail prices for the prescription drugs of highest demand whose prices are not regulated by the state, as well as the drugs used in cardiology, has demonstrated that in Russia, these prices are generally high compared with other countries, even for the drugs having counterparts.

However we should remember the complexity of comparing the prices for medicines across various countries and the ambiguity of deliverables obtained in terms of

inhomogeneous character of accumulated data, a large number of drivers affecting prices and insufficient information about the extent of their influence. International comparisons are not always objective, therefore the conclusion therefrom should be very cautious.

The unresolved problems of determining interchangeable drugs under one INN name lead to a demand in the market of similar products (with the same active substance in one pharmaceutical form and dosage) with a significant price margin. For example, in Russia, the spread of registered ceiling manufacturers' prices for various trade names of "Ondansetron" drug (INN) makes 59 times.

Thereby, the drugs of lower price category continue to disappear from pharmacies portfolio, since manufacturers reduce unprofitable sales volumes of cheap products, whereby the wholesalers and retailers in the environment of limited markups are interested to deal with the most expensive drugs. According to "Roszdravnadzor", almost half of EDL product range is missing from pharmacies of some regions. As a result, although the state regulation of prices for specific drugs restrains the price elevation, in broad terms, the population' expenses for medicines tend to increase.

The survey has revealed that pricing is regulated one way or another in most of the surveyed countries with the purpose to reduce the cost of health care in resource-limited environment. International practice reflects a variety of models for drugs supply and price control, which must be taken into account in the comparative studies of prices and relevant administrative decision-making. However, the main way of regulation is outside the mainstream of administrative restrictions, but in the creation of sound competition environment and incentives to push down the drug prices.

Issues of competition have a greater impact on the prices of drugs than their administrative regulation. It is obvious that a system of measures to promote competition alongside with promotion and acceleration of market launch for generics will encourage all participants in the distribution chain to reduce drug prices. Administrative price regulation will be efficient, especially for the segment of drugs in the environment of reduced or absent competition (first of all, these are innovative medicines prior the expiry of their patent protection).

To create conditions for medicines price reduction in Russia and to improve price and physical affordability of the drugs to the public, the FAS of Russia has put forward the below measures:

1. To implement a set of efforts to promote competition in the pharmaceutical markets, i.e.:

- introduce the "interchangeable drugs" notion to the legislation determining the order for drugs interchangeability and to develop a database for interchangeable products;
- establish the uniformity of user manual wording for reproduced or original drugs, automatic changes in all similar medicines in cases of data modifications related to contraindications or side effects of one of the interchangeable medicine; create the nomenclature of pharmaceutical forms allowing to unify the list of pharmaceutical

forms of drugs for medical use; introduce registration requirements for standard dosages;

- ensure the equal quality of drugs in circulation across the country; all industry enterprises must unconditionally migrate to GMP standards; it necessary to ban the circulation of drugs produced in violation of GMP standards in the Russian Federation; the Russian Law must authorize the requirement to satisfy GLP, GCP, GSP, GDP and GPP alongside with a stronger pharmaceutical supervision;
- lift the unjustified barriers for drugs registration, simplify the registration of generic medicines, especially under international nonproprietary names where only one trade name was registered and recognize international clinical studies and in certain cases – certificates awarded by FDA or EMA;
- ensure compliance with the requirements of drugs prescription on relevant forms for international nonproprietary names enabling patients to choose among several interchangeable drugs so as to find the best option;
- establish a transparent procedure for the development of medicine lists and frequency of their updates; delete indications to specific pharmaceutical forms and to replace the same by the methods of administration;
- take other organizational steps to push up the demand for cheaper drugs (provided that all pharmaceutical producers obey GMP rules), including informing the medical community, government customers and general public about interchangeable medicines so as to encourage manufacturers to reduce prices both for original and reproduced drugs.

2. Given the lack of competition at monopoly drug market and inability to achieve a tangible price cut for such drugs at auctions, it is necessary to develop special procurement procedures for expensive monopoly drugs: to sign long-term government contracts on the basis of direct negotiations with producers before expiry of drug patents so as to reach significant discount or guarantees. Inter alia, such negotiations should take into account drug prices in different countries, actual monopolist's expenses including direct production costs, would-be reduction of marketing expenses thanks to direct secured supplies as well as manufacturers' opportunities to purchase substances at the lowest prices. In the framework of reached agreements, it is advisable to make direct purchases of drugs from manufacturers excluding third-party suppliers to conduct separate bids for medicines storage and delivery services for the independent entities of the Russian Federation.

3. As regards the pharmaceuticals traded in competitive markets (with analogues), it is necessary to migrate from the public procurement system and rigid administrative price regulation facilities to the system of medicines reimbursement. By virtue of medicines reimbursement, registration of factory prices can be done in a declarative manner, but citizens will be able to obtain the cheapest prescription medicines from the group of interchangeable products. A patient can purchase more expensive drugs of this group at his/her partial expense. Medicines reimbursement system will stimulate competition and lower prices within the groups of interchangeable drugs covered by this scheme. Medicines

reimbursement system can be implemented only provided that the manufacturers operating in accordance with international GMP standards and ensuring equal quality drugs are admitted therein.

4. Prior to the transition to the system of drug reimbursement, it is essential to implement measures to improve the existing regulations for EDL prices as follows.

4.1. Factory prices for drugs without analogues in the commodity market occupying a monopoly position should be established by virtue of comparison with external reference prices, since only pricing comparison for a specific drug in the country and abroad will correctly assess its feasibility. It is advisable to consider the establishment of ceiling factory prices at a level not exceeding 30% of the minimum price in the reference countries.

4.2. Review the list of reference countries represented in the Methods as the benchmarks for foreign manufacturers. Currently, the list covers 21 countries – countries with initially high prices and those with traditionally low prices, as well as countries suffering a serious economic crisis whose drug prices are stipulated by interim arrangements between governments and pharmacological companies.

It is desirable to search for reference countries similar to Russia in terms of economic development levels. To select reference countries, can be used the annual ranking of the countries as regards the gross national income, which is calculated by the World Bank¹⁰, and include in the list the countries similar in terms of development level, whose gross national income per capita (estimated on the basis of purchasing power parities) differs no more than 10-15% from the same in the Russian Federation, both upwards or downwards. For example, according to the World Bank rankings compiled by countries in 2012 in terms of gross national income, Lithuania, Estonia, Czech Republic, Chile, Slovakia, Poland, Latvia, Hungary, Portugal, Croatia, Malta and Greece belong to this group.

In addition, it is proposed to provide the accounting system for special situations in individual countries, when the prices for drugs in these countries will not be accounted for.

4.3. Introduce a mechanism of pharmacological and economic studies for innovative medicines re-entering the market.

4.4. Provide for price registration of home-made drugs above the weighted averages, as well as re-price the rates that are higher than the forecasted inflation in circumstances equally affecting all manufacturers of certain drugs and triggering a substantial escalation of production costs (for example, a significant rise in prices for pharmaceutical substances).

4.5. Introduce a tool for mandatory verification of data submitted by foreign companies related to prices of medicines in other countries and on the pricing structure including direct production costs; establish an administrative responsibility for providing false information.

¹⁰ Gross National Income (GNI) means an aggregate value of all commodities and services produced in a year within a country (i.e. GDP) plus the incomes received by this country citizens from overseas, less the incomes that foreigners bring out from the country.

4.6. For exceptional cases, provide an option to revise, modify or change already registered pricing level (for example in cases of tangible technical errors or corrupted data when calculating the ceiling factory prices for drugs when a manufacturer offers to cut a price that was previously registered or where the production costs have changed dramatically, etc.).

4.7. Eliminate the need to register drug prices in the event of changes in registration documents not affecting the pricing.

4.8. Provide for a procedure to amend the State Register of ceiling factory prices and their timely synchronization with the State Register of medicines.

4.9. Introduce a transitional period enabling to register prices for new medicines included in EDL before the sales ban stipulated by Part 3 of Article 61 of the Federal Law of 12.04.2010 № 61-FZ "Circulation of Medicines" takes effect.

4.10. It is essential to consider the transition from maximum wholesale and retail markups expressed in percentage to maximum markups in natural and fixed terms (RUB) differentiated by price groups. This option will create equal competitive conditions for the manufacturers of similar pharmaceuticals encouraging them to reduce ceiling factory prices, as the demand for their products will be determined by the needs of end-customers (i.e. general public) rather than by the wholesalers' strive for maximum profits.

5. Strengthen control over enforcement of EDL pricing procedures at all levels of distribution of drugs including automated detection of such violations through information systems automatically searching inflated drug prices over the Internet.

6. Consider the imposition of direct or indirect control over the prices for basic drugs with the largest sale volumes.

7. Consider the abolishing of assignment to the state authorities of the independent entities of the Russian Federation the power of the Russian Federation on procurement of medicines included in the program "7 Nosologies" and centralizing procurement of drugs for the prevention, detection, treatment and monitoring of persons infected with human immunodeficiency virus and hepatitis B or C.

The assignment of power for the procurement of expensive drugs to the independent entities of the Russian Federation can trigger higher costs of the federal budget and narrow the affordability of medicines to the categories of population entitled to benefits. The FAS of Russia believes that the centralized purchasing of expensive drugs enables a more efficient use of budgetary resources and reduces the risks of social unrest due to the absence or deficiency of essential drugs.

8. Develop proposals to improve the Patent Law. Patents for pharmaceutical products are designed to protect new drugs and to encourage research in the field of medicine and pharmaceuticals. However, in practice the number of patents issued to actually new drugs is constantly decreasing, whereby the total number of patents for pharmaceutical products is going up thanks to patents for minor modifications to existing

products (additional or new indications for use, therapeutic methods, combinations of active ingredients, pharmaceutical forms, production techniques, etc.).

Prices for patented drugs are always much higher versus the prices for products with expired patents or having market competitors as reproduced drugs. This is explained by the need to recover the costs of research and production and to raise a profit. But often, pharmaceutical industry players spend considerable amounts of money on marketing and carry these costs over to the final price.

In order to mitigate the effects of ill-founded patents leading to an artificial extension of the monopoly status of individual companies, it is necessary to improve the patent system including:

- more rigid criteria for patentability through limiting the number of patents for the discovery of any new property or new application of already known substances;
- discussions of objections preventing the issue of a patent and
- authorization (compulsory license) for the production of patented pharmaceutical products to address public health problems, etc.

9. Negotiate the matter of enhancing the affordability of monopoly drugs for patients through a compulsory licensing institution.

10. Evaluate the possibility of using parallel import of medicines and elaborate its implementation within the Russian Federation.

11. Build an information platform to publish information about wholesale/retail prices for medicines in various countries so as to use the same in the framework of state regulation of drug prices, compute the initial (maximum) contract price, identify unreasonably high prices for specific drugs in Russia and automate relevant comparative studies.

