

Access to Drugs for Treating Hepatitis C in Russia in 2013



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BACKGROUND INFORMATION

The purpose of this report was to investigate the situation regarding access to drugs treating the hepatitis C virus (HCV) in Russia. To this end, Treatment Preparedness Coalition made an overview of the applicable legislation, and likewise analyzed the data relating to governmental drug procurements, statistics on the prevalence and incidence of hepatitis C in various territories of the Russian Federation, and data regarding the financing of HCV treatment programs.

The relevance of this report is above all due to the extent of the epidemic in Russia. According to the World Health Organization (WHO), Russia falls into the group of countries with an HCV prevalence of **2% to 2.9%** of the general population¹. According to official data, cited in the recommendations of the Russian Ministry of Health on diagnosing and treating HCV (hereafter: MH Recommendations), in 2011 alone 57,028 people were registered with chronic HCV. According to the statements of experts, cited in the mass media, the estimated prevalence of HCV in Russia is approximately 5 million people². According to the Analytical Survey of Viral Hepatitis in the Russian Federation, at the end of 2012 the official rate of chronic HCV was 337.5 per 100,000 people³. According to data obtained from medical agencies in RF territories responding to questions about the incidence of HCV, there are no less than **287,000** patients with HCV officially registered in 45 regions of the RF, of which approximately **86,000** are HIV/HCV co-infected (see the relevant sections below).

Based on this heterogeneous data, it can be concluded that: **the number of people with HCV in Russia falls within the range of a few hundred thousand people (official data) to several million (estimated). Accurate statistics are not available due to the lack of a unified system for collecting and analyzing data related to the HCV epidemic on the federal level.**

The legislative base that regulates the financial and clinical aspects of the fight against the HCV epidemic in Russia are as follows. In Russia there is no federal law on combating the HCV epidemic, similar to Law No. 38-F3 from 30 March 1995 for HIV and to No. 77-F3 from 18 June 2001 for tuberculosis, both of which stipulate, among other things, free drugs and testing for patients.

Viral hepatitis C is included in the list of socially significant diseases and in the list of diseases posing danger to others, in accordance with the resolution of the government of the Russian Federation from 1 December 2004, amended 13 July 2012⁴.

Certain drugs for treating HCV⁵ are included in the List of Medicines, available by prescription from a doctor (paramedic), as part of additional free medical aid to specific categories of people who have the right to receive governmental social assistance in accordance with the decree from the Ministry of Health and Social Development of the Russian Federation No. 665 from 18 September 2006 (latest amendment: 10 November 2011)⁶. This resolution was adopted in accordance with No. 178-F3 from 17 June 1999, "On Governmental Social Assistance".

Consequently, as specified by this law, drugs treating HCV can be provided free of charge to certain categories of people.

A number of drugs for treating HCV are included in the List of Vital and Essential Medicines (EML) per the amendment from 1 January 2014⁷, and the government regulates the maximum selling price for these drugs.

¹ WHO recommendations for treating viral hepatitis C, 2014. Available on WHO's website: <http://who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/>

² <http://www.medpulse.ru/health/prophylaxis/prof/12051.html>

³ Viral Hepatitis in the Russian Federation. Analytical Review. 9 Edition.

⁴ <http://www.referent.ru/1/201835>

⁵ Pegylated interferons alpha-2a and alpha-2b, and ribavirin.

⁶ <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=122209>

⁷ Pegylated interferons alpha-2a and 2b, interferons alpha-2a and 2b, ribavirin. The current version is available online at grls.rosminzdrav.ru

Analyzing auctions for the procurement of HCV drugs in RF territories in 2013 showed that the main sources of procurement financing are:

- Inter-budgetary transfers within the framework of Resolution No. 1438, for procuring drugs to meet the needs of specific categories of people, including those with HIV.
- Funds for procuring drugs to meet the needs of specific categories of people in accordance with Law No. 178-F3.
- Funds for target-oriented programs of RF territories, dedicated to combating socially significant diseases, including HCV.

Government Resolution No. 1438⁸ as amended on 1 March 2014 describes regulations for funding procurements of testing materials and drugs for treating HIV, HBV, and HCV at the expense of the federal budget. Among other things, this resolution contains a list of medicines subject to purchase. As a rule, for inclusion in Resolution No. 1438, the drug must be on the EML.

In accordance with Federal Law No. 349-F3 from 2 December 2013 "On the Federal Budget for 2014 and for the Planning Period 2015 and 2016", the total amount allocated for procuring drugs treating HIV, HBV, and HCV is a little more than **14 billion roubles, or approximately USD400 000 000 (14 061 597 600)**⁹. This corresponds exactly with the sum allocated in 2013. There are no guidelines as to how to allocate these funds to specific diseases. **This means that it is impossible to say exactly what sum from the federal budget will be dedicated specifically to procuring HCV drugs.** This sum can only be determined after completing all bidding and executing the contracts.

At present, the list of medicines from Resolution No. 1438 includes five drugs that are used in treating HCV. This list (using the international non-proprietary names, INN) is shown below: **interferon alpha-2a, interferon alpha-2b, peginterferon alpha-2a, peginterferon alpha-2b, and ribavirin**¹⁰. All of these drugs are including in the EML list, regulating the maximum selling price.

As has already been mentioned in previous publications¹¹, unifying procurement funding for drugs treating HIV and hepatitis B and C within the framework of one resolution in practice results in the fact that in most cases, procuring drugs for treating HCV within the framework of Resolution No. 1438 takes place on the "leftover" principle. In other words, antiretroviral drugs for treating HIV are purchased first, and only thereafter are auctions announced for procuring drugs that treat hepatitis C, based on the amount of the remaining funds.

It is important to note that within the regional target-oriented programs, health-care administrators can often purchase HCV drugs that are not included in Resolution No.1438 or the EML, including the recently registered protease inhibitors for treating HCV: boceprevir¹², telaprevir¹³, and simeprevir¹⁴, as well as cepeginterferon alpha-2b.

The documents regulating the process of providing medical care to patients with HCV include:

- Ministry of Health Decrees:
 - from 23 November 2004, RF No. 260 "On the Approval of the Standard of Medical Care for Patients with Chronic Hepatitis B and Chronic Hepatitis C",

⁸ <http://www.rg.ru/2013/01/07/vich-gepatit-site-dok.html>. Here and hereinafter the numbers are given in RUB. For USD, a rate of 35 RUB per 1 USD can be applied.

⁹ http://itpcru.org/files/files_532.html. Here and hereinafter the rate of 35 RUB per 1 USD is applied.

¹⁰ In accordance with the Recommendations for Testing and Treating Adult Patients with Hepatitis C, RF Ministry of Health, available online at http://itpcru.org/files/files_430.html

¹¹ Treatment Preparedness Coalition. "Yellow Twilight". Available online at http://itpcru.org/files/files_440.html

¹² http://grls.rosminzdrav.ru/Grls_View.aspx?idReg=142452&isOld=0&t=fbbe3b54-f676-4243-95cd-bcc594ee4d13

¹³ http://grls.rosminzdrav.ru/Grls_View.aspx?idReg=35490&isOld=1&t=59145764-1773-4a5f-aa9a-bf0a9f934b55

¹⁴ <http://grls.rosminzdrav.ru/grls.aspx?s=%u0441%u0438%u043c%u0435%u043f%u0440%u0435%u0432%u0438%u0440>

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- from 6 October 2005 No. 621 "On the Approval of the Standard of Medical Care for Patients with Chronic Active Hepatitis in Conjunction with Primary Biliary Cirrhosis",
 - from 13 October 2005 No. 634 "On the Approval of the Standard of Medical Care for Patients with Chronic Active Hepatitis in Conjunction with Chronic Hepatitis C",
 - Recommendations for testing and treatment of adult patients with hepatitis C, RF Ministry of Health from 4 March 2013.

The last document is of an advisory nature; treatment standards were adopted almost ten years ago and urgently require revision.

METHODOLOGY

The data for analyzing auctions, the results of which will be presented in the following sections, was taken from the official site for posting information about governmental procurements zakupki.gov.ru.

The sample included auctions published on the site zakupki.gov.ru in the period from 1 January 2013 to 31 December 2013, with a delivery due date per the contract of no later than March 2014 and with an initial maximum auction price of 500,000 roubles or more¹⁵. Relevant parameters were entered into the search filters on the website zakupki.gov.ru.

333 auctions: peginterferon alpha-2a and alpha-2b

14 auctions: boceprevir and telaprevir

Drugs included in the analysis were determined according to the list of drugs in Decree No. 1438 as amended on 1 March 2014. This list includes:

- Peginterferon alpha-2a
- Peginterferon alpha-2b
- Interferon alpha-2a
- Interferon alpha-2b
- Ribavirin

The standard interferons alpha-2a and alpha-2b were excluded from the analysis due to the fact that according to the guidelines of the leading medical associations, these drugs are no longer recommended for HCV treatment. In accordance with Russian recommendations, non-pegylated interferons are allowed for use only "in cases of limited economic resources"; their use is also subject to a number of additional conditions¹⁶. The drug ribavirin, included in standard treatment regimens for hepatitis C, is likewise excluded from the analysis due to the market presence of a large number of generic drugs and their comparatively low cost.

The drug cepeginterferon alpha-2b, registered in the RF for HCV treatment, was not included in the analysis because it does not appear in Resolution No. 1438.

During the search process, key words were used: "peginterferon" (main request) as well as "pegylated interferon", "peginterferon", "antiviral drugs", "Hepatitis B and C", "Resolution 1438" and other grammatically related word forms. Relevant requests were entered into the search engine system on the website zakupki.gov.ru.

Altogether **333** auctions were analyzed for the procurement of the pegylated interferons alpha-2a and alpha-2b in 68 regions of the RF¹⁷ and 14 auctions were analyzed for procuring antiviral drugs.

To calculate the number of patients that could potentially receive treatment based on the number of purchased drug units, the treatment regimen of 48 weeks / 1 injection per week was used.¹⁸

¹⁵ Upon searching for the key word peginterferon with a filter of less than 500,000 over the period 1 January 2013 to 1 December 2013, the search engine for the website zakupki.gov.ru returned results for 85 auctions from various periods for amounts starting from 27,348 roubles; 3 results were returned for "peiginterferon" and zero results were returned for "pegylated interferons". The average price is 419,000 for one treatment regimen of pegylated interferon (2012). Accordingly, the chance of error should not be more than 88 potential treatment regimens with a duration of 48 weeks.

¹⁶ In situations of limited financial resources, standard interferons can be used only in patients with genotypes 2 or 3, people under the age of 40, with no significant fibrosis / cirrhosis, no co-infections etc.

¹⁷ Some auctions could have been missed due to technical reasons.

In searching the auctions for antiviral drugs the international nonproprietary names (INN) were used, registered with the Government Drug Register at the time of writing the report. In total, three drugs were included in the analysis: boceprevir, simeprevir, and telaprevir. The INN for antiviral drugs were taken from the report by Treatment Action Group (the current version is available at <http://www.pipelinereport.org/>).

To calculate the number of patients who could potentially receive treatment with antiviral drugs based on the volume of units purchased, basic treatment regimens were used as specified in the Recommendations of the RF Ministry of Health¹⁸.

- Boceprevir. 4 tablets, 200 mg, 3 times a day for 44 weeks.
- Telaprevir. 2 tablets, 375 mg, 3 times a day for 12 weeks.

A total of 14 auctions for procuring antiviral drugs treating HCV, returned by the search request using the INN at the website zakupki.gov.ru, were analyzed.

To collect information on the incidence and prevalence of HCV, as well as the existence of specific anti-HCV programs on the level of RF territories, the method of officially requesting information from competent medical agencies was used.

¹⁸ The main recommended treatment regimen in accordance with Russian Recommendations for testing and treating hepatitis C in adults, from 4 March 2013.

¹⁹ The drug simeprevir is not mentioned in the Ministry of Health's Recommendations and at the date of the Recommendation's publication was not registered in the RF.

THE HCV EPIDEMIC AND FINANCIAL MEASURES FOR FIGHTING THE EPIDEMIC IN RF TERRITORIES

In order to obtain more accurate data on the scale of the HCV epidemic in the RF, in 2013 Treatment Preparedness Coalition sent a request regarding the epidemiological situation and the accessibility of drugs for patients to the competent medical agencies at the level of RF territories. Among other things, information was requested about the following items: the number of registered patients with viral hepatitis C, the estimated number of patients with viral hepatitis C, the number of registered patients with viral Hepatitis C and the Human Immune Deficiency Virus (HIV), and the existence of regional programs to combat the HCV epidemic. Replies were received from 50 RF territories, five of them did not contain information about the prevalence of the disease.

According to the data provided, no less than 287,000 patients with HCV have been officially registered in 45 regions²⁰, whereby in some of the responses information was provided only about people registered with HIV/HCV co-infection (for example Ivanovskaya Oblast, Krasnoyarski Krai, Novgorodskaya Oblast, St. Petersburg, Sverdlovskaya Oblast, and Chelyabinskaya Oblast). **This number includes no less than 86,000 patients with HIV/HCV in 45 RF territories** (whereby not all of the 45 regions provided information about the number of registered patients with HIV/HCV).

Judging by the information in the official responses, in many RF regions **there are well-established systems in place for registering patients with HCV**, including those co-infected with HIV/HCV. In several territories, patients requiring treatment are registered, including the Voronezhskaya, Irkutskaya, Orlovskaya, Kostromskaya and Tyumenskaya Oblasts, St. Petersburg, the Bashkortostan Republic, etc. The official responses from Orlovskaya Oblast and the Bashkortostan Republic both indicated that a register for patients' clinical data is kept, which is used in making decisions about starting treatment.

In the majority of RF territories, the decision about which patients should be prescribed drugs **is made in consultation with a special commission**. Examples of such commissions are: an expert group for problems related to testing, treating and preventing viral hepatitis B and C (Altaiski Krai), the Commission for the Rational Use of Expensive Drugs (St. Petersburg), etc. Similar commissions are functioning in, among other places, Archangelskaya, Astrakhanskaya, Bryanskaya, Kalyzhskaya, Kirovskaya, and Pskovskaya Oblasts, and in the Republic of Mordovia.

In some territories, a so-called "**waiting list**" is kept of patients, who are waiting in line to receive drugs. The presence of waiting lists was indicated in responses received from medical agencies in Bryanskaya, Voronezhskaya, Myrmanskaya, Orlovskaya, and Tyumenskaya Oblasts. The main indicators for prescribing treatment **are the degree of liver fibrosis and liver enzyme levels; in several regions, adherence was noted among the factors that influence prescribing treatment²¹**.

The existence of regional programs to combat hepatitis C (or socially significant diseases in general) was indicated in responses from Altaiski Krai, Bashkortostan, Kamchatski Krai, Kirovskaya Oblast, Leningradskaya Oblast, Orlovskaya Oblast, Pskovskaya Oblast, and Chelyabinskaya Oblast. In several regions, funds for treating viral hepatitis are allocated from regional programs for promoting health care (Saratovskaya Oblast, Penzenskaya Oblast, Archangelskaya Oblast, and Astrakhanskaya Oblast). Over the course of monitoring, the existence of regional programs for combating the HCV epidemic was noted in Novosibirskaya Oblast, Krasnoyarski Krai, Permski Krai, Khabarovski Krai, etc.

The graph below shows the distribution of the total bidding budget for procuring pegylated

²⁰ As of different dates in 2013 and early 2014.

²¹ Patient compliance with the drug regimen.

interferons in RF territories, including auctions conducted by the RF Ministry of Health to meet the needs of institutions under federal jurisdiction. Only data from the auction sample analysis (333 auctions) is included. As can be seen in the graph, the larger procurement volumes take place in St. Petersburg (7.84%), Moskovskaya Oblast (6.1%), Permski Krai (5.4%), Krasnoyarski Krai (4.29%), Irkutskaya Oblast (4.02%), Novosibirskaya Oblast (4.04%), Orenburgskaya Oblast (3.77%), Khabarovski Krai (2.47%), Khanti-Mansiski AO (2.14%) and Moscow (2%). Purchases conducted by the RF Ministry of Health account for the largest portion: 19.46% (in absolute terms, 256 million roubles).

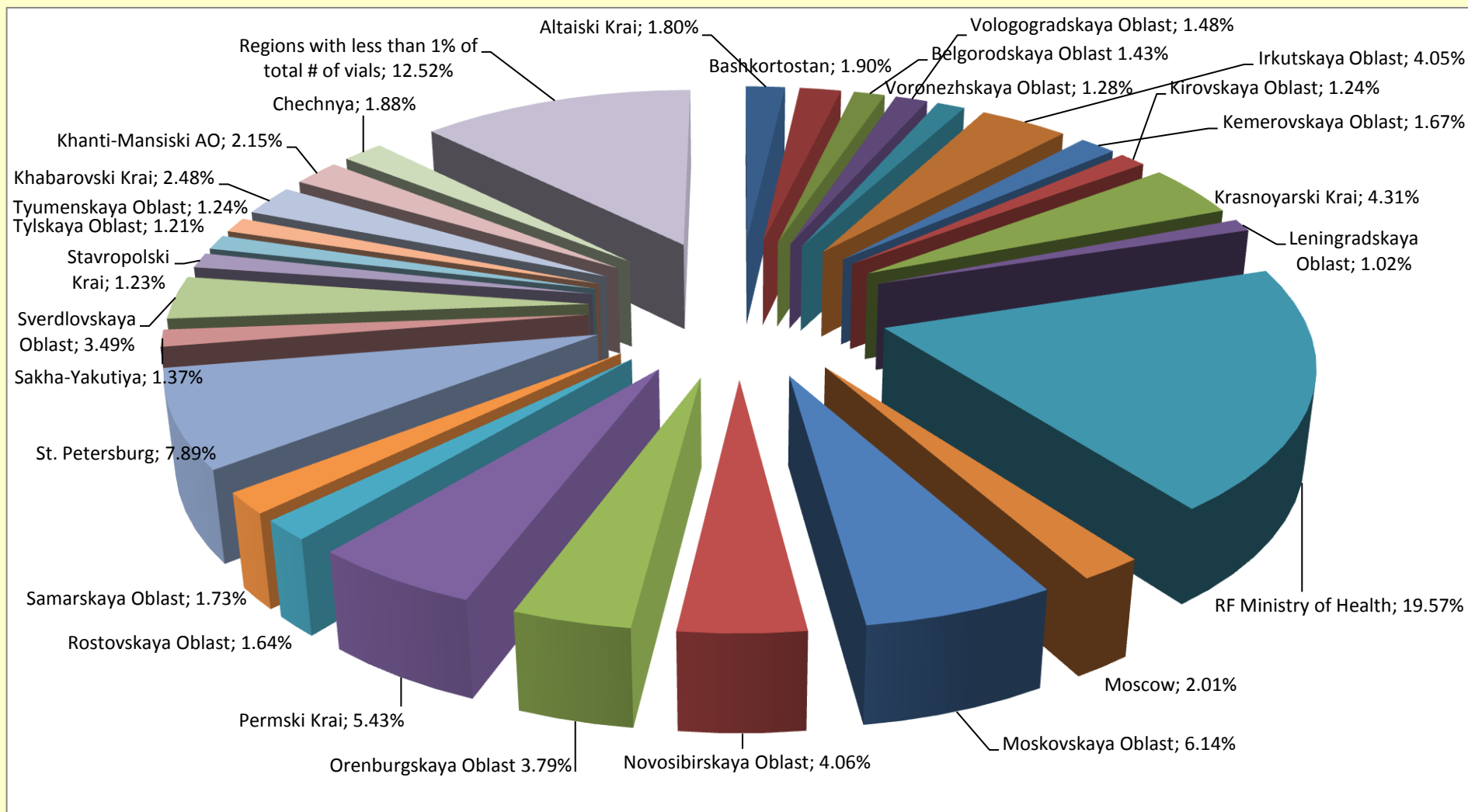
Purchase volumes in the region (based on data analysis of 333 auctions) in monetary terms are presented in the table below²²:

Region	Number of Vials	Contract Amount, Roubles
Altai Republic	73	790 276.10
Altaiski Krai	3172	30 037 680.00
Amurskaya Oblast	96	763 372.80
Archangelskaya Oblast	834	9 220 324.80
Bashkortostan	3356	33 244 530.30
Belgorodskaya Oblast	2513	24 527 536.68
Bryanskaya Oblast	937	9 053 172.50
Vladimirskaya Oblast	72	756 000.00
Volgogradskaya Oblast	2611	25 911 280.25
Vologodskaya Oblast	288	2 764 800.00
Voronezhskaya Oblast	2262	21 347 905.45
Dagestan	1604	17 221 682.16
Zabaikalski Krai	686	7 289 708.04
Irkutskaya Oblast	7139	67 679 871.38
Kabardino-Balkariya	816	8 318 407.68
Kaliningradskaya Oblast	931	8 049 412.04
Kaluzhskaya Oblast	1008	10 444 926.71
Karachaevo-Cherkessiya	360	3 039 442.80
Karelia	1433	13 798 300.00
Kemerovskaya Oblast	2940	28 281 111.32
Kirovskaya Oblast	2184	20 530 248.52
Kostromskaya Oblast	384	3 561 600.00
Krasnodarski Krai	336	3 267 439.20
Krasnoyarski Krai	7604	82 030 392.49
Leningradskaya Oblast	1800	17 959 995.00
Lipetskaya Oblast	639	6 253 780.52
Magadanskaya Oblast	193	1 897 078.47
Mari-El	568	5 812 979.60
Ministry of Health RF	34511	256 101 159.82
Mordovia	1616	14 985 762.21
Moscow	3538	35 617 076.77
Moskovskaya Oblast	10820	110 191 085.40
Murmanskaya Oblast	770	8 014 657.06

²² The analysis does not include contracts for an amount of less than 500 thousand roubles. For details, see the Methodology section. Some of the auctions may have been missed due to technical reasons.

Nizhegorodskaya Oblast	155	1 232 551.66
Novosibirskaya Oblast	7164	69 163 794.68
Omskaya Oblast	820	7 388 317.80
Orenburgskaya Oblast	6688	65 436 332.00
Orlovskaya Oblast	89	1 126 648.33
Penzenskaya Oblast	491	4 983 819.22
Permski Krai	9568	88 707 483.78
Pskovskaya Oblast	259	2 468 985.48
Rostovskaya Oblast	2892	28 819 741.08
Ryazanskaya Oblast	50	527 885.50
Samarskaya Oblast	3045	28 017 370.62
St. Petersburg	13909	135 542 638.50
Saratovskaya Oblast	930	8 226 633.36
Sakha-Yakutiya	2418	21 949 418.28
Sakhalinskaya Oblast	223	2 303 879.17
Sverdlovskaya Oblast	6147	58 854 496.00
Severnaya Ossetia-Alaniya	148	1 654 936.00
Smolenskaya Oblast	248	2 362 822.99
Stavropolski Krai	2172	18 322 686.52
Tambovskaya Oblast	805	7 931 997.25
Tatarstan	690	6 147 296.75
Tverskaya Oblast	400	4 169 284.00
Tomskaya Oblast	192	1 862 922.24
Tylskaya Oblast	2130	21 213 097.51
Tyva	319	3 321 219.55
Tyumenskaya Oblast	2178	19 733 500.00
Udmurtskaya Oblast	480	4 570 560.00
Ulyanovskaya Oblast	114	1 095 156.96
Khabarovski Krai	4382	47 003 236.74
Khakassiya	108	1 328 747.76
Khanti-Mansiski AO	3798	37 087 147.76
Chelyabinskaya Oblast	1405	12 454 158.65
Chechnya	3315	35 366 761.10
Chuvashiya	355	3 632 281.72
Chukotski AO	164	1 699 999.40
TOTAL	176 345	1 644 470 804.43
TOTAL USD		46 984 880

Table 1. Procurement volumes for pegylated interferons in RF territories and by the RF Ministry of Health, based on data analysis of 333 auctions.



Graph 1. Distribution of the total bidding budget for procurement of pegylated inteferons in RF territories, including auctions conducted by the RF Ministry of Health to meet the needs of institutions under federal jurisdiction, 2013.

PROCUREMENT OF PEGYLATED INTERFERONS

Procurement Volumes and Expenditures

Five drugs to treat HCV were permitted for purchase with funds from the RF federal budget in 2013: peginterferon alpha-2a, peginterferon alpha-2b, interferon alpha-2a, interferon alpha-2b, and ribavirin. Standard interferons and ribavirin have been excluded from this report (see Methodology).

Based on the data from 333 auctions for procuring pegylated interferons in 68 regions, the following drugs and dosages were purchased in the RF in 2013:

- Peginterferon alpha-2a, 180 µg (according to the registry grls.rosminzdrav.ru, registered in the RF only under the brand name Pegasys);
- Peginterferon alpha-2b, dosages 50 µg, 80 µg, 100 µg, 120 µg, and 150 µg (according to the register grls.rosminzdrav.ru, registered in the RF only under the brand name PegIntron).

Based on the data from 333 auctions in 68 regions, a total of **1,644,470,804.43** roubles (around 47 mln USD) was spent on procurements of pegylated interferons, which resulted in a total of **176,345** vials purchased. In terms of the number of patients who could potentially receive treatment, this amounts to **3,700 48-week treatment regimens**.

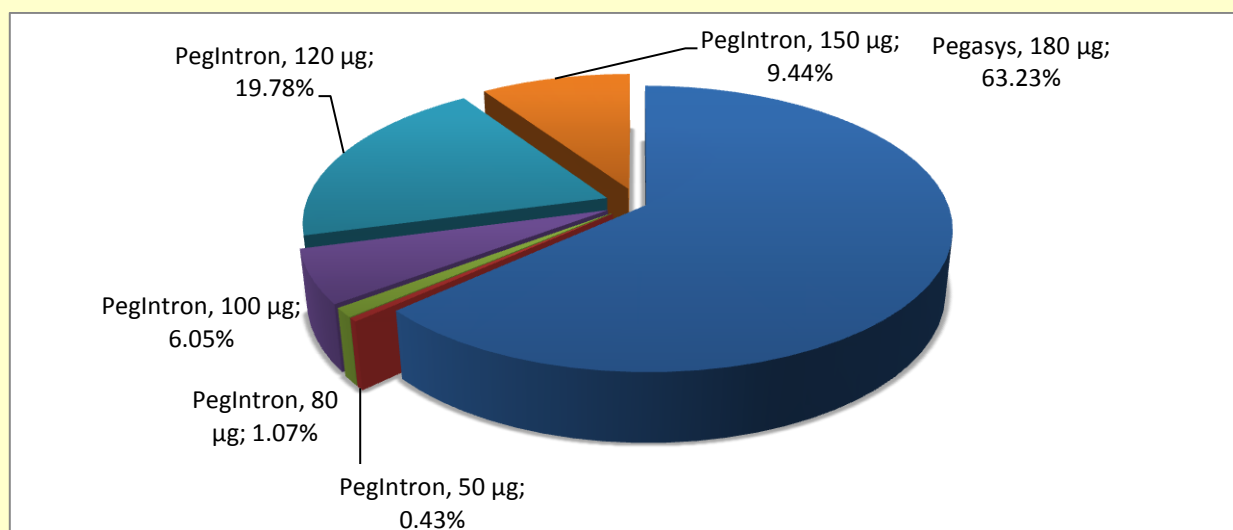
In 2012, with funds exclusively from the federal budget (omitting regional programs) **1,358,064,526** roubles were spent (according to data from monitoring federal auctions, conducted by the Treatment Preparedness Coalition, approximately **45 mln. USD**, exchange rate 30). Based on the prices of drugs and the quantities purchased by the Ministry of Health in 2012, this sum could potentially provide 48-week treatment regimens to 3 625 patients.

It can be concluded that the level of drug availability and funding for HCV drugs in the RF in 2013 remained at basically the same level as in 2012. Given the fact that the 2012 analysis did not take into account funds from RF territorial programs, there is reason to believe that the level of drug availability for treating HCV in 2013 decreased in comparison to 2012.

Pegylated interferon procurement volumes in 2013, based on the results of analyzing 333 auctions, are summarized in Table 2 and Graph 2 below.

Drug	Total Amount of Contracts, Roubles	Total Number of Vials	Share of Drug from Total Contract Value, %	Share of Drug from Total Number of Vials, %
Pegasys, 180 µg	1 039 724 492.51	105 690	63.23%	59.93%
PegIntron, 50 µg	7 104 154.83	575	0.43%	0.33%
PegIntron, 80 µg	17 639 269.28	2 047	1.07%	1.16%
PegIntron, 100 µg	99 500 151.88	11 427	6.05%	6.48%
PegIntron, 120 µg	325 313 009.60	40 184	19.78%	22.79%
PegIntron, 150 µg	155 189 726.33	16 422	9.44%	9.31%
Total	1 644 470 804.43, 46 984 880 USD	176 345	100%	100%

Table 2. Procurement volumes of pegylated interferons in the RF in 2013 and the distribution of market share by product, data analysis of 333 auctions in 68 regions.



Graph 2. Market share for different dosages of peginterferons based on the amount of money spent.

Graph 2 shows the market distribution of drugs treating HCV among various manufacturers. 63% of the market for pegylated interferons from the EML and Resolution No. 1438, according to the data analyzed, goes to the drug peginterferon alpha-2a (brand name Pegasys, manufactured by Roche). The remaining 37% is comprised of various dosages of the peginterferon drug alpha-2b (brand name PegIntron, manufactured by MSD), whereby the basic dosages are 120 µg (19.78%) and 150 µg (9.44%). Approximately the same market share ratio for the peginterferons alpha-2a and alpha-2b was recorded in 2012.

Pricing

The prices for drugs treating HCV based on the cost of a 48-week treatment regimen are shown in Table 3. Depending upon the drug and the dosage, **the weighted average prices vary between 388,588 roubles, approximately 11 100 USD (PegIntron 120 ug) to 593,042 roubles, approximately 17 000 USD (PegIntron 50 µg).**

Drug Name	Region	Regimen Cost, Roubles	Weighted Average Price, Roubles	Price per Treatment Regimen in 2012, Ministry of Health Auction
Pegasys, 180 µg	Chelyabinskaya	383 520.00	472 199.60	419 199
	Sakha-Yakutiya	581 010.24		
PegIntron, 50 µg	Tulskaya Region	460 800.00	593 042.49	385 095
	Krasnoyarski Krai	694 077.09		
PegIntron, 80 µg	Ministry of Health RF	318 336.96	413 622.34	318 337
	Archangelskaya Region	551 040.00		
PegIntron, 100 µg	Ministry of Health RF	346 930.56	417 958.11	346 931
	Khakasiya	663 288.96		
PegIntron, 120 µg	Stravropolski Krai	292 384.68	388 588.11	292 402
	Khanti-Mansiski AO	584 417.28		
PegIntron, 150 µg	Ministry of Health RF	346 745.28	453 605.34	346 745
	St. Petersburg	529 200.00		

Table 3. Prices for peginterferons in the RF based on a 48 week treatment regimen.

Compared to federal procurements in 2012, the average prices for all dosages increased. Thus, the price for peginterferon alpha-2a rose from 419,199 roubles to 472,199 roubles, and peginterferon alpha-2b 50 ug rose from 385,095 to 593,042 roubles.

The minimum prices for a number of drugs were lower in 2013 than in 2012, **which indicates the possibility for RF territories to decrease prices, even in conditions of decentralized procurements.**

The maximum and minimum prices for drugs and dosages as well as the weighted average prices are shown in Table 2.

Compared to federal procurements in 2012, the average prices for all dosages increased. At the same time, the minimum prices for a number of drugs in some regions were lower in 2013 than in 2012, which indicates the possibility for RF territories to decrease prices, even in conditions of decentralized procurements.

The analysis also showed that the prices for one and the same dosage varied significantly in different regions. **As in the case of procuring HIV drugs, decentralization has lead not only to an increase in weighted-average prices for a number of drugs, but also to a significant variation in price depending upon the RF territory.** As indicated in the report on the decentralization of ARV drugs²³, this phenomenon is connected with the system of regional markups for drugs, the policies of distributors, and the practice of setting initial maximum prices for contracts.

Case in point: the highest price for PegIntron (100 µg) was noted in the Khakassiya Republic (almost two times higher than the price paid by the Ministry of Health); at the same time, the level of federal funding allocated to the republic for purchasing drugs treating HIV and HCV decreased from 18 million to 12 million roubles based on the analysis of the federal budget²⁴. Obviously, in such circumstances it is practically impossible to improve access to drugs.

Drug Name	Region	Vial Price, Roubles	Difference Min/Max Price, %	Weighted Average Price, Roubles
Pegasys, 180 µg	Chelyabinskaya Oblast	7 990.00	1.51	9 837.49
	Sakha-Yakutiya	12 104.38		
PegIntron, 50 µg	Tulskaya Oblast	9 600.00	1.51	12 355.05
	Krasnoyarski Krai	14 459.94		
PegIntron, 80 µg	RF Ministry of Health	6 632.02	1.73	8 617.13
	Archangelskaya Oblast	11 480.00		
PegIntron, 100 µg	RF Ministry of Health	7 227.72	1.91	8 707.46
	Khakassiya	13 818.52		
PegIntron, 120 µg	Stavropolski Krai	6 091.35	2.00	8 095.58
	Khanti-Mansiski AO	12 175.36		
PegIntron, 150 µg	RF Ministry of Health	7 223.86	1.53	9 450.11
	St. Petersburg	11 025.00		

Table 4. Minimum and maximum prices for peginterferons in 2013, data from the results of an analysis of 333 auctions in 68 regions.

²³ http://itpcru.org/files/files_536.html

²⁴ http://itpcru.org/files/files_532.html

As the table shows, prices for one and the same drug differ by 1.5 to two times in different RF territories. The smallest price variation was observed with the drug Pegasys/180 µg and PegIntron/50 µg (1.51 times). The largest difference was for the drug PegIntron/120 µg (2 times).

Prices for one and the same drug within a single region in some cases varied by 1.5 times.

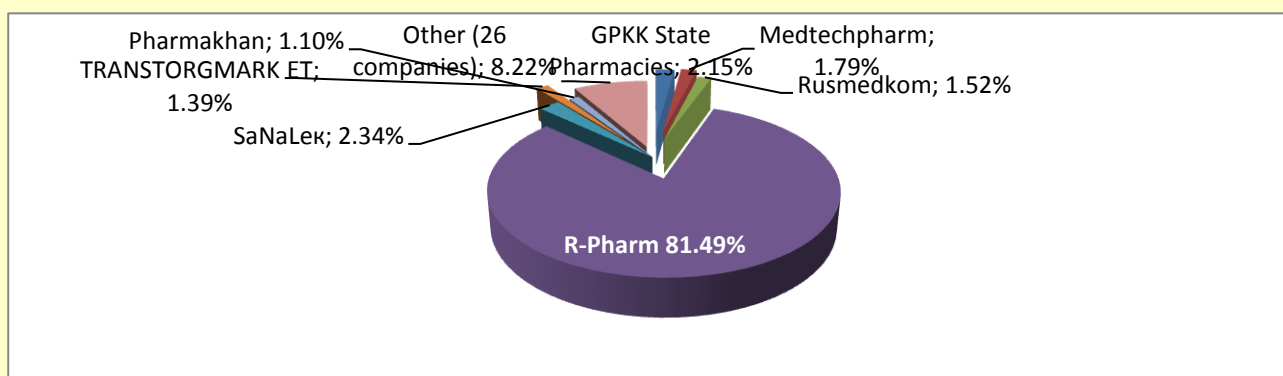
Prices for one and the same drug within a single region also vary. The table below shows the variation in prices for one and the same brand name with one and the same dosage within the same region.

Region	Minimum Price, Roubles	Maximum Price, Roubles	Difference
Irkutsk Region, PegIntron 120 µg	8301.32	9 526.63	14.76%
Krasnoyarski Krai, Pegasys 180 µg	10286,82	10 610.06	3.14%
Moskovskaya Region, Pegasys 180 µg	9985.47	10 274.22	2.89%
Novosibirskaya Region, PegIntron 120 µg	8212.82	10 303.15	25.45%
Orenburgskaya Region, PegIntron 120 µg	9116.00	10 770.00	18.14%
Permski Krai, PegIntron 150 µg	7902.40	9 600.00	21.48%
St. Petersburg, PegIntron 120 µg	6091.71	8 963.95	47.15%
Sverdlovskaya Region, PegIntron 100 µg	8759.00	9600.00	9.60%
Khabarovski Krai, Pegasys 180 µg	9600.00	10 759.45	12.08%
Khanty–Mansiysk, PegIntron 120 µg	7990.00	12 175.36	52.38%

Table 5. Difference in prices for pegylated interferons within a single region.

Distribution and Competition

In regard to distributors, the market for HCV drugs can be safely termed a monopoly. According to monitoring data, all RF Ministry of Health auctions for pegylated interferon in 2012 were won by the company R-Pharm. In 2013, according to the analysis of 333 auctions, R-Pharm attained 81.5% of the total volume of peginterferon vials. Allocation of procurement volume by distributor is shown in the graph below.



Graph 3. Allocation of procurement volume for peginterferons in procurements which took place in 2013.

The auction analysis also showed that in 88% of the cases of bidding, only one company participated. Furthermore, as is shown in the table below, in auctions where there was competition (that is, where two or more companies participated) the final contract price **was not significantly lower than the weighted-average price, and in some cases, even surpassed it. Thus, competition did not lead to a significant reduction in price in 2013.**

Drug Name	Money Expended, Roubles	Vials Purchased, Units	Weighted-Average Price at Auctions with Competition, Roubles	Weighted-Average Price for The Entire Auction Sample, Roubles	Reduced Prices
Pegasys, 180 µg	35073408,00	3508	9998.12	9 837.49	1.02
PegIntron, 50 µg	-	-	-	12355.05	-
PegIntron, 80 µg	-	-	-	8 617.13	-
PegIntron, 100 µg	7488839,82	889	8423.89	8 707.46	0.97
PegIntron, 120 µg	33030850,28	4031	8194.21	8 095.59	1.01
PegIntron, 150 µg	1673523,57	202	8284.77	9 450.11	0.88

Table 6. The difference in the weighted-average price for pegylated interferons in auctions with competition and for the entire auction sample.

Competition:

In 333 auctions, only in **12%** the number of competitors was more than one.

ANTIVIRAL DRUG PROCUREMENTS

At the time of writing this report, the following antiviral drugs used in treating HCV have been registered in the Russian Federation:

- Boceprevir (brand name Victrelis): a protease inhibitor manufactured by MSD;
- Simeprevir (brand name Sovriad): a protease inhibitor manufactured by Janssen
- Telaprevir (Insivo): a protease inhibitor manufactured by Janssen

According to the instructions for usage published on the official website grls.rosminzdrav.ru, all these drugs are used in conjunction with pegylated interferon and ribavirin.

Boceprevir and telaprevir:

At least 167 mln. RUB in 2013 (approximately 4 800 000 USD)

Approximately 120 patients

From 1.2 to 1.5 mln RUB per patient (approximately 35 to 43 thousand USD)

Around 10 regions

According to the website zakupki.gov.ru, the total volume of procurements for boceprevir in 2013 was **3,813,318.80** roubles²⁵ whereby the quantity of capsules purchased was 9,744. Based on the treatment regimen for boceprevir, this quantity of capsules should be sufficient for approximately 2.5 treatment regimens. The price for a boceprevir treatment regimen ranged from 1,375,000 roubles (Magadanskaya Oblast) to 1,517,340 roubles (Samarskaya Oblast).

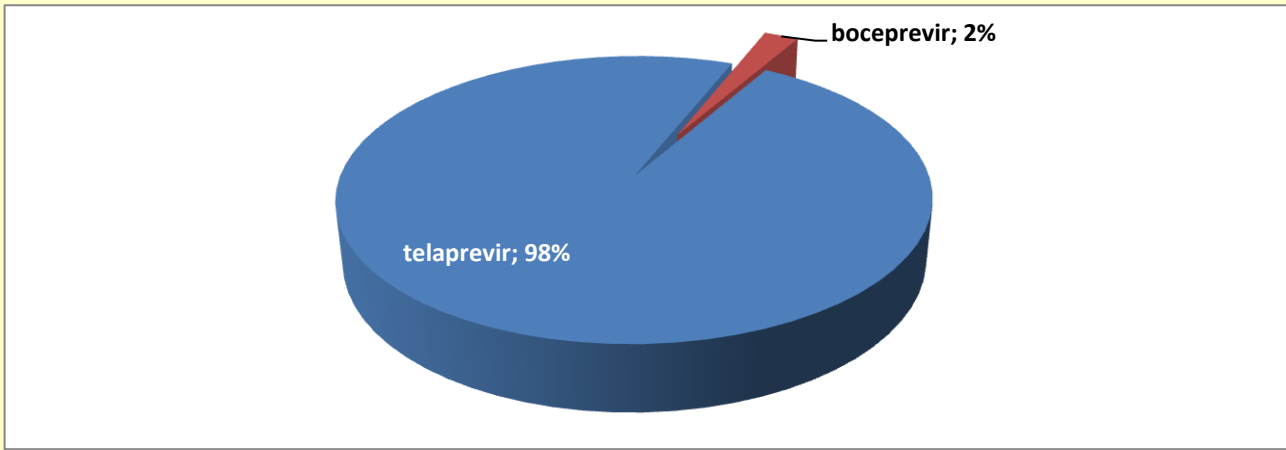
According to the website zakupki.gov.ru, the total volume of procurements for telaprevir in 2013 was **163,140,997.51** roubles²⁶, the total quantity of capsules purchased was 58,128. Based on the treatment regimen for telaprevir, this quantity of capsules should be sufficient for approximately 115 treatment regimens. The price for a telaprevir treatment regimen ranged from 1,241,010 roubles (St. Petersburg) to 1,485,000 roubles (Khabarovski Krai).

At the time of searching the website zakupki.gov.ru, the search engine did not produce any auctions for simeprevir procurements when the INN was used as the search term.

The graph below shows the budget allocation for procurements of antiviral drugs used in treating HCV based on expenditures according to the results of an analysis of 14 auctions.

²⁵ The search was conducted using the drug INN. A portion of the auctions might not have been detected due to technical reasons.

²⁶ See above.



Graph 4. Budget allocation for procurements of antiviral drugs used in treating HCV in the RF in 2013 based on data from the website zakupki.gov.ru.

The total budget for the procurement of antiviral drugs used in treating HCV in the RF thus amounted to almost **167 million roubles (approximately 4 800 000 USD)**. Based on the drug treatment regimens, this sum would make it theoretically possible to provide treatment to approximately **120 patients**.

PATIENT COMMUNITY ACTION

The problem of organizing access to drugs treating HCV has repeatedly been the focus of attention of patient organizations in Russia and in the world. Among the main reasons cited were inflated drug prices fixed by manufacturers and the reluctance of the government to develop and implement governmental programs to treat patients with HCV.

Thus, at a meeting of the Community Advisory Board in Eastern Europe and Central Asia (EECA CAB) with HCV drug manufacturers in July 2012²⁷, the position was voiced that the main obstacle hindering access to treatment is **the speculative pricing policy of pharmaceutical companies, unacceptable for this region**. Representatives from organizations, including EECA CAB, demanded that the companies reduce prices for a treatment course of 48 weeks to 2,000 USD (the price for Egypt's governmental program).

In October 2012, activists from the movement Patients in Control held a demonstration at the head office of the pharmaceutical company Roche with the appeal to reduce prices on peginterferon alpha-2a (according to the monitoring data, more than 60% of the total peginterferon procurements are for this specific drug). Activists pointed out that among other things, the cost of a yearly treatment regimen is approximately half a million roubles, which is almost two times higher than the average yearly income in the RF. On the same day, activists sent an open letter to the RF Minister of Health, V.I. Skvortsova, with the appeal to adopt measures to expand the government treatment program for patients with HCV and to negotiate with pegylated interferon manufacturers regarding multiple reductions in the price for drugs²⁸.

On 24 July 2013, a similar demonstration took place in front of the RF Ministry of Health and the offices of Hoffmann-La Roche, and Merck, Sharp and Dohme (manufacturers of peginterferon alpha-2b). The demands remained the same: multiple reductions in the prices for peginterferons and a significant expansion in the government treatment program for patients with HCV. On approximately the same date, similar demonstrations took place in Ukraine, Georgia, Armenia, Latvia, the USA, Moldova, Thailand, India and other countries²⁹.

On the eve of World Hepatitis Day 2013, 83 community organizations from Eastern Europe and Central Asia region signed an open letter addressed to pegylated interferon manufacturers regarding the necessity of a sharp decrease in the prices of these drugs³⁰. As a result of this letter, a meeting took place in St. Petersburg between Roche and representatives from patient organizations in the EECA region.³¹

In August 2013, activists from the Andrei Rylkov Foundation held a demonstration in front of the RF Ministry of Health, during which participants demanded that the Ministry adopt a program for treating HCV³². Likewise, activists submitted to the Ministry a report about the situation of HCV treatment in Russia, in which was mentioned, among other things, the virtual lack of access for vulnerable groups, especially people using drugs³³.

In November 2013, Patients in Control activists submitted a complaint in connection with the auction for procuring pegylated interferons alpha-2a and 2b in St. Petersburg, in which it was planned to purchase 4,370 vials of one drug and 960 vials of another. According to the activists, this parceling was unfounded, and considering the severe epidemiological situation in the region and the goal of ensuring competition and price reduction, documentation should have been processed in such a way as to permit peginterferon manufacturers to compete with each other. This complaint was reviewed by the Federal Anti-Monopoly Service in St. Petersburg, but was

²⁷ <http://eeeca-cab.org/ru/2012/06/14/vstrecha-soveshatelnogo-soobshestva-pacientov-regiona-veca-po-dostupu-k-lecheniyu-gepatita-s/>

²⁸ <http://packontrol.livejournal.com/8935.html>

²⁹ <http://packontrol.livejournal.com/14569.html>

³⁰ http://eeeca-cab.org/media/2013/08/19/open_letter_merck_roche_final_rus.pdf

³¹ <http://eeeca-cab.org/ru/2010/05/06/roche/>

³² <http://rylkov-fond.org/blog/novosti/actionminzdrav/>

³³ <http://rylkov-fond.org/blog/health-care/hepatitis/hepatitis-report/>

rejected. In the end, the drug peginterferon alpha-2a was procured for a price of 8 733.32 roubles per vial, and peginterferon alpha-2b for 6 091 roubles, approximately 175 USD per vial, or 8 500 USD per treatment course (the lowest price for pegylated interferon according to the monitoring data). Moreover, the volume for the alpha-2a procurement was significantly larger than the volume for the alpha-2b procurement. The supplier in both cases was R-Pharm.

During the period 2011-2013, patient organizations repeatedly demanded that the Essential Medicines List be revised. The main demand of HIV activists was that tenofovir be included in the list, however, in the case of viral hepatitis C, this list needs to be revised and updated. A special commission must review the possibility of adding newly registered HCV drugs to the EML on a regular basis.

CONCLUSIONS AND RECOMMENDATIONS

Data analysis shows that in conditions of a large-scale HCV epidemic in the RF -- which even according to official data amounts to hundreds of thousands of people, but according to estimates by Russian and foreign experts is several million -- access to medicines for treating HCV and providing patients with drugs remains at an extremely low level. At best, approximately 4000 patients could be provided treatment with budgetary funds from various levels in 2013, according to the results of the analysis that was conducted. The volume of the allocated budget has remained at a level of more than 1.5 billion roubles, or 47 mln USD. **If all the drugs for treating HCV were purchased at the minimum price, fixed by the monitoring results (6 091 roubles, approximately 175 USD), then it would be potentially possible to save almost 600 million roubles (over 17 mln USD), and with this money provide treatment to almost 2 000 additional patients.**

However, even the price of 6 091 roubles per vial is extremely high. In a number of countries (India, Thailand, Ukraine, Georgia, and Vietnam), the cost of a vial of pegylated interferon costs approximately 1,500 to 3,500 roubles. Moreover, in these countries bidding terms often allow for competition between various pegylated interferon manufacturers, in as much as the meta-analysis of random clinical trials has demonstrated the interchangeability of the pegylated interferons alpha-2a and 2b³⁴. When biosimilar versions of these peginterferons and the drugs cepeginterferon alpha-2a and peginterferon lambda enter the market, competition between manufacturers, if it is encouraged, should lead to a decrease in pricing and to improved access.

In circumstances where increasing the budget is problematic, the only viable way to significantly increase the number of patients in treatment programs is **a sharp decrease in prices for registered drugs and drugs in the process of being registered.**

Another necessary measure is **introducing into the federal budget a separate line for financing the procurement** of drugs, testing and preventative services to counteract the HCV epidemic. To allocate target funds to combat hepatitis C a special governmental program is needed, similar to ones adopted in Egypt, Thailand, Ukraine and a number of other countries.

To determine the extent of need, it is necessary to implement a centralized system of registering patients with HCV (patient register), similar to that which already exists in many RF territories.

The current documents governing the process of providing medical care to patients with HCV require urgent and regular review in order to take into account the appearance of new drugs and new data on efficacy and safety.

Recommendations

1. **Recommendation to the RF Government.** Initiate the development of a national strategy and program for treating viral hepatitis C with a separate budget for preventative measures, testing, and treatment of viral hepatitis C, involving the widest possible range of interested people, including representatives from patient organizations. Ratify this strategy and program via a Decree from RF Government.
2. **Recommendation to the RF Government.** In order to optimize the procurement and delivery process and to lower prices through increased volume of procurements, review the possibility of centralized procurements for HCV drugs. In such a situation, the purchaser could be the RF Ministry of Health or the Federal Consumer Protection Service (Rosпотребнадзор).

³⁴ (McHutchison JG et al. N Engl J Med. 2009;361:580-593)

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3. **Recommendation to the RF Government.** Work systematically with HCV drug manufacturers in order to obtain a **sharp decrease in price** for these drugs.
 4. **Recommendation to the RF Ministry of Health.** In expedited form, update the current regulatory framework for viral hepatitis C, including standards and recommendations for treating HCV, based on current international guidelines. Approve recommendations with a Ministry of Health Decree in order to give them the status of a binding document. Set up a mechanism to ensure that they are regularly reviewed to take into account newly registered antiviral and biosimilar drugs for treating HCV.
 5. **Recommendation to the RF Government.** Use the flexibility of the Trade Related Aspects of Intellectual Property Rights to improve access to drugs treating HCV. Consider the possibility of compulsory licensing for new antiviral drugs for treating viral hepatitis C and the revocation of existing patents for drugs treating HCV that do not meet the criteria for patentability.
 6. **Recommendation to the RF Ministry of Health.** Regularly review the EML in order to ensure the possibility of including new drugs for treating HCV in the EML and making them available for treatment programs.
 7. **Recommendation to the RF Ministry of Health and the Federal Consumer Protection Service in the area of protecting consumers' rights.** Introduce a unified register of patients with hepatitis C in order to adequately assess the epidemiological situation and treatment needs.
 8. **Recommendation to the RF Federal Anti-Monopoly Service.** Clarify the possibility of setting up the documentation of electronic auctions in such a way as to provide the opportunity for competition between manufacturers of various forms of pegylated interferon.