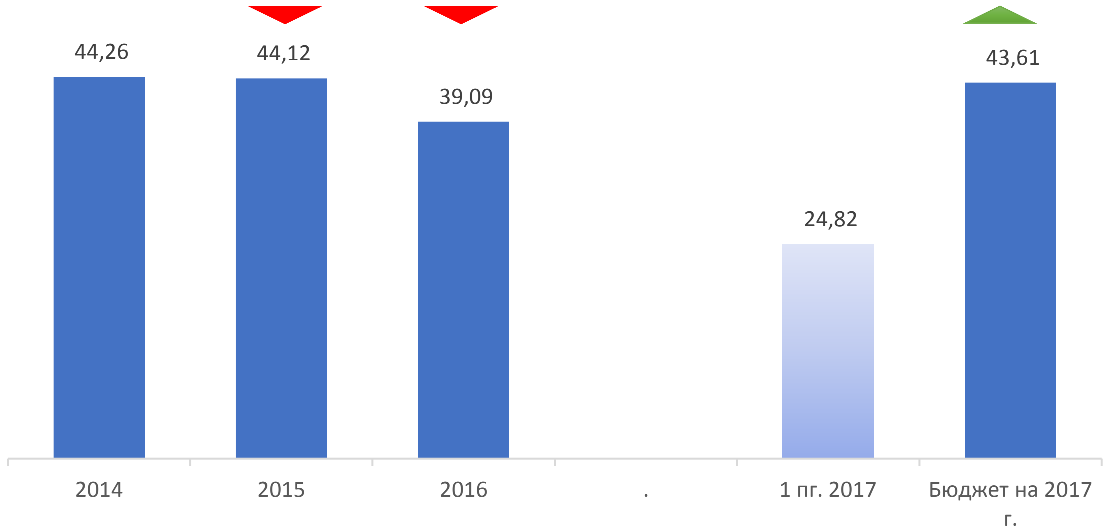
Overview of the supply of medicinal products based on the results of public procurement in the segment of high-cost diseases in the first half of 2017

Based on the results of the first half of 2017, medicinal products deliveries were made under the High-cost diseases (HCD) program for the amount of almost 25 billion rubles. This is more than a half of the amount budgeted for this item of expenditure for the year. It is assumed that by the end of 2017, the costs of procurement for HCD will exceed 2016's costs, and will reach the level of previous years (Fig. 1). Over 40% of all expenses in the first half of 2017 were directed towards purchasing medicinal products for hemophilia treatment, almost 30% for the treatment of multiple sclerosis, and about 20% for the treatment of chronic myelogenous leukemia.

Dynamics of supplies for public procurement in the segment of WNV, billion rubles.



Source: AlphaRM Audit of the federal segment of preferential drug procurement in the Russian Federation Fig. 1

Despite the fact that a foreign company (*Baxter*) with the drugs for hemophilia therapy is still the leader of the drug producers rating, the next three positions in the rating belong to Russian corporations producing drugs for the treatment of hemophilia, chronic myelogenous leukemia and multiple sclerosis: *Generium, Nativa*, and *Biocad* (Table 1).

TOP-10 corporations in the HCD segment, by the supplies in value, rubles, 1st half of 2017

Rating	Corporation	Disease	Market share (%)
1	Baxter	Hemophilia	16.0
2	Generium	Hemophilia, multiple sclerosis	15.4
3	Nativa	Chronic myelogenous leukemia, multiple sclerosis	15.0
4	Biocad	Chronic myelogenous leukemia, multiple sclerosis	9.3
5	Octapharma	Hemophilia	6.0
6	CSL Behring	Hemophilia	5.6
7	Merck	Multiple sclerosis	5.0
8	Laboratorio Tuteur S.A.C.I.F.I.A.	Multiple sclerosis	5.0
9	Roche	Cystic fibrosis	3.4
10	Sanofi	Gaucher's disease	3.0

Source: AlphaRM Audit of the federal segment of preferential drug procurement in the Russian Federation Table 1

The first line of the rating of suppliers for public procurements of medicinal products for HCD treatment is occupied by *Pharmstandart*, the exclusive supplier for cystic fibrosis and pituitary dwarfism. *Nacimbio* is on the second position, accounting for about 50% of all supplies for the treatment of hemophilia within the HCD program. *Biotech* is on the third position; it carries out the shipments of approximately 60% of the value of brands produced by the company *Nativa* (Table 2).

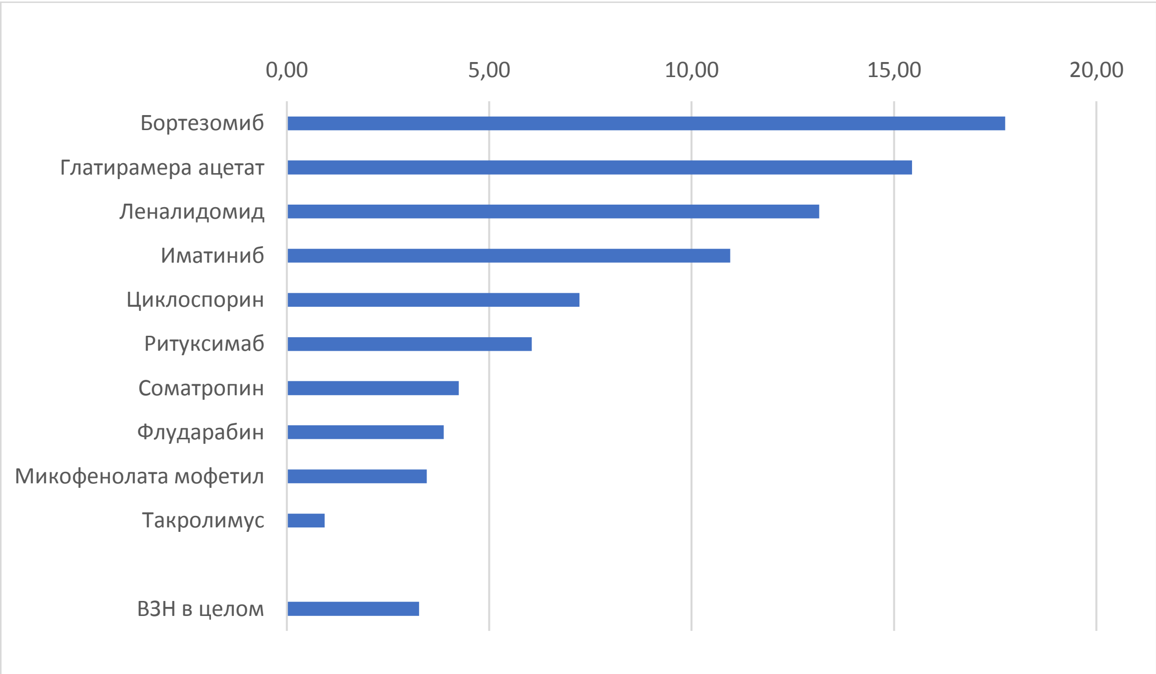
TOP-10 suppliers in the HCD segment, by contract value, rubles, 1st half of 2017

Rating	Supplier	Brands	Market share (%)
1	Pharmstandart	Coagil-VII, Octofactor, Pulmozim, Rastan, Tizabri, Cerezim	25.48
2	Nacimbio	Beriate, Vilate, Hemate P, Hemophil M, Immunat, Immunin, Coate-Dvi, Mononine, Octanine F, Octanat, Feiba	21.89
3	Biotec	Axoglatiran FS, Genfaxon, Rebif, Philachromin	17.56
4	Biocad	Acellbia	6.94
5	Medipal-Onco	Adveit, Coagil-VII, Novoseven	6.58
6	R-Pharm	Advagraf, Maifortic, Mycophenolate mofetil-TL, Mycophenolate -Teva, Panimun Bioral, Redditux, Flidarin, Ecoral	6.55
7	Protec	Boramilan	5.40
8	NPK Katren	Interferon beta-1b, Infibeta	5.03
9	Irvin 2	Sinnovex, Tacrolimus	2.99
10	Propharm	Neopax	0.79

Source: AlphaRM – Monitoring of the public procurements. Contracts. Table 2

The savings on procuring the drugs based on HCD programs amounted to about 3% based on the results of the tenders in the 1st half of 2017. Most savings were achieved on the procurements of the INN bortezomib, glatiramer acetate and lenalidomid (fig.2).

Top 10 INNS in savings at auction from the initial maximum contract price, RUR (%)



1. CHRONIC MYELOGENOUS LEUKEMIA

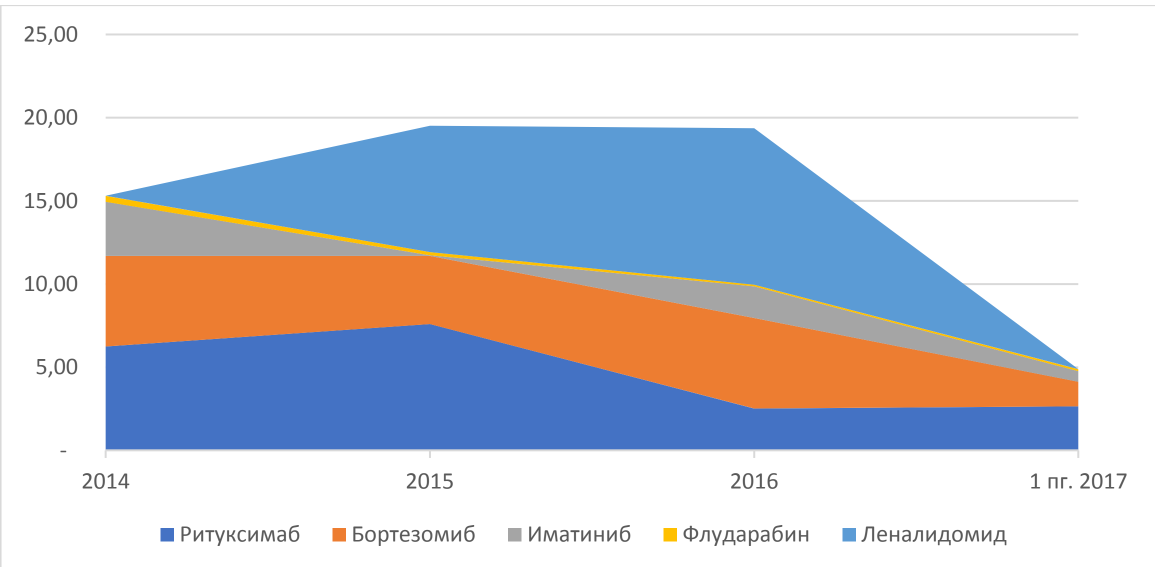
The supplies of drugs the treatment of patients with chronic myelogenous leukemia under the HCD program mostly lie ahead. The bidding for the supply of the drug with INN Lenalidomid that has not been supplied in the 1st half of 2017, promises to be the suspense of the year. The originator Revlimid from *Celgene* (packaged by OJSC *Pharmstandard-Leksredstva*) has increasing difficulty in maintaining its position in the bidding for this INN. In 2016, its exclusivity was infringed by Metablastan (*Laboratory Tutor*, packaged by the *OJSC Kurgan Synthesis*) and Russian Lenalidomid-Nativ (*Nativa*). The case came to trial, but Revlimid defended its rights and remained the only provider of INN lenalidomid in 2016. In April 2017, another Russian analogue was registered, Lenalidomid from *Pharmasynthez*. This drug will make the upcoming tender of the 2nd half of the year more interesting. It was *Pharmstandart* that supplied Revlimid for the Ministry of Health in 2016.

The supplies of INN rituximab in the 1st half of 2017 are already comparable with their volume in 2016. At the end of 2016, Acellbia from the company *Biocad* succeeded in becoming the only winning brand in the bidding for this INN, completely replacing the original Mabthera manufactured by the company *Roche*; in 2017, this brand had to make room for other ones. The third drug, Redditux manufactured by the company *Dr.Reddy's* represented by R-*Pharm,* that withdrew from bidding in 2016, was one of the winners in the first half of 2017. According to the data of the State Register of Medicinal products, January 2017, Redditux localized the manufacturing as well as the packaging of the drug at the production facilities of *R-Pharm*, thus becoming a full-fledged competitor in the field. Redditux was supplied by *R-Pharm*, and Acellbia, by *Biocad*.

The INN bortezomib was represented only by one brand in the first half of 2017: Boramilan manufactured by the company *Nativa*, supplied by *Protek*. The competition for this INN is even more aggressive in 2017: new drugs have joined the ranks, such as Milatib from the company *Pharm-Synthez* (December 2016) and Bortesol from *Pharmasynthez-Nord* (March 2017), which still can participate in the bidding this year.The INN Imatinib was represented, in the first half of 2017, by Philachromin from *Nativa* (supplied by *Biotec*) and Neopax from *KRKA* (supplied by *Propharm*). At present, more than 20 marketing authorizations have been issued on the territory of the Russian Federation for the drugs with INN Imatinib; more new brands are being registered in 2017.

The INN fludarabine was represented, in the first half of 2017, by another Nativa's brand: Flidarin supplied by R-Pharm (Fig. 3, Table 3).

Dynamics of supplies of pharmaceuticals for the treatment of chronic myeloid leukemia within the framework of WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 3

Distribution of the supplies of medicinal products for treating chronic myelogenous leukemia within HCD program, by brands

INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Rituximab	Acellbia	Biocad	2516	1902	40.7	35.1
	Redditux	Dr.Reddy's	-	737	-	6.6
Bortezomib	Bartisar	PROTEK GK	990	-	33.0	-
	Boramilan	Nativa	3087	1479	33.0	15.3
	Velcade	Johnson & Johnson	1359	-	33.0	-
Imatinib	Imatinib	Pharmasynthez	652	-	25.3	-
	Neopax	KRKA	-	217	-	10.4
	Filachromin	Nativa	1259	423	25.6	9.8
Fludarabin	Flidarin	Nativa	38	124	16.1	12.8
	Flutotera	Laboratorio Tuteur S.A.C.I.F.I.A.	52	-	16.1	-
Lenalidomid	Revlimid	Celgene	9,418	-	413.8	-

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 3

2. MULTIPLE SCLEROSIS

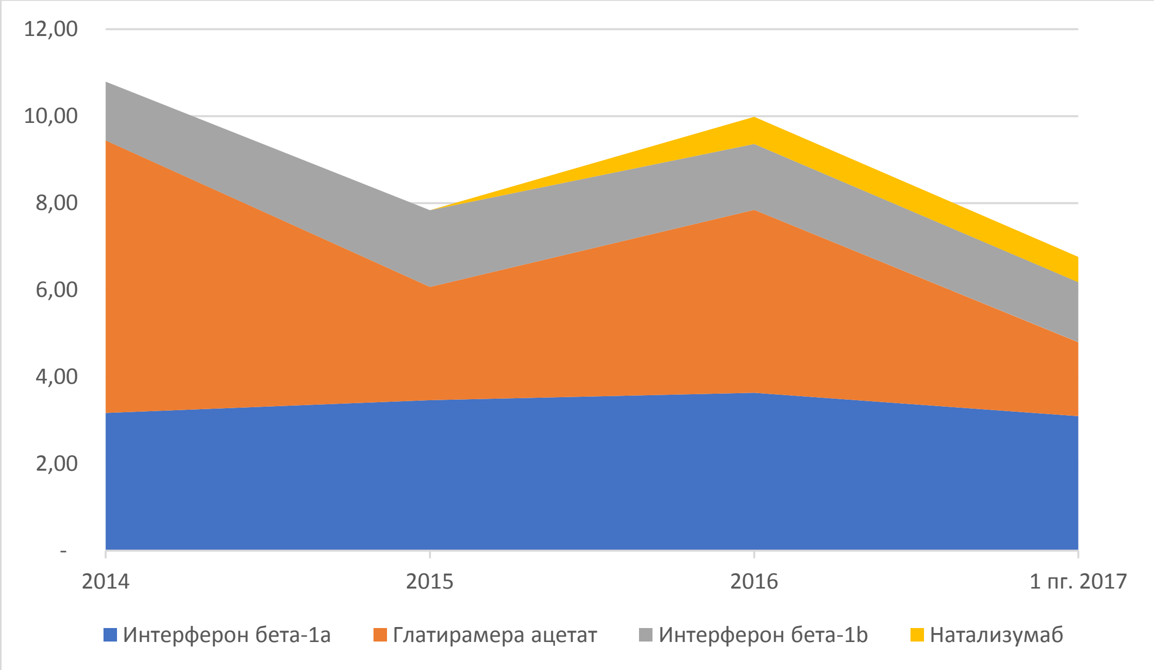
The volume of the supplies of INN interferon beta-1a in the first half of 2017 almost reached the total supply volume of 2016. As in the previous year, the winning bids were represented by three brands: Genfaxon (*Laboratorio Tuteur S.A.C.I.F.I.A*. supplied by *Biotec*), Rebif (*Merck*, supplied by *Biotec*) and Sinnovex (*SIA AFS*, supplied by *Irvin* 2). The first brand with INN interferon beta-1a produced in Russia in full cycle and registered in early 2017, Terebif from the company *Biocad* has not yet reached the triumphant finale.

In the first half of 2017, the INN glatiramer acetate was represented by the brand Axoglatiran FS manufactured by *Nativa*, supplied by *Biotec*. At the end of 2016, another brand was registered with this INN, Timexon from the company *Biocad*. It is possible that it will participate in the bidding this year.

The volume of supplies of INN interferon beta-1b, based on the results of the first half of 2017, is slightly less than total supplies volume in 2016, and includes the same brands of Russian production: Interferon beta-1b from *Biocad* and Infibeta from *Generium* (the supplier of both being *NPK Katren*).

For the INN natalizumab, that was included in the list of medicinal products provided within the framework of the HCD program only in 2016, there is only one player in Russia as yet: *Biogen Idec* with Tisabri. The bidding on this INN took place in the first half of 2017, in the approximate volume of 2016, and *Pharmstandard* became the supplier again (Fig. 4, Table 4).

Dynamics of supplies of pharmaceuticals for the treatment of multiple sclerosis in the framework of the WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 4

Distribution of the supplies of medicinal products for treating multiple sclerosis within HCD program, by brands

INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Interferon beta-1a	Genfaxon	Laboratorio Tuteur S.A.C.I.F.I.A.	1458	1236	10.2	10.2
	Rebif	Merck	1457	1240	10.0	9.6
	Sinnovex	SIA AFS	718	619	17.1	17.1
Glatiramer acetate	Axoglatiran FS	Nativa	3810	1702	21.1	14.2
	Glatirat	R-Pharm	403	-	18.0	-
Interferon beta-1b	Interferon beta-1b	Biocad	423	414	6.1	6.1
	Infibeta	Generium	1092	965	18.2	18.2
Natalizumab	Tisabri	Biogen Idec	624	581	98.8	99.0

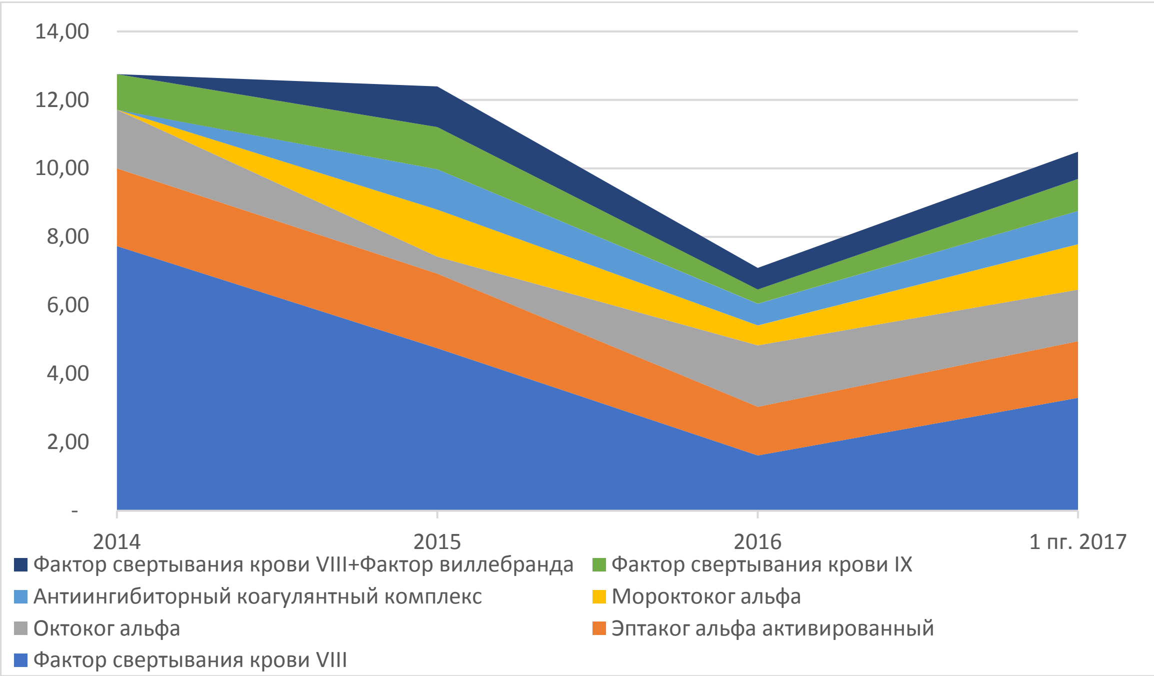
Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 4

3. HEMOPHILIA

The coagulation factor VIII accounted for the largest value of supplies for the provision of medicinal products for patients with hemophilia within the HCD program in the first half of 2017. The total value of the drugs with this INN in the first half of 2017 was more than 2.5 times higher than that in the previous year. Five foreign brands were procured (supplied by *Nacimbio*). The second position in terms of the procurements belongs to the INN Heptacog alpha activated, with a domestic brand from the company *Generium*: Coagil-VII.

The second representative of the *Generium* production for hemophilia therapy was procured under the INN Moroctocog alfa (Octofactor), the remaining 4 brands were produced by foreign corporations (Fig. 5, Table 5).

Dynamics of supplies of pharmaceuticals for the treatment of haemophilia in the framework of the WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 5

Distribution of the supplies of medicinal products for treating multiple sclerosis within HCD program, by brands

INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Blood clotting factor VIII	Beriate	CSL Behring	265	659	6.1	5.6
	Hemoctine	Biotest Pharma	199	-	7.7	-
	Hemophil M	Baxter	265	659	5.3	4.9
	Immunat	Baxter	265	659	6.1	5.6
	Coate-Dvi	Grifols	67	659	3.1	4.5
	Octanate	Octapharma	486	659	4.4	5.6
	Emoclot d.i.	Kedrion	67	-	17.3	-
Heptacog alfa activated	Coagil-VII	Generium	1,321	1,536	47.2	41.5
	Novoseven	Novo Nordisk	100	116	13.5	13.5
Octocog alfa	Advate	Baxter	1797	1513	9.7	9.4
Moroctocog alfa	Octofactor	Generium	581	1322	10.1	10.1

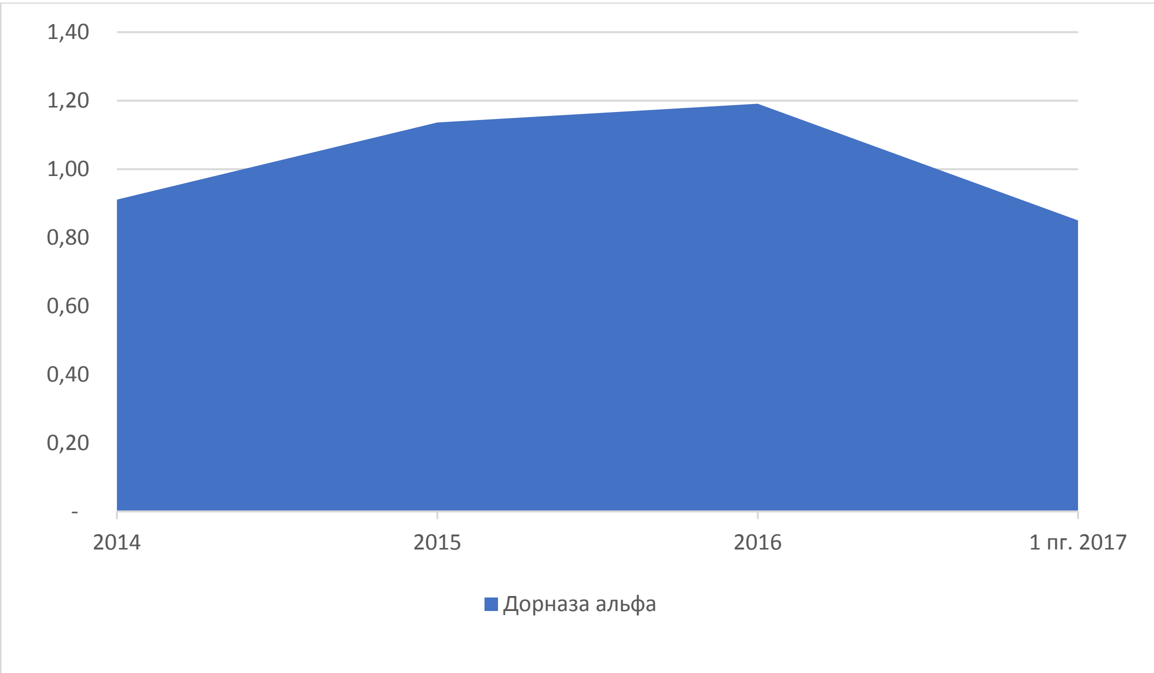
Anti-inhibitory coagulant complex	Feiba	Baxter	636	978	38.7	38.8
	Immunin	Baxter	61	165	14.3	14.3
Blood clotting factor IX	Mononine	CSL Behring	143	385	7.6	7.6
	Octanine F	Octapharma	210	385	7.6	7.6
Blood clotting factor VIII + Willebrand factor	Vilate	Octapharma	290	443	14.8	15.3
	Hemate P	CSL Behring	336	346	31.5	18.7

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 5

4. CYSTIC FIBROSIS

Within the framework of public provision of drugs under the HCD program, the public procurement provides one INN for the treatment of cystic fibrosis, dornase alpha represented in Russia by the only brand Pulmozym manufactured by *Roche*. The Russian full cycle drug Tigerase from the company *Generium* is now at the stage of clinical studies, waiting to enter the market. Pulmozym is supplied by *PJSC Pharmstandart*, and packaged at *Pharmstandart-UfaVITA JSC* (Fig. 6, Table 6).

Dynamics of supplies of pharmaceuticals for the treatment of cystic fibrosis in the framework of the WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 5

Distribution of the supplies of medicinal products for treating cystic fibrosis within HCD program, by brands

INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Dornase alfa	Pulmozym	Roche	1191	850	8.0	6.4

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 6

5. AFTER TRANSPLANTATION

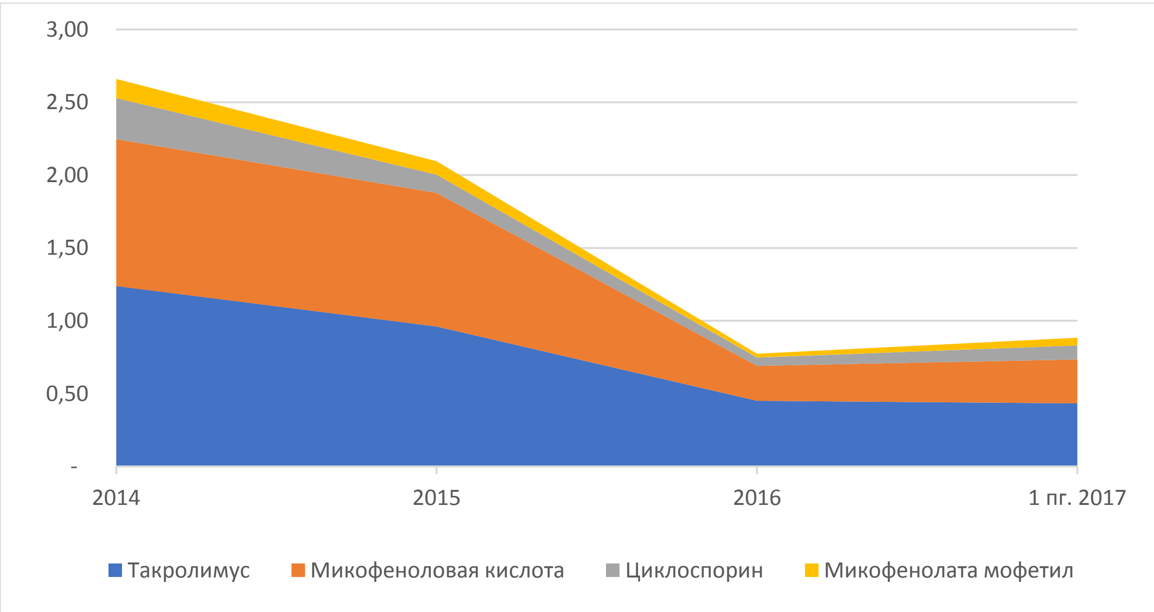
The supplies of the INN tacrolimus are represented by two brands in the first half of 2017: Advagraf (Astellas, packaging by *CJSC Ortat* of the corporation *R-Pharm*) supplied by R-Pharm, and *Tacrolimus* (Ozone, marketing authorization obtained in 2016), supplied by *Irwin* 2. In 2016, the INN tacrolimus began to include brands manufactured in Russia; three drugs were approved for circulation in Russia, and in the first half of 2017, a Russian drug won the bid for this INN for the first time.

The INN mycophenolic acid is still supplied under the single brand Mayfortic manufactured by *Novartis*, not localized in Russia. The product is steadily delivered by R-*Pharm*.

Despite the fact that there is a local drug in the Russian market with a valid marketing authorization (the brand is not, however, represented on the manufacturer's official website), the tenders for INN cyclosporine are won by foreign companies that do not have any office in Russia. In the first half of 2017, it was the Indian drug Panimun Bioral (*Panacea Biotec*) and Ecoral produced in the Czech Republic (*Teva*). The supplies of the drugs are shared by *R-Pharm* and *Coral-Med*. A small part of Ecoral is supplied by the company *Torgovy Dom BF*.

As to the INN mycophenolate mofetil, most of the shipments in the first half of 2017 consist of the brand Mycophenolate mofetil-TL manufactured by *Technologia Lekarstv*, the second drug by volume being Mycophenolate-Teva supplied by R-*Pharm* (Fig. 7, Table 7).

Dynamics of supplies of LP applied after transplantation in the framework of the WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 7

Distribution of the supplies of medicinal products used after transplantation, within HCD program, by brands

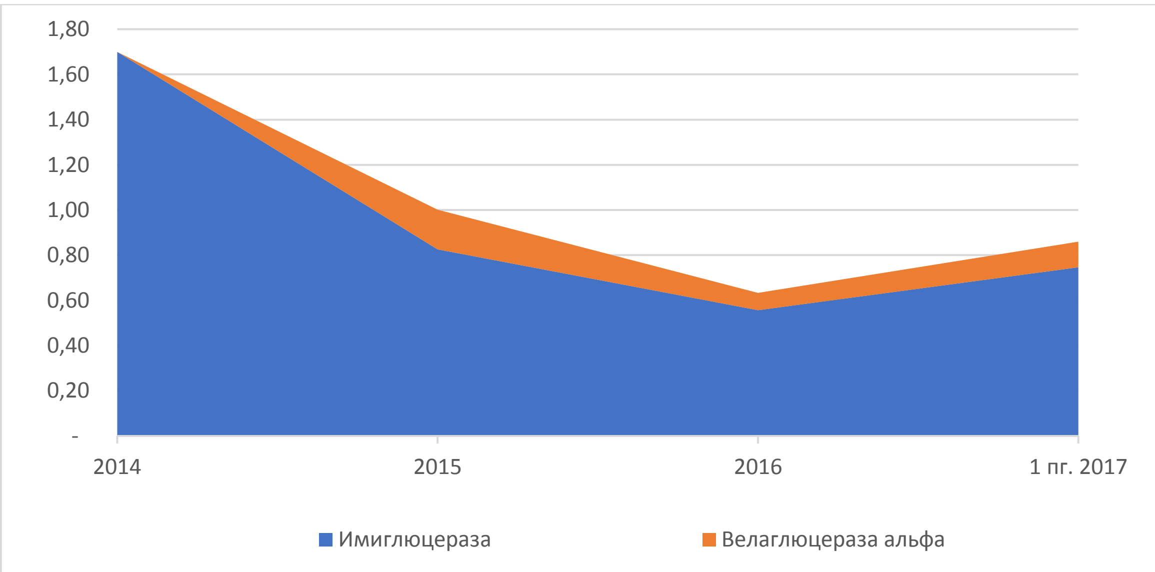
INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Tacrolimus	Advagraf	Astellas	247	232	4.8	3.5
	Prograf	Astellas	85	-	1.7	-
	Redinesp	Dr. Reddy's	7	-	17.2	-
	Tacrolimus	Atoll	-	201	-	1.2
	Tacrolimus Stada	Stada	11	-	3.4	-
	Tacrolimus-Teva	Teva	2	-	3.4	-
	Tacrosel	Novartis	98	-	3.4	-
Mycofenolic acid	Myfortic	Novartis	239	301	12.5	4.1
Cyclosporin	Panimun Bioral	Panacea Biotec	36	45	0.8	1.0
	Sandimmun	Novartis	7	-	3.7	-
	Ecoral	Teva	15	52	1.8	1.0
Mycofenolate mofetil	Mysept	Panacea Biotec	11	-	2.0	-
	Mycofenolate mofetil-TL	Technologia Lekarstv	5	43	2.0	2.0
	Mycofenolate-Teva	Teva	9	10	2.0	2.0

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 7

6. GAUCHER's DISEASE

Among the drugs used to treat Gaucher's disease within the HCD, there are no domestic analogues in Russia. The Russian bio-analogue of Cerezym under the name of *Glurazym* (Generium) is now in the first phase of clinical trials. In the first half of 2017, the supplies of these INNs already exceeded those in 2016: Cerezym was supplied by *Pharmstandart*, which delegated its packaging to the company *Pharmstandart-UfaVITA*, and Vpriv was supplied by *Pharmimex* (Fig. 8, Table 8).

Dynamics of supplies of pharmaceuticals for the treatment of Gaucher disease in the framework of the WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 8

Distribution of the supplies of medicinal products for the treatment of Gaucher disease within HCD program, by brands

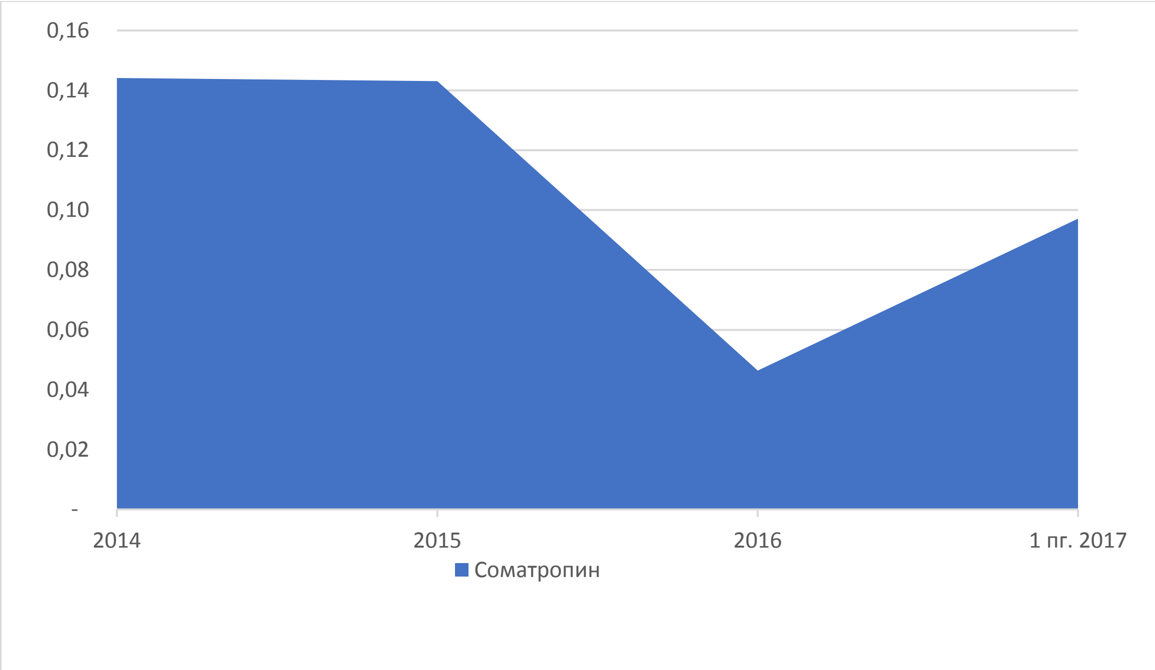
INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Imiglucerase	Ceresym	Sanofi	556	746	71.0	71.0
Velaglucerase alfa	Vpriv	Shire	77	114	70.3	70.4

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 8

7. PITUITARY DWARFISM

The HCD includes only one INN for the treatment of pituitary dwarfism: somatropin. For several years, the company Rastan procures this INN that is manufactured and supplied by the structural units of the Russian corporation *Pharmstandart* (Fig. 9, Table 9).

Dynamics of supplies of pharmaceuticals for the treatment of pituitary dwarfism within the framework of WNV, billion rubles.



Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Fig. 9

Distribution of the supplies of medicinal products for the treatment of pituitary dwarfism within HCD program, by brands

INN	Brand	Corporation	Total supplies, million rubles		Average price, thousand rubles	
			2016	1st half of 2017	2016	1st half of 2017
Somatropin	Rastan	Pharmstandart	46	97	2.0	2.1

Source: AlphaRM, Audit of the federal segment of the preferential provision in drugs in RF Table 9

SUMMARY

More than a half of the year's budget was spent on purchasing the medicinal products for treating the patients according to the HCD program in the first half of 2017. The products for hemophilia therapy, tor treating the patients after the transplantation of organs and tissues, and for the treatment of Gaucher's disease and pituitary dwarfism were supplied in the volumes comparable to those of 2016. The share of Russian drugs in this segment continues to grow. Noticeable success has been achieved in the field of the INN tacrolimus: the Russian full cycle brand won in the bidding on this INN for the first time.