

# The Analysis of Procurement of ARV Drugs in the Russian Federation in 2018



## ACKNOWLEDGEMENTS

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## CONTENTS

<b>AUTHORS AND ACKNOWLEDGEMENTS</b> .....	<b>2</b>
<b>DISCLAIMER</b> .....	<b>3</b>
<b>CONTENTS</b> .....	<b>4</b>
<b>ABBREVIATIONS LIST</b> .....	<b>5</b>
<b>INTRODUCTION</b> .....	<b>6</b>
<b>VOLUME AND STRUCTURE OF PROCUREMENTS OF ARV DRUGS IN RUSSIA IN 2018</b> .....	<b>8</b>
<b>PROCUREMENT STRUCTURE OF ARV DRUGS IN 2018 BY EXPENSES</b> .....	<b>9</b>
<i>Budget distribution for different groups of drug products</i> .....	<i>10</i>
<b>COST OF ARV DRUGS IN 2018</b> .....	<b>13</b>
<i>Comparison of prices of contracts of the Ministry of Health of Russia in 2017 and 2018</i> .....	<i>13</i>
<i>Non-nucleoside reverse transcriptase inhibitors (NNRTIs)</i> .....	<i>13</i>
<i>Protease inhibitors (PI)</i> .....	<i>14</i>
<i>Integrase inhibitors (II)</i> .....	<i>15</i>
<b>COST OF THE MOST COMMON TREATMENT REGIMENS</b> .....	<b>16</b>
<b>NUMBER OF PATIENTS ON ART</b> .....	<b>17</b>
<i>The dynamics of treatment coverage</i> .....	<i>18</i>
<b>CONCLUSIONS</b> .....	<b>20</b>
<b>RECOMMENDATIONS</b> .....	<b>22</b>
<b>APPENDIX 1. THE WEIGHTED AVERAGE COST OF ARV DRUGS IN 2018</b> .....	<b>24</b>
<b>APPENDIX 2. RECOMMENDED TREATMENT REGIMENS IN RUSSIA</b> .....	<b>25</b>

## ABBREVIATIONS LIST

ARV, ART, ARVD	antiretroviral drugs
AA	autonomous area
CBA	CCR5 co-receptor Blocking Agent
HIV	Human Immunodeficiency Virus
WHO	World Health Organization
SRD	State Register Of Drugs
UISP	Unified Information System in Procurement
VED	Vital and Essential Drugs List
ID	Infectious Diseases
II	Integrase Inhibitors
TIN	Taxpayer Identification Number
PI	Protease Inhibitors
MoH RF	the Ministry of Health of the Russian Federation
INN	International Non-propriety Name
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NRTI2	2nd generation Nucleoside Reverse Transcriptase Inhibitors
NtRTI	Nucleotide Reverse Transcriptase Inhibitors
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
TN	Trade name
RF	Russian Federation
AIDS	Acquired Human Immunodeficiency Syndrome
FAS	Federal Anti-Monopoly Service
FSFIS	Federal State-Funded Institution of Science
FSBEI (HE)	Federal State Budgetary Educational Institution of Higher Education
FL (FZ)	Federal Law
FDC	Fixed-Dose Combination
FTI	Federal Treasury Institution
PKE	Pharmacokinetic Enhancer
AC	AIDS Center
3NRTI	3 INN NRTI in one tablet

## INTRODUCTION

Officially, according to “HIV infection in the Russian Federation in 2018” report of the Federal Scientific and Methodological Center for Prevention and Control of AIDS of the Central Research Institute for Epidemiology FSFIS of Rospotrebnadzor<sup>1</sup>, as of December 31<sup>st</sup>, 2018, the cumulative number of registered HIV infections among citizens of the Russian Federation amounted to 1,326,239 people. With the number of those who died subtracted, **1,007,369 Russians living with HIV** were living in the country, by the end of 2018.

According to preliminary data, **101,345 new cases of HIV infection** were reported in 2018 in the Russian Federation, excluding anonymously identified patients and foreign citizens.

The prevalence of HIV infection as of December 31, 2018 was 686.2 people per 100,000 of population. An increase of the number of regions with a high prevalence of HIV infection (more than 0.5% of the population) was registered: from 22 regions in 2014 to 35 regions in 2018. More than half of the total population of the country lived in these regions (59% in 2018).

The number of people who died because of HIV infection is constantly growing. In 2017, according to Russian Federal State Statistics Service (RosStat), HIV infection was the cause of more than half of all deaths from infectious diseases (57.2%). In 2018, **36,868 people with HIV infection died from all causes**, which is 15.6% more than in 2017. Tuberculosis remains the leading cause of death among people with HIV.

**751,712 Russians with HIV were registered in dispensaries in 2018**, which was 72.0% of the number of people living with the diagnosis of HIV in that period. In 2018, **443,000 patients** were receiving antiviral therapy in Russia (including 44,319 people in prisons), of which 31,493 patients interrupted ART in 2018. The treatment coverage in the Russian Federation in 2018 was 42.4% of the number of people living with the diagnosis of HIV infection, and 58.9% of those who were under medical check-up in dispensaries.

By the end of December 2018, **the viral load was suppressed in 345,147 patients** (HIV RNA less than 500 copies/mL), which was 77.9% of those who were receiving ART in 2018 and 53.9% of those tested for viral load. During 2018, 120,876 people living with HIV were first taken for antiretroviral therapy, and 83,965 were first put under medical check-up in dispensaries.

HIV infection went beyond the vulnerable groups of the population: more than half of the people first identified in 2018 were infected during heterosexual intercourse (57.5%). The proportion of people infected with HIV through drug use dropped to 39%. 2.5% of people were infected during homosexual intercourse, and their share is increasing annually.

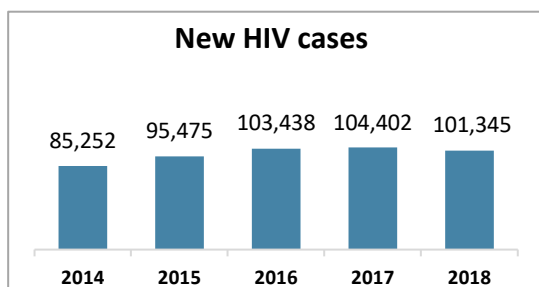


Figure 1. New HIV cases in 2014-2018

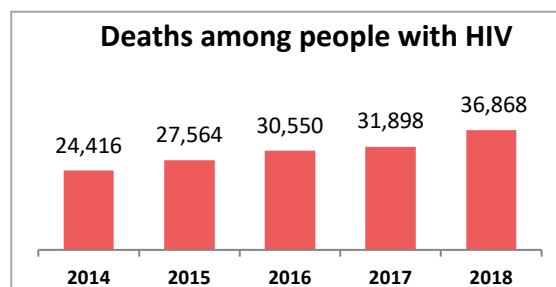


Figure 2. Deaths among people with HIV in 2014-2018

<sup>1</sup> Hereinafter data from “HIV infection in the Russian Federation in 2018” report of the Federal Scientific and Methodological Center for Prevention and Control of AIDS of the Central Research Institute for Epidemiology FSFIS of Rospotrebnadzor will be used.

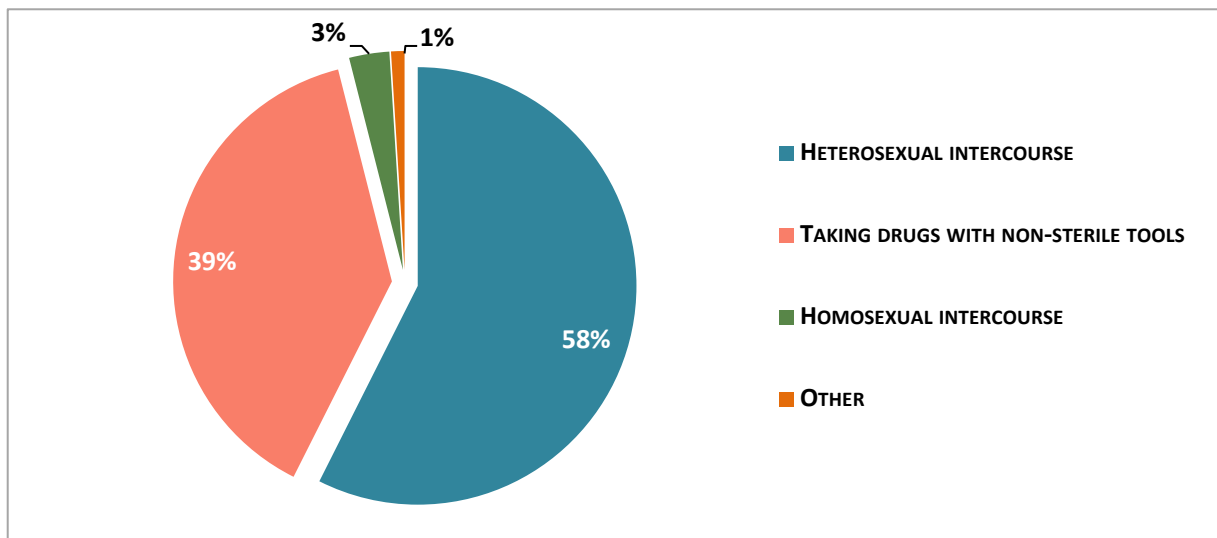


Figure 3. Ways of HIV transmission in 2018

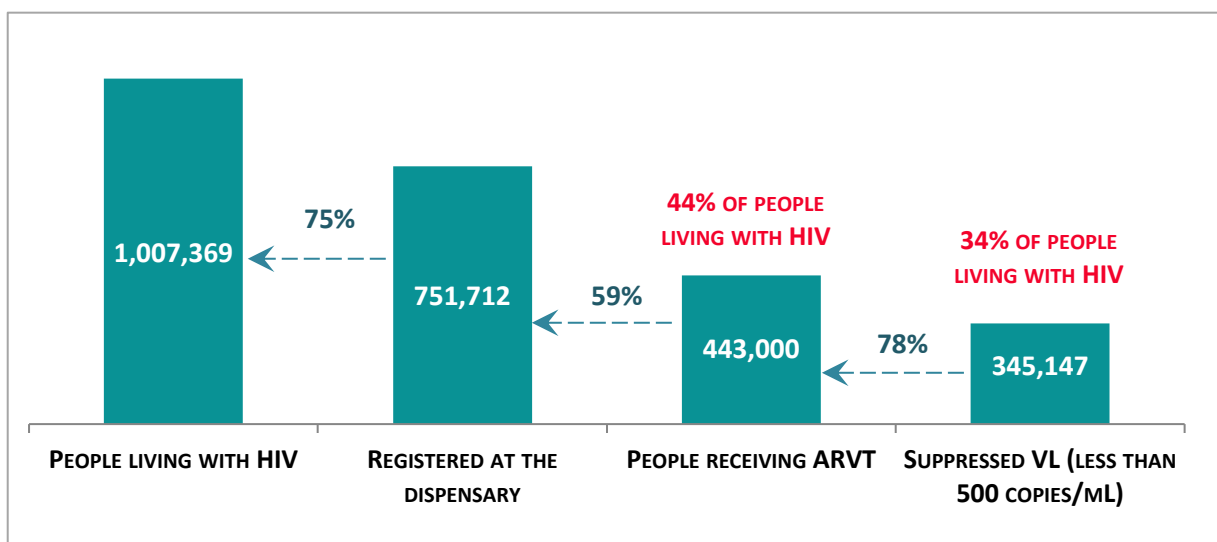


Figure 4. Coverage and treatment efficacy in the Russian Federation in 2018

## VOLUME AND STRUCTURE OF PROCUREMENTS OF ARV DRUGS IN RUSSIA IN 2018

In 2018, the total procurement amount was **380,124,906 USD**, including:

- **326,661,304 USD**: total amount of expenses of the Ministry of Health of Russia for centralized procurement
- **51,008,748 USD**: total amount of regional procurement
- **2,454,854 USD**: total amount of procurement by federal institutions

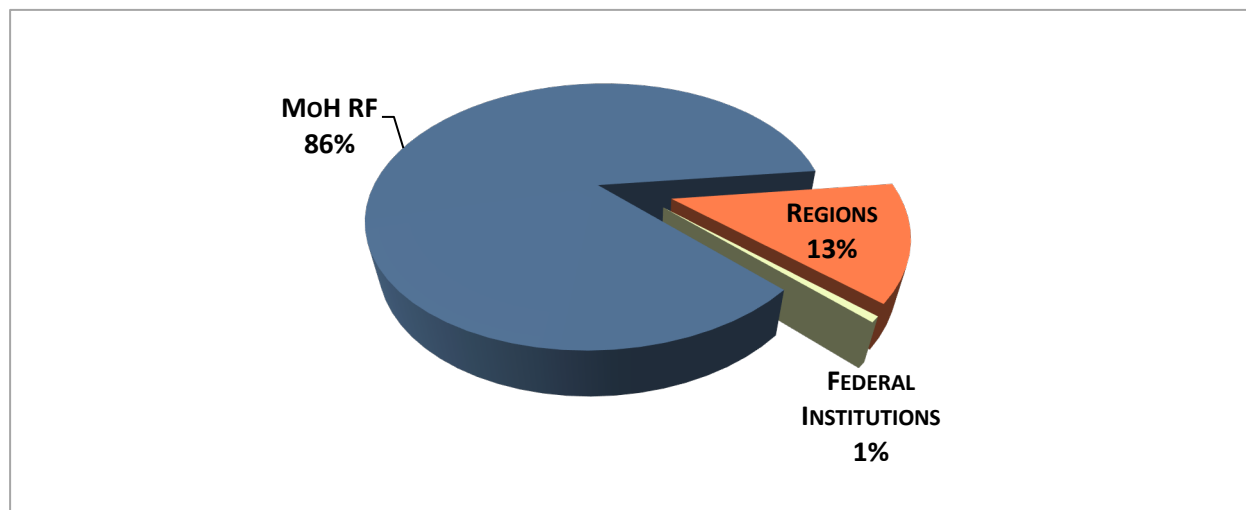


Figure 5. Budget distribution for the procurement of ARV drugs in 2018 by type of procurement

In 2018, the total amount of expenses of the Ministry of Health of Russia on ARV drugs decreased compared to 2017 by 12.2 million USD. We remind that the amount of a little more than 270 million USD was originally planned for the procurement of ARV drugs in the federal budget of 2017, and at the end of 2017 additional funds were allocated from the Reserve Fund for the procurement of ARV drugs in the amount of 63.5 million USD (total budget amounted to 338,880,259 USD).

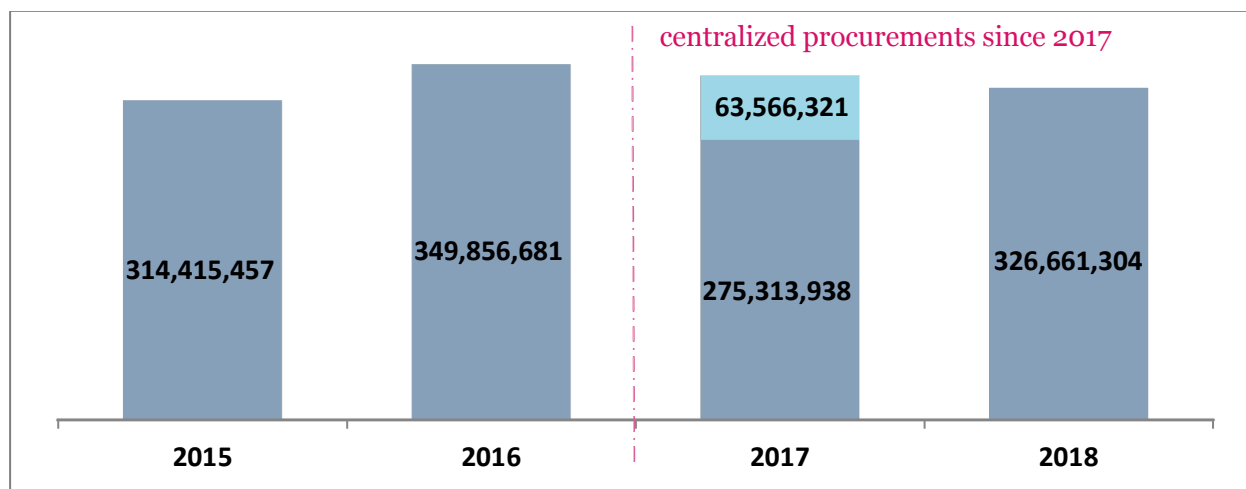


Figure 6. The expenses of ARV drugs in the Russian Federation by year, in USD (in 2015 and 2016: all procurements; in 2017 and 2018: only the Ministry of Health of Russia)



## PROCUREMENT STRUCTURE OF ARV DRUGS IN 2018 BY EXPENSES

In 2018, most of the ARV drugs budget (68.7%) was spent on the procurement of five drug products:

- **Lopinavir/ritonavir** 200/50 mg, 100/25 mg, oral solution 60 mL: 83,669,369.72 USD (22.01% of the total amount of procurements)
- **Raltegravir** 400 mg, 25 chewable tablets, 100 mg: 45 690 031.59 USD (12.02%)
- **Emtricitabine/tenofovir/rilpivirine**: 42,714,886.68 USD (11.24%)
- **Etravirine** 200 mg: 33 619 019.47 USD (8.84%)
- **Atazanavir** 150, 200, 300 mg: 31,338,068.82 USD (8.24%)

Compared to 2017, the top five products (in terms of the amount of money spent) no longer include Darunavir, which was on the second place in recent years. This was due to a significant reduction in the price of all dosages of Darunavir in the procurements of the Ministry of Health of Russia. Despite the fact that since 2015 several generics of the drug were registered, the price practically did not decrease until 2018.

For the first time, the combination drug emtricitabine/tenofovir/rilpivirine, which has no analogues on the market, was included in the list of leaders in terms of expenses.

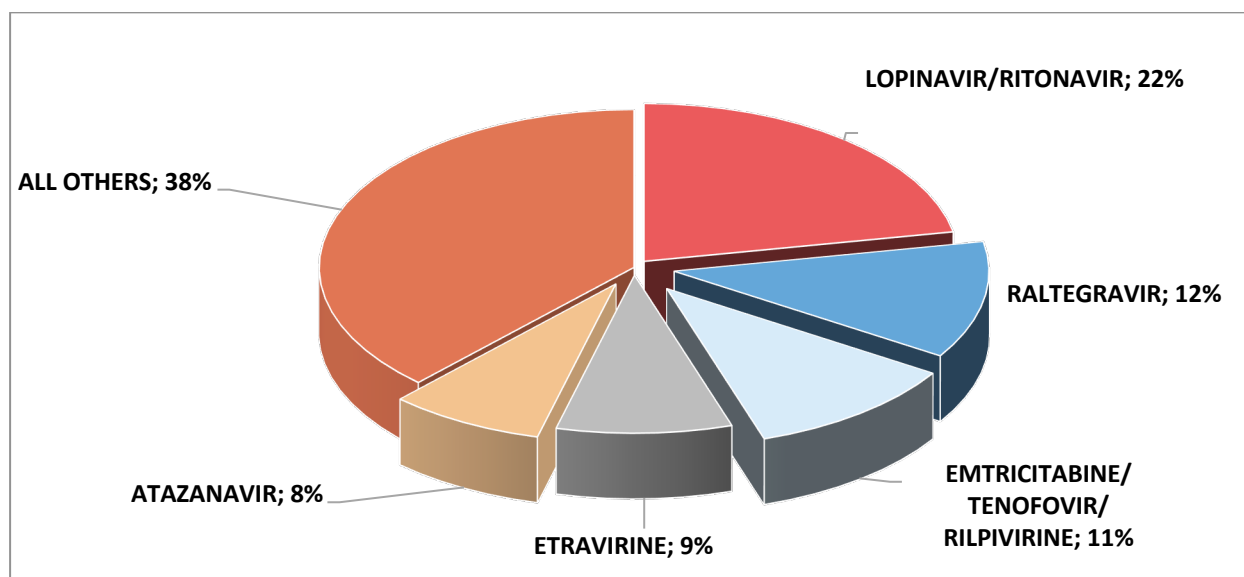


Figure 7. Distribution of funds for the top procured ARV drugs of the total budget

Table 1. Expenses on each INN in procurement in 2018, regardless of budget

INN	Prices of Contracts, USD	Share	Drug type
Lopinavir/ritonavir	83,669,369.72	22.01%	third drug
Raltegravir	45,690,031.59	12.02%	third drug
Emtricitabine/tenofovir/rilpivirine	42,714,886.68	11.24%	3-in-1
Etravirine	33,619,019.47	8.84%	third drug
Atazanavir	31,338,068.82	8.24%	third drug
Dolutegravir	28,025 344.91	7.37%	third drug
Efavirenz	22,834,918.60	6.01%	third drug
Darunavir	18,887,313.66	4.97%	third drug
Tenofovir	11,366,349.67	2.99%	NRTI
Ritonavir	8,968,516.33	2.36%	PKE
Abacavir/lamivudine*	7,960,418.25	2.09%	NRTI
Fosamprenavir	7,428,203.81	1.95%	third drug

INN	Prices of Contracts, USD	Share	Drug type
Lamivudine	6,500,811.06	1.71%	NRTI
Abacavir	6,011,632.51	1.58%	NRTI
Phosphazide	5,440,892.65	1.43%	NRTI
Elsulfavirine	4,770,158.42	1.25%	third drug
Saquinavir	4,096,291.16	1.08%	third drug
Lamivudine/zidovudine	3,330,265.74	0.88%	NRTI
Rilpivirine	2,694,594.22	0.71%	third drug
Zidovudine	1,944,736.63	0.51%	NRTI
Nevirapine	1,021,479.20	0.27%	third drug
Tenofovir/emtricitabine*	847,888.77	0.22%	NRTI
Emtricitabine	646,468.68	0.17%	NRTI
Maraviroc	185,938.97	0.05%	third drug
Stavudin	99,232.67	0.03%	NRTI
Efavirenz/tenofovir/emtricitabine*	12,020.43	0.0032%	3-in-1
Didanosine	14,472.02	0.0038%	NRTI
Abacavir/zidovudine/lamivudine	5,581.38	0.0015%	3NRTI
	<b>380,124,906.03</b>	<b>100.00%</b>	

\* Including broken into mono-components as a result of bidding.

## Budget distribution for different groups of drug products

Table 2. Share of the price of contracts by type of drug products of the total amount of all procurements (by groups, excluding pediatric forms)

Drug type	Contract price, USD.	Share of contracts prices, %
Third drug	284,260,732.60	74.78%
NRTI	44,163,168.62	11.62%
3-in-1	42,726,907.10	11.24%
Ritonavir	8,968,516.33	2.36%
3 NRTI*	5,581.38	0.001%
<b>Total</b>	<b>380,124,906.03</b>	<b>100.00%</b>

\*3NRTI is a drug product consisting of three NRTI: abacavir, lamivudine, zidovudine.

The distribution within the classes, including 3-in-1 drug products that are added to individual drug products (efavirenz or rilpivirine), is shown in Table 3.

Table 3. Distribution within groups of third drugs

INN	Type	Number of patients	Share inside class
Etravirine	NNRTI2	9,954	44.93%
Rilpivirine (including 3-in-1)	NNRTI2	8,859	39.99%
Elsulfavirine	NNRTI2	3,259	14.71%
<b>Total for NNRTI2</b>		<b>22,072</b>	<b>100.00%</b>
Efavirenz (including 3-in-1)	NNRTI	181,165	93.34%
Nevirapine	NNRTI	12,931	6.66%
<b>Total for NNRTI</b>		<b>194,096</b>	<b>100.00%</b>
Lopinavir/ritonavir	PI	92,032	64.33%
Atazanavir	PI	29,583	20.68%
Darunavir	PI	13,507	14.44%
Saquinavir	PI	4,274	2.99%

INN	Type	Number of patients	Share inside class
Fosamprenavir	PI	3,671	2.57%
<b>Total for PI</b>		<b>143,067</b>	<b>100.00%</b>
Dolutegravir	II	14,760	61%
Raltegravir	II	9,436	39%
<b>Total for II</b>		<b>24,195</b>	<b>100.00%</b>

Efavirenz and nevirapine conventionally belong to the first generation NNRTI (NNRTI1) class drugs. Inside this class, the largest number of courses includes efavirenz (93.4%). Compared to 2017, its share increased by 5.4%. The share of nevirapine decreased accordingly.

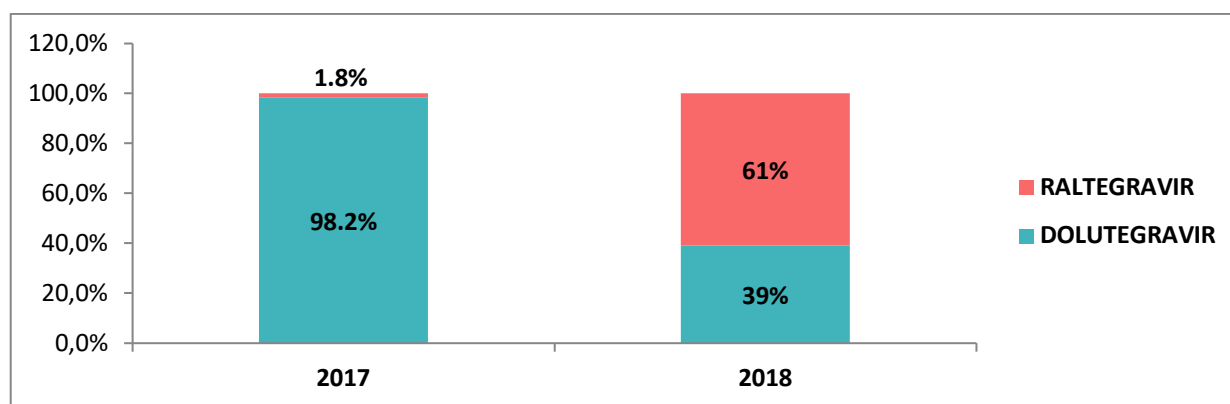
Etravirine, rilpivirine and el sulfavirine conventionally belong to the second generation NNRTI (NNRTI2). Although el sulfavirine was virtually absent in the VED list in 2018 (with el sulfavirine included in the revised VED edition in 2019), its share in total procurements increased. Compared to 2017, the share of el sulfavirine courses in the NNRTI2 group increased from 0.5% to almost 15%.

The share of rilpivirine increased from 19% to 40% only due to the combination drug emtricitabine/tenofovir/rilpivirine. This combination was procured in the amount of 8,347 12-months' courses (2,905 courses in 2017). The volume of procurements of rilpivirine as a separate drug amounted to 512 12-months' courses (229 courses in 2017).

The share of etravirine within the group decreased from 97.7% to 45% compared to 2017.

Lopinavir/ritonavir (~64%) is the most procured drug in the group of protease inhibitors (PI); atazanavir remains the second most popular in this group (20.68%). As mentioned above, the volume of procurements of both drugs decreased in 2018.

At the time of writing this Report, II class was represented by two drugs in the Russian Federation: raltegravir and dolutegravir. In 2018, the ratio of the number of courses within II class changed. In 2017, dolutegravir accounted for only 1.8%. After the inclusion of the drug in the VED in 2018, the share of dolutegravir within the class increased significantly and amounted to 61%. The main volume of dolutegravir was procured by the Ministry of Health of Russia at the expense of the federal budget, which became possible due to the inclusion of the drug in the VED list.



**Figure 8. Changes in the procurement structure within the class of integrase inhibitors 2017–2018**

The share of 2-in-1 drugs also decreased. In 2016, prior to centralization, the share of 2-in-1 drugs was 38%, in 2017 it was 24%, in 2018 it was 16%. Thus, for two years of centralization, the share of 2-in-1 drugs in the total volume of procurements decreased by 22%.

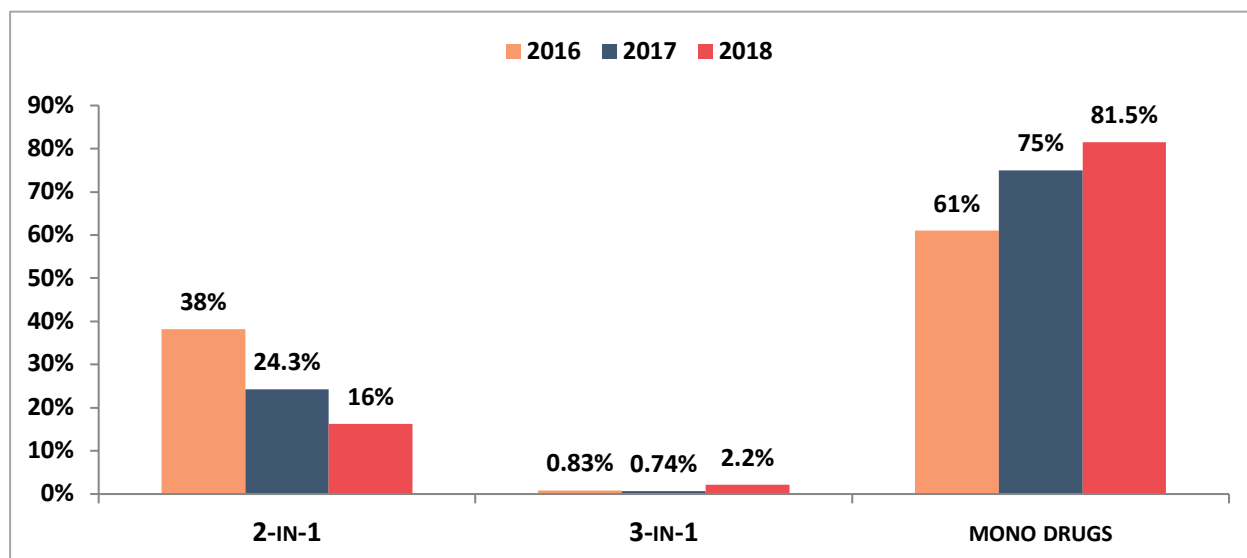


Figure 9. Comparison of the share of combination and mono drugs in the number of courses procured in 2016-2018

## COST OF ARV DRUGS IN 2018

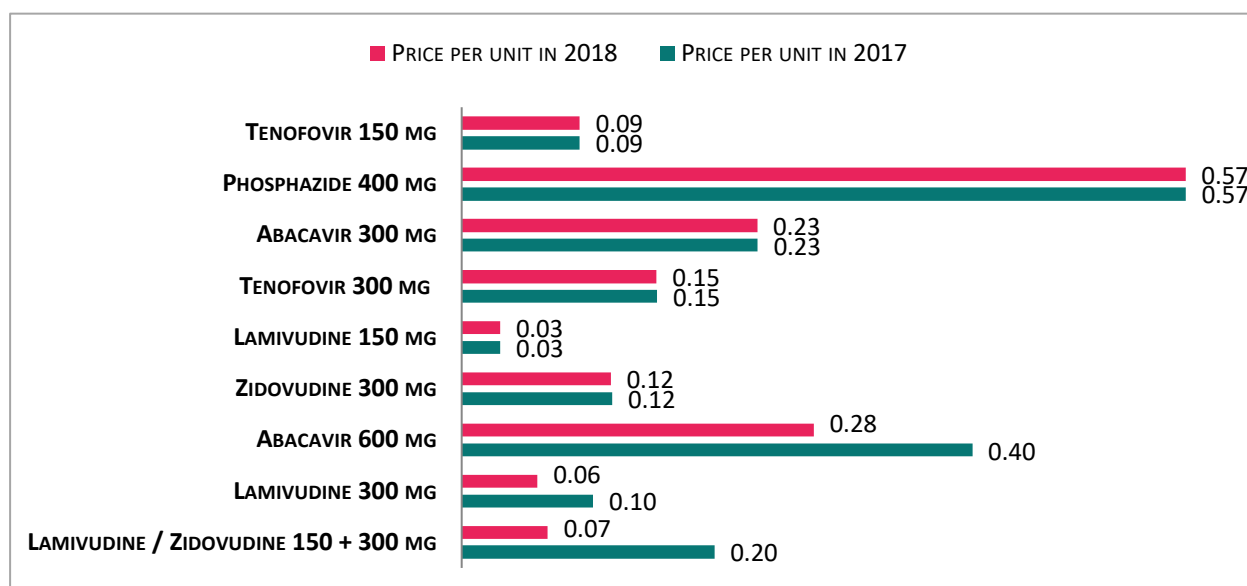
See the prices for ARV drugs per packaging in [Appendix 1. The weighted average cost of ARV drugs in 2018.](#)

### Comparison of prices of contracts of the Ministry of Health of Russia in 2017 and 2018

When comparing prices in the procurements of the Ministry of Health of Russia 2017 and 2018, it is clear that prices for several drug products from the NRTI group have decreased significantly:

- Lamivudine/zidovudine 150+300 mg: 65.94%
- Lamivudine 300 mg: 42.44%
- Abacavir 600 mg: 31.05%

However, prices for the rest of the drugs of the NRTI group changed slightly or remained at the level of 2017.



**Figure 10. Weighted average prices per unit (tablet) for drug products from the NRTI group procured by the Ministry of Health of Russia in 2017 and 2018 (USD)**

Let us consider how the prices have changed within the classes of ARV drugs.

### Non-nucleoside reverse transcriptase inhibitors (NNRTIs)

When comparing the prices of drugs in the NNRTI group in the framework of centralized procurement of the Ministry of Health of 2018, it is clear that prices have decreased for the following drug products:

- Nevirapine tablets 200 mg (decreased by 10.88%)
- Efavirenz 600 mg tablets (decreased by 1.57%)

At the same time, as noted above, efavirenz 400 mg dosage (recommended by WHO) appeared in the procurements of the Ministry of Health of Russia, which was not there in 2017.

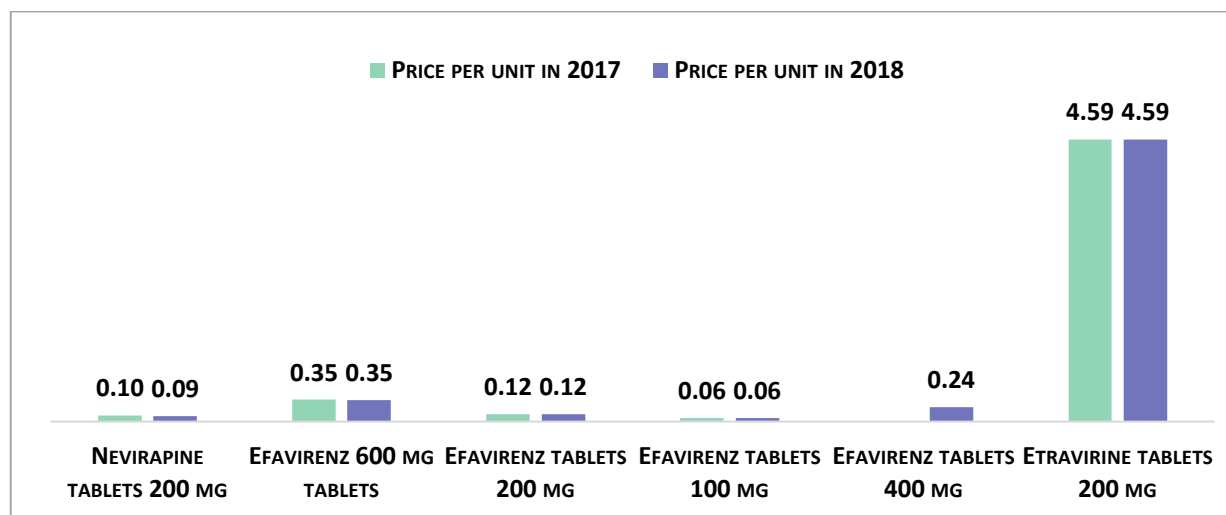


Figure 11. Weighted average prices per unit (pill) for drug products of NNRTI group procured by the Ministry of Health of Russia in 2017 and 2018 (USD)<sup>2</sup>

## Protease inhibitors (PI)

In the procurements of the Ministry of Health of Russia, the prices for all dosages of darunavir were significantly reduced. The maximum decrease was for the dosage of 600 mg (by 67.76%). The price of 400 and 800 mg dosages decreased by 50%.

The price of saquinavir 500 mg in 2018 decreased by 11.12%. As in the previous year, the auction was won by a supplier with a generic version of the drug. At the same time, in 2017 the price increased by 50% compared with 2016.

It is worth noting individually that, despite participation of atazanavir generic in auctions, the price for all three dosages remained at the level of 2017. At the same time, the original drug TN Reataz did not participate in the auctions of the Ministry of Health of Russia in 2018.

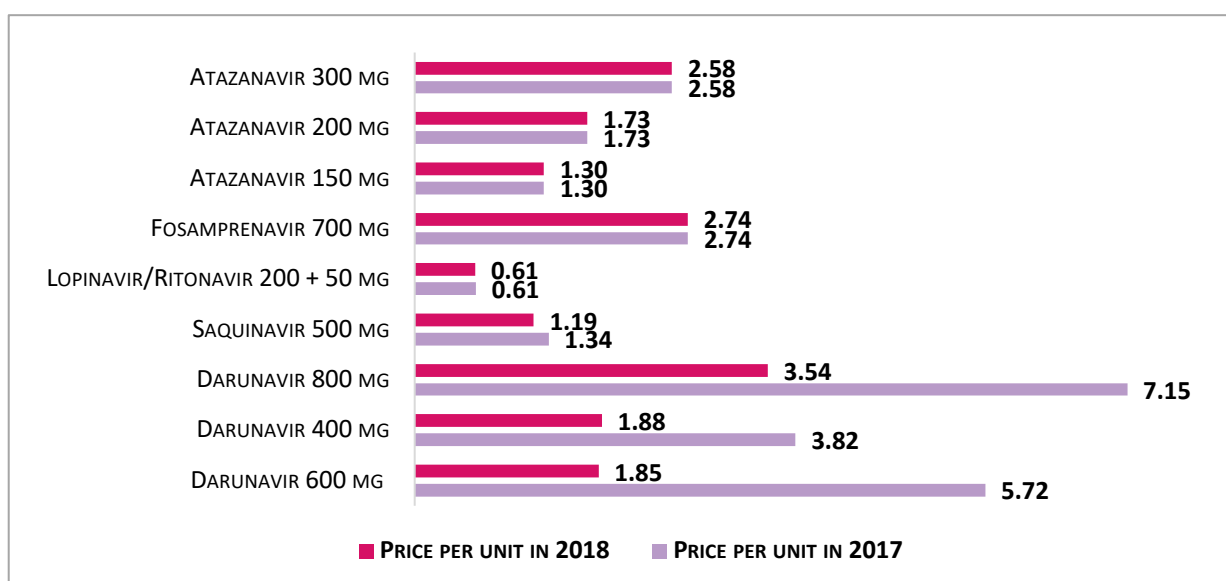


Figure 12. Weighted average prices per unit (pill) for drug products of the PI group procured by the Ministry of Health of Russia 2017 and 2018 (USD)

<sup>2</sup> The Ministry of Health of Russia did not procure Efavirenz tablets 400 mg in 2017.

## Integrase inhibitors (II)

The class of integrase inhibitors is represented by two drugs: dolutegravir and raltegravir. Both drugs have no analogues in the Russian market.

The graph below shows that in 2017 the price of dolutegravir decreased slightly (by 4%), and in 2018 it decreased by 32%. This was largely due to the inclusion of dolutegravir in the VED list for 2018. In 2018 the price of raltegravir decreased by 10% (a similar trend was recorded in 2017). However, despite this relatively small decrease, raltegravir remains the most expensive drug product in the line of ARV drugs.

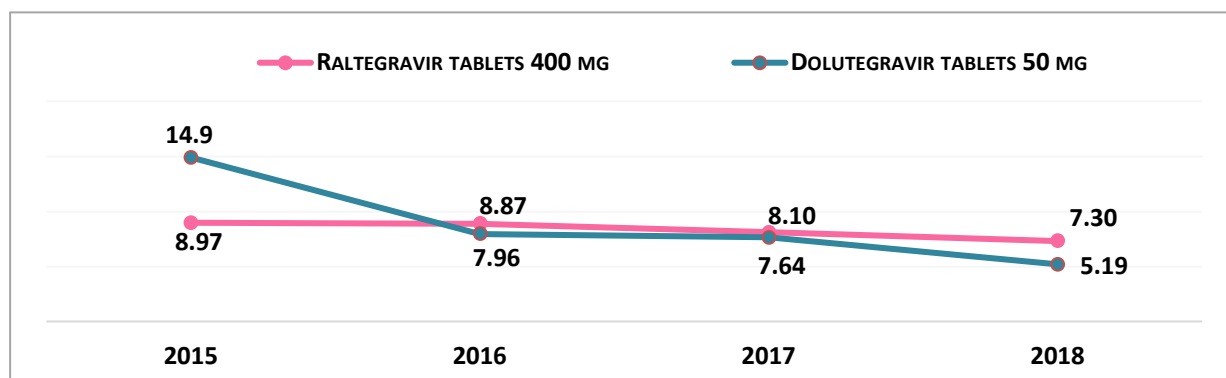


Figure 13. Weighted average unit prices (tablets) for drug products from II group procured in 2015–18 (USD per tablet)

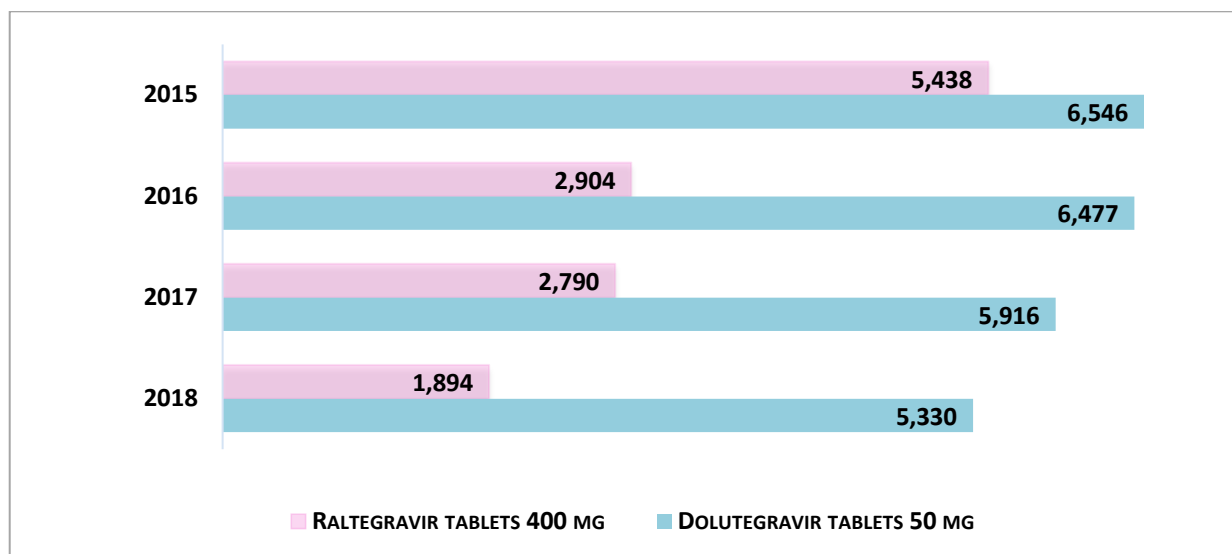


Figure 14. The dynamics of the cost of a 12-months' course for drugs of II group in the period from 2015 to 2018 (USD)

The graph clearly shows the significant difference in price for a 12-months' course and in the dynamics of the decrease in price by year between dolutegravir and raltegravir. The price of Raltegravir remains steadily high, in contrast to the price of dolutegravir, which in four years has fallen by almost 3 times. At the same time, the price of raltegravir in 2018, as already noted, was almost three times higher than the price of dolutegravir.

## COST OF THE MOST COMMON TREATMENT REGIMENS

According to the Russian recommendations for the treatment of HIV infection in 2017 and the procurement analysis, the most prescribed first-line regimens were the regimens shown in Table 4 below. The cost of 12-months' courses treatment course was calculated based on the contract prices of the Ministry of Health of Russia.

**Table 4. The cost of 12-months' courses of treatment in first-line regimens in 2018**

First-line regimen	Cost per patient per year in USD
Efavirenz 600 mg + lamivudine 150 mg + tenofovir 300 mg	206
Efavirenz 600 mg + lamivudine 150 mg + abacavir 600 mg	251
Efavirenz 600 mg + lamivudine /zidovudine 150+300 mg	177
Nevirapine 200 mg + lamivudine 150 mg + tenofovir 300 mg	143
Nevirapine 200 mg + lamivudine 150 mg + abacavir 600 mg	188
Nevirapine 200 mg + lamivudine /zidovudine 150+300 mg	114

Thus, the cost of first-line regimens varies from 114 to 251 dollars per year per patient. The most commonly used **efavirenz 600 mg + lamivudine 150 mg + tenofovir 300 mg regimen costs approximately 206 USD** per patient per year.

In accordance with the recommendations of the Ministry of Health of Russia, preferred regimens of the second line are regimens containing lopinavir/ritonavir, atazanavir, atazanavir + ritonavir, dolutegravir. According to the analysis, they were among the most common regimens. Dolutegravir can also be used as an alternative first-line regimen.

**Table 5. Cost of a 12-months' treatment in second-line regimens in 2018**

	Cost per patient per year in USD
Lopinavir/ritonavir 200+50 mg + lamivudine 150 mg+ tenofovir 300 mg	966
Lopinavir/ritonavir 200+50 mg + lamivudine 150 mg+ abacavir 600 mg	1,011
Lopinavir/ritonavir 200+50 mg + lamivudine /zidovudine 150+300 mg	938
Atazanavir 300 mg + ritonavir 100 mg + lamivudine 150 mg+ tenofovir 300 mg	1,228
Atazanavir 300 mg + ritonavir 100 mg + lamivudine 150 mg+ abacavir 600 mg	1,273
Atazanavir 300 mg + ritonavir 100 mg + lamivudine /zidovudine 150+300 mg	1,199
Dolutegravir 50 mg + lamivudine 150 mg + tenofovir 300 mg	1,979
Dolutegravir 50 mg + lamivudine 150 mg + abacavir 600 mg	2,024
Dolutegravir 50 mg + lamivudine /zidovudine 150+300 mg	1,951
Darunavir 400 mg + ritonavir 100 mg + lamivudine 150 mg+ tenofovir 300 mg	1,861
Darunavir 400 mg + ritonavir 100 mg + lamivudine 150 mg+ abacavir 600 mg	1,906
Darunavir 400 mg + ritonavir 100 mg + lamivudine/zidovudine 150+300 mg	1,833

The cost of second-line regimens in 2018 ranged **from 966 to 1,833** per patient per year.

It should be noted that, due to lower prices for darunavir in procurements by the Ministry of Health of Russia, the cost of regimens containing darunavir has more than doubled (from over 4,700 USD to 1,800-1,900 USD per patient per year).



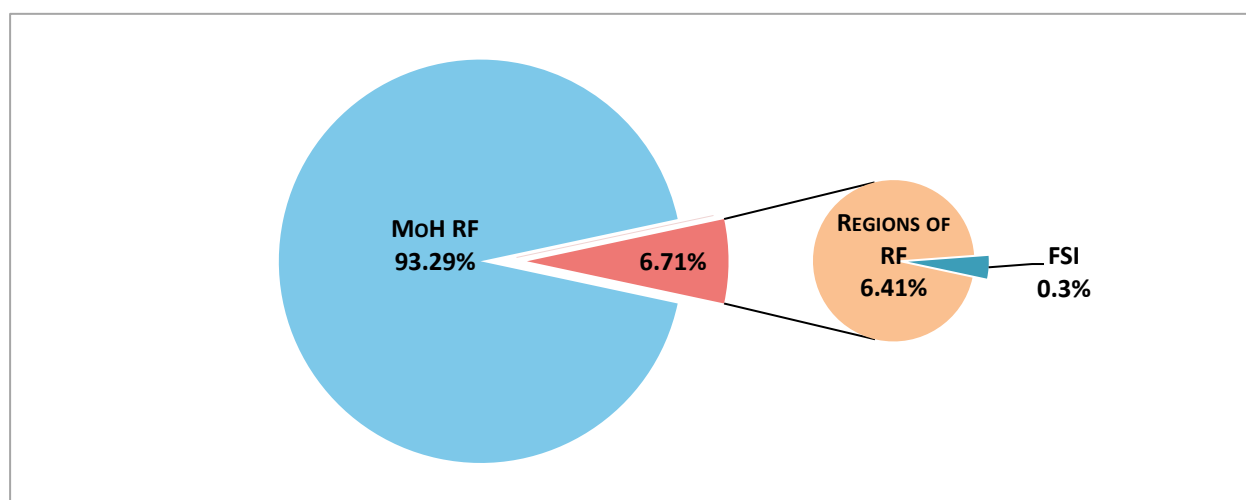
## NUMBER OF PATIENTS ON ART

According to international and Russian recommendations, antiretroviral therapy regimens should consist of three drugs: two base drugs of the nucleoside/nucleotide inhibitor reverse transcriptase class (NRTI) and the third drug of the non-nucleoside inhibitor reverse transcriptase class (NNRTI), protease inhibitors (PIs), integrase inhibitors (IIs), CCR5 inhibitors. As a rule, Lamivudine or Emtricitabine should be among the two drugs of the NRTI class. This rule may not apply to the so-called third-line regimens or reserve regimens, the selection of which must be done individually.

Based on this principle, the authors of the Report divided the further analysis into two parts: 1) drugs of the NRTI group, 2) third drugs, including NNRTI, PI, II, as well as CCR5 inhibitors and fusions.

Based on the analysis of the structure of procurement of ARV drugs in Russia in 2018, it can be concluded that the **amount of drugs procured is intended for approximately 384 thousand patients**. This figure does not include patients taking pediatric forms of drugs<sup>3</sup>, the dosages of which are calculated individually, depending on age and body weight.

Approximately 7% of the total number of procured courses account for drugs purchased at the expense of Russian regional budgets (24,584 courses) and FSI budgets (1,165 courses).



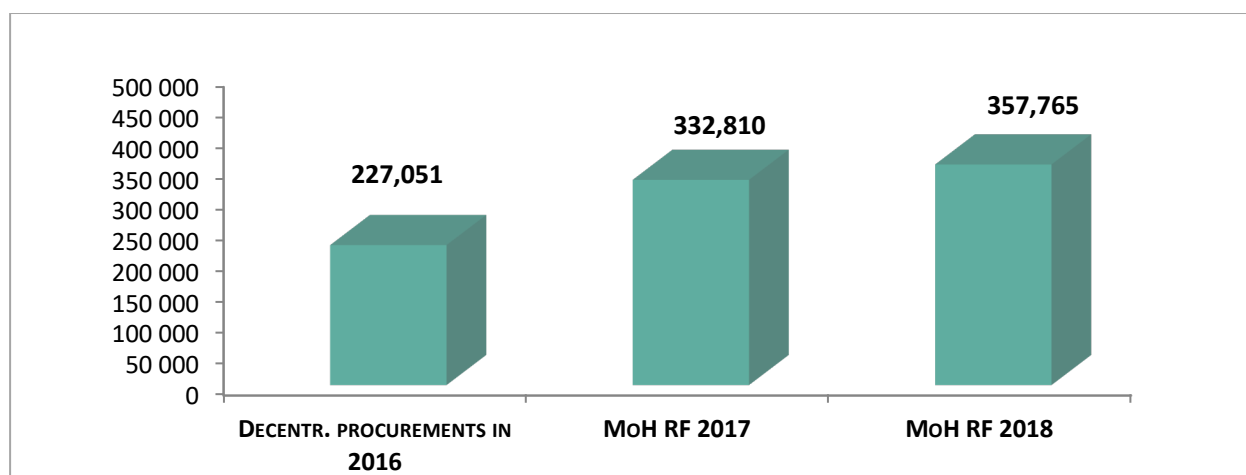
**Figure 15. The share of the Ministry of Health of Russia in the total number of procured treatment courses in 2018**

Compared to 2017, the number of 12-months' courses with third drugs increased by 6.65%, or by 23,902 12-months' courses.

Within the framework of centralized procurements, the Ministry of Health of Russia spent 326,661,304 USD for the procurement of ARV drugs in 2018. In 2017, the total amount of procurements by MoH RF was 338,880,259 USD. The total amount of procurements of MoH RF in 2018 decreased by 3.61%. At the same time, MoH RF procured by 24,955 12-months' courses more (7.5%) compared with 2017.

We can conclude that in 2018 in the procurement of the Ministry of Health of Russia there was no significant increase in the volume of courses, but still there was an increase in the coverage of treatment, at lower cost.

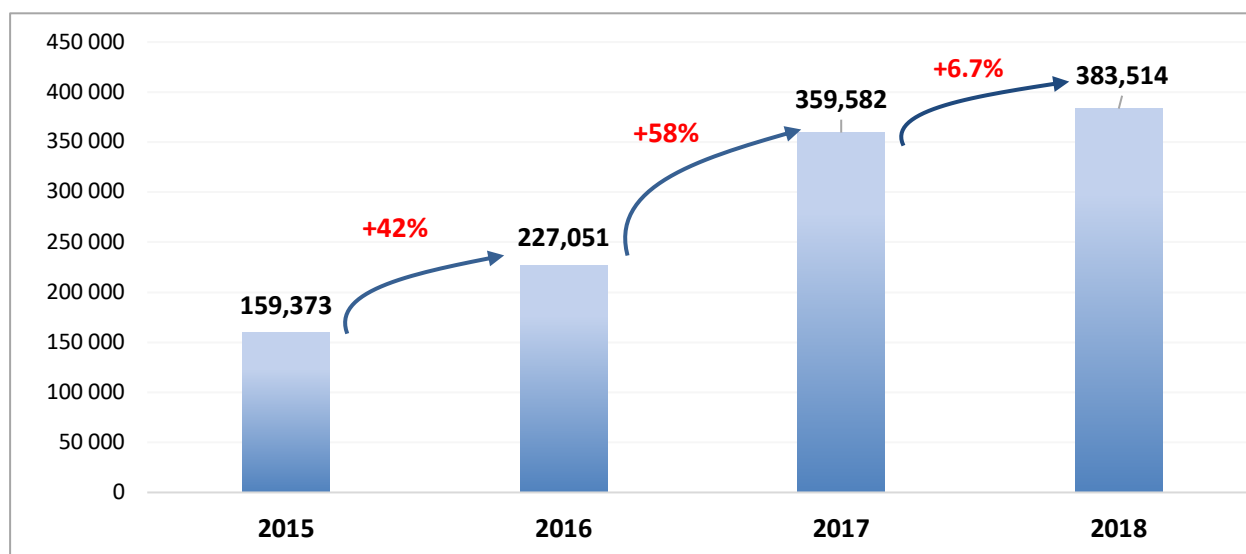
<sup>3</sup> Only pediatric forms of Raltegravir 25 mg and 100 mg are used in the calculations.



**Figure 16. Estimated number of patients in 2016-2018 (excluding regional procurements in 2018)**

Considering that regional procurements were reduced by 6%, it can be concluded that the total number of courses increased by 6.7% only due to procurements by MoH RF at the expense of the federal budget.

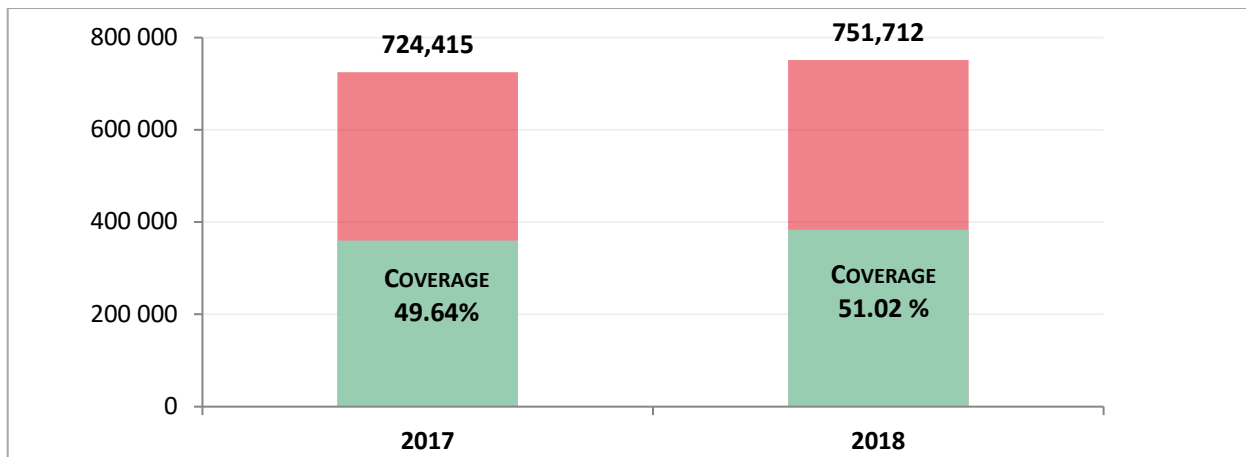
### The dynamics of treatment coverage



**Figure 17. The estimated number of 12-months' treatment courses in government procurements in 2015-2018**

Compared to 2016, when procurements were decentralized, the estimated number of patients increased by 69% during the two years of centralized procurements (2017–2018).

According to the Federal Supervision Agency for Customer Protection and Human Welfare (Rospotrebnadzor) as of December 31, 2018, 751,712 patients with HIV were registered in dispensaries. Based on the volume of 12-months' courses procured in the Russian Federation in 2018, the coverage of ARV therapy in 2018 could reach 51.02% (59% according to official data).



**Figure 18. The percentage of treatment coverage, based on the volume of ARV drugs procured in 2018**

## CONCLUSIONS

1. The estimated number of 12-months' courses of ARV therapy in 2018, according to the monitoring data, was 383,514. This covers 51% of the total number of people registered in dispensaries in 2018, and about 38% of the registered number of people with HIV infection. The increase in the number of procured courses in comparison with 2017 amounted to only 6.65% (23,902 12-months' courses). The authors of the Report regretfully note a decrease in the rate of coverage of ARV therapy.
2. According to official data, the number of people receiving therapy at the end of 2018 amounted to 443 thousand people. The difference between official and estimated figures, in the first place, can be explained by the fact that official statistics include all patients who started taking therapy and then stopped for various reasons.
3. The Ministry of Health of Russia spent a total of 380.12 million USD for the procurement of ARV therapy in 2018, which is 12.2 million USD less than in 2017 (taking into account the fact that 63.5 million USD was additionally allocated from a reserve fund in 2017). The trend to reduce federal funding for ARV drugs is extremely alarming.
4. 68.7% of the budget was spent on the procurement of five drugs (lopinavir/ritonavir, raltegravir, tenofovir/emtricitabine/rilpivirine, etravirine, atazanavir). 60% of this was spent on four drug products under patent protection (lopinavir/ritonavir, raltegravir, tenofovir/emtricitabine/efavirenz, etravirine).
5. The analysis showed that the main regimens in Russia are tenofovir + lamivudine + efavirenz in the form of separate drugs (the weighted average cost of a 12-months' course of treatment in centralized procurements is 206 USD per patient) and tenofovir + lamivudine + lopinavir/ritonavir (the cost of a 12-months' course is 966 USD). The number of patients receiving efavirenz 600 mg increases, while lopinavir/ritonavir decreases, but remains high.
6. In 2018, during the procurements of the Ministry of Health of Russia, the prices for several drugs were significantly reduced compared with 2017, primarily for darunavir 600 mg (67.76%), lamivudine/zidovudine (65.94%), darunavir 400 mg and darunavir 800 mg (about 50%).
7. The analysis showed that the savings achieved were primarily aimed at increasing the number of courses of efavirenz, dolutegravir, tenofovir/emtricitabine/rilpivirine and raltegravir. The increase in volumes of dolutegravir, tenofovir/emtricitabine/rilpivirine and raltegravir speaks of the optimization of treatment regimens, which cannot be said about the increase in the volumes of efavirenz. In the procurement structure, a decrease in the number of atazanavir, darunavir, nevirapine (significantly) and etravirine courses can also be noted.
8. Due to the increase in tenofovir/emtricitabine/rilpivirine, the number of patients taking combinations of fixed doses as single-tablet regimens has increased. However, in percentage terms, the number of such patients remains extremely small (2.2%).
9. At the same time, there still is the tendency to break up the combination drugs into mono-components. In 2018, patients in the Russian Federation, in fact, had only one drug as a single-tablet regimen (tenofovir/emtricitabine/rilpivirine), and only one combination of two NRTIs (lamivudine/zidovudine) not included in the list of preferred regimens, available. This trend is largely dictated by the position of the Federal Antimonopoly Service.
10. At the same time, the results of the monitoring indicate that by dividing the combination drug into mono-components, real saving is often not achieved. As the analysis of the auctions at abacavir/lamivudine and tenofovir/emtricitabine shows, it was possible to save

at least 3.8 million USD in addition in 2018, if the customers had initially announced auctions for mono-components.

11. The analysis showed that in 89% of the auctions of the Ministry of Health of Russia there was no competition. Compared to last year, the already low number of auctions with competition decreased by another 5%. At the same time, as noted above, the prices for a number of drugs were significantly reduced compared with 2017. Technically, the decline occurs mainly at the stage of announcing the initial maximum contract price by the Ministry of Health of Russia and is primarily due to the dynamics of the market as a whole, and not to competition in the bidding.
12. The analysis showed that the majority of drugs used in the Russian market are generics. In this case, 65% of the total budget is spent on the procurement of original drugs. A significant number of drug products (including the originals) are the drug products of domestic production. Among the generics, there are practically no products made in India that are registered in the Russian Federation in large quantities. This may be due to the “odd on out” principle, according to which, if two suppliers with products made in Russia or EAEU participate in the bidding, the participants with products from other countries are not allowed to bid.
13. In 2018, the number of drugs quality-related claims from patients increased. This situation requires further close attention of regulatory authorities, primarily the Ministry of Health of Russia and Rospotrebnadzor.
14. In 2018, according to Pereboi.ru website, the interruptions in supply of antiretroviral drugs continued, despite the fact that auctions in 2018 were announced on the same dates as in 2017. This indicates that with an already established system of centralized procurement, there is still a shortage of ARV drugs in the regions of the Russian Federation, which may indicate an insufficient volume of procured drugs and, thus, the lack of both federal and regional funding and/or incorrect procurement planning.

## RECOMMENDATIONS

1. **Continue efforts to expand the ARV treatment coverage.** In accordance with the State strategy to fight HIV infection in the Russian Federation, by 2020 (with the availability of adequate funding), the number of people receiving therapy in Russia should reach the level of 90% of the total number of people living with HIV. At the end of 2018, even according to official data, this level was below 45%, or 443 thousand patients out of 1,007,369 living with HIV (in accordance with the text of the Strategy, the target indicator for 2018 was 60.2%, or about 600 thousand patients). Taking into account the rate of detection of new HIV cases (about 100 thousand new cases in 2018), in our opinion, in the next two years, it is necessary to additionally provide therapy to at least 200 thousand patients in order to approach the target level of the Strategy.
2. Such results can be achieved using an integrated approach:
  - a. By accordingly increasing the federal and regional budgets for the procurement of ARV drugs (as indicated in the State Strategy). According to rough estimates, to meet the need for ARV drugs, it is necessary to have a 2-3 times' increase of federal funding.
  - b. By saving in the procurement of ARV drugs that are already being used.
3. Significant saving can be achieved in the procurement of ARV drugs that are currently under patent protection, for which a significant portion of the budget is spent: raltegravir, tenofovir/emtricitabine/rilpivirine, etravirine, dolutegravir.

The price can be reduced through direct negotiations, by developing a system of long-term contracts or by using a compulsory licensing mechanism (production/supply of simulated versions of the drug at reduced prices for state needs with compensation to the patent owner in accordance with Article 1362 of the Civil Code of Russia), or by using a combination of these methods.

4. Given the recent recommendations of WHO, individual efforts to reduce the price should focus on Dolutegravir. The benchmark for reducing prices could be the price achieved during the negotiations in Brazil (given the comparable level of income and the size of the epidemic), namely about 50 USD per month.
5. The Ministry of Health of Russia should continue working to improve standards of treatment with ARV drugs:
  - a. One of the main directions should be an increase in the share of Dolutegravir in the first-line regimens in accordance with the recommendations of WHO and the European AIDS Clinical Society (EACS), as well as a gradual transition to a lower dosage of Efavirenz (400 mg instead of 600 mg).
  - b. In the segment of protease inhibitors, a gradual decrease in the share of lopinavir/ritonavir is recommended, replacing it with more preferred options (darunavir, atazanavir) in accordance with the recommendations of EACS. Atazanavir, judging by the data from auctions in 2019, may also be a cheaper option than lopinavir/ritonavir.
  - c. In the segment of non-nucleoside reverse transcriptase inhibitors, a gradual replacement of etravirine with rilpivirine and elvitegravir is recommended (in case the drug confirms its efficacy and safety during phase 4 trials).<sup>4</sup>
6. Regulators should review the procurement of vital and essential combination **drugs for life-long use**. In our opinion, when procuring ARV drugs, it should be possible to indicate in

<sup>4</sup> EACS treatment guidelines for HIV <https://itpcru.org/2017/10/26/opublikovany-obnovlennye-rekomendatsii-eacs-po-lecheniyu-vich-infektsii/>

the auction documentation the need to supply the combination form, without the possibility of breaking it down into mono-components.

7. It is recommended that the VED list be updated to include (subject to manufacturers filing the dossier) such drugs as rilpivirine, tenofovir/emtricitabine, tenofovir/emtricitabine/efavirenz, emtricitabine, in order to expand the range of options for treating HIV infection.
8. Also, in order to expand options for treating children, the authors urge manufacturers of pediatric forms of integrase inhibitors (dolutegravir and raltegravir) to take measures to bring these drugs to the Russian market as soon as possible.
9. The manufacturers, the Ministry of Health of Russia, the Federal Service for Supervision in the Sphere of Health Care (Roszdravnadzor) should pay special attention to the quality standards of ARV drugs, including having additional checks for compliance with applicable standards in the production and circulation in the market. The experience of 2018 shows that a closer monitoring is required in this area. It is also necessary to further apply more efforts to fight against counterfeit ARV drugs.

## APPENDIX 1. THE WEIGHTED AVERAGE COST OF ARV DRUGS IN 2018

Drug name	Tablets per packaging	Price per pack in 2018 (USD)
Abacavir 150 mg	60	4.76
Abacavir 300 mg	60	13.94
Abacavir 600 mg	30	8.30
Abacavir solution 240 mL	1	19.86
Abacavir/Zidovudine/Lamivudine 300/300/150 mg	60	15.56
Abacavir/Lamivudine 600/300 mg	30	53.05
Atazanavir 150 mg	60	78.16
Atazanavir 200 mg	60	104.20
Atazanavir 300 mg	30	77.76
Darunavir 400 mg	60	113.13
Darunavir 600 mg	60	111.13
Darunavir 800 mg	30	106.70
Didanosine 125 mg	30	27.09
Didanosine 400 mg	30	31.06
Didanosine powder for ingestion, 2 g	1	15.75
Dolutegravir 50 mg	30	156.29
Zidovudine 100 mg	100	3.96
Zidovudine 300 mg	60	7.02
Zidovudine solution 200 mL	1	8.00
Zidovudine solution for injection, 20 mL	5	29.64
Lamivudine 150 mg	60	1.81
Lamivudine 300 mg	30	1.78
Lamivudine solution 240 mL	1	19.10
Lamivudine/Zidovudine 150/300 mg	60	4.06
Lopinavir/Ritonavir 100/25 mg	60	54.24
Lopinavir/Ritonavir 200+50 mg	120	73.03
Lopinavir/Ritonavir 80/20 mg, solution 60 mL	5	114.65
Maraviroc 150 mg	60	176.97
Maraviroc 300 mg	60	321.63
Nevirapine 200 mg	60	5.33
Nevirapine suspension 240 mL	1	11.49
Raltegravir 400 mg	60	439.71
Raltegravir chewable tablet 100 mg	60	123.57
Raltegravir chewable tablet 25 mg	60	30.89
Rilpivirine 25 mg	30	433.45
Ritonavir 100 mg	60	33.46
Saquinavir 500 mg	120	143.89
Stavudin 30 mg	56	14.98
Stavudin powder 260 mL	1	11.12
Tenofovir 150 mg	60	5.57
Tenofovir 300 mg	30	4.59
Tenofovir/Emtricitabine 300+200 mg	30	187.83
Fosamprenavir 700 mg	60	165.08
Fosamprenavir suspension 225 mL	1	44.62
Phosphazide 200 mg	30	17.21
Phosphazide 400 mg	60	34.12
Elsulfavirine 20 mg	30	120.76
Emtricitabine 200 mg	30	25.80
Emtricitabine/Rilpivirine/Tenofovir 200/25/300	30	420.64
Etravirine 200 mg	60	276.15
Efavirenz 100 mg	100	6.01
Efavirenz 200 mg	90	10.82
Efavirenz 400 mg	30	7.19
Efavirenz 600 mg	30	10.52
Efavirenz/Tenofovir/Emtricitabine 600/300/200	30	265.86
Efavirenz/Tenofovir/Emtricitabine 600/300/200 (set)	30	157.92



## APPENDIX 2. RECOMMENDED TREATMENT REGIMENS IN RUSSIA

	Preferred 1-line ART	Alternative 1-line ART	Special cases of 1-line ART	Preferred 2-line ART	Alternative 2-line ART	3-line ART
<b>NNRTI</b>	Efavirenz	Nevirapine Elsulfavirine Efavirenz	Rilpivirine Etravirine	Nevirapine Efavirenz	Etravirine	Nevirapine
<b>PI</b>			Atazanavir Ritonavir	Atazanavir Darunavir Ritonavir	Atazanavir Darunavir Ritonavir Saquinavir Fosamprenavir	Darunavir Ritonavir
<b>II</b>		Dolutegravir	Raltegravir	Dolutegravir	Raltegravir	Dolutegravir Raltegravir
<b>CCR5</b>						Maraviroc
<b>NRTI</b>	Lamivudine Tenofovir Emtricitabine	Abacavir Zidovudine Lamivudine Tenofovir Phosphazide Emtricitabine	Abacavir Didanosine Zidovudine Lamivudine Tenofovir Phosphazide Emtricitabine	Abacavir Zidovudine Lamivudine Tenofovir Emtricitabine	Abacavir Didanosine Zidovudine Lamivudine Phosphazide	Abacavir Zidovudine Lamivudine Tenofovir Emtricitabine
<b>Combinations</b>	Tenofovir+ Emtricitabine	Abacavir+ Lamivudine Zidovudine+ Lamivudine Tenofovir+ Emtricitabine	Abacavir+ Lamivudine Zidovudine+ Lamivudine Lopinavir+ Ritonavir Rilpivirine+ Tenofovir+ Emtricitabine Tenofovir+ Emtricitabine	Abacavir+ Lamivudine Zidovudine+ Lamivudine Lopinavir+ Ritonavir Tenofovir+ Emtricitabine	Abacavir+ Lamivudine Zidovudine+ Lamivudine Lopinavir+ Ritonavir Rilpivirine+ Tenofovir+ Emtricitabine	Abacavir+ Lamivudine Zidovudine+ Lamivudine Rilpivirine+ Tenofovir+ Emtricitabine Tenofovir+ Emtricitabine