
Analysis of ARV Procurement in the Russian Federation in 2021



AUTHORS AND ACKNOWLEDGEMENTS

N.V. Egorova

K.A. Babikhina.

S.E. Golovin

D.V. Soloviev

Yu.O. Vereshchagina

D.V. Godlevsky

A.V. Mikhailov

T.A. Khan

M.V. Shibaeva.

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LIST OF ABBREVIATIONS

ARV, ART, ARVD	antiretroviral drugs
BR	coreceptor blockers (inhibitors)
HIV	human immunodeficiency virus
VL	viral load
WHO	World Health Organization
CC RF	Civil Code of the Russian Federation
SRM	State Register of Medicines
PrEP	pre-exposure prophylaxis
EACS	European AIDS Clinical Society
IDs	infectious diseases
EML	Essential Medicines List
INI	integrase inhibitors
PI	protease inhibitors
MoH RF	Ministry of Health of the Russian Federation
INN	international nonproprietary name
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NNRTI2	Generation 2 Non-Nucleoside Reverse Transcriptase Inhibitor
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
Rospotrebnadzor	Russian Federal State Agency for Health and Consumer Rights
RF	Russian Federation
CIS	Commonwealth of Independent States
AIDS	Acquired Human Immunodeficiency Syndrome
USA	United States of America
TN	trade name
FBIS	Federal Budgetary Institution of Science
FL	Federal Law
FDC	fixed dose combination
FSI FSPOMPC	Federal State Institution Federal Center for Planning and Organization of Medicine Provision for Citizens
FPSR	Federal Penitentiary Service of Russia
AIDS Center	Center for AIDS and Infectious Diseases

KEY FINDINGS

1. The volume of antiretroviral drugs procured in 2021 could potentially cover **391,070** people living with HIV¹. This covers about **49 %** of the number of people registered for HIV care in 2021 (i. e. 15 % less than in 2020) and about **34.4 %** of all registered people with HIV infection (i. e. an 11 % decrease over one year). Decreasing rates of ARV therapy coverage points at the need for a set of measures to come closer to achieving the goals of the State Strategy on fighting the spread of HIV infection in the Russian Federation for the period until 2030. Proposed measures are listed in the recommendations.
2. According to official data, the number of people on antiretroviral therapy at the end of 2021 was 660,821 (which is 55,822 more than in 2020). The difference between the official and estimated numbers can be explained by the fact that the official statistics include patients who started therapy and then stopped for one reason or another, patients who started therapy at the **end** of 2021, and children, who were only partially included in the analysis. According to official data, treatment coverage in 2021 was 82.2 % of those on follow-up and 58 % of those living with the diagnosis of HIV infection. Undetectable viral load was achieved in 527,705 people (79.9 % of those on ART and 46.4 % of those living with HIV).
3. The negative trend of recent years persists, when the number of newly diagnosed people with HIV infection in Russia annually exceeds the number of people who started ARV therapy. According to official data, in 2021 in the Russian Federation **71,019 new cases of HIV infection** were detected for the first time, while only 55,822 people started ARV therapy for the first time.
4. The total cost of all ARV procurements in the Russian Federation in 2021 amounted to **31 billion 699 million 986 thousand 865 rubles (\$430,238,692)**. **Of this amount, 27.83 billion rubles (\$378 million)** is the total amount of centralized procurement by the Ministry of Healthcare of the Russian Federation. Despite the formal increase of the centralized procurement budget by 2.88 billion rubles (+11 %), in fact it increased by only 1.53 billion rubles (+6.1 %), because 1.36 billion was spent on procurements for the Federal Penitentiary Service of Russia (hereinafter referred to as FPSR), which in 2020 was not included in the total amount of the MoH procurement.
5. The total number of **regional** contracts for ARV procurement in 2021 was 3,715,808,553.90 rubles (\$50,431,712). Compared to the previous year, the amount decreased slightly (in 2020, the amount was 3.77 billion).
6. In 2021 the auctions for supply of ARV drugs were held in 62 regions of Russia. 72.2 % of the total amount accounted for three regions: Moscow (39 %), the Moscow Region (19.7 %) and St. Petersburg (10 %). Only 21 regions conducted procurements for a total amount of over 10 million rubles. In 14 regions the total amount of procurements did not exceed 1 million rubles. 23 constituent territories of the Russian Federation have not made any procurements since centralization. This fact can indicate a lack of funds at the regional level or a lack of political will to spend the available funds on procuring ARV drugs.
7. In 2021, most of the consolidated budget for ARVs, i. e. 77 % of the funds or 24.43 billion rubles (\$332 million), was spent on five drugs, namely dolutegravir, emtricitabine/rilpivirine/tenofovir, raltegravir, lopinavir/ritonavir, and etravirine.

For the first time, the federal procurement agency (hereinafter referred to as FSI FSPOMPC) signed three-year contracts for the supply of dolutegravir, raltegravir, and etravirine. Due to this, it was possible to increase the volume of procurements and reduce prices.

¹ According to the methodology of this report.

A record 7.14 billion rubles (\$97 million) was spent on dolutegravir, which is 15 % more than in 2020.

Rilpivirine/tenofovir/emtricitabine (Eviplera), with 5.51 billion rubles (\$74,795,094) spent, is on the second place in expenses. This is an increase of 29 % from the amount spent in 2020. The expenses on this drug increased by 133 % over three years at virtually the same price.

5.28 billion rubles (\$71.68 million) was spent on raltegravir, i. e. a 15 % increase and 680 million rubles (about \$8 million) more than in 2020 (4.6 billion rubles or \$63.8 million).

If we look at the ratio "budget to number of patients per year, ppy" in the 2021 MoH procurements, only three drugs have a bigger share of the spent budget than the total number of ppy, that is raltegravir, rilpivirine/tenofovir/emtricitabine and etravirine. 41.5 % (11.72 billion/159 million rubles) of the total ARV budget was spent on them, but the estimated share of patients receiving regimens with them is only 14.9 %.

8. Along with the drugs that traditionally lead in expenses, in 2021 elsulfavirine was in 7th place with an amount of 1.32 billion rubles (\$18 million). In 2019, this amount was only 428 million rubles; in 2021 the budget for elsulfavirine tripled against the background of the overall decline in the volume of the so called 'third choice drugs' (-23 %), it is one of the few exceptions (+56 %). Elsulfavirine is used exclusively in Russia and, accordingly, is not in the international recommendations. Despite a 56 % increase in volume, its price did not decrease and was 218.17 rubles (\$2.96) per tablet. The ppy cost of elsulfavirine is 79,628 rubles (\$1,080.7).

9. For the first time, dolutegravir became the leader in terms of ppy volumes, being slightly ahead of efavirenz, which was traditionally procured in the largest volumes. In 2019, efavirenz accounted for 46 % of total 'anchor drugs', 41 % in 2020, and about 20 % in 2021. There can be two reasons for this decrease: MoH RF is really implementing a strategy to switch from efavirenz to dolutegravir, or a number of constituent entities of the Russian Federation have a significant amount of unused efavirenz, and the Ministry is taking these carryover balances into account.

The amount of dolutegravir increased by 34% compared to 2020 (+24,000 annual courses), and its share of the 'anchor drug' group increased by 10%, i.e. up to 24%. Efavirenz decreased by 60% (-138.2 thousand annual courses). Its share among all drugs decreased by 22%, but it is still one of the most procured options. The difference in the sum of procurements of efavirenz in 2020 and 2021 was minus 737.77 million rubles.

10. A number of constituent entities of the Russian Federation procured even less ritonavir than in 2020, and in several regions, there were no procurements at all. In this regard, in 2021 there were reports from the regions about the absence of ritonavir, which was the result of two years' reduction in volumes. The budget of the FPSR decreased by 708 million rubles (\$9,609,120); as a consequence, the number of annual courses procured also decreased. The difference was 23,400. It is clear from the procurements that funds were reallocated to cheaper drugs, while more expensive ones were rejected.
11. Lopinavir/ritonavir contracts for 26,837 annual courses were made for the 2022 budget in late 2021 to avoid shortages. These contracts were to be delivered in late 2021 to early 2022. These contracts were considered as the procurements of 2022.
12. The total volume of 'anchor drugs' in 2021 decreased mainly due to a reduction in the volume of efavirenz. The overall increase did not happen, even despite the multi-year contracts and reduction of prices for a number of items.
13. In 2021, the volume of lamivudine decreased; probably because of the carryover from 2020.

In 2021, the procured volume of lamivudine and emtricitabine (calculated as the number of patients per year) was 175,283 (-71 % by 2020) and 22,906 (+52 % vs 2020), respectively, the total number being 198,189.

Despite the fact that emtricitabine is listed as a preferred option in the clinical guidelines, and despite the inclusion of the drug in the Essential Medicines List (EML), its volume remains small. At the same time, the volume has been steadily increasing over the past few years.

The volume of other NRTIs (abacavir, zidovudine, tenofovir, phosphazide) amounted to **335,748 ppy**, which is also significantly less than in 2020 (–46.5 %).

The decrease in the volume of NRTIs may indicate more frequent use of reduced regimens (bi-therapy) that use only one NRTI, i. e. lamivudine (INI + lamivudine, PI/ritonavir + lamivudine).

14. The price of dolutegravir in 2021 decreased by 14 % to 204.82 rubles (in 2020 the price per tablet was 238.04 rubles (\$3.23). Correspondingly, the ppy cost decreased from 86,885 rubles to 74,759 rubles (\$1,015) per patient per year.

The price of raltegravir 400 mg tablet decreased from 459.43 rubles to 307.82 rubles (–33 %). The cost per patient per year dropped from 335,384 (\$4,551.9) to 224,709 rubles (\$3,049), but the drug still remained one of the most expensive. It should be taken into account that modern combination drugs were included in the EML for 2022, after which their price dropped significantly (Fig. 13). Thus, since the price of raltegravir is fixed in the contract for three years, raltegravir in 2022 should take second place in the list of the most expensive ARVs after Eviplera, which, unlike raltegravir, is a complete one-pill regimen.

15. In 2021, the volume of FDC drugs increased compared to 2020. The entire regimen in one pill became available to 5.5 % of patients compared to 2.7 % in 2020.
16. The biggest increase compared to 2020 was for the combination of rilpivirine/tenofovir/emtricitabine (Eviplera). The number of patients who could receive this drug was 17,878 (13,241 in 2020). The volume of procurements of this drug has increased by 143 % since 2019. The combined procured volume of Biktarvy, Delstrigo, and Genvoya FDCs increased more than 10-fold, from 310 ppy in 2020 to 3,440 ppy 2021. At the same time, costs for these drugs also increased, from 14 % in 2020 to 20.02 % in 2021.
17. The cost of rilpivirine/tenofovir/emtricitabine FDC (Eviplera TN) decreased by only 5 %. In 2020 a tablet cost 879 rubles (\$11.92), in 2021 it was ... rubles (\$11.33). The ppy cost dropped from 320,000 rubles to 305,000 rubles (\$4136.38). The patent for this combination is valid till 2027, and Janssen company in a dialogue with the representatives of public organizations stated that 'further reduction on one local market (Russian; editor's note) is not planned'. In this regard, a possible forecast for Eviplera may look as follows: given the refusal to reduce the price, the long-term patent and the availability of more modern combination drugs in the EML at significantly lower prices, the share of Eviplera from 2022 is likely to begin to decline if the patent holder's pricing policy does not change.

18. Below most often used regimens are shown (according to public procurement data):

lamivudine 300 mg + tenofovir 300 mg + efavirenz 600 mg;

lamivudine 300 mg + tenofovir 300 mg + dolutegravir 50 mg.

The cost of the first-line regimens ranged from 11,000 rubles to almost 90,000 rubles (from \$149 to \$1,221.5), depending on the 'anchor drug' in the regimen. The most expensive drugs in first-line regimens are dolutegravir and elvitegravir. The cheapest first-line regimens include efavirenz, and the dosage (600 or 400 mg) did not affect the cost.

19. The cost of the main second-line regimens ranges from 25 thousand rubles to 305 thousand rubles (\$345 to \$4,136). The most affordable regimens include atazanavir (25–33 thousand rubles per year). Regimens with lopinavir/ritonavir are 60–70 thousand rubles per year (from \$814 to \$950).

The most expensive 'anchor drugs' in second-line regimens are etravirine, raltegravir, and emtricitabine/rilpivirine/tenofovir. Costs range from 153,000 to 305,000 rubles, respectively (\$2076.5 to \$4139.5).

The most popular reduced regimen is dolutegravir + lamivudine. Its cost is 78 thousand rubles (\$1,058).

The most expensive regimen in 2021 is bictegravir/tenofovir alafenamide/emtricitabine (Biktarvy) in one tablet with administration once a day. Its cost is 389,287.10 rubles per patient per year (\$5,283.48) (at the weighted average price).

20. The share of original drugs in the total amount of contracts concluded by the FSI FSPOMPC was 78.76 % (21.9 billion rubles), the share of generic drugs was 21.24 % (5.9 billion rubles). In the segment of 'anchor drugs', original drugs accounted for 85 % of all contracts. If counted by the number of patients per year, the share of original drugs is 53 %. The share of originals increased compared to 2020 from 27 % to 47 % due to an increase in dolutegravir. Thus, an **impressive part of the centralized procurement budget (85 %) is spent on originals, which have no analogues. At the same time, based on the number of ppy, these original drugs account for only 53 % of all 'anchor drugs'.** The main share of spending on 'anchor drugs' is on INI and NNRTI2, with NNRTI2 being used to a much smaller extent than PI.
21. In 2021, almost 89 % of the auctions of FSI FSPOMPC were held without competition, and the contracts were concluded at the initial maximum price. In monetary terms, ≈ 96 % of the funds were spent on bidding without competition (26.67 billion rubles). In recent years, the leader in terms of concluded contracts and the amount of funds has been R-Pharm JSC.
22. From 01.01.2021 to 31.12.2021, 365 messages were received on the website pereboi.ru, 230 of them about stock-outs of ARV drugs and diagnostic equipment from 42 regions of the Russian Federation, 2 institutions of FPSR and 3 institutions of the Federal Medical and Biological Agency. The volume reduction in 2021 caused disruptions in the beginning of 2022, as procurements for 2022 are announced only in February, while supplies take place in April or May. During the first quarter of 2022, there were 82 messages about stock-outs of ARV drugs and diagnostic tools, including 65 reports of shortages of ARVs from 21 regions, 8 FPSR institutions and one FMBA institution.

RECOMMENDATIONS

From our point of view, these recommendations, repeating those of 2021, are still relevant. With the rapidly changing legislation and the financial and economic situation in the Russian Federation, an assessment of the situation with further drug provision after the situation has stabilized will be required, but the strategic directions remain the same. Further work in the field of drug provision for patients living with HIV in Russia should serve three goals:

1. Increase ARV coverage to the target of 95 % of people on ARV therapy of the estimated number.
2. Optimization of the nomenclature of procured drugs taking into account the most up-to-date scientific evidence.
3. Implementation of a set of measures to control the quality of procured ARV drugs.

To achieve our goals, we believe it is important to focus on the following five steps.

Given the 2021 procurement and early 2022 trends, the key recommendation is to increase the budget.

1. It is necessary to increase the budget for ARV procurement by at least 1.5 times (according to some estimates, up to 60 billion rubles), without compromising budget items for diagnostics, prevention and other components of the HIV response. In addition, we believe it is necessary to separate the budgets for hepatitis C and HIV infections in Decree No. 1512 allocating specific amounts for each disease.
2. Reduction of prices for patented drugs. This can be achieved by the following algorithm of actions:
 - A. Price-volume negotiations with patent holders, providing long-term commitments, preferences, etc. Further negotiations with manufacturers of patented drugs (primarily dolutegravir, bictegravir, doravirine, rilpivirine) on the price/volume principle under multi-year contracts to increase therapy coverage.
 - B. Negotiations to obtain non-exclusive voluntary licenses or voluntary licenses that imply a significant price reduction.
 - C. If the first two strategies fail, measures should be taken to remove patent barriers, including government use of inventions in the public health interest without the consent of the patent holder (compulsory licensing).
3. Harmonization of current clinical guidelines and treatment standards with the most modern world practices using evidence-based approach. This should primarily include the following:
 - A. Widespread introduction of dolutegravir.²
 - B. Replacement of efavirenz 600 mg with efavirenz 400 mg in alternative first-line regimens.
 - C. Maximum use of combination drugs forms.
 - D. Evaluating appropriateness of using drugs that are not included in the international guidelines and drugs whose efficacy and safety have not been confirmed by multicenter randomized clinical trials in thousands of patients.

² If the international guidelines change from dolutegravir to another drug that is recommended by the international community as a first-line essential drug product, the recommendations should be revised accordingly in a timely manner.

4. Control of the ARV dispensing system through the following steps:
 - A. Taking measures to improve maintenance and use of the federal registry of people living with HIV.
 - B. Increasing control and building up the system of uninterrupted ARV supply.
 - C. Upgrading the existing system of pharmacovigilance to simplify data collection from the patient community.
5. Optimization of the registration and procurement chain of drug products from manufacturer to patient.

Set of measures to be taken:

- A. Simplifying the drug registration process, including the option of registering drugs based on data from international randomized clinical trials without conducting trials in the Russian Federation. As an additional control measure, there could be a requirement to have a World Health Organization prequalification certificate.
- B. Expanding the 'odd-one-out' mechanism by including the BRICS countries (in particular, Brazil, China, India, South Africa) in the list of countries whose companies can receive preferences under this mechanism.
- C. Developing and introducing a flexible mechanism for the procurement of unregistered drugs of confirmed quality, defining a list of situations in which such a mechanism can be applied.
- D. Developing 'flexible provisions' of FZ-44 (Federal Law on Procurement) for procuring medicines for the benefit of public health, with a focus on establishing simplified drug procurement procedures, including at the regional level.

EPIDEMIOLOGY

According to official data³, as of December 31, 2021 the cumulative number of registered cases of HIV infection among citizens of the Russian Federation was 1,562,570. By the end of 2021, there were 1,137,596 Russians with laboratory-confirmed HIV diagnoses, excluding 424,974 patients who died during the entire period of observation (27.2 %).

According to preliminary data, 71,019 new cases of HIV infection were reported in the Russian Federation in 2021, which is 1.4 % less than in 2020.

In 2021, there were 34,093 reported deaths of people with HIV infection, i. e. 5.9 % more than in 2020.

In 2021, 803,796 Russians with HIV infection were registered for HIV dispensary care, representing 68.6 % of those living with a diagnosis of HIV infection during this period.

In 2021, 660,821 people in Russia were receiving antiviral therapy (including 58,105 prisoners).

The treatment coverage in 2021 was 58 % of the number of people diagnosed with HIV-infection, and 82.2 % of the number of people registered for outpatient treatment.

By the end of December 2021, 527,705 patients had a suppressed viral load, representing 79.9 % of those receiving ART in 2021.

The number of new cases of HIV transmission via heterosexual contacts is increasing (67.8 %). The share of people infected with HIV through drug use has decreased to 27.8 %. 3 % of people were infected through homosexual contacts.

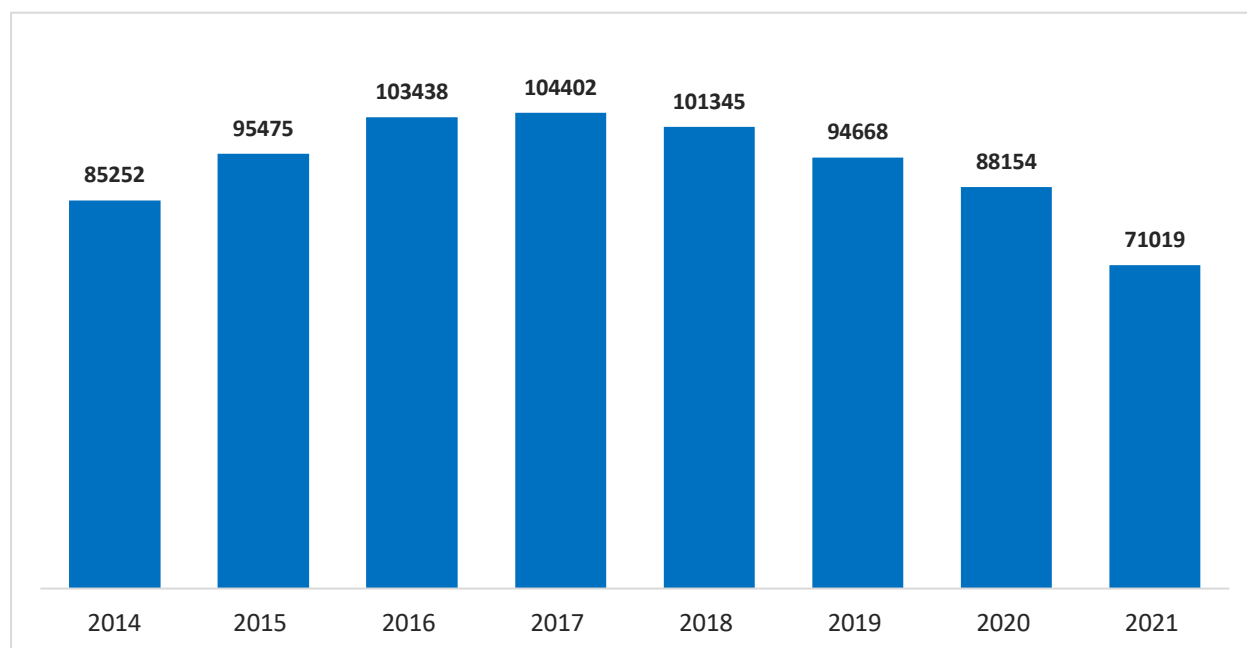


Figure 1. New HIV cases in 2014–2021 according to official data from the Federal AIDS Center

³ Here and below the data is taken from the report 'HIV-infection in the Russian Federation as of December 31, 2021' of Federal Scientific and Methodological Center for AIDS Prevention and Control Federal State-Funded Scientific Institution Central Research Institute of Epidemiology, Rospotrebnadzor, <http://www.hivrussia.info/wp-content/uploads/2022/03/Spravka-VICH-v-Rossii-na-31.12.2021-g..pdf>

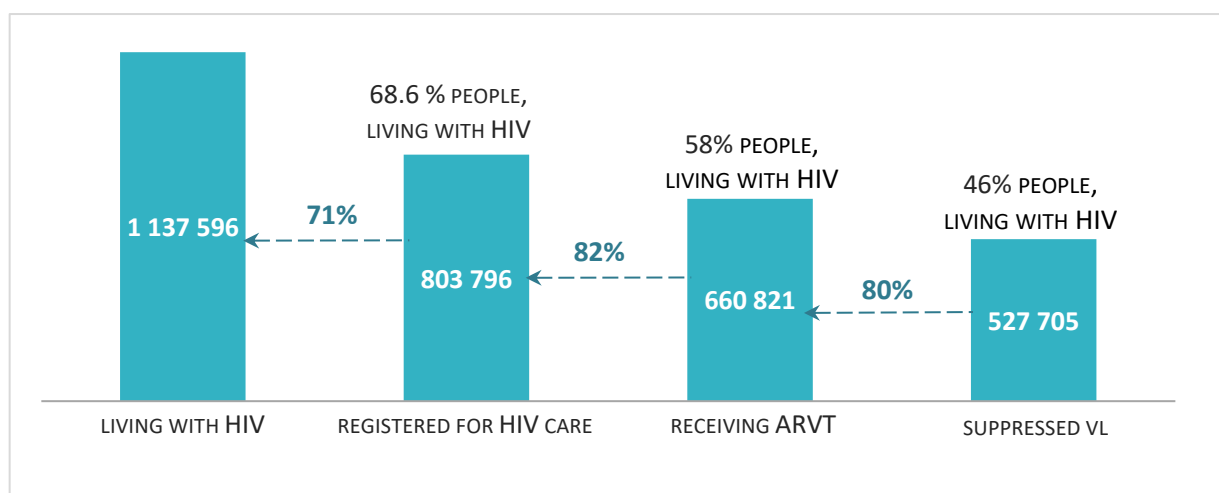


Figure 2. Treatment cascade in Russia in 2021, based on official data from the Federal AIDS Center

THE SIZE AND STRUCTURE OF ARV DRUG PROCUREMENT IN RUSSIA IN 2021

ARV drugs budget

The total amount of all procurements in 2021 was **31,699,986,865 rubles** (\$430,238,692) of which: **27,832,705,644 rubles (\$377,751,162)** was the total amount of FSI FSPOMPC contracts in centralized procurements (including procurements for FPSR);

3,715,808,554 rubles (\$50,431,712) was the total amount of all procurements at the level of constituent entities of the Russian Federation;

151,472,667 rubles (\$2,055,818) was the total amount of procurements by federal state medical institutions (FSI) under the MoH RF;

Compared to 2020, the amount of centralized procurements by the MoH RF (FGI) **increased by 2,884,284,700.80 rubles (+11.6 %)** in 2021.

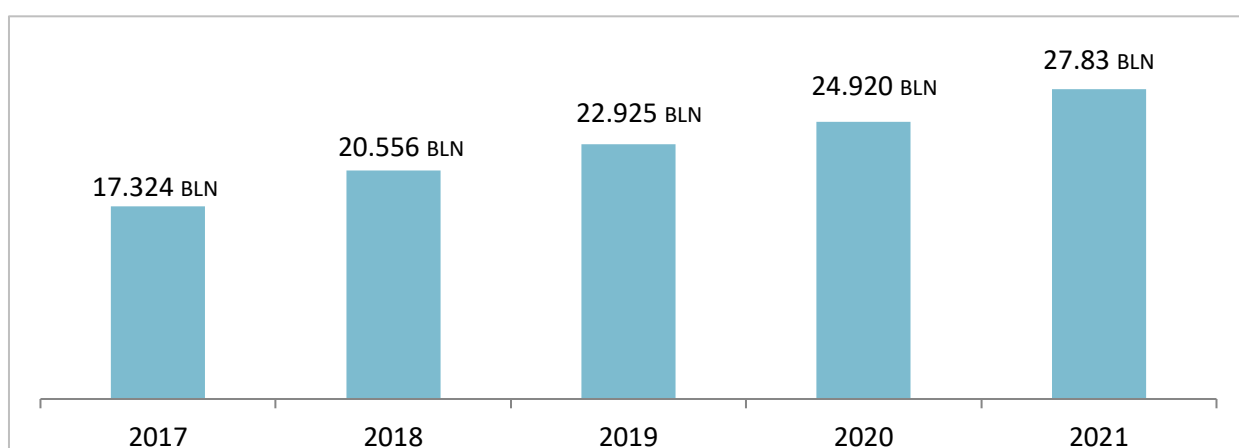


Figure 3. Budget for ARV drugs of MoH RF by year (in billions of rubles)

The increase in the centralized procurement budget is explained not only by additional funding, but also by the fact that the authority to procure ARVs for the Federal Penitentiary Service of Russia (FPSR) in 2021 was returned to MoH RF again. In 2020, the total amount of procurements by FPSR (independent procurements) was 2,066,131,586 rubles, in 2021 it was 1,358,230,295 rubles. However, if the amount of the budget was shown in dollars⁴, due to the fall of the ruble in 2021, the amount remained virtually unchanged, i. e. \$378 million in 2020 and in 2021.

Thus, despite the apparent increase of the centralized procurement budget by 2.88 billion rubles (+11 %), the total budget for centralized ARV procurement in 2021 increased by only 1.53 billion rubles (+6.1 % in total), since 1.36 billion was spent on procurement for FPSR, which was not included in the total amount of the MoH RF procurement in 2020.

⁴ See archived dollar rate at: <https://myfin.by/currency/cb-rf-archive/usd>

ARV procurement structure in 2021 by expenditures

In 2021 most of the total budget for ARVs was spent on the procurement of five drugs, i. e. 77.08 % of funds (24.43 billion rubles).

Table 1. Costs by amount of procurements for all signed contracts 2021 (MoH RF + constituent entities of RF)

INN*	Amount of contracts, in USD	Share of all procurements
Dolutegravir	\$96,858,074.20	22.51 %
Emtricitabine/rilpivirine/tenofovir	\$74,795,093.83	17.38 %
Raltegravir	\$71,685,178.10	16.66 %
Lopinavir/ritonavir	\$49,158,668.52	11.43 %
Etravirine	\$39,170,824.66	9.10 %
Other drug products	\$98,570,853.21	22.92 %
Total	\$430,238,692.52	100 %

*INN in all dosages

It should be noted that the MoH RF signed three-year contracts for the ARV drugs dolutegravir, raltegravir, and etravirine for the first time. Due to this, it was possible to increase the volume of procurements of these drugs and reduce the prices.

The leader in monetary terms was again dolutegravir; in 2021 it cost a record 7.14 billion rubles, which is 940 million rubles more than in 2020 (+15 %).

Rilpivirine/tenofovir/emtricitabine (Eviplera) came in second place in terms of expenses with the amount of 5.51 billion rubles, which is 1.25 billion rubles more than in 2021 (+29 %). Spending on Eviplera in 2019 amounted to 2.37 billion rubles. Thus, over three years the costs increased by 133 % with the price virtually unchanged (see section Cost of ARV drugs). As in the previous two years, Eviplera was in the first place in spending in the constituent entities of the Russian Federation with 1.35 billion rubles (33 % of the total regional ARV procurements).

5.28 billion rubles was spent on raltegravir, which is 15 % and 680 million rubles more than in 2020 (4.6 billion rubles).

The amount of contracts for etravirine increased from 2.49 billion rubles to 2.8 billion rubles (+16 % compared to 2020).

Along with the drugs that traditionally lead in terms of costs, in 2021 elvitegravir was in the seventh place with an amount of 1.32 billion rubles. In 2019, this amount was only 428 million rubles, and the budget growth for elvitegravir over three years was 208.2 %.

Distribution of the budget for different groups of drugs

The analysis was performed by the following groups: 1) NNRTI drugs, 2) 'anchor drugs' including NNRTIs, PIs, INIs, CCR5 inhibitors and fusion inhibitors, 3) 'one-pill regimen' drugs, and 4) ritonavir.

The distribution of money in the total amount of ARV drug procurements was as follows:

Table 2. Share of drugs in the total amount of all procurements by type of ARV in 2021.

Type of drug	Contract amount in rubles	Share of the contract amount
Anchor drug	\$309,460,459.87	71.93 %
One-pill regimen	\$86,133,973.42	20.02 %
NRTI	\$27,310,157.35	6.35 %
Ritonavir	\$7,334,101.88	1.70 %
Total	\$430,238,692.52	100 %

The share spent on the procurement of 'anchor drugs' (~72 % of the total amount) has remained virtually unchanged in recent years, despite the redistribution of costs between INNs within the group. The amount of NIOT procurement has decreased from 14 % in 2020 to 6.35 % in 2021.

The growth of costs of 'one-pill regimen' drugs is worth noting: it rose from 14 % in 2020 to 20.02 % in 2021. Since 2019 the share of combined 'one-pill regimen' drugs in the total cost structure increased almost 3-fold.

In the 'anchor drug' group, the monetary share of INI increased from 35 % to 41.3 % and from 25 % to 31.3 % in the NNIOT2 group against 2020. The share of PI decreased slightly, from 20 % to 17.7 %. The amount of NNIOT procurements decreased significantly: from 13 % to 1.62 %.

The complete list of drugs and contract amounts are shown in Appendix 3.

Table 3: Share of drugs in the total amount of all procurements by group, 2021

Class of drug	Contract amount in rubles	Share of the contract amount, %
INI: raltegravir, dolutegravir, bictegravir*, elvitegravir*	\$177,730,881.68	41.31 %
NNRTI2: etravirine, elvitegravir, rilpivirine**, doravirine*	\$134,654,445.28	31.3 %
PI: darunavir, atazanavir, lopinavir/ritonavir, saquinavir, fosamprenavir	\$76,128,261.55	17.69 %
NNRTI: efavirenz, nevirapine	\$6,981,289.93	1.62 %
BR: maraviroc	\$99,554.86	0.02 %
NRTI: abacavir, lamivudine, tenofovir, zidovudine, phosphazide, emtricitabine	\$27,310,157.35	6.35 %
Ritonavir	\$7,334,101.88	1.7 %
Total	\$430,238,692.52	100 %

* in combination

** in combination and separately

The reallocation of funds between drug classes compared to 2020 is clearly shown in Table 6.

Procurement structure by ppy, class and type of drugs

NRTI drugs

According to international and Russian recommendations, lamivudine or emtricitabine should be present in the main NRTI combinations in almost all regimens. The number of NRTIs was calculated based on this condition.

In 2020, the procured volume of lamivudine amounted to 609,316 ppy (+34 % of 2019), which obviously exceeds the number of 'anchor drugs' which lamivudine must be taken in the same regimen with. Therefore, the volume of lamivudine in procurements has decreased in 2021. This is probably due to the 2020 lamivudine carryover.

In 2021, the procured volume of lamivudine and emtricitabine (calculated as the number of patients per year) was 175,283 (-71 % by 2020) and 22,906 (+52 % vs 2020), respectively, the total number being 198,189.

Despite the fact that clinical guidelines and standards recommend the use of emtricitabine in preferred regimens, and despite the inclusion of the drug in the EML, the number of emtricitabine in procurements remains small. At the same time, the volume of contracts has been steadily increasing in recent years.

The volume of other NRTIs (abacavir, zidovudine, tenofovir, phosphazide) amounted to **335,748** ppy, which is also significantly less than in 2020 (-46.5 %).

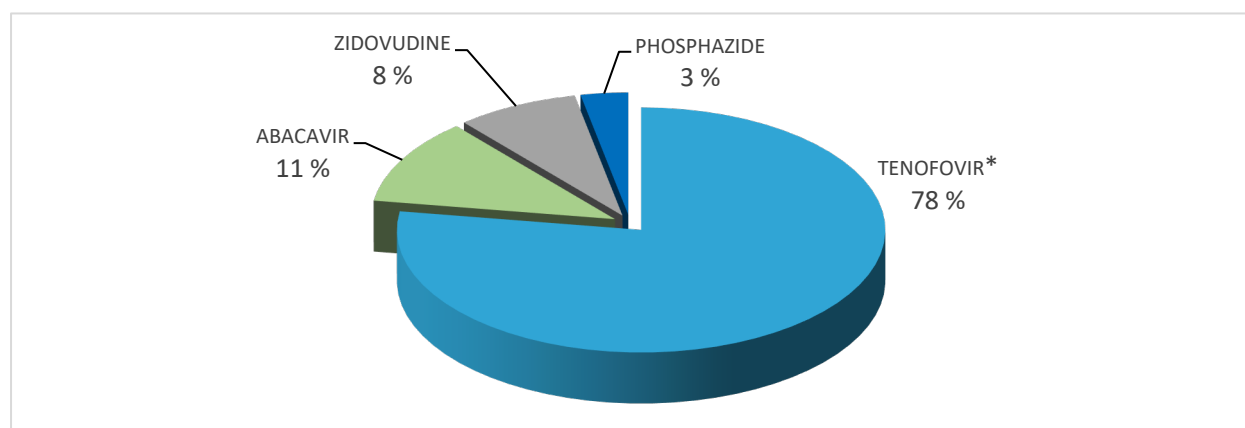
In 2021, most regimens potentially included two NRTIs (lamivudine and tenofovir) as separate drugs. According to the CR, only lamivudine is used in the dual regimens.

The volume of the other NRTIs, as well as lamivudine, has decreased.

Table 4: Procurement of NRTIs and the 2020–2021 dynamics

INN	Estimated number of patients taking the drug, 2020	Estimated number of patients taking the drug, 2021	Difference, ppy, 2020 vs 2021	Change in share within the group, 2021–2020	Difference, ppy, 2019 vs 2021
Tenofovir*	426,773	259,948	-166,825	9 %	-39 %
Abacavir	100,742	38,002	-62,740	-5 %	-62 %
Zidovudine	76,434	27,241	-49,193	-4 %	-64 %
Phosphazide	23,264	10,557	-12,707	-1 %	-55 %

*Including tenofovir alafenamide in combination therapies in 2021.



*Including tenofovir alafenamide in combination therapies in 2021

Figure 4: Distribution of INN in the NRTI group (excluding lamivudine and emtricitabine), 2021

The reduction in procurements of all NRTIs in 2021 can also be explained by a significant increase in the previous year (627,213 ppy).

Analysis of data for previous years showed that the ratio of 'anchor drugs' and NRTIs was relatively balanced until 2020 (based on the calculation that the scheme should include one 'anchor drug' and two NRTIs).

The graph (Figure 5) clearly shows the growth in procurements of lamivudine, emtricitabine and other NRTIs in 2020, as well as a comparison with the ppy volume of 'anchor drugs'. Following the dramatic rise, we can clearly see a decline in 2021, which should probably be compensated by the carryover from 2020.

Note: lamivudine (emtricitabine) and other NRTIs do not add up because treatment regimens should predominantly include two NRTIs, one of which is lamivudine or emtricitabine in the vast majority of cases.

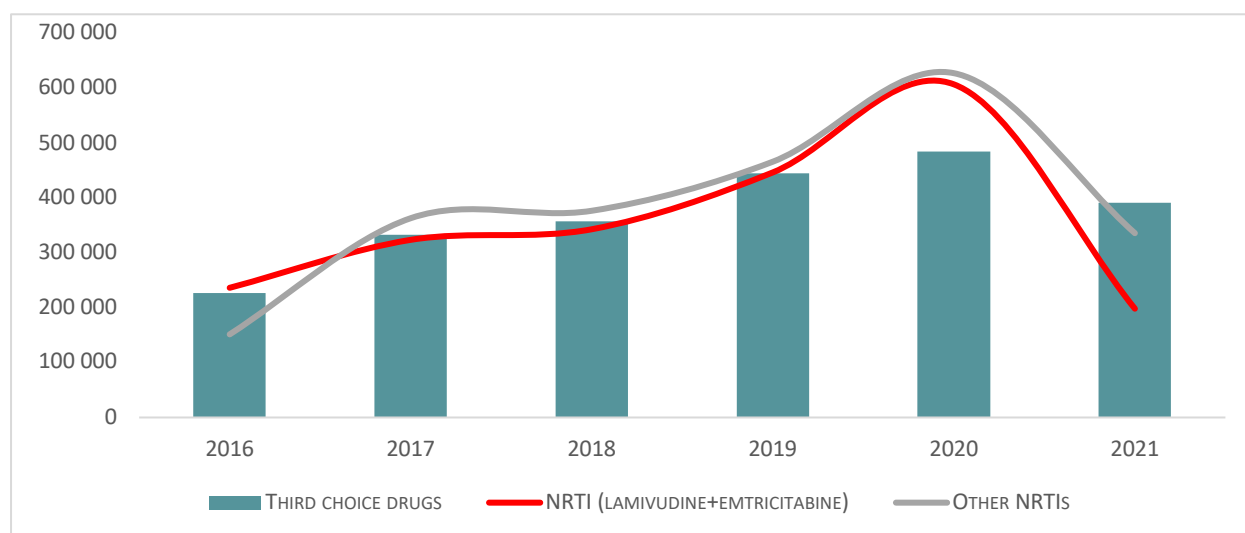


Figure 5. Ratio of the ppy number of lamivudine and emtricitabine, other NRTIs, and 'anchor drugs' by year.

The decrease in NRTI volumes may indicate more frequent use of reduced regimens when only one NRTI is used, namely lamivudine (INI + lamivudine, PI/ritonavir + lamivudine).

'Anchor drugs'

In 2021, the total procured volume of anchor drugs amounted to **391,070 ppy**⁵. Compared to 2020, the total number decreased by 114,121 (+23 %).

Dolutegravir was the leader in the number of courses for the first time, slightly ahead of efavirenz, which has traditionally been procured in the largest volumes. In 2019, efavirenz accounted for 46 % of total 'anchor drugs', in 2020 it was 41 %, and in 2021 it was only about 20 %. There could be two reasons for this decrease: MoH RF is reducing the priority of this drug by reducing the volume of procurements, or a number of constituent entities of RF have a significant amount of unused efavirenz, procured in previous years, which the Ministry accounts for as carryover balances.

Compared to 2020, the amount of dolutegravir increased by 34 % (+24,000 ppy), and its share in the group of 'anchor drugs' increased by 10 %, amounting to 24 %.

⁵ One-year course = the number of pills per day recommended in the instructions for use * 365 days.

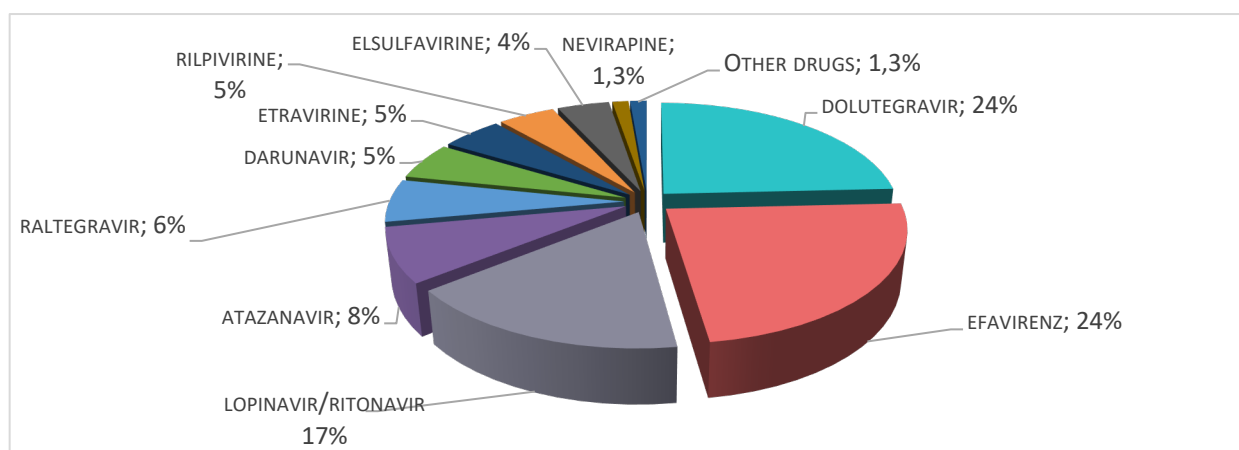


Figure 6. Procurement structure in the group of 'anchor drugs' (share by number of courses), 2021

Table 5. Dynamics of changes in the volume and share of 'anchor drugs' in procurements, 2020–2021

INN	Estimated number of patients taking the drug, 2020	Share by number of patients in 2020	Estimated number of patients taking the drug, 2021	Share by number of patients in 2021	Increase, 2020–2021	Change in the share within the group 2020–2021
Dolutegravir	70,847	14 %	94,766	24 %	34 %	10 %
Efavirenz	230,164	46 %	91,984	24 %	-60 %	-22 %
Lopinavir/ritonavir	66,070	13 %	64,695	17 %	-2 %	3 %
Atazanavir	48,542	10 %	30,544	8 %	-37 %	-2 %
Raltegravir	15,600	3 %	24,046	6 %	54 %	3 %
Darunavir	21,261	4 %	20,970	5 %	-1 %	1 %
Etravirine	11,741	2 %	19,277	5 %	64 %	3 %
Rilpivirine*	13,353	3 %	17,942	5 %	34 %	2 %
Elsulfavirine	10,588	2 %	16,487	4 %	56 %	2 %
Nevirapine	11,769	2 %	5,105	1 %	-57 %	-1 %
Elvitegravir*	215	0 %	2,367	1 %	-	1 %
Fosamprenavir	3,180	1 %	1,266	0,3 %	-60 %	-0,3 %
Doravirine*	196	0 %	595	0,2 %	204 %	0,1 %
Bictegravir	4	0 %	564	0,1 %	-	0,1 %
Saquinavir	1,582	0,3 %	427	0,1 %	-73 %	-0,2 %
Maraviroc	79	0 %	35	0,0 %	-56 %	0,0 %
Total	505,190	-	391,070	-	-23 %	-

* rilpivirine, doravirine, bictegravir, elvitegravir are included as 'anchor' components and within the combination drug

The volume of efavirenz decreased by 60 % (–138.2 thousand ppy). The share among all drugs decreased by 22 %, but efavirenz is still one of the most procured options. The difference in the amount of efavirenz procurements in 2020 and 2021 was minus 737,773,026.50 rubles.

The volume of lopinavir/ritonavir in procurements decreased by 2 % (–1,375 ppy). The drug is in third place by volume with 17 %. The new clinical guidelines list lopinavir/ritonavir as the drug of choice in special cases for patients who cannot be treated with the main preferred regimens and as an alternative drug in second-line regimens. However, at the moment, judging by the procurement pattern, the drug is being used more widely.

It is worth noting that at the end of 2021, in order to avoid a deficit, contracts for lopinavir/ritonavir were signed for 26,837 ppy for the 2022 budget. Distributors were supposed to supply the drugs in late 2021 or early 2022.

Against the background of a general decrease in the volume of ‘anchor drugs’ (–23 %), it is important to note a significant increase in the volume of elvitegravir in terms of estimated number of patients per year (+56 %).

The graph below (Fig. 7) shows how the size of procurements of ‘anchor drugs’ has changed. It can be concluded that the decrease in 2021 was mainly due to a decrease in procurements of efavirenz. At the same time it was not possible to increase the volume at the expense of other ‘anchor drugs’, even despite the conclusion of multi-year contracts and price reduction for a number of INNs.

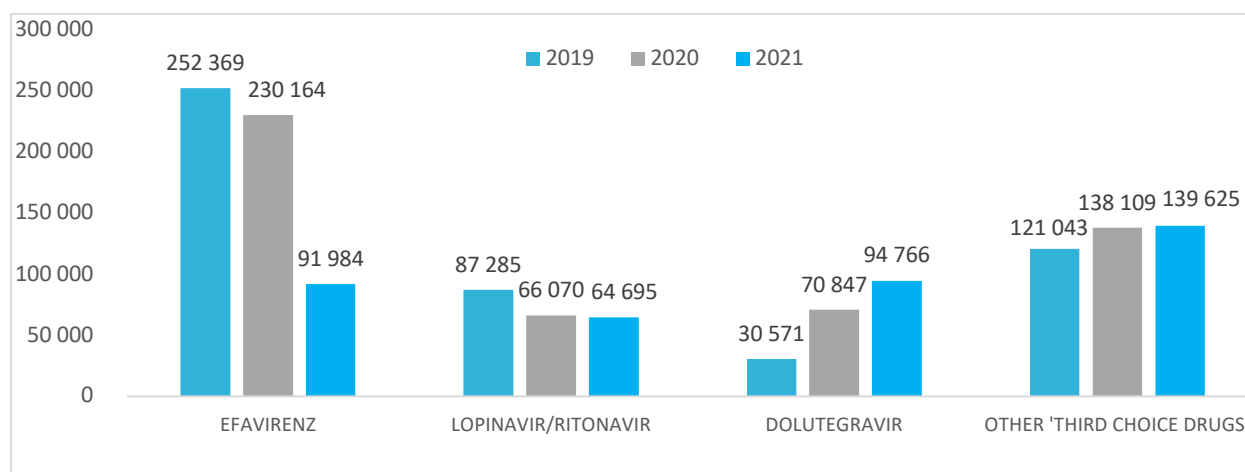


Figure 7. Changes in annual INN efavirenz; lopinavir/ritonavir; dolutegravir and other ‘anchor drugs’ for the period 2019–2021

Combination dosage forms

The new Russian Clinical Guidelines HIV Infections in Adults contain the following guidance: “It is recommended that physicians responsible for the supervision of HIV-infected patients, when prescribing first-line ART (starter ART), use less toxic and more convenient regimens in the form of fixed-dose combination therapies (FDCs)”.

In fact, access to drugs with FDC remains limited, despite the inclusion of a number of new combinations in the EML.

Table 6. Number of courses of combination drugs ‘one-pill regimen’ in the 2021 procurement

Drug name	Number of courses, 2020	Number of courses, 2021	Difference in courses, 2020 vs. 2021	Share in the group, 2021
Bictegravir/tenofovir alafenamide/emtricitabine	4	564	560	3 %
Doravirine/lamivudine/tenofovir disoproxil	92	509	417	2 %
Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine	215	2,367	2,152	11 %
Emtricitabine/rilpivirine/tenofovir disoproxil	13,241	17,878	4,636	84 %
Total	13,552	21,318	7,765	100 %

Compared to 2020, rilpivirine/tenofovir/emtricitabine under the trade name of Eviplera showed the largest increase in procurements. The number of people who could receive this drug was 17,878 compared to 13,241 in 2020. It should be noted that the volume of procurements of this drug has increased by 143 % since 2019. The volume of other FDC drugs also increased. The combined volume of procurements of Biktarvy, Delstrigo, and Genvoya increased more than 10-fold, from 310 courses in 2020 to 3,440 courses in 2021.

The share of patients who take combination drugs and/or one-pill regimen is still small.

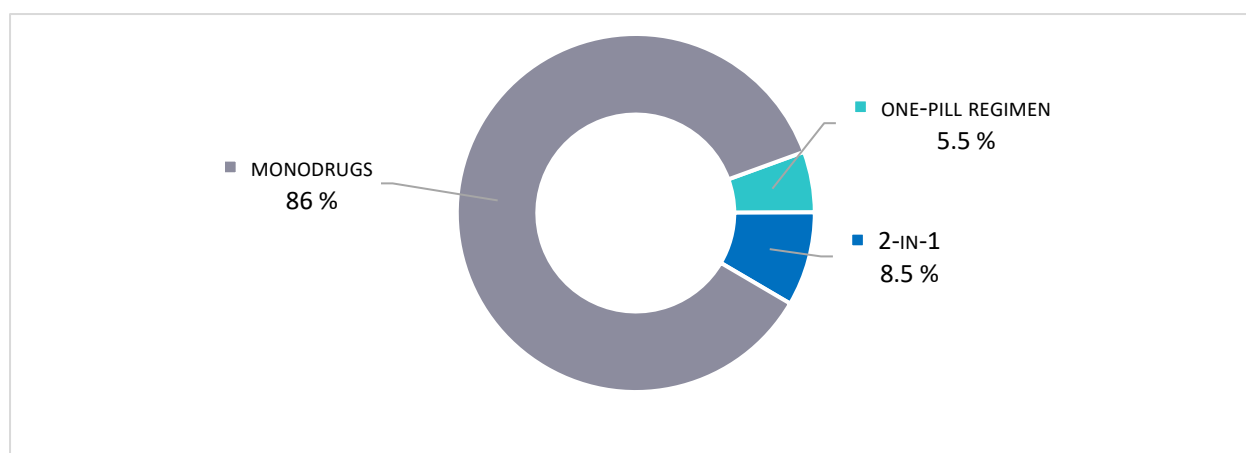


Figure 8. Share of FDC drugs in 2021

At the same time, compared to 2020, there was an increase in the number of courses of FDC drugs. One-pill regimens were available to 5.5 % of patients compared to 2.7 % in 2020.

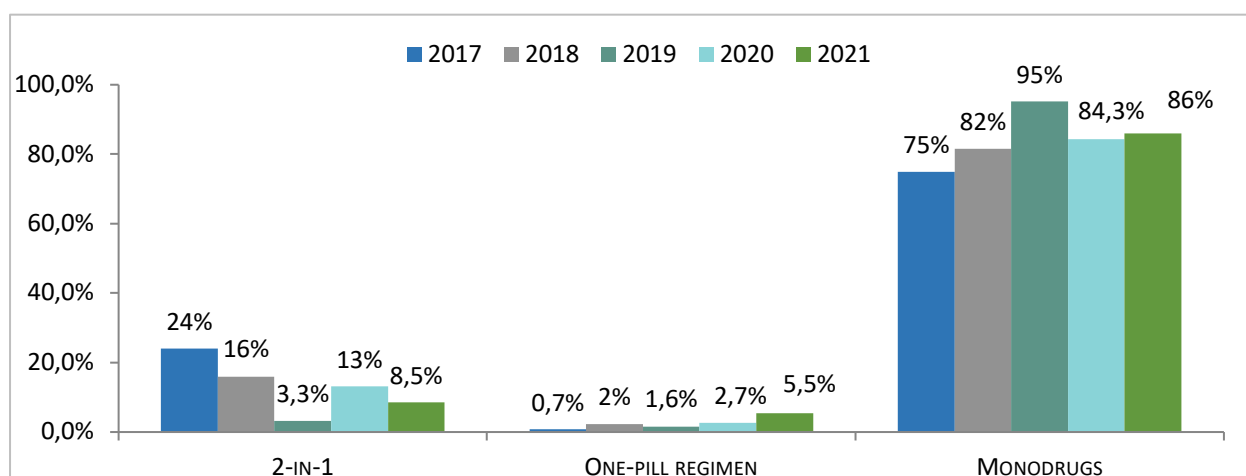


Figure 2. Ratio of the share of FDC drugs in the total estimated ppy volume in 2017–2021

THE COST OF ARV DRUGS IN 2021

‘Anchor drugs’

The table below shows the prices of 'anchor drugs' compared to 2020.

Table 7. Price dynamics of ‘anchor drugs’ in procurement of MoH RF (FSI FSPOMPC) in 2020–2021

INN and dosage	Type	Weighted average price per unit, \$, 2020	Weighted average price per unit, \$, 2021	Price difference, 2020–2021
Atazanavir 150 mg	PI	\$0.18	\$0.18	0 %
Atazanavir 200 mg	PI	\$0.23	\$0.23	0 %
Atazanavir 300 mg	PI	\$0.35	\$0.35	0 %
Darunavir 400 mg	PI	\$1.28	\$1.28	0 %
Darunavir 600 mg	PI	\$1.57	\$1.57	0 %
Darunavir 800 mg	PI	\$3.01	\$2.57	-14.8 %
Dolutegravir 50 mg	INI	\$3.23	\$2.78	-14 %
Cobicistat/tenofovir alafenamide / elvitegravir/emtricitabine	INI	-	\$7.12	-
Lopinavir/ritonavir 100/25 mg	PI	\$0.77	\$0.77	-0.4 %
Lopinavir/ritonavir 200/50 mg	PI	\$0.51	\$0.51	0 %
Lopinavir/ritonavir 200/50 mg	PI	\$0.51	\$0.51	0 %
Maraviroc 150 mg	BR	\$2.51	\$2.51	0 %
Maraviroc 300 mg	BR	\$4.56	\$4.56	0 %
Nevirapine 100 mg	NNRTI	\$0.08	\$0.08	0 %
Nevirapine 200 mg	NNRTI	\$0.08	\$0.07	-0.5 %
Raltegravir 400 mg	INI	\$6.24	\$4.18	-33 %
Saquinavir 500 mg	PI	\$0.89	\$0.89	0 %
Fosamprenavir 700 mg	PI	\$2.34	\$1.25	-46.5 %
Elsulfavirine 20 mg	NNRTI2	\$2.96	\$2.96	0 %
Emtricitabine/rilpivirine/tenofovir	NNRTI2	\$11.93	\$11.33	-5 %
Etravirine 200 mg	NNRTI2	\$3.92	\$2.74	-30 %
Efavirenz 100 mg	NNRTI	\$0.04	\$0.04	0 %
Efavirenz 200 mg	NNRTI	\$0.09	\$0.00	-
Efavirenz 300 mg	NNRTI	\$0.15	\$0.15	-0.1 %
Efavirenz 400 mg	NNRTI	\$0.20	\$0.20	0 %
Efavirenz 600 mg	NNRTI	\$0.20	\$0.20	-0.5 %

First of all, it should be noted that the prices for the drugs that were supplied under three-year contracts (dolutegravir 50 mg, raltegravir 400 mg and etravirine 200 mg) decreased.

The agreement to reduce the price by increasing the volume (the so-called ‘price-volume’ principle) was reached through consultations between MoH RF and the manufacturer at the procurement planning stage. Accordingly, the price reduction as a result of such procurements is being fixed already at the level of maximum starting price of contract, not as a result of bidding.

The price of dolutegravir has been gradually decreasing over the past few years, due to which the volume of the drug supply has been steadily increasing.

Using the 'price-volume' approach, it was possible to increase the amount of dolutegravir from 70.9 thousand courses in 2020 to 83 thousand courses in 2021. The price of dolutegravir in 2021 decreased by 14 % and amounted to 204.82 rubles (the price in 2020 was 238.04 rubles per tablet (\$3.23). Correspondingly, the cost of the course decreased from 86,885 rubles to 74,759 rubles (\$1,015) per patient per year.

It should be noted, however, that two additional auctions for $\approx 7,000$ courses (83,828 packs) were held after the three-year contract for dolutegravir had already been signed. This may indicate that the initial volume requirement under the multi-year contract was not determined properly; probably, the price could have been reduced even more if the volume under the multi-year contract had been immediately increased to 90,000 courses per year, which MoH ended up procuring in 2021.

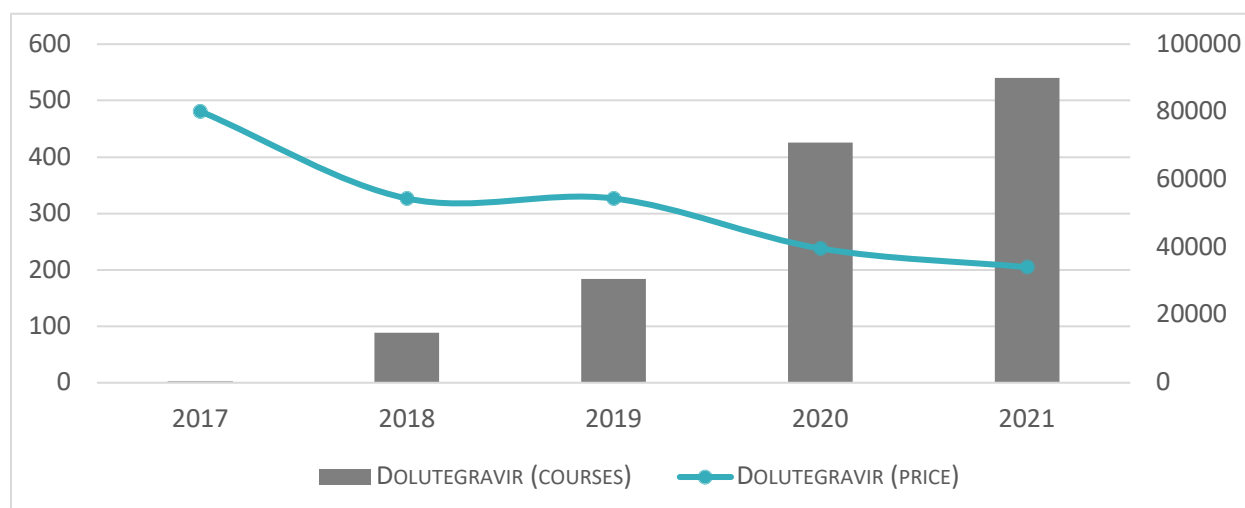


Figure 10. Changes in dolutegravir procured volumes and prices (per tablet)

The price of **raltegravir** in public procurement remained consistently high for several years. It is worth reminding that raltegravir should be taken twice a day (compared to taking dolutegravir, bictegravir, or elvitegravir once a day), and the manufacturer does not plan to register the dosage for once-a-day administration in the Russian Federation⁶. In 2020, the price was 459.43 rubles (\$6.24) per tablet despite the fact that production of the drug was localized in Russia several years ago. In 2021 due to conclusion of multi-year contract the price per tablet dropped down to 307.82 rubles (\$4.18) (–33 %). The cost per patient per year raltegravir dropped from 335,384 (\$4,552) to 224,709 rubles (\$3,050) per patient per year, but the drug is still on the list of most expensive options. It should be taken into account that modern combination drugs were included in the EML for 2022, after which their price dropped significantly (Fig. 13). Thus, since the price of raltegravir is fixed in the contract for three years, raltegravir in 2022 should take second place in the list of the most expensive ARVs after Eviplera, which, unlike raltegravir, is a one-pill regimen.

The price of **etravirine** 200 mg also decreased as part of a multi-year contract, from 288.53 rubles (\$3.92) in 2020 to 201.97 rubles in 2021 (\$2.74) (–30 %).

Raltegravir 400 mg and etravirine 200 mg have been used in clinical practice for many years in a small number of patients (6 % raltegravir, 5 % etravirine). In new clinical guidelines, raltegravir is included in the preferred second-line ARV regimen, etravirine is in the alternative second-line regimens. At the same time, their prices have decreased very insignificantly over the years, and these drugs have always been the leaders in terms of burdening the budget. Despite the fact that prices in three-year contracts were once reduced by one-third, **these prices were actually frozen for three**

⁶ Minutes of the meeting on improving access to treatment of HIV, hepatitis and tuberculosis in the Russian Federation with MSD (MSD Pharmaceuticals LLC) <https://www.eeca-cat.info/wp-content/uploads/2018/10/Protokol-MSD-Irkutsk-2021-Final.pdf>

years, and the drugs are still the expense leaders in their class. Therefore, the choice of these drugs for multi-year contracts, according to the opinion of the authors of this report, is not justified.

Notably, the patent for the main chemical compound etravirine in the Russian Federation expires on June 17, 2023⁷. After that, generics should appear on the market, which are likely to be cheaper than the original. According to the State Register of Medicines, at least one application for registration of generic etravirine⁸ had been submitted as of early April 2022.

As a result, initially 7.27 billion rubles (\$98,684,511) (the amount of contracts for etravirine 200 mg and raltegravir 400 mg) must be budgeted for ARVs in 2022 and 2023. At the same time, the ARV line includes cheaper modern combination drugs, which are a one-pill regimen. Through the use of these combinations, it would be possible to significantly increase therapy coverage while optimizing treatment. The volume and length of contracts for raltegravir and etravirine are actually a barrier to increasing the number of people on ARV therapy and improving treatment standards.

The cost of FDC **rilpivirine/tenofovir/emtricitabine** (Eviplera) decreased by only 5 %. The cost of the course decreased from 320 thousand rubles to 305 thousand rubles per year (from \$4354 to \$4136). The patent for this combination is valid until 2027, and Janssen stated in the dialogue with representatives of public organizations that ‘further reduction on the local market (i. e. Russian market – editor’s note) is not planned’.⁹ In this regard, a possible forecast for Eviplera may look as follows: given the refusal to reduce the price, the long-term patent and the availability of more modern combination drugs in the EML at significantly lower prices, the share of Eviplera from 2022 is likely to begin to decline, if the patent holder’s pricing policy does not change.

Rilpivirine as a separate component is practically unavailable in the Russian Federation: it is not included in the EML, and its price remains consistently high (about 320,000 rubles per patient per year or \$4,343). The price is almost equal to the price of the 3-in-1 combination drug, which contains rilpivirine, tenofovir and emtricitabine, included in the EML. Taking into account the clinical role of the drug, as well as the low cost of the original drug on other markets, measures are needed to increase the availability of rilpivirine in the Russian Federation (inclusion in the EML with a reduction in price or use of the patent by the state without Janssen’s consent).

Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine (Genvoya) was included in the EML for 2021, which allowed reducing its cost from 345,241 rubles to 191,380 rubles per course (from \$4,686 to \$2,597).

As mentioned above, the increase in procurements of **elsulfavirine** in 2021 was 56 %, but the price for it did not decrease and was 218.17 rubles (\$2.96) per tablet. The cost of elsulfavirine is 79,628 rubles (\$1,080.7) per patient per year. Since 2017, public procurements of elsulfavirine have increased from 61 to 11,000 ppy at an unchanged price. At the same time, FSI FSPOMPC auctions in 2022 saw a record increase in the volume of elsulfavirine to 35,000 courses, while the price decreased by 0.01 rubles per tablet.

According to the authors of this report, the principle of ‘price-volume’ should be strictly applied in public procurement, when the price of the drug should be reduced if the volume of procurement is increased. This is justified both by the peculiarities of the production process and the need to increase the amount of ARV therapy procured for people living with HIV in conditions of a limited budget. We call for additional negotiations to be held between representatives (and, if necessary, beneficiaries) of the drug manufacturing company and representatives of the government procurer in order to drastically reduce the price of this drug.

⁷<https://www.medspal.org/?product%5B%5D=Etravirine+200+mg&countries%5B%5D=Russian+Federation&page=1>

⁸<https://grls.rosminzdrav.ru/StatementRUInfo.aspx?all=0&&TradeName=&MnnR=%d1%8d%d1%82%d1%80%d0%b0%d0%b2%d0%b8%d1%80%d0%b8%d0%bd&lf=&Applicant=&Developer=&producer=&pageNum=1&pageSize=20>

⁹ https://www.eeca-cat.info/wp-content/uploads/2021/03/Protokol-YAnsen_final-22.03.2021.pdf

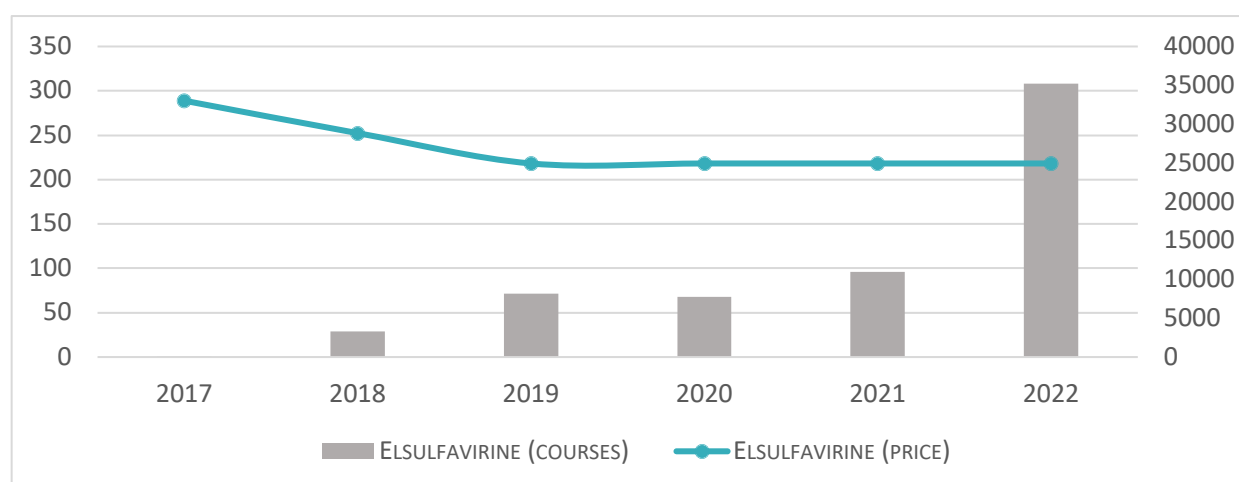


Figure 3. Growth rates and lack of price dynamics of el sulfavirine, 2017–2022

Elsulfavirine (Elpida) was included in the updated Russian clinical guidelines for HIV treatment as a drug recommended for the first-line preferred regimen along with dolutegravir and efavirenz. Elsulfavirine is used exclusively in Russia and is not included in international guidelines.

Prices for **efavirenz** in dosages of 400 mg and 600 mg have remained virtually unchanged. The price of efavirenz 400 mg compared to 600 mg is high. If you calculate the price based on the price for 600 mg, the 400 mg dosage should cost about 9.73 rubles (\$0.13) per tablet (2/3 of 14.59 rubles (\$0.19). Given that efavirenz in the 400 mg dosage form is listed in the new clinical guidelines, its volumes will probably begin to gradually increase starting in 2022.

Since the centralization of procurement at the federal level in 2017, it has been possible to significantly reduce the cost of many ARVs. The reduction in price was due to a complex of factors: the expiration of patent protection for a number of key drugs; a significant number of generics entering the market; negotiations of MoH RF with manufacturers on price reduction and volume increase; multi-year contracts; registration of new INNs; rapid inclusion of a number of modern drugs in the EML; increased funding from the federal budget for ARV procurement.

Table 8: Price dynamics for 'anchor drugs' in procurements since centralization in 2017 and 2021 (in rubles)

Drug	Weighted average price per item, 2017	Weighted average price per item, 2021	Difference 2017 vs 2021
Atazanavir 150 mg	\$1.40	\$0.18	-87.16 %
Atazanavir 200 mg	\$1.87	\$0.23	-87.42 %
Atazanavir 300 mg	\$2.78	\$0.35	-87.35 %
Bictegravir/tenofovir alafenamide/emtricitabine 50/25/200 mg	-	\$14.48	#VALUE!
Darunavir 400 mg	\$4.12	\$1.28	-69.00 %
Darunavir 600 mg	\$6.17	\$1.57	-74.60 %
Darunavir 800 mg	\$7.71	\$2.57	-66.70 %
Dolutegravir 50 mg	\$8.24	\$2.78	-66.28 %
Doravirine 100 mg	-	\$11.20	-
Doravirine/lamivudine/tenofovir 100/300/245 mg	-	\$11.59	-
Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine 150/10/150/200 mg	-	\$7.12	-
Lopinavir/ritonavir 100/25 mg	\$1.05	\$0.77	-27.20 %
Lopinavir/ritonavir 200/50 mg	\$0.66	\$0.51	-22.12 %
Maraviroc 150 mg	\$3.56	\$2.51	-29.43 %
Maraviroc 300 mg	\$6.37	\$4.56	-28.43 %

Drug	Weighted average price per item, 2017	Weighted average price per item, 2021	Difference 2017 vs 2021
Nevirapine 100 mg	-	\$0.08	-
Nevirapine 200 mg	\$0.11	\$0.07	-30.18 %
Raltegravir 400 mg	\$8.74	\$4.18	-52.20 %
Raltegravir chewable tablet 100 mg	\$2.53	\$1.75	-30.85 %
Raltegravir chewable tablet 25 mg	\$0.66	\$0.47	-29.24 %
Ritonavir 100 mg	\$0.68	\$0.38	-43.98 %
Fosamprenavir 700 mg	\$2.96	\$1.25	-57.65 %
Elsulfavirine 20 mg	\$4.95	\$2.96	-40.19 %
Emtricitabine/rilpivirine/tenofovir 200/25/300	\$15.07	\$11.33	-24.80 %
Etravirine 100 mg	-	\$2.18	-
Etravirine 200 mg	\$4.94	\$2.74	-44.56 %
Etravirine 25 mg	-	\$0.93	-
Efavirenz 100 mg	\$0.06	\$0.04	-30.89 %
Efavirenz 200 mg	\$0.13	\$0.14	10.29 %
Efavirenz 300 mg	-	\$0.15	-
Efavirenz 400 mg	\$0.30	\$0.20	-33.76 %

- this drug began to be procured after 2017

Drugs not included in the EML are traditionally the most expensive of all the ARVs. In 2021, as in 2020, the most expensive option was the bicitegravir/tenofovir alafenamide/emtricitabine combination (Biktarvy).

Table 9. Prices for new drugs not included in the EML in procurements in 2021 (in rubles)

INN	Weighted average price per tablet	The cost per patient per year, in rubles
Bicitegravir/tenofovir alafenamide/emtricitabine (Biktarvy)	\$14.48	\$5,283.48
Doravirine 100 mg (Pivelta)	\$11.20	\$4,086.93
Doravirine/lamivudine/tenofovir (Delstrigo)	\$11.59	\$4,230.79

The drugs in Table 9 were included in the EML starting in 2022 and have maximum selling prices. For this reason, their cost in the 2022 procurement will be significantly reduced.

The prices for ARVs per tablet and per patient per year in 2021 are given in [Appendix 1](#) and [Appendix 2](#).

NRTI drugs

The cost of NRTI drugs in 2021 remained mostly unchanged, except for a few options, whose prices have dropped significantly.

Table 1. Prices for NRTI drugs, 2020–2021 (in rubles)

INN	Weighted average price per item, MoH, 2020	Weighted average price per item, MoH, 2021	Comparison 2020 vs 2021, per item
Abacavir 150 mg	\$0.07	\$0.07	0 %
Abacavir 300 mg	\$0.20	\$0.19	-0.56 %
Abacavir 600 mg	\$0.39	\$0.39	-0.56 %
Abacavir/lamivudine 600/300 mg	\$1.44	\$0.60	-58.37 %
Zidovudine 100 mg	\$0.03	\$0.03	0 %

INN	Weighted average price per item, MoH, 2020	Weighted average price per item, MoH, 2021	Comparison 2020 vs 2021, per item
Zidovudine 300 mg	\$0.07	\$0.07	0 %
Lamivudine 150 mg	\$0.04	\$0.02	-35.79 %
Lamivudine 300 mg	\$0.09	\$0.06	-32.48 %
Lamivudine/zidovudine 150/300 mg	\$0.14	\$0.14	-1.47 %
Lamivudine/phosphazide 150/400 mg	-	\$1.20	-
Tenofovir 150 mg	\$0.08	\$0.09	9.97 %
Tenofovir 300 mg	\$0.09	\$0.09	0 %
Tenofovir/emtricitabine 300/200 mg*	\$6.48	\$5.09	-21.53 %
Phosphazide 200 mg	\$0.49	\$0.49	0 %
Phosphazide 400 mg	\$0.48	\$0.48	0 %
Emtricitabine 200 mg	\$0.31	\$0.30	-4.49 %

* not included in the EML

The price of the abacavir/lamivudine combination dropped the most (-56 %). This happened because a generic was procured at the federal level for the first time.

The weighted average price of tenofovir/emtricitabine decreased by 23.5 % in contracts of the constituent entities of the Russian Federation due to the appearance of generics, even if it was in quite small quantities. At the same time, the price of the drug has not decreased for 6 years; moreover, it was gradually becoming more expensive up to 2020.

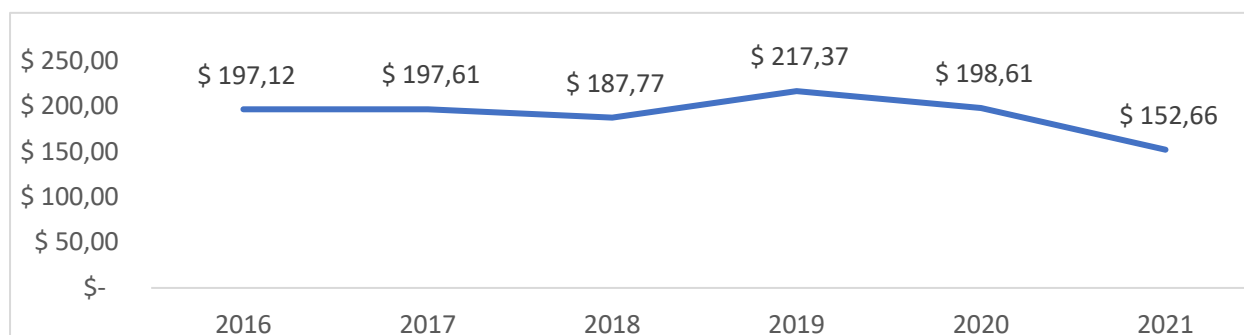


Figure 4. Dynamics of weighted average cost per pack (No. 30) of tenofovir/emtricitabine, 2016–2021 (in rubles)

Tenofovir/emtricitabine was registered in Russia in 2011. In 2017, Gilead applied for inclusion of the drug in the EML, but the Commission considered the proposed price too high. At the same time tenofovir and emtricitabine were included in the EML as separate drugs. Inclusion in the EML would have allowed procuring the combination in large quantities at the expense of the federal budget, which in turn would have allowed to further reduce the price (the 'price-volume' principle). This combination is protected by patent (EA 15145) until 2024. The patent holder, Gilead, has repeatedly stated in public discussions¹⁰ with representatives of patient organizations that it is not interested in promoting tenofovir/emtricitabine on the Russian market.

It is important to note that the EA 15145 patent was revoked in Kazakhstan, and the other CIS countries (Armenia, Azerbaijan, Belarus, Kyrgyzstan, etc.) are part of the voluntary license issued by Gilead. Under the license, the price of a 30 tablets package of tenofovir/emtricitabine is about \$5 (about 500 rubles).

¹⁰ Minutes of the meeting with Gilead <https://www.eeca-cat.info/wp-content/uploads/2018/10/Protokol-Gilead-16.10.2019.-Final-1.pdf>

Tenofovir/emtricitabine is of particular importance because this combination is currently the main option recommended for use as pre-exposure prophylaxis (PrEP) of HIV infection. Due to the fact that the drug is under patent protection and the patent-holding company has no plans to include it in the EML, the access situation remains unsatisfactory.

Emtricitabine was included in the EML for 2021, but in 2021 it was not procured by MoH RF as a separate drug; auctions were held only in constituent entities of the Russian Federation.

The NRTI nomenclature as a whole has not changed for many years, with the exception of the abandonment of stavudine and didanosine in accordance with international recommendations; neither international nor Russian companies are doing much development in this area.

Table 2. Dynamics of prices for NRTI drugs since the start of centralized procurement in 2017–2021.

INN	Weighted average price per item, 2017	Weighted average price per item, 2021	Difference 2017 vs 2021, %
abacavir 150 mg	\$0.09	\$0.07	-20.80 %
abacavir 300 mg	\$0.25	\$0.19	-22.27 %
abacavir 600 mg	\$0.43	\$0.39	-9.84 %
abacavir solution 240 mL	\$42.27	\$23.88	-43.51 %
abacavir/zidovudine/lamivudine 300/300/150 mg	-	-	-
abacavir/lamivudine 600/300 mg	\$2.47	\$0.60	-75.72 %
didanosine 125 mg	\$0.97	#VALUE!	-
didanosine 400 mg	\$1.39	#VALUE!	-
zidovudine 100 mg	\$0.04	\$0.03	-21.12 %
zidovudine 300 mg	\$0.13	\$0.07	-45.14 %
lamivudine 150 mg	\$0.03	\$0.02	-23.72 %
lamivudine 300 mg	\$0.11	\$0.06	-45.12 %
lamivudine/zidovudine 150/300 mg	\$0.21	\$0.14	-36.01 %
lamivudine/phosphazide 150/400 mg	-	\$1.20	-
stavudine 30 mg	\$0.35	-	-
stavudine powder 260 mL	-	-	-
tenofovir 150 mg	\$0.10	\$0.09	-12.91 %
tenofovir 300 mg	\$0.17	\$0.09	-44.82 %
tenofovir/emtricitabine 300/200 mg	\$6.59	\$5.09	-22.77 %

Prices in the NRTI group dropped significantly a few years ago due to the emergence of a large number of generics, but not as much as in the 'anchor drug' group. Probably, NRTI prices have practically stopped dropping because they are closer to the cost of production, at least according to the companies' statements.

The situation with prices for phosphazide 200 mg and 400 mg is exceptional. This drug has been the most expensive option in the NRTI group for several years, both as a single drug and as a combination (based on the cost of the annual course).

THE COST OF THE MOST COMMON TREATMENT REGIMENS

According to public procurement data, the most common first-line regimens are:

- lamivudine 300 mg + tenofovir 300 mg + efavirenz 600 mg;
- lamivudine 300 mg + tenofovir 300 mg + dolutegravir 50 mg.

The cost of first-line regimens ranged from 11,000 to almost 90,000 rubles per patient per year (from \$150 to \$1,200), depending on the third drug in the regimen. The most expensive drugs in first-line regimens are dolutegravir and elvitegravir. The cheapest first-line regimens include efavirenz, and the dosage (600 or 400 mg) did not affect the cost.

Table 13. Cost per patient per year with the most procured first-line ARVs in 2021

Treatment regimen	Cost per patient per year, 2021	
	in rubles	in US dollars
Preferred regimens		
lamivudine 300 mg + tenofovir 300 mg + efavirenz 600 mg	11,052.20	\$150
lamivudine 300 mg + tenofovir 300 mg + dolutegravir 50 mg	80,486.15	\$1,092
lamivudine 300 mg + tenofovir 300 mg + elvitegravir 20 mg	85,355.25	\$1,158
Alternative regimens		
lamivudine 300 mg + abacavir 600 mg + dolutegravir 50 mg	88,486.95	\$1,201
lamivudine 300 mg + tenofovir 300 mg + efavirenz 400 mg	11,026.65	\$150

Compared to 2020, of all the first-line regimens listed above, only the dolutegravir regimen became cheaper. The decrease was approximately 12–13 % due to a drop in the price of dolutegravir (in 2020 it was 91,761 rubles per patient per year, in 2021 it was 80,486 rubles per patient per year).

The cost of the main second-line regimens ranges from 25 thousand rubles to 305 thousand rubles (from \$345 to \$4,136). The cheapest second-line regimens include atazanavir. On average, the cost of such regimens is 25–33 thousand rubles per patient per year. Regimens with lopinavir/ritonavir cost about 60–70 thousand rubles per patient per year. According to an analysis of procurements in 2021, about 20 % of patients in the Russian Federation took lopinavir/ritonavir.

Regimens with darunavir cost about the same as regimens with dolutegravir, i. e. about 100,000 rubles per patient per year (which is a decrease of 12–13 % compared to 2020).

The most expensive common regimens include etravirine, raltegravir, and emtricitabine/rilpivirine/tenofovir. The cost ranges from 153,000 to 305,000 rubles, respectively. The most expensive regimen in 2021 was the bictegravir/tenofovir alafenamide/bictegravir (Biktarvy) combination, i. e. 389,287.10 rubles per patient per year (\$5,283).

According to the study results¹¹, the most popular dual regimen is dolutegravir + lamivudine. It costs 78,000 rubles (\$1,059).

Table 14. Cost per patient per year with the most commonly used second-line ARVs in 2021

Regimen	Cost per patient per year, 2021	
	in rubles	in US dollars
lamivudine 300 mg + tenofovir 300 mg + dolutegravir 50 mg	80,486.15	\$1,092
lamivudine 300 mg + tenofovir 300 mg + darunavir 800 mg + ritonavir 100 mg	84,972.00	\$1,153

¹¹ <https://itpcru.org/2020/11/27/rezultaty-issledovaniya-izuchenie-rasprostranennosti-koronavirusnoj-infekczii-covid-19-sredi-inficirovannyh-vich-pacientov-v-rossii-i-vliyaniya-epidemii-koronavirusnoj-infekczii-covid-19-na/>

Regimen	Cost per patient per year, 2021	
lamivudine 300 mg + abacavir 600 mg + darunavir 800 mg + ritonavir 100 mg	92,972.80	\$1,262
lamivudine 300 mg + tenofovir 300 mg + atazanavir 300 mg + ritonavir 100 mg	25,414.95	\$345
lamivudine 300 mg + abacavir 600 mg + atazanavir 300 mg + ritonavir 100 mg	33,415.75	\$454
lamivudine 300 mg + tenofovir 300 mg + raltegravir 400 mg	230,435.45	\$3,127
lamivudine/zidovudine 150/300 mg + lopinavir/ritonavir 200/50 mg	62,619.40	\$850
lamivudine 300 mg + tenofovir 300 mg + lopinavir/ritonavir 200/50 mg	61,002.45	\$828
lamivudine 300 mg + abacavir 600 mg + lopinavir/ritonavir 200/50 mg	69,003.25	\$936
lamivudine 300 mg + tenofovir 300 mg + etravirine 200 mg	153,165	\$2,079
emtricitabine/rilpivirine/tenofovir 200/25/300 mg	304,779	\$4,136
lamivudine 300 mg + dolutegravir 50 mg	78,037.00	\$1,059

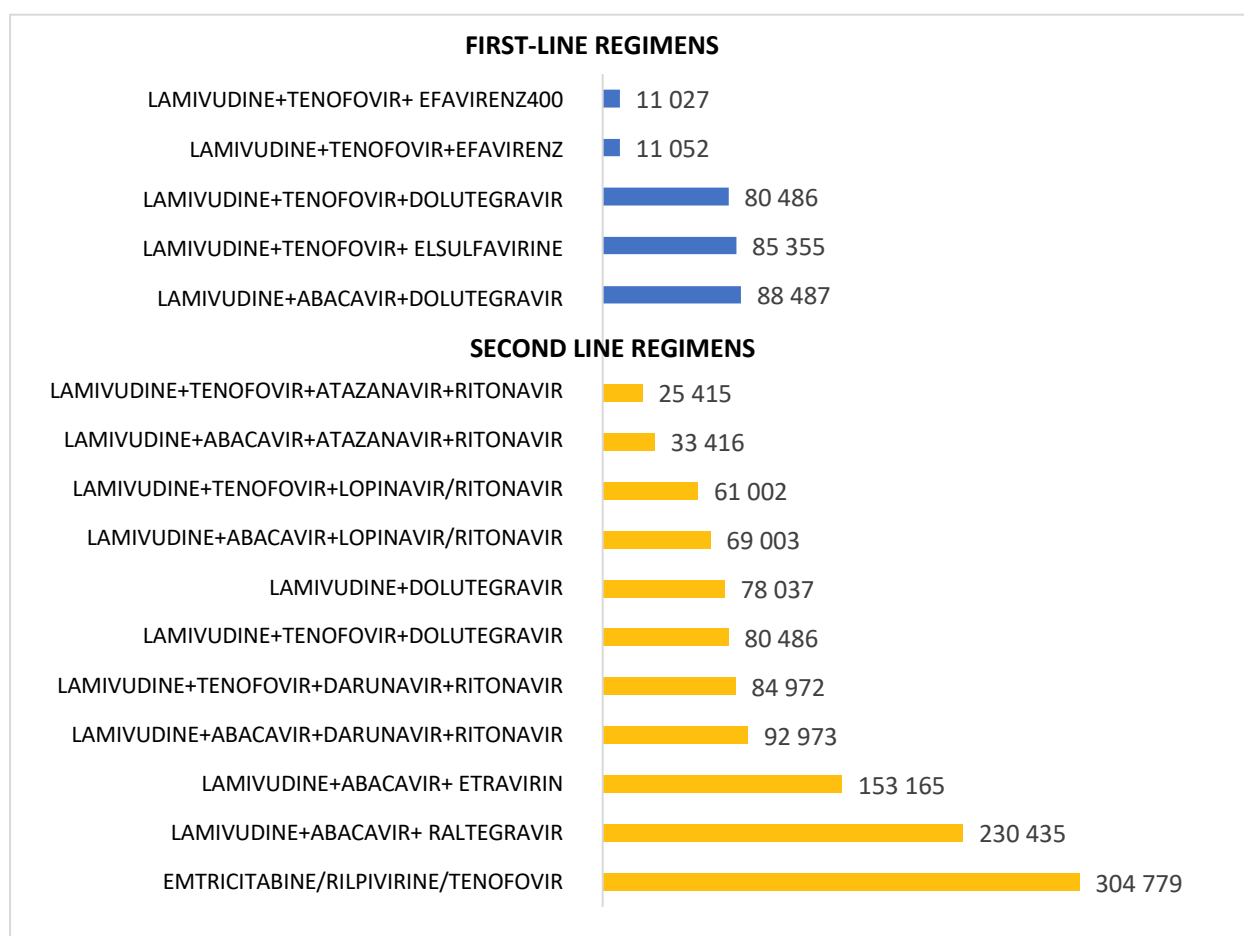


Figure 13. Cost per patient per year with the most procured first- and second-line regimens in 2021, in rubles

NUMBER OF PATIENTS ON ARVT

According to the monitoring data, the **amount of ARV drugs procured in 2021 was calculated for approximately 391,070 people living with HIV.**¹² This figure **does not** include patients taking pediatric formulations¹³, the doses of which are calculated individually depending on age and body weight. Compared to 2020, the estimated ppy number based on the procured volume of ‘anchor drugs’ has decreased by 23 % or 114,121 ppy.

Treatment coverage dynamics

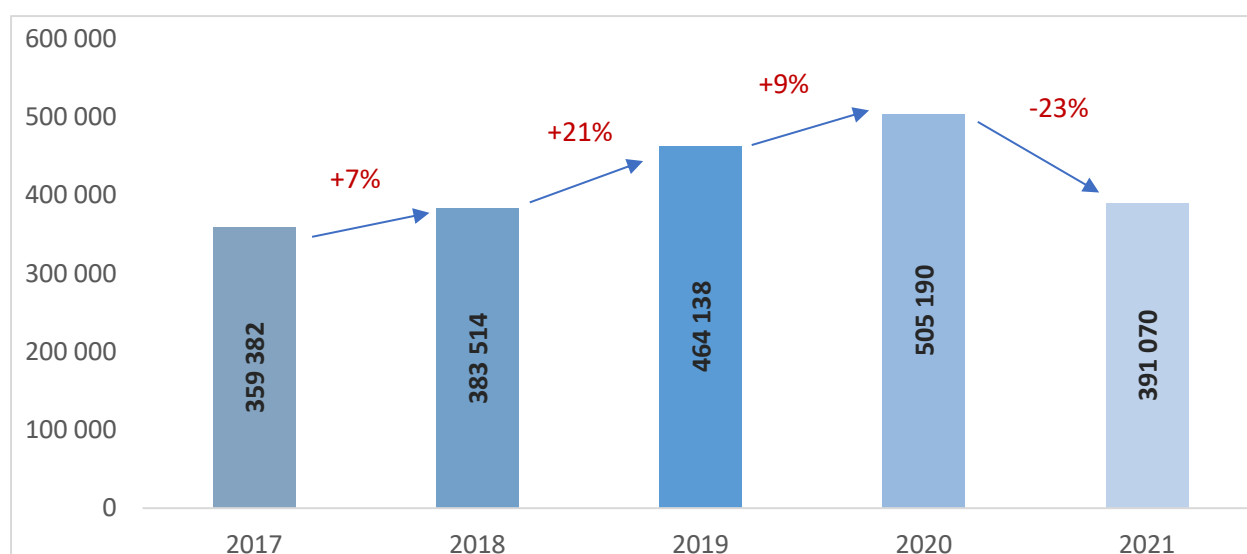


Figure 14. Estimated number of ppy as measured based on the public procurement figures, 2017–2020.

This analysis does not take into account situations where patients start treatment and interrupt it for one reason or another, as well as patients who started therapy within a year.

According to the authors, in 2021 the volume of drugs decreased due to significant changes in the nomenclature of procurement:

- Gradual switch to dolutegravir after inclusion in the preferred regimen according to the clinical guidelines;
- Reduction in the volume of efavirenz, which has been the key drug used for increasing treatment coverage for a long time;
- Multi-year contracts for expensive drugs (raltegravir, etravirine);
- Increased procurement volume of several drugs without a proportional price decrease (rilpivirine/tenofovir/emtricitabine, elvitegravir);
- Insufficient budget increase.

¹² The calculation is for a full year's course per one patient.

¹³ The calculations take into account only tableted pediatric forms.

This situation could have been prevented by allocating additional funding for 2021. According to previous reports¹⁴, MoH (FSI FSPOMPC) initially planned a different size of procurement. This followed from the list of drugs with volumes that the agency sends to manufacturers each year before the procurement cycle begins. In the December 2020 letter, the procurement plan was 478,000 ppy. At that time, Treatment Preparedness Coalition in EECA appealed to MoH, warning that it was impossible to procure the expected volume with the planned funds, based on the nomenclature and prices that were current at the time. The estimated deficit was at least 10 billion rubles. Therefore, ITPC EECA appealed to the Government of the Russian Federation and MoH with a request to take measures to reduce prices and allocate additional funds.

As a result, for the procurement of the planned volume of drugs at 2021 prices, there was a shortfall of about 6 billion rubles.

As a result, the coverage dynamics based on the estimated number of ppy went down.

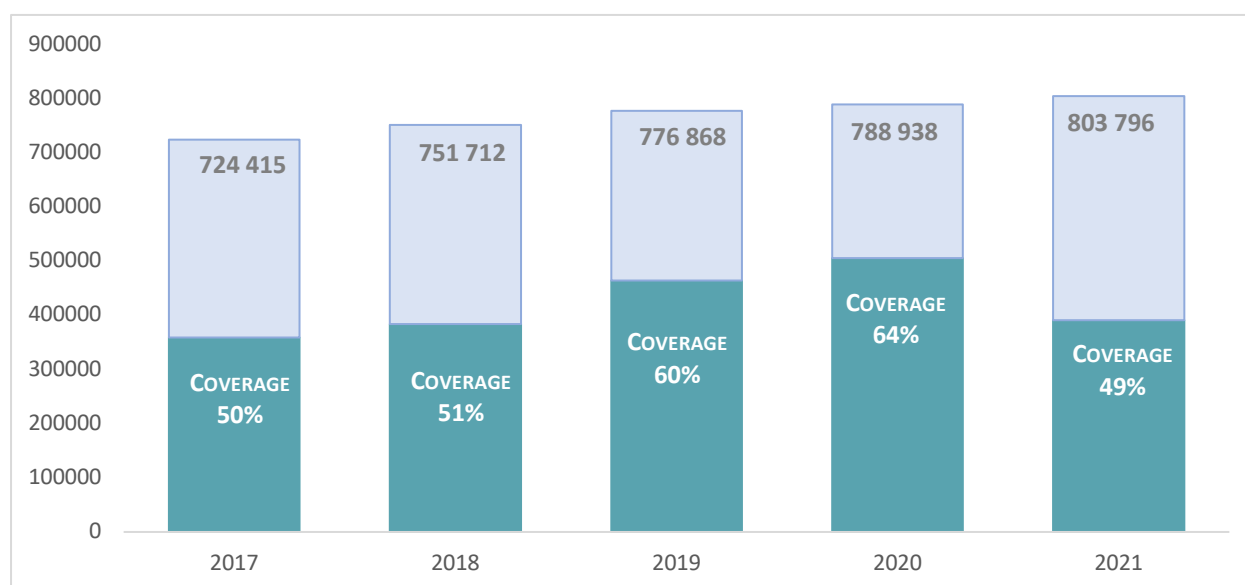


Figure 15. Percentage of treatment coverage of the number of people on treatment registry, based on procured ppy volume in 2021

¹⁴ ARV procurement for 2021. Forecast: <https://itpcru.org/2020/12/01/zakupki-arv-preparatov-na-2021-god-prognoz/>

DRUG STOCK-OUTS AND ACTIONS DURING MONITORING

This section is based on posts at pereboi.ru¹⁵ and messages from activists in the Patient Control movement¹⁶.

From 01.01.2021 to 31.12.2021, there were 365 messages, 230 of them about stock-outs of ARVs and diagnostic tools from 42 regions of the Russian Federation, from two institutions of the FPSR and from three institutions of the Federal Medical and Biological Agency.

The analysis excluded reports (135) that were not related to the topic of HIV treatment disruptions, including problems with TB drugs and viral hepatitis therapy.

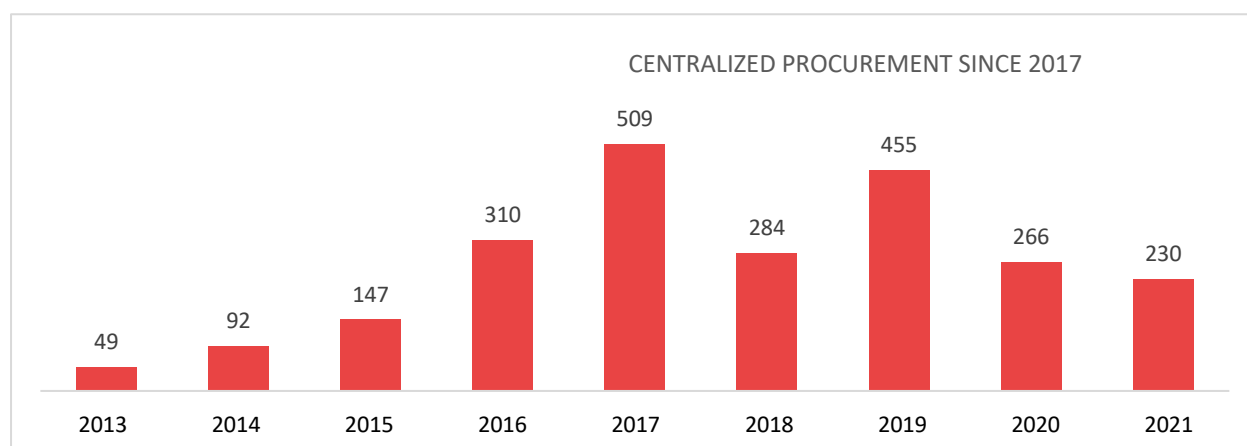


Figure 5. Dynamics by the number of messages on the website pereboi.ru for the period 2013–2021

In 2021, the number of reports remained almost at the same level as in 2020. It is worth noting that despite the situation with the COVID-19 epidemic, for the second year in a row, it was possible to avoid large-scale stock-outs.

Reports were coming in throughout the year. The maximum number of reports related to drug shortages came from mid-February through May, and the second wave of stock-outs began in mid-September. This year, as in 2020, the stock of ARVs ran out long before new supplies began. Despite the fact that centralized procurement of ARV drugs is based on 15 calendar months, the stock of drugs is insufficient for the patients even till the end of the year. Reports related to diagnostic drug shortages (viral load, immune status) were also coming in waves; the peak came at the end of the year.

The reduction in the procured volume in terms of ppy in 2021 caused stock-outs at the beginning of 2022, as the tenders for 2022 were not announced until February, and the first deliveries did not begin until April. During the first quarter of 2022, there were 82 reports about stock-outs in the supply of ARV drugs and diagnostic equipment, including 67 reports about shortages of ARVs from 21 regions, from 8 FPSR institutions and one FMBA institution. Often even a single report can indicate a shortage of a particular ARV drug in a constituent entity of the Russian Federation.

¹⁵ The website www.pereboi.ru was created to monitor the situation with the provision of drugs for socially significant diseases.

¹⁶ A movement that brings together people affected by HIV/AIDS and other socially significant diseases.

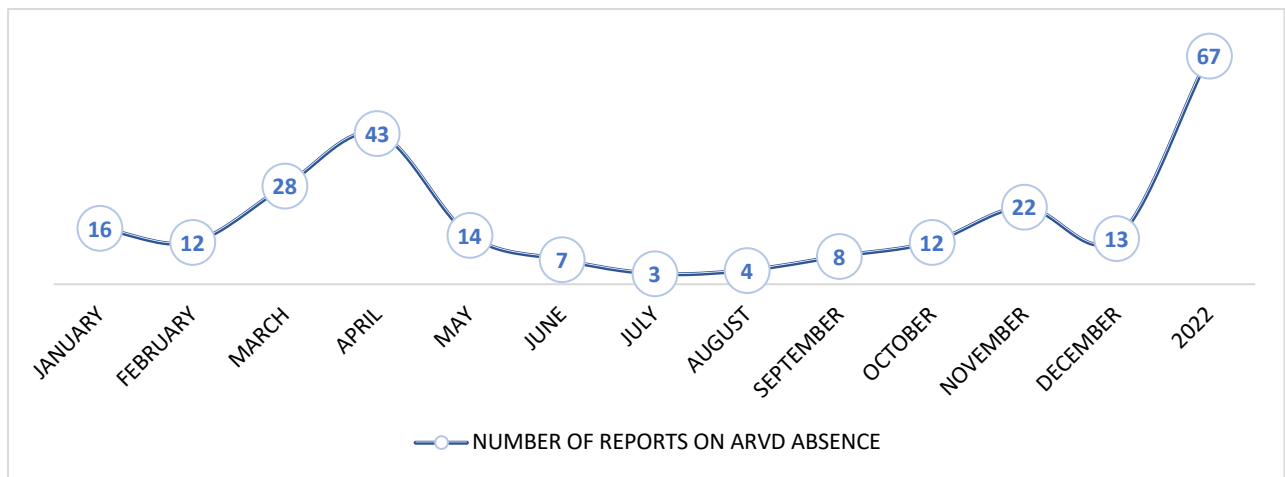


Figure 6. Number of reports by months of 2021 and the first quarter of 2022

The reports received in 2021 are divided into five groups based on problems identified by patients.

As in previous years, the majority of reports (79 %) were related to drug shortages. 32 % of the reports were related to refusals to dispense ARVs. 29 % of reports were related to changing the treatment regimen without clinical reasons due to lack of drugs.

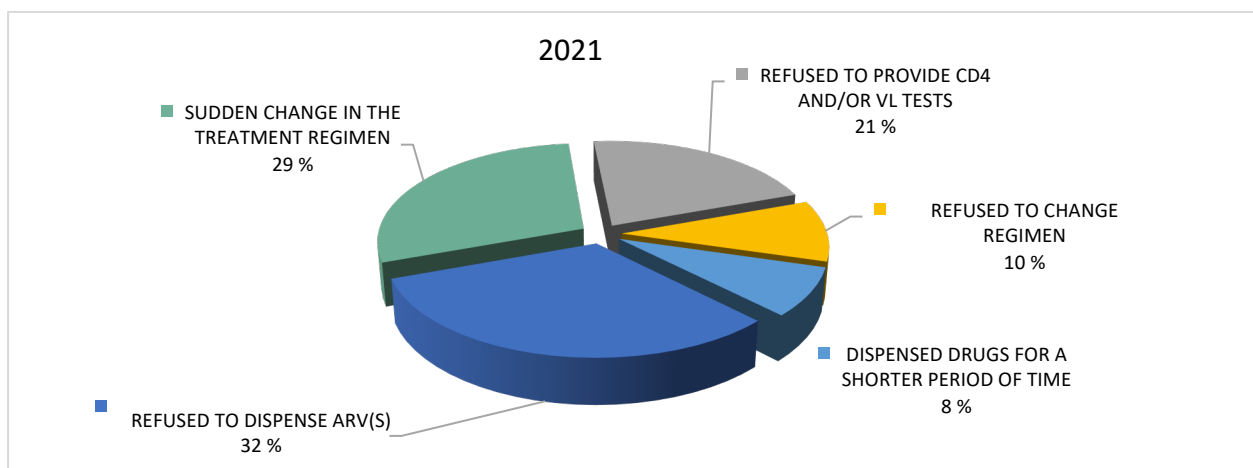


Figure 7. Problems mentioned in the 2021 reports

In 2021, the largest number of reports (74) was related to refusals to dispense drugs (failure to dispense the entire regimen or dispense an incomplete regimen). In second place, there were complaints about drug replacement without medical indications (67), which traditionally led in previous years.

Patients were more likely than in previous years to report having to go on a 'therapy vacation' or take an incomplete treatment regimen. In addition, there were cases of refusals to prescribe therapy, as well as refusals to replace the current ineffective regimen (high viral load).

Most complaints related to replacement regimens were poor tolerance or intolerance of ARV drugs given to replace the missing ones.

In total there were 182 reports of ARV drug shortages in 2021 from 39 regions of the Russian Federation, from 2 FPSR institutions and 3 FMBA institutions.

In 2021, the most complaints about shortages of the following ARVs were received: dolutegravir (30), ritonavir (28), elvitegravir (14), tenofovir (13), darunavir (12), lamivudine (12), abacavir (10), lopinavir/ritonavir (9), rilpivirine/tenofovir/emtricitabine (8), etravirine (8), atazanavir (6), raltegravir (6).

In 2022 67 reports on ARV shortages were received from 22 regions, from 9 institutions FPSR and 1 FMBA institution. The largest number came from Sverdlovsk Region (22 reports) and FPSR (14 reports).

The distribution of reports by the identified problems is comparable with 2021.

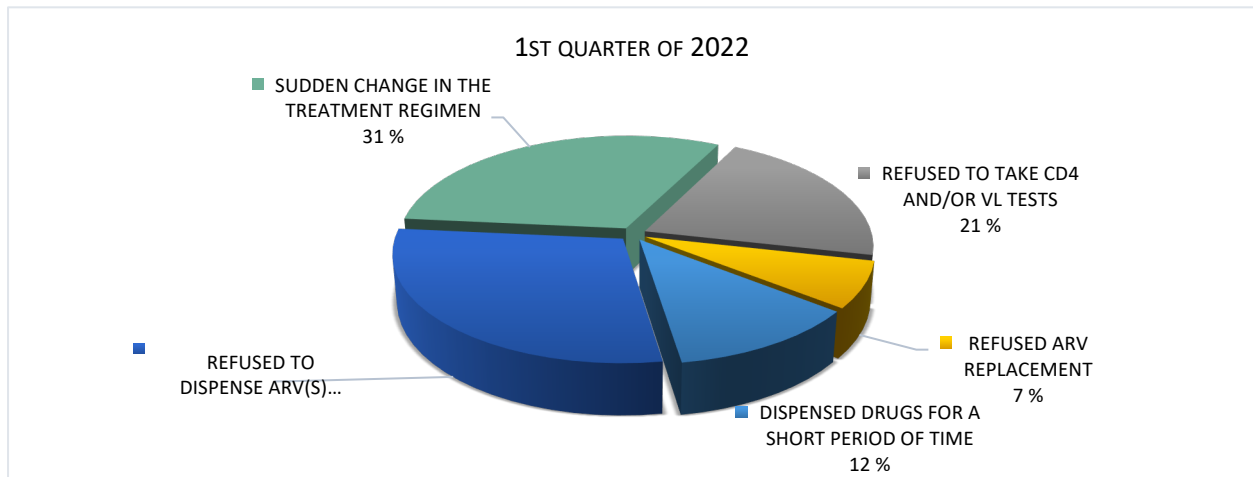


Figure 19. Problems mentioned in the 1st quarter of 2022

APPENDIX 1. THE COST OF ARV DRUGS IN 2021

INN and dosage	Items per pack	Weighted average price per unit, 2021, rubles	Weighted average price per unit, 2021, US dollars
Abacavir/lamivudine 600/300 mg	30	44.16	\$0.60
Abacavir solution 240 mL	1	1,759.20	\$23.88
Abacavir 150 mg	60	4.97	\$0.07
Abacavir 300 mg	60	14.31	\$0.19
Abacavir 600 mg	30	28.63	\$0.39
Atazanavir 150 mg	60	13.24	\$0.18
Atazanavir 200 mg	60	17.30	\$0.23
Atazanavir 300 mg	30	25.95	\$0.35
Atazanavir/ritonavir 300/100 mg	30	103.18	\$1.40
Bictegravir/tenofovir alafenamide/emtricitabine 50/25/200 mg	30	1,066.54	\$14.47
Darunavir 400 mg	60	94.08	\$1.28
Darunavir 600 mg	60	115.52	\$1.57
Darunavir 800 mg	30	189.12	\$2.57
Dolutegravir 50 mg	30	204.82	\$2.78
Doravirine 100 mg	30	825.00	\$11.20
Doravirine/lamivudine/tenofovir 100/300/245 mg	30	854.04	\$11.59
Zidovudine 100 mg	100	2.48	\$0.03
Zidovudine solution 200 mL	1	520.00	\$7.06
Zidovudine solution for infusion, 20 mL	5	371.60	\$5.04
Zidovudine 300 mg	60	5.14	\$0.07
Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine 150/10/150/200 mg	30	524.33	\$7.12
Lamivudine/zidovudine 150/300 mg	60	10.06	\$0.14
Lamivudine solution 240 mL	1	964.80	\$13.09
Lamivudine 150 mg	60	1.83	\$0.02
Lamivudine 300 mg	60	4.49	\$0.06
Lamivudine/phosphazide 150/400 mg	60	88.77	\$1.20
Lopinavir/ritonavir 100/25 mg	60	56.45	\$0.77
Lopinavir/ritonavir 200/50 mg	120	37.86	\$0.51
Lopinavir/ritonavir 80/20 mg, p-p 60мл	5	672.60	\$9.13
Maraviroc 150 mg	60	184.91	\$2.51
Maraviroc 300 mg	60	336.05	\$4.56
Nevirapine 100 mg	30	5.80	\$0.08
Nevirapine 200 mg	60	5.51	\$0.07
Nevirapine suspension 240 mL	1	748.80	\$10.16
Raltegravir 400 mg	60	307.82	\$4.18
Raltegravir chewable tablets 25 mg	60	34.28	\$0.47
Raltegravir chewable tablets 100 mg	60	129.11	\$1.75
Rilpivirine 25 mg	30	872.63	\$11.84
Ritonavir 100 mg	30	27.99	\$0.38
Saquinavir 500 mg	120	65.85	\$0.89
Tenofovir 150 mg	60	6.40	\$0.09

INN and dosage	Items per pack	Weighted average price per unit, 2021, rubles	Weighted average price per unit, 2021, US dollars
Tenofovir 300 mg	30	6.71	\$0.09
Tenofovir/emtricitabine 300/200 mg	30	374.81	\$5.09
Fosamprenavir 700 mg	60	92.27	\$1.25
Phosphazide 200 mg	60	35.97	\$0.49
Phosphazide 400 mg	60	35.53	\$0.48
Elsulfavirine 20 mg	30	218.16	\$2.96
Emtricitabine/rilpivirine/tenofovir 200/25/300	30	835.01	\$11.33
Emtricitabine 200 mg	30	21.89	\$0.30
Etravirine 25 mg	120	68.21	\$0.93
Etravirine 100 mg	120	160.29	\$2.18
Etravirine 200 mg	60	201.97	\$2.74
Efavirenz 100 mg	30	3.29	\$0.04
Efavirenz 200 mg	30	10.50	\$0.14
Efavirenz 300 mg	30	10.89	\$0.15
Efavirenz 400 mg	30	14.52	\$0.20
Efavirenz 600 mg	30	14.59	\$0.20

APPENDIX 2. THE COST PER PATIENT PER YEAR¹⁷

INN and dosage	Cost, in rubles	Cost, in US dollars ¹⁸	Type of drug	Customer
Abacavir 150 mg	7,256.20	\$98.48	NRTI	MoH RF
Abacavir 300 mg	10,446.30	\$141.77	NRTI	MoH RF
Abacavir 600 mg	10,449.95	\$141.82	NRTI	MoH RF
Abacavir solution 240 mL	-	-	NRTI	MoH RF
Abacavir/lamivudine 600/300 mg	16,118.40	\$218.76	NRTI	MoH RF
Atazanavir 150 mg	9,665.20	\$131.17	3rd drug	MoH RF
Atazanavir 200 mg	12,629.00	\$171.40	3rd drug	MoH RF
Atazanavir 300 mg	9,471.75	\$128.55	3rd drug	MoH RF
Atazanavir/ritonavir 300/100 mg	37,660.70	\$511.12	3rd drug	Regions
Bictegravir/tenofovir alafenamide/emtricitabine 50/25/200 mg	389,287.10	\$5,283.31	One-pill regimen	Regions
Darunavir 400 mg	68,678.40	\$932.09	3rd drug	MoH RF
Darunavir 600 mg	84,329.60	\$1,144.50	3rd drug	MoH RF
Darunavir 800 mg	69,028.80	\$936.84	3rd drug	MoH RF
Dolutegravir 50 mg	74,759.30	\$1,014.62	3rd drug	MoH RF
Doravirine 100 mg	301,125.00	\$4,086.80	3rd drug	Regions
Doravirine/lamivudine/tenofovir 100/300/245 mg	311,724.60	\$4,230.65	One-pill regimen	Regions
Zidovudine 100 mg	5,431.20	\$73.71	NRTI	MoH RF
Zidovudine 300 mg	3,752.20	\$50.92	NRTI	MoH RF
Zidovudine solution 200 mL	-	-	NRTI	MoH RF
Zidovudine solution for infusion, 20 mL	-	-	NRTI	MoH RF
Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine 150/10/150/200 mg	191,380.45	\$2,597.37	One-pill regimen	MoH RF
Lamivudine 150 mg	1,335.90	\$18.13	NRTI	MoH RF
Lamivudine 300 mg	3,277.70	\$44.48	NRTI	MoH RF
Lamivudine solution 240 mL	-	-	NRTI	MoH RF
Lamivudine/zidovudine 150/300 mg	7,343.80	\$99.67	NRTI	MoH RF
Lamivudine/phosphazide 150/400 mg	64,802.10	\$879.48	NRTI	Federal institution
Lopinavir/ritonavir 100/25 mg	82,417.00	\$1,118.54	3rd drug	MoH RF
Lopinavir/ritonavir 200/50 mg	55,275.60	\$750.19	3rd drug	MoH RF
Lopinavir/ritonavir 80/20 mg, p-p 60 mL	-	-	3rd drug	MoH RF
Maraviroc 150 mg	134,984.30	\$1,831.97	3rd drug	MoH RF
Maraviroc 300 mg	245,316.50	\$3,329.38	3rd drug	MoH RF
Nevirapine 100 mg	8,468.00	\$114.93	3rd drug	MoH RF
Nevirapine 200 mg	4,022.30	\$54.59	3rd drug	MoH RF
Nevirapine suspension 240 mL	-	-	3rd drug	MoH RF
Raltegravir 400 mg	224,708.60	\$3,049.69	3rd drug	MoH RF
Raltegravir chewable tablets100 mg	94,250.30	\$1,279.14	3rd drug	MoH RF
Raltegravir chewable tablets25 mg	50,048.80	\$679.25	3rd drug	MoH RF
Rilpivirine 25 mg	318,509.95	\$4,322.74	3rd drug	Regions
Ritonavir 100 mg	10,216.35	\$138.65	3rd drug	MoH RF

¹⁷ Except for pediatric formulations.

¹⁸ At the rate of 73.6824 rubles per US dollar.

INN and dosage	Cost, in rubles	Cost, in US dollars ¹⁸	Type of drug	Customer
Saquinavir 500 mg	96,141.00	\$1,304.80	3rd drug	MoH RF
Tenofovir 150 mg	4,672.00	\$63.41	NRTI	MoH RF
Tenofovir 300 mg	2,449.15	\$33.24	NRTI	MoH RF
Tenofovir/emtricitabine 300/200 mg	136,805.65	\$1,856.69	NRTI	Regions
Fosamprenavir 700 mg	67,357.10	\$914.15	3rd drug	MoH RF
Phosphazide 200 mg	39,387.15	\$534.55	NRTI	MoH RF
Phosphazide 400 mg	12,968.45	\$176.00	NRTI	MoH RF
Elsulfavirine 20 mg	79,628.40	\$1,080.70	3rd drug	MoH RF
Emtricitabine 200 mg	7989.85	\$108.44	NRTI	Regions
Emtricitabine/rilpivirine/tenofovir 200/25/300	304,778.65	\$4,136.38	One-pill regimen	MoH RF
Etravirine 100 mg	234,023.40	\$3,176.11	3rd drug	MoH RF
Etravirine 200 mg	147,438.10	\$2,000.99	3rd drug	MoH RF
Etravirine 25 mg	99,586.60	\$1,351.57	3rd drug	MoH RF
Efavirenz 100 mg	7,205.10	\$97.79	3rd drug	MoH RF
Efavirenz 200 mg	11,497.50	\$156.04	3rd drug	Regions
Efavirenz 300 mg	7,949.70	\$107.89	3rd drug	MoH RF
Efavirenz 400 mg	5,299.80	\$71.93	3rd drug	MoH RF
Efavirenz 600 mg	5,325.35	\$72.27	3rd drug	MoH RF

APPENDIX 3. THE BUDGET OF MOH RF FOR ARVT BY INN

INN (combined for all dosages)	Amount of contracts, 2021, in rubles	Amount of contracts, 2021, in US dollars	Share of the contract amount, 2021, %
Dolutegravir	7,136,502,906.70	\$96,854,919.31	22.51 %
Emtricitabine/rilpivirine/tenofovir	5,510,902,513.32	\$74,792,657.59	17.38 %
Raltegravir	5,281,763,922.25	\$71,682,843.15	16.66 %
Lopinavir/ritonavir	3,622,010,696.87	\$49,157,067.32	11.43 %
Etravirine	2,886,106,361.12	\$39,169,548.78	9.10 %
Darunavir	1,513,656,673.80	\$20,542,988.20	4.77 %
Elsulfavirine	1,319,537,439.90	\$17,908,448.15	4.16 %
Tenofovir	583,513,122.41	\$7,919,301.25	1.84 %
Ritonavir	540,376,626.74	\$7,333,862.99	1.70 %
Efavirenz	492,524,747.94	\$6,684,428.68	1.55 %
Lamivudine	473,110,782.30	\$6,420,946.96	1.49 %
Cobicistat/tenofovir alafenamide/elvitegravir/emtricitabine	457,290,619.40	\$6,206,239.47	1.44 %
Abacavir	340,632,951.65	\$4,622,989.37	1.07 %
Atazanavir	333,576,349.37	\$4,527,218.84	1.05 %
Bictegravir/tenofovir alafenamide/emtricitabine	219,653,913.60	\$2,981,090.65	0.69 %
Lamivudine/zidovudine	171,527,335.32	\$2,327,928.18	0.54 %
Phosphazide	166,982,991.40	\$2,266,253.43	0.53 %
Doravirine/lamivudine/tenofovir	158,504,115.00	\$2,151,180.13	0.50 %
Abacavir/lamivudine	141,016,362.48	\$1,913,840.52	0.44 %
Fosamprenavir	85,257,480.00	\$1,157,094.23	0.27 %
Tenofovir/emtricitabine	76,680,325.40	\$1,040,687.13	0.24 %
Saquinavir	41,451,356.85	\$562,567.95	0.13 %
Zidovudine	31,594,285.03	\$428,790.12	0.10 %
Doravirine	25,869,556.80	\$351,095.47	0.08 %
Nevirapine	21,856,693.83	\$296,633.85	0.07 %
Rilpivirine	20,419,542.00	\$277,129.17	0.06 %
Lamivudine/phosphazide	15,371,413.20	\$208,617.16	0.05 %
Atazanavir/ritonavir	13,177,754.40	\$178,845.35	0.04 %
Emtricitabine	11,782,824.20	\$159,913.69	0.04 %
Maraviroc	7,335,201.72	\$99,551.61	0.02 %
Total	31,699,986,865.00	\$430,224,678.69	100.00 %