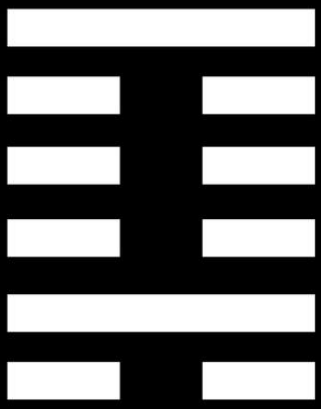
ITPCru
International Treatment Preparedness Coalition
Eastern Europe and Central Asia

Analysis of ARV Procurement in the Russian Federation in 2019



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"International Treatment Preparedness Coalition in EECA: Analysis of ARV Procurement in the Russian Federation in 2019".

Comments on this report are accepted by email: office@itpcru.org.

FROM AUTHORS

This publication is special to us. Its release marks the 10th anniversary of our work on monitoring the public procurement of ARV drugs in Russia. Although our first report was released in 2012, it covered a period of 4 years at once - from 2009 to 2012.

A lot has changed in 10 years. The Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the Ministry of Health of the Russian Federation, and regions of the Russian Federation were the main organizers of drug procurement in that time. The legal framework regulating the provision of therapy, procurement nomenclature and, of course, procurement volume has changed significantly. ARV therapy coverage in Russia has increased more than 10 times - from 43,000 persons in 2009 to half a million in 2019. However, it should be noted that in some aspects progress is almost absent and, in some areas, there has been a regression. This includes the continued widespread use of obsolete drugs, refusal to procure combination drugs, and interruptions in supply. However, first of all, we are talking of the fact that the epidemic growth continues to outpace the provision of antiretroviral therapy to people living with HIV.

Our organization has also changed a lot since then. We turned from a group of enthusiasts into a highly professional team of experts, began to apply the acquired skills throughout the Eastern Europe and Central Asia region. The number of our publications and projects in general is growing, and we do not plan to stop there. We hope that we can continue to provide an interesting and important product for discussion and analysis by market participants and the community of people living with HIV. We sincerely thank everyone who has worked with us over the years to create all of our publications - medical specialists, sociologists, team members, authors, partners, sponsors and philanthropists. Without you, this fascinating journey would not have been possible.

DISCLAIMER

This document is a brief translated version of the full report dedicated to ARV procurements in Russia in 2019. Full report is available on the ITPCru website[1]. This document is mainly intended to support the efforts taken by the government authorities of the Russian Federation in combating the HIV -epidemic. ITPCru shall not be responsible for the use and interpretation of data, findings and recommendations contained in this report by any third parties.

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Reference to any international non-proprietary or trade names of drugs does not mean that the ITPCru prefers or, on the contrary, does not recommend these drugs.

Reference to any treatment regimen in the report, under no circumstances, can be used as an alternative to consulting a medical specialist.

[1] https://itpcru.org/wp-content/uploads/2020/04/itpcru-otchet-arv-preparaty-2019-28.04.20-final_prep.pdf

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LIST OF ACCEPTED ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
ARV, ART, ARV drugs	antiretroviral drugs
CCR5 antagonist	CCR5 coreceptor antagonist
EACS	European AIDS Clinical Society
FPS	Federal Penitentiary Service of Russia
FSMC AIDS	Federal Scientific and Methodological Center for the Prevention and Control of AIDS
FSFRI	Federal State-Funded Research Institution
HIV	human immunodeficiency virus
IS	immune status
II	integrase inhibitor
INN	international non-proprietary name
LLC	limited liability company
MOH of Russia	Ministry of Health of the Russian Federation
NRTI	nucleoside reverse transcriptase inhibitor
2nd generation NNRTI	second-generation non-nucleoside reverse transcriptase inhibitors
NNRTI	non-nucleoside reverse transcriptase inhibitors
OJSC	open joint stock company
PE	pharmacokinetic enhancer
PI	protease inhibitor
PreP	pre-exposure prophylaxis
PLHIV	people living with HIV
Rospotrebnadzor	Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing
Roszdravnadzor	Federal Service for Surveillance in Healthcare
RF	Russian Federation
SRM	State Register of Medicines
UNAIDS	Joint United Nations Program on HIV/AIDS
VAT	value added tax
VED List	List of Vital and Essential Drugs
VL	viral load
WHO	World Health Organization

FINDINGS

1. The estimated number of annual ARV therapy courses in 2019 was **464,318**. This covers approximately 60% of the total number of people being under regular medical check-up in 2019, and about 43% of all registered people living with HIV. The increase in the number of purchased courses as compared to 2018 amounted to **21%** (80,864 annual courses).

2. According to the official data, the number of people receiving therapy at the end of 2019 was 534,990 persons. The difference between the official and estimated figures, first of all, may be explained by the fact that official statistics include all patients who started therapy and then stopped for some reason or started therapy at the end of 2019, as well as children who are not included in our analysis.

3. The total expenses for all ARV procurements in the Russian Federation in 2019 amounted to **26,509 million rubles**, where **22.9 billion rubles** is the share of the Ministry of Health of the Russian Federation in the centralized procurements. As compared to the budget of 2018, the total expenses of the Ministry of Health of the Russian Federation for purchasing ARV drugs increased by **2.399 billion rubles** (+ 11.5% by 2018).

4. The total amount spent for purchasing ARV drugs by constituent entities of the Russian Federation was 2.47 billion rubles (9.33% of the total amount spent for purchasing ARV drugs in 2019, but 10 times less than the total amount spent by the Ministry of Health of the Russian Federation).

5. At the level of constituent entities of the Russian Federation, ARV procurement auctions were found only in 56 regions. This may be caused by a lack of funds at the regional level or a lack of political will to spend the available funds for purchasing ARV drugs. The amount spent for purchasing ARV drugs for HIV treatment at the regional level decreased by 23% as compared to 2018.

6. According to monitoring data, in 2019 less than 4% of the total number of annual treatment courses were purchased out of the funds of regional budgets.

7. In 2019, 64.6% of the procurement budget were spent for the purchase of five drugs. All of them are under patent protection in the Russian Federation:
    a) lopinavir/ritonavir – 18.8% (4.98 billion rubles)
    b) raltegravir – 13.8% (3.66 billion rubles)
    c) dolutegravir – 13.8% (3.65 billion rubles)
    d) etravirine – 9.3% (2.46 billion rubles)
    e) rilpivirine/tenofovir/emtricitabine – 8.9% (2.37 billion rubles)

    In this regard, it is important to focus on lowering the prices for these drugs. The experience of other countries shows that lower prices are quite achievable (up to 5 USD and below for a monthly course of dolutegravir, up to 18 USD and below for a monthly course of lopinavir/ritonavir, up to 6.5 USD for a monthly course of rilpivirine).

8. Atazanavir is no longer included in the top 5 drugs of 2019 in terms of the amount spent. This happened due to the reduction in prices for all doses of this drug by almost 80% in procurements of the Ministry of Health of the Russian Federation.

9. In 2019, the prices for certain drugs increased significantly:
    a) lamivudine/zidovudine 150/300 mg - by 283.96%,
    b) lamivudine 300 mg - by 90.35%,

c) lamivudine 150 mg - by 72.49%,

d) abacavir 600 mg - by 51.61%.

It is important to note that all these drugs are not protected by patent and are supplied to the market as generics. In this regard, their price is already so low that even fluctuations in prices from 100 to 200% have little impact on the total budget due to small absolute values.

10. In 2019, dolutegravir for the first time entered the top 5 drugs in terms of the amount spent. At the same time, although its price decreased at the end of 2019, at the time of procurement in 2019 it remained the same as in 2018. The share of dolutegravir in terms of the amount spent in procurement almost doubled - from 7.37% to 13.75%.

11. A number of changes occurred in the drug procurement structure:

    a) The number of dolutegravir courses more than doubled (from 14,760 to 30,571 annual courses). The need of constituent entities of the Russian Federation for dolutegravir could, in its turn, affect the twofold increase in the funds allocated for this drug in procurement. However, based on the general nomenclature of ARV procurement, dolutegravir accounted for only 7% of the total number of "third" drug courses in 2019, which does not comply with the recommendations of WHO and EACS.

    b) In the group of core drugs, the number of lopinavir/ritonavir courses remains high (19%), however, as compared to 2018, its number decreased by 5%, which, in our opinion, is a positive trend.

    c) The number of elsulfavirine courses increased 2.5 times (from 3,259 to 8,179 annual courses).

    d) Almost half of ARV therapy courses purchased in the Russian Federation in 2019 included efavirenz in a dose of 600 mg (49% of the courses). Its number increased by 24% as compared to 2018. The fact that concerns us is that the widespread use of the drug in a dose of 400 mg instead of 600 mg, as recommended by WHO and EACS, was not implemented.

    e) The number of atazanavir courses increased (+ 53%).

    f) In 2019, the trend of increasing the number of tenofovir courses continued in NRTI group (+ 58%).

    The increase in dolutegravir procurement volumes may be a sign of the beginning of the treatment regimen optimization process. As for the increase in efavirenz procurement volumes, this trend cannot be considered contemporary without transition to a dose of 400 mg instead of 600 mg.

12. The analysis showed that the main treatment regimens in the Russian Federation are still purchased as separate drugs:

    a) tenofovir + lamivudine + efavirenz

    b) tenofovir + lamivudine + lopinavir/ritonavir.

13. The weighted average cost of an annual treatment course with efavirenz in the centralized procurements in 2019 was **11,753 rubles.** The cost decreased by 9% as compared to 2018.

14. The cost of an annual treatment course with lopinavir/ritonavir was **60,681 rubles** (no significant decrease since 2018).

15. The number of people taking drugs in the form of a fixed dose combination remains negligibly small in the Russian Federation. The single-tablet regimen is available only to 1.6% of

patients, and "2 in 1" drugs are available to 3.3% of patients. Moreover, as compared to the previous year, the rilpivirine/tenofovir/emtricitabine procurement volume decreased - the number of people who could receive this drug was 7,352, which is 1,000 less than in 2018.

16. The trend to refuse to purchase combination drugs and replace them with monocomponents continues. In 2019, patients in the Russian Federation, in fact, had access to only one drug "single-tablet regimen" (rilpivirine/tenofovir/emtricitabine) and only one combination of two NRTIs (lamivudine/zidovudine) not included in the list of preferred regimens. This trend is largely caused by the position of the Federal Antimonopoly Service. At the same time, the monitoring results show that, when dividing combination drugs into monocomponents in bidding, actual savings are often not achieved. The analysis of abacavir/lamivudine and tenofovir/emtricitabine auctions shows that in 2019 at least 50 million rubles could have been saved if customers had initially announced auctions for separate drugs.

17. Over the past years, a vast majority of auctions was held in the absence of competition in bidding. So, in 2019, there was no competition in 82% of auctions of the Ministry of Health of the Russian Federation. More than 90% of the budget were allocated to contracts concluded as a result of bidding without competition (more than 23 billion rubles). However, FPS procurements do not provide for competition (procurement from a single supplier) and are not taken into account in the determination of competition.

18. The analysis showed that most of the drugs used on the Russian market are generics. In NRTI group, almost 100% are generics. The substitution of originals for generics in most cases occurred due to the expiration of patents, which is ordinary practice for all countries.

19. A significant number of drugs in the segment of NRTIs, NNRTIs and PI in 2019 are domestic drugs. Among the purchased generics, there are almost no foreign-made drugs, however a vast number of foreign-made drugs is registered in the Russian Federation. This may be caused by the "odd-man-out" rule, according to which bidders with drugs from other countries are not allowed to bid if two suppliers with drugs manufactured in Russia or EEU countries are involved in the bidding. At the same time, since domestic products are mainly manufactured out of foreign substances (China and India), in the event of unforeseen situations, there may be a risk that domestic companies will not be able to produce the required amount of drugs promptly and on time.

20. In 2019, the website pereboi.ru recorded 455 reports of interruptions in the provision of ARV therapy. The number of reports doubled as compared to the last year. In our opinion, the increase in the number of reports is associated with 1) the general increase in the number of PLHIV receiving therapy, 2) the wide dissemination of information on the website pereboi.ru, 3) the repeated failures of lamivudine procurement auctions.

21. The number of reports complaining of the quality of drugs also increased.

22. In 37% of cases, reports on the website pereboi.ru concerned the substitution of drugs without medical indications due to the lack of drugs (in 2018 - 31%), 26% of reports were related to the refusal to provide ARV drugs (in 2018 - 27%).

RECOMMENDATIONS

1. **To continue work on increasing ARV therapy coverage.** Given the rate of detection of new HIV infections (about 100 thousand new cases in 2018 and 2019), in our opinion, it will be necessary to provide additional therapy to at least 300 thousand patients within the next two years. Thus, the growth rate of the number of people receiving therapy will significantly exceed the growth rate of the epidemic. This, in its turn, should result in further decrease in the growth rate of the epidemic, taking into account the concept of "treatment as prevention". In addition, it will bring us closer to the targets of the State Strategy[2].

2. Such results may be achieved with an integrated approach:

   a. Corresponding increase in the federal and regional budgets for ARV procurement (by including the relevant financial indicators in accordance with the instructions of the President dated December 30, 2019 in the HIV program). According to rough estimates of FSMC AIDS, for covering the need for ARV drugs, it is necessary at least to double federal funding as compared to the budget of 2019-2020[3].

   b. Providing for the possibility of direct negotiations with manufacturers and conclusion of long-term contracts for patented drugs with patent protection of at least 3 years, subject to revision, for example, provided that legitimate generic options appear in the market.

   c. Given the clinical relevance, the patent protection period and the potential availability of generics, it is necessary to consider the possibility of using a compulsory licensing mechanism (production/delivery of generics at reduced prices for state needs with payment of compensation to the patent holder in accordance with Article 1360 of the Civil Code of the Russian Federation).

   d. Optimizing treatment regimens by phasing out more expensive and, at the same time, less clinically relevant options.

3. Using a combination of these methods, in our opinion, the most significant financial effect will bring work with a special emphasis on 5 drugs that occupy the largest share in the budget structure:

   a. *Lopinavir/ritonavir*. In our opinion, further reduction in the price for this drug is extremely necessary and, moreover, possible, given its long circulation in the market and much lower prices in the world as compared to the Russian Federation. At the same time, gradual decrease in the share of lopinavir/ritonavir is recommended, with substitution for more preferred options (dolutegravir, darunavir, atazanavir, etc.) in accordance with the recommendations of EACS and WHO.

   b. *Raltegravir.* It is necessary to take a package of measures aimed at reducing the price for this drug. Since the drug is under patent protection, such a package, first of all, should include negotiations between the purchaser and the manufacturer on the basis of the "price-volume" principle. In the longer term, if negotiations fail, the option of compulsory licensing may be considered, taking into account the clinical relevance of the drug and the potential availability of generics (two drugs are currently undergoing bioequivalence tests).

   c. *Dolutegravir*. Given the latest WHO recommendations, certain efforts to lower prices should be focused on dolutegravir. The benchmark could be the price achieved in the negotiations in Brazil (taking into account the comparable level of income and the size of the epidemic), namely, about 50 US dollars (about 3,250 rubles at the rate of 65) for a monthly course. At the same time, it is necessary to increase the share of dolutegravir in first-line regimens and, as a result, in procurement in accordance with the recommendations of WHO and EACS (European AIDS Clinical Society).

[2]Such increase is not possible without a sharp increase in test coverage and return of "lost" patients, but this is not the subject matter of this report.

[3] https://www.rbc.ru/society/18/04/2018/5ad783979a7947394b3b96e8

d. *Etravirine.* Given the fact that this drug is not a drug of choice according to the recommendations of WHO and EACS, it is recommended to evaluate the feasibility of transition of most patients to more clinically preferred and cheaper options. At the same time, it is necessary to work with the manufacturer to reduce prices. We consider it inappropriate to issue a compulsory license for this drug in the long term, mainly due to the rather low clinical relevance of the drug.

e. *Rilpivirine/tenofovir/emtricitabine*. It is recommended to work on significant reduction in prices and increase in procurement volumes for this drug as a drug for continuation therapy (2-3-line drug).

4. It is necessary to accelerate the adoption of new recommendations on HIV treatment, the draft of which complies with WHO standards. Thereafter, it is necessary to immediately begin to change treatment standards and HIV treatment procedures.

5. The Ministry of Health of the Russian Federation should continue to optimize ARV therapy regimens used:

   a) Transition to a reduced dosage of efavirenz (400 mg instead of 600 mg);

   c) Increase in the share of patients receiving dolutegravir;

   d) Reduction in the use of lopinavir/ritonavir and etravirine;

   e) Evaluation of the feasibility of further expansion of the clinical use of elsulfavirine until obtaining data specifying the mode of administration, dosage, efficiency and safety profile, including during phase 4 trials[4];

   f) Expansion of the clinical use of the following drugs: rilpivirine, tenofovir/emtricitabine, emtricitabine:

      - *Rilpivirine*: this drug is more preferable for use in NNRTI segment in comparison with etravirine and is a part of the so-called "gentle strategy" regimen (DTG + RPV and DRV + RPV).
      - *Tenofovir/emtricitabine*: this drug is the preferred PreP regimen and the combination basis for the preferred regimen for initiating ARV therapy.
      - *Emtricitabine* (as a separate drug): this drug is a part of the preferred NRTI regimen and may be used as a substitute for PLHIV with lamivudine intolerance.

   For making this expansion possible, the following package of measures is recommended:

      - For all of these drugs: submission of a dossier for inclusion in VED list by any stakeholders.
      - For rilpivirine and tenofovir/emtricitabine: removal of patent barriers, including filing objections to patents by any stakeholders or providing patent holders with letters of waiver of patent rights.

6. The regulatory authorities should reconsider their position on the procurement of combination forms of **life-time drugs**. In our opinion, when procuring ARV drugs, it should be possible to specify in the auction documentation the need to supply a *combination drug*.

7. For expanding the number of options for treating children, the authors appeal manufacturers of children's formulations of integrase inhibitors (dolutegravir and raltegravir) to take measures to bring these drugs to the Russian market as soon as possible.

8. For optimizing treatment regimens, it is necessary to assess the feasibility of procurement of significant volumes of drugs containing zidovudine (azidotimidine), and, where applicable, to reduce these volumes, replacing these drugs with more advance and safe ones.

9. Manufacturers, the Ministry of Health of the Russian Federation, and the Federal Service for Surveillance in Healthcare (Roszdravnadzor) should pay particular attention to the quality

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

standards of ARV drugs, including through additional inspections to ensure the compliance with applicable standards in the field of production and market circulation. Experience of 2018-2019 shows that more detailed monitoring is required in this area. It is also necessary to further strengthen combating counterfeit ARV drugs.

a. *For patient organizations*: to educate people living with HIV to use the pharmacovigilance system, as well as continue monitoring reports of problems with ARV quality and inform the relevant authorities of potential problems;
b. *For medical specialists*: to take the initiative in completing pharmacovigilance forms and provide support to patients and organizations defending their interests in completing such forms;
c. *For pharmaceutical companies*: to continue to respond to patient organizations' requests related to potential problems with the quality of ARV drugs, including ensuring prompt substitution of drugs, if necessary, as well as increasing the transparency of the current quality control and pharmacovigilance system;
d. *For MOH and Roszdravnadzor*: to strengthen the work on quality control (including unscheduled and selective quality control) of ARV drugs.

10. For the Ministry of Health and the Federal Antimonopoly Service: to analyze the current mechanism for determining the maximum starting price of contract to identify and eliminate/correct system flaws that may result in announcement of auctions at prices not allowing suppliers to participate therein. Such analysis should include discussion with market participants (distributors and manufacturers) and public organizations.

11. The practice of allocating separate budgets for ARV procurement at the level of constituent entities of the Russian Federation is positive and should be scaled to the maximum possible number of constituent entities of the Russian Federation.

12. For all stakeholders: these recommendations should be taken into account when developing and approving the new State Strategy to Combat the Spread of HIV in Russia for the period until 2030.

INTRODUCTION

According to the official data[5], as of December 31, 2019, the cumulative number of registered cases of HIV among citizens of the Russian Federation was 1,423,999 persons. Except for deceased, by the end of 2019, **1,068,839 Russians** were diagnosed with **HIV infection** in the country.

According to the preliminary data, **2019, 94,668 new cases of HIV infection** were reported in the Russian Federation (excluding those identified anonymously and among foreign citizens).

In 2019, **33,577 persons living with HIV died from all causes**, which is 8.9% less than in 2018. Tuberculosis remains the leading cause of death among people living with HIV.

In 2019, 776,868 Russians living with HIV were under regular medical check-up, which accounted for 70.5% of the total number of people living with HIV in this period.

In 2019, **534,990 patients** (including 55,273 persons in prison) **received antiviral therapy** in Russia, of whom 36,703 persons discontinued antiretroviral therapy. Treatment coverage in 2019 was 48.5% of the number of people living with HIV, and 68.9% of the number of people under regular medical check-up.

By the end of December 2019, **408,088 patients had the viral load suppressed** (HIV RNA less than 500 copies/ml), which is 76.3% of the number of people receiving ART in 2019. In 2019, 116 510 persons were first taken for antiretroviral therapy, and 81,058 were first taken for regular medical check-up.

The number of new cases of HIV transmission through heterosexual contacts is growing (62.7%). The proportion of HIV-infected people who use drugs decreased to 33.6%. 2.5% of people infected through homosexual contacts.

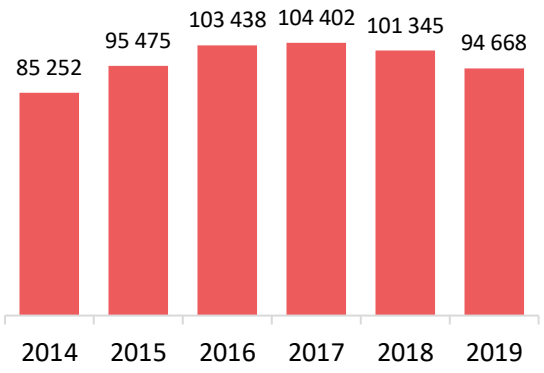

Figure 1. Number of new HIV cases in 2014-2019

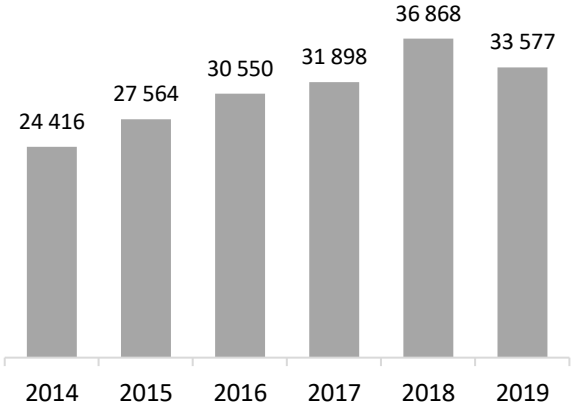

Figure 2. Number of deaths among people living with HIV in 2014-2019

[5]Hereinafter data from the information statement "HIV in the Russian Federation in 2019" Federal Scientific and Methodological Center for the Prevention and Control of AIDS FSFRI of Central Research Institute for Epidemiology of Rospotrebnadzor, http://www.hivrussia.info/na-sajte-razmeshhena-spravka-po-vich-infektsii-v-rossijskoj-federatsii-v-2019-g/

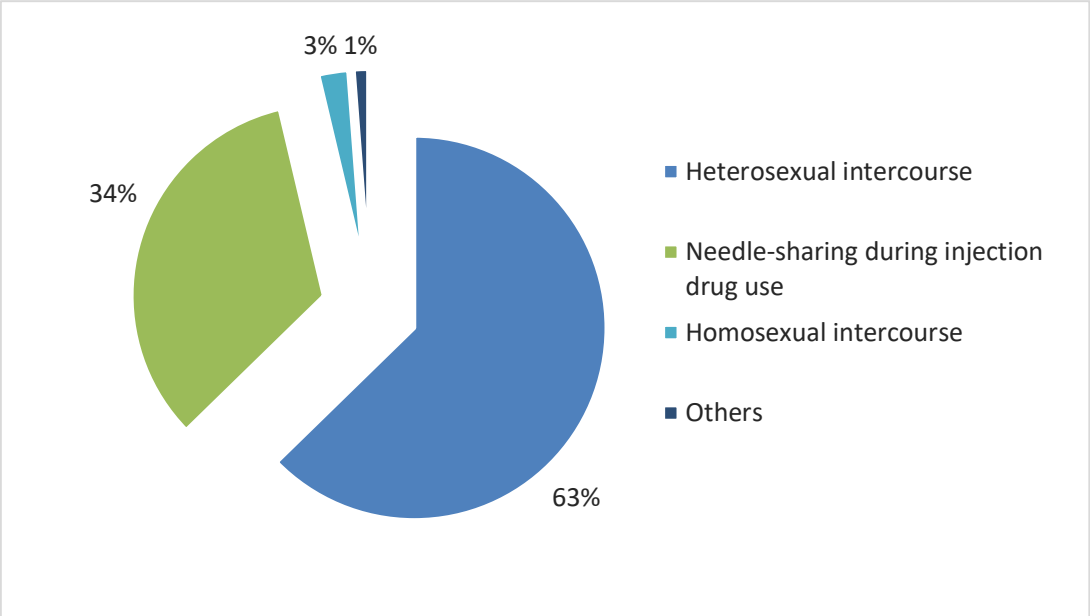

Figure 3. Routes of HIV transmission in 2019

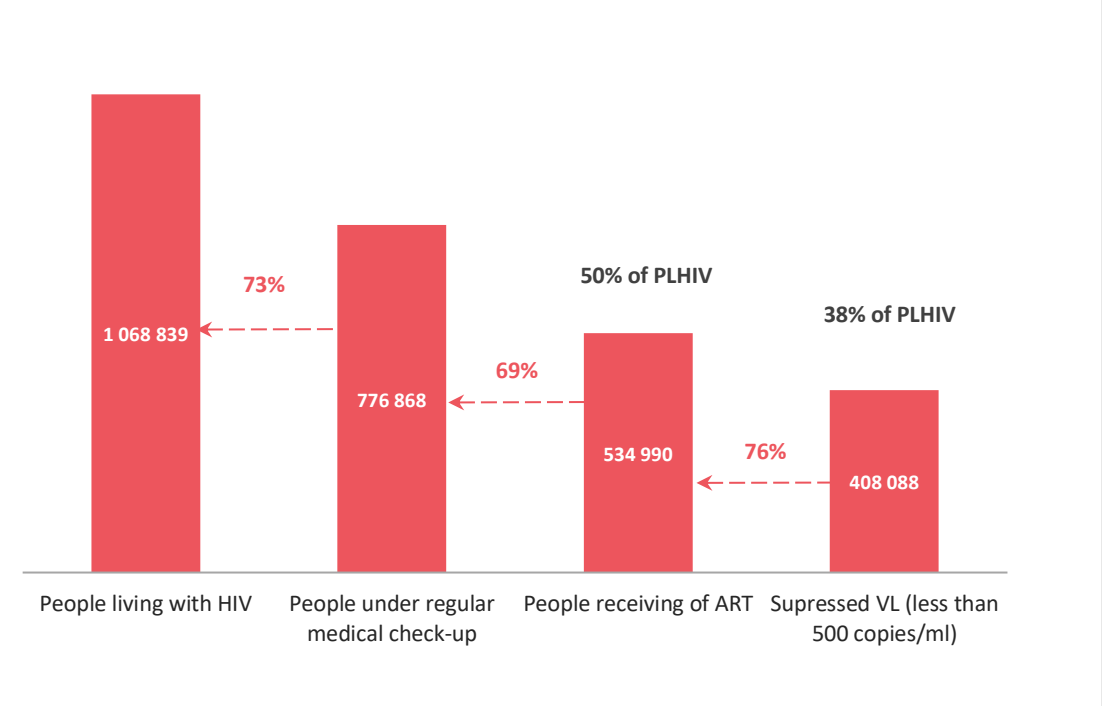

Figure 4. Treatment coverage and effectiveness in the Russian Federation in 2019

ARV PROCUREMENT VOLUMES AND STRUCTURE IN THE RUSSIAN FEDERATION IN 2019

ARV PROCUREMENT VOLUMES

In 2019, the total amount of all procurements was **26,509,339,986** rubles, including:

22,924,992,167 rubles – the total expenses of the Ministry of Health of the Russian Federation in the centralized procurements;

2,474,130,667 rubles – the total amount of all procurements at the level of constituent entities of the Russian Federation;

180,900,594 rubles – the total amount of procurements of federal institutions;

929,316,558 rubles – the total amount of procurements of FPS (independent procurements);

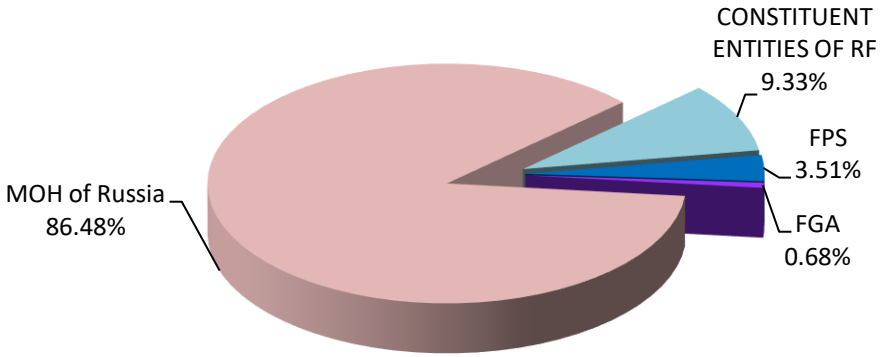

Figure 5. Distribution by the type of budget for ARV procurement in 2019

In 2019, the total expenses of the Ministry of Health of the Russian Federation on antiretroviral drugs as compared to 2018 **increased by 2.399 billion rubles** (+ 11.5% by 2018).

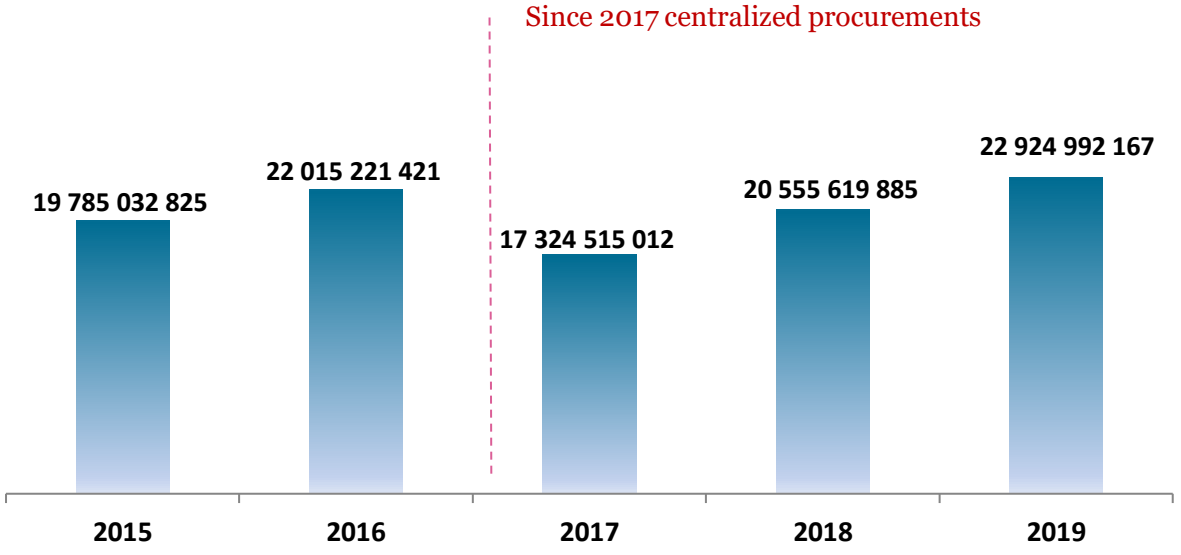

Figure 6. Cost of ARV drugs in the Russian Federation by years
(2015 and 2016 - all procurements, 2017-2019, only the Ministry of Health of the Russian Federation)

ARV PROCUREMENT STRUCTURE IN 2019 BY FUNDS SPENT

In 2019, the bulk of the budget (64.6%) for ARV drugs was spent on the procurement of five drugs:

Table 1. Top 5 by procurement amounts for all contracts concluded in 2019

INN	Contract amount, in rubles	Share of total procurement
LOPINAVIR/RITONAVIR (ALL DOSES)	4,982,684,448.85	18.80%
RALTEGRAVIR (ALL DOSES)	3,656,955,360.68	13.79%
DOLUTEGRAVIR	3,645,892,134.84	13.75%
ETRAVIRINE	2,457,350,095.18	9.27%
RILPIVIRINE/TENOFOVIR/EMTRICITABINE	2,370,048,263.29	8.94%

In 2019, atazanavir, which over the past few years has been consistently ranked among the top five drugs, was no longer included in the top 5 drugs in terms of the amount spent. This happened due to the significant reduction in prices for all doses of atazanavir in procurements of the Ministry of Health of the Russian Federation.

BUDGET ALLOCATION FOR VARIOUS DRUG GROUPS

Based on international and Russian recommendations, the authors of the report provide an analysis by the following groups: 1) NRTI group drugs, 2) so called "third" drugs, including NNRTI, PI, II, CCR5 inhibitors and fusion inhibitors 3) "single-tablet regimen" drugs, 4) ritonavir.

Table 2. Share of the amount of contracts by type of drugs of the total amount of all procurements (by groups, excluding pediatric formulations)

Drug type	Contract amount, rubles	Share of the amount of contracts, %
"THIRD" DRUGS	20,051,496,847.48	75.64%
NRTI	3,498,335,942.18	13.20%
"3 IN 1"	2,370,048,263.29	8.94%
RITONAVIR	589,458,932.82	2.22%
TOTAL	26,509,339,985.77	100.00%

Obviously, the main burden on the budget falls on the procurement of "third" drugs (~ 76% of the total amount).

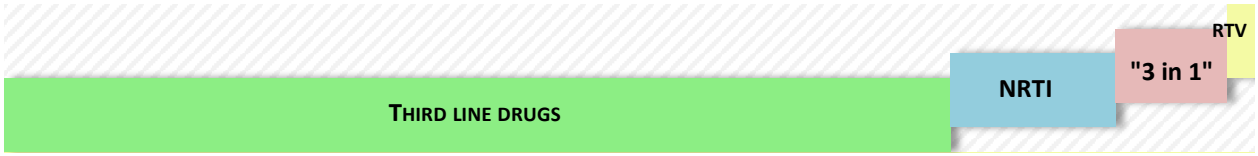

Figure 7. Budget burden in 2019

PROCUREMENT STRUCTURE BY CLASS AND TYPE OF DRUGS

NRTI GROUP DRUGS

In accordance with international and Russian recommendations, lamivudine or emtricitabine should be included in almost all cases in the main NRTI combinations. The number of courses of combination drugs containing lamivudine or emtricitabine was added to the relevant second-line combination drugs.

In 2019, **455,628** courses of lamivudine were purchased (+ 31% by 2018) and **8,189** courses of emtricitabine (-25% as compared to 2018). In total, the number of courses of lamivudine and emtricitabine, in general, corresponds to the purchased volume of other NRTIs, in combination with which they should be used in treatment regimens. All other NRTIs (tenofovir, abacavir, phosphazide and zidovudine) were purchased for **465,918 annual courses**.

Despite the recommendations on the use of emtricitabine in the preferred treatment regimens in the standards and clinical guidelines, its quantity in procurement remains insignificant and even decreased as compared to 2018. This may be explained by the absence of this drug in VED list.

In 2019, the trend to increase tenofovir procurement continued. The number of tenofovir courses increased by 58%, and the share of tenofovir in NRTI group increased from 57% in 2018 to 73% in 2019. Tenofovir is the most procured drug in NRTI class (less lamivudine) and is included **in most HIV treatment regimens in the Russian Federation**.

In 2019, the majority of regimens simultaneously included two NRTIs in the form of separate drugs - tenofovir and lamivudine.

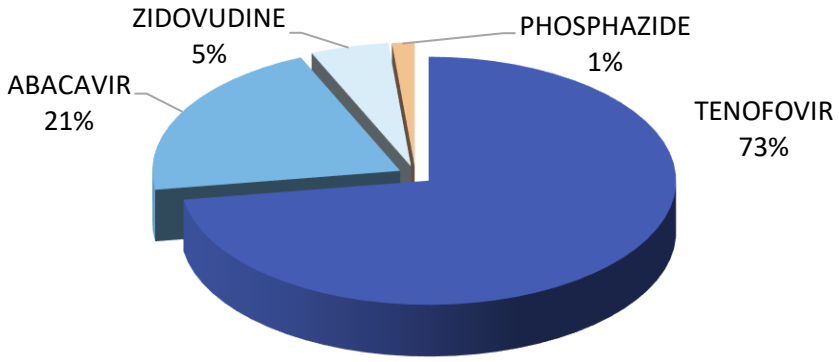

Figure 8. Distribution of NRTIs in the general group (except for lamivudine and emtricitabine)

Table 3. Distribution of NRTI class drugs and dynamics in 2018-2019.

INN	Number of courses 2018	Number of courses 2019	Difference 2018-2019	Share change within the group 2018-2019	Difference in the number of courses 2018-2019
TENOFOVIR	214,489	338,072	123,583	+16%	58%
ABACAVIR	77,868	97,199	19,331	0%	25%
ZIDOVUDINE	70,688	23,815	-46,873	-14%	-66%
PHOSPHAZIDE	13,000	6,831	-6,169	-2%	-47%

It should be noted that obsolete drugs, stavudine and didanosine (didanosine remained in small quantities in the form of a powder for solution preparation), are no longer purchased in the Russian Federation. In 2019, the number of zidovudine courses significantly decreased, however, according to preliminary monitoring data, in 2020, the Ministry of Health of the Russian Federation plans to purchase zidovudine in a volume approximately equal to the volume of 2018. The feasibility of returning to the purchase of zidovudine in such volumes (approximately 70 thousand annual courses) should be assessed, given the reduction that has already occurred in 2019.

CORE DRUGS

In 2019, **464,138** annual courses of core drugs were purchased. The leader in purchased annual courses, as in the previous few years, was efavirenz - almost half of all core drugs.

ARV procurement structure in 2019 by funds spent

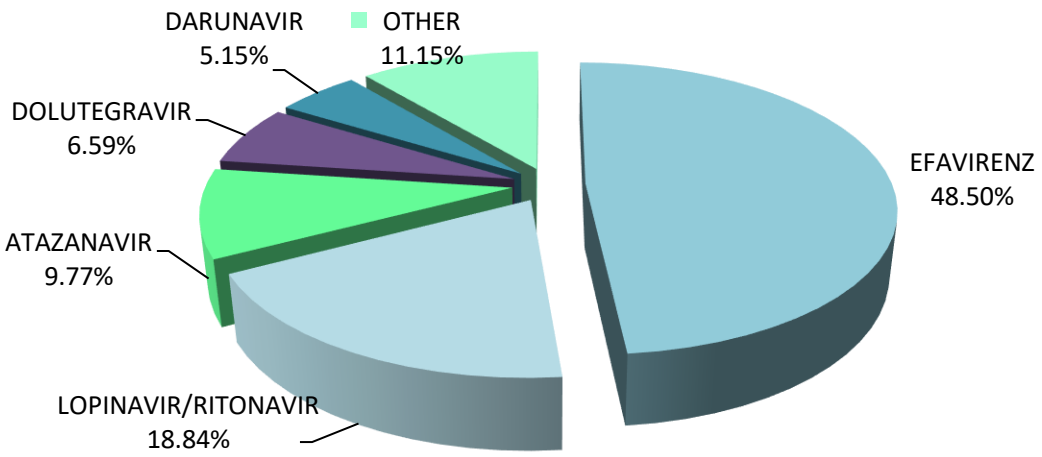

Figure 9. Procurement structure of top-5 core drugs (share by the number of courses)

As compared to 2018, the amount of efavirenz increased by 24% (+44 thousand annual courses), including the dose of 400 mg increased from 3,912 annual courses in 2018 to 12,064 in 2019.

The share of lopinavir/ritonavir in procurement decreased by 5% (-4,747 annual courses).

Owing to a significant reduction in prices, the amount of atazanavir in all doses increased by 53% (+15 804 annual courses).

Table 4. Dynamics of changes in volumes of the core drugs in procurement, 2018-2019

INN	Number of courses 2018	Number of courses 2019	Absolute difference	Difference in %
EFAVIRENZ	181,165	225,239	44,074	24.33%
LOPINAVIR/RITONAVIR	92,032	87,285	-4,747	-5.16%
ATAZANAVIR	29,583	45,387	15,804	53.42%
DOLUTEGRAVIR	14,760	30,571	15,811	107.12%
DARUNAVIR	13,507	23,930	10,423	77.16%
RALTEGRAVIR	9,436	12,452	3,016	31.97%
ETRAVIRINE	9,954	11,569	1,615	16.22%
ELSULFAVIRINE	3,259	8,179	4,920	150.96%
NEVIRAPINE	12,931	7,779	-5,152	-39.84%
RILPIVIRINE*	8,859	7,438	-1,421	-16.04%
FOSAMPRENAVIR	3,671	2,783	-888	-24.18%
SAQUINAVIR	4,274	1,445	-2,829	-66.20%
MARAVIROC	54	81	27	-49.70%
TOTAL	**383,485**	**464,138**	**80,653**	**21.0%**

** here rilpivirine is taken into account as a single drug and as a part of a combination drug*

In addition to efavirenz, other core drugs — dolutegravir, atazanavir, and darunavir — also increased significantly in volume. In updated WHO guidelines for ARV treatment, dolutegravir is recommended as a preferred option in first-line HIV treatment regimens. In Russia, such recommendations are still only in the project, but it should be noted that the number of dolutegravir increased in 2019 - the volumes more than doubled. However, based on the general nomenclature of ARV procurement, dolutegravir accounts for only 7% of the total number of core drug courses, while efavirenz and lopinavir/ritonavir account for 49% and 19%, respectively. 25% of all annual courses are accounted for the remaining 10 INN included in the core drug group.

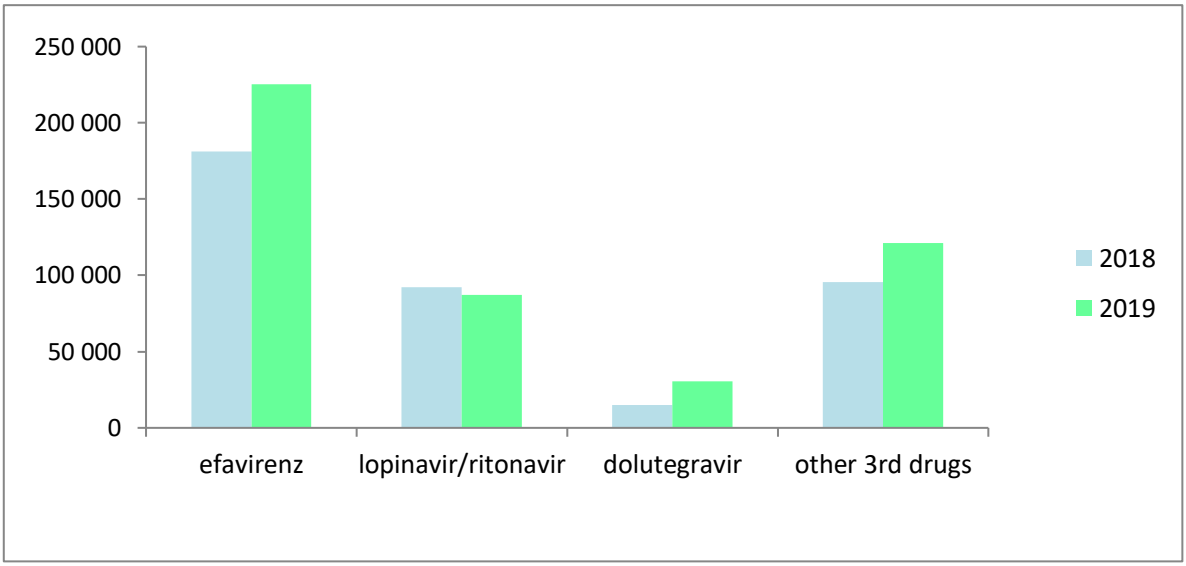

Figure 10. Change in the volume of annual courses of efavirenz, lopinavir/ritonavir, dolutegravir and other core drugs in 2018-2019.

Upon inclusion of elsulfavirine in the List of Vital and Essential Drugs, the number of purchased courses increased 2.5 times (from 3,259 to 8,179 annual courses).

COST OF ARV DRUGS IN 2019

Due to the fact that in 2019 ARV drugs were purchased mainly centrally by the Ministry of Health of the Russian Federation (MOH RF), the analysis is focused on the prices recorded in the bidding of the Ministry of Health of the Russian Federation.

For drugs not purchased by the Ministry of Health of the Russian Federation, data from auctions held at the expense of constituent entities of the Russian Federation and the Federal Government Agency were used.

NRTI GROUP DRUGS

In 2019, the prices for several NRTI drugs have increased significantly.

Table 6. Dynamics of changes in price for NRTI class drugs in procurement, 2018-2019

Drug name	Weighted average per tablet/capsule MOH 2018	Weighted average per tablet /capsule MOH 2019	2018/ 2019, in rubles	2018/ 2019, in %
LAMIVUDINE/ZIDOVUDINE 150/300 MG	4.24	16.28	12.04	283.96%
LAMIVUDINE 300 MG	3.73	7.1	3.37	90.35%
LAMIVUDINE 150 MG	1.89	3.26	1.37	72.49%
ABACAVIR 600 MG	17.34	26.29	8.95	51.61%
TENOFOVIR/EMTRICITABINE 300/200 MG*	392.5	469.06	76.56	19.51%
ABACAVIR 150 MG	4.97	4.97	0.00	0.00%
ZIDOVUDINE 100 MG	2.48	2.48	0.00	0.00%
TENOFOVIR 150 MG	5.82	5.82	0.00	0.00%
PHOSPHAZIDE 200 MG	35.97	35.97	0.00	0.00%
PHOSPHAZIDE 400 MG	35.65	35.53	-0.12	-0.34%
ABACAVIR 300 MG	14.56	14.47	-0.09	-0.62%
ZIDOVUDINE 300 MG	7.34	7	-0.34	4.63%
EMTRICITABINE 200 MG	53.91	46.75	-7.16	-13.28%
TENOFOVIR 300 MG	9.60	6.71	-2.89	-30.10%
LAMIVUDINE/PHOSPHAZIDE 150/400 MG	-	69.35	-	-

** not included in the VED list*

When purchasing the combination drug abacavir/lamivudine by the Ministry of Health of the Russian Federation in 2019, as in the previous two years, the cost of separate components in the contract was higher than in auctions announced for each of the drugs separately.

The main reason for the breakdown of combination drugs is still the position of regulatory authorities and the lower price for separate drugs.

The combination drug, tenofovir/emtricitabine 300 + 200 mg, was purchased only out of regional budgets and the Federal Government Agency, since it was not included in VED list. The price for it is still very high in comparison with its monocomponents and other NRTI group drugs. At the same time, as a result of bidding, in almost half of the cases, the combination drug was purchased as separate drugs. This drug is particularly important since it is currently the main option recommended for use as HIV pre-exposure prophylaxis (PreP). In this regard, it should be noted that the manufacturer no longer plans to submit this combination drug for inclusion in VED list[6]. Such

[6] https://eeca-cat.info/wp-content/uploads/2019/04/Protokol-GSK-16.10.2019.-Final.pdf

inclusion would have made it possible to purchase it in large volumes out of the federal budget, which, in its turn, would ensure further price reduction (price-volume ratio). Unfortunately, due to the fact that the drug is under patent protection, and the patent owner does not plan to include the same in VED list, the situation with access to the combination of tenofovir/emtricitabine remains unsatisfactory.

The absence of emtricitabine in VED list and the registered maximum selling price does not allow increasing its volume out of federal procurements and results in a price dispersion. So, the minimum price in 2019 in the procurement of constituent entities of the Russian Federation was 466.20 rubles, and the maximum price was 3,671.25 rubles per package, provided that these prices were fixed in procurements of the same constituent entity and for the trade name of the same manufacturer.

CORE DRUGS

Prices in contracts of the Ministry of Health for dolutegravir 50 mg, lopinavir/ritonavir 100/25 mg, maraviroc 150, 200 mg, raltegravir 400 mg, saquinavir 500 mg, fosamprenavir 700 mg, rilpivirine/tenofovir/emtricitabine 200/25/300, etravirine 200 mg in the procurements of the Ministry of Health remained the same as in 2018.

Table 5. Dynamics of changes in prices for the core drugs in procurement, 2018-2019

INN	Weighted average per tablet/capsule MOH 2018	Weighted average per tablet/capsule MOH 2019	2018/ 2019, in rubles	2018/ 2019, in %
DOLUTEGRAVIR 50 MG	326.59	326.59	0	0%
LOPINAVIR/RITONAVIR 100/25 MG	56.67	56.67	0	0%
MARAVIROC 150 MG	184.91	184.91	0	0%
MARAVIROC 300 MG	336.05	336.05	0	0%
RALTEGRAVIR 400 MG	459.43	459.43	0	0%
SAQUINAVIR 500 MG	75.17	75.17	0	0%
FOSAMPRENAVIR 700 MG	172.48	172.48	0	0%
RILPIVIRINE/TENOFOVIR/EMTRICITABINE 200/25/300	879.00	879.00	0	0%
ETRAVIRINE 200 MG	288.53	288.53	0	0%
LOPINAVIR/RITONAVIR 200/50 MG	38.15	38.11	-0.04	-0.10%
DARUNAVIR 800 MG	222.97	221.85	-1.12	-0.50%
DARUNAVIR 600 MG	116.11	115.52	-0.59	-0.51%
EFAVIRENZ 400 MG	15.02	14.53	-0.49	-3.26%
EFAVIRENZ 100 MG	3.77	3.64	-0.13	-3.45%
EFAVIRENZ 600 MG	21.98	18.39	-3.59	-16.33%
DARUNAVIR 400 MG	118.20	94.56	-23.64	-20.00%
ATAZANAVIR 150 MG	81.66	17.24	-64.42	-78.89%
ATAZANAVIR 200 MG	108.87	22.18	-86.69	-79.63%
ATAZANAVIR 300 MG	162.50	32.84	-129.66	-79.79%
NEVIRAPINE 100 MG	-	5.8	-	-
RILPIVIRINE 25 MG*	905.77	872.63	-33.14	-3.66%
ELSULFAVIRINE 20 MG**	252.36	218.17	-34.19	-15.5%
EFAVIRENZ 300 MG	-	11.15%	-	-

** not included in VED list*

** in 2018, the procurement price of constituent entities of the Russian Federation

Despite the increase in the volume of the reduced dosage of efavirenz, its share is still insignificant. Efavirenz 400 mg is recommended by WHO as a drug with less toxicity and improved tolerability as compared to efavirenz 600 mg, but is as effective as the latter. Russian recommendations also allow the use of a dose of 400 mg in treatment regimens. The price for 400 mg efavirenz is quite high due to the lack of competition among manufacturers. However, even at this price, if the Ministry of Health of the Russian Federation replaced the purchase of efavirenz 600 mg with a dose of 400 mg, it would be possible to save about 273 million rubles.

Prices for atazanavir in all doses dropped most of all - by almost 80%. Such drop occurred for the first time, despite the fact that generics of atazanavir have been circulating on the Russian market for several years. This corresponds to the trend of the Ministry of Health of the Russian Federation to achieve a reduction in prices for core drugs, the purchase of which imposes a significant burden on the budget. Since the beginning of centralization, the cost of all doses of lopinavir/ritonavir, darunavir and atazanavir significantly decreased.

The price for raltegravir remains almost unchanged for several years. In 2019, it amounted to 27,565.8 per package, despite the localization of the drug production in Russia and the enormous burden on the budget (3.5 billion rubles). In this regard, the authors of the report believe that the price of the drug should be significantly reduced.

The price for elsulfavirine upon inclusion of the drug in VED list for 2019 decreased by 15.5% and amounted to 218.17 rubles per tablet (6,545.10 rubles per package versus 7,570.80 rubles per package in 2018).

Rilpivirine as a separate component is almost unavailable in the Russian Federation: it is not included in VED list, and its price remains stably high (about 320 thousand rubles per patient per annum). Given the clinical relevance and the low cost of the original drug in other markets, measures to increase the availability of rilpivirine in the Russian Federation are required (inclusion in the List of Vital and Essential Drugs and price reduction).

We should also mention the price of dolutegravir, which has remained unchanged for several years. Due to the manufacturer's proposal to reduce the price by 27%[7] in case of increase in the number of courses, which was finally approved by the Ministry of Health of the Russian Federation, the price for a course in 2020 will be **86,884.60 rubles (7,141 rubles** per package). In 2019, the price for an annual DTG course was **119,205 rubles (9,797.70 rubles** per package). However, according to our estimates, the new price is not reasonable.

According to information obtained from publicly available sources, including official press releases[8], ViiV Healthcare (represented in Russia by GSK office) in 2016 provided [9]the Ministry of Health of Brasilia with 70% discount on dolutegravir and price equivalent to **37,956 rubles** per annual treatment course for one patient, subject to the purchase of 100,000 annual treatment courses. At the same time, the company received a satisfactory profit, and the state provided the necessary coverage with an innovative drug.

We believe that this price should become a reference and determining one when deciding on the price for dolutegravir in Russia for the following reasons:

1. Brazil and Russia are BRICS countries.
2. Brazil and Russia are very similar both by the World Bank classification[10], which a company owning the rights to dolutegravir uses as a ground for developing the access policy and the

[7] https://itpcru.org/2019/10/17/kommersant-slozhnoe-preparatnoe-reshenie-farmkompanii-podstraivayut-czeny-pod-spros/

[8] https://viivhealthcare.com/en-gb/media/press-releases/2016/december/new-agreement-with-ministry-of-health-will-enable-access-to-dolutegravir-for-the-treatment-of-hiv-under-the-national-health-programme-in-brazil/#ref

[9] https://www.aidsmap.com/news/jul-2018/brazil-confirms-dolutegravir-most-effective-drug-first-line-hiv-treatment

[10] https://data.worldbank.org/indicator/NY.GNP.PCAP.CD

epidemic scope[11] (while the epidemic spread in Russia is much higher than in Brazil, which means that the need for therapy is potentially higher).

In 2020, the Ministry of Health of the Russian Federation announced purchase of 61,596 courses - this volume is about 62% of the volume purchased in Brazil in 2016. Based on this, we insist that the manufacturer should offer the price for the drug not exceeding **61,489 rubles** per annual course (**5,054 rubles** per package, including VAT).

If a package of measures is implemented in the Russian Federation to provide dolutegravir to 100 thousand people living with HIV or more, the price for dolutegravir manufacture by ViiV/GSK should not exceed **37,956 rubles** per annual course (**3,120 rubles** per package, including VAT), which is equivalent to the price in Brazil in 2016.

Prices for ARV drugs per package in 2019 may be found in Appendix 2. Cost of ARV drugs.

[11] https://www.unaids.org/en/regionscountries/countries/brazil

COST OF THE MOST COMMON TREATMENT REGIMENS

As mentioned above, the most procured NRTIs in 2019 were: tenofovir (72.6% of the total estimated number of purchased annual courses), abacavir (20.9%).

The most procured core drugs included efavirenz (48.5%), lopinavir/ritonavir (18.8%), atazanavir (9.8%), dolutegravir (6.6%), darunavir (5.2%).

Table 8 provides a list of the most procured first-line treatment regimens. The cost of an annual treatment course was calculated at the prices of contracts of the Ministry of Health of the Russian Federation. The cost in US dollars was calculated based on the average annual course in 2019 (1 US dollar – 64.6625 rubles).

Table 7. Cost of PPPY with first-line drugs in 2019

Treatment regimen	Cost per patient per year, 2019	
	in rubles	in US dollars
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + EFAVIRENZ 600 MG	11,753	182
LAMIVUDINE 300 MG + ABACAVIR 600 MG + EFAVIRENZ 600 MG	18,900	292
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + DOLUTEGRAVIR 50 MG	124,246	1,921
LAMIVUDINE 300 MG + ABACAVIR 600 MG + DOLUTEGRAVIR 50 MG	131,393	2,032

Thus, the cost of first-line treatment regimens in 2019 ranged from 11,753 to 131,393 rubles per patient per year.

The most commonly used first-line regimen - **lamivudine 300 mg + tenofovir 300 mg + efavirenz 600 mg – in 2019 amounted to 11,753 rubles (approximately 182 US dollars)** per patient per year. As compared to the previous year, the cost of this regimen decreased by almost 9%.

In accordance with the recommendations of the Ministry of Health of the Russian Federation, the preferred second-line regimens were those containing lopinavir/ritonavir, atazanavir, darunavir, dolutegravir. According to the analysis of ARV procurement structure, they were among the most purchased drugs.

Table 8. Cost of PPPY with second-line drugs in 2019

Treatment regimen	Cost per patient per year, 2019	
	in rubles	in US dollars
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + ATAZANAVIR 300 MG + RITONAVIR 100 MG	25,200	390
LAMIVUDINE 300 MG + ABACAVIR 600 MG + ATAZANAVIR 300 MG + RITONAVIR 100 MG	32,346	500
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + LOPINAVIR/RITONAVIR 200+50 MG	60,681	938
LAMIVUDINE 300 MG + ABACAVIR 600 MG + LOPINAVIR/RITONAVIR 200+50 MG	67,828	1,049
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + DARUNAVIR 800 MG + RITONAVIR 100 MG	94,188	1,457
LAMIVUDINE 300 MG + ABACAVIR 600 MG + DARUNAVIR 800 MG + RITONAVIR 100 МГ	101,335	1,567

The cost of the most common second-line regimens in 2019 ranged from 25,200 to 101,335 rubles per patient per year.

Schemes that include dolutegravir, included in both the first and second lines, depending on the NRTIs in the scheme, cost from 124,246 to 131,393 rubles per patient per year and are the most expensive in both the first and second lines.

It should be noted several relatively common second-line regimens - regimens with etravirine and raltegravir. These are the schemes that are next in terms of "popularity" in 2019 - in total, approximately as many patients received them as the schemes with darunavir. As mentioned earlier, etravirine and raltegravir are among the top five drugs for which most of the budget was spent in 2019.

The cost of treatment regimens with these drugs ranged from 215,668 to 347,571 rubles per patient per year (table 9).

Table 9. The cost of PPPY with etravirine and raltegravir regimens in 2019

Treatment regimen	Cost per patient per year, 2019	
	in rubles	in US dollars
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + ETRAVIRINE 200 MG	215,668	3,335
LAMIVUDINE 300 MG + ABACAVIR 600 MG + ETRAVIRINE 200 MG	222,814	3,446
LAMIVUDINE 300 MG + TENOFOVIR 300 MG + RALTEGRAVIR 400 MG	340,425	5,265
LAMIVUDINE 300 MG + ABACAVIR 600 MG + RALTEGRAVIR 400 MG	347,571	5,375

NUMBER OF PATIENTS RECEIVING ART

Based on the analysis of ARV procurement structure in Russia in 2019, we may conclude that the **purchased number of drugs is designed for approximately 464,138 patients**. This figure **does not** include patients receiving pediatric formulations of drugs[12], doses of which are calculated individually depending on age and body weight.

90.6% of all courses purchased in 2019 fell to the Ministry of Health of the Russian Federation, 5.26% fell to the Federal Penitentiary Service, 3.82% to the constituent entities of the Russian Federation, 0.26% to federal institutions.

Compared to 2018, the number of annual courses for core drugs increased by 21%, or by 80,864 annual courses.

TREATMENT COVERAGE DYNAMICS

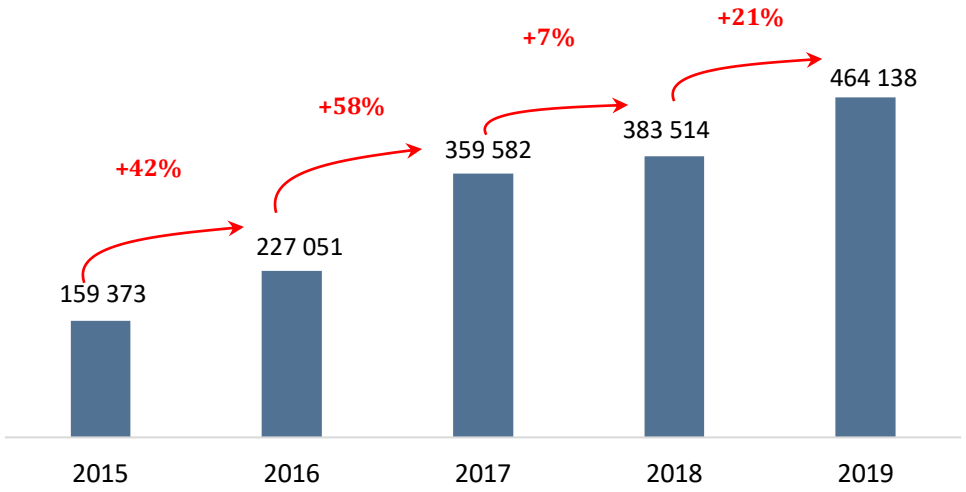

Figure 11. Estimated number of annual treatment courses in public procurements 2015-2019

This analysis does not take into account the situation in which patients begin treatment and interrupt it for one reason or another (according to official data, 36,703 people interrupted ARV therapy in 2019 [13]). The extremely limited distribution of adherence programs, especially targeting vulnerable groups, lack of specialists and limited resources, still, in our opinion, makes refusal of therapy the most likely reason for the discrepancy between the official number of patients on treatment and the number of courses stated in this report.

According to official data, as of December 31, 2019, 776,868 patients with HIV infection were under regular medical check-up. Based on the purchased volume of annual courses in the Russian Federation in 2019, coverage with ARV therapy in 2019 could be 60% of the number of people under regular medical check-up (68.9% according to official data).

It should be noted that with an annual high increase in newly diagnosed cases of HIV infection, an increase in the number of people under regular medical check-up is extremely slow. So, with 94,668

[12] In the calculations, only children's formulations of raltegravir 25 and 100 mg are taken into account.

[13] Data from the certificate "HIV infection in the Russian Federation in 2019" Federal Scientific and Methodological Center for the Prevention and Control of AIDS FSFRI of the Central Research Institute for Epidemiology of Rospotrebnadzor

registered cases of HIV infection in 2019, the number of people registered in the dispensary increased by about 25,000 people. [14]

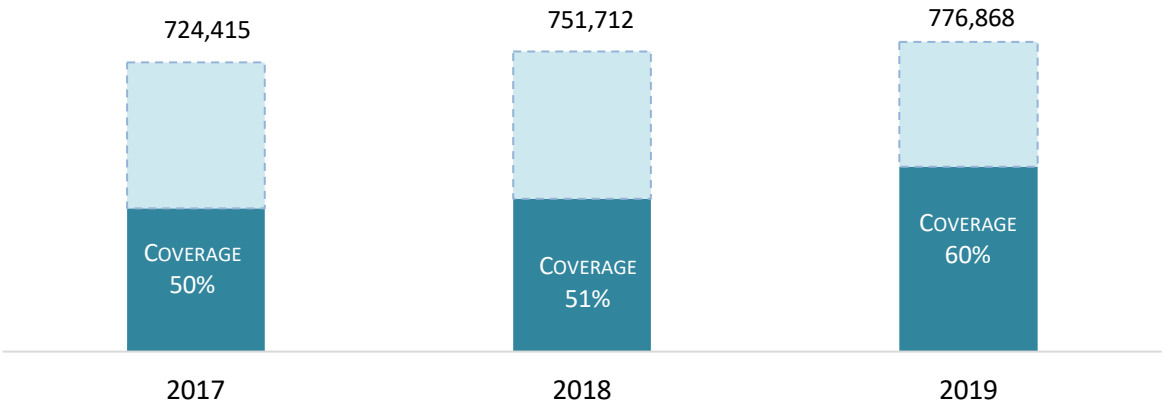

Figure 12. Percentage of treatment coverage on the number of people in the dispensary, based on the purchased amount of ARV drugs in 2019

[14] The problem of bringing patients to hospitals and their registration at the dispensary is not the subject of this publication. At the same time, it is obvious that if all these patients are registered, this, in turn, can cause a serious decrease in the percentage of treatment coverage of the number of patients registered in the dispensary.

APPENDIX 1. ARV DRUGS: REGIMENS

	Preferred ART of the 1st line	Alternative ART of the 1st line	Special cases of ART of the 1st line	Preferred ART of the 2nd line	Alternative ART of the 2nd line	ART of the 3rd line
NNRTI	EFAVIRENZ	NEVIRAPINE ELSULFAVIRINE EFAVIRENZ	RILPIVIRINE ETRAVIRINE	NEVIRAPINE EFAVIRENZ	ETRAVIRINE	NEVIRAPINE
PI			ATAZANAVIR RITONAVIR	ATAZANAVIR DARUNAVIR RITONAVIR	ATAZANAVIR DARUNAVIR RITONAVIR SAQUINAVIR FOSAMPRENAVIR	DARUNAVIR RITONAVIR
INI		DOLUTEGRAVIR	RALTEGRAVIR	DOLUTEGRAVIR	RALTEGRAVIR	DOLUTEGRAVIR RALTEGRAVIR
CCR5						MARAVIROC
NRTI	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
Combined	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

APPENDIX 2. ARV-DRUGS: PER PATIENT PER YEAR COST IN PROCUREMENT OF MOH RF[1516]

Drug name	Cost PPPY 2019, US dollars
ABACAVIR/LAMIVUDINE 600/300 MG*	$572
ABACAVIR 150 MG	$112
ABACAVIR 300 MG	$163
ABACAVIR 600 MG	$148
ATAZANAVIR 150 MG	$195
ATAZANAVIR 200 MG	$250
ATAZANAVIR 300 MG	$185
DARUNAVIR 400 MG	$1,068
DARUNAVIR 600 MG	$1,304
DARUNAVIR 800 MG	$1,252
DOLUTEGRAVIR 50 MG	$1,844
ZIDOVUDINE 100 MG	$84
ZIDOVUDINE 300 MG	$79
LAMIVUDINE/ZIDOVUDINE 150/300 MG	$184
LAMIVUDINE/PHOSPHAZIDE 150/400 MG**	$783
LAMIVUDINE 150 MG	$37
LAMIVUDINE 300 MG	$40
LOPINAVIR/RITONAVIR 100/25 MG	$1,280
LOPINAVIR/RITONAVIR 200/50 MG	$860
MARAVIROC 150 MG	$2,088
MARAVIROC 300 MG	$1,897
NEVIRAPINE 100 MG	$65
NEVIRAPINE 200 MG	$63
RALTEGRAVIR 400 MG	$5,187
RALTEGRAVIR CHEWABLE TABLETS 25 MG	$364
RALTEGRAVIR CHEWABLE TABLETS 100 MG	$1,458
RILPIVIRINE 25 MG*	$4,926
RITONAVIR 100 MG	$126
SAQUINAVIR 500 MG	$1,697
TENOFOVIR/EMTRICITABINE 300/200 MG*	$2,648
TENOFOVIR 150 MG	$66
TENOFOVIR 300 MG	$38
FOSAMPRENAVIR 700 MG	$1,947
PHOSPHAZIDE 200 MG	$609
PHOSPHAZIDE 400 MG	$401
ELSULFAVIRINE 20 MG	$1,232
EMTRICITABINE/RILPIVIRINE/TENOFOVIR 200/25/300	$4,962
EMTRICITABINE 200 MG	$264
ETRAVIRINE 200 MG	$3,257
EFAVIRENZ 100 MG	$123
EFAVIRENZ 300 MG	$126
EFAVIRENZ 400 MG	$82
EFAVIRENZ 600 MG	$104