ANTIRETROVIRAL PROCUREMENT AND SUPPLY CHAIN STRATEGY FOR THE EECA REGION

Countries: Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan

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2020

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List of abbreviations:

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
ATV	Atazanavir
AZT	Zidovudine
CD4	Cluster of Differentiation 4
CIP	Carriage and Insurance Paid
DDP	Delivered Duty Paid
DRV	Darunavir
DTG	Dolutegravir
EAEU	Eurasian Economic Union
EECA	Eastern Europe and Central Asia
EFV	Efavirenz
EMA	European Medicines Agency
EML	Essential Medicines Lists
EU	European Union
EXW	EX-works
FDA	US Food and Drug Administration
FTC	Emtricitabine
GF	Global Fund
GMP	Good manufacturing Practice
HIV	Human Immunodeficiency Virus
IPA	International Procurement Agency
LPV	Lopinavir
MOH	Ministry of Health
NFM	New Funding Mechanism
NGO	Non-governmental Organization
NNRTI	Non-Nucleoside Reverse-Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
PI	Protease Inhibitor
PPM	Pooled procurement Mechanism
PSM	Procurement and Supply Chain Management
r	Ritonavir
RAL	Raltegravir
SD	Sole Distributor
TAF	Tenofovir Alafenamide
TDF	Tenofovir
UN	United Nations
VAT	Value-Added Tax
WHO	World Health Organization

Executive Summary

With millions of HIV-infected people still lacking access to lifesaving ARVs within the EECA region and with funding shifting from the GF to domestic financing, it is critical to adjust procurement and supply chain strategies within the region and the individual countries. The analysis as performed and described in this report about the current situation and challenges shows that, without strategic changes, the fight against HIV will have a significant impact on national budgets and will ultimately impact the treatment of people living with HIV.

A 2019 workshop on the PSM cycle and regulatory framework for ARVs provided an opportunity to understand many of the existing barriers and bottlenecks for ARV procurement within the eight selected EECA countries. Further desk research and online interviews resulted in a better understanding of the situation and challenges in each of the countries. The challenges found at the country level concerned institutional, bureaucratic, and legislation restrictions; a lack of skilled procurement personnel; and specific limitations and barriers to efficient ARV procurement.

The detailed country analyses and interviews identified a significant number of challenges. To overcome these challenges specific recommendations have been developed for each country. These include updating the procurement system and procedures for ARVs, improving forecasting and visibility, improving procurement and supply chain skills, outsourcing procurement and supply chain functions for a multi-level pooled procurement mechanism at national, regional, and international levels, and creating budget flexibility.

The countries analysed all have their own challenges, but a unified strategy for the EECA region would benefit all countries in the region and ensure the treatment of people living with HIV remains affordable. The key solution is to outsource ARV procurement processes. Outsourcing is a strategy that leverages power in numbers to achieve process improvements and reduced costs of procurement.

Best practices in international medicine procurement show the efficiency of pooling procurement at national, regional, and international levels. The EU uses several effective pooling procurement models, including the pooling of specific medicine groups, both with short-term or long-term schemes. The most important result of pooling procurement is the scale effect of pooling, which leads to more acceptable conditions for buyers. From this point of view international pooling procurement has visible advantages. Several countries and regions have experience in pooling procurement. This document will be focus on competitive pooling procurement. Multi-level pooling organisations have several levels of efficiency. This strategy will provide a roadmap for the introduction of a unique competitive procurement system in three high impact countries (Belarus, Kazakhstan, and Moldova).

The ARV procurement and supply chain strategy for the EECA region includes the following elements:

1. Seeking opportunities for greater regional cooperation.

2. Simplifying ARV procurement procedures.

3. Initiating legislative changes for ARV procurement.

4. Outsourcing procurement and supply chain functions to specialised agencies.

5. Advocating for intellectual property flexibility for ARV formulations recommended in the WHO treatment guidelines.

1. Desk study and survey about current PSM systems for ARVs in the selected EECA countries

As part of developing recommendations on how the individual countries and the region can change the procurement and supply chain of ARVs, a desk study and online survey were conducted on the current PSM systems for ARVs in the selected EECA countries.

The desk study included a review on prices paid for key ARV products and a review of publicly available reports related to the procurement and supply chain. To complement the review, two online surveys were developed and shared with government and NGO representatives in the eight selected countries. Six of those countries completed and returned the surveys. The key findings from the desk review and online survey are summarised in this report.

The desk study analysed ARV procurement procedures in the region, as well as other procurement related factors that can impact ARV procurement processes. The data for this analysis was taken mainly from open sources and surveys.

The key challenges found across the countries in the region include the following:

- The relatively low level of demand for ARV products creates an unhealthy competition and supply environment. The lack of registered sources for ARV formulation often results in single source procurements within tender processes in these countries.

- The procurement cycles are lengthy, from the HIV programme identifying a need to the delivery of ARVs to patients. This is mainly due to incorrect forecasts, bureaucratic tender procedures and suppliers not adhering to the agreed delivery timelines.

- Preference is sometimes given to local ARV manufacturers in government tenders, which limits the interest from international ARV manufacturers to participate in tenders.

- Most national-level procurement legislation and guidelines do not allow ARV procurements to be outsourced to IPAs, except to UN agencies. The complex tender procedures and payment terms create barriers for IPAs to participate in government managed tenders.

- Many EECA countries are excluded from voluntary licences issued by innovator companies for new ARV products.

- Budgets for the procurement of ARV products are approved on an annual basis and are often only available in the first quarter of the year, with the requirement that products should be delivered within the same year. These budget regulations make it impossible to negotiate long-term agreements and subsequently the procurement is often conducted in an ad-hoc emergency mode.

- The WHO publishes new treatment guidelines relatively often and the ARV suppliers offer the most attractive prices and supply conditions for ARV products in line with these guidelines. Within the EECA countries the procurement of non-optimal products are often requested, which results in higher prices and less availability.

- There are not enough local producers. This results in dependency on international manufacturers and procurement via local distributors.

Belarus

Introduction

According to the latest estimates (results of 2019)[1], made in collaboration with the United Nations Programme on HIV/AIDS (UNAIDS), the estimated number of people infected with HIV/AIDS in Belarus is about 28,000 and the prevalence of HIV is 0.5% [0.4%-0.6%].

The epidemiological situation regarding HIV/AIDS infection in Belarus:

- Adult and child deaths due to AIDS — <200
- People living with HIV who know their status — unknown
- Adults and children newly infected with HIV — 1 900
- People living with HIV who are on ART — 18 000
- HIV incidence per 1 000 population (all ages) — 0.20
- Coverage of adults and children receiving ART (%) — 63
- Total country-reported HIV expenditure (USD) — unknown

Among the problems in Belarus, the WHO country office highlighted the late diagnosis of HIV. Pharmacies do always have express tests for self-diagnosis. Also, Belarus has no pre-contact diagnosis of HIV. The WHO noted that a working group has already been created in Belarus to develop and implement a new diagnostic algorithm. The aim is to speed up diagnosis, preferably in one day, and for patients to start receiving therapy on the day of diagnosis (or within seven days in some cases, depending on the need for additional testing).

ARV financing has two sources: state budget and GF resources. The ratio for these two sources was 93.5% state funds and 6.5% GF funds in 2019, and 95.6% and 4.4% in 2020. The aim for 2020 was to procure ARVs exclusively via the state budget. A number of past tender procedures for ARV procurement failed, which is why the country applied to the GF for buffer procurement. The ARV purchase aim for 2021 is from state budget funds only[2].

GF transition provisions

GF transition plan for Belarus[3] includes the following main provisions:

- GF funded procurement is not integrated into the national system.
- Supply chain management is integrated into the national system.
- No emergency procurements organized for ARV drugs.

1 https://www.unaids.org/en/regionscountries/countries/belarus

2 https://itpcru.org/strany/belarus/

3 Transition From Global Fund Support and Programmatic Sustainability Research in Four CEE/CIS Countries Belarus Country Report Tamar Gotsadze, MD. PhD 2015

Registration

Fast-track registration is possible in Belarus for WHO-prequalified ARVs, EMA-registered ARVs, or ARVs registered in the USA, Japan and some other countries, but registration usually takes 2-3 months[4].

Non-registered ARVs can be imported with permission from the Ministry of Health, although this is not an available procedure for non-residents who can apply for tenders.

There is no mechanism for the procurement of unregistered medicines if there are registered ones available of the same international non-proprietary name. Unregistered medicinal products are only procured in cases where the procurement of registered medicines was unsuccessful for whatever reason. As a rule, the decision to procure unregistered medicines takes a long time.

GMP quality criteria are only mandatory for non-registered ARVs. For non-registered ARV procurements there are several prequalification criteria:

- The medicine must be registered in one of the following countries: Australia, the United States of America, Canada, Switzerland, Japan, Austria, the United Kingdom of Great Britain and Northern Ireland, Germany, Denmark, the Netherlands, Sweden, Spain, Portugal, or
- The medicine must be EMA registered, or
- The medicine must be WHO prequalified, or
- The medicine is not currently registered in Belarus, but was previously registered (registration ended after 11 May 2015).

Treatment Guidelines

Belarus currently conducts procurement according to the 2017 WHO treatment guidelines and plans to update its guidelines in line with the 2019 version this year. This delay in adopting the guidelines has led to non-optimal ARV products being included in tenders in which fewer suppliers are participating, in turn resulting in higher prices and longer lead times.

Forecasting

State organisation “Belpharmacy” (Belpharmacy) is the responsible institution for ARV forecasting procedures in Belarus[5]. And the forecasting is done based on internal Belpharmacy forecasting procedures. NGOs have no opportunity to participate in formulating technical specifications for the subject of procurement, including forecasting.

Procurement mechanisms

The procurement contract for ARV products under state budget resources is held by Belpharmacy[6]. ARV products under GF programmes are procured through the Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health (RSPC MT). The PPMs are used only for the GF programmes. A state tender procedure could be organised if the government approves the financing of ARV procurement.

Belpharmacy holds the procurement of ARVs via

4 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/belarus/

5 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/belarus/

6 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/belarus/

a tendering procedure for the registered products. If no offers are received for a product or the price offered is higher than the budgeted indicator, the tender for the specific product is considered failed. In that case, the tender can be re-announced one more time. If another tender fails, it becomes single source procurement. This allows for manufacturers and IPAs to be approached directly for a quotation. This procedure is not clearly established anywhere in the law. This results in high prices being offered by the few registered sources or by the single source providers, and often leads to a lengthy procurement process and in turn emergency procurements.

While non-registered products are permitted via single source procurement, the government procurement rules stipulate that a supplier must still comply with the same tender requirements, such as submitting all documentation and products with instructions in Russian or Belarusian and with a delivery period of 30. The short delivery timelines are often not feasible due to the language requirements and/or are not economically efficient for small quantities.

Belarus has a legal regulation for a 15% price preference for local production. This preference can be used if the medicine is fully produced by a Belarusian plant (from active pharmaceutical ingredients to finished pharmaceutical product). If a medicine is only packed and packaged (production from a bulk product) in Belarus, then the products are not entitled to the 15% price preference. This preference applies to goods from other countries that are permitted national regimens in Belarus in accordance with international agreements (Russia, Armenia, Kazakhstan, Kyrgyzstan). The law also states that if two Belarusian or Russian manufacturers participate in the tender, foreign organisations applications should be rejected. These rules apply only to the full-cycle production of a drug.

Belarus has social contracting legislation, but it does not regulate processes for ARV procurement.

Belarus has lacked the possibility of prepayment for a long time now. In accordance with currency control regulations, Belarus residents are obliged to ensure the completion of each foreign trade operation in full upon import □ no later than 90 calendar days from the date of the payment. However, 90 days is not enough to conduct a tender, sign an agreement, submit an application for production, produce or deliver goods, arrange customs clearance, conduct quality control and ship goods. So in most cases it is impossible for goods to be delivered within 90 days from the date of prepayment. Currently, all drug purchases are paid for on a performance basis[7].

Any funds saved from ARV procurement procedures cannot be used in ARV procurement in a following year. In Belarus no VAT applies to ARV drugs, only a 3% customs clearance is applicable.

NGOs have only very limited access to the procurement process through the efforts of volunteers.

Belarus ARV prices are shown in Annex 1.

Distribution

Belpharmacy is the responsible institution for ARV distribution and logistics for the whole country[8]. At the local level, regional pharmacies are responsible for distribution. The country also has long lead times for the delivery of ARV products.

Belarus generally struggles with delivery times for ARV products in the first quarter of a year. The main reason for this is the late deadline for approval of the procurement plan. As a rule, the procurement plan for supplying drugs in the first quarter of the next year are finalised in September. The plan is developed so late because the preliminary budget for a following year is not known until September. And only after this information is available can a drug

7 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/belarus/

8 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/belarus/

procurement plan be approved. And it still takes time to conduct a tender, conclude a contract and deliver products. As such the supply of drugs is seriously delayed.

Belarus practices require the supply of drugs once every quarter, so four times a year.

The reason for this is that funding is given on a quarterly basis. Unregistered medicines are an exception they can be delivered in one to two batches.

Reforms

In 2019, the Ministry of Health discussed scenarios for reforming the ARV procurement system. This should create opportunities for procurement through IPAs or directly from manufacturers.

Belarus has already started taking concrete steps to modernise the ARV procurement system. One of those steps is that the government now pays for ARV procurement and most of the purchased drugs are produced in Belarus.

Georgia

Introduction

According to the latest estimates (results of 2019)[9], made in collaboration with the United Nations Programme on HIV/AIDS (UNAIDS), the estimated number of people infected with HIV/AIDS in Georgia is about 9,100 and the prevalence of HIV is 0.4% [0.2%-0.6%].

The epidemiological situation regarding HIV/AIDS infection in Georgia:

- Adult and child deaths due to AIDS — <100
- People living with HIV who know their status — 5 900
- Adults and children newly infected with HIV — unknown
- People living with HIV who are on ART — 5 100
- HIV incidence per 1 000 population (all ages) — unknown
- Coverage of adults and children receiving ART (%) — 56
- Total country-reported HIV expenditure (USD) — 15,900,000

HIV prevention and treatment and care services have been free of charge at the point of care (excluding co-payments for substitution treatment discontinued in 2017). For the period of the current HIV/AIDS National Strategic plan (2019-2022), universal access to HIV services will remain in place. In addition, access to several services will be expanded[10].

First-line ARVs are fully covered by state funds. Second-line ARVs are procured at the expense of both state and GF grant funds, 70% and 30% respectively. Funds are generally distributed when the annual budget is set and approved both for grant and state funding. State financing for ARV drugs started in 2015, and for other ARV related products in 2017. The division of government and donor spending for second line ARVs for 2021 is 85% and 15% respectively[11].

GF transition provisions

The main GF transition efforts in Georgia are the following[12]:

Funding for the national HIV national response in Georgia has been increasing and is projected to continue rising as the number of diagnosed HIV cases is expected to rise substantially. Also, international, and national targets call for increased

9 https://www.unaids.org/en/regionscountries/countries/georgia

10 GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 - 2022

11 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

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coverage and access to prevention, treatment and care services.

After the GF transition, Georgia plans to continue using the current procurement mechanisms, as Georgia procures small quantities and wishes to guarantee high quality and low prices. Georgia's HIV/AIDS National Strategic plan stipulates that all ARV procurement should be handled by IPAs. The procurement mechanism may have to change after the transition period due to GF regulations, but this mechanism remains one of the most convenient and cost-effective for quality assured drugs. There are also plans to review the state procurement law and relevant regulations to identify potential barriers for non-state actors.

In the past years, the national HIV/AIDS expenditure has increased. From 2016 to 2018, the total annual expenditure for HIV response increased by 17% and is expected to remain atapproximately 26 million USD per year throughout the 2018-2022 period.

As the transition process from the GF funding to domestic funding intensifies, the national HIV funding will undergo a profound transformation in funding sources. Compared with 2016, the plan is to increase annual domestic expenditure by 45% for 2022 and for it to account for 96% of the total projected expenditure for HIV. This will also include services currently funded by the GF.

International funding mostly received from the GF is projected to nearly halve from 2016 to 2022 and will account for only 3% of total HIV funding in 2022, compared to 28% in 2016. Overall, for the following period (2019-2022), the plan is to increase annual expenditure for prevention by 15%, compared to 2018. If Georgia uses national procurement regulations for ARV procurement after the GF transition period, it will not allow for the purchase of non-registered ARVs.

Registration

According to national legislation, the import of non-registered ARVs is permitted provided it has markings in English, Russian or another EU language[13]. In the case of other languages, a Georgian patient information leaflet must be attached. Only products from locally based pharmaceutical companies are registered in Georgia: Ritonavir (Norvir), Lopinavir-Ritonavir (Aluvia) and Raltegravir (Isentress). This poses no issues however, because of the flexible mechanisms of non-registered ARV procurement and fast-track registration procedures for recognised products.

Georgia does not have a fast-track registration procedure for WHO prequalified products. However, Georgia uses a "recognition procedure", which is a fast-track timeline with fewer requirements. Recognition procedures cover medicines that are formally recognised by the EMA, FDA and regulators of certain developed countries. The administrative procedure takes up to seven days, from the submission of documents to the product being added to the registry. This mechanism could also be very efficient in the case of changes to treatment regimens or for other non-predictable situations.

A GMP certificate is one but not the only mandatory requirement for ARV tendering procedures. Some products have additional requirements such as being on the GF eligibility list or registration in an EU country, or WHO prequalification. Georgia mostly follows the criteria set by the GF[14].

13 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

14 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

Treatment Guidelines

Georgia follows the WHO 2019 treatment guidelines.

Forecasting

The National AIDS Center of Georgia is the main organisation responsible for ARV forecasting and the development of treatment guidelines[15]. Forecasting is based on the dedicated methodology of the National AIDS Center and on GF recommendations. NGOs are not directly involved in the forecasting process. They mostly participate in monitoring the access and availability of ARVs for HIV positive people.

Procurement mechanisms

The National Center for Disease Control and Public Health and the GF are the two main organisations responsible for the procurement of ARV and HIV test systems in Georgia[16]. ARV procurement in Georgia is carried out through the GF PPM, which ensures the procurement of quality products at a low price.

Georgia use simplified procurement mechanisms which allows it to avoid e-tendering (the main procurement method according to national procurement legislation) and which allows for agreements with IPAs. Based on its procurement scheme, Georgia can cooperate with IPAs with 100% prepayment. There are no legal limitations for buying brand or generic ARV.

Since 2014 Georgia has used PPM for international direct procurement of ARVs through IPAs. The country uses a wide range of international procurement mechanisms for ARV and TB procurement, such as PFSCM, i+solutions, IDA Foundation, UNICEF, UNOPS and the wamboo.org platform. Permission for this scheme is annually approved by the corresponding legislative act.

The current challenge in the procurement system is that legislation stipulates a limitation of one-year contracts for ARV procurement. Like in some other EECA countries, Georgia has no mechanism for supporting local ARV manufacturers in the procurement process. As such, Georgia has no local ARV manufacturers. This factor creates opportunities for equal competition.

Any savings made on state funded ARV procurement cannot be used in ARV procurement a following year. In the case of GF grant programmes these savings could be used for additional second-line ARV procurement.

Georgia does not apply VAT on ARVs or any other drugs. When drugs are procured under grant agreements, a special waiver is obtained from the Ministry of Finance for exemption from any taxes for ARV import. Financial resources saved in ARV procurement procedures can only be used for ARV procurement in a following year if those resources are from donor funding[17].

ARV prices in Georgia are shown in Annex 1.

15 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

16 Mentioned sources analyzed and used some materials in this section LAW OF GEORGIA ON PUBLIC PROCUREMENT, 20 April 2005, N1388-IS; Order No 2 of the Chairman of the State Procurement Agency February 10, 2011 on Approving the Rules of Reporting of Procuring Entities, Published on11.02.2011 Registered at the Ministry of Justice of Georgia Registration Code 040.170.050.21.014.016.011

17 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

Distribution

The National Center for Disease Control and Public Health in Georgia and the National AIDS Center of Georgia are responsible for ARV warehousing at the central and district levels[18]. In recent year there have been no delays on ARV deliveries.

Under the GF grant, several initiatives will be carried out in the following years to ensure the proper functioning of existing procurement and supply chain systems currently utilised by the National Center for Disease Control and Public Health. The outcome of these initiatives will include the establishment of a new warehouse at the Lugar Center and the introduction of a logistics management information system. Policy dialogue will take place to decide which national agency/structure will assume responsibility for the procurement and supply of HIV products. If this responsibility is shifted from the National Center for Disease Control and Public Health and transferred to another structure, such as the Social Service Agency, which currently procures health commodities for other state health programmes, additional capacity building activities will be required[19].

As a result of the COVID-19 situation, Georgia has experienced logistical problems for ARV and other deliveries. This reflects negatively on freight prices, as the country only imports small quantities of ARV drugs. Freight costs can sometimes be up to 50% of the product price. This creates difficulties for governmental procurement, with the cost of PSM being higher than the cost of the product itself.

Reforms

Georgia has no plans for ARV procurement reform, as the current system of using international agencies is considered the best practice.

18 Mentioned sources analyzed and used some materials in this section TRANSITIONING FROM DONOR SUPPORT FOR TB & HIV IN EUROPE GEORGIA: ENSURING TIMELY ACCESS TO AFFORDABLE QUALITY ASSURED DRUGS; GEORGIA HIV/AIDS NATIONAL STRATEGIC PLAN 2019 – 2022; HIV/AIDS treatment and care in Georgia Evaluation report September 2014; https://itpcru.org/strany/georgia/

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Kazakhstan

Introduction

According to the latest estimates (results of 2019),[20] made in collaboration with the United Nations Programme on HIV/AIDS (UNAIDS), the estimated number of people infected with HIV/AIDS in Kazakhstan is about 33,000 and the prevalence of HIV is 0.3% [0.3%-0.3%].

The epidemiological situation regarding HIV/AIDS infection in Kazakhstan:

- Adult and child deaths due to AIDS — <500
- People living with HIV who know their status — 26 000
- Adults and children newly infected with HIV — 3 700
- People living with HIV who are on ART — 18 000
- HIV incidence per 1 000 population (all ages) — 0.20
- Coverage of adults and children receiving ART (%) — 52
- Total country-reported HIV expenditure (USD) — 35,200,000

In Kazakhstan, medicines for treating HIV are purchased by state funds. The funds are transferred directly from the national budget to the Social Health Insurance Fund. The Ministry of Health in coordination with the Social Health Insurance Fund develops a budget request that includes all necessary calculations such as the number of patients and required quantities of medicines.

ARV treatment is completely free of charge for patients. All expenses are covered by the government[21].

GF transition provisions

Kazakhstan is the only country among the five Central Asian countries in this report that exclusively finances ARVs with state budget resources.

As such, Kazakhstan has no GF transition plan.

Registration

A mandatory condition for obtaining state registration, re-registration and modification of a drug registration dossier is that the manufacturing organisations must have a GMP certificate[22]. A GMP prequalification is mandatory for single source procurement. Kazakhstan experiences bottlenecks in its legislation for non-registered drug imports. Registration under the WHO Prequalification of Medicines Programme is a very long process and can officially take up to 135 working days, and in actual practice up to one year.

20 https://www.unaids.org/en/regionscountries/countries/kazakhstan

21 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

22 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

Non-registered drugs can be imported with approval from the Ministry of Health if the product has WHO prequalification. Only in the case of emergencies can non-registered drugs be imported without WHO prequalification. All markings for non-registered drugs must be in the country's official language. An exception is import through UN agencies, who can import without registration and without mandatory language marking[23].

Treatment Guidelines

Kazakhstan fully follows the WHO 2019 treatment guidelines[24].

Forecasting

Kazakhstan has a high level of waste of ARV drugs because of non-efficient forecasting and distribution procedures[25]. It has no specific system for ARV forecasting. No NGOs are involved in the ARV forecasting process in Kazakhstan.

Procurement mechanisms

Public procurement legislation in Kazakhstan does not include the procurement of medical products, including ARVs, in the framework of its Statutory Free Medical Assistance programme or in its Mandatory Social Health Insurance system. Medical products intended for the Statutory Free Medical Assistance programme and additional medical care are purchased under their international non-proprietary names, and in the case of individual patient intolerance under the trade names. In the case of procurement of a poly component medicinal drug, its composition must be specified.

ARV procurement in Kazakhstan is held by state enterprise SK-Pharmacy, which is the sole distributor of health products and medicines for government and state health institutions. Kazakhstan uses single source procurement mechanisms, long-term contracting mechanisms with local manufacturers, and international procurement mechanisms fixed by international agreements with UNDP and UNICEF. The main evaluation criteria for ARV procurement are: price, product registration, labelling conformity, consumer packaging and instructions, and a registered price for trade names. According to international agreements, the sole distributor can organise ARV procurement through UN agencies. In some cases when ARV procurement is conducted by UN agencies in Kazakhstan, ARV product registration is not mandatory. Full prepayment may apply for this method of procurement.

The Kazakhstan state procurement legislation for ARV drugs offers a large range of preferences to local manufacturers. These include price preferences during the procurement process, permission to procure local non-WHO prequalified ARV products, and long-term contracts of up to 10 years. This process creates non-health competition for ARV procurement and step-by-step low interest rates for international manufacturers in this market. Local manufacturing mainly involves the re-packaging of ARV drugs.

The country is currently changing protocols for new ARV products, allowing these to be procured through IPAs rather than local manufacturers. No municipal-level procurement is practised in Kazakhstan. All ARV procurement is organised by centralised mechanisms. Kazakhstan is a member of the Eurasian Economic Union together with Belarus, Russia, Armenia and Kyrgyzstan.

23 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

24 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

25 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

These countries share single market regulations, which give Kazakhstan the opportunity to use other member country's brand holder prices and import them into Kazakhstan with the same conditions.

ARV prices are shown in Annex 1.

It should be noted that in 2018 the Ministry of Health introduced a new law stipulating that it only purchases original drugs for the treatment of children. As such, the sole distributor conducts separate bidding procedures to provide drugs for children. Generics are purchased for all other patients. No social contracting is practised for ARV procurement in Kazakhstan.

There are some special procurement aspects for organisations incorporated by the United Nations General Assembly:

- Procurement is carried out according to the sole distributor's list.
- Quotations (prices for medical drugs; additional charges for delivery) must not exceed the marginal prices.
- Medical drugs should include the following: existing registration, labelling conformity, consumer packaging and instructions, existing registered price for a trade name.
- Shelf life and transportation conditions in accordance with the submitted quotation.
- An advance payment is permitted in the amount specified in the agreement.
- Third parties may be engaged to organise the delivery of goods.
- In accordance with Kazakhstan legislation, the following requirements apply to suppliers: experience in the Kazakhstan market, solvency, presence of unfair suppliers in the list or suspension of activities, bankruptcy, and legal capacity.

Each year the Ministry of Health sets maximum prices for generics. These prices apply to all methods of procurement. Financial resources saved in ARV procurement procedures cannot be used for ARV procurement in a following year.

Since Kazakhstan has purchased drugs through the UNICEF mechanism for over a year, price reductions in 2018 ranged from 2.45% to 21.69% (in 2017 from 4.68% to 96.91%)[26].

Distribution

The sole distributor applies centralised mechanisms to the standard distribution and logistics mechanisms for ARV drugs, as also used for other procured and distributed drugs[27]. Kazakhstan follows good distribution practices in its activities.

Kazakhstan has delivery delays at the regional level. The main reason for this is insufficient information exchange mechanisms between AIDS centres, and insufficient forecasting. No buffer stocks are stored in regional AIDS centres.

The late approval of ARV lists by the sole distributor results in delays in the procurement process and delivery of ARVs. This is likely the result of frequent changes in treatment regimens. NGOs have limited functions in the ARV delivery monitoring process and preparation of ARV procurement reports. The main challenge for ARV procurements through UN agencies is on-time delivery.

Reforms

At this moment Kazakhstan has no plans for any significant changes to the current ARV procurement legislation.

26 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

27 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kazakhstan/

Kyrgyzstan

Introduction

According to the latest estimates (results of 2019)[28], made in collaboration with the United Nations Program on HIV / AIDS (UNAIDS), the estimated number of people infected with HIV / AIDS in Kyrgyzstan is about 10,000 and the prevalence of HIV is 0.2% [0.2% -0.3%].

The epidemiological situation regarding HIV/AIDS infection in Kyrgyzstan:

- Adult and child deaths due to AIDS — <500
- People living with HIV who know their status — 6 300
- Adults and children newly infected with HIV — 1 000
- People living with HIV who are on ART — 4 100
- HIV incidence per 1 000 population (all ages) — 0.25
- Coverage of adults and children receiving ART (%)— 40
- Total country-reported HIV expenditure (USD) — 6,900,000

HIV treatment is free of charge for all patients in Kyrgyzstan.

GF transition provisions

Until 2018, the entire need for ARV drugs was covered by the GF, and from 2011 to 2018 procurement was carried out by UNDP, the main recipient of the GF funds[29]. In the face of shrinking donor funding since 2016, a transition process has been initiated in Kyrgyzstan for state funding of HIV prevention and treatment programmes.

There are now two sources for the supply of ARVs. Some ARVs (Tenofovir, Atripla, Truvada) are procured under the state budget. These amount to 40% of the total need. Others are supplied within the framework of the GF funds through UNDP.

A roadmap for the transition to public funding has been developed and approved. It includes a series of actions to improve access to HIV treatment, including the allocation of public funds for the purchase of ARVs, improvement of registration mechanisms, timely development of clinical protocols, updates to the guidelines and improvements to procurement mechanisms.

According to the roadmap and joint procurement plan prepared as part of the country's 2018-2020 application to the GF, the following percentages are envisaged for the two ARV procurement sources: 20% from state budget in 2019 and 30% in 2020 and the rest from GF funds.

28 https://www.unaids.org/en/regionscountries/countries/kyrgyzstan

29 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

Registration

The drug registration process in Kyrgyzstan usually takes 180 days[30]. If information is needed from third parties for the registration process, another 180 days is added. If the submitted package of documents is incomplete, the authorised body sends a request for the submission of missing information or documents. The term for providing information is 90 days from the date of the request. This term for submitting missing data and/or documents is not included in the period of the primary review.

Fast-track registration may be requested for medicines on the WHO Prequalified Medicines List as well as medicines registered with regulatory authorities such as the FDA, EMA (under centralised procedure), Japanese Pharmaceuticals and Medical Devices Agency, Swiss Therapeutic Products Agency (Swissmedic) and the UK Medicines and Health Products Regulatory Agency. There are no laboratory tests for expedited testing for medicine registration. Testing takes 45 days from the date of application.

Applicants registering orphan drugs and medicines received through humanitarian aid (including from the GF) are exempted from paying the costs associated with the registration of medicines in the manner approved by the government of Kyrgyzstan. This regulation was effective until 31 October 2020. It no longer applies now since Kyrgyzstan is a member of the EAEU, and new regulatory documents were adopted within the union in 2016, introducing uniform standards for registration and circulation of medicines from 2021.

A separate list of medicines is still temporarily allowed for import and medical use without registration. That list includes the following:

- Medicines for the treatment of rare and socially significant diseases.
- Medicines for the prevention of vaccine-preventable infections and for epidemiological indications.
- Medicines needed for preventive measures in the case of an outbreak and complications in the epidemiological situation of infectious diseases.
- Medicines required for humanitarian aid in health programmes.

Non-registered ARVs can be imported with packaging and instruction in languages other than the national language.

Kyrgyzstan is in need of improvement in terms of legislation for the import of non-registered drugs and for the creation of more flexible conditions for applications in procurement processes with non-registered ARV drugs. All currently procured ARVs are either WHO prequalified or FDA approved, including drugs procured under the state budget. GMP criteria are not mandatory for the national procurement of ARVs[31].

Treatment Guidelines

Kyrgyzstan does not fully follow the WHO 2019 treatment guidelines. The nomenclature for ARVs is formed in accordance with national treatment guidelines, the list of essential drugs, and available drugs on the local market. Due to budget limitations, this leads to the exclusion of purchasing expensive drugs.

30 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

31 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

Forecasting

The Kyrgyzstan National AIDS Center is responsible for treatment guideline development and ARV forecasting processes[32]. NGOs are also involved in these processes. NGOs also have access to ARV pricing procedures.

Procurement mechanisms

The procurement of medicines for HIV treatment in Kyrgyzstan is carried out according to the law on HIV/AIDS, which guarantees access to all types of health care and drugs for people living with HIV/AIDS, free of charge and on preferential terms[33]. This is in line with the Program of State Guarantees for the Provision of Citizens with Health Care.

ARV procurement under GF financing with UNDP as the grant recipient is conducted through UNDP procurement procedures. The purchase of medicines, diagnostic tests and other consumables through public funds is conducted centrally by the Kyrgyzstan National AIDS Center in accordance with the law on public procurement.

After the transition period, ARV procurement will be conducted through national procurement mechanisms. Local drug manufacturers have no price preference in tender processes. Also, there are limited opportunities for ARV procurement by single source procurement procedures, and Kyrgyzstan has no pooling procurement experience.

The coming years will see a growing need for HIV medicines, which will soon have to be covered entirely by the state budget. The procurement of ARVs through IPAs is a major problem in the health system, but Kyrgyzstan is currently exploring options for more efficient mechanisms. Although current legislation does not provide for regional procurement, Kyrgyzstan is interested in exploring regional PPMs and framework agreements. Social contracting is practised in Kyrgyzstan, but not for ARV procurement.

Financial resources saved in ARV procurement procedures cannot be used for ARV procurement in a following year.

The majority of EML drugs are exempted from the regular 12% VAT. The EML however has not been updated since 2018 and so some ARV drugs are not included in that list. As a result some ARV drugs are taxed with VAT [34].

Distribution

The National AIDS Center is responsible for ARV logistics and distribution at a central and municipal level[35]. ARV procurement is organised at a central level for the whole country. Kyrgyzstan does not experience any significant problems with on-time delivery of ARVs.

Reforms

Since 2017, the Partnership Network Association, a local NGO that advocates for equal rights and better health for everyone, has twice initiated a process of amendments to the current law on public procurement[36]. The changes would allow EML drugs to be purchased under the state budget through international procurement mechanisms.

32 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

33 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

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36 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/kyrgyzstan/

A draft of law has been prepared, including a justification note, comparative table and draft amendments. This draft met with very strong opposition from the pharmaceutical industry and parliamentarians. It has been rejected twice by the country's parliament, but efforts for the reform are still ongoing.

Changes have become necessary amid dwindling donor funding and increased procurement under state funds. The option of conducting procurement through international organisations would significantly reduce the risks of corruption in public procurement. Purchasing experience in 2018 and 2019, as well as a number of studies, show that the prices of drugs purchased in the local market are twice as high, which is partly due to the monopoly position of a number of pharmaceutical companies and to corruption in the procurement process.

Moldova

Introduction

According to the latest estimates (results of 2019)[37], made in collaboration with the United Nations Program on HIV / AIDS (UNAIDS), the estimated number of people infected with HIV / AIDS in Moldova is about 15,000 and the prevalence of HIV is 0.7% [0.6% -0.9%].

The epidemiological situation regarding HIV/AIDS infection in the Republic of Moldova:

- Adult and child deaths due to AIDS — <500
- People living with HIV who know their status — 9 400
- Adults and children newly infected with HIV — 1 000
- People living with HIV who are on ART — 6 700
- HIV incidence per 1 000 population (all ages) — 0.23
- Coverage of adults and children receiving ART (%) — 46
- Total country-reported HIV expenditure (USD) — 8,700,000

Since 2014, the Ministry of Health, Labour and Social Protection has used state budget resources to purchase all first-line ARVs for adults and adolescents, and since 2015 also some second-line drugs, all HIV test consumables (for hospitals, clinics and primary care centres) and CD4 and VL tests for patients receiving ARV treatment. HIV treatment is free of charge for all patients. Since 2017, HIV prevention among high-risk groups has been partially funded by the Compulsory Health Insurance Funds. During the reporting period, the amount of state funding for HIV programmes increased by 11%. In 2019, state expenditure related to the national response to the HIV epidemic rose by about 28.8%, from 4.22 million USD in 2018 to 5.43 million USD in 2019. Contributions to the response to the HIV epidemic from international resources decreased by about 7.6%, from 4.1 million USD in 2018 to 3.59 million USD in 2019. Dependence on donor funding persists, representing about 40% of the total spending in 2019. Particularly low funding is typical for HIV prevention. The share of state expenditures for HIV prevention in key populations covers only about 10% of the total prevention expenditure.

ART-related expenditures have decreased significantly over the past three years after the optimisation of ART regimens from 18 to 8 with the wider use of ART analogue (generic) preparations and the introduction of dolutegravir.

The main challenges are the following:

- Ensuring the continuation of the state takeover of the national program activities currently financed by GF sources. This is essential to ensure the sustainability of the national program.
- Increasing access to ART, by decentralising and bringing specialised services closer to the patient (district level), and ensuring sufficient medical staff specialised in HIV/AIDS.

37 https://www.unaids.org/en/regionscountries/countries/republicofmoldova

GF transition provisions

The plan for transitioning from donor funding to public funding and ensuring the sustainability of the activities under the national program has been developed in accordance with the national program for the Prevention and Control of HIV/AIDS and STIs for 2016-2020. This plan[38] includes two basic aims: modifying policies, practices, and regulatory documents to ensure the sustainability of the activities provided by the national program and determining the estimated costs of supporting HIV prevention activities. The national program budget for the period 2021-2025 includes actions for the transition to state funding and continues the upward trend in the share of state funding. To improve the planning and coordination process, related activities will be reflected in detailed operational plans rather than an updated individual transition plan.

The two main directions of the transition plan are as follows:

- Developing a legislative basis for ARV procurement through IPAs.
- Updating, optimising and approving HIV treatment protocols.

Starting from 2021 all ARV procurement will be covered by state budget resources.

Registration

Moldova has a low level of registered ARVs. The involvement of suppliers in the registration of generic ARVs in Moldova is a priority. A fast-track registration process is available for drugs which have GMP and WHO prequalification. Non-registered ARV drugs can be imported with packaging in a language other than the national language.

Non-registered ARVs can be procured if they are included in the EML. Lopinavir/Ritonavir; Tenofovir/Emtricitabine; Abacavir/Lamivudine; Dolutegravir are registered under their respective trade names in Moldova. All ARVs in Moldova must have WHO prequalification or be EMA registered or EMA approved and must be listed in the national HIV treatment protocols.

Treatment Guidelines

Moldova does not fully follow the WHO 2019 treatment guidelines. Its ARV treatment protocol will be updated soon, but predictable regimens are used for procurement and treatment based on the latest WHO recommendations. NGOs are actively involved in the development of national treatment protocol.

Universal access to ARV therapy is provided in eight regional ART sections. There are no waiting lists for ART, which is consistent with the testing and treatment strategy, regardless of the availability of health insurance, identification documents and citizenship.

The treatment protocol approved in 2018 recommends regimens based on Dolutegravir as a basic first-line treatment for both adults and adolescents and children over the age of six.

Forecasting

ARV forecasting and internal circulation is regulated by legislation. The procedures are based on international best practices and take into account country specifics. One of the main reasons for the weakness of the ARV forecasting process is the lack of an information system

38 http://www.ccm.md/node/2231

for monitoring the HIV epidemic in real time. This is further hampered by problems related to legislation restrictions regarding the protection of personal data. NGOs have representation in working groups that are making forecasts for ARV procurement.

Procurement mechanisms

The Center for Centralized Public Procurement is responsible for ARV procurement in Moldova. State procurement law does not allow for ARV procurement through IPAs. It is possible only in the case of international agreements between the government and an IPA. Moldova had a pilot programme for ARV procurement through the IPA UNDP in 2017-2018. Some procurement is also conducted under GF grants through the IDA Foundation, which is also an IPA. In 2017, UNDP organised tenders for ARV procurement under state budget funds. The main criteria for ARV procurement in local procurement procedures relate to compliance with technical specifications of the product and price.

ARV prices in Moldova are shown in Annex 1.

No VAT is charged on ARVs procured through international mechanisms, like those used by the GF.

There are no mechanisms in place to ensure savings obtained in one or another budget line can be transferred to procurement in a following year. An exception is the GF Project, where it is possible.

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Distribution

The Moldovan Dermatology and Communicable Diseases Hospital is responsible for ARV warehousing at the central and district levels. The hospital is also responsible for ARV in-country logistics. They have been able to resolve problems with medicines, equipment and reagent supply, as well as storage and delivery. High staff turnover however has created a risk of losing the results obtained. A lack of financial resources also hinders adequate efforts to provide quality services.

Reforms

- Increasing access to ART, by decentralising and bringing specialised services closer to the patient (district level).
- Developing and piloting the electronic information system (Stock Management System) for managing stocks and planning medical supplies and medicines (including ARV) in the public health system.
- As part of the reform of the law on the protection of inventions, a project is being developed to change the procedure for issuing a compulsory licence. The plan is to issue compulsory licences by administrative means (e.g. through the Ministry of Health, Labour and Social Protection).
- The community monitoring platform scorecard-hiv.md started as a tool for regular monitoring of performance at the following levels: epidemiological, programme, budgetary, ARV procurement and human rights.
- Contracting authorities in Moldova will be able to use a framework agreement in public procurement as a special way of awarding contracts.
- At the start of 2021 a new treatment protocol will be developed.

Russia

Introduction

No Russian epidemiological data is available on HIV/AIDS according to the latest estimates (results of 2019), made in collaboration with the United Nations Programme on HIV/AIDS (UNAIDS).[39]

The total expenses for all ARV procurements in Russia in 2019 amounted to 410.9 million USD, with 354.9 million USD covered by the Russian Ministry of Health in centralised procurements. Compared to the 2018 budget, the total expenses of the Russian Ministry of Health for purchasing ARV drugs in 2019 increased by 32.4 million USD (+ 11.5% compared to 2018).

The total amount spent for purchasing ARV drugs by Russian constituent entities was 32.28 million USD (9.33% of the total amount spent for purchasing ARV drugs in 2019, but 10 times less than the total amount spent by the Russian Ministry of Health). At the level of Russian constituent entities, ARV procurement auctions were found in only 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% compared to 2018. According to monitoring data, less than 4% of the total number of annual treatment courses were purchased under funds from regional budgets in 2019[40].

GF transition provisions

ARVs in Russia are fully financed by state budget resources, so there are no GF grants or transition plans in place.

Registration

Most of the drugs used on the Russian market are generics. In the NRTI group, almost 100% are generics[41]. Originals are generally substituted by generics when patents expire, which is regular practice in all countries.

A significant number of drugs in the segment of NRTIs, NNRTIs and protease inhibitors were domestic in 2019. Among the purchased generics, there are almost no foreign-made drugs; however, a vast number of foreign-made drugs are registered in Russia. This may be due to the “odd-man-out” rule, according to which bidders with drugs from other countries are not allowed to bid if there are two other suppliers involved in the bidding with drugs manufactured in Russia or EU countries. Since domestic products are mainly manufactured with foreign substances (China and India), this can create a risk in unforeseen situations that domestic companies are unable to produce the required amount of drugs promptly and on time.

39 https://www.unaids.org/en/regionscountries/countries/russianfederation

40 Source analysed and parts used in this section: https://itpcru.org/strany/russia/

41 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/russia/

Russia regulates the list prices of essential drugs. Only some ARV drugs are included in that list.

In the contracts of the Russian Ministry of Health, which is the main purchaser, the share of original drugs in all concluded contracts amounts to 62% and the share of generics to 38%. Foreign and Russian drugs undergo the same registration procedure[42]. That is why prequalification criteria do not lead to fast-track registration.

Treatment Guidelines

Russia does not fully follow the WHO 2019 treatment guidelines.

Forecasting

Central and local governmental institutions are responsible for ARV forecasting procedures[43]. The forecasting procedures are based on local drug forecasting methodologies. No NGOs are involved in the forecasting procedures.

Procurement mechanisms

The Ministry of Health in Russia and Russian regions is the main authorities responsible for ARV drug procurement[44]. Procured by the Ministry of Health ARVs go to the federal level healthcare facilities (civil sector) and to the Federal penitentiary service while locally procured ARVs go to the local healthcare facilities. Tenders are announced in a Unified informational system in procurement which functions online.

ARV prices are shown in Annex 1.

Distribution

Russia uses centralised and decentralised models for ARV distribution, similar to distribution mechanisms used for other medicine groups[45]. Reforms in ARV procurement are expected to bring about changes in ARV distribution mechanisms. Russia has issues related to on-time delivery of ARV drugs at central and regional levels.

Reforms

On 3 November 2020 the Russian government created a Federal Institution “Federal centre for planning and organising drug provision for citizens” subordinated by the Ministry of Health[46]. The centre will be responsible for the purchase of medicines within the framework of federal programmes, and will monitor and predict the need for medicines. The centre’s responsibilities within the framework of federal programmes will cover the procurement of medicines for treating patients with orphan and oncological diseases and HIV and tuberculosis, as well as vaccines included in the national vaccination schedule.

42 https://ldv-group.ru/en/services/drug-registration/

43 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/russia/

44 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/russia/

45 Mentioned source analyzed and used some materials in this section https://itpcru.org/strany/russia/

46 https://yandex.ru/turbo/vademec.ru/s/news/2020/11/03/pravitelstvo-tsentralizovalo-zakupki-lekarstv-dlya-federalnykh-programm/

The centre will also monitor the procurement of medicines and forecast the need for medicines in the regions. This will help prevent possible interruptions in the supply of drugs and build up the necessary buffer stocks.

The organization will also monitor the procurement of medicines and forecast the need for medicines in the regions. This will help prevent possible interruptions in the supply of drugs and build up the necessary buffer stocks.

Tajikistan

Introduction

According to the latest estimates (results of 2019)[47], made in collaboration with the United Nations Program on HIV / AIDS (UNAIDS), the estimated number of people infected with HIV / AIDS in Tajikistan is about 14,000 and the prevalence of HIV is 0.2% [0.2% -0.3%].

The epidemiological situation regarding HIV/AIDS infection in Tajikistan:

- Adult and child deaths due to AIDS — <500
- People living with HIV who know their status — 8 600
- Adults and children newly infected with HIV — 1 600
- People living with HIV who are on ART — 7 100
- HIV incidence per 1 000 population (all ages) — 0.17
- Coverage of adults and children receiving ART (%) — 51
- Total country-reported HIV expenditure (USD) — unknown

GF transition provisions

UNDP started the implementation of the GF NFM grant in October 2015[48]. Under the NFM programme, UNDP continues to provide prevention services to key populations. The outcomes and outputs of the NFM Project documents are harmonised with two UN strategic documents (UNDP's country programme action plan for 2016-2020 and the United Nations Development Assistance Framework for Tajikistan for 2016-2020) as well as with the National Strategic Plan to Fight HIV/AIDS in the Republic of Tajikistan for 2015-2017.

Tajikistan currently has one ongoing GF grant, under the name Strengthening Supportive Environment and Scaling up Prevention, Treatment and Care to Reduce the Burden of HIV and TB in the Republic of Tajikistan.

Registration

Permission can be obtained from the Ministry of Health for the one-time import of non-registered ARVs[49]. Not all ARVs are registered in Tajikistan, but they do all have WHO prequalification.

GMP certification and in-country registration are the minimum requirements for participation in local tenders in Tajikistan[50].

47 https://www.unaids.org/en/regionscountries/countries/tajikistan

48 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

49 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

50 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017;

Treatment Guidelines

Tajikistan does not follow the WHO 2019 treatment guidelines.

Forecasting

ARV forecasting is conducted by the Tajikistan National AIDS Centre[51].

The World Bank Communication and Awareness Action Plan introduced Electronic HIV Case Management System. This tool is used for ARV forecasting. No NGOs are involved in the ARV forecasting process in Tajikistan.

Procurement mechanisms

In Tajikistan, ARVs are procured under GF funds through UNICEF and UNDP procurement mechanisms[52]. An e-procurement system was introduced in Tajikistan in 2017. This system is now used for ARV procurement financed by the state budget. In 2017, Tajikistan cancelled the obligatory VAT for the local production of medicines53. Tajikistan has social contracting practices set by law, but these do not apply to ARV procurement.

Distribution

A PSM module was also added into the Electronic HIV Case Management System, which will help control the distribution of ARV drugs to avoid stock-outs[54]. Tajikistan experiences interruptions in the ARV delivery process at central and district levels. NGOs have limited functions in the ARV delivery monitoring process.

Reforms

No information is available on the current situation regarding reforms in ARV procurement.

51 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

52 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

53 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

54 Mentioned sources analyzed and used some materials in this section HIV/AIDS treatment and care in Georgia Evaluation report September 2014 Legal and regulatory environment assessment for HIV/AIDS in the Republic of Tajikistan, Dushanbe 2017; ANNUAL PROJECT REPORT 2017 United Nations Development Programme Tajikistan, Strengthening the supportive environment and scaling up prevention, treatment and care to contain HIV epidemic in the Republic of Tajikistan 01 January – 31 December 2017; Background document Tajikistan, Sustainable funding of the national HIV response UNDP- Involvement of civil society in the framework of social order. Background paper – Tajikistan Feb 2016

Uzbekistan

Introduction

According to the latest estimates[55] (results of 2019), made in collaboration with the United Nations Program on HIV / AIDS (UNAIDS), the estimated number of people infected with HIV / AIDS in Uzbekistan is about 50,000 and the prevalence of HIV is 0.2% [0.2% -0.2%].

The epidemiological situation regarding HIV/AIDS infection in Uzbekistan:

- Adult and child deaths due to AIDS — <1 000
- People living with HIV who know their status — n/a
- Adults and children newly infected with HIV — 4 400
- People living with HIV who are on ART — 29 000
- HIV incidence per 1 000 population (all ages) — 0.13
- Coverage of adults and children receiving ART (%) — 58
- Total country-reported HIV expenditure (USD)— 3,000,000

ARV therapy is free for all patients in Uzbekistan[56].

GF transition provisions

Based on Uzbekistan transition plan[57] and discussions with country experts, the main principles and provisions for the GF grant transition are the following:

- Strengthened access to affordable and quality health products via the use of international procurement platforms, in-country drug registration, or strengthened national public health supply chains
- Completed assessment of legal framework for contracting with public funds acting as providers of prevention services for key and affected populations.
- Creation of opportunities between 2018 and 2020 for involving more financial resources (until 2022) for HIV/AIDS programmes, including ARV procurement.
- Improvement of ARV procurement and supply management mechanisms up until the end of 2020 and regular review of treatment protocols.
- Periodic training for staff responsible for ARV forecasting and procurement processes.
- Creation of regulation mechanism for importing ARV generics and registering ARV generics under state budget resources.

55 https://www.unaids.org/en/regionscountries/countries/uzbekistan

56 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

57 Preparing for sustainable transition in EECA Global Fund's approach to sustainability, transitioning and co-financing November 2019, The Global Fund " Plan for the immediate passage of the financing of the fight against HIV-infection and tuberculosis of the state budget " approved by Minister of Health of Uzbekistan 23.01.2018

- Fast-track registration for non-registered WHO prequalified ARVs.
- Introduction of a periodic process of including ARV drugs in the EML.
- Introduction of IPA mechanisms for ARV procurement, with approval by government decree.
- Analysis and improvement of ARV transportation and logistics mechanisms.
- Development of national procurement mechanism for uninterrupted ARVs based on international quality standards for procurement and delivery.
- Construction of new warehouse for ARVs.

The transition from GF financing for the procurement of ARVs to state budget financing is in an active phase, in particular:

2018 year

2.99 million (Global Fund) – 55%

$ 2.4 million (State budget) – 44%

2019 year

$ 1.94 million (Global Fund) – 42%

$ 2.66 million (State budget) – 57%

2020 year

$ 3.1 million (Global Fund) – 52%

$ 2.9 million USD (State budget) – 48%

Estimations for 2021-2022 are as follows:

2021 year

$ 1.1 million (Global Fund) – 15%

$ 6.137 million (State budget) – 85%

2022 year

$ 1.6 million (Global Fund) – 16%

$ 8.535 million (State budget) – 84%.

Registration

A legal procedure, introduced in 2018, allows for the recognition of the results of registrations in countries with high regulatory requirements[58].

The processing term for an application and registration of medicines is 15 working days. Uzbekistan has no list of essential medicines. There is a list of socially important medicines and medical devices. However, ARVs are not included in this list.

One of the conditions for tender documents in biddings for ARV procurement is that the supplier must have a registration certificate or another document confirming the registration of the ARVs in countries with high regulatory requirements. Considering that ARV registration is not required in Uzbekistan, there is no need for suppliers to apply for registration.

Non-registered ARVs may be imported with packaging in a language other than the national language. However, upon arrival they must obtain a positive conclusion from the State Center of Expertise and Standardization of Medicines, Medical Devices and Medical Equipment under the Agency for the Development of the Pharmaceutical Industry under the Uzbekistan Ministry of Health. In Uzbekistan, procured ARV drugs must be prequalified by WHO. The list of orphan drugs includes the whole range of ARVs. GMP requirements are not obligatory for tendering procedures or single source procurement[59].

58 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

59 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

Treatment Guidelines

Uzbekistan mainly follows the WHO 2019 treatment guidelines. There are some minor deviations based on local detailing processes for certain patient groups

Forecasting

ARV forecasting procedures are fully run by the National AIDS Centre based on local and GF forecasting methodologies[60]. NGOs are unable to participate in the ARV forecasting process.

Procurement mechanisms

The Ministry of Health is the executive agency and the Republican AIDS Centre the implementation agency responsible for ARV procurement in Uzbekistan[61].

The law and by-laws on public procurement do not apply in the following situations:

- The GF has established a different procedure for the procurement of goods (works, services). Within the framework of the GF project, the procurement of medical and non-medical goods is carried out in accordance with the procurement guidelines developed for the project and approved by the GF.

- Medicines, medical and non-medical goods included in the project budget (with the exception of ARVs) are procured through the PPM of the GF through wambo.org or through other international agencies or organisations. As such, ARVs are purchased through the UNDP country office, with which a memorandum has been signed regarding technical cooperation.

ARV procurement in Uzbekistan is held by the UNDP Tashkent office, and is covered by both state and GF financing.

The Ministry of Health approved a list of medicines and medical products which may be procured through direct contracts. The following ARVs are not included in this list:

- Lopinavir/Ritonavir (Aluvia), 200 mg / 50 mg, tablet/PAC-120;

- Atazor R (Atazanavir + Ritonavir), 300 mg / 100 mg, tablet/PAC-30;

- Lamivudine / Tenofovir disoproxil fumarate / Dolutegravir, 300 mg / 300 mg/50 mg, tablet/PAC-30.

The main criteria for ARV procurement are the same for both the state budget funds and GF funds:

1. WHO prequalification;

2. Inclusion in the medicines list approved by the Ministry of Health according to the adopted WHO protocols;

3. Compliance with the GF technical specifications and reference prices or the prices of previously procured drugs.

60 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

61 Mentioned sources analyzed and used some materials in this section- Ministry of Health, Republican AIDS Center, Regional project "Sustainability of services for key populations in the EECA region", funded by a grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF STM) TRAINING MODULE "Procedures for national and international procurement of medical and non-medical products necessary to combat HIV infection in the country"-Tashkent 2019; Ministry of Health, Republican AIDS Center, GF PROCUREMENT GUIDELINES, APPROVED BY DIRECTOR OF REPUBLICIAN AIDS CENTER-16-JAN-2019

Brand products are rarely purchased, even in cases of stock-outs. The procurement of brand products is carried out under direct contracts as agreed with the customer. The procurement and supply of ARV drugs has been carried out in close cooperation with UNDP since 2012. There are no legislative restrictions for cooperation with IPAs. All other medical product procurement under governmental budgeting in Uzbekistan is held by the separate state institution Uzmedimpex. The prices for ARV procurement are the same for state and GF sources.

If the procurement of ARVs is carried out at the expense of investment projects, saved or unused funds can be reallocated and used in the next financial year. However, if the procurement and supply of ARVs is funded by the state budget, savings cannot be used in a next year due to the closure of the fiscal year[62].

There is no local production of ARV drugs. But Uzbekistan has legislation for a 20% price preference for local production.

ARV drugs procured under investment projects are exempt from VAT and customs duties. Procurement carried out by international organisations such as the UN agencies (UNDP, UNICEF, etc.) is not subject to customs duties or taxes either.

Distribution

The delivery of ARVs is carried out centrally, by the Ministry of Health and the National AIDS Centre[63]. The Ministry of Health's planning for ARV procurement is based on a six-month buffer period. Regional AIDS centres have a buffer stock of three months.

At the central level, the Project Implementation Unit at the Republican AIDS Center of the Ministry of Health is responsible for ARV logistics and warehousing issues. At the regional level, the Oblast (regional) AIDS centres are responsible for logistics and warehousing. Since 2018 Uzbekistan has had no significant problems with ARV deliveries.

Reforms

An agreement is currently in place between the Ministry of Health and UNDP for the procurement and supply of ARVs at the expense of the state budget. This agreement is updated on an annual basis, each year with an increase of the government's contribution. There is also an agreement between the Republican AIDS Center and UNDP for ARV procurement at the expense of the GF. The term of this agreement is three years.

Since 2018, 100% prepayment has applied for ARV procurement. The prepayment scheme works without any kind of bank guarantee.

Currently, there are no plans for changes to the legislation on ARV procurement.

62 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

63 Mentioned source analyzed and used some materials in this section- FORECASTING, QUANTIFICATION AND BUDGETING NEED IN ARV MEDICINES IN UZBEKISTAN, CONSULTANCY REPORT, IGOR NOVYKOV, UNICEF-TASHKENT, JANUARY 2020

2. Market research on ARV procurement in three high impact countries

2.1 Market research on ARV procurement in Belarus

Current market research on Belarus is mainly based on online interviews with Belarus NGOs and government sector representatives and survey results of sector experts.

SUMMARY OF SURVEY RESULTS:

1. Fast-track registration could be introduced for prequalified ARVs.
2. Stickers and insert instructions in Russian are required for the approval for one-time import of unregistered ARV drugs in packaging in a foreign language.
3. The customs clearance rate for ARV drugs is 3%.
4. Savings in financial resources for ARV procurement cannot be reallocated to a next fiscal year.
5. Twenty-one ARV drugs are registered in Belarus.
6. ARV procurement must be fully conducted under budget resources from 2021.
7. NGOs are not involved in ARV forecasting processes or in the development of treatment regimens.
8. ARVs must be included in the EML. These are updated every year or every two years.
9. The republican unitary enterprise Belpharmacia is responsible for ARV distribution and warehousing at the national level, and the republican unitary enterprise Pharmacy at the regional level.
10. Treatment regimens deviate somewhat from the WHO 2019 guidelines.
11. The republican unitary enterprise Belpharmacia and the Republican Scientific and Practical Center of Medical Technologies (purchases within the framework of the GF grant) are responsible for ARV procurement.
12. There are no legal opportunities for ARV procurement or direct procurement through IPAs.
13. Local manufacturers may have preferences in ARV procurement processes.

Conclusions presented here and for other two countries (Moldova and Uzbekistan) are based on the information resulting from survey results, discussions with country stakeholders and consultants, collected research data on procurement details. Market research analyses showing more risks and challenges were presented to country decision-makers directly and through local country consultants. A number of important conclusions are outlined below:

- There are huge differences, with price differences of up to 230%, and some GF PPM prices as much as 53 times lower. These differences are mainly the result of inefficient planning, a lack of open market regulations, a lack of flexibility in new ARV generic registration processes, long and non-flexible procurement procedures, and local manufacturer price advantages. The last factor has a mid-term and long-term effect on ARV pricing processes. The mid-term effect is reflected by the current procurement results and the long-term effect by the decrease of interest from global market players to enter the Belarus market.
- The government mainly agrees with the challenges and is ready to initiate reforms, participate in pooling processes and make some legislation changes.
- The change in tendering methodology for

grouping ARV products (small and large quantities) could help solve the problem of products needed in small quantities not drawing enough market players. An important factor here is that groupings should be logical so no additional risks are created for the procurement of those product groups.

- Harmonising treatment guidelines and demand formation, procurement and supply chain management could bring efficiencies. Our research clearly showed these processes do not work well as one system.

2.2 Market research on ARV procurement in Moldova

The current market research is mainly based on online interviews with NGOs in Moldova and government sector representatives and survey results of sector experts.

SUMMARY OF SURVEY RESULTS:

1. Non-registered ARV can be imported with packaging in a language other than the national language.

2. Savings made on ARV procurement can only be used for ARV procurement in the current reporting year and cannot be transferred to the next year.

3. Lopinavir/ritonavir; Emtricitabine/Tenofovir; Abacavir/lamivudine; Dolutegravir are the only registered ARV products in Moldova.

4. Since 2021, ARVs will be procured exclusively from the state budget.

5. NGOs actively participate in ARV forecasting and development of treatment regimens.

6. ARVs are not included in the EML.

7. The Dermatology and Communicable Diseases Hospital, which is the coordinating authority for the National Programme on HIV/AIDS and STIs is responsible for ARV distribution and warehousing.

8. Moldovan clinical protocols are fully in line with WHO recommendations.

9. Moldova has difficulties in purchasing ARV drugs necessary for the Transnistrian region (frozen conflict zone), due to its requirement of very small quantities.

10. The legislation does not offer preferences for local ARV manufacturers.

11. WHO prequalification or EMA or FDA registration are mandatory for single source or IPA procurement of ARVs.

12. 1National legislation does not allow for long-term agreements.

13. Moldova used UNDP as its IPA in the 2017-2018 period.

14. After the GF transition all ARV procurement will be conducted by the Public Procurement Agency.

A number of important conclusions are outlined below:

- The annex shows comparative data from the survey between the GF pooled procurement prices and the local and GF procurement prices. Most price differences range from 28 to 74% for state procurement and 124 to 149% for GF procurement. There are other cases where differences are even higher, but the main reason in these cases is the small quantities procured. As such, they are not considered a systematic procurement problem.

- Some of the price efficiency achieved through procurement by UNDP sometimes led to long procurement procedures, which eventually led to inefficient ARV procurement. As such, price factor should not be discussed as a standalone factor within efficiency indicators but should

be discussed within the complex picture of procurement indicators.

- The UNDP price indications have several components, which made precise comparisons difficult.
- Non-competitive procurement quantities of ARVs led to inefficient procurement prices and also access.
- COVID-19 related logistic restrictions and challenges will have a significant influence on ARV procurement in small markets like Moldova.
- A lack of ARV planning and stock management also causes inefficiency, which is difficult to monitor and quantify.
- Independent procurement systems lead to inefficient results for state and GF sectors. As such it is important to bring all procurement under one system. That is the future design presented later in the research recommendations section.
- The government mainly agree with the existing challenges and is ready to initiate reforms, participate in pooling processes and make some legislation changes.
- The change in tendering methodology for grouping ARV products (small and large quantities) could help solve the problem of products needed in small quantities not drawing enough market players. An important factor here is that groupings should be logical so no additional risks are created for the procurement for those product groups.
- Harmonising treatment guidelines and demand formation, procurement and supply chain management could bring efficiency. Our research clearly showed these processes do not work well as one system.

2.3 Market research on ARV procurement in Uzbekistan

The current market research is mainly based on online interviews with Uzbekistan NGOs and government sector representatives and survey results of sector experts.

SUMMARY OF SURVEY RESULTS:

1. There is no procurement of ARV products produced in the local market.
2. WHO prequalified ARVs are eligible for fast-track registration within 15 working days.
3. Non-registered ARVs can be imported with packaging in a language other than the national language.
4. ARVs procured under investment projects are exempt from VAT and customs duties.
5. If ARVs are procured at the expense of investment projects, saved or unused funds can be reallocated and used in the next financial year. However, if the ARV procurement and supply is funded from the state budget, savings cannot be used in the next year due to the closure of the fiscal year.
6. All ARVs used in Uzbekistan are included in the list of orphan drugs, and so suppliers and IPAs do not have to register ARVs.
7. NGOs are not involved in ARV forecasting or procurement.
8. At the central level, the Project Implementation Unit at the Republican AIDS Center of the Ministry of Health is responsible for ARV logistics and warehousing. At the regional level, the Oblast AIDS centres are responsible for logistics and warehousing.
9. The Ministry of Health is the executive agency and the Republican AIDS Center is the implementation agency responsible for ARV procurement.

10. Local manufacturers may have preferences in the ARV procurement processes.

11. ARV procurement and supply has been carried out in close cooperation with UNDP since 2012.

12. After the transition, all ARV procurement activities will be carried out by the state unitary enterprise Uzmedimpex.

A number of important conclusions are outlined below:

- The annex shows comparative data from the survey between the GF pooled procurement prices and the local and GF procurement prices. ARV procurement prices for Uzbekistan are mostly similar to PPM prices and in some cases cheaper than GF PPM reference prices.

- The only ARV procured with a higher local price is Nevirapine 10mg/ml oral suspension 100ml, where the price difference is about 37%.

- Starting in 2021, the government organisation Uzmedimpex will take over all GF and state procurement from 2022. This will change the situation significantly, as Uzmedimpex has no experience in international procurement.

- After the transition, the comparatively small procurement quantities and the lack of experience in international procurement could cause the same level of inefficiency in ARV procurement as seen in most other EECA countries.

- COVID-19 related logistic restrictions and challenges will have a significant effect on Uzbekistan.

- The government mainly agrees with the existing challenges and is ready to initiate reforms, participate in pooling processes and make some legislation changes.

- The change in tendering methodology for grouping ARV products (small and large quantities) could help solve the problem of products needed in small quantities not drawing enough market players. An important factor is that grouping should be logical so no additional risks are created for the procurement of those product groups.

3. PSM strategies for three high impact countries

3.1 PSM strategy for Belarus

IDENTIFIED CHALLENGES

Based on our study of the Belarus procurement and supply chain management system there are bottlenecks which are common for the entire cycle

- Low level of competition in the local market with limited local manufacturers.
- A 15% price preference for ARV procurement tender procedures and a 25% price preference if a company has over 50% of employees who have a disability. Exclusion of foreign manufacturers if two Belarusian and/or Russian manufacturers apply for the tender.
- High prices for ARV products.
- Delays and long lead times for the delivery of ARV products.
- Fast-track registration of 2-3 months is possible for WHO-prequalified ARVs, EMA-registered ARVs.
- Non-registered ARVs can be imported with permission from the Ministry of Health, although this is not an available procedure for non-residents who can apply for tenders.
- NGOs cannot participate in the development of technical specifications and treatment protocols.
- Funds saved during ARV procurement procedures cannot be used in ARV procurement in the following year.
- There is no legislation on ARV procurement through IPA or from manufacturers.
- There is no legislation base for long-term ARV procurement contracts: this is fixed by legislation for a maximum one-year period concurrent with the fiscal year.
- There is no legislation base for pooled procurement.
- Requirement for the supply of drugs for every quarter, so four times a year.
- Lack of possibility of prepayment for a long time. Residents are obliged to ensure the completion of each foreign trade operation in full upon import no later than 90 calendar days from the date of payment.
- There is no mechanism for the procurement of unregistered medicines if registered ones are available.
- ARV drugs must be supplied with Russian instructions in each package. And if a medicine is to be sold through a pharmacy network, then a sticker in Russian is also required on each package.
- Non-resident participants within the tender procedure are required to submit some documents at a very short notice.
- Tenders are held on the electronic trading platform and the agreement is also signed electronically which puts a burden onto bidder representative to be physically presented in Belarus because of procedure specifics.
- Short delivery times for ARV products in the first quarter of the year. The main reason for this is the late deadline for approval of the procurement plan.
- Transition to a new treatment regimens (update of the treatment protocol) takes a long time.
- Patent protection and high-cost create barriers to the inclusion of new drugs.

PROPOSED RECOMMENDATIONS

Forecasting

- Implement a national tool for forecasting ARVs, receipts, movements and unused drugs. The mechanism must work online and be accessible to specialists of all levels (Ministry of Health, Belpharmacy, regional pharmacies, infectious disease specialists and attending physicians).
- Create legislative bases for NGO involvement in ARV forecasting procedures.
- Develop guidelines for the formation of a buffer stock of ARV drugs.
- Develop ARV and TB drug forecasting methodologies and enhance the capacity of staff at national, local and facility levels.

Distribution

- Remove all restrictions and approvals in the redistribution of drugs between regions.
- Streamline logistics system for timely distribution of commodities procured through GF and public sources.

Procurement

- Simplify the procurement process to shorten the overall procurement process.
- Allow for standard package supplied in English with a leaflet in Russian or Belarusian to be made available via a barcode on the package.
- Allow for import documentation to be in English.
- Allow long-term agreements that exceed the budget cycle.
- Tender registered and non-registered products at the same time and determine a scoring preference for registered drugs.
- Develop a fast-track registration approval process.
- Remove the rule that foreign manufacturers will be excluded if two Belarusian or Russian manufacturers apply for the tender.
- Allow for prepayment to suppliers.
- Increase the capacity on procurement and supply chain of staff at Belpharmacy and the Ministry of Health so they are better able to forecast the need for ARVs.
- Contract a procurement agency (local or international) and outsource the procurement and supply chain functions to this agency.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.
- Allow the opportunity to start tendering process before financial approval of procurement from Government, with condition that contract will force only in case such financial resource allocation will be approved in the future.
- Create a buffer fund from savings on previous ARV procurements that can be used in case of urgent needs.

3.2 PSM strategy for Moldova

IDENTIFIED CHALLENGES

Based on our study of the Moldova procurement and supply chain management system there are bottlenecks which are common for the entire cycle.

› Lack of an information system for monitoring the HIV epidemic in real time, further hampered by the legislation restrictions regarding the protection of personal data.

› Lack of foreign suppliers to participate in national tenders. Legislation prohibits prepayment, procurement from a single source, as well as the need for the distribution of medicines between medical institutions within the country.

› Insignificant volumes of ARVs being procured to the Transnistrian region;

› Continuation of the takeover by the state of the activities stipulated in the NP HIV/AIDS currently financed from GF sources.

PROPOSED RECOMMENDATIONS

Product selection

- Increase the participation of civil society at the stage of development and approval of the terms of reference for ARV procurement.
- Increase the number of generic drugs registered in the country.

Forecasting

- Develop algorithm/SOP on a data exchange or MIS.

Distribution

- Decentralize ARV distribution by piloting medical and social services on a one-stop basis using community organizations.

Procurement

- Organize the centralized government procurement of medicines and medical goods, including ARVs, through the transparent electronic procurement system SIA RSAP M-Tender.
- Build on the capacity of the Center for Centralized Public Procurement in Healthcare to conduct market research in accordance with the updated contracting cycle of centralised medical procurement.
- Implement a competitive two-stage ARV procurement mechanism in Moldova (IPAs & national tender).
- Contract a procurement agency (local or international) and outsource the procurement and supply chain functions to this agency.
- Strengthen the capacity of civil society organizations to monitor ARV procurement.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

3.3 PSM strategy for Uzbekistan

IDENTIFIED CHALLENGES

Based on our study of the Uzbekistan procurement and supply chain management system there are bottlenecks which are common for the entire cycle.

- Budget resource allocation for ARV products fixed in the national HIV programme, which allows for no flexibility for covering emergency ARV products.
- No mechanisms for long-term agreements.
- No electronic integrated information system that could be used to manage clinical, supply and financial data.
- The only experience in terms of pooled procurement is in cooperation with the wamboo.org platform under GF grant programmes.
- State procurement procedures are not flexible for non-registered drugs, or for changing quantities and prices of contracts.
- Storage conditions are a problem in some regions.
- Some regions have insufficient ARV reserves.
- NGOs have no opportunities to participate in the ARV forecasting process.
- Not all ARV drugs are included in the list of goods (works, services) for procurement carried out by direct contracts. ARVs in this list are procured within GF funds, not with state budget funds.
- The Uzbekistan Ministry of Finance aims to transfer the UNDP procurement of ARVs and consolidate it into one state structure under Uzmedimpex after ARV financing has been fully transitioned to the government in 2021.
- UNDP is the only IPA approved by the Uzbekistan government for ARV procurement. There are no mechanisms or procedures in place to conclude contracts with other IPAs.
- Locally produced goods are given up to a 15% preference on the price of CIP over imported goods within the evaluation process of bidder proposals.
- The transition of ARV procurement from UNDP to Uzmedimpex could increase ARV prices if the regulatory function is not given to Uzmedimpex as it was to UNDP.
- Uzbekistan has no legally based system for cooperation with IPAs or manufacturers. Each case of possible cooperation is discussed by the government separately, which creates barriers for on-time ARV procurement contracts with IPAs and budgeting processes for ARV products.
- No systematic approach has been introduced to the ARV procurement system/process.

PROPOSED RECOMMENDATIONS

Forecasting

- Implement a national electronic tool for ARV forecasting.
- Create a legislative basis for NGO involvement in ARV forecasting procedures.

Procurement

- Update the procurement mechanisms, which would create opportunities for cooperation with several IPAs or international manufacturers and allow for long-term agreements.
- Increase the capacity and procurement and supply chain management skills of the staff of the Republican AIDS Center and the Ministries of Health and Finance so they are better able to forecast the need for ARVs.
- Contract a procurement agency (local or international) and outsource the procurement and supply chain functions to this agency.
- Transfer all ARV procurement functions to IPAs. Exclude the role of Uzmedimpex. Involving them would be risky, because this organisation has no experience with the purchase of ARV drugs.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

3.4 Strategic ARV procurement roadmaps for selected high impact countries

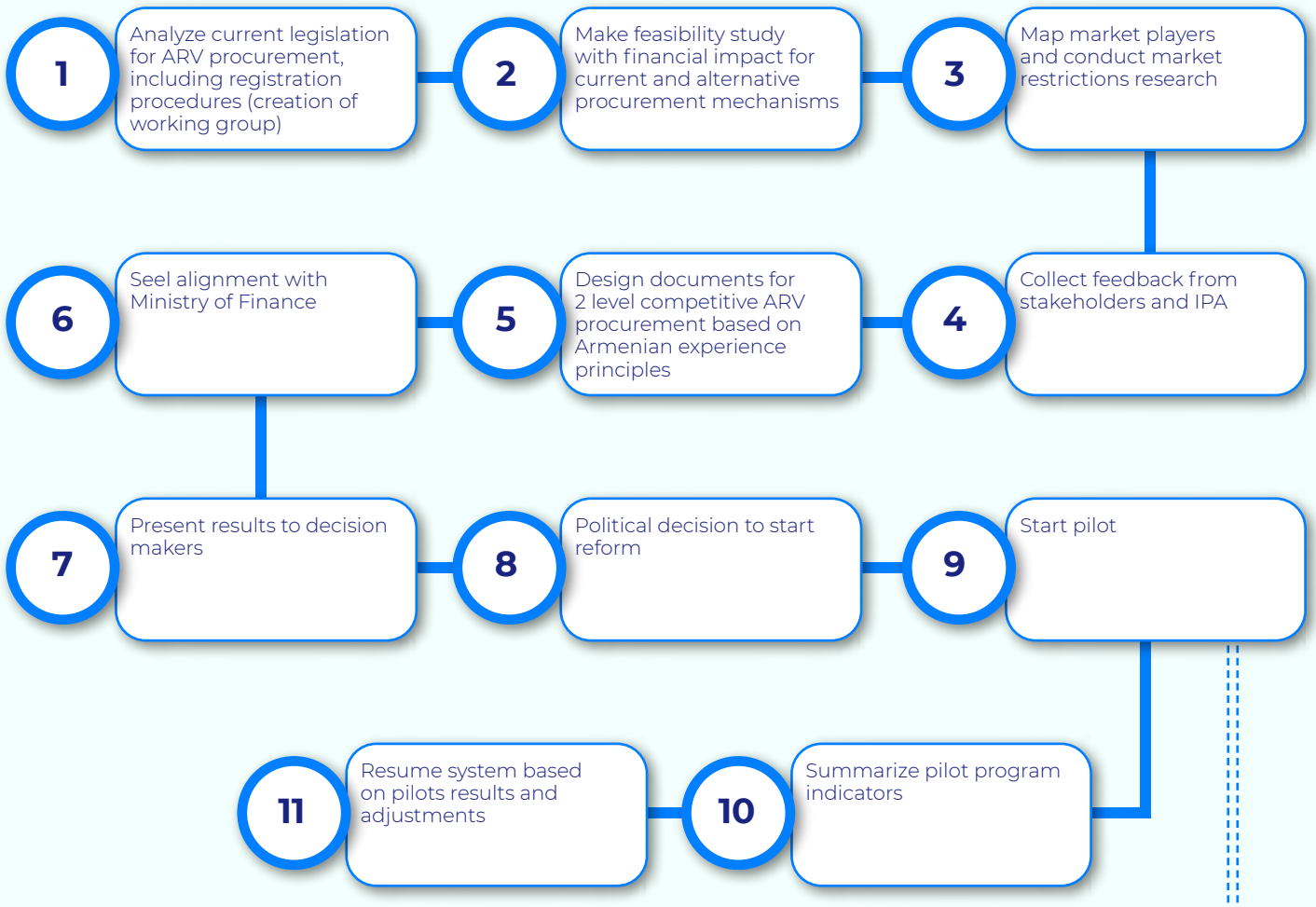
This strategy document presents and analyses several format discussions with experts, ARV procurement decision-makers and NGO sector representatives from three high impact countries. It shows the need to develop an ARV procurement strategy. The goal for the strategy is more efficient ARV procurement mechanisms and flexible tools for obtaining that goal.

The highest-level resource needed to realise this strategy is political will from various government structures. The medium level resource needed to implement this strategy step-by-step is the creation of expert groups to streamline processes between all governmental and NGOs stakeholders and provide technical support for activities (especially important for Uzbekistan).

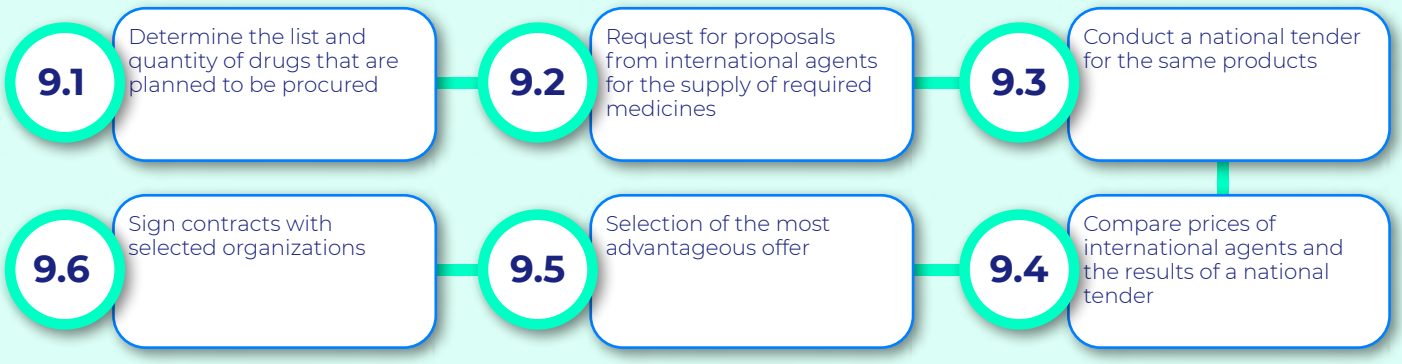
This strategy creates a sustainable mechanism for ARV procurement after the GF transition period. One of the main challenges after the GF transition in EECA countries is ensuring a sustainable, efficient and uninterrupted ARV procurement mechanism. This mechanism could be used not only for ARV procurements, but also for all other products procured with government funds.

3.5 Roadmap and strategy for a competitive ARV procurement mechanism through IPAs for the selected high impact countries

Below a unified stepwise overview for a reforming process for high impact countries is shown.



ARV procurement two stage competitive procurement process with IPA involvement after the above described reform process is completed.



The image below shows a two-stage competitive ARV procurement process with IPA involvement after the completion of the reform process described above. Mentioned above "Starting pilot" under point 9 based on the below scheme (points 9.1-9.6 cycle).

Similar mechanism practices are used in Armenia. The Armenian system of competitive two-stage ARV procurement was introduced in 2018. Below are a number of results based on their two years of experience that could be useful for decision-makers in designing the roadmap for the reform process.

- Local suppliers became more active in local ARV tenders.
- Armenia solved the problem of full access to ARVs and the majority of ARV products can now be procured through the new mechanism.
- In 90% of cases IPA prices are lower than those of local suppliers.
- There are difficulties imposing penalties on IPAs for late delivery. The procedure for local suppliers is simpler.
- The government has been able to use the new procurement mechanism for other product groups (TB, Hepatitis B and C, Methadone, and testing).
- The main competition between local suppliers and IPA are for ARV products.
- There are some cases where IPAs request more time to present their price offer.
- Armenia announced a local tender with the same price conditions as for IPAs. This means local suppliers can now also apply with non-registered products. This still only happens very rarely, however.
- Armenia is now prepared for flexible decision-making during the operation of this mechanism, including some contract points that differ significantly from local standards.
- UNDP has privileges of simplified custom clearance and low logistic expenditures in many countries. This may create unequal conditions for competition through IPAs.

Common outcomes after introduction of two-stage competitive model for ARV procurement in three countries:

- The short-term prospective is that the mechanism will increase price effectiveness, which will create opportunities for the government to implement future reforms for sustainable procurement systems.
- The mechanism will also lead to more attractive prices with predictable delivery terms for at least the same quality of ARV drugs previously procured by the country.
- The long-term prospective is that of a sustainable and effective ARV procurement mechanism.

3.5.1 Country specifics for Belarus

Currently, there is no provision in Belarus legislation that allows for the state procurement of medicines through IPAs. The implementation of an international procurement mechanism would be possible if changes were made to public procurement legislation (e.g. the inclusion of international procurement and conditions for its enforcement) and new regulatory acts were imposed on the structure of their implementation. Belarus has started taking steps in these directions.

Belarus preliminary identified some details for competitive two-stage ARV procurement with IPA involvement. Within point 9.1, the list and quantity of drugs planned to be purchased with the involvement of international agents could be developed based on the current treatment protocols. Decisions regarding quantities should be made with buffer stocks in mind (approximately six months). The Belarus Ministry of Health will be responsible for the process.

Within point 9.2, the Ministry of Health will also be responsible for the request of proposals from international agents for the supply of required medicines (independently or with the involvement of other non-profit government organisations such as Belpharmacy or the Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health, RSPC MT).

Belpharmacy will be the responsible body for conducting national tenders (point 9.3).

The Ministry of Health, independently or with the involvement of other non-profit organisations such as Belpharmacy or the RSPC MT, will organise the comparisons of prices between international agents and the selection of the most affordable offer (points 9.4 and 9.5). This should lead to the selection of the most advantageous offer and to contracting management.

The contract management process will also be handled by the Ministry of Health and non-profit government organisation Belpharmacy (point 9.6, signing contract with selected organisations).

3.5.2 Country specifics for Moldova

Based on discussions with the Moldovan representatives responsible for ARV procurement, it is recommended that the first step be to create a working group with representatives from the government and NGOs who make recommendations on policy reforms and steps for developing an implementation plan.

A number of steps have been identified that can provide a base for key principles for the working groups and the reform process:

- Use GF PPM prices as a reference point for prices in the newly developed model.
- Create a new model with a legislative base not only with conditions for competitive two-stage ARV procurement, but also with legal conditions for inclusion in the regional pooling procurement system.
- Develop a package of competitive advantages for negotiation with the Ministry of Finance. This package should answer the following questions: What are the potential budget resource savings per year? How will the quality criteria of ARVs be incorporated and improved compared to the previous system? How will the new mechanism ensure a higher response percentage, especially for low volume items? What will the key performance indicators and mechanism be to ensure on-time delivery in the new model?
- Armenian and Georgian models of procurement through IPAs will be the basis for the reform process.

Within point 3 (market players and market restrictions research) key stakeholder identification, (responsible for making decisions on removing barriers and implementing the 2 level ARV competitive procurement mechanism in Moldova) will be the main principle for the stakeholder mapping process.

Within point 1 (analysing current legislation on ARV procurement including registration procedures (creation of working group) the country is recommended to focus on primary and secondary legislation adaptation for a competitive two-stage ARV procurement mechanism. This is because of the existing barriers for the implementation of such a system.

3.5.3 Country specifics for Uzbekistan

Uzbekistan is not yet ready to take over the procurement of several specific groups of products including ARVs. That is why Uzbekistan applies to international procurement platforms every year. Each time, the Ministry of Health first submits feasibility studies to the Ministry of Finance for approval for procurement through international platforms. This takes three to five

months and makes the procurement process and result inefficient. The recommended first step would be to create a working group with government and NGO representatives who can make recommendations for the policy reform. An approach should first be established to give the working group a set of guiding principles to work with.

The strategy development process will include an analysis of the existing law on public procurement and by-laws and will focus on methods and mechanisms of cooperation through IPAs (see point 1: analysing current ARV procurement legislation including registration procedures, creation of working group):

- Determine procurement mechanisms and methods used in Uzbekistan.
- Address registration issues.

Under point 2 (conduct feasibility study with financial impact for current and alternative procurement mechanisms) the recommendation for Uzbekistan is to focus on:

- Mechanisms of cooperation in ARV procurement through IPAs.
- Mechanisms for registration or recognition of the results of ARV registrations in countries with high regulatory requirements.
- Cooperation mechanism with IPAs, in particular to highlight methods of selection/bidding, direct contracting and financing of procurement on a 100% basis.

An assessment of IPA capabilities is an important part of the feasibility study. This includes the following:

- Technical capacity (availability of a procurement implementation group, availability of procurement procedures or guidelines, experience in ARV procurement).
- Price quotations for PSM of ARVs.
- Evaluation/comparison of IPAs based on technical and financial conditions.
- A feasibility study with concrete proposals and findings.

After the feasibility study, Uzbekistan should develop a list of the IPAs in the new model.

Under the 3 point (Market players and market restrictions research) an important step is the identification of key procurement officers/organisations by the following activities:

- Analysing existing IPAs. Organising meetings with existing IPAs.
- Exploring the capabilities of IPAs in the supply of ARVs.
- Analysing the feedback on PSM for ARVs.

Within points 7 and 8 (presenting results to decision-makers and political decisions for implementing reforms), the recommendation is for Uzbekistan to focus on the following during the preparations and adoption process of the government decree on the improvement/modernisation of PSM:

- Introduce a new mechanism of cooperation in ARV procurement (may include vaccines, TB drugs or other essential drugs) through IPAs, international platforms, and PPMs.
- Adopt procedures for selection/bidding, direct contracting and funding.
- Introduce a new mechanism of recognition or reorganisation of the results of ARV registrations in countries with high regulatory requirements.
- Introduce a new mechanism with customs and tax exemptions.

4. ARV procurement and supply chain strategy for the EECA region

4.1 Key challenges for ARV procurement within the EECA region

The countries completed an online survey, which helped them focus on the main challenges during the face-to-face discussions. Further desk research and online interviews resulted in a better understanding of the situation and challenges within each of the countries.

The surveys, presentations from country representatives, brainstorm sessions and discussions during the 2019 workshop provided a baseline view about the general challenges within the region. These challenges found at the country level concerned institutional, bureaucratic, and legislation restrictions; a lack of skilled procurement personnel; and specific limitations and barriers to efficient ARV procurement. The next section of the report discusses the specific individual country challenges.

The key challenges across the countries in the region are the following:

a) Absence of competition in the internal market that results in high prices

The relatively low level of demand for ARV products creates an unhealthy competition and supply environment. The lack of registered sources for ARV formulation often results in single source procurements within tender processes in these countries.

b) Long lead times and interrupted deliveries

The procurement cycles, from the HIV programme identifying a need for the delivery of ARVs to the patients, takes very long. This is mainly due to incorrect forecasts, bureaucratic tender procedures and suppliers not adhering to the agreed delivery timelines.

c) Government regulations to advance local manufacturers

Preference is sometimes given to local ARV manufacturers in government tenders, which limits interest from international ARV manufacturers to participate in tenders.

d) National legislation that limits procurement through IPAs

Most national-level procurement legislation and guidelines do not allow for ARV procurement to be outsourced to IPAs, except to UN agencies. The complex tender procedures and payment terms create barriers for IPAs to participate in government managed tenders.

e) Patents on key ARV products and a lack of voluntary licences

Many EECA countries are excluded from voluntary licences issued by innovator companies for new ARV products.

f) Annual and on-time budget preparation

Budgets for procurement of ARV products are approved on an annual basis and are often only available in the first quarter of the year, with the requirement that products should be delivered within the same year. These budget regulations make it impossible to negotiate long-term agreements and procurement is subsequently often conducted in an ad-hoc emergency mode.

g) Procurement as per the latest WHO treatment guidelines

The WHO publishes new treatment guidelines every other year, and the ARV suppliers offer the most attractive prices and conditions for ARV products in line with these guidelines. Within the EECA countries the procurement of non-optimal products are often requested, which results in higher prices and less availability.

h) Limited local production of ARVs

There are insufficient local producers. This results in dependency on international manufacturers and procurement via local distributors.

4.2 Recommendations for more efficient ARV procurement for the selected countries

The detailed country analyses described above identified a significant number of challenges. Specific recommendations that are not covered by separate PSM strategies are listed here in this section of the report for each of the countries.

Georgia

- Ensure the national legislation continues to allow direct ARV procurement as per the current system.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.
- Create flexibility within the procurement mechanism to allow for multi-year contracts. This will give more assurance to suppliers who would then be more willing to register the products in Georgia and offer more attractive terms.

Kazakhstan

- Expand the range of international organisations that provide services for ARV procurement. Procurement is currently only possible through the organisations established by the United Nations General Assembly.
- Revise measures to support domestic producers, to optimise the cost of ARV therapy, and to reduce prices and increase patient coverage.
- Transition from long-term supply contracts to mid-term contracts based on international tender procedures with equal participation opportunities for local and international entities.
- Create legislative bases for NGO involvement in ARV forecasting procedures.
- Use IPA knowledge and experience for ARV planning and logistic procedures.
- Develop guidelines for non-registered ARV procurement.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

Kyrgyzstan

- Create conditions for ARV procurement through international organisations that provide services for ARV procurement and through direct procurement from manufacturers.
- Create legislative opportunities for long-term supply contracts with local and international suppliers and partners.
- Use IPA knowledge and experience for ARV planning and logistic procedures.
- Develop flexible guidelines for non-registered ARV procurement.
- Create EECA or EAEU pooling mechanisms for ARV procurement. Mechanisms could be created based on i+solutions.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

Russia

- Provide for the possibility of direct negotiations with manufacturers and long-term contracts for patented drugs with patent protection of at least three years, subject to revision, for example, provided that legitimate generic options appear in the market.
- Remove the odd-man-out act from the ARV procurement regulation.
- Optimise treatment regimens by phasing out more expensive and less clinically relevant options.
- Accelerate the adoption of new recommendations on HIV treatments that comply with WHO standards. Once this has been achieved, immediately start changing treatment standards and HIV treatment procedures.
- Analyse the current mechanism for determining the maximum starting price of contracts to identify and eliminate/correct system flaws that may result in the announcement of auctions at prices that do not allow suppliers to participate. Analyses should include discussions with market participants (distributors and manufacturers) and public organisations.
- Use IPA knowledge and experience for ARV planning and logistic procedures.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

Tajikistan

- Expand the range of international organisations that provide services for ARV procurement.
- Create legislative bases for NGO involvement in ARV forecasting procedures.
- Continue using IPA knowledge and experience for ARV planning and logistic procedures.
- Participate in a regional EECA or EAEU pooling mechanism for ARV procurement when this becomes available.

4.3 ARV procurement and supply chain strategy for the EECA region

With millions of HIV-infected people still lacking access to lifesaving ARVs within the EECA region and with funding shifting from the GF to domestic financing, it is critical to adjust procurement and supply chain strategies within the region and the individual countries. The analysis described about the current situation and challenges shows that, without strategic changes, the fight against HIV will have a significant impact on national budgets and will ultimately impact the treatment of people living with HIV.

The countries analysed all have their own challenges, but a unified strategy for the EECA region would benefit all countries in the region and ensure that the treatment of people living with HIV remains affordable.

The ARV procurement and supply chain strategy for the EECA region includes the following elements:

1. Seek opportunities for greater regional cooperation.
2. Simplify ARV procurement procedures.
3. Initiate legislative changes for the procurement of ARVs.
4. Outsource procurement and supply chain functions to specialised agencies.
5. Advocate for intellectual property flexibility for ARV formulations recommended in the WHO treatment guidelines.

4.3.1 Seek opportunities for greater regional cooperation on procurement and supply chain

While individual markets are relatively small, the total number of HIV patients in the region is substantial. The countries should seek more opportunities to cooperate on the procurement and supply chain of HIV drugs. The EECA countries can cooperate by jointly investing in a regional ARV manufacturing market and by developing a mechanism for regional drug registrations.

The most significant advantage can be gained by establishing a regional EECA or EAEU pooling mechanism for ARV procurements. Once established all ARV procurement activities across the region would be handled by one organisation that represents all participating countries. The single mechanism would be able to negotiate attractive prices and conditions for all participating countries by combining the volumes from the individual countries. A well-functioning regional mechanism could be expanded into a regional pharmaceutical marketplace with transparency on prices and the ability for suppliers and buyers to work together on one platform.

4.3.2 Simplify ARV procurement procedures

Considering the relatively low HIV population in the EECA countries, it is important to create an environment in which quality-approved ARV manufacturers participate in local tenders and are willing to offer attractive prices and conditions. ARV manufacturers are used to simplified procurement procedures as used by the GF PPM, the United Nations procurement mechanism and the USAID Global Health Supply Chain Program.

The simplified ARV procurement mechanism should include the following:

- An online registration process for participation in ARV tenders.
- A tender process in which manufacturers can offer a price and lead time without the need to submit a variety of other technical documents.
- Tenders that are announced for registered and non-registered products at the same time.
- Allowance of non-registered products if the manufacturer is willing to submit the product for registration before delivery.
- Approval to offer products with standard labels in English, with the possibility of making product leaflets available online in the local language.
- Permission to import products with documentation in English.
- No or limited preference for local manufacturers.

4.3.3 Initiate legislative changes for ARV procurement

While many countries have special provisions for procurements conducted with donor funding, the same does not generally apply for procurement with domestic funding. HIV should be considered a pandemic for which special conditions should apply in national legislation.

The national ARV procurement legislations should include:

- A fast-track registration process for products already approved by the EMA, FDA or the WHO prequalification process.
- A provision that allows for prepayment of suppliers.
- A provision that allows for contracting IPAs.

- A provision that allows for long-term agreements with suppliers exceeding the period for which the ARV budget is approved.
- A provision that allows for regional pooled procurement.
- Removal of the possibility to exclude foreign bidders when local manufacturers bid on tenders.
- Redistribution of financial savings from ARV procurement procedures to ARV procurement for the next fiscal years.

4.3.4 Outsource procurement and supply chain functions to specialised agencies

Outsourcing is a procurement strategy that leverages power in numbers to achieve process improvements and reduced costs of procurement. This strategy works by partnering with third party agents from either the public or private sector to manage the procurement process in a particular region, country, state or programme. The third party agents may be responsible for a variety of activities, including planning, contracting, and/or purchasing of goods. These procurement agencies may charge service fees at a percentage of the procurement costs.

Procurement agents typically have greater resources and capacity to ensure that manufacturers or suppliers adhere to GMP guidelines and are well situated to obtain the highest quality commodity at the lowest price possible.

This expertise helps ensure that countries or programmes are not overcharged for the procurement of goods and provides an important service for locations with limited technical capacity in specific procurement activities. In addition, greater enforcement and adherence to established policies by third party agents may help to ensure that the procurement process functions as intended and that the number of emergency orders needed is kept to a minimum.

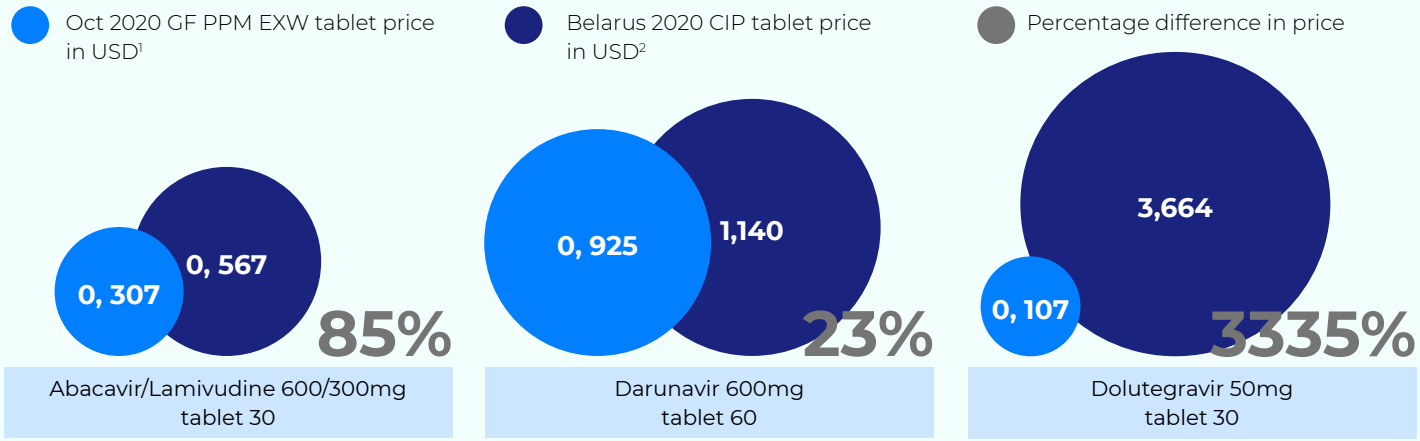
4.3.5 Advocate for intellectual property flexibility for ARV formulations

With the continuous investments in research and development within the HIV market, new ARVs and molecules become available every year. To ensure access to these new molecules at affordable prices the countries should seek proactive agreements with innovator companies on intellectual property flexibility. With support from the Medicines Patent Pool, the individual EECA countries should become eligible for tiered pricing and included in voluntary licence agreements to allow generic procurements when available.

ARV prices comparison with GF PPM prices by countries

Belarus

Key ARV products procured both via the GF PPM mechanism and Belarus government procurement mechanism



1 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf

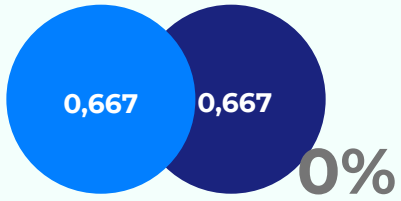
2 Questionnaire results with local consultant justifications for Belarus prices

Georgia

Oct 2020 GF PPM EXW tablet price in USD[3]

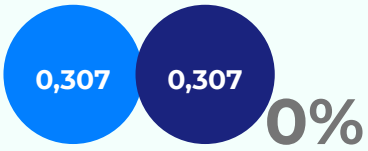
Georgia 2020 EXW tablet price in USD[4]

Percentage difference in price

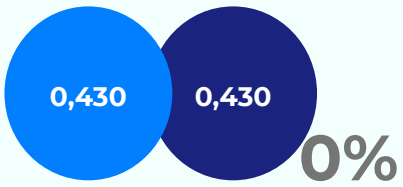


Abacavir/Dolutegravir/Lamivudine 600/50/300mg tablet 30

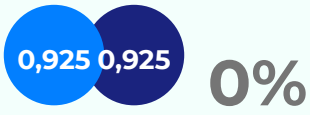
Abacavir/Lamivudine 120/60mg tablet dispersible 30



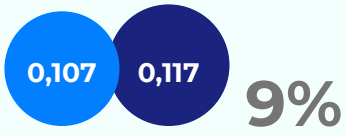
Abacavir/Lamivudine 600/300mg tablet 30



Atazanavir/Ritonavir 300/100mg tablet 30



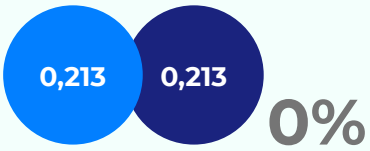
Darunavir 600mg tablet 60



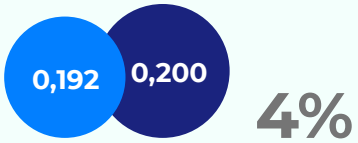
Dolutegravir 50mg tablet 30

Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 30

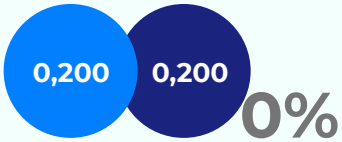
Efavirenz 600mg tablet 30



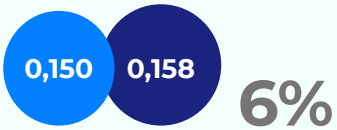
Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 30



Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet 30



Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 30



Emtricitabine/Tenofovir 200/300mg tablet 30

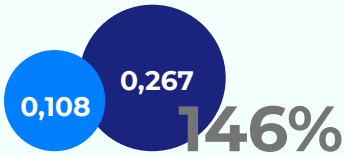
Lamivudine/Tenofovir 300/300mg tablet 30

Lamivudine/Zidovudine 150/300mg tablet 60

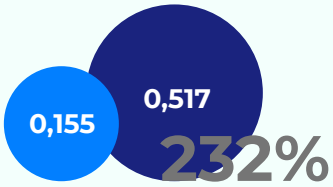
Lamivudine/Zidovudine 30/60mg tablet dispersible 60

3 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf

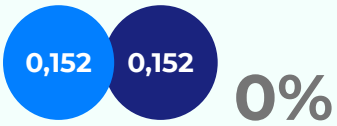
4 Questionnaire results.



Lopinavir/Ritonavir 100/25mg tablet 60

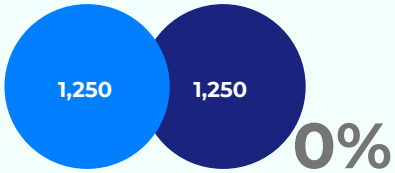


Lopinavir/Ritonavir 200/50mg tablet 120



Lopinavir/Ritonavir 40/10mg oral granules – 120 sachets

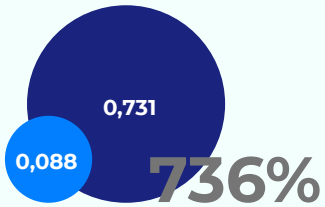
Lopinavir/Ritonavir 40/10mg pellets capsule 120



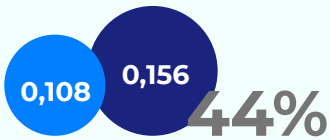
Nevirapine 10mg/ml oral suspension 100ml

Kazakhstan

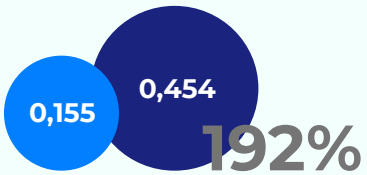
- Oct 2020 GF PPM EXW tablet price in USD[5]
- Kazakhstan 2020 CIP tablet price in USD[6]
- Percentage difference in price



Lamivudine/Zidovudine 150/300mg tablet 60



Lopinavir/Ritonavir 100/25mg tablet 60

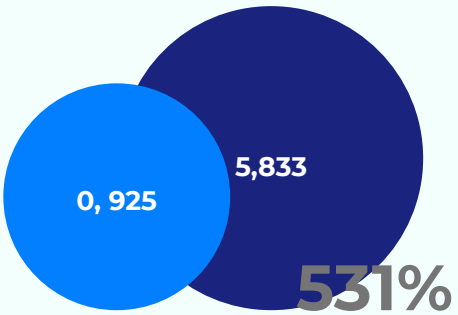


Lopinavir/Ritonavir 200/50mg tablet 120

Kyrgyzstan

- Oct 2020 GF PPM EXW tablet price in USD[7]
- Kyrgyzstan 2020 EXW tablet price in USD[8]
- Percentage difference in price

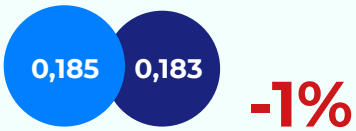
Abacavir/Lamivudine 600/300mg tablet 30



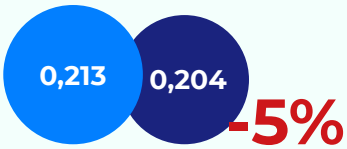
Darunavir 600mg tablet 60

Dolutegravir 50mg tablet 30

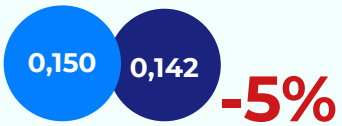
5 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf
6 https://itpcru.org/2020/10/12/otchet-po-monitoringu-zakupok-preparatov-dlya-lecheniya-vich-infekczii-i-virusnogo-gepatita-s-v-kazahstane-v-2019-godu/
7 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf
8 https://itpcru.org/2020/06/18/opublikovan-analiz-zakupok-arv-preparatov-i-preparatov-dlya-lecheniya-gepatita-s-v-kyrgyzstane-v-2019-godu/



Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 30



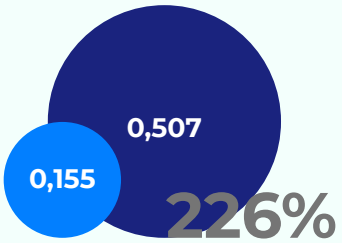
Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 30



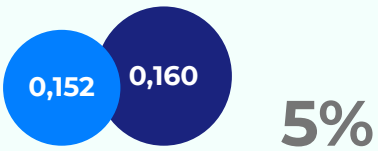
Emtricitabine/Tenofovir 200/300mg tablet 30

Lamivudine/Zidovudine 150/300mg tablet 60

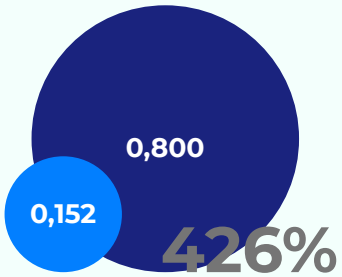
Lamivudine/Zidovudine 30/60mg tablet dispersible 60



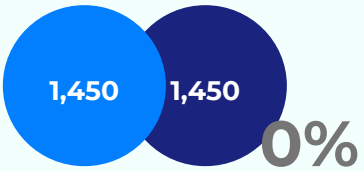
Lopinavir/Ritonavir 200/50mg tablet 120



Lopinavir/Ritonavir 40/10mg oral granules – 120 sachets



Lopinavir/Ritonavir 40/10mg pellets capsule 120



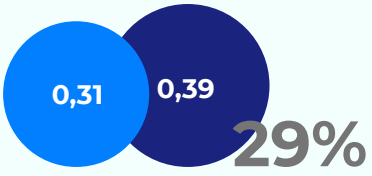
Nevirapine 10mg/ml oral suspension 100ml

Moldova

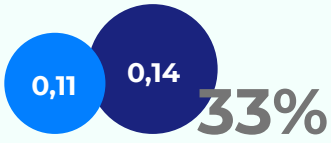
Oct 2020 GF PPM EXW tablet price in USD[9]

Moldova 2020 CIP tablet price in USD[10]

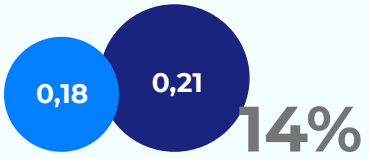
Percentage difference in price



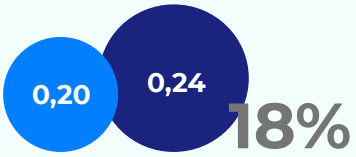
Abacavir/Lamivudine 600/300mg tablet 30



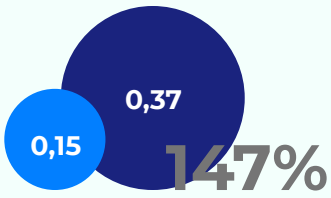
Dolutegravir 50mg tablet 30



Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 30



Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 30

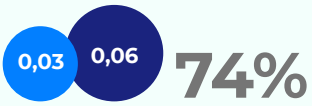


Emtricitabine/Tenofovir 200/300mg tablet 30

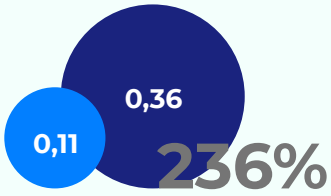
Lamivudine/Zidovudine 150/300mg tablet 60

9 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf

10 Questionnaire results with local consultant justifications



Lamivudine/Zidovudine 30/60mg tablet dispersible 60



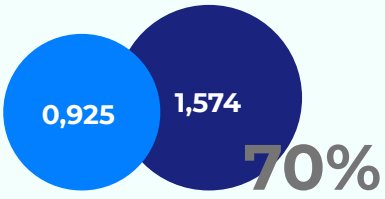
Lopinavir/Ritonavir 100/25mg tablet 60

Russian Federation

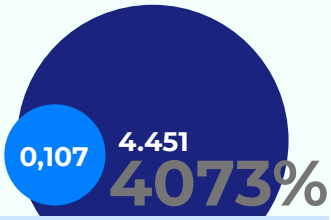
Oct 2020 GF PPM EXW tablet price in USD[11]

Russian Federation 2019 DDP tablet price in USD[12]

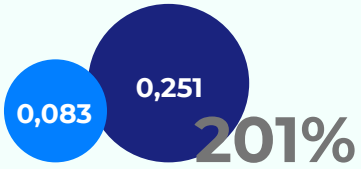
Percentage difference in price



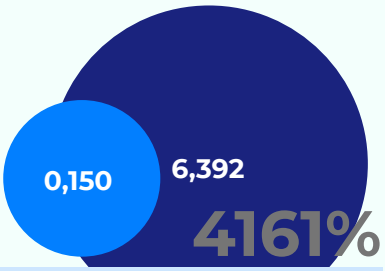
Darunavir 600mg tablet 60



Dolutegravir 50mg tablet 30

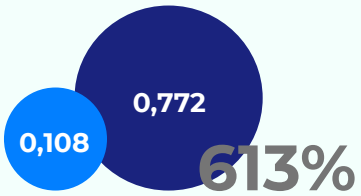


Efavirenz 600mg tablet 30

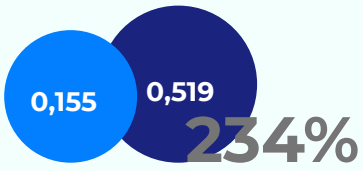


Emtricitabine/Tenofovir 200/300mg tablet 30

Lamivudine/Zidovudine 150/300mg tablet 60



Lopinavir/Ritonavir 100/25mg tablet 60



Lopinavir/Ritonavir 200/50mg tablet 120

11 https://www.theglobalfund.org/media/5813/ppm_arvreferencepricing_table_en.pdf

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