ECONOMIST IMPACT

Mechanisms used to reduce the price of antiretroviral medicines in Eastern Europe and Central Asia

Supported by

#SOS_PROJECT 2.0

Alliance for Public Health

Contents

About this report

Mechanisms used to reduce the price of antiretroviral medicines in Eastern Europe and Central Asia is a report by Economist Impact. It describes the marketing authorisation, funding, and procurement processes for antiretroviral medicines in select countries (Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine) in Eastern Europe and Central Asia (EECA), focussing on different mechanisms for achieving price reductions and improving access to treatment for people with HIV. The report also summarises good practice from individual countries that can be applied more broadly in EECA to reduce the price of antiretroviral medicines.

We would like to thank the following experts who contributed to this report through interviews and correspondence (in alphabetical order):

- **Nurali Amanzholov**, Executive Director of Central Asian Association of People Living with HIV (CAA PLHIV), Kazakhstan
- **Daryna Bondarenko**, Senior Advocacy Officer, 100% LIFE, Ukraine
- **Constantin Cearanovski**, Member of the Board of Directors, Initiative Pozitiva, Moldova
- **Mari Chokheli**, Project Manager, Network TBpeople, Georgia
- **Denis Godlevskiy**, Regional coordinator, International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA)
- **Sergiy Kondratyuk**, Project Manager, ITPC Global, Ukraine
- **Aibar Sultangaziev**, Director, Partnership Network Association, Kyrgyzstan

Economist Impact bears sole responsibility for the content of this report. The findings and views expressed in the report do not necessarily reflect the views of the sponsor or the experts.

The research and literature review were undertaken by Aanisah Khanzada with support from Anelia Boshnakova. The report was written by contributing writer Chrissy Bishop with input from the research team. Rob Cook and Michael Guterbock oversaw the research programme.

The publication was published as part of the regional project Sustainability of Services for key populations in the region of Eastern Europe and Central Asia (SoS project 2.0) and was implemented by a consortium of organizations led by the Alliance for Public Health in partnership with the CO "100% LIFE" with financial support from the Global Fund. The views expressed in this publication are those of the authors and may not reflect the views of the consortium organizations as well as the Global Fund. The Global Fund was not involved in agreeing and approving either the material itself or the possible conclusions from it.

DISTRIBUTED FOR FREE

Executive summary

The region of Eastern Europe and Central Asia (EECA) has one of the fastest-growing HIV rates in the world. Over the last decade, weak progress has been made in the region towards meeting the UNAIDS targets, and by some measures the situation has become worse. New HIV infections and AIDS-related deaths are increasing rather than decreasing. The main HIV treatment and key to controlling the HIV epidemic globally is antiretroviral therapy (ART). Generic versions of antiretrovirals (ARVs) and support from international donors to procure them mean that they are widely available at a relatively low cost. Despite this, countries in EECA pay more than other global regions for this life-saving treatment. High prices can be attributed partly to government corruption, such as overly complicated procurement processes, limited competition and intellectual property and trade framework restrictions. A failure to challenge high prices by seeking out alternative lower-cost suppliers further contributes to higher ART spends.

Many low- and middle-income countries rely heavily on support from donor funds to procure ARVs and control the HIV epidemic, yet there have been reductions in donor funds across the globe. In EECA, many countries are experiencing decreases in grants from the Global Fund, encouraging countries to develop self-sustained HIV responses and to purchase ARVs using state funds. For countries to afford this change, reducing the price of ART is crucial. Through the lens of five EECA countries, all amid funding transitions, this report examines some of the initiatives and solutions to reduce ART prices:

- **Improving ART price transparency:** National governments must publish procurement documents and pricing information to encourage efficient pricing and avoid corruption.
- **Community action:** Civil society organisations—often led by people living with HIV—and budget advocacy groups have been central to obtaining affordable ARVs in EECA. Public campaigns, publishing drug prices, opposing patents and negotiating with pharmaceutical manufacturers are among the methods advocated by civil society organisations to achieve affordability.

- **National procurement:** National procurement agencies have been developed to replace donor-fund procurement mechanisms in some countries eg Ukraine. Political will, transparent national laws, generic competition and ongoing advocacy efforts from civil society organisations are required for national agencies to achieve international purchasing power.
- **Generic competition:** Bringing multiple generics to market is a key strategy to lower the average price per person for ART. Generic competition is partly facilitated by the work of civil society organisations but also through Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and other provisions in national laws governing registration of medicines and procurement.
- **The support of donor funds and international organisations:** Despite transitioning away from donor funds to buy ART, the Global Fund, United Nations Development Programme and UNICEF continue to support broader HIV response and provide guidelines to enable a successful transition.

Background

In 2014, the Joint United Nations Program for HIV/AIDS (UNAIDS) set out its 90-90-90 targets, which aimed to provide a diagnosis to 90% of people who are HIV positive, provide antiretroviral therapy (ART) to 90% of those diagnosed and to achieve viral suppression for 90% of people treated by 2020.[1] The region of Eastern Europe and Central Asia (EECA) has one of the fastest-growing HIV rates in the world and fell short of achieving the 90-90-90 targets in 2020.[1] Between 2010 and 2021, new HIV infections and AIDS-related deaths increased by 48% and 32%, respectively, in EECA (Figure 1). The launch of the new, more ambitious 95-95-95 targets in December 2022[1] proved challenging for both EECA and globally, following a period of faltering response due to the covid-19 pandemic.[2] HIV/AIDS therefore remains at the forefront of international donors' agendas. These donors, as of June 2022, have committed 40% of the total US$21.4 billion funding allocated to programs to prevent and treat those with HIV/AIDS in low- and middle-income countries (LMICs).[3] A range of factors contributes to the growing HIV epidemic in EECA, thus continued investment remains critical. These factors include limited or corrupt government involvement, high ART costs, negligible coverage of harm reduction services as a HIV response and discrimination towards key HIV populations. In this report, we place specific focus on high ART costs, namely the pharmaceutical regulations, procurement systems and pricing processes in the region that affects both access and costs of HIV medicines.[1,4-6]

It is estimated that US$4.7 billion was spent on HIV medications in LMICs in 2020, which represented 25% of total HIV spending.[7] It has been noted that some of the key factors contributing to reduced access and high medicine prices are corruption, lack of transparency, lack of competition, poor procurement processes and intellectual property and trade frameworks.[8] To meet the 95-95-95 targets, releasing funds through more efficient drug purchasing and procurement would be an innovative and cost-neutral way to take some strain off already stretched health budgets.[7] HIV treatment includes combined ART that helps to suppress the viral load (the amount of virus an individual has in their bloodstream) and to allow the immune system to repair itself.[6,9,10] While ART prices can be expected to vary somewhat according to local economies, the EECA region pays more than other global regions for ARVs (Figure 2). In 2021, the regional average price of first- and second-line ART in EECA was $409 and $1,206 per year, respectively.[6] This is 118% more expensive for first-line and 78% more expensive for second-line therapies compared to Latin America, a region also paying higher prices than most (Figure 2).

UNAIDS suggests price reductions can be achieved by strategically adapting restrictive legislation and rearranging procurement and supply management systems to benefit from economies of scale. As donor funding for HIV treatment—which many countries in EECA have relied on—is decreasing, EECA must eventually fund HIV response domestically using limited health budgets. Paradoxically, the removal of donor funds has sparked improvements across the region, and this report—guided by the experience of five countries in the region (Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine)—aims to shine a light on good practices and success stories.

The objectives were as follows:

- Describe the marketing authorisation, funding, and procurement processes for ARV medicines in select EECA countries, focussing on mechanisms used to achieve price reductions and improve access for people with HIV, and
- Summarise good practices from the individual countries of focus.

Figure 1: Number of new HIV infections and AIDS-related deaths in EECA, 2000-2021[6]

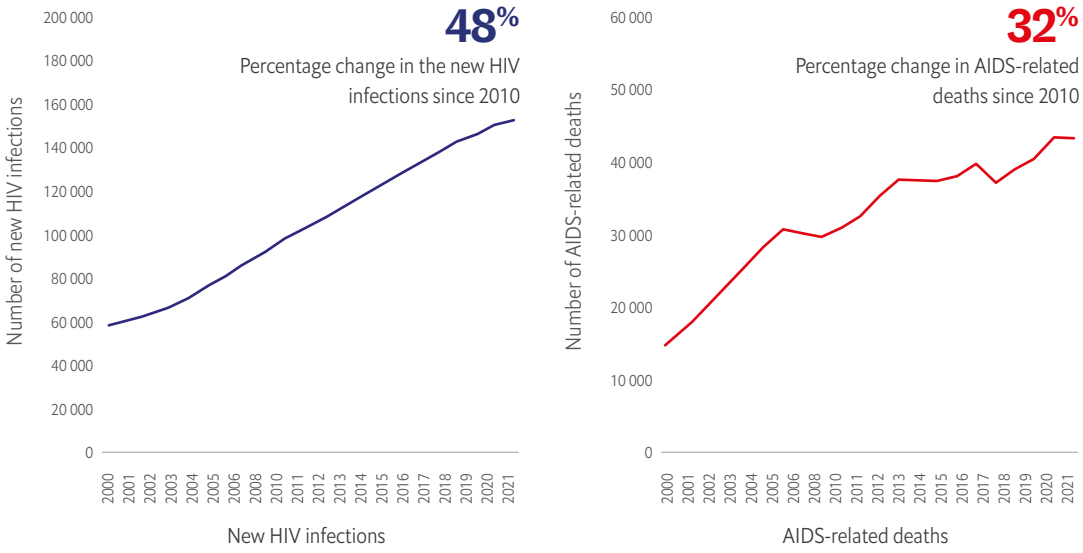
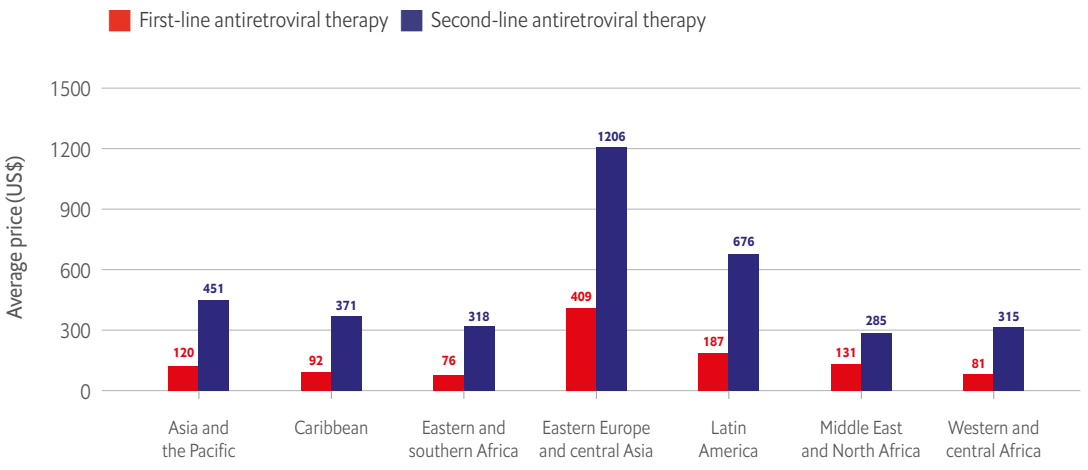


Figure 2: Average price (US$) per person-year for first- and second-line ART by region, 2021[6,11]



Factors influencing ART pricing in EECA

WHO Essential Medicines List and treatment guidelines

In 2002, the World Health Organisation (WHO) took a vital step towards improving access to care and treatment in LMICs by adding ARVs to the WHO essential medicines list. Treatment for HIV includes a combination of drugs to prevent the virus from adapting and becoming resistant. The WHO essential medicines list and WHO HIV treatment guidelines recommend prioritising fixed-dose combinations of ARVs where possible, especially important for scaling up ART in resource-poor, high-prevalence settings.[12-14] The combination is recommended because it is easier to take and less expensive to distribute than combinations in which each drug is dosed as a separate tablet.[15] The 2021 WHO essential medicines list includes six different fixed-dose regimens (Table 1). Not all these regimens are expected to be available in every EECA country. From a brief availability search based on unpublished data across the five countries of interest, it appears that between 2019 and 2021, the efavirenz + emtricitabine + tenofovir regimen was procured the most and across more countries than any other regimen.

In 2019, the WHO guidelines were updated to recommend the same ARV—dolutegravir—as the preference for both first- and second-line HIV regimens.[16] A systematic review conducted to support the guidelines update confirmed the use of dolutegravir as the preferred first-line treatment. This review suggested that compared with older, efavirenz-based regimens, dolutegravir combined with two nucleotide reverse transcriptase inhibitors leads to higher

Table 1: Fixed-dose ARV regimens on the WHO list of essential medicines[13]

abacavir + lamivudine
dolutegravir + lamivudine + tenofovir
efavirenz + emtricitabine + tenofovir
efavirenz + lamivudine + tenofovir
emtricitabine + tenofovir
lamivudine + zidovudine

viral suppression and therefore a lower risk of discontinuing treatment and developing HIV drug resistance.[16]

Countries often use the WHO essential medicines list as a guide in creating their own essential medicines lists. National lists do not always mirror WHO recommendations because different countries consider different medicines to be essential. This decision is not completely explained by differences in health needs across countries, which suggests there is room for improvement.[17] The WHO provides a Global Essential Medicines atlas, which quantifies the extent to which countries' national lists differ from the WHO essential medicines list. Three countries of interest, Georgia, Kyrgyzstan and Ukraine, are included in this atlas, with national essential medicines lists deemed 83%, 65% and 80% compatible with WHO lists, respectively.[18] This atlas was published in 2017; as such, national lists may have since been updated according to newer WHO HIV treatment guidelines. Even so, the atlas serves as a barometer of countries' adherence to the WHO essential medicines lists.

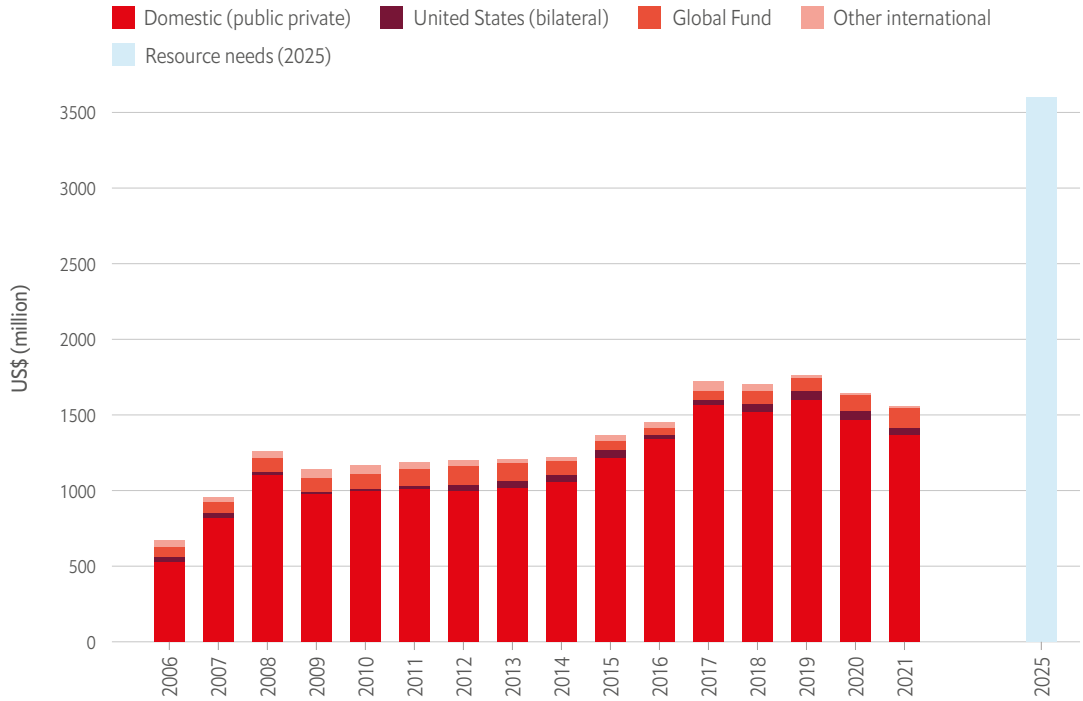
Changing funding structures

For many LMICs, ART procurement and control of HIV epidemics are based on support from donor funds. Countries with higher disease burdens and lower income levels are prioritised for donor assistance, and in EECA, several organisations have provided ongoing support for HIV response, including the Open Society Foundation, UN agencies, USAID and the Global Fund.[19] In 2021, 12% and 88% of total HIV funding in EECA came from external and domestic funds, respectively.[11]

HIV financial resources, both from donors and the state, are being pressured from multiple angles. On a global scale, overseas development assistance for HIV from bilateral donors (other than those from the US) has dropped by 57% in the last decade.[2] The World Bank has projected 52 countries, amounting to 43% of people living with HIV, will experience reductions in spending capacity by 2026.[2] At the same time, in 2022 UNAIDS announced global HIV funding must increase by 30% to respond to growing epidemics and to end AIDS by 2030 (Figure 3). What ultimately seems like a catch-22 situation is particularly devastating for countries that rely on donor funding for buying ARVs. International donors such as the Global Fund and the US President's Emergency Plan for AIDS Relief (PEPFAR) are consequently encouraging sustainable financing and country-led HIV responses.[20] The Global Fund's Sustainability, Transition and Co-Financing (STC) Policy[21] stipulated that all countries with upper-middle income status, regardless of disease burden, and all countries with lower-middle income status and low or moderate disease burden, should begin preparing to domestically fund their HIV response.[22]

Several countries in EECA have progressed along the development continuum, either economically or by lowering HIV disease burden.[21] To further assist with country transitions, the Global Fund launched a multi-country initiative called Sustainability of Services for Key Populations in Eastern Europe and Central Asia project (the SoS project) (2019-2021). This project provided a guide for the EECA region on how to generate domestic funding for HIV programmes, as well as strategies for accruing savings via efficient ART procurement programmes.[19] Many countries in the region have deployed budget advocacy groups, which comprise experts, civil society organisations (CSOs) and communities aiming to directly influence how the government allocates and spends its money.[23] Budget advocacy can be used as a tool to increase the amount of funds spent on ARVs or to improve the efficiency of spending by increasing the amount of oversight.[19] The Open Society Foundation, for example, invested 28% of its resources into budget advocacy for select EECA countries, including Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine.[19]

Figure 3: Resource availability for HIV response in the EECA region, 2006-2021, and estimated resource needs by 2025[6, 11]



Note: The figure for 2025 has been estimated from the graph in the original source[6]

Increased availability of generics

One of the key drivers of lower ART costs is the availability of generics. When a new drug is created, patents provide the owner a legal right to prevent other companies from manufacturing and selling the drug for 20 years.[24] This prevents the sale of generic drugs (the same drug produced by a different company) at a lower price until the patent expires.[24] Generics are usually a lot cheaper than in-patent drugs, not least because generic manufacturing can be carried out by multiple suppliers and thus is more competitive. The sale of generics is often complicated and restricted by in-country legislation and procurement processes. TRIPS agreement was introduced to harmonise patent laws internationally. It is an international legal agreement among members of the World Trade Organisation (WTO), establishing a set of intellectual property rules. One of these rules requires TRIPS member countries to apply patents to pharmaceuticals for a period of 20 years. Before TRIPS, patent protection was classed as "weak" in LMICs, with patent terms much shorter (four to seven years).[25] Its adoption meant expanding intellectual property protection to developing countries.[26] This decision was considered detrimental to public health, especially in countries with public health emergencies such as HIV. As a result, TRIPS flexibilities were introduced, allowing WTO member states certain provisions in national laws. One such provision is compulsory licensing, so countries can produce medicines domestically without authorisation of the patent holder. Because many LMICs have limited to no domestic manufacturing capabilities, an additional provision allows countries to source patented medicines from a foreign supplier.[27,28] Compulsory licences—which are defined by a country's national patent law and should comply with certain requirements of the TRIPS agreement—can be issued in situations of national emergency or when countries have attempted to negotiate a voluntary licence

but have failed.[29] However, not all countries in the EECA region take advantage of TRIPS flexibilities, which will be discussed in more detail in the country profiles.

Voluntary licences can also boost the supply of generics in a country and are sometimes offered by the patent holder when the drug in question remains under patent. This is a deal that involves a generic manufacturer paying a royalty in exchange for the right to create a generic version of the patented drug at a lower price.[30,31] Most high- and upper middle-income countries are excluded from voluntary licences,[32] a decision made similarly to how donor funding is allocated—by prioritising countries with a higher burden of disease and economic instability.[31]

The Medicines Patent Pool (MPP), a UN-backed public health organisation aiming to increase access to essential medicines in LMICs, and ViiV Healthcare, a pharmaceutical manufacturer, signed a voluntary licence in 2014. This enabled better access and reduced pricing of the WHO-recommended ART dolutegravir for LMICs with high HIV prevalence.[33] Of the five countries of focus, the voluntary licence included Georgia, Kyrgyzstan, Moldova and Ukraine, initially excluding Kazakhstan due to its upper middle-income status. In 2020, following the involvement of local CSOs, Kazakhstan also became part of this voluntary licence.[33]

An ongoing barrier to the sale of generics is the extension of patents through a process called evergreening, in which pharmaceutical companies re-patent an old invention that has undergone slight modifications, which usually provide minimal or no additional therapeutic benefits.[34,35] Evergreening allows pharmaceutical companies to retain revenues and prevent generics from entering the market, stalling price reductions.[36] Some CSOs in EECA have helped oppose evergreening via lawsuits.[37]

Procurement strategies

Procurement strategies are policies aiming to foster competition and improve access to medicines. Procurement policies need to align with the policies of each national healthcare system,[38] which means they undoubtedly vary across countries, often reflecting differences in public/private healthcare coverage, cultural practices, and government structures. Procurement inefficiencies may arise when the process is corrupted in some way by suppliers and/or procurement bodies. Corruption might involve compromising the transparency of procurement, avoiding competitive tendering processes and reducing competition from alternate suppliers, thus inflating ART prices.[39,40] The WHO tried to reduce corrupt procurement practices in 2017 through the Fair Pricing Initiative, which noted that the lack of transparency surrounding drug development costs, pricing and processes was a key obstacle to achieving fair pricing of medicines globally.[41]

A variety of procurement processes have been adopted in EECA. Some of these are imposed by multilateral organisations for those reliant on donor funding, while others have been created by local government bodies and CSOs. A common procurement strategy for those in

receipt of donor funds is pooled procurement, a formal arrangement among different purchasing authorities, allowing financial resources to be combined in favour of procuring health products as a single entity, rather than individual procurements from separate purchasing authorities.[42] It is usually managed by Ministries of Health or by international donors. Some countries use the Global Fund's 'in-house' pooled procurement mechanism and the online purchasing platform wambo.org, which gathers ARV orders from a range of countries, highlighting price discrepancies and variations in delivery conditions from manufacturers. Using this platform helps buyers make informed purchases and equips countries with negotiation leverage to help reduce ARV prices.[34] Other e-procurement processes have been developed locally through the work of CSOs, dramatically increasing transparency of state procurement processes and bringing together suppliers and customers onto one online platform. Together, this strengthened local governments' ability to acquire products or services at the best price. Some EECA countries—such as Moldova and Ukraine—attribute significant ART savings to the implementation of e-procurement systems.[43] In the absence of online platforms, open contracting is an alternative option for countries with corrupt procurement processes. Open contracting involves the publication of government medicines contracts, which can highlight inflated pricing.[44,45]

CSOs and budget advocacy networks play a pivotal role in reducing medicine prices in EECA. The aim of harm reduction budget advocacy is to achieve sustainable, efficient domestic funding for harm reduction (including ARTs).[23] In the HIV space, CSOs have helped garner mass public attention from the HIV community and policy makers. Through collaboration with government departments responsible for medicine procurement, CSOs help combat issues such as inadequate transparency of procurement processes, overpricing and outdated treatment protocols. In some countries, CSOs and budget advocacy networks have played a crucial role in securing the continued support from international actors like the Global Fund.[46] Organisations such as the International Treatment Preparedness Coalition and 100% LIFE (patient-led organisation) have helped simplify first-line treatment options and obtain generic ARTs. CSO advocacy has also helped countries achieve provisions in national laws for greater procurement freedoms.[47] As EECA countries transition towards self-sufficient HIV responses, the work of CSOs and budget advocacy networks will be fundamental to ensure that domestic HIV treatments are sustainably financed.[23,48]

Progress towards ART price reductions in Georgia, Kazakhstan, Kyrgyzstan, Moldova, and Ukraine

The EECA region has seen some ART price reductions, which can in part be attributed to the Global Fund's Sustainability of Services project but also to individual country efforts to improve the public procurement of medicines. Based on official country data collated by the Alliance for Public Health, the average price of ARVs per person decreased in all five target countries between 2018 and 2021 (Table 2). The most significant ARV per-person cost reductions were in Kyrgyzstan, which halved costs between 2018 and 2020. The smallest cost reduction (29%) was in Kazakhstan. In Moldova, Georgia and Ukraine, there were reductions of 39-42%. In 2021, Ukraine had the lowest average cost of ARV treatment (US$79.72), and Kazakhstan had the highest (US$661.32) (Table 2). Although prices of ARVs have declined, coverage has not increased substantially. Figure 4 shows that steady increases in ART coverage were achieved between 2014 and 2018, followed by a trailing off between 2018 and 2021. Georgia experienced no increases in ART coverage in three years (2019-2021), with very marginal increases in coverage (1%) in Kazakhstan and a 2-4% increase in the other three countries.

Table 2 also shows changes in the total budget allocated to ARV procurement from the state and donors in the target countries between 2018 and 2021. In all but Kazakhstan, budgets decreased, most significantly in Kyrgyzstan, by 33%, followed by 29% in Moldova, 15% in Georgia and 13% in Ukraine. In Kazakhstan, the total budget for ARV procurement increased by 18% between 2018 and 2021. Budgets decreased most significantly in Kyrgyzstan and Moldova, but those countries also achieved the largest average ARV price reductions (Table 2). Table 3 shows a crude estimate of the total ARVs savings, by country, between 2018 and 2021. Ukraine saved the most, closely followed by Kazakhstan, with Kyrgyzstan saving the least. However, these small improvements are likely not enough to meet the 95% coverage targets set by UNAIDS.

Further ARV price reductions in Kazakhstan and Kyrgyzstan may be stalled due to the recent introduction of a new supranational drug registration process, regulated by the Eurasian Economic Commission (EEC).[49] The EEC is an institution within the Eurasian Economic Union (EAEU or EEU), which aimed to create a common market—a formal agreement among several countries to adopt the same external tariffs—among Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia. Headquartered in Moscow, the EEC drug registration process came into force on 1 July 2021, with the intention of ensuring registered medicines are based on the best scientific expertise available and greater transparency of documents relating to the analysis, testing and registration of medicines. However, the complicated processes and supranational decision-making make it difficult for countries to pursue their own interests. Further concerns include the significant increase in registration terms, meaning it may take some time to convert national registration procedures to centralised ones and delay the entry of drugs to market. These difficulties could also deter pharmaceutical companies from registering drugs in the EAEU, consequently reducing competition and increasing the cost of medicines. Taken together, the EEC regulations may affect the availability of ARV medicines for HIV patients in countries that are part of the EAEU, such as Kazakhstan and Kyrgyzstan.[49]

Figure 4: Historical trend of ART coverage for people who have HIV (2014-2021)[50]

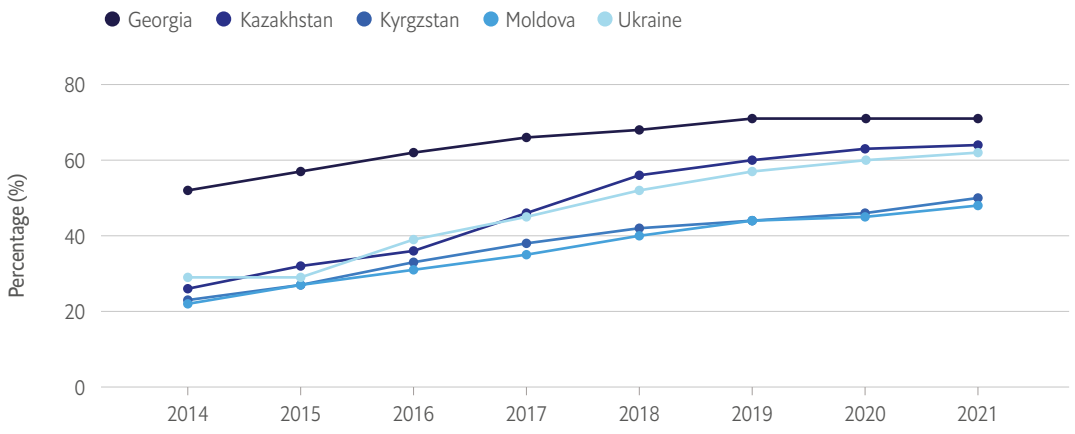


Table 2. Yearly budget for drug procurement and average costs to treat one person from 2018 to 2021 (in US$)

	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Ukraine
Actual budget (state and donors) for all procurement of all ARVs, 2018	904,523.55	13,983,410.74	773,736.86	1,069,551.8	11,880,711.75
Average cost of treatment for 1 patient, 2018	196.76	935.28	208.10	179.42	131.64
Actual budget (state and donors) for all procurement of all ARVs, 2019	1,124,428.72	13,324,624.43	772,798.94	812,404.77	12,201,291.37
Average cost of treatment for 1 patient, 2019	220.56	844.56	190.43	121.43	107.93
Actual budget (state and donors) for all procurement of all ARVs, 2020	896,696.12	15,078,348.47	440,002.71	764,702.4	12,286,814.43
Average cost of treatment for 1 patient, 2020	163.03	747.30	99.08	112.29	100.75
Actual budget (state and donors) for all procurement of all ARVs, 2021	769,346.18	16,504,494.98	519,743.25	760,052.17	10,383,256.61
Average cost of treatment for 1 patient, 2021	116.62	661.32	103.12	104.59	79.72

Note: Price per patient is calculated by dividing the amount of money spent on procurement of ARVs by the number of patients receiving ART as of December 31 of each year. One of the limitations of this method is that sometimes countries procure more ARVs than required to allow for an emergency surplus, which would also result in higher costs per patient.

Table 3: Savings across Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine from 2018 to 2021 (in US$)

	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Ukraine
Actual savings 2018/2019*	–121,326.47	1,431,329.77	71,693.85	387,947.78	2,680,501.67
Actual savings 2019/2020*	316, 398.81	1,962,340.32	405,734.13	62,274.65	875,141.14
Actual savings 2020/2021*	306,200.06	2,145,965.57	–20,380.05	55,967.26	2,738,806.09
Total actual savings*	501,272.40	5,539,635.67	457,047.92	506,189.69	6,294,448.91

*Formulas used:
2018/2019 = Actual number of patients on ART, 2019 × average cost to treat one patient, 2018 – actual budget (state and donor) for procurement of all ARVs, 2019
2019/2020 = Actual number of patients on ART, 2020 × average cost to treat one patient, 2019 – actual budget (state and donor) for procurement of all ARVs, 2020
2020/2021 = Actual number of patients on ART, 2021 × average cost to treat one patient, 2020 – actual budget (state and donor) for procurement of all ARVs, 2021
Total savings = The total of columns 1, 2 and 3.

Price-reduction mechanisms in target countries

In this section, individual country procurement mechanisms and funding streams are discussed in the five countries of focus (Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine). Each country section includes a brief description of the marketing authorisation process, the structure of funding (donor versus state) and the procurement processes adopted, highlighting good practices.

Georgia

Price-reduction mechanisms	Pooled procurement (Global Fund) Budget advocacy by civil society organisation
Average cost of ART per person (2021) (US$)[51]	116.62*
Cost of first line ARV treatment (2021) (US$)[51]	78.84**
HIV expenditure from domestic public sources (2021) (US$)[52]	14,000,000
HIV expenditure from international sources (2021) (US$)[52]	2,500,000
% coverage of people receiving ART (2021) (all ages)[52]	71% [95% confidence interval (CI), 67-75]
Income level[53]	Upper middle-income country

*See also Table 2.
**Cost of first-line ARV treatment includes TDF/XTC/EFV

"Transparent procurement is not enough. Transparent procurement plus a competitive market together will help reduce the risk of monopolisation of drug supply and look to reduce the prices of ARV medicines."

Mari Chokheli, Project Manager, Network TBpeople, Georgia

Marketing authorisation

By law, Georgia requires that state funds be used to purchase registered medicines, and only registered medicines are allowed to be manufactured, purchased and used.[46,54] Drug registration has two mechanisms: national registration for branded and generic drugs and recognition procedures for drugs that are already formally approved by the European Medicines Agency, the US Food and Drug Administration or by regulators of other developed countries.[47,54] The recognition procedure is a much quicker process, taking a week between submitting documents and adding the pharmaceutical product to the registry. This process is useful when quick changes to treatment regimens are required.[47,54] Unlike many LMICs, Georgia does not have fast-track procedures for registration of WHO-prequalified medicines,[55] and as of 2020 only four out of 24 medicines procured by the Global Fund were registered in the country by manufacturers.[46] However, there is an ARV drug waiver in the national law, which means Georgia can skip the registration process due to the country's Global Fund donor status and import nonregistered ARVs if they have markings in Russian, English or an EU language.[55] Further, ART and second-line anti-TB drugs are procured using state funds through the Global Drug Facility.[54] In other countries, procurement using state funds through the Global Drug Facility is prevented by national legislation. Georgia is also part of a voluntary licensing agreement between MPP and ViiV allowing the in-patent ARV dolutegravir to be produced by generic manufacturers.[56]

Structure of funding

Since 2003, Georgia has been dependent on Global Fund support and has received five grants for a total of US$88m to support its national HIV/AIDS programs. Since transitioning from a lower-middle income country to an upper middle-income country, donor funding is set to decrease. Because the HIV prevalence is high, the Global Fund continues to support Georgia, but overall donor funding is decreasing. As such, in 2015, Georgia started to shift procurement of ARVs—as well as anti-TB medicines—from donor to state funds.[54] To help with the transition, the Global Fund continues to work alongside Georgia on the implementation of its five-year national strategic plan to transition away from Global Fund support.[57] By 2020, state funds had covered more than half (60%) of the total cost of ARV drugs. First-line ARV drugs are procured with state funds and second-line drugs through the state and the Global Fund together.

The transition comes at a challenging time economically for Georgia. CSOs have noted that, in the national HIV budget, a lion's share is spent on procurement of ARVs over other activities required for HIV response, such as testing, opioid substitution therapy and outreach support. The procurement price for ARV drugs was noted to be higher than the reference price, despite making use of the pooled procurement method.[58] The procurement price was as much as to two, five and six times higher than the reference price for lopinavir, darunavir and abacavir, respectively.[58] Ms. Chokheli elaborates: "A challenge that needs further exploration is how to achieve the purchase of drugs with state funds at an international price all the while exchange rates continue to fluctuate." The Georgian lari has devolved against the US dollar, with further devaluations risking considerable barriers to procuring ARVs at an international price.[58,59] This leaves Georgia in a situation where donor budgets for HIV response—and thus ART funds—are decreasing, while the weak exchange rate risks making ART unaffordable at international prices.

Procurement process

ART donor funds are managed by Georgia's National Centre for Disease Control and Public

Health, in contrast to traditional processes in which funds are managed using the common state procurement. A waiver in the State Budget Law allows the National Centre to procure ARVs using the pooled procurement method through the Global Fund. In this way, Georgia obtains reduced prices for both patented and generic ARVs across the country.[47,59] Georgia has further established two budget advocacy networks to help reduce the price of ART: the Georgian Harm Reduction Network and the Open Society Georgia Foundation. Georgia also has the benefit of not paying VAT (value-added tax) on ART purchases due to a special waiver from the Ministry of Finance.[59]

Summary of lessons learnt

- Since becoming an upper middle-income country, Georgia has committed to increasing the scope and scale of HIV interventions, ensuring that all affected populations can access treatment and other programs. The government has increased domestic investment in HIV programs while transitioning away from Global Fund support.
- Provisions in the national law on drug procurement allows Georgia access to ARV drugs without the need for registration due to their Global Fund status.
- Remaining donor funds for ARV procurement are managed by the National Centre for Disease Control and Public Health rather than the state, to ensure that inequalities in access to ART are avoided and areas with the highest prevalence are targeted.
- The pooled procurement method allows bulk purchases of ARVs at a reduced price.
- Georgia is included in a voluntary licensing agreement between MPP and ViiV for dolutegravir that allows generic ARVs to enter the market.
- The government of Georgia is accountable for the procurement of first-line ARV drugs and subsequently covered 60% of total ART costs in 2020.
- The government and CSOs have established budget advocacy networks to help identify overspending on essential medicines for HIV. As such, Georgia aims to improve transparency of procurement processes, tenders and contracts to help achieve the best possible ARV price.

Kazakhstan

Price reduction mechanisms	Pooled procurement (via UNICEF) Budget advocacy by civil society organisations
Average cost of ART per person (2021) (US$)[51]	661.32*
Cost of first line ART treatment (2021) (US$)[51]	92.72**
HIV expenditure from domestic public sources (2021) (US$)[60]	60,000,000
HIV expenditure from international sources (2021) (US$)[60]	9,200,000
% coverage of people receiving ART (2021) (all ages)[60]	64% [95% CI, 57-71]
Income level[61]	Upper middle-income country

*See also Table 2.
**Cost of first-line ART treatment includes TDF/XTC/EFV

Marketing authorisation

The national registration process in Kazakhstan requires manufacturing organisations to have a good manufacturing practice certificate. The process required to register WHO-prequalified drugs in Kazakhstan can take almost a year, so nonregistered drugs can be approved for import by the Ministry of Health on the condition that they have WHO prequalification in the source country. Only in emergencies can nonregistered drugs be imported without WHO prequalification.[55]

Kazakhstan's economic position as an upper middle-income country resulted in the exclusion from the 2014 MPP and ViiV voluntary licensing agreement, which allowed generic dolutegravir suppliers to enter the market in select LMICs, subsequently lowering prices.[62] In 2019, the Ministry of Health tried and failed to argue for Kazakhstan's inclusion in the MPP and ViiV voluntary licence that, at the time, one source estimated could have reduced the price of dolutegravir from US$118 to US$4.5 for a 90-tablet bottle.[63] As a result, the government took legal steps in pursuit of a compulsory licence[64]—which essentially forces ARV manufacturers to license the drug to the country and opens up the right for any other manufacturer to supply a generic ART to increase the number of people receiving HIV treatment.[65] In addition, CSOs wrote to ViiV Healthcare advocating in favour of Kazakhstan's inclusion in the voluntary licence.[66] Consequently, in 2020, ViiV created a special dolutegravir voluntary licence for several upper middle-income countries, including Kazakhstan, with high HIV prevalence.[56,64,65,67]

On 1 July 2021, the EEC took over from the national registration process in Kazakhstan

"Only WHO-prequalified medicines that are registered can be procured in Kazakhstan apart from a one- time collection if necessary."

Nurali Amanzholov, Executive Director of Central Asian Association of People Living with HIV (CAA PLHIV), Kazakhstan

as the regulating body for the registration of medicines. Due to the aforementioned complications of the EEC regulation process, Hetero and Viatris (generic suppliers of ART) both tried to register generic ARVs in Kazakhstan before the EEC regulations were set.[68] Only Hetero was successful in doing so, and Viatris withdrew. The price of Hetero's generic ARV is yet to be confirmed officially (Sergiy Kondratyuk, Project Manager, ITPC Global, Ukraine, personal communication, 15 March 2023). Adding only one generic manufacturer is not likely to generate competition from other generic suppliers and as such lower prices. Also the special voluntary licence in Kazakhstan included higher royalty fees than those previously charged in MPP voluntary licences[69] and allowed expressions of interest from just three generic manufacturers. The LMIC MPP voluntary licence allowed up to 16.[69,70] The current EEC regulations could also result in Kazakhstan losing access to the voluntary licence eventually, and so the country has started a discussion to save their national registration process.[49]

Structure of funding

Kazakhstan was one of the first countries in the EECA region to lose access to HIV donor funds. In 2006, the country transitioned to an upper middle-income country, and donor funds began to decrease. With a higher GDP per capita than many countries in the region, Kazakhstan was considered by donor organisations to have an economic advantage and be in a stronger position to independently fund the HIV response.[62] Nevertheless, in 2012, 20% of HIV spending still came from international donors.[62] Kazakhstan has shown strong commitment to supplementing donor funding gaps, with 94% of HIV response (including but not limited to ART) supported domestically as of 2020.[48,71,72] The costs of procuring ARTs in Kazakhstan, however, are 110% higher than the average cost in the region.[62] In 2017, it was estimated that Kazakhstan needed to reduce the price of ART by 35% to achieve the 2020 national HIV targets.[62]

Procurement process

There are three ways to procure ART in Kazakhstan.[73] These include either a two-stage national tender, purchasing under long-term supply contracts from domestic manufacturers, or through a single source (for example, UNICEF).[73] Although some efforts have been made to improve the transparency of drug registration, not all procurement methods are made public, and those procurement methods are mainly two-stage tenders.[73]

Kazakhstan still leverages the support of multilaterals and, since 2016, has procured ARVs via UNICEF, which tripled the number of people accessing ART with the same level of funding. In 2017, procurement of two generic ARVs—abacavir and lamivudine (which previously had the trade name Kivexa)—were purchased through UNICEF. The introduction of generic ARVs through UNICEF's procurement agency contributed to price reductions as well as expanded treatment protocols.[5] In 2020, the country was able to provide ARV drugs to approximately[19],211 people living with HIV, an increase of 42% from 2016.[73]

One of the main forces helping to reduce ART prices in Kazakhstan is the HIV community itself. The Central Asian Association of People Living with HIV (CAAPL)—a CSO—helps build resilience in HIV communities and leads efforts

"The high level of bureaucracy as it relates to drug registration in Kazakhstan is in need of great attention."

Nurali Amanzholov, Executive Director of Central Asian Association of People Living with HIV (CAA PLHIV), Kazakhstan

to improve efficiencies in HIV budgets.[48] CAAPL, together with 100% LIFE (a Ukrainian patient-led organisation), International Treatment Preparedness Coalition in EECA, WHO/Europe and the Kazakh Scientific Centre of Dermatology and Infectious Diseases, reviewed HIV treatment protocols with a view to making the then-patented dolutegravir (brand name Tivicay) available as a first-line treatment. This suggestion faced significant opposition because it was considered too expensive to buy dolutegravir at its patented price point.[48] CAAPL continued to work to create an alternative first-line solution, and in 2020, bictegravir, a cheaper generic ARV, was successfully added to the country's treatment protocol.[48] CSOs also positively influenced Kazakhstan's inclusion in the MPP and ViiV voluntary licence and the creation of a generics sublicensing agreement with Hetero.[51] The Minister of Health of Kazakhstan endorsed access to generics as a key mechanism for driving down ARV prices, greatly benefiting people living with HIV infection.[56]

Mr Amanzholov, Executive Director of CAA PLHIV, Kazakhstan, stated, "There has been some successful reduction in price, meaning more coverage for people to be treated will take place without extending the burden on the budget. ARV therapy is now almost 100% funded from the state." And yet, the price of ARVs remained high, and in 2021, Kazakhstan, had not achieved an affordable price for dolutegravir.[74] This could also be due to a lack of transparency in medicine contracts, with only 13% of total government expenses on ARVs open to public monitoring.[73,74] As Mr Amanzholov explains, "Transparency of drug procurement gets lost at the civil society stage, meaning that citizens who are taking these medicines daily are not able to see how the procurement process takes shape. There needs to be integrated legislation which allows for simplified market entry as well as a transparent tendering process, which could help reduce prices."

Summary of lessons learnt

- Kazakhstan's higher economic position than many of its neighbours has resulted in earlier cuts in donor funds. As a result, Kazakhstan has made more progress towards switching to a domestically funded HIV response. As of 2020, 94% of HIV response was funded domestically.
- Kazakhstan pays higher ARV prices than other countries in the region. CSOs played a huge role in improving access to generic ARVs and thus reducing prices, including access to the MPP and ViiV voluntary licence, and creating a generics sub-licensing agreement.

Kyrgyzstan

Price reduction mechanisms	Generic competition Pooled procurement (via UN Development Programme and Global Fund) Budget advocacy by civil society organisations
Average cost of ART per person (2021) (US$)[51]	103.12*
Cost of first line ART treatment (2021) (US$)[51]	89.43**
HIV expenditure from domestic public sources (2021) (US$)[75]	1,900,000
HIV expenditure from international sources (2021) (US$)[75]	5,100,000
% coverage of people receiving ART (2021) (all ages)[75]	50% [95% CI, 47-55]
Income level[76]	Low and middle-income country

*See also Table 2.
**Cost of first-line ART treatment includes TDF/XTC/EFV

Marketing authorisation

There have been several legislative changes in Kyrgyzstan that provide the country with drug registration freedoms. In 2015, the Patent Law was amended, which enabled the use of TRIPS flexibilities.[77] This allowed parallel import opportunities from the cheapest source in any country worldwide and an improved compulsory licensing mechanism that makes it possible for the government to import generic versions of patented products in public health emergencies.[78] In 2017, a new law called the Circulation of Medicines was introduced, which sought to improve the quality of medicines available and accelerate the registration process. Specifically, this law aimed to facilitate registration of medicines from countries with more-complicated regulatory processes and create a list of essential medicines mirroring that of the WHO. This law also grants some medicines a unique exemption from the registration process if they are used to treat diseases that pose a significant threat to the health of the population—including HIV. The essential medicines list created under the Circulation of Medicines law must be updated every two years to ensure continued efficacy and value for money. Dolutegravir was included in this list, along with three other generic ARTs—darunavir, raltegravir and atazanavir.[77,79] According to the 2022 International Treatment Preparedness Coalition EECA report, a total of 51 ARVs were registered in Kyrgyzstan, half of which were registered in 2020 alone.[80] Further, more than 90% of registered ARTs were generics, which was likely influenced by the amendments to the Patent Law in 2015.[80] This legal change

"There are already drugs on the local market that compete with international prices, meaning our domestic tender procedures allow us to supply the drug faster than those provided by the UN."

Aibar Sultangaziev, Director, Partnership Network Association, Kyrgyzstan

made Kyrgyzstan a lucrative market for generics companies and significantly contributed to lowering the costs of ARVs.[80]

However, similar to Kazakhstan, Kyrgyzstan is now a member of the EAEU, meaning the EEC regulations for medicine registration came into force on 1 July 2021.[49] Existing pharmaceuticals legislation in Kyrgyzstan, which grants recognition of clinical trials conducted outside of the county, specifically for medicines prequalified by the WHO, may be jeopardised by the EEC regulations. To resolve this issue, legal acts relating to medicine registration within the EAEU require amending. Consequently, discussions continue, in order to decide under what circumstances, and for which medicines, the requirement of conducting local clinical trials can be removed.[49] Since 1 July 2021, only one new generic ART has been registered in Kyrgyzstan. It is thought that the reasons for this are that most registered drugs were supplied from factories in India or Pakistan, which do not have the appropriate registration documents to meet the EEC regulations. As a result, the previous flurry of interest from generic manufacturers has declined.[49]

Structure of funding

Kyrgyzstan is classified as an LMIC and as such continues to receive donor support from the Global Fund. In 2016, Kyrgyzstan also developed a plan to transition towards state funding, which was integrated in the National HIV programme, 2018-2021.[80,81] Before the launch of this programme, all ARV drugs were funded by the Global Fund and procured by the UN Development Programme (UNDP).[80] After the launch of the programme, for the first time the state budget was being used to support 40% of the HIV response,[77] and 90% of ARTs were purchased from the state budget, except for paediatric medicines (Aibar Sultangaziev, Director, Partnership Network Association, Kyrgyzstan, personal communication, 14 November 2022). Amendments to procurement legislation allowed international organisations to manage the public procurement process, and they are usually able to obtain lower prices compared with local procurement organisations.[80] As such, USAID-funded programs facilitated in-country capacity to engage in state social contracting, and in 2019, the Ministry of Health started state funding of HIV services delivered by nongovernmental organisations.[81]

Procurement process

The main mechanism used to procure ARVs in Kyrgyzstan is pooled procurement through the UNDP.[80] However, following Global Fund donor reductions, CSOs have worked alongside the UNDP to help transition away from donor to state funding, to improve the transparency of procurement processes and to lower the price of ART.[77] For example, the Budget Coalition for Budget Advocacy in the field of HIV and other Socially Significant Diseases was set up in 2017, comprising 40 HIV community organisations and supported by the Open Society Foundation and the Soros Foundation. The Budget Coalition facilitates capacity building, budget analysis, budget transparency and state and local social contracting, and it provides advice to budget holders such as the Ministry of Finance and Health.[81] In a review of progress since its inception (2017) to 2020, it was estimated that the Budget Coalition helped increase Kyrgyzstan's health budget from US$215m to approximately US$239m in 2020. In addition, Kyrgyzstan's official joining of the Open Government Partnership (OGP) was heavily influenced by the Coalition. The OGP is a group of activists inside and outside government with a mission to reduce corruption.[81,82] Becoming a member of the OGP was seen as a continuation of the country's efforts to build an open and democratic society, which in the context of medicines includes providing transparent procurement processes.[82] As part of its membership with the OGP, Kyrgyzstan adopted a National Action Plan (2018-2020), in which Kyrgyzstan promised to improve its web portal allowing the public to view procurement contracts and terms, create an independent complaints body, and provide more information

on how the health budget is spent. An Open Budget portal is currently being planned.[82]

Another CSO—the Partnership Network, funded by the SoS Project—strives to normalise political processes and change procurement legislation to obtain medicine price reductions. The Partnership Network hopes that exposing ART price disparities will enable price reductions, the savings from which can be used to expand the HIV response to more people. For example, in 2019, a patented version of darunavir was purchased at US$350 per pack, US$295 more expensive than the recommended Global Fund price of US$55 per pack.[83] At Global Fund prices, the country could have saved US$53,000, equivalent to 5.7% of the total budget for HIV drugs per year in Kyrgyzstan.[83] After conducting a freedom-to-operate analysis—a legal review of whether it is possible to commercialise a product or technology—the Partnership Network Association urged the UNDP, responsible for the darunavir purchase, to consider substituting the patented product for a generic version at the price of US$75 per pack.[84] The price reduction from US$350 to US$75 generated US$56,000 in savings.[84] Similarly, the Partner Network Association led discussions with pharmaceutical companies to reduce the price of the TLD combination (tenofovir, lamivudine and dolutegravir) through public procurement from US$23 to US$8 per pack between 2018 and 2020.[80,81] Even so, procurement through the UNDP, with the price of TLD sitting at $6.20 per pack versus the local market, resulted in more savings overall. The Partnership Network reports that their work on access to HIV medicines saved more than US$100,000 in 2020 alone.[19]

Summary of lessons learnt

- Amendments to the Patent Law, introducing and improving several TRIPS flexibilities such as compulsory licensing mechanisms, and expanding parallel import opportunities improved access to ARVs.
- A new law called the Circulation of Medicines was introduced to accelerate the registration process and allow ARV medicines an exemption from the process so they can more rapidly reach populations in need.
- Progression away from donor funds has been achieved, with 40% of state budgets being used to support HIV response.
- CSOs set up the Budget Advocacy Coalition, which has enabled a greater proportion of the state budget to be allocated to health and has improved the transparency of procurement processes.
- The Partnership Network, another CSO, has helped expose ART price disparities and source cheaper generic ARTs.

Moldova

Price reduction mechanisms	Generic competition E-procurement Budget advocacy by civil society organisations (Initiativa Pozitiva)
Average cost of ART per person (2021) (US$)[51]	104.59*
Cost of first line ART treatment (2021) (US$)[51]	76.65**
HIV expenditure from domestic public sources (2021) (US$)[85]	5,300,000
HIV expenditure from international sources (2021) (US$)[85]	4,500,000
% coverage of people receiving ART (2021) (all ages)[85]	48% [95% CI, 40-58]
Income level[86]	Upper middle-income country

*See also Table 2.
**Cost of first-line ART treatment includes TDF/XTC/EFV

"The most effective way to reduce medicine prices is by promoting strong competition and engaging pharmaceutical companies, since domestic pharmaceutical representatives may have limited possibilities and medicine offerings."

Constantin Cearanovski, Member of the Board of Directors, Initiative Pozitiva, Moldova

Marketing authorisation

In 2018, before the start of the SoS project,[51] it was not possible to procure unregistered medicines and it was not mandatory to use the country's tender system. Many of the HIV drugs registered in Moldova were patented, and there was generic competition for only four of 17 registered ARV drugs in Moldova as of 2018.[87] Increased advocacy from CSOs has helped improve market competition in Moldova, and more manufacturers have registered to take part in the country's tendering processes.[51] The drug registration process has been reduced to the following key requirements: all ARVs must have WHO prequalification or European Medicines Agency approval and must be included in the national HIV treatment protocols.[55] Nonregistered ARVs can be procured if they are included in the essential medicines lists.[55] Importantly, with a transparent tendering system in place that allows tracking and monitoring of medicines, the time between the announcement of a new tender and a contract being signed has been reduced by two months.[88]

Structure of funding

Moldova has fully transitioned away from Global Fund support to state funding to purchase HIV

treatments.[87] Like other countries in the EECA region, this means Moldova loses the purchasing power of the Global Fund and instead must negotiate fair prices independently. Moldova still receives Global Fund support for HIV prevention activities and for financing the work of CSOs. These organisations—such as the Key Affected Population Committee and Initiativa Pozitiva—lead on budget advocacy.[43] Moldova's status as a candidate for joining the European Union (EU) in June 2022, could also lead to changes in ARV prices. Moldova has agreed to TRIPS Plus provisions as part of the EU free trade agreement, including the extension of patents beyond 20 years and imposing data exclusivity on patented medicines.[89] All of these provisions could lead to a spike in ARV prices.

Procurement process

From 2017 to 2019, the UNDP was responsible for the procurement of affordable medicines. The UNDP has been since replaced by the state Centre for Centralised Public Procurement in Healthcare (CAPCS), which is a Ministry of Health organisation responsible for most of Moldova's medicine purchases. In 2018, the CSO Initiativa Pozitiva participated in the Open Contracting Partnership's impact accelerator programme, which aimed to explore the list of government medicines purchased with a view to substituting them, where possible, with generic versions. The same CSO also formed a collaboration with the CAPCS, and together they helped reform the ARV budget. In 2018, it was discovered that 55% of the national HIV budget was being used to purchase Aluvia, a patented ARV. In 2020, the share of the budget spent on Aluvia was reduced to 3%, with a WHO-recommended generic ARV combination (tenofovir/lamivudine/dolutegravir), accounting for about 50% of the HIV budget. This treatment switch

saved 19% of the HIV budget allocated to first-line treatments.[90] Usually buying in bulk results in lower prices, yet Moldova, despite being a smaller country and purchasing smaller quantities, pays among the lowest prices in the EECA region for some ART combinations, including lopinavir and ritonavir. For example, Moldova pays 8% less for generic combination ARTs than Ukraine, despite the volume of the order being nine times higher in Ukraine.[90] This is due in part to Moldova's involvement with the Open Contracting Partnership's impact accelerator program Lift, which resulted in an in-depth analysis of the country's medicine list and exploration of alternative, cheaper generics.[90] International Treatment Preparedness Coalition EECA and 100% LIFE, a Ukrainian patient organisation, played a major role in the creation of an e-procurement system in 2021, with support from the Ministry of Finance.[90] This e-procurement system, known as MTender, allows CAPCS to monitor the procurement and distribution of medicines, aiming to make the process more efficient and competitive. Some successes facilitated by MTender include reducing the average time between the announcement of a tender and contract signature by two months[88] and noting unnecessary terms in the ARV tender documentation, which restricted competition to branded ARVs only (emtricitabine/tenofovir, disoproxil and ritonavir). Initiative Pozitiva found that there were no patent barriers impeding access to generic ARVs, so this particular tender was cancelled. Replacing this patent-focussed tender and bringing generic ARV suppliers to market saved approximately US$650,000.[43] Altogether, between January and October 2021, MTender helped generate savings of 18% compared to the planned value.[88] Mr Cearanovski, member of the Board of Directors at Initiative Pozitiva, stated: "There is a crucial need to continue reforming and enhancing e-procurement in Moldova, with significant civil society expert participation, as its development dynamics have slowed. Transparent, standardised electronic procurement data is vital for monitoring and developing digital tools for medicine stock management, ensuring robust effectiveness and public goods management."

Summary of lessons learnt

- The drug registration process has been simplified to few key requirement— all ARVs must have WHO prequalification or European Medicines Agency approval and must be included in the national HIV treatment protocols.
- Moldova has significantly progressed away from relying on donor support and funds 100% of ARV medicines using state funds.
- The CSO Initiativa Pozitiva has helped Moldova achieve significant ARV budget reforms. These include reducing the proportion of the budget spent on patented ARVs and setting up an e-procurement system.

Ukraine

Price reduction mechanisms	Pooled procurement (via Global Fund) State procurement agency E-procurement Budget advocacy by civil society organisations
Average cost of ART per person (2021) (US$)[51]	79.72*
Cost of first line ART treatment (2021) (US$)[51]	87.60**
HIV expenditure from domestic public sources (2021) (US$)[91]	42,900,000
HIV expenditure from international sources (2021) (US$)[91]	48,600,000
% coverage of people receiving ART (2021) (all ages)[91]	62% [95% CI, 55-71]
Income level[92]	Low and middle-income country

*See also Table 2.
**Cost of first-line ART treatment includes TDF/XTC/EFV

Marketing authorisation

The intellectual property protection for medicine manufacturers is quite stringent in Ukraine. A state registration applicant must provide a patent copy or a licence indicating that the patentees' rights are not violated by registration, which is called a patent linkage. Further, when Ukraine joined the WTO, the law on pharmaceuticals prohibited the registration of generics using data from another pharmaceutical (eg the patentee) for a period of five years, a process known as data exclusivity.[93] In 2016, Ukraine became part of the MPP and ViiV voluntary licence, granting access to generic versions of the WHO-recommended tenofovir/lamivudine/dolutegravir combination.[94] In 2020, several changes were made to the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models" regarding medicines. (Daryna Bondarenko, Senior Advocacy Officer, 100% LIFE, Ukraine, personal communication, 28 February 2023). These changes included establishing new criteria for patentability of medicines, including limiting evergreening patenting, simplifying the registration process, and introducing patent opposition procedures (Daryna Bondarenko, Senior Advocacy Officer, 100% LIFE, Ukraine, personal communication, 28 February 2023).

"Today we have a totally rebooted public procurement system. Drugs are purchased at the expense of the state with limited corruption and precise monitoring by patient organisations. In 2022, ARV drugs were procured by donor organisations, and it seems that this will be the case in 2023 as well."

Daryna Bondarenko, Senior Advocacy Officer, 100% LIFE, Ukraine

Structure of funding

Ukraine is an LMIC and as such still receives support from the Global Fund. Between 2002 and 2022, the Global Fund has distributed US$748m in grants to Ukraine.[95] The principal

"It is critical to have a transparent and efficient procurement process to ensure affordable ARVs. In Ukraine, medical procurement is now centralised for the whole country. This means we can procure medicines in large quantities at once, helping to achieve the best price, reducing transaction costs and training staff in efficient procurement practices."

Daryna Bondarenko, Senior Advocacy Officer, 100% LIFE, Ukraine

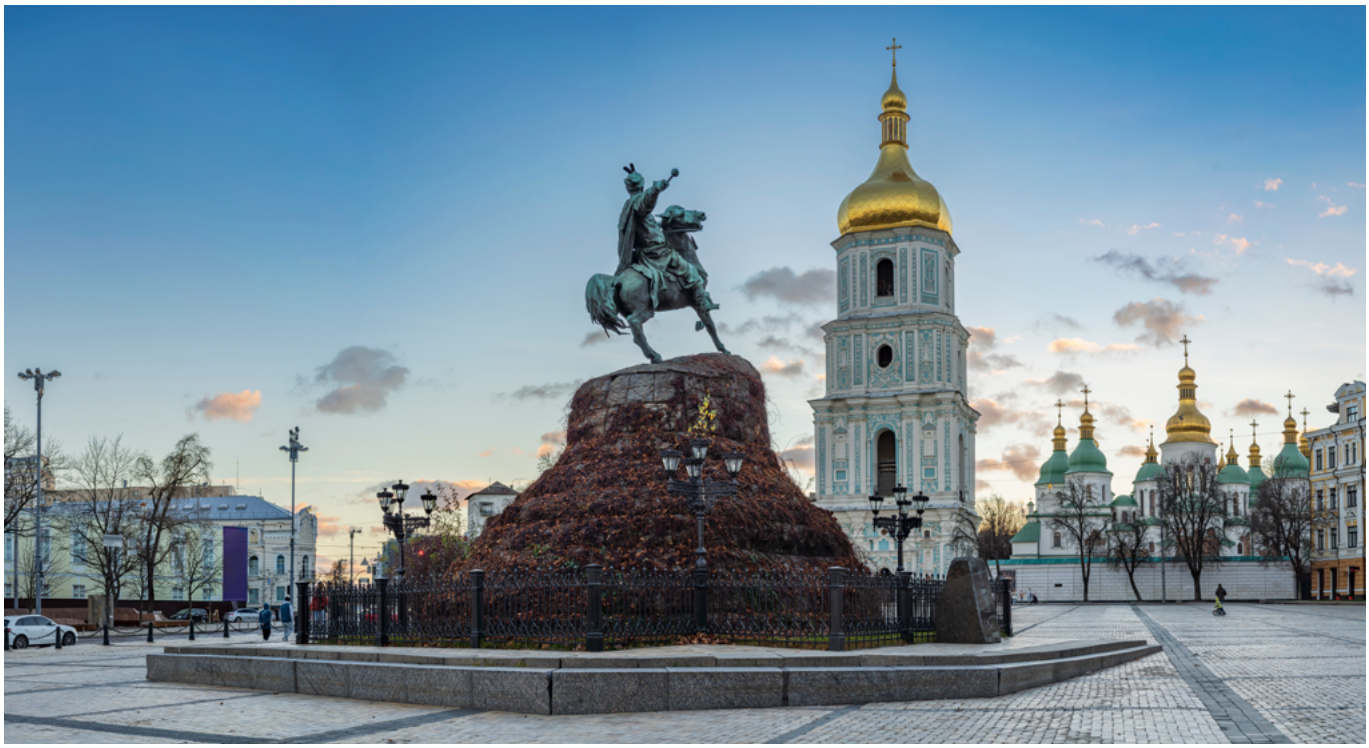
recipients of grants were the Alliance for Public Health, 100% LIFE and the Public Health Centre of the Ministry of Health.[95] Before the outbreak of the war with Russia, Ukraine had made progress in its HIV response and agreed to what was referred to by UNAIDS as a 20-50-80% transition plan.[96] This plan began in 2018 with the aim of the Ukrainian government gradually increasing its share of funding spent on HIV programmes over three years. In 2019 and 2020, the transition plan progressed, with around US$4m (50%) and US$12.5m (80%) allocated to HIV programmes, respectively.[96] In 2020, Ukraine funded all its ARV procurement (excluding wider HIV response such as harm reduction) with state funds—no support from international donors.[94] This excludes the non-government-controlled regions of Lugansk and Donetsk, which continue to be Global Fund recipients.[95]

Unfortunately, progress towards national HIV goals and medicine supplies were devastated in February 2022 by the war in the country. To prevent disruptions to ART coverage, one study suggested implementing an intellectual property security waiver to allow imports of essential medicines.[97] Security waivers—outlined in Article 73 of TRIPS—allow WTO members to take measures to protect essential security interests during a war. This would enable Ukraine to waive all intellectual property rights related to essential medicines and medical products, enabling domestic production and imports of essential generics.[97] Since a security waiver has not been implemented to date, it is expected that ARV supply chains and control of the HIV epidemic will be significantly affected in Ukraine until the end of the war.

Procurement process

In 2014, the Maidan revolution sparked the formation of a new government committed to reforms and recognising the role of CSOs in service delivery. This helped promote many changes in the way medicines are procured in Ukraine. The Ministry of Health was initially in control of procurement, but the department in charge—the central procurement agency for medical products—was deemed inefficient due to corruption, lengthy procurement procedures and limited supply chain management. In 2015, it was estimated that around 40% of funds allocated to medicine procurement were wasted due to excessive overpayment or were used for other purposes. Further, it was reported that the Ministry of Health was not making effective use of the state budget to procure HIV treatments, with only 45% of available finances used to buy ARVs in 2020.[95] These inefficiencies led to medicine shortages, which international procurement agencies had to mediate through emergency procurements.

The involvement and actions led by CSOs aiming to reduce corruption are a significant success story in Ukraine. Following years of corrupt government processes, CSOs' first victory was to direct procurement of ARVs to the Global Fund and UNICEF, to help reduce prices and corruption. Second, a transparent, open-source e-procurement system was developed, known as Prozorro. Similar to MTender in Moldova, this system allows government information on public contracts to be accessed online, including tenders and competitive auctions.[98] According to a study by the Kyiv School of Economics, since the transition to Prozorro, healthcare facilities have saved 6% from previous costs, equivalent to US$12m annually.[98] Towards the end of 2017, Prozorro was integrated into Ukraine's medicine registry. Using Prozorro,



Transparency International Ukraine developed an analytical tool that allows the whole country to access medical procurement data and compare ART prices.[98]

In 2018, further improvements were made when another Ukrainian NGO—the Anti-Corruption Action Centre—highlighted that more work was needed in order to make regionally procured medicine prices the same as those provided by international procurement organisations. The Ministry of Health created a state procurement agency, the Medical Procurement of Ukraine, which by 2020 reported savings of around US$39m in purchases of essential medicines compared to prices in the previous year.[98] Ms. Bondarenko, Senior Advocacy Officer at 100% LIFE in the Ukraine, stated, "The patient community is responsible for the switch in procurement responsibility from the Ministry of Health to the central procurement agency in Ukraine. Without them, it would not be possible to provide high-quality ARVs at low costs. Each year we see the prices of drugs purchased at the expense of the state budget getting lower and lower as a result of this approach." The success of the state procurement agency is attributed to the corruption reduction, simplified registration processes, VAT exemptions, and feedback from pharmaceutical companies on how to improve tender documentation.[98]

Summary of lessons learnt

- Despite being an LMIC, with help from UNAIDS, Ukraine has implemented a plan to transition away from donor fund support. By 2020, Ukraine had funded 100% of HIV treatment using state funds (excluding non-government-controlled areas).
- CSOs helped reform ARV procurement to reduce corruption by introducing integrational procurement agencies, enabling medicine contracts to be directed to overseas manufacturers (excluding local corruption intermediaries).
- CSOs helped set up an e-procurement system that has helped generate 6% of savings in ARV procurement fees in one year.
- Creation of a state procurement agency generated estimated total medicines savings (not just ARVs) of US$39m in 2020 compared to the previous year.
- Overall, CSOs in Ukraine played a huge role in improving access to generic ARVs and thus reducing prices.

Successes across EECA

This report summarises the mechanisms involved in registration, funding and procurement of ARVs for HIV and the strategies used to reduce the prices of ARVs in five select EECA countries (Georgia, Kazakhstan, Kyrgyzstan, Moldova and Ukraine). These countries are all at different stages of a transition away from donor-funded HIV response, and they have all made varying progress towards procuring ARVs using state funds. EECA countries must continue to negotiate prices and procure ARVs domestically, hoping to mirror the purchasing power of large-scale international organisations such as the Global Fund and the UNDP. Across EECA, some of the most successful strategies adopted to lower ARV prices include the following:

Price transparency: Encouraging local governments to publish procurement documents and pricing information helps to reduce corruption and encourage efforts to source lower prices. Some countries have made great achievements in this area, including setting up e-procurement platforms that help track prices and source cheaper alternatives.

Community action: Budget advocacy groups, usually led by community CSOs, can be very effective. Their work includes public campaigns, publishing drug prices, patent oppositions, and negotiations with manufacturers and government agencies. This community work is supported by international donors such as the Global Fund.

National procurement: Some countries are in the process of or have already set up their own national procurement agencies to replace donor-fund procurement mechanisms to buy ARVs. This is great progress, but it remains to be seen whether national procurement efforts will achieve prices as low as international organisations. There needs to be political will, transparent national laws and generic competition supported by the ongoing action of CSOs.

Generic competition: Some countries have introduced more generics to the market than others. This is a key strategy for lowering the average price per person for ART. Generic competition is partly facilitated by the work of CSOs but also through TRIPS flexibilities and other provisions in national laws such as ARV drug waivers to skip registration processes.

The support of donor funds and international organisations: Despite transitioning away from donor funds to buy ARV drugs, the Global Fund and UNDP are still influential in the region. For example, pooled procurement platforms hosted by the Global Fund are used to purchase ARVs in Georgia,

and the UNDP leads pooled procurement in Kyrgyzstan. Direct contracting with foreign suppliers via international procurement agencies such as Global Fund and UNICEF removes the need for intermediate local distributors, which was often a source of corruption and increased prices. The purchasing power of international organisations means they can usually achieve much lower prices than small orders for individual countries led by the state. In addition, access to voluntary licences facilitated by the MPP has helped all five countries featured in this report access a generic version of the WHO-recommended ARV dolutegravir.

Simplifying medicine registration processes: Some countries have created conditions or waivers in national laws that permit exemptions from registration processes for ARVs. Others have taken advantage of TRIPS flexibilities or amendments to national laws that allow simplified registration processes. For countries that are part of the EEU, discussions are ongoing to decide whether national registration processes are kept or adoption of the EEC regulations are required. Following the rules of the Commission will involve many more registration terms than most national registration processes and could prove detrimental to ARV procurement.

References

[1] UNAIDS. UNAIDS data 2021. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2022. Available from: https://www.unaids.org/sites/default/files/media_asset/JC3032_AIDS_Data_book_2021_En.pdf.

[2] UNAIDS. In danger: UNAIDS global AIDS update 2022. Summary. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2022. Available from: https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update-summary_en.pdf.

[3] UNAIDS. Global HIV & AIDS statistics — Fact sheet. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [cited 30 January 2023]. Available from: https://www.unaids.org/en/resources/fact-sheet#.

[4] EIU. Drug control policies in Eastern Europe and Central Asia: The economic, health and social impact. London: Economist Intelligence Unit (EIU), 2021. Available from: https://impact.economist.com/perspectives/sites/default/files/eiu_aph_investing_hiv_launch.pdf.

[5] UNAIDS. Miles to go: the response to HIV in Eastern Europe and Central Asia. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2018. Available from: https://www.unaids.org/sites/default/files/media_asset/miles-to-go_eastern-europe-and-central-asia_en.pdf.

[6] UNAIDS. In danger: UNAIDS global AIDS update 2022. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS). Available from: https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf.

[7] Hayes R. Second-line treatment nearly nine times more expensive than first-line in upper-middle income countries. London: NAM Publications; [9 August 2022; cited 30 January 2023]. Available from: https://www.aidsmap.com/news/aug-2022/second-line-treatment-nearly-nine-times-more-expensive-first-line-upper-middle-income.

[8] High Level Panel on Access to Health Technologies - United Nations Secretary General. Report of the United Nations Secretary General's High Level Panel on Access to Medicines. New York, NY: United Nations, 2016. Available from: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

[9] WHO. Global HIV Programme: Treatment and care. Geneva: World Health Organization; [cited 30 January 2023]. Available from: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/treatment.

[10] NHS. Treatment: HIV and AIDS. London: NHS; [22 April 2021; cited 30 January 2023]. Available from: https://www.nhs.uk/conditions/hiv-and-aids/treatment/.

[11] UNAIDS. Welcome to the HIV Financial Dashboard. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [cited 30 January 2023]. Available from: https://hivfinancial.unaids.org/hivfinancialdashboards.html.

[12] WHO. WHO model list of essential medicines - 21st list, 2019. Geneva: World Health Organization; [cited 30 January 2023]. Available from: https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06.

[13] WHO. WHO model list of essential medicines - 22nd list, 2021. Geneva: World Health Organization; [30 September 2021; cited 30 January 2023]. Available from: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

[14] WHO. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; [16 July 2021; cited 30 January 2023]. Available from: https://www.who.int/publications/i/item/9789240031593.

[15] Fixed-dose ARV combinations: choices and challenges. London: NAM Publications; [19 March 2004; cited 30 January 2023]. Available from: https://www.aidsmap.com/news/mar-2004/fixed-dose-arv-combinations-choices-and-challenges.

[16] WHO. Update of recommendations on first- and second-line antiretroviral regimens. Geneva: World Health Organization, 2019. Available from: https://apps.who.int/iris/bitstream/handle/10665/325892/WHO-CDS-HIV-19.15-eng.pdf?

[17] Persaud N, Jiang M, Shaikh R, et al. Comparison of essential medicines lists in 137 countries. Bull World Health Organ. 2019;97(6):394-404c.

[18] Persaud N, Jiang M, Shaikh R, et al. Global Essential Medicines. Toronto: St. Michael's Hospital and the University of Toronto; [cited 9 March 2023]. Available from: https://global.essentialmeds.org/dashboard/countries/129.

[19] Eurasian Harm Reduction Association. Taking stock of budget advocacy efforts in Eastern Europe, South-Eastern Europe and Central Asia. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://cdn.sanity.io/files/6u5teakk/production/cfc0aef5b7368aa631673430b0eca027908347c0.pdf?dl=.

[20] Heath K, Levi J, Hill A. The Joint United Nations Programme on HIV/AIDS 95-95-95 targets: worldwide clinical and cost benefits of generic manufacture. AIDS. 2021;35:S197-S203.

[21] Varentsov I. Status of transitions from Global Fund support in the EECA region. Regional Platform EECA; [2018; cited 30 January 2023]. Available from: https://eecaplatform.org/en/status-of-transitions-from-gf-support-in-the-eeca/.

[22] Zardiashvili T. Seven countries in the EECA region projected to transition by 2025: Overview on the GF's 2017 Eligibility List and Transition Projection Tool. [1 November 2016; cited 30 January 2023]. Available from: https://www.aidspan.org/fr/c/article/3966.

[23] Serebryakova L, Szubert O, Rowe E. Getting ready for harm reduction budget advocacy: a guide for civil society and communities. London: Harm Reduction International, 2020. Available from: https://hri.global/wp-content/uploads/2022/10/HRI-BUDGET-ADVOCACY-GUIDE-PAGES.pdf.

[24] Agarwal D. A question of human rights? Patents as barriers between essential drugs and those who most need them. London: London School of Economics and Political Science (LSE); [14 February 2022; cited 30 January 2023]. Available from: https://blogs.lse.ac.uk/internationaldevelopment/2022/02/14/a-question-of-human-rights-patents-as-barriers-between-essential-drugs-and-those-who-most-need-them/.

[25] Subramanian A. Medicines, patents, and TRIPS: Has the intellectual property pact opened a Pandora's box for the pharmaceuticals industry. Washington, DC: International Monetary Fund (IMF); [cited 14 April 2023]. Available from: https://www.elibrary.imf.org/display/book/9781589063419/ch06.xml.

[26] MSF Access Campaign. Spotlight on: TRIPS, TRIPS Plus, and Doha. Geneva: MSF Access Campaign - Médecins Sans Frontières; [cited 30 January 2023]. Available from: https://msfaccess.org/spotlight-trips-trips-plus-and-doha.

[27] Nicol D, Owoeye O. Using TRIPS flexibilities to facilitate access to medicines. Bull World Health Organ. 2013;91(7):533-9.

[28] Motari M, Nikiema JB, Kasilo OMJ, et al. The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. BMC public health. 2021;21(1):490.

[29] WTO. Compulsory licensing of pharmaceuticals and TRIPS. Geneva: World Trade Organization; [cited 9 March 2023]. Available from: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

[30] MSF Access Campaign. Voluntary licenses and access to medicines: Recommendations to governments to safeguard access to medicines in pharmaceutical voluntary license agreements. Summary. Geneva: MSF Access Campaign - Médecins Sans Frontières, 2020. Available from: https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_summary-brief_Oct2020_ENG.pdf.

[31] IFPMA. Voluntary licenses and non-assert declarations. Geneva: International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) [20 July 2010; cited 30 January 2023]. Available from: https://ifpma.org/news/voluntary-licenses-and-non-assert-declarations/.

[32] MSF Access Campaign. Voluntary licenses and access to medicines: Médecins Sans Frontières Technical Briefing Document. Geneva: MSF Access Campaign - Médecins Sans Frontières, 2020. Available from: https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf.

[33] Medicines Law & Policy. Voluntary Licences: Case study: Dolutegravir adult formulations. Medicines Law & Policy; [cited 30 January 2023]. Available from: https://medicineslawandpolicy.org/tools/voluntary-licences/.

[34] Kondratyuk S, Hatsko V, Lezhentsev K. Implementation of TRIPS public health flexibilities to improve access to medicines in Belarus, Georgia, Moldova and Ukraine. Kyiv: East Europe and Central Asia Union of PLWH, 2013. Available from: https://ecuo.org/wp-content/uploads/2016/12/analytical_report_ecuo_trips_eng.pdf.

[35] MSF Access Campaign. Untangling the web of antiretroviral price reductions, 18th Edition – July 2016. Geneva: MSF Access Campaign - Médecins Sans Frontières, 2016. Available from: https://msfaccess.org/sites/default/files/HIV_report_Untangling-the-web-18thed_ENG_2016.pdf.

[36] Collier R. Drug patents: the evergreening problem. Cmaj. 2013;185(9):E385-6.

[37] Make Medicines Affordable. Moldovan patients and CSOs stood against the patent monopoly on bedaquiline. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [8 August 2021; cited 15 February 2023]. Available from: https://makemedicinesaffordable.org/moldovan-patients-and-csos-stood-against-the-patent-monopoly-on-bedaquiline/.

[38] European Commission, European Health Digital Executive Agency, Vogler S, et al. Study on best practices in the public procurement of medicines: final report. Brussels: Publications Office of the European Union, 2022. Available from: https://data.europa.eu/doi/10.2925/044781.

[39] Berdud M, Chalkidou K, Dean E, et al. The future of global health procurement: Issues around pricing transparency. CGD Working Paper 507. Washington, DC: Center for Global Development. Available from: https://www.cgdev.org/sites/default/files/the-future-global-health-procurement-issues-around-pricing-transparency.pdf.

[40] Ferrario A, Kanavos P, Humbert T, et al. Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. Copenhagen: WHO Regional Office for Europe, 2016. Available from: https://www.euro.who.int/__data/assets/pdf_file/0003/323598/Challenges-opportunities-improving-access-medicines-efficient-public-procurement.pdf.

[41] WHO. Fair pricing forum 2017 meeting report. Geneva: World Health Organization; [18 October 2017; cited 30 January 2023]. Available from: https://www.who.int/publications/i/item/WHO-EMP-IAU-2017-10.

[42] WHO. Pooled procurement: WHO guideline on country pharmaceutical pricing policies. A plain language summary. Geneva: World Health Organization, 2021. Available from: https://apps.who.int/iris/bitstream/handle/10665/341901/9789240024670-eng.pdf?sequence=1&isAllowed=y.

[43] Eurasian Harm Reduction Association. Taking stock of budget advocacy efforts in Eastern Europe, South-Eastern Europe and Central Asia: Moldova: Country case. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://harmreductioneurasia.org/wp-content/uploads/2022/02/Молдова-англ..pdf.

[44] Chene M. The benefits of open contracting. Berlin: Transparency International, 2012. Available from: https://www.u4.no/publications/the-benefits-of-open-contracting.pdf.

[45] Transforming public contracting through open data & smarter engagement. Washington, DC: Open Contracting Partnership; [cited 31 January 2023]. Available from: https://www.open-contracting.org/what-is-open-contracting/.

[46] Eurasian Harm Reduction Association. Taking stock of budget advocacy efforts in Eastern Europe, South-Eastern Europe and Central Asia: Georgia: Country case. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://harmreductioneurasia.org/wp-content/uploads/2022/02/Грузия-англ..pdf.

[47] TB Europe Coalition. Transitioning from donor support for TB & HIV in Europe: Georgia: ensuring timely access to affordable quality assured drugs. TB Europe Coalition, 2020. Available from: https://www.tbcoalition.eu/wp-content/uploads/2020/02/Transitioning-from-Donor-Support-for-TB-HIV-in-Europe-Georgia.pdf.

[48] Eurasian Harm Reduction Association. Taking stock of budget advocacy efforts in Eastern Europe, South-Eastern Europe and Central Asia: Kazakhstan: Country case. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://harmreductioneurasia.org/wp-content/uploads/2022/02/Казахстан-англ..pdf.

[49] Sultangaziev A, Novikova E. A review of the legal basis for the regulation of medicinal products circulation in the Eurasian Economic Union. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA), 2021. Available from: https://itpcru.org/wp-content/uploads/2021/06/analiz-npa-eaes-final-07.06.2021.pdf.

[50] UNAIDS. Countries [data]. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2021. Available from: https://www.unaids.org/en/regionscountries/countries.

[51] Rahman F, Dang G, Montgomery R. Sustainability of services for key populations in Eastern Europe and Central Asia region project (SoS project): Final evaluation report. Matahari Global Solutions and Act for Involvement, 2022. Available from: https://eeca.aph.org.ua/wp-content/uploads/2022/09/Sustainability-of-Services.pdf.

[52] UNAIDS. Country: Georgia. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2021. Available from: https://www.unaids.org/en/regionscountries/countries/georgia.

[53] World Bank. Georgia. Washington, DC: World Bank; [cited 31 January 2023]. Available from: https://data.worldbank.org/country/georgia.

[54] Chkhatarashvili K, Zardiashvili T. Transition from Global Fund support and programmatic sustainability research in four CEE/CIS countries: Georgia country report. Tbilisi: Curatio International Foundation (CIF), 2015. Available from: http://curatiofoundation.org/wp-content/uploads/2017/01/GEORGIA-TS-CASE-STUDY_Final_Jan25-2016.pdf.

[55] Kreft W, Sayadyan H. Antiretroviral procurement and supply chain strategy for the EECA region: Countries: Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan. Kyiv: Alliance for Public Health, 2021. Available from: https://eeca.aph.org.ua/wp-content/uploads/2021/10/Додаток-1.18.1-PSM-strategy-in-EECA-region-ENG.pdf.

[56] Medicines Patent Pool. ViiV Healthcare and the Medicines Patent Pool expand access to dolutegravir-based regimens for people living with HIV in Azerbaijan, Belarus, Kazakhstan and Malaysia with innovative new licensing agreement. Geneva: Medicines Patent Pool; [30 November 2020; cited 15 February 2023]. Available from: https://medicinespatentpool.org/news-publications-post/viiv-and-mpp-expand-access-to-dtg-to-four-new-countries.

[57] Zardiashvili T, Garmaise D. Georgia develops 5-year plan for transitioning from global fund support. Nairobi: AIDSPAN; [8 August 2017; cited 15 February 2023]. Available from: https://www.aidspan.org/fr/c/article/4297.

[58] Eurasian Harm Reduction Association. Georgia: Benchmarking sustainability of the HIV response among key populations in the context of transition from global fund support to domestic funding. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://harmreductioneurasia.org/wp-content/uploads/2022/06/EHRA-TMT-Assessment-Georgia-December-2021-ENG-FINAL.pdf.

[59] Georgia Country Coordinating Mechanism (CCM). Georgia HIV/AIDS national strategic plan 2019 - 2022. Tbilisi: Ministry of Health, 2019. Available from: http://www.georgia-ccm.ge/wp-content/uploads/Georgia-HIV-AIDS-National-Strategic-Plan-2019-20222.pdf.

[60] UNAIDS. Country: Kazakhstan. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [cited 15 February 2023]. Available from: https://www.unaids.org/en/regionscountries/countries/kazakhstan.

[61] World Bank. Kazakhstan. Washington, DC: World Bank; [cited 31 January 2023]. Available from: https://data.worldbank.org/country/kazakhstan.

[62] Shattock AJ, Benedikt C, Bokazhanova A, et al. Kazakhstan can achieve ambitious HIV targets despite expected donor withdrawal by combining improved ART procurement mechanisms with allocative and implementation efficiencies. PLoS ONE. 2017;12(2):0169530.

[63] Kazakhstan: Reducing stigma and pills – improving adherence to treatment. Amsterdam: AFEW International; [9 May 2019; cited 15 February 2023]. Available from: https://afew.org/kazakhstan-hiv-adherence-eng/.

[64] Alyokhova A. [We are struggling to reduce prices for each drug - Birtanov] Мы бьемся над снижением цен на каждый препарат — Биртанов. [18 December 2019; cited 28 March 2023]. Available from: https://365info.kz/2019/12/my-bemsya-nad-snizheniem-tsen-na-kazhdyj-preparat-birtanov.

[65] [Kazakhstan is included in the license agreement for dolutegravir] Казахстан включен в лицензионное соглашение по долутегравиру. Almaty: Казахстанский Фармацевтический Вестник; [20 December 2020; cited 28 March 2023].

[66] Make Medicines Affordable. Letter to ViiV Healthcare: No more time to waste – increase access to dolutegravir in Eastern Europe and Central Asia. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [9 July 2020; cited 14 April 2023]. Available from: https://makemedicinesaffordable.org/letter-to-viiv-healthcare-no-more-time-to-waste-increase-access-to-dolutegravir-in-eastern-europe-and-central-asia/.

[67] Biryukov S, Rastokina E. [Analysis of procurement of ARV drugs for HIV treatment and of drugs for hepatitis C treatment in the Republic of Kazahstan in 2021] Исследование закупок антиретровирусных препаратов для лечения вич-инфекции и препаратов для лечения вирусного гепатита С на 2021 год в Республике Казахстан. Almaty: International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA). Available from: https://pereboi.kz/wp-content/uploads/2022/07/Otchet-o-zakupokah-ARV-preparatov-dlya-lecheniya-VICH-infektsii-i-preparatov-dlya-lecheniya-virusnogo-gepatita-S-v-RK-za-2021-god.pdf.

[68] European Directorate for the Quality of Medicines & HealthCare (EDQM). Press release: The Eurasian Economic Commission and the EDQM agree to extend and strengthen international collaboration in the circulation of medicines. Strasbourg: Council of Europe; [15 June 2021; cited 15 February 2023]. Available from: https://www.edqm.eu/documents/52006/84827/Press+Release+-+The+Eurasian+Economic+Commission+and+the+EDQM+agree+to+extend+and+strengthen+international+collaboration+in+the+circulation+of+medicines+-+June+2021.pdf/95ceb6ba-ba23-140f-eaf0-11819da96e51?t=1636382977682.

[69] Baker B. New ViiV license with the Medicines Patent Pool expands access but eviscerates transparency. Washington, DC: Health GAP; [7 December 2020 cited 14 April 2020]. Available from: https://healthgap.org/new-viiv-license-with-the-medicines-patent-pool-expands-access-but-eviscerates-transparency/.

[70] Medicines Patent Pool. Dolutegravir – adult (DTG). Geneva: Medicines Patent Pool; [April 2014; cited 14 April 2023]. Available from: https://medicinespatentpool.org/licence-post/dolutegravir-adult-dtg.

[71] Ministry of Health and Social Development. [National report about progress achieved in the implementation of global measure in response to AIDS] Национальный доклад о достигнутом прогрессе в осуществлении глобальных мер в ответ на СПИД. Astana: Ministry of Health and Social Development, 2016. Available from: https://www.unaids.org/sites/default/files/KAZ_narrative_report_2016.pdf.

[72] Biryukov S, Rastokina E. [Analysis of procurement of ARV drugs for HIV treatment and of drugs for Hepatitis C treatment in the republic of Kazahstan in 2018] Исследование закупок антиретровирусных препаратов для лечения вич-инфекции и препаратов для лечения вирусного гепатита с на 2018 год в Республике Казахстан. Almaty: International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA), 2019. Available from: https://pereboi.kz/2019/09/18/issledovanie-zakupok-antiretrovirusnyh-preparatov-dlya-lecheniya-vich-infektsii-i-preparatov-dlya-lecheniya-virusnogo-gepatita-s-na-2018-god-v-respublike-kazahstan/.

[73] Uteulin GM, Biryukov SA, Tabagobyl L. [Study of procurement of ARV drugs for treatment of HIV infection and drugs for Hepatitis C treatment in the Republic of Kazakhstan in 2020] Исследование закупок антиретровирусных препаратов для лечения Вич-инфекции и препаратов для лечения вирусного гепатита С на 2020 год в Республике Казахстан. Almaty: Международной коалиции по готовности к лечению в Восточной Европе и Центральной Азии (ITPC), 2021. Available from: https://pereboi.kz/wp-content/uploads/2021/10/Otchet-po-zakupkam-za-2020-god.pdf.

[74] Make Medicines Affordable. MMA's partners in Kazakhstan call for systemic changes to the country's intellectual property and access to medicines framework in their annual report. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [29 November 2021; cited 15 February 2023]. Available from: https://makemedicinesaffordable.org/annual-report-from-mmas-partners-in-kazakhstan-calls-for-a-systematic-change-on-the-countrys-ip-and-access-to-medicines-framework/.

[75] UNAIDS. Country: Kyrgyzstan. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2021. Available from: https://www.unaids.org/en/regionscountries/countries/kyrgyzstan.

[76] World Bank. Kyrgyz Republic. Washington, DC: World Bank; [cited 31 January 2023]. Available from: https://data.worldbank.org/country/kyrgyz-republic?view=chart.

[77] Make Medicines Affordable. Kyrgyzstan. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [1 February 2019; cited 1 February 2023]. Available from: https://makemedicinesaffordable.org/country/kyrgyzstan/.

[78] New hope for healthcare in Kyrgyzstan. New York, NY: Global Commission on HIV and the Law; [cited 30 Mar 2023]. Available from: https://hivlawcommission.org/2015/04/20/new-hope-for-healthcare-in-kyrgyzstan/.

[79] Medicines Patent Pool. Aibar Sultangaziev. Geneva: Medicines Patent Pool; [30 July 2019; cited 1 February 2023]. Available from: https://medicinespatentpool.org/story-post/aibar-sultangaziev.

[80] Sultangaziev A, Novikova E. [Analysis of procurement of ARV drugs and drugs for Hepatitis C treatment in the Kyrgyz Republic in 2021] Анализ закупок АРВ- препаратов и препаратов для лечения гепатита С в Кыргызской Республике в 2021 г. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA), 2022. Available from: https://itpc-eeca.org/wp-content/uploads/2021/08/kyrgyzstan_analiz-zakupok-arv-10.08.21.pdf.

[81] Eurasian Harm Reduction Association. Taking stock of budget advocacy efforts in Eastern Europe, South-Eastern Europe and Central Asia: Kyrgyz Republic: Country case. Vilnius: Eurasian Harm Reduction Association (EHRA), 2021. Available from: https://harmreductioneurasia.org/wp-content/uploads/2022/02/Кыргызстан-англ..pdf.

[82] Open Government Partnership: Kyrgyz Republic. National Action Plan on building of the Open Government in the Kyrgyz Republic for 2018-2020. Bishkek: 2019. Available from: https://www.opengovpartnership.org/wp-content/uploads/2018/12/Kyrgyz-Republic_Action-Plan_2018-2020_REV.pdf.

[83] [Darunavir in Kyrgyzstan, USD 53,000 that could be saved]. Дарунавир в Кыргызстане: 53 тысячи долларов США, которые можно сэкономить. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [21 September 2020; cited 1 February 2023]. Available from: https://itpc-eeca.org/2020/09/21/darunavir-v-kyrgyzstane-53-tysyachi-dollarov-ssha-kotorye-mozhno-sekonomit/.

[84] [56 thousand dollars savings on darunavir in Kyrgyzstan]. 56 тысяч долларов экономии на дарунавире в Кыргызстане. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [1 February 2023; cited 28 March 2023]. Available from: https://pereboi.kg/2023/02/01/56-tysyach-dollarov-ekonomii-na-darunavire-v-kyrgyzstane/.

[85] UNAIDS. Country: Republic of Moldova. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [cited 15 February 2023]. Available from: https://www.unaids.org/en/regionscountries/countries/republicofmoldova.

[86] World Bank. Moldova. Washington, DC: World Bank; [cited 15 February 2023]. Available from: https://data.worldbank.org/country/moldova?view=chart.

[87] Make Medicines Affordable. Moldova. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC EECA); [cited 16 February 2023]. Available from: https://makemedicinesaffordable.org/country/moldova/.

[88] Open Contracting Partnership. Moldova: a powerful combination therapy. Washington, DC: Open Contracting Partnership; [cited 16 February 2023]. Available from: https://www.open-contracting.org/impact-stories/impact-moldova/.

[89] European Commission. EU-Moldova deep and comprehensive free trade area. Brussels: European Commission; [cited 14 April 2023]. Available from: https://trade.ec.europa.eu/access-to-markets/en/content/eu-moldova-deep-and-comprehensive-free-trade-area.

[90] Open Contracting Partnership. Patients, experts, and openness: a powerful combination therapy for unaffordable medicines in Moldova. Washington, DC: Open Contracting Partnership; [23 November 2021; cited 16 February 2023]. Available from: https://www.open-contracting.org/2021/11/23/patients-experts-and-openness-a-powerful-combination-therapy-for-unaffordable-medicines-in-moldova/.

[91] UNAIDS. Country: Ukraine. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [cited 15 February 2023]. Available from: https://www.unaids.org/en/regionscountries/countries/ukraine.

[92] World Bank. Ukraine. Washington, DC: World Bank; [cited 16 February 2023]. Available from: https://data.worldbank.org/country/ukraine?view=chart.

[93] European Observatory on Health Systems and Policies. Ukraine: country overview. Brussels: European Observatory on Health Systems and Policies; [2021; cited 16 February 2023]. Available from: https://eurohealthobservatory.who.int/countries/ukraine/.

[94] Medicines Patent Pool. 100% LIFE – Ukraine. Geneva: Medicines Patent Pool; [30 November 2020; cited 15 February 2023]. Available from: https://medicinespatentpool.org/story-post/100-life-ukraine.

[95] Global Fund. Global Fund grants in Ukraine. Geneva: Global Fund to Fight AIDS, Tuberculosis and Malaria; [7 March 2022; cited 16 February 2023]. Available from: https://www.theglobalfund.org/media/11823/oig_gf-oig-22-002_report_en.pdf.

[96] UNAIDS. 20–50–80 to reach 100 in Ukraine. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); [6 November 2020; cited 15 February 2023]. Available from: https://www.unaids.org/en/resources/presscentre/featurestories/2020/november/20201106_ukraine-20-50-80#:~:text=The%2020–50–80%20formula,failed%20to%20meet%20its%20obligations.

[97] Gurgula O. Saving Ukrainian lives during the Russian war: Ukraine must waive IP rights under Article 73 TRIPS to provide access to essential medicines. GRUR International. 2022;71(8):719-30.

[98] Hrytsenko Y. Fight for life: how Ukraine is fixing medical procurement and serving patients better. Washington, DC: Open Contracting Partnership; [22 February 2021; cited 16 February 2023]. Available from: https://www.open-contracting.org/2021/02/22/fight-for-life-how-ukraine-is-fixing-medical-procurement-and-serving-patients-better/.

ECONOMIST IMPACT

LONDON

The Adelphi
1-11 John Adam Street
London WC2N 6HT
United Kingdom
Tel: (44) 20 7830 7000
Email: london@economist.com

GENEVA

Rue de l'Athénée 32
1206 Geneva
Switzerland
Tel: (41) 22 566 2470
Fax: (41) 22 346 93 47
Email: geneva@economist.com

SÃO PAULO

Rua Joaquim Floriano,
1052, Conjunto 81
Itaim Bibi, São Paulo - SP
04534-004
Brasil
Tel: +5511 3073-1186
Email: americas@economist.com

NEW YORK

900 Third Avenue
16th floor
New York, NY 10022
United States
Tel: (1.212) 554 0600
Fax: (1.212) 586 1181/2
Email: americas@economist.com

DUBAI

Office 1301a
Aurora Tower
Dubai Media City
Dubai
Tel: (971) 4 433 4202
Fax: (971) 4 438 0224
Email: dubai@economist.com

HONG KONG

1301
12 Taikoo Wan Road
Taikoo Shing
Hong Kong
Tel: (852) 2585 3888
Fax: (852) 2802 7638
Email: asia@economist.com

SINGAPORE

8 Cross Street
#23-01 Manulife Tower
Singapore
048424
Tel: (65) 6534 5177
Fax: (65) 6534 5077
Email: asia@economist.com