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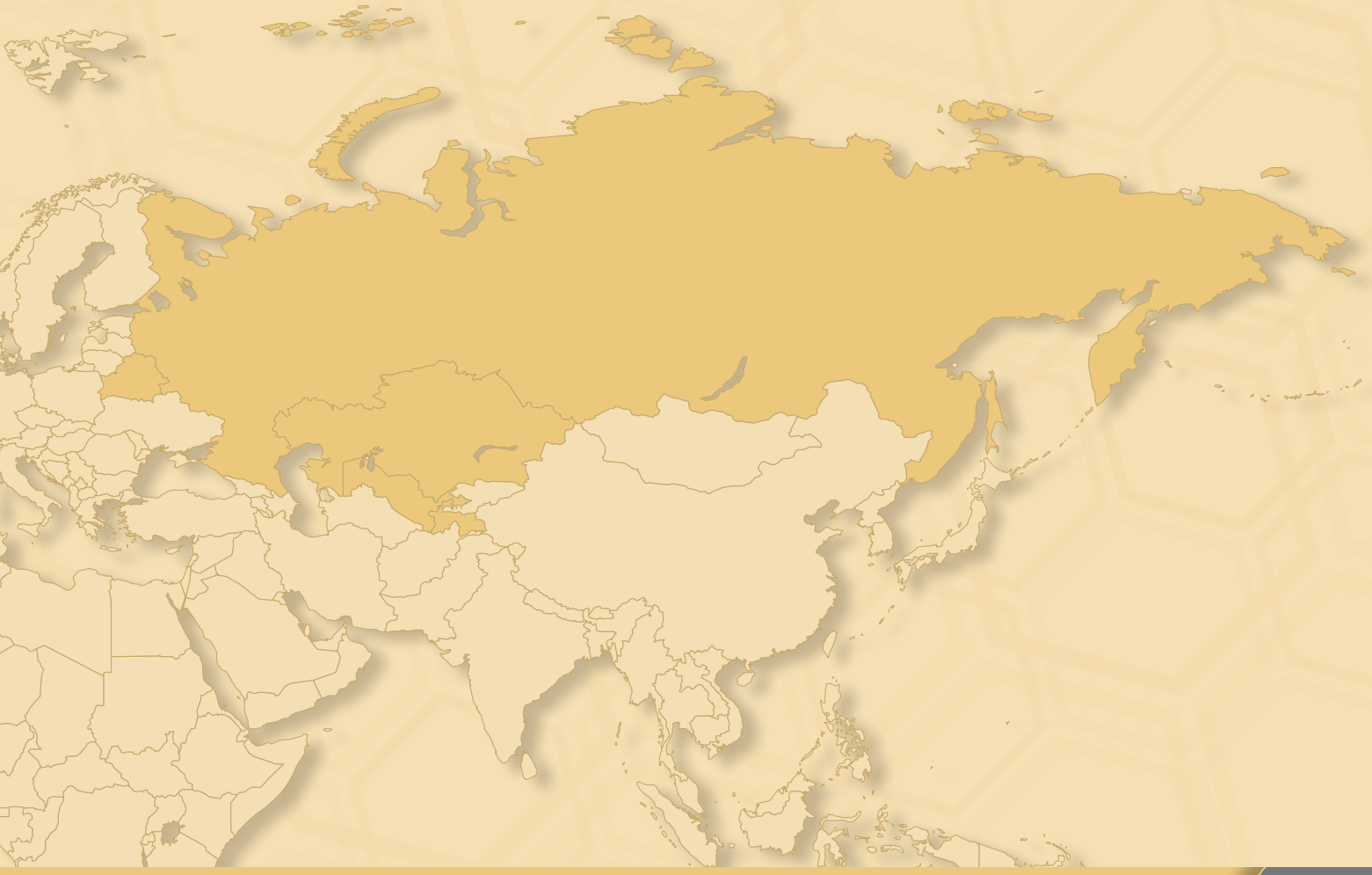
Legal and regulatory frameworks for antiretroviral medicines and treatment in selected countries of the Commonwealth of Independent States

A Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan



Sustainable Financing of National HIV Responses

Legal and regulatory frameworks for antiretroviral medicines and treatment in selected countries of the Commonwealth of Independent States. A Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan

Sustainable Financing of National HIV Responses

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Disclaimer: This report is produced to inform discussions around the implementation of the regional project "Sustainable Financing of National HIV Responses and Reducing Cost of Treatment in Select CIS Countries with focus on the Customs Union". It does not in any way express, nor does it necessarily reflect the official position of UNDP, its employees or board members, as well as the position of the studied countries.

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Acronyms and abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
bPI	Ritonavir-boosted protease inhibitor
BYR	Belarusian rouble
CIS	Commonwealth of Independent States
DRS	WHO Drug Regulatory Status
EAEU	Eurasian Economic Union
EAPC	Eurasian Patent Convention
EAPO	Eurasian Patent Organisation
EEC	Eurasian Economic Commission
EECA	Eastern Europe and Central Asia
EurAsEC	Eurasian Economic Community
EU	European Union
FDA	U.S. Food and Drug Administration
FDC	Fixed-dose combination
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GFATM (GF)	Global Fund to fight AIDS, Tuberculosis and Malaria
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GOST	State Standard
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
INN	International non-proprietary name
IP	Intellectual property
ISA	International Searching Authority
KZT	Kazakhstan tenge
MSM	Men who have sex with men
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
PCT	Patent Cooperation Treaty
PI	Protease inhibitor
PLHIV	People living with HIV
PSM	Procurement and supply management
PWID	People who inject drugs
RUB	Russian rouble
SES	Single Economic Space
SWs	Sex workers
TB	Tuberculosis
TJS	Tajikistan somoni
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USD	United States dollar
UZS	Uzbekistan soum
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Acronyms of ARV medicines

3TC	Lamivudine
ABC	Abacavir
ATV	Atazanavir
AZT	Zidovudine
d4T	Stavudine
ddI	Didanosine
DRV	Darunavir
EFV	Efavirenz
ENF	Enfuvirtide
ETV	Etravirine
FPV	Fosamprenavir
FTC	Emtricitabine
IDV	Indinavir
LPV	Lopinavir
NFV	Nelfinavir
NVP	Nevirapine
r, RTV	Ritonavir
RAL	Raltegravir
SQV	Saquinavir
TDF	Tenofovir

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This report would not be possible without joint efforts of the HIV focal points and GFATM partnership staff at UNDP country offices, of regional and national consultants for Belarus, Kazakhstan, Russia, Tajikistan and Uzbekistan, as well as team members of the HIV, Health and Development Team of UNDP. Thanks to Olga Atroshchanka, Lusine Aydinyan, Farrukh Ilnazarov, Umida Islamova, Zebo Jalilova, Alisher Juraev, Saodat Kasymova, Zakir Khodjaev, Shahruh Khushmuradov, Olga Kim, Inga Latysheva, Alisher Latypov, John Macauley, Tedla Mezemir, Dildora Mustafaeva, Irina Petrenko, Elena Potapchik, Flora Salikhova, Vladimir Shoukhov, and many others.

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EXECUTIVE SUMMARY

The 2013 UNAIDS Report on the Global AIDS Epidemic identifies the region of Eastern Europe and Central Asia (EECA) as the one with a still-growing HIV epidemic, with Russia and Ukraine having the highest HIV burdens. Over the past decade, countries in the EECA region have made significant progress in their national responses to HIV and improving the prevention, treatment, care and support of people living with HIV, as well as the key populations most at risk of HIV infection. However, the coverage of most key interventions is still too low in the region to serve the needs of people affected and infected by HIV.

This report focuses on one aspect of the national HIV responses, namely to increase the access of HIV treatment. As emphasized in the WHO/UNAIDS initiative "Treatment 2.0", which aims to catalyse HIV treatment scale up through innovation and efficiency, increasing access to treatment is a complex task. It relates to the optimization of treatment regimens, procurement and supply planning and implementation, as well as to lowering the cost of treatment without compromising the quality, safety and efficacy of medicines.

Increasing and improving access to treatment in the EECA region is crucial for countries to meet their international public health obligations, made in the 2011 Political Declaration on HIV and AIDS, and to achieve Millennium Development Goal 6, specifically its targets to halt and start reversing the HIV epidemic and to ensure universal access to treatment for those who need it.

While all EECA countries have increased their national financial contributions to HIV and AIDS responses, some of them still depend on international financial support to sustain and expand these responses. In this regard, the Global Fund to Fight AIDS, Tuberculosis and Malaria is the biggest international grant-giver in the region. Meanwhile, Kazakhstan and Russia now finance their national HIV programmes mostly from their country budgets.

The regional project "Sustainable Financing of National HIV Responses and Reducing Cost of Treatment in Select CIS Countries with focus on the Customs Union", which is implemented by UNDP in its role as UNAIDS co-sponsor with financial support from the Russian Federation, aims to support this process in Belarus, Tajikistan and Uzbekistan. These are countries in the region where UNDP is a principal recipient of Global Fund grants. In addition, it draws from lessons learnt in Kazakhstan and Russia which have transitioned from Global Fund grants to domestic funding. The present report is a component of the regional project focusing on the guidelines and regulatory frameworks for antiretroviral medicines and treatment. The report also complements several other UNDP efforts to tackle intellectual property (IP) rights and cost of treatment, including a study on the nexus between pharmaceutical patents and prices which is being carried out at the UNDP Bureau for Development Policy (presently – UNDP Bureau for Policy and Programme Support) in New York.

The present report focuses on the analysis of critical factors affecting the affordability and accessibility of antiretroviral (ARV) medicines in the selected countries on the level of treatment guidelines, regulatory frameworks related to registration, licensing, and other forms of marketing authorization, procurement and supply management, as well as IP rights status which predetermines the opportunity to access generic equivalents. It aims to provide decision makers and other stakeholders on the country and regional levels with practical background information and an analytical review which will assist to optimize

strategies for the selection and provision of affordable, quality ARVs at the quantities required to scale-up ART to universal coverage, with particular focus on key populations most at risk.

It concludes with a series of observations and recommendations regarding the opportunities to update national treatment regimens in a regional and global context under optimization of national regulatory frameworks, to include public health flexibilities in national IP laws, where applicable, to avoid excessive protection and to consider opportunities to mitigate the possible negative effect of such provisions where they have been adopted, without infringing on international legal obligations. The report further elaborates on opportunities to make registration and licensing regimes more conducive to access to essential medicines, and consider the implications of common economic spaces on the trade in and access to essential medicines, including essential medicines for HIV. Finally, the report offers a set of recommendations on possible improvements of regulating public procurements.

1. INTRODUCTION

In recent years the EECA region has witnessed the further rise in HIV infections, although some countries have shown declines since 2012. The estimated number of people living with HIV and aged 15 and over has reached 1.3 million [1,000,000–1,700,000] in this region.[1] The epidemic remains concentrated among key populations at higher risk of HIV exposure, including people who inject drugs (PWID) and their sexual partners, men who have sex with men (MSM), sex workers (SWs), prisoners and migrants.[2] Prevalence of HIV among PWID is still high in many countries of the region, with more than half of PWID infected with the virus in some geographic areas.[3]

As in all other regions across the globe, HIV/AIDS is a development issue in the EECA region, inextricably linked to social and economic progress. The reciprocal relationships between HIV/AIDS and development are reflected in the Millennium Development Goals.[4] Availability and access to HIV/AIDS services is a human rights issue, and promoting the rights of key populations is a critical enabler for the reduction of HIV transmission.[5]

1 UNAIDS. *Global Report: UNAIDS Report on the Global AIDS Epidemic 2013* (UNAIDS / JC2502/1/E).

2 GFATM. *Draft Concept Note and Consultation Agenda for the Development of a Global Fund Strategy on HIV/AIDS for Eastern Europe and Central Asia* (Geneva, 26 September 2013).

3 L. Platt, E. Jolley, V. Hope, A. Latypov, F. Hickson, L. Reynolds, and T. Rhodes. *HIV Epidemics in the European Region: Using Evidence to Strengthen Policy and Programmes* (Washington, DC, World Bank, 2013).

4 UN Millennium Declaration (UN Doc. A/res/55/2; http://www.un.org/millennium/declaration/ares552e.htm). More information about Millennium Development Goals: http://www.un.org/millenniumgoals.

5 UNDP. *The Role of Human Rights in Responses to HIV, Tuberculosis and Malaria, Discussion Paper* (New York, 2013). See also: EU Agency for Fundamental Rights. *A Rights-Based Approach to HIV in the European Union. Contribution of the European Union Agency for Fundamental Rights to the International AIDS Conference 2010, Vienna 18-23 July*. (http://fra.europa.eu/sites/default/files/fra_uploads/945-AIDS_2010_FRA_factsheet.pdf).

In recognition of the importance to focus on key populations and their rights and acknowledging the contribution of poverty and underdevelopment to the spread of HIV, countries of the region adopted the Dublin Declaration to Fight HIV/AIDS in Europe and Central Asia in 2004 and made a number of commitments, including scaling up treatment and prevention programmes.[6] These commitments reaffirmed the Declaration of Commitment on HIV/AIDS adopted by the UN General Assembly Special Session on HIV/AIDS on 27 June 2001. However, as the Political Declaration on HIV and AIDS was adopted in New York in June 2011, representatives of states and governments expressed "deep concern that funding devoted to HIV and AIDS responses is still not commensurate with the magnitude of the epidemic" and noted that "many national HIV-prevention

> Treatment guidelines, IP and other components of the regulatory framework substantially affect the prices of ARVs. Countries should maintain policy space that allows them to meet public health obligations while seeking optimal macroeconomic benefits through international trade

6 Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia, 24 February 2004, Dublin, Ireland.

strategies inadequately focus on populations that epidemiological evidence shows are at higher risk."[7]

HIV prevention and treatment recommendations issued and updated by UN agencies over recent years include well-defined interventions for key populations at higher risk of HIV exposure. These include, for example, "comprehensive packages" of nine interventions for the prevention, treatment and care of HIV among PWID,[8] and of fifteen interventions in prisons and other closed settings,[9] as well as recommendations for prevention and treatment of HIV and other sexually transmitted infections for SWs,[10] and among MSM and transgender people.[11]

While there has been an increase in access to ARV treatment in EECA countries over the past decade and significant resources have been mobilized, particularly in Russia, UNAIDS data suggest that coverage remains low as only an estimated 35 percent of adults eligible for ART actually receiving it.[12] There have been indications that key populations at higher risk have particular difficulties to access treatment and yet have the greatest need.[13] The recent WHO's 2013 ARV treatment guidelines, which recommend a CD4 threshold of 500 for initiation of HIV treatment, broaden the eligibility for ART considerably resulting in a further decrease of the current estimated coverage once adopted by countries in the region.[14] To expedite and expand coverage to achieve the global target of 15 million people on ART by 2015, the new *Treatment 2015* framework has three fundamental pillars, with one of them – invest – implying mobilizing sustained investment, giving priority to innovation and using the available resources as strategically as possible.[15] Ensuring that all people eligible for ART receive it is of critical importance to fulfilling the vision of zero new infections and zero AIDS-related deaths.[16]

The UNAIDS investment framework helps countries to develop a context-specific, outcome-driven, country-owned investment package and to guide investment priorities that are cost-effective, efficient and produce maximum impact.[17] In addition to the key programme interventions particularly for people at higher risk of HIV exposure, it highlights critical enablers and synergies with other development policies and interventions. This requires a continuous review of current action, under a long term perspective based on sustainable financing strategies. In the EECA region, however, the national HIV responses in many countries still rely on external funding mainly from the GFATM for most of the well-defined and evidence-based interventions including for ART.

While external funding for ART will stagnate, decrease or completely cease for many countries in the EECA region as recently evidenced through new eligibility

7 Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS, adopted by the UN General Assembly, Resolution 65/277. Sixty-fifth session, 10 June 2011.

8 WHO, UNODC, UNAIDS. *Technical Guide for Countries to Set Targets for Universal Access to HIV Prevention, Treatment and Care for Injecting Drug Users* (2012 revision).

9 UNODC, ILO, UNDP, WHO, UNAIDS. *Policy Brief: HIV Prevention, Treatment and Care in Prisons and Other Closed Settings: A Comprehensive Package of Interventions.* Vienna, 2013.

10 WHO, UNFPA, UNAIDS, NSWP. *Prevention and Treatment of HIV and Other Sexually Transmitted Infections for Sex Workers in Low- and Middle-income Countries. Recommendations for a Public Health Approach*. Geneva, 2012.

11 WHO, UNAIDS, GIZ, MSMGF, UNDP. *Prevention and Treatment of HIV and Other Sexually Transmitted Infections among Men Who Have Sex with Men and Transgender People. Recommendations for a Public Health Approach*. Geneva, 2011.

12 UNAIDS. *Report on the Global AIDS Epidemic 2013*, http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf

13 WHO Regional Office for Europe. *European Action Plan for HIV/AIDS 2012-2015*. Copenhagen, 2011 (http://www.euro.who.int/__data/assets/pdf_file/0011/153875/e95953.pdf).

14 WHO. *Consolidated Guidelines on The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach.* Geneva, 2013 (http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf).

15 UNAIDS. *Treatment* 2015 (UNAIDS/ JC2484/1/E, 2012; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2484_treatment-2015_en.pdf)

16 UNAIDS. *Getting to Zero: 2011-2015 Strategy* (UNAIDS/10.12E / JC2034E, December 2010; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2010/jc2034_unaids_strategy_en.pdf)

17 UNAIDS. *Investing for Results. Results for People. A People-Centred Investment Tool towards Ending AIDS* (UNAIDS/PCB(30)12.CRP.4, 2012; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2359_investing-for-results_en.pdf).

criteria for GFATM grants,[18] even for countries still eligible the domestic counterpart financing requirements to access external funds will increase, as will the need for the provision of ARVs in order to fulfil commitments and rights to universal access to affordable ART at defined quality standards. In view of this, the financial sustainability of national HIV treatment programmes has become a critical concern for countries in the EECA region.

Treatment guidelines, IP rights and other components of the regulatory framework addressing production, importation, licensing and registration of medicines, as well as procurement regulations substantially affect the prices of and access to essential medicines, including ARVs. Recent developments in trade negotiations and agreements in the region have caused and will further cause considerable changes of these rights and regulations in several countries. The Customs Union between Belarus, Kazakhstan and the Russian Federation, the accession of CIS countries to the WTO and the movement of some countries towards association with the EU all have an impact on rights and regulations affecting access to and prices of essential medicines, including ARVs. It is therefore important for countries in the region to maintain policy and negotiating space that allows them to meet public health obligations while seeking optimal macroeconomic benefits through international trade negotiations and their obligations.

As a co-founding partner of the Joint UN Programme on HIV/AIDS (UNAIDS), guided by the health-related MDGs and in particular MDG 6, UNDP provides policy advice and technical assistance to governments in reforming the legislation, policies and practices in order to facilitate the responses to HIV and AIDS. As part of this process, since 2009, UNDP has advised several governments in Eastern Europe and Central Asia on issues related to accession to the World Trade Organization and access to essential medicines, integration and utilization of the TRIPS Agreement public health flexibilities, the impact of standards that exceed the TRIPS levels of protection on access to essential medicines and the opportunities to mitigate such negative public health impact of trade agreements. UNDP experts have provided substantial advice on draft legislation and policies related to HIV, medicines, key populations most at risk of HIV and many other topics. In this process of providing advice and support UNDP works with all stakeholders including governments, civil societies, the family of UN organizations, health financing institutions like the GF, bilateral development partners and the private sector.

As part of a regional project on sustainable financing of national HIV responses that works with the critical enablers and development programme synergies as outlined in the UNAIDS Investment Framework,[19] and in collaboration with UNAIDS and its co-sponsors, UNDP supports governments and civil society organizations in the region to develop strategies and practical approaches to reduce dependencies on external funding through domestic investments, particularly for the universal access to affordable ART for PLHIV. Detailed country-specific knowledge and analysis of the guidelines and regulatory frameworks that affect the selection and procurement of ARVs is critical for highlighting current opportunities, future options and recommendations aimed at the provision of quality ARVs for all in need at the lowest costs.

This sub-regional report summarizes and expands the findings and recommendations of the analysis of regulatory frameworks for ARV medicines and treatment of five country reports on sustainable financing for national HIV responses of Belarus, Kazakhstan, Russia, Tajikistan and Uzbekistan.

18 GFATM. *Draft Concept Note and Consultation Agenda for the Development of a Global Fund Strategy on HIV/AIDS for Eastern Europe and Central Asia*. Geneva, 26 September 2013; GFATM, *The Global Fund Eligibility And Counterpart Financing Policy* (Thirtieth Board Meeting, Geneva, Switzerland, 7-8 November 2013, GF/B30/6, Revision 1, Attachment 1); EHRN. *Quitting While Not Ahead: The Global Fund's Retrenchment and the Looming Crisis for Harm Reduction in Eastern Europe and Central Asia*. Vilnius, 2012.

19 UNAIDS. *Investing for results. Results for people. A people-centered investment tool towards ending AIDS.* (UNAIDS/PCB(30)12.CRP.4; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2359_investing-for-results_en.pdf).

This sub-regional report is based on:

- reviews of WHO and national ART recommendations;
- comprehensive research of IP legislation and trade regimes in study countries with the focus on their impact to secure access to essential medicines, particularly ARVs;
- analyses of implications of the Customs Union between Belarus, Kazakhstan and Russia, accession to the WTO and association with the EU on the importation of and trade with essential medicines, particularly ARVs;
- analyses of ARV registration, related procurement regulations and practices in the study countries.

2. OBJECTIVES AND METHODOLOGY

2.1 Study goal and objectives

The goal of this study is to contribute to scaling-up quality ART services at the most affordable prices. To this end, the study has the following objectives:

- Summarize ART options under the current national treatment guidelines, and highlight opportunities and challenges for future guideline updates in view of the WHO 2013 consolidated ART guidelines;
- Review global, sub-regional and national patent regimes and regulatory frameworks and highlight current patent status of ARV medicines in each study country;
- Provide an analysis of country specific regulations for licensing of pharmaceutical activities and registration of pharmaceuticals highlighting the current registration status of ARV medicines;
- Identify opportunities and challenges of the public sector procurement systems relevant for the procurement of ARV medicines through national authorities and highlight current procurement mechanisms of ARV medicines under GFATM grants in some of the study countries;
- Provide recommendations for strategies and practical action that will facilitate the access to quality ARVs at affordable prices, and share good practices within the sub-region and beyond.

This report, as well as policy briefs developed on its basis, is an essential tool for raising awareness and advocacy among regional and national policy and decision makers among governments, civil society organizations and other stakeholders.

2.2 Research methodology

In order to achieve the above objectives, we conducted an extensive review and analysis of existing contextual frameworks including:

- WHO and national ART guidelines; [20]
- global, sub-regional and national IP frameworks specifically relating to medicines;
- legal systems regulating circulation of medicines, including issues of registration;
- procurement systems in study countries and those used in GFATM procurements.

In addition, we determined the country-specific status of patent protection and registration of ARV medicines recommended by WHO and national ART guidelines.

The study team was comprised of national and international consultants, UNDP specialists and an international lead consultant. Methodology and report structure were developed and reviewed in two technical consultation meetings conducted in Tashkent and Minsk in 2013. Initial findings and a pre-final draft of the report were peer reviewed.

2.3 Sources of data

This detailed review relied to a large extent on available published literature, policies and

20 In addition to its global guidelines, WHO Europe also produced clinical protocols on treatment of HIV infection: In 2004, protocols were developed for the CIS countries; in 2007, these were replaced with protocols for the entire European Region of WHO, which were later revised in 2010 and 2012. After publication of the global WHO 2013 Consolidated ART guidelines it was decided to discontinue the practice of developing regional protocols, but to rather encourage countries to adopt their national guidelines based on global WHO recommendations. Therefore, this report is using only global WHO guidelines in its review.

legislation, programmatic and internal institutional documentation. The following documents and data were used for the study:

- WHO guidelines and national documents (guidelines and protocols) on ART;
- Applicable global and regional IP-related instruments;
- National legislations on IP, licensing and registration of essential medicines, as well as national strategies, laws and bylaws that regulate national responses to HIV;
- National medicines registration databases;
- International, regional (Eurasian) and national patent databases;
- Reports on current access-to-treatment situations in the selected countries.

When documents were not available in English, official Russian titles are given in footnotes.

Where further clarifications were necessary or where existing information was not readily available, key informant interviews were conducted.

3. ART GUIDELINES

3.1 WHO ART guidelines

Given various factors associated with ARV therapy, such as efficacy, side-effects, cost, interaction with other treatments (e.g., TB or hepatites), evidence-based recommendations have been developed and are periodically updated on how to best treat HIV-positive individuals with ARVs. To support ART delivery in national programmes and by treatment service providers WHO established its first guidelines for ART in 2002, primarily focused on a public health approach for resource-limited settings. These recommendations were updated in 2003, 2006, 2010, and 2013 incorporating changes reflecting progressive increase in the knowledge of HIV pathogenesis, development of new medicines and diagnostics, and increased experience of HIV treatment and prevention programmes. Before 2013, WHO produced separate guidelines for adolescents and adults,[21] and for infants and children,[22] but in 2013 it was decided to put both in the same document, the Consolidated Guidelines.[23]

The Consolidated Guidelines provide guidance on the diagnosis of HIV infection, the care of PLHIV and the use of ARV medicines for treating and preventing HIV infection. They are structured along the continuum of HIV testing, care and treatment. The 2013 consolidation process combined and harmonized recommendations from a range of WHO guidelines and other documents, including the 2010 guidelines on using ART for HIV infection in adults and adolescents, in infants and children and for treating pregnant women living with HIV and preventing HIV infection in infants. The 2013 guidelines reflect important advances in HIV responses since 2010:

- Simple, safer, and if available once-daily, single-pill FDCs of ARV regimens that are suitable for use in most populations and age groups;
- Earlier start of ART with a CD4 threshold for treatment initiation of 500 cells/mm^3;
- Initiation of ART regardless of CD4 count for HIV-positive people with active TB, HBV co-infection with severe chronic liver disease, HIV-positive partners in serodiscordant couples, pregnant and breastfeeding women and children younger than five years of age;
- Phasing out of ARVs that are no longer recommended.

The most important implication of these changes is that the number of PLHIV eligible for treatment will increase significantly. According to 2013 UNAIDS estimates, only 35 percent of adults eligible for ART in the region were receiving it,[24] Introduction of 2013 WHO guidelines means that countries will need to significantly scale up access to ART to ensure universal coverage, if the 2013 WHO guidelines will be nationally adopted.

Table 1 below presents a summary of recommendations of 2010 and 2013 WHO guidelines in terms of ART for children and adults. It shows only those combinations, which are recommended as preferred or alternative options for first- and second-line treatment; it does not contain "acceptable" regimens, those for special circumstances and salvage therapy regimens.

21 WHO. *Antiretroviral therapy for HIV infection in adults and adolescents. Recommendations for a public health approach: 2010 revision* (http://www.who.int/hiv/pub/arv/adult2010/en/).

22 WHO. *Antiretroviral therapy for HIV infection in infants and children: Towards universal access. Recommendations for a public health approach: 2010 revision* (http://www.who.int/hiv/pub/paediatric/infants2010/en/index.html).

23 WHO. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach* (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/).

24 UNAIDS Report on the Global AIDS Epidemic 2012, UNAIDS document JC2417E.

This was done in order to analyse to what extent national ART guidelines and programs follow WHO recommendations in terms of most widely used ARV medicines and combinations.

Table 1: ARV medicines and triple combinations recommended for first- and second-line treatment of HIV-positive children and adults in 2010 and 2013 WHO guidelines

Treatment regimens	Categories of patients	WHO ART Guidelines, 2010			WHO ART Guidelines, 2013		
		Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment
		Single	FDC		Single	FDC	
First line	Adults	3TC	3TC/AZT	3TC/AZT/EFV[25]	3TC	3TC/AZT	3TC/EFV/TDF
		AZT	3TC/AZT/NVP	3TC/AZT/NVP	AZT	3TC/AZT/NVP	EFV/FTC/TDF
		d4T	3TC/d4T	3TC/EFV/TDF	EFV	3TC/EFV/TDF	3TC/AZT/EFV
		EFV	3TC/d4T/NVP	3TC/NVP/TDF	FTC	3TC/TDF	3TC/AZT/NVP
		FTC	EFV/FTC/TDF	EFV/FTC/TDF	NVP	EFV/FTC/TDF	3TC/NVP/TDF
		NVP	FTC/TDF	FTC/NVP/TDF	TDF	FTC/TDF	FTC/NVP/TDF
		TDF		3TC/d4T/EFV			
				3TC/d4T/NVP			
	Children	3TC	3TC/ABC	3TC/AZT/EFV	3TC	3TC/AZT	3TC/ABC/EFV
		ABC	3TC/AZT	3TC/AZT/LPV/r	ABC	3TC/AZT/NVP	3TC/ABC/LPV/r
		AZT	3TC/d4T	3TC/AZT/NVP	AZT		3TC/AZT/LPV/r
		d4T	3TC/d4T/NVP	3TC/ABC/EFV	EFV		3TC/AZT/EFV
		EFV		3TC/ABC/LPV/r	FTC		3TC/AZT/NVP
		LPV/r		3TC/ABC/NVP	LPV/r		3TC/EFV/TDF
		NVP		3TC/d4T/EFV	NVP		3TC/NVP/TDF
				3TC/d4T/LPV/r	TDF		EFV/FTC/TDF
				3TC/d4T/NVP			FTC/NVP/TDF
Second-line regimens	Adults	3TC	3TC/AZT	2 NRTIs+bPI	3TC	3TC/AZT	3TC/AZT/ATV/r
		ATV/r	FTC/TDF	3TC/AZT/ATV/r	ATV/r	3TC/TDF	3TC/AZT/LPV/r
		AZT		3TC/AZT/LPV/r	AZT	FTC/TDF	3TC/TDF/ATV/r
		DRV/r		3TC/TDF/ATV/r	FTC		3TC/TDF/LPV/r
		FTC		3TC/TDF/LPV/r	LPV/r		FTC/TDF/ATV/r
		LPV/r		FTC/TDF/ATV/r	TDF		FTC/TDF/LPV/r
		TDF		FTC/TDF/LPV/r			
				3TC/AZT/DRV/r			
				3TC/TDF/DRV/r			
				FTC/TDF/DRV/r			
	Children	3TC	3TC/ABC	NNRTI+2 NRTIs	3TC	3TC/ABC	3TC/ABC/LPV/r
		ABC	3TC/ABC/AZT	2 NRTIs+bPI	ABC	3TC/AZT	3TC/ABC/EFV
		ATV/r	3TC/AZT	3TC/ABC/LPV/r	AZT	3TC/AZT/NVP	3TC/AZT/EFV
		AZT		3TC/AZT/LPV/r	EFV		3TC/AZT/LPV/r
		d4T		ABC/ddI/LPV/r	FTC		3TC/ABC/NVP
		ddI		AZT/ddI/LPV/r	LPV/r		3TC/AZT/NVP
		DRV/r		ddI/EFV/LPV/r	NVP		3TC/NVP/TDF
		LPV/r		ddI/NVP/LPV/r	TDF		3TC/TDF/LPV/r
		NVP		3TC/ABC/AZT			FTC/TDF/LPV/r
				3TC/ABC/d4T			

25 Combinations highlighted in yellow are those recommended as preferred; combinations without highlighting are alternative.

3.2 National ART guidelines in the study countries

As mentioned above, WHO guidelines are published to support countries in implementing national ART programmes and serving as a basis for development of national guidelines and protocols. Table 2 below summarizes the national ART guidelines adopted in the five study countries.

Given that harmonization of national protocols with WHO guidelines requires considerable time and effort, by the time of writing this report countries did not have sufficient time to update their national ART guidelines and protocols in line with 2013 WHO guidelines. Moreover, some countries' national guidelines have not yet been aligned with 2010 WHO guidelines as can be seen from the dates of some of the current national guidelines in table 2.

Table 2: National ART guidelines and protocols adopted in study countries

Country	National guideline or protocol
Belarus	Optimization of diagnosis and administration of ART for adults and adolescents - application instructions (Minsk, 2012) Clinical protocol for treatment of children with HIV/AIDS - application instructions (Minsk, 2005)
Kazakhstan	Order of acting Minister of Health of the Republic of Kazakhstan No. 8 of 5 January 2011, amended by Order of Minister of Health of the Republic of Kazakhstan No. 165 of 11 March 2012. Annex 1: Protocol for diagnosis and treatment of HIV infection and AIDS in adults; Annex 2: Protocol for diagnosis and treatment of HIV infection and AIDS in children
Russia	The Russian Federation is in the process of adopting its official guidelines. Presently there are several clinical recommendations are published: by the National Scientific Society of Infectiologists (authored by leading scholars from the Federal Scientific and Methodological Centre for the Prevention and Control of AIDS at the Federal Service for Supervision of Consumer Rights Protection and Human Well-Being)[26], by the Scientific and Practical Centre for the Prevention and Treatment of the HIV Infection among Pregnant Women and Children[27], and by Moscow City AIDS Centre[28 29 30]
Tajikistan	Clinical protocols for HIV/AIDS treatment and care. Annex 1: Diagnosis and ART for adults and adolescents; Annex 11: Treatment and care for children with HIV/AIDS (Dushanbe, 2008)
Uzbekistan	Ministry of Healthcare Ordinance No. 88 "On Introduction of Adapted National WHO Protocols on HIV-Infection". Annex 1: Diagnosis and ART among Adults and Adolescents; Annex 5: Provision of Medical Care for Children with HIV/AIDS (Tashkent, 2012)

Table 3 presents recommended ART options for first- and second-line treatment of adults and children in the study countries. Similarly to table 1, data here are shown in a simplified way (i.e., only containing preferred and alternative treatment options) while regimens used in special circumstances (such as TB or HBV co-infection or intolerance of recommended ARV medicines) are not presented.

26 В.В. Покровский, О.Г.Юрин, А.В.Кравченко и др., Эпидемиология и инфекционные болезни. Актуальные вопросы. - № 6 /2013 – стр. 1-27 (www.hivrussia.org/files/docs/protokol6-2013.pdf)

27 Л.Ю. Афонина, Ю.А. Фомин, Е.Е. Воронин. Антиретровирусная терапия у детей с ВИЧ-инфекцией: клинические рекомендации – М., 2009.

28 А.И.Мазус, Г.Д.Каминский, В.Н.Зимина и др. Национальные клинические рекомендации по диагностике и лечению ВИЧ-инфекции у взрослых. М., 2013.

29 А.И.Мазус, Г.Д.Каминский, Ю.Ф.Влацкая и др. Национальные клинические рекомендации по диагностике и лечению ВИЧ-инфекции у детей и подростков. М., 2013.

30 Note: even though the recommendations of Moscow City AIDS Centre were approved by the Profile Commission on HIV Diagnosis and Treatment under the Ministry of Healthcare and by the National Association of Virology, they are not normative documents.

Table 3: Summary of regimens recommended in the study countries

Treatment regimens	Categories of patients	National ART guidelines of Belarus			National ART guidelines of Kazakhstan			Russia: ART protocols (adults: National Society of Virologists; children: Centre on HIV Infection in Pregnant Women and Children)			Russia: ART protocols (Moscow City AIDS Centre)			National ART guidelines of Tajikistan			National ART guidelines of Uzbekistan		
		Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment
		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs	
First line regimen	Adults	3TC	n/a	3TC/EFV/TDF8[31]	3TC	n/a	3TC/AZT/EFV	3TC	3TC/ABC	3TC/ABC/EFV	3TC	n/a	3TC/ABC/ATV/r	3TC	n/a	3TC/ABC/EFV	3TC	n/a	3TC/EFV/TDF
		ABC		EFV/FTC/TDF	AZT		3TC/AZT/NVP	ABC	3TC/AZT	3TC/AZT**/EFV	ABC		3TC/ABC/DRV/r	ABC		3TC/ABC/NVP	AZT		3TC/NVP/TDF
		ATV/r		3TC/ABC/ATV/r	EFV		3TC/EFV/TDF	ATV/r	3TC/AZT/NVP	3TC/EFV/TDF	AZT		3TC/ABC/EFV	AZT		3TC/AZT/EFV	d4T		EFV/FTC/TDF
		AZT		3TC/ABC/LPV/r	FTC		3TC/NVP/TDF	AZT**	FTC/TDF	EFV/FTC/TDF	ATV/r		3TC/ABC/FPV/r	EFV		3TC/AZT/NVP	EFV		FTC/NVP/TDF
		DRV/r		3TC/ABC/NVP	NVP		EFV/FTC/TDF	EFV		3TC/ABC/ATV/r	DRV/r		3TC/ABC/LPV/r	FTC		EFV/FTC/TDF	FTC		3TC/AZT/EFV
		EFV		3TC/AZT/ATV/r	TDF		FTC/NVP/TDF	FTC		3TC/ABC/LPV/r	EFV		3TC/ABC/RAL	NVP		FTC/NVP/TDF	NVP		3TC/AZT/NVP
		FTC		3TC/AZT/LPV/r				LPV/r		3TC/ABC/NVP	FPV/r		3TC/ABC/RPV	TDF		3TC/ABC/AZT	TDF		3TC/d4T/EFV
		LPV/r		3TC/AZT/NVP				NVP		3TC/AZT**/ATV/r	FTC		3TC/EFV/TDF			3TC/AZT/TDF			3TC/d4T/NVP
		NVP		ABC/FTC/ATV/r				TDF		3TC/AZT**/LPV/r	LPV/r		3TC/RAL/TDF						
		TDF		ABC/FTC/LPV/r						3TC/AZT**/NVP	RAL		3TC/RPV/TDF						
				ABC/FTC/NVP						3TC/NVP/TDF	RPV		3TC/TDF/ATV/r						
				AZT/FTC/ATV/r						3TC/TDF/ATV/r	SQV/r		3TC/TDF/DRV/r						
				AZT/FTC/DRV/r						3TC/TDF/DRV/r	TDF		3TC/TDF/FPV/r						
				AZT/FTC/LPV/r						3TC/TDF/LPV/r			3TC/TDF/LPV/r						
				AZT/FTC/NVP						FTC/NVP/TDF			EFV/FTC/TDF						
										FTC/TDF/ATV/r			FTC/RAL/TDF						
										FTC/TDF/LPV/r			FTC/RPV/TDF						
													FTC/TDF/ATV/r						
													FTC/TDF/DRV/r						
													FTC/TDF/FPV/r						
													FTC/TDF/LPV/r						
													3TC/ABC/AZT						
													3TC/ABC/NVP						
													3TC/ABC/SQV/r						
													3TC/AZT/ATV/r						
													3TC/AZT/DRV/r						
													3TC/AZT/EFV						
													3TC/AZT/FPV/r						
													3TC/AZT/LPV/r						
													3TC/AZT/NVP						
													3TC/AZT/RAL						
													3TC/AZT/RPV						
													3TC/AZT/SQV/r						
													3TC/NVP/TDF						
													3TC/TDF/SQV/r						
													FTC/NVP/TDF						
													FTC/TDF/SQV/r						

31 Combinations highlighted in yellow are those recommended as preferred; combinations without highlighting are alternative.

Table 3: Summary of regimens recommended in the study countries (cont.)

Treatment regimens	Categories of patients	National ART guidelines of Belarus			National ART guidelines of Kazakhstan			Russia: ART protocols (adults: National Society of Virologists; children: Centre on HIV Infection in Pregnant Women and Children)			Russia: ART protocols (Moscow City AIDS Centre)			National ART guidelines of Tajikistan			National ART guidelines of Uzbekistan		
		Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment
		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs	
First line regimen	Children	3TC	n/a	3TC/ABC/AZT	3TC	n/a	3TC/ABC/EFV	3TC	3TC/ABC	3TC/ABC/EFV	3TC	n/a	3TC/ABC/EFV	3TC	n/a	3TC/ABC/EFV	3TC	n/a	3TC/AZT/EFV
		ABC		3TC/ABC/EFV	ABC		3TC/ABC/NVP	ABC	3TC/AZT	3TC/ABC/LPV/r	ABC		3TC/ABC/LPV/r	ABC		3TC/ABC/NVP	ABC		3TC/AZT/LPV/r
		AZT		3TC/ABC/NFV	AZT		3TC/AZT/EFV	AZT**		3TC/ABC/NVP	AZT		3TC/ABC/NVP	AZT		3TC/AZT/EFV	AZT		3TC/AZT/NVP
		EFV		3TC/ABC/NVP	EFV		3TC/AZT/NVP	ddI		3TC/AZT**/EFV	EFV		3TC/AZT/LPV/r	EFV		3TC/AZT/NVP	d4T		3TC/ABC/EFV
		LPV/r		3TC/AZT/EFV	LPV/r		3TC/ABC/AZT	EFV		3TC/AZT**/LPV/r	FTC*		3TC/TDF*/LPV/r	NVP		3TC/ABC/AZT	EFV		3TC/ABC/LPV/r
		NFV		3TC/AZT/LPV/r	NVP		3TC/ABC/LPV/r	LPV/r		3TC/AZT**/NVP	LPV/r		FTC*/TDF*/LPV/r				LPV/r		3TC/ABC/NVP
		NVP		3TC/AZT/NFV			3TC/AZT/LPV/r	NFV		3TC/ddI/FPV/r	NVP		3TC/AZT/EFV				NVP		3TC/d4T/EFV
				3TC/AZT/NVP				NVP		3TC/ddI/LPV/r	TDF*		3TC/AZT/NVP						3TC/d4T/LPV/r
										3TC/ddI/NFV			3TC/EFV/TDF*						3TC/d4T/NVP
										3TC/ddI/NVP			3TC/NVP/TDF*						3TC/EFV/TDF
													EFV/FTC*/TDF*						3TC/NVP/TDF
													FTC*/NVP/TDF*						EFV/FTC/TDF
																			FTC/NVP/TDF
Second line regimen	Adults	3TC	n/a	2 NRTI/ATV/r	ABC	n/a	3TC/AZT/LPV/r	ABC	n/a	ABC/ddI/ATV/r	3TC	n/a	2 NRTIs + NNRTI	ABC	n/a	ABC/ddI/LPV/r	3TC	n/a	3TC/AZT/LPV/r
		ABC		2 NRTI/DRV/r	ATV/r		3TC/TDF/LPV/r	ATV/r		AZT**/TDF/ATV/r	ABC		2 NRTIs + PI	AZT		ABC/TDF/LPV/r	ABC		ABC/ddI/LPV/r
		ATV/r		2 NRTI/LPV/r	AZT		ABC/ddI/LPV/r	AZT**		ddI/TDF/LPV/r	AZT		2 NRTIs + II	ddI		AZT/ddI/LPV/r	AZT		ABC/d4T/LPV/r
		AZT		3TC/TDF/ATV/r	ddI		ABC/TDF/LPV/r	ddI		ABC/ddI/EFV	ATV/r			LPV/r		AZT/TDF/LPV/r	d4T		AZT/ddI/LPV/r
		ddI		3TC/TDF/LPV/r	EFV		AZT/ddI/LPV/r	DRV/r		ABC/ddI/LPV/r	DRV/r			TDF		ABC/ddI+bPI	ddI		FTC/TDF/LPV/r
		DRV/r		AZT/ddI/ATV/r	FTC		ddI/TDF/LPV/r	EFV		ABC/ddI/NVP	EFV			ATV/r		ABC/TDF+bPI	FTC		3TC/ABC/LPV/r
		FTC		AZT/ddI/LPV/r	LPV/r		EFV/FTC/TDF	FPV/r		AZT**/EFV/TDF	FPV/r			DRV/r		AZT/ddI+bPI	LPV/r		3TC/ddI/LPV/r
		LPV/r		FTC/TDF/ATV/r	NVP		FTC/NVP/TDF	IDV/r		AZT**/NVP/TDF	FTC					AZT/TDF+bPI	TDF		3TC/d4T/LPV/r
		TDF		FTC/TDF/LPV/r	TDF		FTC/TDF/LPV/r	LPV/r		AZT**/TDF/DRV/r	LPV/r								3TC/TDF/LPV/r
				3TC/ABC/DRV/r				NVP		AZT**/TDF/FPV/r	RAL								AZT/FTC/LPV/r
				3TC/AZT/DRV/r				RAL		AZT**/TDF/IDV/r	RPV								
				ABC/FTC/DRV/r				SQV/r		AZT**/TDF/LPV/r	TDF								
				AZT/ddI/DRV/r				TDF		AZT**/TDF/RAL									
				AZT/FTC/DRV/r						AZT**/TDF/SQV/r									
				AZT/FTC/LPV/r						ddI/EFV/TDF									
										ddI/NVP/TDF									
										ddI/TDF/ATV/r									
										ddI/TDF/DRV/r									
										ddI/TDF/FPV/r									
										ddI/TDF/IDV/r									
										ddI/TDF/LPV/r									
										ddI/TDF/RAL									
										ddI/TDF/SQV/r									

Table 3: Summary of regimens recommended in the study countries (cont.)

Treatment regimens	Categories of patients	National ART guidelines of Belarus			National ART guidelines of Kazakhstan			Russia: ART protocols (adults: National Society of Virologists; children: Centre on HIV Infection in Pregnant Women and Children)			Russia: ART protocols (Moscow City AIDS Centre)			National ART guidelines of Tajikistan			National ART guidelines of Uzbekistan		
		Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment	Recommended treatment building blocks		Recommended treatment
		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs		Single	FDCs	
Second line regimen	Children	ABC	n/a	ABC/ddI/EFV	3TC	n/a	3TC/ABC/bPI	3TC	3TC/ABC	2NRTI+NNRTI	3TC	n/a	3TC/ABC/EFV	AZT	n/a	AZT/ddI/LPV/r	3TC	n/a	3TC/ABC/EFV
		ddI		ABC/ddI/LPV/r	ABC		3TC/AZT/bPI	ABC	3TC/AZT	2NRTI+bPI	ABC		3TC/ABC/LPV/r	ddI		ddI/EFV/LPV/r	ABC		3TC/ABC/LPV/r
		EFV		ABC/ddI/NFV	AZT		AZT/ddI/bPI	AZT**			AZT		3TC/AZT/EFV	EFV		ddI/NVP/LPV/r	AZT		3TC/ABC/NVP
		LPV/r		ABC/ddI/NVP	ddI		ddI/EFV/bPI	ddI			EFV		3TC/AZT/LPV/r	LPV/r		AZT/ddI/NFV	ddI		3TC/AZT/EFV
		NFV			EFV		ddI/NVP/bPI	DRV/r			FTC*		3TC/EFV/TDF*	NFV		AZT/ddI/SQV/r	EFV		3TC/AZT/LPV/r
		NVP			LPV/r		ABC/ddI/bPI	FPV/r			LPV/r		3TC/TDF*/LPV/r	NVP		ddI/EFV/NFV	FTC		3TC/AZT/NVP
					NFV			LPV/r			TDF*		EFV/FTC*/TDF*	SQV/r		ddI/EFV/SQV/r	LPV/r		3TC/EFV/TDF
					NVP								FTC*/TDF*/LPV/r			ddI/NFV/NVP	NVP		3TC/NVP/TDF
					SQV/r											ddI/NVP/SQV/r	TDF		3TC/TDF/LPV/r
																			ABC/ddI/EFV
																			ABC/ddI/LPV/r
																			ABC/ddI/NVP
																			AZT/ddI/EFV
																			AZT/ddI/LPV/r
																			AZT/ddI/NVP
																			EFV/FTC/TDF
																			FTC/NVP/TDF
																			FTC/TDF/LPV/r

Notes:

*FTC and TDF may only be used in children after they are officially allowed for paediatric use in Russia.

** In guidelines by Pokrovskiy et al (on adults) and Afonina et al (on children), phosphazide (FAZT), a Russian made ART, can be used instead of AZT

In **Belarus** national ART guidelines for adults were adopted in 2012, after 2010 WHO ART guidelines, meaning that WHO recommendations were available at the time of national guidelines development. Belarus adopted national ART guidelines for children in 2005, which explains significant differences between ART combinations recommended by WHO and by the national guidelines. Analysis of Belarus guidelines shows that they have a number of deviations from WHO recommendations:

- The preferred first-line combinations of two NRTIs with NVP in the 2010 WHO guidelines on ART for adults are alternative in Belarus guidelines;
- Use of bPIs in the first line is recommended by national guidelines on ART for adults and adolescents as alternative regimens, while according to WHO guidelines bPIs should be used in the first line in special circumstances only;
- National guidelines recommend ABC for alternative first-line combinations for adults and adolescents, which is not recommended by the WHO;
- Even though 2010 WHO guidelines do not recommend the use of ddI, it is recommended by national guidelines for preferred and alternative combinations of second line regimens for adults and adolescents;
- In contrast with WHO guidelines, national guidelines on ART for children recommend using ABC in the first line and NFV in both first and second line regimens.

The 2013 WHO guidelines emphasize the importance of FDCs, both in terms of clinical benefits as well as in simpler logistics of distribution and improved patient adherence. As per the summarized Guidelines principles it is preferable to use age-appropriate FDCs for any regimens if such formulations are available. National guidelines do not contain such recommendations; the protocol on ART in adults mentions using FDCs as one of the methods of ensuring treatment adherence.

Belarus guidelines are in line with the WHO 2010 recommendations in terms of ART eligibility criteria. The national guidelines exceed WHO standards by including additional indications to start ART in people with active TB disease and HBVco-infection (if treatment HBV-infection is required), in all pregnant women regardless of clinical stage and CD4 count and in patients with HCV co-infection if their CD4 count is 500 cells/mm^3 or less.

In order to bring national guidelines on ART in line with WHO 2013 guidelines, Belarus will need to review the recommendation to use bPIs in alternative first-line regimens for adults, to reconsider the role of ABC for first line adults regimen, and to phase out ddI and NFV. It will also need to review ART eligibility criteria to include the following:

- ART should be started in all adults and adolescents with CD4 cell count ≤500 cells/mm^3;
- All children under five years of age should receive ART regardless of WHO clinical stage and CD4 cell count;
- ART should be started in all children above five years of age with CD4 cell count ≤500 cells/mm^3;
- Using lifelong ART for all pregnant and breastfeeding women: maintain ART after delivery and cessation of breastfeeding regardless of WHO clinical stage or CD4 cell count.

In **Kazakhstan** national ART guidelines for adults and children were adopted in 2011 and revised in 2012, that is after 2010 WHO guidelines were introduced. There are variations compared to the WHO 2010 guidelines:

- 3TC/AZT/LPV/r is a preferred first-line combination for children in WHO 2010 guidelines, but in national guidelines this combination is alternative;
- WHO recommends combinations containing ABC as alternative for first-line regimens for children; in the national guidelines these are among preferred options;
- Combinations with ABC and ddI are not recommended by WHO 2010 guidelines for second-line ART in adults; still, two ABC-containing and three ddI-containing combinations are among preferred combinations in national guidelines;
- Along with LPV/r, WHO also recommends combinations with ATV/r (preferred bPI) and DRV/r (alternative bPI) for second line treatment of adults; national guidelines prioritise LPV/r and as alternative bPIs mention ATV/r, FPV/r, IDV/r or SQV/r, but not DRV/r;

- Different PIs are recommended as part of second-line regimens for children in national guidelines (LPV/r, NFV and SQV/r) and WHO 2010 guidelines (ATV/r, DRV/r and LPV/r).

According to the 2013 WHO guidelines' summarized principles it is preferable to use age-appropriate FDCs for any regimens if such formulations are available. National protocols allow using FDCs, but do not contain a general recommendation, such as the one in the WHO guidelines.

ART initiation recommendations in national guidelines are almost the same as in WHO 2010 guidelines, except for WHO recommendation to start ART in infants under 18 months with a presumptive clinical diagnosis of HIV infection, which is not present in national guidelines.

WHO guidelines emphasize the importance of FDCs, both in terms of clinical benefits as well as in simpler logistics of distribution and improved patient adherence.

Also, in order to be in line with the 2013 WHO recommendations, national guidelines need to be revised in terms of ART initiation recommendations, so that all patients with CD4 count ≤500 copies/mm^3 are eligible for ART, and all pregnant and breastfeeding women receive lifelong ART. As to ART combinations, they should be changed, so that ddI and NFV are phased out, NVP-containing combinations are moved to alternative, and same PIs are recommended.

In **Russia**, the adoption of national ART treatment guidelines is still pending. Several ART guidelines were produced by leading national experts in the area and distributed among specialists. For the purpose of this research, a brief analysis of the recommendations listed in table 2 is provided.

Clinical Recommendations (CR) of the Moscow City AIDS Centre: A.I.Mazus et al. National clinical recommendations for diagnosis and treatment of HIV infection of adults (2013) and A.I.Mazus et al. National clinical recommendations for diagnosis and treatment of HIV infection of children and adolescents (2013).

The following discrepancies with current WHO guidelines were identified:

- WHO does not recommend ABC for first-line treatment in adults, but in the CR ABC-containing combinations are recommended as both preferred and alternative;
- WHO does not recommend using PIs and integrase inhibitors (IIs) in the first-line for adults; the CR recommend, both as preferred and alternative, combinations with ATV/r, DRV/r, FPV/r, LPV/r and RAL, and combinations with SQV/r as alternative;
- WHO guidelines do not contain recommendations regarding the use of rilpivirine (RPV), which is recommended by the CR as part of preferred and alternative first-line combinations for adults;
- The CR on ART in children include preferred combinations with FTC and TDF both in first- and second-lines, subject to formal approval (as of the date of writing this report, these ARVs were not allowed for use in treatment of children), while these ARVs are recommended by WHO 2013 guidelines as part of alternative combinations.

While the summarized principles of the WHO 2013 guidelines and the guidelines themselves indicate that it is preferable to use age-appropriate FDCs for any regimens if such formulations are available, the CRs (both for adults and children) do not have such a recommendation.

It should be noted that the CR on ART in adults do not contain specific ARV medicines or combinations for use in the second-line therapy. Instead, there is a list of principles which should guide the choice of second-line combinations, including a recommendation to change ARV medicines within the same class.

In terms of indications for starting ART in adults, the ones in the protocol are wider than those recommended by the WHO 2013 guidelines. In addition to standard ART indications, the protocol recommends initiation of ART in adults regardless of their CD4 count:

- in patients with HIV-associated nephropathy;
- in patients requiring long-term immunosuppressive treatment;
- in patients above 60 years of age;
- in patients with viral load >100 000 copies/ml; and
- in patients with chronic HCV co-infection.

As to ART initiation for children, the CR follow the recommendations of the WHO 2013 guidelines, except the recommendation to initiate ART in any child under 18 months who has been given a presumptive clinical diagnosis of HIV infection.

In order to bring its guidelines in line with WHO recommendations of 2013, both adult and children CRs will need to be reviewed in terms of the indications for ART and first- and second-line combinations, so that:

- ART is started in all children under 18 months of age who have been given a clinical diagnosis of HIV infection;
- use of boosted PIs, integrase inhibitors, ABC and rilpivirine is not recommended for first-line treatment in adults;
- specific regimens are recommended for second-line ART in adults;
- use of FDCs is explicitly recommended both for children and adults.

Protocols of the National Scientific Society of Infectologists: V. Pokrovskiy et al. Protocols for dispensary supervision and treatment of patients with HIV infection (2013)

The following discrepancies with WHO guidelines were identified:

- The protocols recommend the use of FAZT, a Russian ARV medicine, as a substitute of AZT; however, FAZT is not recommended by WHO;
- WHO does not recommend ABC for first-line treatment in adults, but in the protocols 3TC/ABC/EFV is among preferred combinations;
- WHO does not recommend using PIs in the first-line for adults; the protocols recommend combinations with ATV/r, DRV/r and LPV/r as alternative;
- For second-line ART in adults, the protocols contain preferred and alternative combinations with ABC and ddI, which is not recommended by WHO;
- In the protocols, neither preferred nor alternative second line regimens for adults contain combinations with 3TC and FTC, recommended by WHO as preferred for second-line regimens in adults;
- While both WHO and the protocols recommend ATV/r and LPV/r as bPI components of preferred second-line regimens for adults and DRV/r as alternative, the protocols go further and for alternative regimens recommend other bPIs (FPV/r, IDV/r, SQV/r) as well as RAL, an integrase inhibitor (II) which is not found in WHO 2010 and 2013 guidelines for first- or second-line treatment of adults;
- While WHO guidelines recommend combinations with bPIs for second-line ART in adults, the protocols also have combinations without bPIs.

The summarized principles of the WHO 2013 guidelines and the guidelines themselves indicate that it is preferable to use age-appropriate FDCs for any regimens if such formulations are available. It has to be noted that the protocols pays considerable attention to FDCs, they only highlight such benefits as the comfort for patients and improved treatment adherence; the protocols do not contain a general recommendation, such as in the WHO guidelines.

Indications for ART-initiation in adults are wider in the protocols than those recommended by the WHO 2013 guidelines. So, in addition to standard ART indications, the protocols recommends initiation of ART:

- regardless of CD4 count: in patients with haematological disorders caused by HIV;
- if CD4 count is 500 cells/mm^3 or less: in patients above 50 years of age; in patients with kidney disorders; in patients with viral load >100 000 copies/ml; in patients with chronic HCV co-infection.

To be in line with current WHO guidelines, the protocols of V. Pokrovskiy et al will need to be reviewed in terms of indications for ART and recommended first- and second-line combinations, so that:

- ART is started in all adults and adolescents if their CD4 cell count is ≤500 cells/mm^3;
- the recommendation to use FAZT is removed;

- ddI is phased out;
- preferred first line regimens contain TDF and 3TC or FTC, and alternative ones have combinations of 3TC/AZT with EFV and NVP;
- second-line regimens are two NRTIs + bPI;
- NVP is used in alternative first-line regimens for children;
- use of FDCs is recommended for any regimens if such formulations are available.

Clinical Protocols of the Scientific and Practical Centre for the Prevention and Treatment of the HIV Infection among Pregnant Women and Children at the Russian Ministry of Health: L. Afonina et al. Antiretroviral therapy for children with HIV. Clinical recommendations (2009)

The following discrepancies with WHO guidelines were identified:

- The protocols recommend the use of FAZT, a Russian ARV medicine, as a substitute of AZT; however, FAZT is not recommended by WHO;
- Alternative first-line combinations for children in the protocol include combinations with ddI and NFV, which are not recommended by WHO.

As to ART initiation for children, the protocol by L.Afonina et al is slightly different from WHO 2010 guidelines in that it recommends initiation of ART for all children with HIV between 12 and 35 months with CD4 count of ≤1000 cells/mm^3 or %CD4+ ≤25, whichever is lower, irrespective of WHO clinical stage and viral load (WHO 2010 recommendation is to start ART in all children with HIV between 12 and 24 months irrespective of CD4 count or WHO clinical stage), and in all children with HIV between 36 and 59 months with CD4 count of ≤500 cells/mm^3 or %CD4+ ≤20, whichever is lower, irrespective of WHO clinical stage and viral load (WHO 2010 recommendation is to start ART in all children with HIV between 24 and 59 months with CD4 count of ≤750 cells/mm^3 or %CD4+ ≤25, whichever is lower, irrespective of WHO clinical stage). Other indications for ART in children are the same in WHO 2010 guidelines and in the protocol (all children with HIV above five years with a CD4 count of ≤350 cells/mm^3, irrespective of WHO clinical stage; all children with HIV in WHO clinical stages 3 and 4, irrespective of CD4 count; and any child under 18 months who has been given a presumptive clinical diagnosis of HIV infection).

If compared with WHO 2013 guidelines, the protocol by L.Afonina et al is outdated, as WHO 2013 guidelines recommend initiating ART:

- in all children with HIV below five years regardless of WHO clinical stage or CD4 count;
- in all children with HIV five years and older with CD4 count ≤500 cells/mm^3;
- in all children infected with HIV with severe or advanced symptomatic disease (WHO clinical stage 3 or 4) regardless of age and CD4 cell count;
- in any child younger than 18 months who has been given a presumptive clinical diagnosis of HIV infection.

The summarized principles of the 2013 WHO guidelines and the guidelines themselves indicate that it is preferable to use age-appropriate FDCs for any regimens if such formulations are available. The protocol allows the use of FDCs, but it does not contain a general recommendation, like in the WHO guidelines.

To be in line with current WHO guidelines, the protocols of V. Pokrovskiy et al and L. Afonina et al will need to be reviewed in terms of indications for ART and recommended first- and second-line combinations, so that:

- all children under five years are eligible regardless of WHO clinical stage and CD4 cell count;
- ART is started in all children above five years if CD4 cell count is ≤500 cells/mm^3;
- the recommendation to use phosphazide is removed;
- ddI and NFV are phased out;
- NVP is used in alternative first-line regimens for children;
- use of age-appropriate FDCs is recommended for any regimens if such formulations are available.

Tajikistan's national guidelines on ART in adults and children are part of a Ministry of Healthcare ordinance on HIV diagnosis, treatment and care. The ordinance, adopted in 2008, was based on WHO 2006 guidelines and is inconsistent with the 2010 revision both in

terms of ART initiation indications and regimens. In particular:

- for first-line treatment of adults, Tajikistan guidelines recommend ABC-containing combinations instead of TDF-containing combinations now recommended by WHO;
- in addition to PIs recommended by WHO as part of second-line ART for adults – ATV/r, DRV/r and LPV/r – Tajikistan guidelines recommend as alternative such bPIs as FPV/r, IDV/r, NFV and SQV/r;
- WHO does not recommend ddI to be used as part of preferred second-line regimens for adults, but they are recommended in national guidelines;
- ABC-containing regimens, recommended as preferred for first-line treatment of children, are recommended as alternative by WHO;
- there are no combinations with PIs recommended for the first line treatment of children, while these are recommended by WHO both as preferred and alternative;
- national guidelines recommend only three preferred combinations for second-line regimens for children;
- WHO does not recommend NFV as part of second-line treatment for children.

Due to their clinical benefits, as well as logistical ease of distribution and improved patient adherence, FDCs are recommended by the 2013 WHO guidelines. As per the summarized principles age-appropriate FDCs should be used for any regimens if such formulations are available. The protocols do not contain such a recommendation.

In general Tajikistan would need a major guideline revision, both for children and adults, to adapt to the 2013 WHO guidelines. The process would require a review of recommendations regarding ART initiation and combinations used. In particular:

- CD4 threshold should be raised;
- ddI and NFV should be phased out;
- TDF and EFV containing regimens should be prioritised;
- combinations with NVP should be moved from preferred to alternative;
- use of age-appropriate FDCs is recommended for any regimens if such formulations are available.

In **Uzbekistan**, ART guidelines are also part of a larger Ministry of Health ordinance on HIV diagnosis, treatment and care. Adopted in 2012, the document is largely consistent with 2010 WHO recommendations. For instance, in terms of commencing ART the only difference between WHO and national guidelines is that WHO recommends ART for all children with HIV between 12 and 24 months irrespective of CD4 count or WHO clinical stage, and national guidelines recommend ART for all HIV-infected children between 12 and 23 months of age with CD4 count of ≤1000 cells/mm^3 or %CD4+ ≤25, whichever is lower. As to ART regimens, it should be noted that national guidelines recommend only one bPI (LPV/r), when WHO recommends two bPIs for second-line ART in adults (ATV/r and LPV/r) and three bPIs in second-line regimens for children (ATV/r, DRV/r and LPV/r).

The summarized principles of the 2013 WHO guidelines and the guidelines themselves indicate that it is preferable to use age-appropriate FDCs for any regimens if such formulations are available. The protocols highlight such benefits as the comfort for patients and improved treatment adherence, but do not contain a general recommendation, such as in the WHO guidelines.

In order to bring Uzbekistan's guidelines in line with 2013 WHO guidelines, one should review eligibility criteria and revise ART regimens so that ddI is phased out, more PIs are introduced and NVP-containing regimens are moved from preferred to alternative. As pointed out in the 2013 WHO Guidelines it is preferable to use age-appropriate FDCs for any regimens if such formulations are available.

In conclusion, national guidelines provide a critical tool for national authorities to ensure the provision of quality ARVs and their most effective and efficient use. Guideline decisions have a major impact on market access and provide particularly pooled purchasers with considerable market power. Whether guidelines result de facto in optimized quality and availability of affordable ARVs, depends on several factors including patent status, licencing, registration and procurement frameworks which will be discussed in subsequent chapters.

4. GLOBAL AND REGIONAL PATENT REGIMES

In EECA, countries are signatories to several international and regional instruments, which regulate – sometimes differently – IP issues, including those related to access to ARVs and other essential medicines. Countries may be influenced by other documents to which they are not parties, such as WTO TRIPS Agreement: while it is only applicable to WTO member states, its provisions may have considerable effects on those countries that are willing to join the WTO, or are signatories of the EurAsEC Agreement on Joint Principles of Regulation in the Sphere of Intellectual Property Rights[32] (Belarus and Kazakhstan). The following sections provide an overview of key global and regional instruments that influence – directly or indirectly – regulatory frameworks of the select countries.

Table 4: Status of Paris Convention for the Protection of Industrial Property in the study countries

Country	Instrument	In force since
Belarus	Declaration of Continued Application: 1993	December 25, 1991
Kazakhstan	Declaration of Continued Application: 1993	December 25, 1991
Russia	Accession: 1965	July 1, 1965
Tajikistan	Declaration of Continued Application: 1994	December 25, 1991
Uzbekistan	Declaration of Continued Application: 1993	December 25, 1991

Source: WIPO website

4.1 Paris Convention for the Protection of Industrial Property

The Paris Convention for the Protection of Industrial Property is one of the first IP treaties.[33] Details of study countries' accession to the Paris Convention are given in table 4 below.

The convention applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models (a kind of "small patent" provided for by the laws of some countries, including several countries in the EECA region), trade names (designations under which an industrial or commercial activity is carried on), geographical indications (indications of source and appellations of origin) and the repression of unfair competition.

The substantive provisions of the convention fall into three main categories: national treatment, right of priority, and common rules.

Under the provisions on **national treatment** the convention provides that regarding protection of IP, each contracting state must grant the same protection to nationals of the other contracting states as it grants to its own nationals. Nationals of non-contracting states are also entitled to national treatment under the convention if they are domiciled or have a real and effective industrial or commercial establishment in a contracting state.

The convention provides for the **right of priority** in patents, meaning that, on the basis of a regular first application filed in one of the contracting states, the applicant may, within 12 months, apply for patent protection in any of the other contracting states; these

32 See section 4.5 below.

33 Signed in Paris, France, on 20 March 1883 and revised in Brussels in 1900, in Washington in 1911, in The Hague in 1925, in London in 1934, in Lisbon in 1958 and in Stockholm in 1967, and amended in 1979. The Convention established a Union for the protection of industrial property. The Convention is open to all states. Presently, there are 175 Contracting Parties to the Convention, including all countries covered by this research.

later applications will then be regarded as if they had been filed on the same day as the first application. In other words, these later applications will have priority (i.e., "right of priority") over applications which may have been filed during the said period of time by other persons for the same invention. One practical advantage of this provision is that, when applicants desire protection in several countries, they are not required to present all their applications at the same time, but have one year to decide in which countries they require protection and to organize the necessary steps to secure protection.

The convention lays down a few **common rules** which all the contracting states must follow. These cover patents, trademarks, industrial designs, trade names, indications of source, and unfair competition.

Patents granted in different contracting states for the same invention are independent of each other: the granting of a patent in one contracting state does not oblige the other contracting states to grant a patent; a patent cannot be refused, annulled or terminated in any contracting state on the ground that it has been refused or annulled or has terminated in any other contracting state.

Even when domestic law contains restrictions or limitations on sale of patented products or products obtained by means of a patented process, the grant of a patent may not be refused and a patent may not be invalidated.

When a contracting state allows compulsory licensing to prevent abuse or negative effects on national interests resulting from the exclusive rights conferred by a patent, it may do so only with certain limitations. Forfeiture of a patent may not be provided for, except in cases where a compulsory license would not be sufficient to prevent the abuse. In this case, patent forfeiture procedure may be initiated after the expiration of two years from the grant of the first compulsory license.

4.2 Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) was concluded in 1970, amended in 1979, and modified in 1984 and 2001. It is open to states party to the Paris Convention for the Protection of Industrial Property (see previous section). As of December 2013, there were 148 contracting states to the PCT. All countries covered by the present study are parties to the PCT (see table 5 below).

Table 5: Status of the PCT in the select countries

Country	Date on which country became bound by the PCT
Belarus	25 December 1991
Kazakhstan	25 December 1991
Russia	29 March 1978*
Tajikistan	25 December 1991
Uzbekistan	25 December 1991

* Date of ratification of the Soviet Union, continued by Russia as from 25 December 1991.
Source: WIPO website

The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a contracting state. It may generally be filed with the national patent office of the contracting state of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva. If the applicant is a national or resident of a contracting state which is party to a regional patent agreement (for instance the EAPC) the international application may also be filed with a respective regional patent office, (e.g., the EAPO). This opportunity has been widely used: all Eurasian ARV patents were filed through PCT procedure. (For more information on the EAPC and EAPO, see section 4.4 below).

The international application is then subjected to an "international search". That search is carried out by the ISA and summarized in an "international search report", containing a listing of the citations of such published documents that might affect the patentability of the invention claimed in the international application. At the same time, the ISA prepares a written opinion on patentability. The international search report and the written opinion

are communicated by the ISA to the applicant who may decide to withdraw his application, in particular where the said report or opinion makes the granting of patents unlikely. If the international application is not withdrawn, it is published together with the international search report by the International Bureau. The written opinion is not published.

The WTO TRIPS Agreement states that the protection and enforcement of IP rights should contribute to the promotion of technological innovation in a manner conducive to social and economic welfare.

The procedure under the PCT has significant advantages for the applicant, the patent offices and the general public:

- The applicant has up to 18 months more than in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees;
- The search and examination work of patent offices can be considerably reduced or virtually eliminated thanks to the international search report, the written opinion and, where applicable, the international preliminary examination report that accompany the international application;
- Since each international application is published together with an international search report, third parties are in a better position to formulate informed opinion about the patentability of the claimed invention.

The PCT created a Union, which has an Assembly. Every state party to the PCT is a member of the Assembly. Among the most important tasks of the Assembly are the amendment of the Regulations issued under the PCT, the adoption of the biennial programme and budget of the Union and the fixing of certain fees connected with the use of the PCT system.

Importantly, the PCT explicitly envisages that "Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each contracting state to prescribe such substantive conditions of patentability as it desires", and that "Nothing in this Treaty and the Regulations is intended to be construed as limiting the freedom of any Contracting State to apply measures deemed necessary for the preservation of its national security" (Article 27).

4.3 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The international TRIPS Agreement is part of the Law of the WTO and is administered by the TRIPS Council, which sets down minimum standards for many forms of IP regulation as applied to nationals of other WTO members. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade in 1994 and came into force in 1995.

The TRIPS Agreement requires patentability of inventions, whether products or processes, in all fields of technology providing they are new, involve an inventive step and are capable of industrial application. The Agreement also introduces the concept of undisclosed test data protection against unfair commercial use, which refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new medicine. This requirement has often been substituted with the provision of "test data exclusivity", which could prevent regulatory authorities from accepting generic application that only rely on the existence of submitted originator data (without using them). In effect, data exclusivity provisions could prevent access of generic equivalents to the market for the duration of the exclusivity and beyond.

Although IP rights are considered by some to be an important incentive for the development of new healthcare products, their protection and enforcement

should take into account the rights of access to affordable health services as well as national and international public health priorities. Article 7 of the TRIPS agreement states that the protection and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare. Even though the TRIPS agreement marked a new era of obligations regarding the protection and enforcement of IP, WTO Members retained important policy options, flexibilities and safeguards, including the liberty to:

- determine the grounds for issuing compulsory licences and for when to order government use. In context of ARVs, this flexibility has been used, for instance, in Brazil, Ecuador India, Indonesia, Malaysia, Thailand and a number of African countries but never in EECA;[34]
- allow for various forms of parallel imports depending on their exhaustion of rights regimes. Given comparatively high prices for ARV medicines in EECA region, parallel import from, for example, Sub-Saharan Africa, where ARVs are available at a lower cost, could make treatment less expensive and, consequently, lead to improved access and coverage;
- apply general exceptions, such as early working for regulatory approval of generic pharmaceutical products or experimental use exceptions. As seen in section 5.2 below, general exceptions (e.g., Bolar exception and experimental use exception) exist in legislations of the study countries;
- make use of transition periods for developing countries and a longer, extendible transition period for least developed countries in particular. This would have given the opportunity for WTO members from EECA region to plan measures for protection of patents and undisclosed information, and, until the transition period expires, to maintain existing IP systems, which may lack certain IP protections required by TRIPS and therefore facilitate access to cheaper generic medicines to their markets. Unfortunately, none of the EECA countries so far has chosen to benefit from these transition periods. The option still remains for negotiating countries such as Belarus, Kazakhstan and Uzbekistan, as well as for potential future WTO candidates. This could happen, for instance, if Turkmenistan decides to join the organization.

In addition, certain key terms relating to TRIPS obligations are not defined in the agreement itself, including such essential patent law concepts as "invention", "new/novel" and "involve an inventive step/non-obvious", which leaves considerable discretion to WTO members as to how to apply the three criteria of patentability – novelty, inventive step and industrial applicability – within their national laws. The knowledge and use of these policy options and other flexibilities provide opportunities to safeguard the international and national public health objectives.

Although these flexibilities could be used by countries to facilitate access to affordable medicines, a political consensus about the right to use these flexibilities to protect public health was not articulated until the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which was adopted at a WTO ministerial meeting. The Doha Declaration is an official, "soft law" document. In addition to other provisions clarifying the nature of TRIPS flexibilities, it extended the transition period for least developed countries to implement protection of patents and undisclosed information and their enforcement for pharmaceutical products until January 2016. These transition periods are subject to further extension upon duly motivated request, Article 66.1 TRIPS Agreement.

Although the importance of the Doha Declaration is significant, it has left one issue unresolved: the application of Article 31(f) of the TRIPS Agreement, which requires that countries issuing compulsory licences for the local manufacture of antiretroviral medicines do so only if the medicines are to be used predominantly in their domestic markets. This restriction potentially constrained the production of ARVs under compulsory licences specifically for export. In turn, it meant that countries with insufficient manufacturing capacity could not effectively use compulsory licensing as a source of affordable medicines. This obstacle was addressed by the 30

34 Beall R, Kuhn R (2012) Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. PLoS Med 9(1): e1001154. doi:10.1371/journal.pmed.1001154.

August 2003 WTO General Council decision, which authorises WTO members to grant compulsory licences for the production and export of generic medicines to developing and least developed countries with insufficient or no manufacturing capacity in the pharmaceutical sector. This so-caled "Paragraph 6 solution" was formalized as an amendment to the TRIPS Agreement in 2005. However, whether this decision solves the problem, given the scope and procedural requirements, is currently the subject of debate in the WTO TRIPS Council.[35]

Of the countries covered by the study, Russia and Tajikistan are members of the WTO; Belarus, Kazakhstan, and Uzbekistan are at different stages of negotiating accession. However, as WTO members, Russia and Tajikistan will need to bring their legislations in line with the organisation's requirements, which is already in progress. Through the Customs Union and its harmonising effect on legislations of member states, this process is likely to affect Belarus and Kazakhstan (more about the Customs Union in section 4.5 below).

4.4 Eurasian Patent Convention

The main purpose of the EAPC is to create a regional system of legal protection for inventions on the basis of a common Eurasian patent covering the territory of all the EAPC contracting states.

At the moment, there are eight states parties to the EAPC: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan and Turkmenistan (see table 6 below). The Republic of Moldova has denounced the EAPC, but will still recognize Eurasian patents, which were issued either before its denunciation, or after in case that patent application was submitted before the date of denunciation, until they expire or become otherwise invalid.[36]

The EAPC constitutes a special agreement within the meaning of Art. 19 of the Paris Convention and therefore all provisions of the Paris Convention are applied to a procedure of obtaining a Eurasian patents. The EAPC is also a regional patent treaty within the meaning of Art. 45 of the PCT, and therefore

Table 6: States parties to the EAPC

Country	Signature	Ratification/Accession	Denunciation
Armenia	9 September 1994	27 November 1995	
Azerbaijan	9 September 1994	25 September 1995	
Belarus	9 September 1994	8 May 1995	
Georgia	*9 September 1994*	*Never ratified*	
Kazakhstan	9 September 1994	4 August 1995	
Kyrgyzstan	9 September 1994	13 October 1995	
Moldova	*9 September 1994*	*16 November 1995*	*26 April 2012*
Russia	9 September 1994	27 June 1995	
Tajikistan	9 September 1994	12 May 1995	
Turkmenistan		1 March 1995	
Ukraine	*9 September 1994*	*Never ratified*	

35 UNDAIS, WHO and UNDP. *Policy Brief: Using TRIPS Flexibilities to Improve Access to HIV Treatment* (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf).

36 http://www.eapo.org/ru/members.html.

Eurasian patents may be obtained on the basis of an international application filed in accordance with PCT. This opportunity is being widely used: for instance, all Eurasian ARV patent applications were filed under the PCT.

The EAPC established the EAPO, based in Moscow. The EAPO accepts applications and issues Eurasian patents, which are automatically recognized on the territory of the EAPC member states, without any process of national recognition. At the same time, member states maintain their national patent systems which issue national patents; thus, within EAPC member states Eurasian and national patent systems co-exist and provide equal protection. Member states have the right to invalidate Eurasian patents on their territory, but if a patent is invalidated in one member state, it continues to apply in other member states. One application, filed in Russian, is sufficient to cover all eight countries. The EAPO is quickly becoming a more popular way of patenting: having a little more than 100 applications filed in 1996,[37] it received about 4,000 patent applications in 2012.[38] Notably, most applicants are filed from outside the EAPC region.[39]

A major comparative benefit from obtaining Eurasian patents is that instead of filing several national applications and going through – and paying for – patent examination in every country of designation, applicants need to submit only one Eurasian application and have one examination, which saves considerable amounts of time and money.

Even though many of the EAPC's provisions are aimed at introducing uniform rules that apply to all member states, it recognizes superiority of the PCT and its Regulations (Art. 20), and that member states retain "complete sovereignty to develop their national systems for protection of inventions" (Article 1(1)). Moreover, in certain respects EAPC and its Regulations fail to create any rules but rather refer to national laws of member states. For example, the EAPC establishes a twenty-year term of validity for Eurasian patents. However, regarding patent extensions, rule 16(5) of EAPC Patent Regulations stipulates that "the period of validity of a Eurasian patent […] may be extended for a Contracting State whose legislation provides for the extension of the period of validity of a national patent". It should be noted, however, that neither the EAPC itself nor the Patent Regulations require member states to allow patent extensions, and it is up to the member states to decide whether or not to provide for patent extension in their laws. Nevertheless, as will be shown in section 5.2 below, except for Tajikistan, all study countries allow patent extensions for up to five years.

The Eurasian Patent Convention was negotiated at about the same time the TRIPS Agreement was, but the two processes were not connected. The Convention provides fewer public health flexibilities and generally more complex procedures for their application.

EAPO does not set its own patent maintenance fees, but charges fees that are applicable to maintenance of national patents in member states. For this purpose, when paying the fee, patent owners must indicate for which countries they wish to designate their patent, and their fee is calculated based on these designations. Table 7 below shows patent maintenance fees for Belarus, Kazakhstan, Russian Federation and Tajikistan.[40]

According to the EAPC, not less than one-fifth of fees paid for maintenance of Eurasian patents shall belong to the EAPO, with the remaining part being transferred to respective national patent offices. These proceeds make up a considerable share of the EAPO budget; notably, member states are not obliged to pay contributions or membership fees. With such a system,

37 http://www.eapo.org/ru/documents/norm/comment_txt.html, and specifically Figure 7.

38 http://www.eapo.org/en/stat.html.

39 http://www.eapo.org/en/stat.html.

40 To see the fees for all member states of EAPO, visit http://www.eapo.org/ru/documents/norm/tabposh.html.

Table 7: EAPO patent maintenance fees, USD (as of December 2013)

Year	Belarus[41]	Kazakhstan	Russia	Tajikistan
1	0	0	0	0
2	0	0	0	0
3	20/100	100	32	66
4	30/150	150	32	66
5	30/150	150	47	88
6	30/150	200	47	88
7	40/200	200	62	108
8	40/200	300	62	108
9	60/300	300	92	159
10	60/300	300	92	159
11	60/300	400	137	255
12	80/400	400	137	255
13	80/400	600	184	319
14	80/400	600	184	319
15	120/600	600	229	446
16	120/600	700	229	446
17	120/600	700	229	446
18	160/800	700	229	446
19	160/800	800	305	510
20	160/800	800	305	510
Fees for maintenance of patents, extended under rule 16(5) of Patent Regulations				
21	200/1000	n/a	451	n/a
22	200/1000	n/a	451	n/a
23	240/1000	n/a	451	n/a
24	240/1200	n/a	451	n/a
25	240/1200	n/a	451	n/a

Source: EAPO website (http://www.eapo.org/ru/documents/norm/tabposh.html -- in Russian; as of December 2013, English page did not contain any numbers).
Note: fees are originally in USD for Belarus, Kazakhstan and Tajikistan; fees for Russia (RUB) are calculated according to exchange rate as of December 4, 2013 (exchange rate as per http://www.xe.com).

the EAPO is inherently interested in granting as many patents as possible in order to generate income.

41 The price before slash is for patent holders from Belarus or Russian Federation, provided they are all from one of the countries.

EAPC entered into force in 1995, the same year the TRIPS agreement was adopted. However, EAPC was drafted and negotiated before the TRIPS agreement and did not contain the TRIPS public health flexibilities. Many of the provisions in this convention have higher, stricter levels of IP protection, that now are referred to

as TRIPS-plus. For instance, EAPC allows the patenting of product and processes, the patenting of new uses of known products, and patent term extensions. It creates a cumbersome and inflexible compulsory licensing regime which requires the intervention of a court and, by referring to the Paris Convention for the Protection of Industrial Property, it maintains the requirement that a compulsory license can be issued only after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, only when the patent was not worked, or worked insufficiently without legitimate reasons. Several other provisions of the EAPC also exceed the minimum requirements of the TRIPS agreement. What it means in context of access to treatment is that these TRIPS 'plus' provisions, when enforced in national laws, delay entry of generic ARV medicines into domestic markets, which discourages originator ARV producers from making treatment more affordable. In spite of different IP regimes envisaged by EAPC and TRIPS, both documents have a binding effect for countries that ratify them, and there is only one country that denounced EAPC – Moldova – in light of its accession to WTO.

4.5 EurAsEC, Customs Union and Eurasian Economic Union

In 1996 Belarus, Kazakhstan, Kyrgyzstan and Russia signed the Treaty on Increased Integration in the Economic and Humanitarian Fields. The Treaty set up basic goals in integration including creation of common markets for goods, services, capitals, labour and developing single transport, energy and information systems. These agreements developed further in 1999 when Belarus, Kazakhstan, Kyrgyzstan, Russia and Tajikistan signed the Treaty on the Customs Union and the Single Economic Space (SES). By signing this Treaty all parties agreed to complete the formation of the Custom Unions and the SES. The treaty on establishment of Eurasian Economic Community (EurAsEC) was signed on 10 October 2000 in Astana and entered into force on 30 May 2001 after being ratified by states parties. On 1 January 2010, the Customs Union of Belarus, Kazakhstan, and Russia came into existence. The Customs Union was launched as a first step towards forming a broader European Union-type economic alliance of former Soviet states.

On 19 November 2011 the member states put together a joint commission on fostering closer economic ties. Since 1 January 2012, the three states form a SES. The Eurasian Economic Commission (EEC) is the regulatory agency for the Customs Union and the EurAsEC. The main purpose of the EEC is to provide conditions for the functioning and development of Customs Union and EurAsEC, and to develop recommendations on further promotion of integration. Decisions of the Commission are binding within the territory of Customs Union and EurAsEC.

In December 2012, it was agreed to reorganise EurAsEC and pass some of its functions to the EEC. EurAsEC kept functions related to humanitarian field, transport and energy and implementation of 15 inter-state programmes. On 29 May 2014 presidents of Belarus, Kazakhstan and Russian Federation signed an agreement on establishment of Eurasian Economic Union (EAEU) on the basis of Customs Union; the agreement will enter into force on 1 January 2015.

A number of documents of the Customs Union and EurAsEC that deal with IP issues should be mentioned:[42]

- *Agreement on Unified Principles of Regulation in Protection of Intellectual Property Rights*,[43] signed on 9 December 2010, entered into force on 1 January 2012. Articles 16-18 of the agreement deal with patent rights; in defining the scope of such rights, the agreement refers to national legislations of member states of the Customs Union. Article 16 states that the minimum period of patent protection shall be 20 years from the date of filing patent application, provided that requirements of national legislations were observed; this is the same as patent validity under the EAPC. Article 24 of the agreement provides for the establishment of the Coordination Council of the Single Economic Space on IP, a permanent mechanism for coordination and information-technical cooperation between

42 Documents that regulate circulation of medicines, including registration issues, are studied in section 6.2.

43 Соглашение о единых принципах регулирования в сфере охраны и защиты прав интеллектуальной собственности (http://www.eurasiancommission.org/ru/Lists/EECDocs/635049885467735867.pdf).

agencies of member states on matters related to protection of IP.

- *Agreement on Unified Customs Registry of Objects of Intellectual Property of Member States of the Customs Union*,[44] signed on 21 May 2010, and *Rules of Procedure for Interaction of Customs Authorities of Member States of the Customs Union Regarding Maintenance of the Unified Register of Objects of Intellectual Property*,[45] approved by decision of the Commission of the Customs Union No. 290 of 18 June 2010. It should be noted, however, that according to the agreement's Article 1, objects of IP include "objects of copyright and neighbouring rights, trademarks and service marks" and does not mention inventions and patents. Therefore, it is not clear whether the unified registry applies to medicines.

- *Customs Code of the Customs Union*,[46] entered into force on 6 July 2010. Chapter 46 of the Customs Code – "Specifics of Customs Procedures in Respect of Goods Containing Objects of Intellectual Property" – contains six articles, which provide for measures for the protection of IP rights, taken by the customs authorities; time limits for such measures; customs registries of IP objects, etc. According to the code, when customs suspects that entry of goods included in the customs registry of IP objects into the territory of the Customs Union may violate IP rights, customs may suspend transition of those goods through customs boarder for up to ten days in order to clarify whether IP rights are being violated. If this is the case, the goods may be seized or confiscated.

- *Draft Agreement on Coordination of Actions Regarding Protection of Rights for Objects of Intellectual Property*[47] was approved by decision of the Eurasian Economic Commission No. 243 of 29 October 2013. The agreement was developed in line with the Agreement on Unified Principles of Regulation in Protection of Intellectual Property Rights (the first bullet in this list). It envisages strengthening of coordination in prevention, detection, halting and investigation of violations of IP rights and building the capacity of responsible agencies. The document foresees harmonisation and development of member states' legislations in the field of IP within the territory of the Customs Union. According to the document, responsible agencies of member states will exchange the following information about:
  - facts of violations of IP rights;
  - persons who were connected to violations of IP rights;
  - movement of goods between member states, which constitutes violation of IP rights, in particular about vehicles used for transportation of such goods;
  - goods being imported into the territory of Customs Union, if this constitutes violation of IP rights.

  It has to be noted that, while the Draft Agreement does not concern patents it is the first document on joint IP enforcement in the Customs Union countries that still have different IP regimes. For a broader discussion of the issue, please refer to 'Conclusions and Recommendations'.

The Customs Union of Belarus, Russia and Kazakhstan (and in the future also EAEU) is likely to play an important role in the trade in medicines not only in the member states, but also to influence the markets in neighbouring countries. There are already discussions under way about certain countries in Eastern Europe and Central Asia joining the Customs Union and EAEU, which would mean that the same rules and regulations will apply to them. The main challenge appears to be the different levels of development of the pharmaceutical markets in the countries of the Customs Union and the doctrines that govern the access to medicines strategies in these countries – for

44 Соглашение о едином таможенном реестре объектов интеллектуальной собственности государств - членов Таможенного союза.

45 Регламент взаимодействия таможенных органов государств-членов Таможенного союза по вопросам ведения единого таможенного реестра объектов интеллектуальной собственности (http://www.eurasiancommission.org/ru/docs/_layouts/Lanit.EEC.Desicions/Download.aspx?IsDlg=0&ID=833).

46 Таможенный кодекс Таможенного союза (in Russian - http://www.tsouz.ru/Docs/Kodeks3; unofficial English translation - http://www.tsouz.ru/Docs/kodeks/Documents/TRANSLATION%20CUC.pdf).

47 Проект Договора о координации действий по защите прав на объекты интеллектуальной собственности (http://www.eurasiancommission.org/ru/act/finpol/dobd/intelsobs/Documents/dog_20_05_2013.pdf).

all essential medicines, not only for ARVs. While Belarus and Kazakhstan rely on supply with generic equivalents, which are traditionally cheaper than the originator versions of medicines, the Russian Federation puts an emphasis on "import-substitution" in its strategy "Pharma 2020", aspiring to produce virtually all essential medicines domestically in the foreseeable future.[48] In addition, the Russian Federation aspires to manufacture innovative pharmaceuticals. The strategic aspiration to produce innovative medicines explains why the country might build a regime of stronger IP protection and enforcement, despite a lack of solid evidence that stronger IP protection has stimulated innovation in the pharmaceutical sector. However, stronger IP protection would prevent the opportunity for production of active ingredients for essential medicines domestically, unless:

- Russian domestic manufacturers obtain voluntary licenses from patent-holders, which are traditionally associated with substantial royalty payments, and in which case the domestically produced medicines may be more expensive than imported equivalents, or;

- So far the Russian Federation has not used the TRIPS Agreement public health flexibilities to give priority to public health needs over IP protection for the need of supplying affordable essential medicines of good quality through domestic production. From the countries included in this study Russia is the only one that is equipped with the manufacturing capacity to do so. Its domestic market is big enough to secure economies of scale that would justify such production. In addition, Russian domestic pharmaceutical production could also benefit from the market of the Customs Union/ EAEU countries. In order to do this, however, Russia will have to integrate the TRIPS Agreement public health flexibilities in a better way in its domestic legislation. Currently, these flexibilities have not been sufficiently well-integrated in Part IV of the Russian Civil Code that tackles IP. Other laws such as the Law on the Turnover of Medicines (N61-FZ from 2010, as subsequently amended) contain provisions that could block the use of the flexibilities, unless mitigating legal provisions are introduced. At the same time, the Russian Federation has retained, notably in its competition law, mechanisms that greatly facilitate the use of the TRIPS flexibilities and could be used to increase access to essential medicines and foster domestic production.

48 Стратегия развития фармацевтической промышленности Российской Федерации на период до 2020 года (www.pharma2020.ru).

While the legal and policy framework of the Customs Union and Eurasian Economic Space are being shaped, it is important to establish norms that foster access to essential medicines, for the whole Union and future member states.

The impact of the Customs Union, the SES and potentially EAEU on the trade in medicines has been a subject of great interest for economists and businesses. The Eurasian Development Bank recently released a study on the pharmaceutical market in the SES and concluded that the Customs Union countries' pharmaceutical market is dominated by imported products, notably from Germany and France but also India. National companies are pushed from the market by foreign producers. There is low competitiveness of domestic products which, together with the dependence on imports, hinders the further growth of the sector. Foreign companies set up joint ventures with national producers in order to benefit from the preferences that these producers enjoy.

The trade in pharmaceuticals between SES countries is insignificant compared to the trade beyond the SES. At the same time the pharmaceutical industries of the SES countries have been advancing, due to increased domestic demands. Local producers focus on generic equivalents and OTC medicines and rely on state support. Producers do not rely on export beyond the region. There is almost no investment in research and

development because of lack of funding, including long-term funding.

While previously in SES countries there was greater demand for less expensive medicines, the market is changing and the demand for more expensive (branded) products is increasing. Still, the market is different from the western markets in that it has low consumption per capita and a greater share of cheaper medicines. The study also points out that the harmonisation of the laws in the framework of the Customs Union and the SES will encourage the free movement of goods made in Russia, Belarus and Kazakhstan, and could lead to the reduction in the prices of medicines and, in the longer run could contribute to an improvement in quality.[49]

49 A. Tashenov, N. Cherednichenko (2013) Development Prospects for the Pharmaceutical Market of the Single Economic Space. Eurasian Development Bank, Sector Report no. 18.

Evidently, the Customs Union, SES and EAEU pose serious challenges but also contain important opportunities for local manufacturers, as well as for importers of medicines, both originator and generic. During the time when the legal and policy framework of the Union and Space are being shaped and their correspondence to commitments within the WTO framework is being established it is of critical importance for the Belarus, Russia and Kazakhstan to establish norms that foster access to essential medicines (including but not limited to ARVs) in their respective countries in such as way so that this access spreads over the whole SES and allows inclusion of future member states. In is also equally important that these provisions foster competition, including from domestic manufacturers and do not allow exclusivities that serve to protect private propriety interests at the expense of national industries and public health. A detailed analysis of these elaborations is provided in the recommendations section of this report.

5. ANALYSIS OF IP REGULATORY FRAMEWORKS

5.1 Brief overview of the countries' legal systems

The legal systems of the countries covered in this study have many similarities, partly due to the common past during the Soviet Union and the process of transition to market economy. To some extent, this uniformity is promoted by Inter-Parliamentary Assemblies of the CIS and EurAsEC: both structures develop model laws, which are then used by member states. In terms of IP, for example, the CIS Inter-Parliamentary Assembly has adopted model laws on IP and on copyright as well as a section on IP of the model civil code. At the same time different economic, political and social priorities lead to differences in the way countries develop their laws. Thus, one can see both trends – harmonization and diversification – in legal systems of the CIS countries.

Due to the common past legal systems of countries of the former Soviet Union have many similarities. At the same time different economic, political and social priorities have led to diversification. New economic alliances are developing and laws are being adapted. Countries should be mindful that trade legislation reforms may affect access to medicines and public health priorities must always be observed.

All countries covered in this report except Russia have laws on normative legal acts, which specify hierarchies of legal documents (in Russia the draft law was prepared in mid-1990s, but has not yet been adopted). As a rule, legal acts of higher level (i.e. constitution, codes and laws, as well as presidential decrees in Belarus and Kazakhstan) provide general, policy-level regulation of certain domains; decisions of the executive branch, including those of president, government, ministries and local governments, are usually adopted to support the implementation of laws and regulate public relations on a more practical level. As a federation, Russia has legal normative acts at federal level and for "subjects of the Federation" (local territories), which have their own legislature and government. The key requirement is that local legislations do not contradict national – or Federal – legislation, and that documents of a lower level (e.g. Ministry of Health ordinances) do not contradict those of a higher level (e.g. laws).

The main agencies in the field of public health are the ministries of healthcare,[50] which are subordinate to government (in Russia, the Ministry of Healthcare of the Russian Federation is subordinate to the Government, and healthcare ministries of subjects of the Federation – accordingly to governments of subjects of the Federation). Together with their agencies, they have a wide range of functions including implementation of national policies, coordination of activities related to healthcare, establishment of service standards and treatment guidelines, registration of medicines, certification and licensing of service providers and of manufacturers of medicines and other medical products, and quality control.

50 In Tajikistan – the Ministry of Healthcare and Social Protection of Population.

Table 8: Patent laws of the study countries

Country	Patent law
Belarus	Law of the Republic of Belarus "On Patents for Inventions, Useful Models, and Industrial Designs" No. 160-Z of 16 December 2002[51]
Kazakhstan	Patent Law of the Republic of Kazakhstan, No. 427-I of 16 July 1999[52]
Russia	Chapter 72 (Patent Law), Civil Code of Russian Federation No. 230-FZ of 18 December 2006[53]
Tajikistan	Law of the Republic of Tajikistan "On Inventions" No. 17 of 28 February 2004[54]
Uzbekistan	Law of the Republic of Uzbekistan "On Inventions, Useful Models and Industrial Designs) of 6 May 1994; new version adopted by the Law of the Republic of Uzbekistan No. 397-II of 29 August 2002[55]

5.2 IP protection and flexibilities

After gaining independence former Soviet republics started redefining their policies in respect of trade and intellectual property. They adopted new legislation on IP which was based on international treaties such as the Paris Convention and the PCT and was, to some extent, influenced by regional instruments and model laws.

Accession to international and regional organizations, such as the WTO, WIPO, EAPO and EurAsEC also had a considerable effect on IP legislation of the countries. Table 9 below shows the status of accession to various international and regional organizations, which on the one hand impose certain legal obligations, and on the other offer certain opportunities for trade development.

Table 9: The status of accession to WTO, WIPO, EAPO and EurAsEC

Country	WTO[56]	WIPO[57]	EAPO[58]	EurAsEC[59]
Belarus	Negotiating accession (observer government)	Member (joined in 1970)	Member (since 12 August 1995)	Member
Kazakhstan	Negotiating accession (observer government)	Member (joined in 1991)	Member (since 5 November 1995)	Member
Russia	Member since 22 August 2012	Member (joined in 1970)	Member (since 27 September 1995)	Member
Tajikistan	Member since 2 March 2013	Member (joined in 1991)	Member (since 12 August 1995)	Non-member
Uzbekistan	Negotiating accession (observer government)	Member (joined in 1991)	Non-member	Non-member

As discussed in section 4.3, the WTO TRIPS agreement and the 2001 Doha Declaration offer a series of flexibilities, which can be used to provide access to more affordable essential medicines. However, countries of the region have not used these public health flexibilities as of yet. Many of their national laws either do not include these provisions, or contain TRIPS-plus standards, which hinder, or completely block the opportunity to use the flexibilities.[60] This is

51 Закон Республики Беларусь «О патентах на изобретения, полезные модели, промышленные образцы» от 16 декабря 2002 г. № 160-З (http://www.pravo.by/main.aspx?guid=3871&p0=h10200160&p2={NRPA}).

52 Патентный закон Республики Казахстан от 16 июля 1999 года № 427-I (http://adilet.zan.kz/rus/docs/Z990000427_).

53 Глава 72 («Патентное право»), Гражданский кодекс РФ от 18.12.2006 N 230-ФЗ (http://www.consultant.ru/popular/gkrf4/79_10.html).

54 Закон Республики Таджикистан «Об изобретениях» от 28 февраля 2004 года № 17 (http://www.ncpi.tj/ncpi_doc/qonun/zakon_izobretenie.pdf).

55 Закон Республики Узбекистан «Об изобретениях, полезных моделях и промышленных образцах» от 6 мая 1994 года (новая редакция, утвержденная Закон Республики Узбекистан от 29 августа 2002 г. № 397-II) (http://www.lex.uz/Pages/GetAct.aspx?lact_id=77168).

56 http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

57 http://www.wipo.int/members/en/.

58 http://www.eapo.org/en/.

59 http://www.eurasiancommission.org/ru/Pages/about.aspx.

60 For more information see: UNDP. *Good Practice Guide: Improving Access to Treatment by Utilizing Flexibilities in WTO TRIPS Agreement*, 2010 (http://content.undp.org/go/newsroom/publications/hiv-aids/good-practice-guide-in-utilizing-flexibilities-in-the-wto-trips-agreement.en).

caused by the outdated IP legislation of some of the study countries, as well as by the outdated texts of the EAPC and the Patent Regulation (Instruction). However, some countries such as the Russian Federation have completely reformed their patent legislation and have still chosen not to include, or to limit the level of integration of, the TRIPS Agreement public health flexibilities. Some flexibilities have been introduced but in laws not directly regulating IP. One such example in Russia is the compulsory license as a remedy against anti-competitive practices. Russia is one of the few developed countries to feature this mechanism in its national laws. Russia also remains the only BRICS country never to have used TRIPS Agreement public health flexibilities to increase access to essential medicines.[61]

Regional IP protection agreements, such as EAPC, and bi- or multilateral trade agreements with IP provisions, such as Customs Union documents, also influence the ability of countries to use the TRIPS flexibilities and access more affordable essential medicines. These concerns are addressed further in 'Conclusions and Recommendations'.

Table 10, below, illustrates the status of integration of IP provisions in the study countries.

5.3 Patent status of ARV medicines in the study countries

Many patented ARVs in the EAPC member states are protected with Eurasian patents instead of national patents. Eurasian patents cover either methods of production or combinations of ARVs used for treatment of HIV. A majority of patents cover all EAPC member states, as evidenced by the EAPO database, though some companies seem to prefer to maintain their patents only for the largest markets. See more on EAPC and EAPO in section 4.4.

Table 11 shows patent status of main ARVs in the selected countries.

Patents for most ARV compounds recommended by WHO 2010 and 2013 guidelines for first- and second-line regimens, with very few exceptions (such as ATV, DRV and EFV in Russia), have already expired. However, patents are still valid when it comes to specific formulations and FDCs. These include:

- hemisulfate salt of ABC (Eurasian patent EA001809, expires in 2018);
- paediatric composition of ABC (Eurasian patent EA002916, expires in 2019);
- solvate form of DRV (Eurasian patent EA007120, expires in 2023);
- liquid composition of 3TC (Eurasian patent EA001990, expires in 2018);
- tablet formulation of LPV/r (Eurasian patents EA011924, expires in 2024, and EA014446, expires in 2026);
- tablet formulation of RTV (Eurasian patent EA011924, expires in 2024);
- combination of ABC with 3TC or FTC and AZT (Eurasian patent EA000626, expires in 2016);
- combination of EFV/FTC/TDF (Eurasian patent EA017764, expires in 2026);
- combinations of FTC/TDF (Eurasian patent EA015145, expires in 2024).

These patents cover all study countries but Uzbekistan, which is not part of the EAPC. Even though patent data on Uzbekistan is not available from open sources, the country is not bound by EAPC and is therefore in a comparatively advantaged position compared to the other study countries and can benefit from using generic versions of most ARVs. This position may also benefit the domestic pharmaceutical industry of Uzbekistan and ultimately greatly benefit healthcare, if economies of scale could be achieved to produce essential medicines of good quality at competitive prices.

The impact of the EAPC on the use of public health flexibilities and on access to ARVs and other essential medicines is discussed in greater detail in 'Conclusions and Recommendations'.

61 Russia only acceded to the WTO in 2012.

Table 10: IP provisions in the study countries and in international and regional instruments

	TRIPS Agreement	Belarus	Kazakhstan	Russia	Tajikistan	Uzbekistan	EAPC
Patent duration	20 years	20 years	20 years	20 years	20 years	20 years	20 years
Patenting of new uses	Not required[62]	Unclear	Yes (art. 2(2))	No	Yes (art.6)	Yes[63]	No provision
Patent extensions	Not required	Up to five years	Up to five years	Up to five years	No	Up to five years	According to EAPC Patent Regulations, patent extension is possible if allowed by national laws, and for the period envisaged by those laws
Exhaustion regime (parallel imports allowed when international)	None of provisions of TRIPS Agreement, except those dealing with non-discrimination, can be used to address the issue of exhaustion of IP rights in a WTO dispute. The Doha Declaration clarifies that governments can choose how to deal with exhaustion in a way that best fits their domestic policy objectives.	Incomplete regional (Customs union with Russia and Kazakhstan)	Incomplete regional (Customs union with Belarus and Russia)	Incomplete regional (Customs union with Belarus and Kazakhstan)	National	National	National (according to EAPC Patent Regulations Rule 19)

62 WHO. *Drug Patents under the Spotlight, 2003. Section 3.3, Patentability is a matter of national policy: example of new use inventions* (http://apps.who.int/medicinedocs/en/d/Js4913e/3.3.html)

63 The Uzbek patent law does not contain any provisions related to patenting new use of a known product, but this is possible in the meaning of para. 2 of Rules for development, submission and consideration of patent application, approved by the order of Director of State Patent Bureau of 02.02.2004 No. 9 ("Правила составления, подачи и рассмотрения заявки на выдачу патента Республики Узбекистан на изобретение (утверждены Приказом директора ГПВ от 02.02.2004 г. N 9 зарегистрированным МЮ 22.03.2004 г. № 1329").

Table 10: IP provisions in the study countries and in international and regional instruments (cont.)

	TRIPS Agreement	Belarus	Kazakhstan	Russia	Tajikistan	Uzbekistan	EAPC
Compulsory licensing (government use)	May be granted on conditions of non-exclusivity, adequate remuneration, judicial or other independent review and other conditions listed in art. 31 of the TRIPS Agreement.	▶ may be granted by court, when patent holder does not use, or does not sufficiently use, the patented invention, without a valid excuse, for 5 years since publication of patent information (art. 38); ▶ use of patented inventions during emergency situations is not considered a violation of a patent (art. 10).	▶ may be granted by court, when patent holder has not continuously used the patented invention, without a valid excuse, during any 4 years since publication of patent information (art. 11(4)); ▶ use of patented inventions during emergency situations is not considered a violation of a patent (art. 12(3)).	▶ may be granted by court, when patent holder does use, or does not sufficiently use, the patented invention, without a valid excuse, for 4 years since the grant of the patent (art. 1362); ▶ use of patented inventions during emergency situations is not considered a violation of a patent (art. 1359); ▶ government may allow use of a patented invention in interests of defence and security, but has to notify patent holder and pay a commensurate compensation (art. 1360).	▶ may be granted by court, when patent holder does not use, or does not sufficiently use, the patented invention, without a valid excuse, for 5 years since publication of patent information (art. 28); ▶ use of patented inventions during emergency situations is not considered a violation of a patent (art. 30).	▶ may be granted by court, when patent holder does not use, or does not sufficiently use, the patented invention, without a valid excuse, for 3 years since registration of the patent (art. 11); ▶ use of patented inventions during emergency situations is not considered a violation of a patent (art. 12).	▶ may be granted in conformity with the Paris Convention for the Protection of Industrial Property by the competent authority of a contracting state with effect in the territory of that state (art. 12 of EAPC).
Exceptions	Governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent (art. 30).	▶ individual not-for-profit use; ▶ experiment; ▶ use during emergency situations (with payment of commensurate compensation); ▶ one-time production of medicines in pharmacies by doctor's prescription (art. 10).	▶ individual use; ▶ experiment, ▶ use during emergency situations (with payment of commensurate compensation), ▶ one-time production of medicines in pharmacies by doctor's prescription (art. 12).	▶ individual not-for-profit use; ▶ research or experiment; ▶ use during emergency situations (with payment of commensurate compensation); ▶ one-time production of medicines in pharmacies by doctor's prescription (art. 1359).	▶ individual not-for-profit use; ▶ research or experiment; ▶ use during emergency situations (with payment of commensurate compensation); ▶ one-time production of medicines in pharmacies by doctor's prescription (art. 30).	▶ individual use; ▶ experiment; ▶ use during emergency situations or other extraordinary circumstances; ▶ one-time production of medicines in pharmacies by doctor's prescription (art. 12).	▶ scientific research or experiment; ▶ one-time production of medicines in pharmacies by doctor's prescription; ▶ use for private not-for-profit purposes (art. 19).
Regulatory exception (Bolar provision)	Though TRIPS agreement does not contain Bolar provision, it has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this.	Yes: registration of generic version not prohibited when original medicine is under patent protection.	Yes: registration of generic version not prohibited when original medicine is under patent protection	Yes: registration of generic version not prohibited when original medicine is under patent protection	Yes: registration of generic version not prohibited when original medicine is under patent protection	Yes: registration of generic version not prohibited when original medicine is under patent protection	No provisions
Test data exclusivity	Test data are protected under Article 39.3.	No	No	Yes	No (may be introduced in connection with WTO accession)	No	No provisions

Table 11: Patent status of key ARVs in the selected countries

INN / Pharmaceutical form	Originator trademark name	Patent holder (mfg.)	Int. patent application or patent of reference	Expected date of expiration (20 years from filing date)	Belarus (as of September 2013)	Kazakhstan (as of September 2013)	Russia (as of September 2013)	Tajikistan (as of September 2013)	Uzbekistan (as of September 2013)
3TC	Epivir	IAF Biochem GSK	EP0382526	Feb. 2010	No	Granted (KZ6138)	Expired (RU2092485)	No	Unknown
crystal form			WO1992021676	June 2012	No	No	Expired (RU2102393)	No	No
liquid composition			WO1998042321	2018	Granted (EA001990)	Granted (EA001990)	Granted (EA001990)	Granted (EA001990)	No
ABC	Ziagen	Wellcome (GSK)	WO1991000282 EP0434450	June/Dec. 2010	No	No	Expired (RU2068849, RU2091386)	No	No
hemisulfate salt			WO1998052949	2018	Granted (EA001809)	Granted (EA001809)	Granted (EA001809)	Granted (EA001809)	No
composition for ped.use			WO1999039691	2019	Granted (EA002916)	Granted (EA002916)	Granted (EA002916)	Granted (EA002916)	No
comb w/ 3TC or FTC (and AZT)			WO1996030025	2016	Granted (EA000626)	Granted (EA000626)	Granted (EA000626)	Granted (EA000626)	Unknown
ATV	Reyataz	Novartis (BMS)	WO1997040029	2017	Lapsed (EA001794)	Lapsed (EA001794)	Granted (EA001794)	Lapsed (EA001794)	No
bisulfate salt		BMS	WO1999036404	2018	No	No	Granted (RU2186070)	No	No
use in HIV therapy			WO2003020206	2022	No	No	Expired (RU2316341)	No	No
process			WO2005108349	2025	No	No	Granted (RU2385325)	No	No
AZT	Retrovir	Glaxo Wellcome	US4724232	2006	No	No	No	No	No
AZT+3TC	Combivir	Glaxo Wellcome	WO1992020344	May 2012	No	No	Expired (RU2139059)	No	No
tablet formulation			WO1998018477	May 2013	Lapsed (EA002437)	Lapsed (EA002437)	Lapsed (EA002437)	Lapsed (EA002437)	Withdrawn (UZ02622)
d4T	Zerit	Yale Univ. (BMS)	EP0273277	Dec. 2007	No	No	No	No	No

Table 11: Patent status of key ARVs in the selected countries (cont.)

INN / Pharmaceutical form	Originator trademark name	Patent holder (mfg.)	Int. patent application or patent of reference	Expected date of expiration (20 years from filing date)	Belarus (as of September 2013)	Kazakhstan (as of September 2013)	Russia (as of September 2013)	Tajikistan (as of September 2013)	Uzbekistan (as of September 2013)
ddI	Videx	US Gov (BMS)	WO1987001284	2006	No	No	No	No	No
improved oral formulation		BMS	US5880106	July 2012	No	No	No	No	No
enteric-coated	Videx EC	BMS	WO1999061002	2018	No	No	Granted (RU2197227)	No	No
DRV	Prezista	Searle, Monsanto	WO1994004492	Aug. 2013	No	No	Granted (RU2173680) may lapse	No	No
method of use		US Gov	WO1999067417	2019	No	No	No	No	No
comb. w/ RTV		Tibotec	WO2003049746	2022	No	No	Lapsed (RU2329050)	No	No
pseudo-polymorph/ solvate form			WO2003106461	2023	Granted (EA007120)	Granted (EA007120)	Granted (EA007120)	Granted (EA007120)	No
prep. of key intermediates			WO2005095410	2025	No	No	Granted (RU2421458)	No	No
comb. w/ RTV & TDF			WO2006005720	2025	No	No	Lapsed (RU2368380)	No	No
EFV	Stocrin/ Sustiva	Merck (MSD, BMS)	WO1994003440	Aug. 2013	No	No	Granted (RU2173680) may lapse	No	No
comb w/ FTC & TDF	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	No

Table 11: Patent status of key ARVs in the selected countries (cont.)

INN / Pharmaceutical form	Originator trademark name	Patent holder (mfg.)	Int. patent application or patent of reference	Expected date of expiration (20 years from filing date)	Belarus (as of September 2013)	Kazakhstan (as of September 2013)	Russia (as of September 2013)	Tajikistan (as of September 2013)	Uzbekistan (as of September 2013)
ETV	Intelence	Janssen (Tibotec)	WO2000027825	2019	Granted (EA004049)	Granted (EA004049)	Granted (EA004049)	Granted (EA004049)	No
novel series		Tibotec	WO2006094930	2026	No	No	Granted (RU2401261)	No	No
new forms			WO2006079656	2026	No	No	Granted (RU2403245)	No	No
FPV	Lexiva	Vertex (GSK)	WO1999033815	2018	Granted (EA003509)	Granted (EA003509)	Granted (EA003509)	Granted (EA003509)	No
calcium salt		GSK	WO2000004033	2019	Lapsed (EA003191)	Lapsed (EA003191)	Granted (EA003191)	Lapsed (EA003191)	No
FTC	Emtriva	IAF Biochem	EP0382526	Feb. 2010	No	Granted (KZ6138)	Expired (RU2092485)	N/a	Unknown
		Emory Univ. (Gilead)	WO1991011186 WO1992014743	Jan. 2011/Feb. 2012	No	No	Expired (RU2125558)	No	No
comb. w/ TDF	Truvada		WO2004064845	2024	Granted (EA015145)	Granted (EA015145)	Granted (EA015145)	Granted (EA015145)	No
comb. w/ TDF + RIL	Complera	Tibotec (Gilead)	WO2005021001	2024	Granted (EA014840)	Granted (EA014840)	Granted (EA014840)	Granted (EA014840)	Unknown
comb w/ EFV + TDF	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	No
IDV	Crixivan	Merck	WO1993009096 WO1994022480	Nov. 2012/ March 2014	Lapsed (EA003191)	Lapsed (EA003191)	Granted (EA003191)	Lapsed (EA003191)	No
LPV	Kaletra	Abbott	WO1997021685	2016	No	No	No	No	No
LPV/r Soft-gel caps			WO1998022106	2017	No	No	No	No	No
LPV/r tablet formulation			WO2005039551	2024	Granted (EA011924)	Granted (EA011924)	Granted (EA011924)	Granted (EA011924)	No
			WO2006091529	2026	Granted (EA014446)	Granted (EA014446)	Granted (EA014446)	Granted (EA014446)	No
NFV	Viracept	Agouron Pharmaceuticals, Inc.	WO1995009843	Oct. 2014	Granted (BY4552)	Unknown	No	Unknown	Unknown

Table 11: Patent status of key ARVs in the selected countries (cont.)

INN / Pharmaceutical form	Originator trademark name	Patent holder (mfg.)	Int. patent application or patent of reference	Expected date of expiration (20 years from filing date)	Belarus (as of September 2013)	Kazakhstan (as of September 2013)	Russia (as of September 2013)	Tajikistan (as of September 2013)	Uzbekistan (as of September 2013)
NVP	Viramune	Boehringer	EP0429987	Nov. 2010	Expired (BY2745)	No	Expired (RU2040527)	No	No
hemihydrate formulation			WO1999009990	2018	Granted (BY4767)	Expired (KZ10633)	Granted (RU2196584)	No	Granted (UZ02502)
extended release formulation			WO2008154234	2028	Filed (EA200900958)	Filed (EA200900958)	Filed (EA200900958)	Filed (EA200900958)	No
RAL	Isentress	Institute for Research in Mol. Biology, Italy, MSD	WO2003035077	2022	Granted (EA007060)	Granted (EA007060)	Granted (EA007060)	Lapsed (EA007060)	Granted (UZ03323)
potassium salt			WO2006060712 WO2006060730	2025	Granted (EA012418)	Granted (EA012418)	Granted (EA012418)	Lapsed (EA012418)	No
RTV	Norvir	Abbott	WO1994014436	Dec. 2013/2014	No	No	No	No	No
crystalline polymorph			WO2000004016	2019	No	No	No	No	No
tablet formulation	Kaletra	Abbott	WO2005039551	2024	Granted (EA011924)	Granted (EA011924)	Granted (EA011924)	Granted (EA011924)	No
SQV	Fortovase	Hoffmann-La Roche	EP0432695	Dec. 2010	Expired (BY1362)	Expired (KZ3849)	Expired (RU2071470)	No	No
improved composition			WO1996039142	2016	Granted (EA001413)	Granted (EA001413)	Granted (EA001413)	Granted (EA001413)	Granted (UZ02240)
oral dosage form			WO2005004836	2024	Granted (EA015349)	Granted (EA015349)	Granted (EA015349)	Lapsed (EA015349)	No
TDF	Viread	Gilead	WO1999005150	2018	No	No	No	No	No
ester prodrug			WO1998004569	2017	No	No	No	No	No
comb. w/ FTC	Truvada		WO2004064845	2024	Granted (EA015145)	Granted (EA015145)	Granted (EA015145)	Granted (EA015145)	No
comb. w/ FTC + RIL	Complera	Tibotec (Gilead)	WO2005021001	2024	Granted (EA014840)	Granted (EA014840)	Granted (EA014840)	Granted (EA014840)	Unknown
comb w/ EFV + FTC	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	Granted (EA017764)	No

Sources: Espacenet.com, Eurasian Patent Organization, Medicines Patent Pool, Patent Offices of Belarus, Kazakhstan and Russian Federation, World Intellectual Property Organization, UNDP Office in Tajikistan. Information is subject to availability in the above-mentioned resources and may change. This table is indicative only and should not be used as an authoritative source.

6. LICENSING AND REGISTRATION OF MEDICINES

6.1 Licensing of pharmaceutical activity

In the EU and the USA, licensing of medicines means approval of a product for sale in a jurisdiction and for application in medical practice. However, in EECA this procedure is usually called *medicine registration* (considered in 6.2), while *licensing* typically refers to obtaining an official permission for an activity, not a product. This is the case in all countries covered by this study.

While details may vary, the systems of licensing (definitions, procedures, requirements, etc.) in all study countries are similar. Obtaining of a license is required for activities, which may entail damage to the rights and legal interests of citizens, their life and health, as well public safety. In all the countries, it is therefore mandatory to obtain licenses in order to produce, import and distribute medicines; such licenses are typically called licenses for *pharmaceutical activity*. Similarly, provision of medical services (so-called *medical activity*) also requires a license; for sale of medicines by medical establishments two different licenses are necessary, one for medical activity and the other for pharmaceutical activity. Bearing in mind the scope of this paper, namely provision of ARVs, this section will only focus on licensing of pharmaceutical activity.

Table 12: Key documents on licensing in study countries

Country	Document
Belarus	Law of the Republic of Belarus "On Medicines", No. 161-Z of 20 July 2006 Regulations "On Licensing of Certain Types of Activities", approved by Presidential Decree No. 450 of 1 August 2010
Kazakhstan	Code of the Republic of Kazakhstan "On Public Health and Healthcare System", No. 193-IV ZRK of 18 September 2009 Law of the Republic of Kazakhstan "On Licensing", No. 214-III of 11 January 2007 Resolution of the Government of the Republic of Kazakhstan "On Adoption of Rules of Licensing and Qualification Requirements for Licensing of Pharmaceutical Activity", No. 692 of 5 July 2005
Russia	Federal Law "On Circulation of Medicines", No. 61-FZ of 12 April 2010 Federal Law on Licensing of Certain Types of Activities, No. 99-FZ of 4 May 2011 Resolution of the Government of Russian Federation "On Licensing of Pharmaceutical Activity", No. 1081 of 22 December 2011
Tajikistan	Law of the Republic of Tajikistan "On Medicines and Pharmaceutical Activity", No. 335 of 28 June 2001 Law of the Republic of Tajikistan "On Licensing of Certain Types of Activities", No. 37 of 17 May 2004 Resolution of the Government of the Republic of Tajikistan "On Adoption of Specifics of Licensing of Certain Types of Activities", No. 172 of 3 April 2007
Uzbekistan	Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activity", No. 415-I of 25 April 1997 Law of the Republic of Uzbekistan "On Licensing of Certain Types of Activities", No. 71-II of 25 May 2000 Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On Measures for Further Improvement of the Procedure for Licensing of Pharmaceutical Activity", No. 91 of 13 May 2010

In order to obtain a license for pharmaceutical activity, an applicant typically needs to meet the following general criteria:[64]

- have premises, equipment and transport necessary and appropriate for carrying out of licensed activity;
- have adequate number of appropriately qualified staff; and
- meet requirements of legislation and technological standards.

Specific requirements regarding the application package and fees to be paid are governed by documents listed in the above table and other legislative acts (for example those establishing the size of calculating indicator or minimum wages). The following were the costs of obtaining a license for production or importation of medicines, as of December 2013: in Belarus 1,040,000 BYR (111 USD), in Kazakhstan 17,310 KZT (113 USD), in Russia 6,000 RUB (183.50 USD), in Uzbekistan 183,060 UZS (84 USD). Information on Tajikistan could not be retrieved. The comparatively low cost of obtaining a license has little, if any, effect on the price of locally produced or imported medicines, including ARVs.

Without compromising quality, safety, and efficacy, countries should ensure that licensing of pharmaceutical manufacturers, importers and sellers is carried out in a timely and cost effective manner which increases competition and does not create disincentives for domestic or foreign entities, regardless of whether they work with originator or generic medicines.

6.2 Registration of medicines

In all study countries medicines – both originator and generic – must be registered before they are allowed to enter the market. This requirement exists in legislations of all the selected countries, though in some countries (e.g. Belarus, Tajikistan and Uzbekistan) one-time waivers may be issued by Ministry of Health for single-time procurement of certain medicines without registration. Such waivers are supposed to be issued on an exceptional basis, and one can expect that all countries will move towards uniform application of registration requirements to all medicines. The GFATM does not require ARVs to be registered in the country and only relies on the appropriate "authorization" of their use in the country. This policy greatly benefits PLHIV since it allows them access medicines which are recommended in guidelines but have not yet been registered in the country. It also addresses the issues of smaller markets where companies – both originator and generic – have no significant incentives to register their products. One such example is Tajikistan where only very few products for diagnostics and treatment of HIV are registered. Due to the size of the market, producers often do not have the incentives to go through a costly and lengthy process of registration. At the same time, there does not appear to be a cost-efficient, fast track registration process due to government interests. This situation results in increase of the number of "one time waivers" and does not promote sustainable solutions for access to essential medicines.

The regulatory process typically focuses on *quality, safety and efficacy*. To be registered, a product must demonstrate that it is generally safe (or has a favourable risk/benefit profile relative to the condition it is intended to treat), that it does what the manufacturer claims, and that it is produced to high standards[65]. The process of registration of medicines is regulated by laws on medicines, government resolutions and decisions of the Ministry of Health. In all of the selected countries,

64 Specific criteria vary from country to country.

65 The selected countries are moving towards introducing GMP rules; countries of the Customs Union are in process of development of unified GMP standards (more on this in section 4.5). As to the GFATM, it requires that the medicines procured within its grants are WHO prequalified (read more in section 7.2).

Ministries of Health or their subordinate specialized agencies are in charge of medicines registration.

According to legislations of the countries covered by the study registration is required for all medicines that are new, generic, or even if already registered produced by different manufacturers, in different formulations and dosage forms, with different additives, or as new combinations of previously registered medicines. Medicines can be exempt from registration procedures if they are:

- produced by pharmacies for individual use (Belarus, Kazakhstan, Russia, Tajikistan, Uzbekistan);
- imported for personal use (Belarus, Kazakhstan, Russia, Tajikistan);
- imported for use as exhibition items (Belarus, Kazakhstan, Tajikistan);
- imported for the purpose of preclinical and clinical trials (Belarus, Kazakhstan, Tajikistan), etc.

In order to register a medicine, a *registration dossier* needs to be submitted to the registration authority. The dossier consists of a set of documents showing that the medicine meets national safety, quality and efficacy standards, and contains samples of the medicine for examination. The applicant also needs to pay a registration fee which is considerably higher than the fee for obtaining a license. In Russia, for instance, in order to register a medicine, a company needs to pay 300,000 RUB, or approximately 10,000 USD. Such a high fee explains why pharmaceutical companies are so selective in terms of where and which products to register.

In addition to standard registration procedure there is an accelerated registration, which exists in Kazakhstan, Russia, Tajikistan and Uzbekistan.

In Kazakhstan, examination of medicines under accelerated registration shall not exceed 130 calendar days (220 for standard registration). It may be used for registration of:

- medicines intended for prevention of emergency situations, and for ensuring national security;
- authorized generics; and
- pharmaceutical substances and bulk-products.

In Russia, examination of medicines under accelerated registration shall not exceed three months (six for standard registration). The accelerated procedure may be applied to:

- generic medicines, which are equivalent to originator medicines already registered in the Russian Federation, even if produced under a different technology or with different additives;
- medicines, which are on the list of essential medicines;
- medicines imported to the Russian Federation as humanitarian aid or in emergency or crisis situations.

Though in Uzbekistan there is no concept of accelerated registration, it actually exists, as in a number of instances it is possible to do registration without otherwise mandatory clinical trials, thus considerably reducing time required for registration of a medicine. This procedure may be used for:

- medicines that are used in medical practice for not less than five years, registered in several countries, necessarily including the manufacturing country, if quality certificate and documents that prove clinical effectiveness and safety of the medicine are available;
- medicines produced under a license and registered in the Republic of Uzbekistan by licensee, if licensor's letter of guarantee confirming quality of the medicine is available; and
- generic medicines, allowed for use in medical practice in the manufacturing country, which are manufactured and registered in one or several countries, if results of bioequivalence studies are available.[66]

In all study countries registration is valid for five years with possible re-registration.

In addition to national regulatory framework for registration of medicines, regional instruments play an increasing role:

66 Instruction "Procedure for Examination, Clinical Trials, Registration and Re-registration of Medicines and Pharmaceutical Substances Produced in Foreign Countries and the CIS", approved by Minister of Healthcare of the Republic of Uzbekistan, 03.08.1998.

Agreement on Cooperation of Member States of Eurasian Economic Community Regarding the Circulation of Medicines (Pharmaceutical Compositions), Medical Products and Medical Instruments (Medical Equipment),[67] signed on 28 September 2012 by representatives of Belarus, Kazakhstan, Kyrgyzstan, Russia and Tajikistan.[68] This document contains the following important commitments:

- to harmonise and unify systems of pre-registration and registration examination, post-registration monitoring of medicines and pharmaceutical products, including standardisation and quality control;
- to recognise results of preclinical, clinical, bioequivalence and other research and trials of pharmaceutical products, as well as results of inspections to pharmaceutical factories, carried out on the territory of states parties;
- to share information on identified unwanted side effects and decisions to recall medicines and medical products or limit their use.

Annex 1 to the Agreement: *Regulations on Basic Requirements to State Registration, Re-Registration or Confirmation of Registration of Medicines and Pharmaceutical Compositions in Member States of Eurasian Economic Community*.[69] According to this document – developed on the basis of WHO recommendations, legislation of EurAsEC member states and generally recognised international standards – one of its objectives is to improve legislations of EurAsEC member states on circulation of medicines. The document promotes mutual recognition of certain types of research on medicines with the purpose of economical use of human and material resources and for shortening periods of time required for development and marketing of new medicines. It contains minimum requirements for:

- the documents and data to be provided for registration;
- the labelling of medicines; and
- the information provided in application instructions/package leaflet.

Regulations on the Procedure for Importing of Medicines and Pharmaceutical Substances into the Customs Territory of the Customs Union,[70] approved by decision of the Commission of Customs Union No. 748 of 16 August 2011. The document allows for import of medicines, including unregistered ones, for personal use by individuals, for treatment of passengers, drivers and crew members of transport vehicles and trains, entering the territory of Customs Union, for treatment of participants of international cultural and sportive events and international expeditions (one can find similar provisions in legislations of the select countries; see above). However, in many respects (customs procedures, time limits, etc.), the regulations do not create any rules but simply refer to legislative provisions of member states.

Draft *Agreement on Unified Principles and Rules for Regulation of Circulation of Medicines within Customs Union and Single Economic Space*,[71] approved by the EEC on 21 May 2013. Once it enters into force, the agreement will have significant impact on the circulation of medicines within the territory of the Customs Union and SES. It foresees a number of important developments to take place, including the following:

- implementation of unified policies regarding the circulation of medicines by harmonising their legislations, adoption of unified rules of circulation of medicines, introduction of unified approaches to ensuring the quality of medicines, etc.

67 Соглашение о сотрудничестве государств-членов Евразийского экономического сообщества в сфере обращения лекарственных средств (лекарственных препаратов), изделий медицинского назначения и медицинской техники (медицинских изделий).

68 As of the date of writing this report, the Agreement entered into force in Kyrgyzstan (Government Resolution was adopted on 2 April 2013), and in Belarus (Law of the Republic of Belarus of 12 July 2013 No.50-Z).

69 Положение об основных требованиях государственной регистрации, перерегистрации или подтверждения государственной регистрации лекарственных средств (лекарственных препаратов) в государствах-членах Евразийского экономического сообщества.

70 Положение о порядке ввоза на таможенную территорию Таможенного союза лекарственных средств и фармацевтических субстанций (http://www.eurasiancommission.org/ru/Lists/EECDocs/P_748.pdf).

71 Соглашение о единых принципах и правилах регулирования обращения лекарственных средств в рамках Таможенного союза и Единого экономического пространства.

- adoption of important documents, including GLP, GCP, GMP, and GDP, rules for development and maintenance of a roster of inspectors of the Customs Union and SES, regulations on pharmaceutical inspectorate of states parties, rules for conducting pharmaceutical inspections, rules for conducting bioequivalence studies, rules for registration and examination of medicines, rules for maintenance of unified registry of registered medicines of the Customs Union and SES, etc.
- implementation of unified procedure for registration of medicines on the territory of states parties to the agreement;
- listing medicines that do not need to be registered (medicines produced by pharmacies; medicines intended to be used as exhibition samples; medicines intended for preclinical research and clinical trials; medicines imported by individuals for personal use; medicines not intended for sale on customs territory of the Customs Union and SES);
- establishing the procedure for mutual recognition of registration certificates for medicines produced in the states parties and registered by their appropriate authorities, and inclusion of such certificates in the unified registry (medicines produced outside of the states - parties to the agreement shall be registered in accordance with national requirements of the states - parties);
- introducing the requirement that production of medicines in states parties for distribution in Customs Union and SES needs to be done in accordance with rules of GMP, adopted by the EEC;
- establishment of a Pharmaceutical Inspectorate of the Customs Union for the purpose of confirming compliance of pharmaceutical companies of states parties with rules of good practice, adopted by the EEC.

Draft *Regulations on Unified Information System of the Customs Union in Respect of Circulation of Medicines*,[72] developed in accordance with decision of the Commission of Customs Union No. 298 of 18 June 2010. The document envisages creation of a unified information system of the Customs Union in respect of circulation of medicines (hereinafter referred to as Unified Information System), which will be a subsystem of the Integrated Information System of the Customs Union for Internal and External Trade. The Unified Information System will consist of the following resources: state registries of medicines registered in member states of the Customs Union; information database of quality standards of medicines (specifications, normative documents, GOSTs, etc.); information database on import/export of medicines; information database on certification of medicines, and on counterfeit and smuggled medicines; information database on side effects, etc. The document and its annexes regulate the flow of information among member states of the Customs Union regarding circulation of medicines, including substandard and falsified ones.[73]

Even though these documents have not yet been fully implemented, one can be certain that further steps will be taken in the near future. For example, the abovementioned decision of the Commission of Customs Union No. 298 of 18 June 2010 has an annexed Plan of Activities on mutual recognition of registration certificates medicines produced under GMP by companies in the Customs Union;[74] among other things it foresees development and adoption of GLP, GMP, GDP, GPP and other relevant standards, as well as other documents aimed at bringing standards of pharmaceutical production in the SES in line with the EU.

6.3 Registration status of ARV medicines in the study countries

Except Tajikistan, all of the study countries provide online access to their registration databases, which is considerably better access compared to other regions such as Latin America. Even some countries in the EU

72 Положение о единой информационной системе Таможенного союза в сфере обращения лекарственных средств.

73 See "Соглашение о сотрудничестве в борьбе с обращением фальсифицированных лекарственных средств 14 ноября 2008 г". See also: В.В. Косенко, А.В. Быков, А.П. Мешковский, Фальсифицированные лекарства – глобальная проблема, Вестник Росздравнадзора № 3- 2009. See also: ICTSD, Фальсифицированные лекарства в России, December 2009, http://ictsd.org/i/news/bridgesrussian/65190/.

74 План мероприятий по взаимному признанию регистрационных удостоверений на лекарственные средства производителей государств – членов Таможенного союза, произведенные в условиях надлежащей производственной практики (GMP).

do not have such easily accessible online databases. They allow a fast overview of which medicines are registered in the country, as well as details of their registration. Even if data in the databases are not always up to date or accurate online resources in the EECA countries provide a good opportunity to verify the registration status of medicines.[75]

For Tajikistan, an inquiry made by the Tajik UNDP Office to the Ministry of Health returned the result that there is only one ARV officially registered in the country, RTV. While classified as a PI, it is not used as a stand-alone medicine, but rather as a booster to other PIs. The rest of ARVs are procured under the above-mentioned one-time (ad hoc) waivers.

As to the other study countries, our analysis led to the following findings:

- In Belarus, the following ARVs are registered: 3TC, ABC, AZT, ENF, ETV, LPV/r, NVP, RTV; 3TC/ABC, 3TC/ABC/AZT, 3TC/AZT, FTC/TDF. Notably, of these, the only generic medicine registered in Belarus is FTC/TDF, while the rest of ARVs are originator. Several ARVs recommended both by WHO and national guidelines, including ATV, ddI, DRV and EFV could not be found.

Online registration databases allow a fast overview of medicines registered in the country, as well as details of their registration. All countries covered in this study except Tajikistan provide online access to their registration databases. However, information needs to be updated and made more accurate.

- In Kazakhstan, the following ARVs are registered: 3TC (generic & originator), ABC (generic & originator), AZT (generic & originator), d4T (generic), ddI (generic), DRV (originator), EFV (generic), ETV (originator), LPV/r (originator), NVP (generic & originator), RTV (generic & originator), TDF (originator); 3TC/ABC (originator), 3TC/ABC/AZT (originator), 3TC/AZT (generic & originator), 3TC/AZT/NVP (generic), 3TC/d4T/NVP (generic), FTC/TDF (originator). ATV, which is recommended by national and WHO Guidelines, does not appear to be registered.
- In Russia, the following ARVs are registered: 3TC (generic & originator), ABC (generic & originator), ATV (generic & originator), AZT (generic & originator), d4T (generic & originator), ddI (generic & originator), DRV (originator), EFV (generic & originator), FAZT (originator), FTC (generic), ENF (originator), FPV (originator), LPV (generic), LPV/r (originator), NFV (generic), NVP (generic & originator), RTV (generic & originator), SQV (generic), TDF (generic & originator); 3TC/ABC/AZT (originator), 3TC/AZT (generic & originator), 3TC/AZT/NVP (generic), FTC/TDF (originator). Therefore, all medicines recommended by WHO and national guidelines are registered. Some medicines recommended by national scholarly publications, and not by WHO, are not registered (FPV, IDV and RAL);
- In Uzbekistan, the following ARVs are registered: 3TC (generic & originator), ABC (generic & originator), AZT (generic), d4T (generic), ddI

75 For instance, in the database for Belarus, for three ARVs instead of INN there are trademark names of medicines, and there is a seemingly wrong registration expiration date for one of 3TC products (see footnotes in table 13). In the Kazakhstan database, INNs for some ARVs are not given ("no data"), which is compensated by presence of Anatomical Therapeutic Chemical Classification System coding. Also, according to the registry, none of the registered antiretroviral are protected by patents, which is clearly not true (see section 5.3 above). Even though the registry contains information regarding medicines' being originator or generic versions, this information can hardly be called reliable (e.g. Zhejiang Huahai's Efavirenz and Ranbaxy's Viro-Z are said to be originator medicines, while Janssen's Intelence or Boehringer Ingelheim's Viramune are recorded as generics). In Uzbekistan, since recently, the registry has become searchable, but it seems to be incomplete, as it does not have some of the medicines that were shown as registered in the earlier online version of the registry.The number of medicines in the new version of the registry as of November 2013 was 2,447, while the older version – as well as currently in the English version of the website – the registry had 3,371 entries. Notably, according to the new version of the registry, no single FDC is registered in the country, which seems not to represent the facts. Therefore, when compiling this table, we entered ARVs, whose registration was supposed to be valid as of December 2013, from both registries – the one given in the English version of the website, and the one in the Russian version.

(generic), EFV (generic), LPV/r (generic & originator), NFV (originator), NVP (generic & originator), RTV (originator), SQV (originator), TDF (originator); 3TC/AZT (originator), 3TC/d4T (generic), FTC/TDF (generic & originator). Therefore, all medicines recommended by national guidelines are registered. However, as was mentioned in section 3.2. above, two PIs recommended by WHO are not recommended by national guidelines (ATV and DRV); they are also not registered in Uzbekistan.

Registration status of ARV medicines in Belarus, Kazakhstan, Russia and Uzbekistan is shown in tables in Annex 1.

7. PROCUREMENT SYSTEMS IN STUDY COUNTRIES

7.1 Overview of countries' public procurement systems

Countries of the Customs Union have signed an *Agreement on Public (Municipal) Procurements*, which entered into force on 1 January 2012.[76] Provisions of the Agreement are mandatory for the countries, and they regulate issues related to public and municipal procurements carried out in the countries, except for procurements information that are considered state secret. Article 3 of the Agreement lists requirements that have to be met by procurement legislations in, and procurements carried out by, the countries; these include the following:

- ensuring national regime;
- ensuring the most favourable treatment;
- ensuring openness and transparency of procurements through, inter alia, establishment of a web-portal with unrestricted free-of-charge access to information on public procurements and to normative legal acts related to procurements;
- establishing a limited number of electronic platforms for executing public procurements;
- carrying out procurements by methods envisaged by the agreement;
- prohibiting ex parte refusal of customers and contractors to perform contractual obligations;
- ensuring rights and legitimate interests of contractors;
- identifying a national supervisory authority in the field of procurements;
- establishing responsibility for violation of legislation on procurements; and
- promoting competitiveness and counteract corruption and other abuses in the area of procurements.

Countries should strive to develop and adopt modern laws and regulations on procurement, which have substantial safeguards of transparency and competitiveness, as well as provisions on procurement monitoring.

Article 5 determines methods of procurements, which include tender, call for proposals/call for bids, open auction, tender through exchange, and single-source procurement. In further articles the agreement provides details of procedures and requirements to be followed in respect of each of these procurement methods. Annex 1 to the agreement lists instances when single-source procurements or procurements through methods that are not listed in Article 5 of the Agreement can be carried out, applicable either to all countries of the Customs Union or to individual country members of the Union. Instances that are valid for all countries of the Union include procurement of goods, works and services in emergencies, due to the need in urgent medical intervention or other urgencies; when total cost of procurements does not exceed a certain threshold established by legislation. At the same time, procurement of goods and services that are subject of IP rights from the owner of these rights, fall among instances that are applicable to Belarus and Kazakhstan, but not Russia. Annex 2 of the Agreement

76 Соглашение о государственных (муниципальных) закупках (http://www.pravo.by/main.aspx?guid=3871&p0=F01000160).

is a minimum list of goods, works and services to be procured through electronic auctions. Importantly, it mentions "products of organic and inorganic synthesis", which include pharmaceutical products. It should be noted that by the list in Annex 2 the agreement does not limit countries in identifying goods and works to be procured through auctions (Article 10).

The agreement entered into legal force by way of ratification: countries adopted national laws describing the procedure of national implementation of the agreement in their jurisdictions. But it is evident that the Agreement itself was drafted in a way to take into account nuances of national regulation of public procurements of Belarus, Kazakhstan and Russia.

7.1.1 Belarus

The legislation of the Republic of Belarus on public procurements consists of the *Law "On Public Procurements of Goods (Works and Services)"* (No. 419-Z of 13 July 2012),[77] Presidential decrees, government resolutions, and ministerial decisions (such as ordinances of the Ministry of Health regarding the procurement of medicines).

The Law on public procurements establishes a general framework for procurement of goods, services and works for public aims. Article 17 of the Law contains a list of procurement procedures to be followed in the country: open competition, closed competition, electronic auction, call for bids, one-source procurement, and procurement through exchange. Legal documents and information about public procurements shall be available to public on official web-site in Belarusian and/or Russian languages unless such information constitutes a state, commercial or professional secret or is subject of IP rights.

The Resolution of the Council of Ministers "On Some Measures for Implementation of the Law of the Republic of Belarus "On Public Procurements of Goods (Works and Services)"" (No. 778 of 22 August 2012)[78] contains a number of important provisions ensuring enforcement of the public procurements law. It provides for setting up the official public procurements website (www.icetrade.by). The document also specifies procedures relating to types of procurements. The resolution has a number of annexes, including the regulations on a commission to be established by the organizer of open and closed competitions, electronic auctions and calls for bids; the regulations on the procedure for publishing of legal documents and the information on public procurement on the official website; regulations on the procedure for accreditation on electronic trading system; the list of goods, works and services, public procurements of which are to be done with participation of small and medium businesses; lists of goods, works and services to be procured through different procurement procedures.

Another key document that regulates public procurements in Belarus is the *Presidential Decree "On some issues of public procurements of goods (works and services)"* No. 576 of 29 December 2012,[79] which assigns the Ministry of Trade as the agency in charge of public procurements.

In the area of procurement of medicines, the *Ministry of Healthcare ordinance No. 723 of 18.06.2013 "On Centralization of Public Procurement of Medicines and Clinical Nutrition"*[80] is particularly relevant, as it describes the system of public procurements in healthcare. This document assigns national unitary enterprise Belfarmatsiya as the organizer of centralized public procurements of medicines and clinical nutrition.

According to the ordinance, regional healthcare departments and state organizations subordinate to the Ministry of Healthcare prepare plans of centralized public procurements of medicines and clinical nutrition and by April 1 submit requests to Belfarmatsiya or regional Farmatsiya enterprises (the

77 Закон Республики Беларусь «О государственных закупках товаров (работ, услуг)» (http://www.pravo.by/main.aspx?guid=3871&p0=H11200419&p1=2).

78 Постановление Совета Министров Республики Беларусь «О некоторых мерах по реализации Закона Республики Беларусь «О государственных закупках товаров (работ, услуг)» (http://pravo.by/main.aspx?guid=3871&p2=5/36226).

79 Указ Президента Республики Беларусь «О некоторых вопросах государственных закупок товаров (работ, услуг)» (http://pravo.by/main.aspx?guid=3871&p2=1/13973).

80 Приказ Министерства здравоохранения Республики Беларусь от 18.06.2013 г. №723 «О централизации государственных закупок» (http://minzdrav.gov.by/ru/static/acts/normativnye/prikazy/o-tsentralizatsii-gosudarstvennyx-zakupok-lekarstvennyx-sredstv-i-lechebnogo-pitanija_i_1738.html).

latter prepare aggregate requests and submit them to Belfarmatsiya by May 1). Based on received requests, Belfarmatsiya prepares a national aggregate request and submits it to the Ministry of Healthcare by 1 June. After the national budget is adopted, the plan of centralized public procurements is approved by a Ministry of Healthcare ordinance in accordance with the amount of funds allocated for these purposes in the national budget.

Another important feature of this ordinance No. 723 is that it provides for the procurements to be done as per an annexed list of medicines and clinical nutrition for centralized public procurements, which also contains the following ARVs: 3TC (tabs, oral solution), ABC (tabs, oral solution), AZT (tabs, infusions), ddI (tabs), DRV (tabs), EFV (tabs, caps), LPV/r (tabs, caps, oral solution), NVP (tabs, oral suspension), RTV (tabs, caps), TDF (tabs), as well as several FDCs: 3TC/ABC/AZT (tabs), 3TC/AZT (tabs), FTC/TDF (tabs).

In accordance with the established procedure, every year the Ministry of Healthcare issues ordinances on annual need in medicines and medical products. *The Ministry of Healthcare ordinance No. 1240 of "On adoption of the 2013 annual plan of centralized procurements of medicines by competition and other procurement procedures"*[81] determines which ARVs and in what amounts should be procured in 2013. These include 3TC (oral solution), AZT (oral solution), EFV (tabs), LPV/r (tabs), NVP (tabs), TDF (tabs), as well as FDC of FTC/TDF (tabs).

7.1.2 Kazakhstan

Kazakhstan's legislation on public procurements consists of the Law "On Public Procurements", provisions of the Civil Code, Resolutions of the Cabinet of Ministers and other normative-legal acts. The *Law "On Public Procurements"*[82] was adopted in 2007. It creates a general framework for public procurement in the country. However, according to Article 4 of the Law, there are a number of instances where the Law does not regulate selection of procurer and conclusion of a contract. For example, when annual amount of goods, works and services to be procured does not exceed two thousand-fold of a monthly estimate indicator, which is set forth by the law on national budget (from 1 January 2014 the monthly estimate indicator is set at 1,852 KZT or approximately 10 USD); or when goods, works and services are procured under grants of foreign countries, international organizations, foreign and Kazakhstan NGOs and funds, including the GFATM, which is explicitly mentioned in the *Government Resolution No. 376 of 20 March 2009*;[83] or in case of procurement of goods or services that are objects of IP from a person or entity that has exclusive rights for these objects. Seemingly, the latter provision may apply to the procurement of patented medicines from patent holders.

The procedure for public procurements is detailed in articles of the Law, as well as the *Resolution of the Government of the Republic of Kazakhstan No. 1301 of 27 December 2007*.[84] The process of public procurements consists of the following stages: development and approval of annual public procurement plan; selection of procurer and conclusion of the contract on public procurements; and execution of the contract. The annual public procurements plan shall be developed on the basis of a respective budget (e.g. business plan or income and expenditure estimate, etc.) within ten days after the budget has been approved. The plan must contain the following information: a full list of goods, works and services to be procured; a method of public procurements; planned timelines and place of delivery. Within five days after approval of the plan, it must be published on the official public procurements website.

81 Приказ Министерства Здравоохранения Республики Беларусь «Об утверждении годового плана централизованных конкурсных (иных видов процедур» закупок лекарственных средств на 2013 год» (http://minzdrav.gov.by/dadvfiles/000129_419600_PrikazMZ_N1240_2012.pdf).

82 Закон Республики Казахстан «О государственных закупках», №303-III ЗРК, 21 июля 2007 года (http://www.zakon.kz/141138-zakon-respubliki-kazakhstan-ot-21.html).

83 Постановление Правительства Республики Казахстан «Об утверждении перечня международных и государственных организаций, зарубежных и казахстанских неправительственных общественных организаций и фондов, предоставляющих гранты» (http://adilet.zan.kz/rus/docs/P090000376_).

84 Постановление Правительства Республики Казахстан от 27 декабря 2007 года N 1301 ЭЭ Постановление Правительства Республики Казахстан от 27 декабря 2007 года N 1301 «Об утверждении Правил осуществления государственных закупок».

The law envisages several methods for carrying out public procurements:

- tendering, including tendering in two stages;
- call for bids;
- one-source procurements;
- auction; and
- commodity exchange.

The method for carrying out public procurements is selected by the one who places the order based on conditions specified by the law. For instance, calls for bids are used when goods to be procured are heterogeneous and when total amount of procurement does not exceed four thousand-fold monthly estimate indicator mentioned above.

Public procurement of pharmaceutical products is regulated by the *Resolution of the Government No. 1729 of 30 October 2009*.[85] According to the document, goods that are to be provided to the population as part of guaranteed free-of-charge healthcare cannot be procured at prices higher than the maximum prices established annually by the Ministry of Healthcare. This price is established based on prices provided by manufacturer, analysis of wholesale prices, and taking into account procurement prices used in the previous year and index of consumer prices. For example, according to Annex 1 to the Minister of Health ordinance No. 224 of 15 April 2013: "List of guaranteed medicines procured from the single distributor within the framework of guaranteed volume of medical assistance for 2014", maximum price for one Abacavir 300 mg tab is 490.32 KZT (or 2.7 USD), and that for a Lopinavir/ritonavir tab (LPV 200 mg/RTV 50 mg) is 91.64 KZT (0.5 USD).

The resolution envisages methods of procurement depending on the agency making such procurement. It may be done through tendering, call for bids, one-source procurement or according to the list of medicines to be procured from the single distributor. When procurements are made by the single distributor they may be made through two-stage tendering, through one-source procurement, through procurement under long-term procurement contracts or through special procedure used for prevention of epidemics or countering consequences of an emergency situation. When procurements are to be made by an entity authorized by the Government of Kazakhstan, such procurements can be done through two-stage tendering or one-source procurement.

According to *Government Resolution No. 150 of 18 February 2013*,[86] the single distributor for procurement of medicines, determined by the Government of Kazakhstan, shall be the single organizer of procurements of ARV medicines.

The annual need in ARVs is initially estimated at the level of regional AIDS centres and submitted to the Republican AIDS Centre for analysis, corrections and development of an aggregated annual forecast of ARV needs. The forecast is submitted to the Department of Organization of Medical Assistance and the Committee for Control of Medical and Pharmaceutical Activities of the Ministry of Healthcare for approval. Once approved, the forecast is submitted to SK Pharmatsiya, which has been assigned to be the single distributor of pharmaceutical and medical products by Government Resolution No 1781 of 7 November 2009.[87] Based on the forecast, SK Pharmatsiya procures ARVs – in accordance with the aforementioned resolutions and not exceeding the prices established by the Ministry of Healthcare – and distributes among regional AIDS centres.

85 Постановление Правительства Республики Казахстан от 30 октября 2009 года № 1729 «Об утверждении Правил организации и проведения закупа лекарственных средств, профилактических (иммунобиологических, диагностических, дезинфицирующих) препаратов, изделий медицинского назначения и медицинской техники, фармацевтических услуг по оказанию гарантированного объема бесплатной медицинской помощи» (http://adilet.zan.kz/rus/docs/P090001729_).

86 Постановление Правительства Республики Казахстан от 18 февраля 2013 года № 150 «Об утверждении Правил использования целевых текущих трансфертов из республиканского бюджета на 2013 год областными бюджетами, бюджетами городов Астаны и Алматы на здравоохранение» (http://adilet.zan.kz/rus/docs/P1300000150#z0).

87 Постановление Правительства Республики Казахстан от 7 ноября 2009 года № 1781 «О едином дистрибьюторе по закупу и обеспечению лекарственными средствами, изделиями медицинского назначения» (http://adilet.zan.kz/rus/docs/P090001781_).

7.1.3 Russia

From 1 January 2014, a new law on public procurement has entered into force in the Russian Federation: *Federal Law "On Contract System in the Area of Procurements of Goods, Works and Services for Public and Municipal Needs" of 05.04.2013 No. 44-FZ*,[88] which will gradually replace the current *Federal Law "On Placement of Orders for Procurement of Goods, Works and Services for Public and Municipal Needs" of 21.07.2005 No. 94-FZ*.[89] Many of the provisions of the new law will enter into force in 2015, and some provision only in 2016 and 2017. Given that the law is not the only document regulating public procurements in Russian Federation, and that there are government resolutions and ministerial decisions, one should expect entry of the new law into force to result in newly adopted bylaws to support implementation of the law and regulate issues that are not covered by the law. However, as these are not yet fully adopted, the bylaws that are effective as of the date of drafting of this report (late 2013 – early 2014) will be analysed here. In addition, a brief summary analysis of the new law (No. 44-FZ) is provided.

Both the 2005 and 2013 laws contain provisions regarding procurements that are not regulated by the law, namely procurements done by international financial institutions, which are approved by Governmental resolutions (presently, *Ordinance of the Government of Russian Federation No. 1968-r of 29 December 2007)*.[90] It should be noted that the GFATM is not among organizations mentioned in the Ordinance.

There are changes in the laws in terms of possible procurement methods. Article 10 of the 2005 law envisaged that procurements may be made through tendering, auction (including electronic auction) or without tendering (call for bids, through exchange or from one source). In the new law, Article 24 also distinguishes competition based and non-competition based methods of selection of contractors. Competition based methods include tendering (open tender, tender with limited participation, two-stage tender, closed tender, closed tender with limited participation, closed two-stage tender), auctions (electronic auction, closed auction), call for bids and call for proposals. Competition is a method whereby the winner is a participant who offered the best overall value for money in relation to the tender specifications, while in an auction the price tends to have a higher weight.

As a rule, procurement of medicines is to be done by auctions: this is foreseen by Article 10 (4) of the 2005 law and the *List of Goods (Works, Services) to be Procured by Auction*,[91] which mentions "products of organic and inorganic synthesis" (code 2400000) that includes medicines (code 2423000: pharmaceutical compositions, medical chemical substances and medical vegetable products).

The procurement of ARVs is regulated by *Resolution of the Government of Russian Federation of 27 December 2012 No. 1438 "On Financial Provision of Procurements of Diagnostic Systems and Antiviral Medicines for Prevention, Detection, Monitoring of Treatment of Persons Infected with HIV and Hepatitis B and C."*[92] The document assigns the Ministry of Healthcare of the Russian Federation as an agency responsible for procurement of diagnostic systems and antiviral medicines, including ARVs, for federal medical institutions, Federal Service for Supervision of Consumer Rights Protection and Human Welfare, Federal Service for Execution of Punishments. These agencies submit requests – before 1 February of each year – to the Ministry of Healthcare for procurement of diagnostic systems and antiviral medicines. The

88 Федеральный закон от 05.04.2013 N 44-ФЗ «О контрактной системе в сфере закупок товаров, работ, услуг для обеспечения государственных и муниципальных нужд» (http://www.consultant.ru/document/cons_doc_LAW_148532/).

89 Федеральный закон от 21.07.2005 N 94-ФЗ «О размещении заказов на поставки товаров, выполнение работ, оказание услуг для государственных и муниципальных нужд» (http://www.consultant.ru/document/cons_doc_LAW_148890/).

90 Распоряжение Правительства Российской Федерации от 29 декабря 2007 г. N 1968-р (http://minfin.tatarstan.ru/rus/file/pub/pub_18996.doc).

91 Перечень товаров (работ, услуг), размещение заказов на поставки (выполнение, оказание) которых осуществляется путем проведения аукциона. Утвержден распоряжением Правительства Российской Федерации от 27 февраля 2008 г. №236-р (http://www.consultant.ru/document/cons_doc_LAW_98879/).

92 Постановление Правительства РФ от 27 декабря 2012 г. № 1438 «О финансовом обеспечении закупок диагностических средств и антивирусных препаратов для профилактики, выявления, мониторинга лечения и лечения лиц, инфицированных вирусами иммунодефицита человека и гепатитов В и С» (http://www.garant.ru/products/ipo/prime/doc/70191708/).

Ministry of Healthcare aggregates the requests and coordinates the aggregate demand with the Ministry of Finances and the Ministry of Regional Development. The Ministry of Healthcare then submits to the Government of the Russian Federation projections of subsidies from federal budget for Federation subjects to co-finance expenditures related to procurement

The new public procurement law of Russia aims to improve efficiency and effectiveness of the procurement of goods and services for public needs, ensuring openness and transparency of such procurement to prevent corruption and other abuses in the field of procurement.

of diagnostic tools, and projections of other inter-budgetary transfers allocated from the federal budget to Federation subjects for financing of the procurement of antiviral medicines.

The resolution has several annexes that regulate different aspects of financial provision of ARV procurements. The last annex is the list of diagnostic tools and antiviral medicines procured for allocations from the federal budget. The list contains the following ARVs: 3TC and 3TC containing FDCs, ABC and ABC containing FDCs, ATV, AZT and AZT containing FDCs, d4T, ddI, DRV, EFV, ENF, ETR, FAZT, FPV, IDV, LPV and LPV containing FDCs, NFV, NVP, RAL, RTV and RTV containing FDCs, and SQV. It should be noted that while the list contains d4T, which WHO advises to phase out, it does not contain FTC and TDF, two very important ARVs that are recommended by the WHO for both first- and second-line regimens

Prices for medicines that are included in the list of essential medicines cannot exceed a certain maximum that is renewed regularly. The procedure for establishment of the maximum price for a medicine is regulated by *Government Resolution No. 865 of 29.10.2010 "On State Regulation of Prices for Medicines Included in the List of Essential and Most Important Medicines."*[93] According to this document, the Ministry of Healthcare, in coordination with the Ministry of Industry and Trade, Ministry of Economic Development and Ministry of Finances, shall submit (annually and not later than on 15 October) the list of essential medicines to the Government of Russian Federation. Maximum prices for essential medicines shall be established on the basis of review of a package of documents submitted by manufacturers by the Ministry of Healthcare and the Federal Service for Tariffs.

The new law public procurement law (No. 44-FZ) of Russia aims to improve efficiency and effectiveness of the procurement of goods and services for public needs, ensuring openness and transparency of such procurement to prevent corruption and other abuses in the field of procurement, in particular in procurement planning, selection of suppliers, contract conclusion and content procurement monitoring and audit, compliance. Its main characteristics feature a comprehensive contract procurement system, which encompasses federal, local and municipal entities and it is connected in a unified information system. The contract system in procurement under the new law is based on the principles of openness, transparency of information, fair competition, professionalism, encouragement of innovation, unified contract system in procurement, as well as responsibility for ensuring of procurement and meeting state and municipal needs. It has the very important features of compulsory public discussions of procurement orders (Article 20), the provisions for participation of small businesses, and NGOs in procurement (Article 30), the opportunities for monitoring and audit of procurement transactions (Chapter 4). The new law also stipulates national treatment of all suppliers and contractors, which is required after the WTO accession of Russia and which could potentially influence the competitiveness of national applicants, who were subject to preferences under the previous legal regime. As mentioned above,

93 Постановление Правительства РФ от 29 октября 2010 г. № 865 «О государственном регулировании цен на лекарственные препараты, включенные в перечень жизненно необходимых и важнейших лекарственных препаратов» (http://www.consultant.ru/document/cons_doc_LAW_135232/).

the full application of the new law will begin in 2015-2017 and it is expected that secondary legislation in relation to this law will also be passed in the meantime. The new procurement law appears to address many gaps in the procurement system in Russia in the recent past and includes several mechanisms that increase the opportunities for monitoring, control and contesting procurement decisions, which could increase transparency and accountability.

7.1.4 Tajikistan

Public procurements in Tajikistan are regulated by the *Law of the Republic of Tajikistan "On Public Procurements of Goods, Works and Services,"*[94] by government resolutions, ministerial decisions and other legal documents. According to the law, the participants of public procurements are procuring organizations, contractors and the authorized agency – "an executive body established by the Government of the Republic of Tajikistan, which ensures implementation of state policy in the area of procurement of goods, works and services for public funds." This body is specified in the *Resolution of the Government of the Republic of Tajikistan of 3 May 2010 No. 228*.[95] It is the Agency for Public Procurements of Goods, Works and Services under the Government of the Republic of Tajikistan. The agency performs a wide range of procurement-related functions, including providing recommendations on targeted use of budget funds for procurement of goods, works and services; ensuring strict compliance with the law on public procurements; and considering complaints and objections on public procurements.

According to Article 24 of the law, public procurements may be carried out through the following methods: unlimited participation tender, limited participation tender, shortlist tender (specific type of tender with limited participation for procurement of consulting services), call for bids, single source procurements, and electronic procurements. Unless otherwise specified by the law, public procurements are made through unlimited participation tender (i.e. tender with unlimited number of participants). Other options may be used in very specific circumstances, which are specified in the law. A tender with limited number of participants may be chosen if costs of considering a large amount of applications would make one-third of the total contract cost (in such a situation, the number of participants may not be less than three), and if only a limited range of suppliers in the market offer the required goods, works or services (Article 26). Calls for bids are used in instances when the cost of contract does not exceed 2,500 estimate indicators or, in special cases established by the government and in agreement with an authorized agency, for an amount not exceeding 12,500 estimate indicators (in 2014, one estimate indicator equals to 40 TJS or 8.1 USD)[96] (Article 27). A decision to do procurements through a single source may be done: for additional procurements that do not exceed 15 percent of the previously made one and not later than within six months after the previous procurement; in case of a contract for research, experiments or preparation of scientific report; if there is only one entity offering the required goods, works or services (Article 28).

According to the law, procuring organizations must either be staffed with officials with a procurement specialist certificate, issued by the authorized agency, or have a special department, staffed with experts, of whom at least one person has a procurement specialist certificate. Under Article 12, the department prepares annual plans of spending on procurements, develops timetable of each procurement, coordinates the choice of procurement methods, prepares tender documentation, and publishes information about upcoming procurements.

Chapter 4 of the law describes the procedure to be followed for a tender, from invitation to tender and submission of tender applications, to consideration and evaluation of the applications and notification of winning bidder. Paragraph 2 of the chapter outlines

94 Закон Республики Таджикистан «О государственных закупках товаров, работ и услуг» №168 от 3 марта 2006г.

95 Постановление Правительства Республики Таджикистан «Об Агентстве по государственным закупкам товаров, работ и услуг при Правительстве Республики Таджикистан» от 3 мая 2010 года №228 (http://base.spinform.ru/show_doc.fwx?rgn=31334).

96 See the Law of the Republic of Tajikistan "On Estimate Indicator" (Закон Республики Таджикистан «О показателе для расчетов» от 5 января 2008 года № 350, http://base.spinform.ru/show_doc.fwx?rgn=21483), as well as article 23 of the Law of the Republic of Tajikistan "On State Budget of the Republic of Tajikistan in 2013" (Закон Республики Таджикистан «О государственном бюджете Республики Таджикистан в 2013 году» от 19 ноября 2012 года №904, http://www.mmk.tj/ru/library/byudzhet_2013.doc).

a two-stage tender procedure, whereby the financial offers are only considered in a second stage after the evaluation of the technical offers have been concluded. Two-stage tenders are conducted only in certain instances (e.g., when the nature of goods, works or services to be procured require negotiations with contractors, or when it is a research, experiment or a scientific conclusion that has to be procured).

As in other study countries, in Tajikistan the law provides a general framework for conducting public procurements; further details, including specific forms, may be found in bylaws, such as the *Regulations on Procedures of Public Procurements*.[97] Annex 3 of the regulations establishes the procedure for development of an annual procurement plan which consists of a set of measures aimed at identifying and planning procuring organizations' needs in goods, works and services for the coming year, which includes analysis of market trends and of own needs as at the end of the current year. A procuring organization starts developing its plan of procurements for the following year in September of the current year; in November the plan must be published. The procurement department of the organization is responsible for the process (i.e., for coordination of all departments of the procuring organizations). Within ten days after approval of the calculation of costs is by finances department, the procurement plan is submitted to the Agency for Public Procurements of Goods, Works and Services under the Government of the Republic of Tajikistan.

Procurement of medicines (other than ARVs, which are currently procured only through the GFATM grant) for public health facilities are carried out by the Republican Centre for Procurement of Pharmaceutical and Medical Products under the Ministry of Healthcare of the Republic of Tajikistan.

Invitations to participate in public procurements are published on the website of the Agency for Public Procurements of the Republic of Tajikistan (http://zakupki.gov.tj).

97 Положения о процедурах государственных закупок. Утверждено Распоряжением Министерства экономического развития Республики Таджикистан от 17 января 2008 года за №4, зарегистрировано Министерством юстиции Республики Таджикистан 11 февраля 2008 года за №357 (http://zakupki.gov.tj/podzakonnye-akty/).

7.1.5 Uzbekistan

Uzbekistan does not yet have a special law on public procurements, but this may happen in near future. At the time of writing this report, the draft law went through discussions with various stakeholders. Currently, there are several legal documents that regulate public procurements of goods and specifically of medicines:

Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On Measures to Improve the Organization of Tenders" (No. 456 of 21 November 2000).[98] According to the resolution, the procurement of imported and domestically produced commodities for the amount exceeding 100,000 USD per contract shall be done through tenders. Tenders are not required when procurements are done in accordance with procedures of donor countries, international and foreign government and non-government organizations, in accordance with conditions of international credits received under the guarantee of the Republic of Uzbekistan, or under international grants.

When the cost of contract is between 300 and 100,000 USD, there is a different procedure for public procurements, which is regulated by *Resolution of the President of the Republic of Uzbekistan "On Optimization of the System of Public Procurements and Increasing the Involvement of Small Businesses"* (No. PP-1475 of 7 February 2011)[99] and by the *Resolution of the Cabinet of Ministers "On Measures to Improve Normative-Legal Framework for Organization of Public Procurements"* (No. 100 of 1 April 2011),[100] which was adopted for implementation of the mentioned Presidential Resolution. In 2013 the President passed another resolution, *"On Optimization of the System of Electronic Tendering and Expanding the Involvement of Small Businesses"* (No. PP-1948 of 5

98 Постановление Кабинета Министров Республики Узбекистан «О мерах по совершенствованию организации тендерных торгов» (http://www.lex.uz/Pages/GetAct.aspx?lact_id=386482).

99 Постановление Президента Республики Узбекистан от 7 февраля 2011 г. № ПП-1475 «Об оптимизации системы государственных закупок и расширении привлечения к ним субъектов малого бизнеса»

100 Постановление Кабинета Министров Республики Узбекистан «О мерах по совершенствованию нормативно-правовой базы по организации государственных закупок» (http://www.lex.uz/Pages/GetAct.aspx?lact_id=1763395).

April 2013),[101] which addressed public procurement of goods from natural monopolies. According to these documents, when the cost of contract is between 300 and 100,000 USD, public procurements of certain types of commodities, which are determined by the Government Commission for Public Procurements, shall be done by electronic tenders organized the Uzbek National Commodity Exchange, except for instances envisaged by the legislation.

One of such instances is public procurement of medicines and medical tools, which is governed by the *Resolution of the Cabinet of Ministers "On streamlining the sale of medicines and medical commodities"* (No. 19 of 14 January 1999)[102], and the *Regulations on procurements of medicines and medical commodities for inpatient institutions providing the population with free medical assistance*, approved on 21 June 2005 by Resolution No. 56 of the Ministry of Finance and Resolution No. 4 of the Ministry of Healthcare.[103] The regulations describe the procedure to be followed in making procurements of pharmaceutical products. Based on requests from medical institutions, the Ministry of Health determines the demand in pharmaceutical products for the following year, and submits the demand to the Ministry of Finances. The latter considers the demand and includes the cost of the demand in the draft of next financial year's national budget. Upon approval of the budget, the Ministry of Finances transfers to the Ministry of Healthcare the approved amount of budgetary allocations. The regulations describe the instances where special procurement procedures are used (procurement of emergency medicines, vaccines, serums, anaesthetics and narcotic substances), but do not explicitly address the procedure for procurement of medical products for treatment of HIV and other "socially dangerous diseases". However, the Regulations repeat that procurement of pharmaceutical products for the amount exceeding 100,000 USD per contract, shall be done through tenders, as envisaged by the aforementioned Cabinet of Ministers Resolution No. 456.

7.2 Procurement systems used within GFATM projects and their compliance with national procurement frameworks

As was mentioned previously, three of five study countries are recipients of GFATM funding with the largest part of ARV medicines being procured through GFATM grants. As funding flow from the GFATM tends to decrease and more domestic funding is required for the ART scale-up, ARV procurement mechanisms used within GFATM project can be seen as a starting point for transition and potentially also as a benchmark for prices using economies of scale of pooled procurement mechanisms.

> Global Fund grant recipient must employ their best efforts to apply national laws and applicable international obligations in IP, including regulations and flexibilities provided in the TRIPS agreement and interpreted in the Doha Declaration in a manner that achieves the lowest possible price for products of assured quality.

Public procurements legislations often exclude procurements made within grants of international organizations, including the GFATM, from

101 Постановление Президента Республики Узбекистан «Об оптимизации системы электронных закупок и расширении доступа к ним субъектов предпринимательства» (http://lex.uz/Pages/GetAct.aspx?lact_id=2152848).

102 Постановление Кабинета Министров Республики Узбекистан «Об упорядочении реализации лекарственных средств и изделий медицинского назначения» (http://www.lex.uz/Pages/GetAct.aspx?lact_id=262863).

103 Положение о закупках лекарственных средств и изделий медицинского назначения для стационарных лечебных учреждений, оказывающих населению в соответствии с законодательством бесплатную медицинскую помощь.

their regulation. Concurrently, according to the requirements of the GFATM, once a proposal has been approved the PR must describe in a PSM plan how it will adhere to the GFATM PSM requirements. The PSM plan will also be used to measure performance during implementation. In order to prepare a PSM plan, the PR should obtain a full understanding of the "Guide to the Global Fund's Policies on Procurement and Supply Management"[104] (the PSM Guide) and use a template[105] developed by the GFATM.

The PSM Guide strongly emphasizes the need for grant recipients to comply at all times with domestic laws and regulations when procuring and managing the supply of health products, including with any required authorizations relating to those health products in a timely manner. Recipients must employ their best efforts to apply national laws and applicable international obligations in the field of IP, including regulations and flexibilities provided in the TRIPS agreement and interpreted in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality. Another requirement is to procure medicines only if they appear in the current national and/or WHO standard treatment guidelines. Otherwise, the recipient must justify such procurement to the GFATM before launching the procurement process. Finally, all ARVs procured for the GFATM money have to be WHO prequalified (Option A) and/or authorized for use by a Stringent Regulatory Authority (Option B); if only one or no Option A or Option B product is available, such ARVs may be permitted for time-limited procurement after review by the Expert Review Panel.

The guide points out the necessity of drawing upon available regional and global pooled procurement services or agents acceptable to the GF, including the voluntary pooled procurement mechanism, whenever pooling of demand can result in, for example, lower prices or improved lead times. In Belarus, Tajikistan and Uzbekistan, ARV procurements of the UNDP managed GFATM HIV grants have been made through the UNICEF pooled procurement mechanism.

The guide requires that, in accordance with good pharmaceutical procurement practices, each recipient shall use transparent competitive procedures for the purchase of health products in order to obtain the lowest possible price with the required assured quality. National preference in procurement decisions is not acceptable to the GFATM. It should be noted that the guide does not offer any specific algorithms to be followed in carrying out procurements under GFATM grants; instead, it refers to a WHO document, *Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement*.[106] The 12 operational principles for good pharmaceutical procurement, which form the bulk of this document, are based on four strategic objectives: procure the most cost-effective medicines in the right quantities; select reliable suppliers of high-quality products; ensure timely delivery; achieve the lowest possible total cost. The operational principles are presented in four groups as follows:

(a) Efficient and transparent management
- Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.
- Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts;
- Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

(b) Medicine selection and quantification
- Public sector procurement should be limited to an essential medicines list or national/local formulary list.

104 Guide to Global Fund Policies on Procurement and Supply Management of Health Products, June 2012 (http://www.theglobalfund.org/documents/psm/PSM_ProcurementSupplyManagement_Guidelines_en/).

105 http://www.theglobalfund.org/documents/psm/PSM_GuideToPSM_Template_en/.

106 Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement. WHO Geneva, 1999 (http://www.who.int/3by5/en/who-edm-par-99-5.pdf).

- Procurement and tender documents should list medicines by their INN.
- Order quantities should be based on a reliable estimate of actual need.

(c) Financing and competition

- Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.
- Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.
- Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders. The guidelines identify four main methods for purchasing medicines: three of them are competitive (restricted tenders, open tenders and competitive negotiations), and the fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favourable pricing, the public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed. As discussed in Operational Principle 5, medicines which are available from multiple sources should be competitively purchased under their INN.
- Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

(d) Supplier selection and quality assurance

- Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process which considers product quality, service reliability, delivery time and financial viability.
- Procurement procedures/systems should include all assurances that the medicines purchased are of high quality, according to international standards.

Given that UNDP is acting as a PR for GFATM HIV grants currently implemented in Belarus, Tajikistan and Uzbekistan, it is important to take into consideration the UNDP Financial Regulations and Rules,[107] which "govern the financial management of the United Nations Development Programme (UNDP) and shall […] apply to all resources administered by UNDP" (Regulation 1.01).

The following general principles shall be given due consideration when exercising the procurement functions of UNDP:

- Best value for money;
- Fairness, integrity and transparency;
- Effective international competition;
- The interest of UNDP (Regulation 21.02).

UNDP adheres to the requirement of competitive procurements (i.e., to the ninth operational principle of good procurement of pharmaceutical products). According to the Rule 121.03, procurement contracts have to be awarded on the basis of effective competition, which includes:

- Acquisition planning for developing an overall procurement strategy and procurement methodologies;
- Market research to identify potential suppliers;
- Competition on as wide a geographical basis as practicable and suited to market circumstances;
- Consideration of prudent commercial practice;
- Formal methods of solicitation: invitations to bid or requests for proposals on the basis of advertisements or direct solicitation of invited suppliers; or informal methods of solicitation, such as requests for quotations.

These effective competition requirements do not apply when the value of the procurement is below the monetary amount established for formal methods of solicitation; there is no competitive market-place for the requirement, such as where a monopoly exists, where prices are fixed by legislation or government regulation, or where the requirement involves a proprietary product or service; the proposed procurement contract is the result of cooperation with other organizations of the UN system (Rule 121.05).

107 http://web.undp.org/execbrd/pdf/UNDPFinRegsRules.pdf.

Finally, it is important to mention the *UN Procurement Manual*,[108] which is:

> "intended to provide guidance on procurement policies, procedures and practices to all staff members involved in the procurement and acquisition processes and activities in all such offices and locations. The Manual is a compendium of regulations approved by the General Assembly and the related rules and in addition an official guide published by the UN Secretariat Procurement Division (UN/PD) and approved by the Assistant Secretary General/ Office of Central Support Service (ASG/OCSS) for use by management and staff in performing the procurement function. Therefore, the […] Manual provides the legal framework to undertake procurement activities in full compliance with current policies and industry practice. […] Equally, the procedures in this Manual are designed to ensure that those seeking to do business with the UN can be confident that their proposals are considered and assessed in a fair, objective and transparent manner" (Chapter 1, Section 1.1, para. 1 (a)).

It specifically includes a section dealing with types and methods of solicitation (Chapter 9, Part 2, Section 9.9), which envisages that the UN uses three standard types of solicitation documents, namely requests for quotation, invitations to bid, and requests for proposals, each used for a different type of procurement. A request for quotation shall be used for the procurement of goods, services or works with standard and clear specifications and a total estimated value above 4,000 USD and up to 40,000 USD. An invitation to bid shall be used for the procurement of goods with standard and clear specifications and a total estimated value in excess of 40,000 USD. A request for proposals shall be used for procurement of goods, services or works that cannot be quantitatively or qualitatively expressed in sufficient detail to allow for use of an invitation to bid, such as professional or other complex goods, services or works.

Tables 17-19 show the ARV procurements with prices done in 2012 under the UNDP administered GF grants in Belarus, Uzbekistan and Tajikistan. They can serve as orientation for prices achievable under international pooled procurement mechanisms.

108 UN Procurement Manual, Revision 7 (www.un.org/depts/ptd/pdf/pm.pdf).

8. CONCLUSIONS AND RECOMMENDATIONS

Access to affordable, quality ARV medicines for PLHIV in the EECA region continues to be an area of major concern. One reason for this is the current ART coverage of around 35 percent of eligible adults[109]. Given the current dynamics of the HIV epidemic and the challenge of improving quality standards in line with recommendations of the WHO 2013 ART guidelines, and also taking into account that the GFATM, the main external funding agent for ART in the region, announced more stringent eligibility criteria (demanding higher responsibility and more domestic resources from recipient countries, while for others eligibility will completely cease), coordinated government action on country and regional level is required in order to:

- maintain access to affordable ARV medicines for PLHIV even if external funding is reduced
- scale up ART coverage to meet the basic rights for universal access to life-saving services fulfilling national and international quality standards

While these two aims require a comprehensive approach to determine an optimized mix of interventions and investments for each country, considering all prevention, treatment, care and support components of the national HIV responses, the report here focuses exclusively on the challenges governments and their partners will face on country and regional level when they develop optimized 'value for money' policies and strategies for the procurement of ARVs with domestic resources which meet the above two aims in a short-, mid-, and long-term perspective.

Guidelines and regulatory frameworks for ARV medicines and treatment are regarded as critical enablers for the provision of affordable, quality ART services with universal coverage. The report has highlighted four components which represent 'enabling modifiers' and therefore potential targets for coordinated action:

- ART guidelines on national and international levels
- Global, regional and country specific IP frameworks and the current status of ARV patents
- Licensing and registration frameworks for medicines, and the current status of ARV registrations and domestic production
- Regulatory frameworks for public sector procurements in general and for medicines and ARVs in particular

Whereas the up-to-date information and intimate knowledge about these enabling modifiers presented in the report are a pre-condition for governments' and partners' effort to optimize their decision making process, each modifier requires a specific strategic approach reflecting different political, legal and operational dimensions of the underlying frameworks. In addition, the detailed analysis clearly calls for a comprehensive strategic approach which will aim to optimize the benefits for PLHIV through the strengthening of a rights-based public health approach in the context of macro-economic and development policy priorities.

ART guidelines on national and international levels:

- National ART guidelines analysed in this research seem to be outdated and need to be brought to compliance with the 2013 WHO guidelines. Naturally, this process also requires taking into

109 UNAIDS Report on the Global AIDS Epidemic 2012, UNAIDS document JC2417E.

consideration the economic implications of such an update.

- Some countries continue to use first-line medicines that are no longer recommended by the WHO, and phasing out of such medicines does not appear to be planned in written documents.
- In certain cases, there are no ART guidelines adopted by national health authorities, while at the same time there appear to be comprehensive guidelines developed by national expert bodies. Their role and applicability are uncertain.
- Experts from the region have participated in the development of the 2013 WHO Guidelines, but this participation should increase further. There is a need to provide a better nexus between the 2013 Guidelines that focus, among others, on earlier start of treatment, better regimens and medicines, increased use of FDCs, and the economic realities of countries in the EECA region.
- Standardized, updated ART guidelines across the region will help to focus systematically on the optimization of patent, licensing, registration and procurement conditions for recommended ARVs and to make use of coordinated purchasing power in the region. From this perspective, national guideline deviations or even outdated guidelines come at a cost and can be detrimental to the key objective of universal access to affordable and quality treatment services.
- While decisions are taken nationally, the CIS Council on HIV, TB and Malaria can be suitable forum for discussions about aligning of treatment guidelines across the region. WHO, UNAIDS, UNDP and other members of the Joint UN Team on AIDS cooperate with the CIS Council, are represented in the CIS member states and could support such a harmonization process.

Global, regional and country specific IP frameworks and the current status of ARV patents:

- Globally, patent status of ARV medicines is recognized as a potential problem for access to treatment. However, the WTO TRIPS Agreement has public health-related flexibilities, which allow countries to overcome IP barriers for public health needs. These flexibilities have been reaffirmed with the 2001 Doha Declaration on the TRIPS Agreement and public health.
- These flexibilities have successfully been used worldwide, including by all BRICS countries, except Russia. Use of the TRIPS flexibilities has led to substantial reduction of ARV prices and increase of treatment access with both generics and originator medicines.
- The TRIPS flexibilities are not sufficiently well-integrated in national laws of the studied countries (those that are WTO member states), or in the text of the Eurasian Patent Convention. This disadvantage is caused by the fact that many national laws pre-date the TRIPS Agreement and were not reformed to include public health flexibilities. Newer laws have also been drafted so as to strengthen patent protection and do not integrate the TRIPS public health flexibilities sufficiently.
- During WTO accession negotiations several countries have agreed on standards that exceed the requirements of the TRIPS Agreement (TRIPS-plus). Most problematic in terms of access to medicines appear to be the provisions of test data exclusivity agreed upon by Russia and Tajikistan and possibly appearing in Belarus and Kazakhstan due to Customs Union harmonization processes. While countries have already introduced, or are about to introduce, exclusivity provisions in their national laws, they have not introduced flexibilities that mitigate the potentially negative impact of exclusivity on access to essential medicines, including ARVs.
- It should be kept in mind that the TRIPS Agreement has limited provisions on IP enforcement. Patent infringement is associated with civil law measures and remedies, enforced by judicial authorities. The TRIPS Agreement allows administrative procedures to be used to order civil remedies only if such procedures conform to principles equivalent in substance to those set forth in Section 2 of Part III of the TRIPS Agreement for judicial authorities. Any administrative procedures that do not conform to these principles violate the TRIPS Agreement.
- It should be considered that border measures, as per the TRIPS Agreement (Section IV, Part III), apply to counterfeit trademark or pirated copyright goods, and not to patents – and any border measures concerning patents are a TRIPS-plus standard. Globally, border measures have sometimes been applied to quality generic equivalents, including

ARVs, which potentially has a negative impact on public health. Patent holders have the opportunity to seek remedies for alleged patent infringements in civil courts and stop the use of the goods.

- Criminal sanctions according to Section 5, Part III of the TRIPS Agreement are required only for cases of wilful trademark counterfeiting or copyright piracy on a commercial scale, not for patent infringement. While TRIPS allows the extension of criminal sanctions over patent infringement it does not require it. Introducing criminal sanctions for patent infringements may have a detrimental effect for generic producers/importers to enter the market and could potentially affect domestic producers as well, thereby restricting competition and driving prices of medicines up. Countries should be mindful that providing fast and efficient civil law process and remedies may reduce this detrimental effect and ultimately benefit public health systems.
- The harmonization of national laws in the frameworks of the Customs Union could provide a useful opportunity for countries to integrate the TRIPS Agreement public health flexibilities, which could facilitate access to essential medicines, including ARVs. The Customs Union Agreement on Unified Principles of Regulation in Protection of IP Rights could serve as the legal document that justifies such integration.
- While most first line ARV medicines are no longer under patent protection, many new forms, formulations, doses and dosages are patented in the EECA region, which extends the patent life and could hinder access to cheaper generic equivalents. This is particularly relevant in relation to FDCs, use of which is strongly recommended by WHO 2013 Guidelines, and paediatric formulations of ARVs: as long as they are protected by patents, countries would either have to procure more expensive originator versions, or go for cheaper single-compound generics, or adult version generics. This is important when considering harmonized regional updates of ART guidelines.
- Newer first line ARV medicines, as well as almost all second line ARVs, are patent-protected. Most patented ARVs in EECA region are protected with Eurasian patents. As a self-financed organization the EAPO is inherently incentivized to provide more patents. Under certain circumstances this could cause proliferation and "evergreening" (artificial extension) of pharmaceutical patents. It is notable that some new forms/formulations patented with Eurasian patents are not patented in other countries, including BRICS countries.
- On the other hand, the Eurasian Patent Information System provides transparency of the patent status of medicines as well as the duration of patents, which could facilitate procurement planning and financial forecasts.
- Countries should be mindful of the detrimental effect joint enforcement actions on patents may have, especially since patents are granted nationally and since patent disputes for Eurasian patents are administered by Eurasian Patent Organization. Countries should therefore refrain from joint actions regarding alleged patent infringement, especially within the framework of the Customs Union.
- Countries' online patent databases are less transparent and information is sometimes incomplete, in particular in Tajikistan and Uzbekistan.

Licensing and registration frameworks for medicines and the current status of ARV registration:

- Most studied countries have searchable online registration databases, which in the EECA region are quite well-developed, compared to other world regions. However, quality of registration information remains problematic: sometimes medicines' trademark names are entered instead of INNs, generic and originator statuses are conflated and registration details are not always consistent.
- Processes for registering medicines are in general lengthy and expensive, in all studied countries. While some countries have reduced fees for registering generic equivalents, this principle is not followed everywhere. It has been established that high registration and registration maintenance fees particularly affect the competitiveness of generic products. Excessive registration pricing and egregious registration requirements, especially in smaller markets, can lead to generic competitors preferring not to enter the market, limiting the procurement choices and drives the prices of medicines up.
- Licensing of manufacturers and importers of medicines is currently not harmonized in countries

of the Customs Union, while the regulations on trade in medicines across country borders within the borders of the Customs Union are being put into place quite fast. This may lead to some discrepancies in products provided on the market of one Customs Union country by manufacturers and importers registered in another country.

- In the studied countries, the vast majority ARVs are imported. There is a strategic decision, manifested in Russia's Pharmaceutical Sector Development Strategy (Pharma 2020) to produce virtually all active pharmaceutical ingredients for essential medicines (which should include ARVs) by 2018. The implementation of this decision in the context of ARVs could potentially provide an important opportunity for Customs Union countries and other countries in the region to access more affordable, locally produced medicines, due to possible economies of scale.

The public health flexibilities under the TRIPS Agreement have successfully been used worldwide, including by all BRICS countries, except Russia. Use of the TRIPS flexibilities has led to substantial reduction of ARV prices and increase of treatment access with both generics and originator medicines.

Regulatory frameworks for public sector procurements in general and for medicines and ARVs in particular:

- The Russian Federation has adopted and is in the process of implementing, a new, modern law on procurement, which has substantial safeguards of transparency and competitiveness of procurement, as well as monitoring. It may be expected that through harmonisation of legislations within the Customs Union, public procurement laws of Belarus and Kazakhstan will also be reformed to meet unified or harmonized procurement standards.
- Procurement legislation in the other studied countries is less modern, which leaves certain regulatory gaps and imbalances. For instance, out-dated laws sometimes lack strict criteria for choosing a method of procurement, leaving an opportunity for the procuring agency to choose a procurement method. When this opportunity is absued, less transparent limited participation methods may be chosen, which may result in lower quality of procured products and increased procurement prices.
- In some countries, the issue of public procurement of medicines is not sufficiently addressed in the legislation. Application of general procurement mechanisms to the procurement of medicines may lead to negative consequences, such as delays (and therefore stock-outs), high procurement prices, purchasing cheaper single-compound medicines instead of FDCs, etc.

Recommendations

There is evidently a need to scale up and intensify substantially measures and interventions that would increase access to treatment. While this is a comprehensive effort that covers many areas, reducing the cost of treatment and thereby increasing the number of people who can access it is critical for the success of these initiatives. Developing, integrating and implementing pro-access laws, policies and practices would allow lowering the cost and increasing the access to treatment not only to medicines for HIV, but also to a broad array of essential medicines. Policy measures in these directions have successfully been implemented by many countries worldwide and in BRICS countries (except the Russian Federation).[110]

If the Customs Union and the Single Economic Space are to expand, as it is envisioned by the concept of

110 UNDP. *Good Practice Guide: Improving Access to Treatment by Utilizing Flexibilities in WTO TRIPS Agreement,* 2010 (http://content.undp.org/go/newsroom/publications/hiv-aids/good-practice-guide-in-utilizing-flexibilities-in-the-wto-trips-agreement.en). See also James Love, Recent Examples of the Use of Compulsory Licenses on Patents, 2007 http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf.

the EurAsEC, the levels of economic development of countries will become even more diverse with low income countries joining the club. It is clear that alignment of regulatory frameworks, IP laws and policies and registration regulation according to the highest common denominators will pose serious challenges to healthcare systems of the poorer states in this trans-continental economic union. Given the developments in patent protection and test data exclusivity as a result of the WTO accession compromises, it is likely that these challenges may increase. Therefore, it appears reasonable to aim at levels of regulatory and IP protection that could benefit all EECA countries, without compromising quality, safety and efficacy of medicines. In the specific context of HIV this has to be done not only with the current state of the HIV epidemic in mind, but also taking into account epidemiologic prognoses and forecasts for medicines and consumables, including diagnostics, the demand for which is likely to increase in the future.

From the BRICS countries Brazil and South Africa are the two countries that have managed to reverse their HIV epidemics and achieve unprecedented scale ups in HIV treatment. Both countries have also implemented policies that have changed the market of ARV medicines and other life-saving pharmaceuticals. India has not only substantially improved its HIV response but is also referred to as "pharmacy of the world", with over 80 percent of the world's ARV medicines (over 90 percent for paediatric ARVs) produced by its pharmaceutical industry. China's national pharmaceutical manufacturing potential is increasing and the country has gained importance as manufacturer of active pharmaceutical ingredients. All these economies are part of the WTO system. However, they have integrated domestic legislation flexibilities that allow them to develop their domestic production and compete on the market. As a BRICS country and WTO member state, the Russian Federation has the opportunity to take the same path and shape a domestic production, legislation and policy space that fosters competition, promotes national industry and increases affordability of essential medicines while remaining compliant with its international trade and regulatory obligations. Through the Customs Union (Single Economic Space) other countries could also benefit from these developments. These countries should also shape their domestic legislation and policies so as to set an emphasis on public health obligations over proprietary interests.

In line with the above, the following sets of recommendations can be made:

ART guidelines on national and international levels

- Countries should strive to amend their national treatment protocols in order to reflect the most recent WHO ART guidelines. Relevant authorities should communicate with local WHO offices and/or WHO Europe in case there are concerns regarding these revisions. Economic implications of the revisions should also be considered and, when necessary, more affordable solutions should be sought out, including by procurements of generic equivalents, without compromising the quality, safety and efficacy of treatment.
- Relevant international agencies should ensure stronger and earlier involvement of national authorities in the discussions of ART treatment guidelines revisions at international level and advocate for engagement of social, legal and financial in addition to health authorities, in order to optimize feasibility of recommended treatment regimens and schemes.
- Where no official national guidelines exist, or where they have been out-dated, these need to be developed/updated and approved at the national levels as a normative regulation.
- ARV medicines that are no longer recommended by WHO (e.g. stavudine) should be phased out and substituted with equivalents that are compliant with WHO recommendations.
- The CIS Council on HIV, TB and Malaria should strive to support harmonisation of national treatment guidelines and their compliance with the WHO guidelines. Support to countries in this process could be coordinated by the CIS Council. The Joint UN Team on AIDS should strive to increase its cooperation with the CIS Council.

Global, regional and country specific IP frameworks and the current status of ARV patents

- EECA countries should be mindful of the impact of IP protection and enforcement on access to medicines. They should also be mindful of their

different levels of economic development and should avoid aligning their laws and policies in IP protection and enforcement according to the "highest common denominators' (i.e. standards imposed by much wealthier knowledge-based economies). Instead, solutions that benefit all Customs Union countries and especially their healthcare systems should be sought. This may be achieved by establishing standards of different priority levels or by allowing certain degree of flexibility in terms of implementation timeframe.

- WTO Members should integrate the TRIPS Agreement flexibilities to the full in their national legislation, policies and practices and should use these flexibilities, especially to access medicines (as confirmed by the Doha Declaration).
- Countries in their negotiations of WTO accession should be mindful of the negative impact that TRIPS-plus measures in IP protection and enforcement could have on access to medicines and should refrain from making such commitments. If such commitments are to be made, exceptions concerning public health should be included. These countries should strive to benefit from transition periods under WTO law to the maximum.
- Countries should allow administrative procedures to be used to order civil remedies for IP infringement only if such procedures conform to principles equivalent in substance to those set forth in Section 2 of Part III of the TRIPS Agreement for judicial authorities.
- Countries that have adopted TRIPS-plus provisions should integrate mitigating mechanisms which would prevent these provisions from negatively impacting public health, including access to medicines. Countries should consider abandoning such TRIPS-plus provisions if they are unrelated to commitments made in binding agreements.
- Countries should avoid applying border measures to patents so that they do not to block access to generic equivalents.
- Countries should strive to introduce criminal sanctions only for wilful trademark counterfeiting or copyright piracy on a commercial scale, not for patent infringement, in order to avoid possible detrimental effect for generic producers/importers to enter their markets. Countries should provide fast and efficient civil law process and remedies instead.
- Countries should put in place mechanisms which enable them to compensate financially for any remaining negative public health impact of trade agreements through the distribution of economic benefits such agreements provides for other sectors.

Customs Union members should:

- Use the Agreement for Harmonizing the Principles of IP between Customs Union countries to advocate the inclusions of all the TRIPS Agreement flexibilities in national laws.
- Avoid TRIPS-plus protection and enforcement during the harmonization process and always consider the possible negative impact of such measure on access to medicines
- Avoid inclusion of patents in the Customs Union Agreement on coordination of actions to protect the rights to objects of IP (currently patents are not included).
- Develop safeguards that guarantee that customs regulations will not be misused to restrict competition and provide market exclusivity at the cost of public health.

Member states of the Eurasian Patent Convention should:

- Further encourage the transparency of the EAPATIS online information system and searchable database.
- Advocate for reform of the EAPC in order to incorporate the TRIPS Agreement public health flexibilities to the full.
- National authorities should not be discouraged to invalidate Eurasian patents, following due process, in case such patents, according to their opinion, do not correspond to the patentability criteria, or if there is another legally valid reason for their invalidation.

Licensing and registration frameworks for medicines and the current status of ARV registrations and domestic production

- Without compromising quality, safety, and efficacy, relevant authorities should ensure that licensing of pharmaceutical manufacturers, importers, sellers, etc. is carried out in an timely and cost

effective manner which increases competition and not creating disincentives for domestic or foreign entities, regardless of whether they work with originator, or generic medicines.

- Countries, through their drug regulatory authorities, should continue and further expand the practice to maintain searchable online databases for registration status of medicines and encourage their regular update and improvement of accuracy.
- Without compromising quality, safety, and efficacy relevant authorities should create incentives to register medicines in fast and cost efficient manner, in order to secure access to the latest pharmaceutical products for the treatment of HIV and generally.
- In case no legal obstacles exist countries should adopt the practice for reduced fees/simplified or accelerated registration procedures for generic equivalents or medicines registered in other jurisdictions.
- Countries should allow registration by reference to submitted test data unless legal prohibitions exist in legislation; such prohibitions could be a result of a commitment of the country during WTO accession or free trade agreement negotiations. In such cases, countries should introduce exceptions to these exclusivity provisions for public health needs.
- Countries should have procedures for fast and less cumbersome authorization of use of medicines provided with Global Fund grants.
- Countries should refrain from de-registering medicines because of IP disputes.
- Where test data exclusivity is not introduced countries should not accept requests to de-register a medicine because of reference to submitted originator's data.
- Where data exclusivity is introduced countries should not accept requests for de-registration due to reference to submitted data, even if they are considered exclusive under national law, if these data are published anywhere in the world, as they are then no longer "undisclosed information" under the TRIPS Agreement definition.
- Countries should strive to register all medicines recommended in the most recent WHO ART guidelines.
- Relevant authorities should invest in transparent patent information databases with a search function (that also allows searching patents based on international application or international patent numbers), which would facilitate making strategic choices by planning procurement and purchasing of medicines.
- Relevant authorities should improve the quality of registration information by always including INNs, not conflating generic and originator status and providing consistent data.
- Licensing of manufacturers and importers of medicines in countries of the Customs Union should be coordinated to address whether these entities have the right to place products on the market of other Customs Union countries.

Regulatory frameworks for public sector procurements in general and for medicines and ARVs in particular

- Countries should strive to develop and adopt modern laws on procurement, which have substantial safeguards of transparency and competitiveness, as well as provisions on procurement monitoring. The experience of the Russian Federation in this legislation development, as well as advice from relevant international organizations (including the Joint UN Team of AIDS) can be used.
- Customs Union countries should strive to harmonize and coordinate their public procurement laws in order to benefit from the larger market opportunities that the Union offers.
- Countries should consider developing special expeditious rules on the procurement of medicines to avoid delays and stockouts, without compromising transparency and competitiveness.
- Where necessary, countries should reform their procurement regimes and cycles in order to ensure no stockouts, or shortages in supply (with ARVs but also with other essential medicines) take place. Reasonable stock availabilities, informed by previous experience and scientific projections, should always be maintained.
- Countries should use available information from international pooled procurement mechanisms and other examples to benchmark their own procurement prices of ARVs. They can also contribute to rising regional purchasing power by sharing procurement data with each other.

Annexes

Annex 1. ARV registration status in the study countries

Table 13: ARV medicines registered in Belarus

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Single/boosted ARVs					
Abacavir	Ziagen	n/a	GlaxoSmithKline Inc., Canada	26.04.2011	26.04.2016
Abacavir	Ziagen	n/a	Glaxo Wellcome Operations, UK / GlaxoSmithKline Pharmaceuticals S.A., Poland	29.04.2011	29.04.2016
Enfuvirtide	Fuzeon	n/a	F.Hoffmann-La Roche Ltd, Switzerland	25.11.2010	25.11.2015
Etravirine[111]	Intelence	n/a	Janssen-Cilag S.p.A., Italy	22.06.2010	22.06.2015
Lamivudine	Epivir	n/a	Glaxo Operations UK Ltd, UK	28.12.2012	06.11.2013[112]
Lamivudine	Epivir/3TC	n/a	GlaxoSmithKline Inc., Canada	20.10.2009	20.10.2014
Lamivudine	Zeffix	n/a	Glaxo Operations UK Ltd, UK / GlaxoSmithKline Pharmaceuticals S.A., Poland	20.08.2012	20.08.2017
Lopinavir / Ritonavir[113]	Aluvia	n/a	Abbott GmbH & Co. KG, Germany	10.12.2009	10.12.2014
Lopinavir / Ritonavir[114]	Kaletra	n/a	Aesica Queenborough Ltd., UK	24.01.2012	24.01.2017
Nevirapine	Viramune	n/a	Boehringer Ingelheim Pharma GmbH & Co. KG, Germany	15.02.2011	15.02.2016
Nevirapine	Viramune	n/a	Boehringer Ingelheim Roxane Inc., USA	30.11.2010	30.11.2015
Nevirapine	Viramune	n/a	Boehringer Ingelheim Ellas A.E., Greece	01.03.2011	01.03.2016
Ritonavir	Norvir	n/a	Abbott GmbH & Co. KG, Germany	01.03.2011	01.03.2016
Zidovudine	Retrovir	n/a	Glaxo Operations UK Ltd, UK	04.09.2009	04.09.2014

111 The database contains drug class (Non-nucleoside reverse transcriptase inhibitors) instead of international name (Etravirine).

112 It seems like there is a mistake in registration expiry date, as under Belarus legislation, registration is valid for five years.

113 The database contains drug class (Protease inhibitors) instead of INN (Lopinavir / ritonavir).

114 The database contains drug class (Protease inhibitors) instead of INN (Lopinavir / ritonavir).

Table 13: ARV medicines registered in Belarus (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Zidovudine	Retrovir	n/a	GlaxoSmithKline Inc., Canada	06.11.2009	06.11.2014
FDCs					
Abacavir / Lamivudine	Kivexa	n/a	Glaxo Operations UK Ltd, UK	10.12.2012	10.12.2017
Abacavir / Lamivudine / Zidovudine	Trizivir	n/a	GlaxoSmithKline Export Ltd, UK, manufactured by Glaxo Operations UK Ltd, UK	25.05.2012	25.05.2017
Abacavir / Lamivudine / Zidovudine	Trizivir	n/a	Glaxo Operations UK Ltd, UK, packed by GlaxoSmithKline Pharmaceuticals S.A., Poland	04.03.2013	04.03.2018
Emtricitabine / Tenofovir	Tenof-EM	n/a	Hetero Labs Ltd., India Packed by Pharmatex ZAO, Belarus	30.05.2013	30.05.2018
Lamivudine / Zidovudine	Combivir	n/a	Glaxo Operations UK Ltd, UK	30.06.2009	30.06.2014

Source: Website of the Centre for Examinations and Trials in Healthcare under the Ministry of Health of the Republic of Belarus (http://rceth.by). Registration data is as of 09.08.2013.

Table 14: ARV medicines registered in Kazakhstan

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Single/boosted ARVs					
Abacavir	Abacavir sulfate	Tabs, 300 mg	Mylan Laboratories Ltd, India	14.06.2013	14.06.2018
Abacavir	Virol	Tabs, 300 mg	Ranbaxy Laboratories Ltd, India	29.11.2011	29.11.2016
Abacavir	Ziagen	Tabs, 300 mg	Glaxo Operations UK Ltd, UK / Glaxo Wellcome Operations, UK	08.02.2012	08.02.2017
Darunavir	Prezista	Tabs, 400 mg	Janssen Ortho LLC, Puerto-Rico	28.01.2013	28.01.2018
Darunavir	Prezista	Tabs, 600 mg	Janssen Ortho LLC, Puerto-Rico	28.01.2013	28.01.2018
Didanozine	Adozine	Tabs, 25 mg	Ranbaxy Laboratories Ltd, India	19.09.2011	19.09.2016
Didanozine	Adozine	Tabs, 50 mg	Ranbaxy Laboratories Ltd, India	19.09.2011	19.09.2016
Didanozine	Adozine	Tabs, 100 mg	Ranbaxy Laboratories Ltd, India	19.09.2011	19.09.2016
Efavirenz	Efavirenz	Tabs, 600 mg	Mylan Laboratories Ltd, Inda	19.07.2013	19.07.2018
Efavirenz	Efcur	Tabs, 600 mg	Emcure Pharmaceuticals Ltd, India	06.05.2013	06.05.2018
Efavirenz	Eferven	Tabs, 600 mg	Ranbaxy Laboratories Ltd, India	10.04.2012	10.04.2017
Efavirenz	Estiva 600	Tabs, 600 mg	Hetero Drugs Ltd, India	06.09.2011	06.09.2016

Table 14: ARV medicines registered in Kazakhstan (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Efavirenz	Stocrin	Tabs, 600 mg	Zhejiang Huahai Pharmaceutical Co., Ltd, China	10.08.2011	10.08.2016
Etravirine	Intelence	Tabs, 100 mg	Janssen-Cilag S.p.A., Italy	17.09.2009	17.09.2014
Lamivudine	Epivir	Tabs, 150 mg	Glaxo Operations UK Ltd, UK	26.01.2010	26.01.2015
Lamivudine	Heptavir-150	Tabs, 150 mg	Hetero Drugs Ltd, India	10.04.2012	10.04.2017
Lamivudine	Lumidine	Tabs, 100 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	02.05.2013	02.05.2018
Lamivudine	Lumidine	Tabs, 150 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	02.05.2013	02.05.2018
Lamivudine	Lumidine	Tabs, 300 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	02.05.2013	02.05.2018
Lamivudine	Mivux	Tabs, 100 mg	Nobel Almaty Pharmaceutical Factory, Kazakhstan	04.09.2012	04.09.2015
Lamivudine	Virolam	Tabs, 150 mg	Ranbaxy Laboratories Ltd, India	10.06.2010	10.06.2015
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Wellcome Operations, UK	24.09.2010	24.09.2015
Lamivudine	Zeffix	Solution, 5 mg/ml	GlaxoSmithKline Inc., Canada	24.09.2010	24.09.2015
Lopinavir / Ritonavir	Aluvia	Tabs	Abbott GmbH & Co. KG, Germany	26.05.2009	26.05.2014
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg/25 mg	Abbott GmbH & Co. KG, Germany	15.09.2010	15.09.2015
Lopinavir / Ritonavir	Kaletra	Solution	Aesica Queenborough Ltd., UK	15.01.2010	15.01.2015
Nevirapine	Nevipan	Tabs, 200 mg	Ranbaxy Laboratories Ltd	01.09.2010	01.09.2015
Nevirapine	Nevir	Tabs, 200 mg	Emcure Pharmaceuticals Ltd, India	09.01.2009	09.01.2014
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	24.06.2010	24.06.2015
Nevirapine	Viramune	Suspension, 50 mg/5 ml	Boehringer Ingelheim Roxane Inc., USA	18.05.2012	18.05.2017
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany	06.05.2011	06.05.2016
Ritonavir	Norvir	Caps, 100 mg	Catalent France Beinheim SA, France	09.11.2009	09.11.2014
Ritonavir	Ritonavir	Tabs, 100 mg	ZAO "Makiz Pharma", Russia	31.08.2010	31.08.2015
Stavudine	Stag 30	Caps, 30 mg	Hetero Drugs Ltd, India	29.12.2011	29.12.2016
Stavudine	Virostav	Caps, 30 mg	Ranbaxy Laboratories Ltd, India	25.06.2010	25.06.2015
Tenofovir	Viread	Tabs, 300 mg	Nycomed GmbH, Germany	04.02.2011	04.02.2016
Zidovudine	Retrovir	Caps, 100 mg	S.C. Europharm S.A.	07.03.2013	07.03.2018
Zidovudine	Retrovir	Solution, 10 mg/ml	GlaxoSmithKline Inc., Canada	20.03.2013	20.03.2018
Zidovudine	Viro-Z	Tabs, 300 mg	Ranbaxy Laboratories Ltd, India	12.11.2010	12.11.2015
Zidovudine	Zido-H 300	Tabs, 300 mg	Hetero Labs Ltd for NV Holding, China	21.06.2012	21.06.2017
Zidovudine	Zidovudine	Tabs, 300 mg	ZAO "Makiz Pharma", Russia	15.12.2010	15.12.2015

Table 14: ARV medicines registered in Kazakhstan (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
FDCs					
Abacavir / Lamivudine	Kivexa	Tabs	Glaxo Operations UK Ltd, UK / Glaxo Wellcome Operations, UK	04.06.2012	04.06.2017
Abacavir / Lamivudine / Zidovudine	Trizivir	Tabs	Glaxo Wellcome Operations, UK	05.09.2008	05.09.2013
Emtricitabine / Tenofovir	Truvada	Tabs	Nycomed GmbH, Germany	29.10.2010	29.10.2015
Lamivudine / Nevirapine / Stavudine	Nevilast-30	Tabs	Hetero Drugs Ltd, India	04.06.2012	04.06.2017
Lamivudine / Zidovudine	Combivir	Tabs	Glaxo Operations UK Ltd, UK	21.11.2012	21.11.2017
Lamivudine / Zidovudine	Farnovir-900	Tabs, 300 mg / 600 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	03.05.2013	03.05.2018
Lamivudine / Zidovudine	Farnovir-450	Tabs, 150 mg / 300 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	03.05.2013	03.05.2018
Lamivudine / Zidovudine	Lazid	Tabs	Emcure Pharmaceuticals Ltd, India	06.05.2013	06.05.2018
Lamivudine / Zidovudine	Virocomb	Tabs	Ranbaxy Laboratories Ltd, India	29.01.2010	29.01.2015
Lamivudine / Zidovudine	Zidolam	Tabs	Hetero Drugs Ltd, India	19.09.2011	19.09.2016
Lamivudine / Zidovudine / Nevirapine	Zidolam – N	Tabs	Hetero Drugs Ltd, India	25.01.2012	25.01.2017

Source: National Centre for Examination of Medical Drugines, Medical Tools and Products (http://www.dari.kz/category/gos_reestr_excel). Registration data is as of 09.08.2013.

Table 15: ARV medicines registered in Russian Federation

INN	Trade name	Dosage form	Company	Registration date	Validity
Single/boosted ARVs					
Abacavir	Abacavir sulfate	n/a	Cdymax Pharma PVT LTD, India	27.05.2013	n/a
Abacavir	Abacavir sulfate	n/a	Tehnologiya lekarstv, Ltd, Russia	19.07.2013	n/a
Abacavir	Ziagen	Tabs, 300 mg	GlaxoSmithKline Pharmaceuticals C.A., Poland	24.06.2010	n/a

Table 15: ARV medicines registered in Russian Federation (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Abacavir	Ziagen	Tabs, 300 mg	GlaxoSmithKline Pharmaceuticals C.A., Poland	15.11.2012	n/a
Abacavir	Ziagen	Tabs, 300 mg	GlaxoSmithKline Pharmaceuticals C.A., Poland	24.06.2010	n/a
Abacavir	Ziagen	Solution, 20 mg/ml	GlaxoSmithKline Inc., Canada	05.05.2010	n/a
Abacavir	Ziagen	Solution, 20 mg/ml	GlaxoSmithKline Inc., Canada	05.05.2010	n/a
Atazanavir	Reyataz	Caps, 300 mg	Bristol-Myers Squibb Co., Italy	26.09.2011	26.09.2016
Atazanavir	Reyataz	Caps, 150 mg	Bristol-Myers Squibb S.r.l., Italy	26.01.2010	n/a
Atazanavir	Reyataz	Caps, 150 mg	PJSC "ORTAT", Russia	26.01.2010	n/a
Darunavir	Prezista	Tabs, 600 mg	Janssen Cilag S.p.A., Italy	15.05.2009	n/a
Darunavir	Prezista	Tabs, 400 mg	Janssen Ortho LLC, Puerto-Rico	15.05.2009	n/a
Darunavir	Prezista	Tabs, 75 mg	Janssen Ortho LLC, Puerto-Rico	18.08.2010	n/a
Didanosine	Didanosine	n/a	Aurobindo Pharma Ltd., India	24.01.2013	24.01.2018
Didanosine	Videx	Caps, 250 mg	Bristol-Myers Squibb Co., USA	12.05.2011	n/a
Efavirenz	Efavirenz	n/a	Cdymax Pharma PVT LTD, India	26.03.2013	n/a
Efavirenz	Stocrin	Tabs, 600 mg	Merck Sharp & Dohme B.V., Netherlands	20.05.2011	n/a
Efavirenz	Stocrin	Tabs, 200 mg	Zhejiang Huahai Pharmaceutical Co., Ltd, China	29.09.2008	n/a
Emtricitabine	Emtricitabine	n/a	Acebright Pharma Pvt Ltd, India	23.08.2013	n/a
Enfuvertide	Fuzeon	Lyophilizate, 90 mg/ml	Roche Diagnostics GmbH, Germany	15.12.2009	n/a
Fosamprenavir	Telzir	Tabs, 700 mg	Glaxo Wellcome Operations, UK	30.06.2010	n/a
Fosamprenavir	Telzir	Tabs, 700 mg	Glaxo Operations UK Ltd., UK	30.06.2010	n/a
Fosamprenavir	Telzir	Tabs, 700 mg	Glaxo Wellcome Operations, UK	30.06.2010	n/a
Fosamprenavir	Telzir	Suspension, 50 mg/ml	GlaxoSmithKline Inc., Canada	30.06.2010	n/a
Lamivudine	Epivir	Tabs, 300 mg	GlaxoSmithKline Pharmaceuticals C.A., Poland	28.09.2011	28.09.2016
Lamivudine	Epivir	n/a	Glaxo Operations UK Ltd., UK	28.09.2011	28.09.2016
Lamivudine	Epivir	Tabs, 150 mg	Glaxo Operations UK Ltd, UK	11.12.2008	n/a
Lamivudine	Epivir	Solution, 10 mg/ml	GlaxoSmithKline Inc., Canada	22.07.2009	n/a
Lamivudine	Epivir 3TC	Solution, 10 mg/ml	GlaxoSmithKline Inc., Canada	22.07.2009	n/a
Lamivudine	Heptavir-150	n/a	Makiz Pharma, Russia	27.02.2012	27.02.2017

Table 15: ARV medicines registered in Russian Federation (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Lamivudine	Heptavir-150	Tabs, 150 mg	Hetero Drugs Ltd, India	27.02.2012	27.02.2017
Lamivudine	Heptavir-150	Tabs, 150 mg	Hetero Drugs Ltd, India	27.02.2012	27.02.2017
Lamivudine	Lamivudine	n/a	Aurobindo Pharma Ltd., India	13.02.2013	13.02.2018
Lamivudine	Lamivudine	Powder substance	Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd., China	02.07.2012	n/a
Lamivudine	Lamivudine	Powder substance	Anhui Biochem United Pharmaceutical Co., Ltd., China	23.08.2012	n/a
Lamivudine	Lamivudine	Powder substance	Hetero Labs Ltd, India	03.12.2012	n/a
Lamivudine	Lamivudine	n/a	Tehnologiya Lekarstv, Ltd., Russia	29.12.2012	n/a
Lamivudine	Lamivudine	n/a	Shanghai Desano Chemical Pharmaceutical Co., Ltd., China	29.12.2012	n/a
Lamivudine	Lamivudine-3TC	Tabs, 150 mg	Tehnologiya Lekarstv, Ltd., Russia	02.07.2012	02.07.2017
Lamivudine	Lamivudine-3TC	n/a	Tehnologiya Lekarstv, Ltd., Russia	02.07.2012	02.07.2017
Lamivudine	Virolam	Tabs, 150 mg	Ranbaxy Laboratories Ltd, India	21.09.2011	21.09.2016
Lamivudine	Zeffix	Tabs, 100 mg	GlaxoSmithKline Trading, Russia	24.06.2010	n/a
Lopinavir	Lopinavir	n/a	Cdymax Pharma PVT LTD, India	15.05.2013	n/a
Lopinavir / Ritonavir	Kaletra	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	28.12.2010	28.12.2015
Nelfinavir	Liracept	Powder, 50 mg/g	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	28.11.2011	28.11.2016
Nevirapine	Nevirapine	Tabs, 200 mg	Hetero Drugs Ltd, India	09.04.2010	n/a
Nevirapine	Nevirapine	n/a	Makiz Pharma, Russia	09.04.2010	n/a
Nevirapine	Nevirapine	Substance	Hetero Labs Ltd, India	08.07.2011	n/a
Nevirapine	Nevirapine	n/a	Shanghai Desano Chemical Pharmaceutical Co., Ltd., China	29.12.2012	n/a
Nevirapine	Nevirapine	n/a	Tehnologiya Lekarstv, Ltd., Russia	25.04.2013	n/a
Nevirapine	Viramune	Suspension, 50 mg / 5 ml	Boehringer Ingelheim Roxane Inc., USA	26.08.2010	n/a
Nevirapine	Viramune	Suspension, 50 mg / 5 ml	Boehringer Ingelheim Roxane Inc., USA	26.08.2010	n/a
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	05.11.2009	n/a
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	05.11.2009	n/a
Ritonavir	Norvir	Tabs, 100 mg	Abbott Laboratories, Ltd, Russia	24.11.2011	24.11.2016
Ritonavir	Norvir	Caps, 100 mg	Aesica Queenborough Ltd., UK	29.02.2008	n/a

Table 15: ARV medicines registered in Russian Federation (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Ritonavir	Rinvir	Caps, 100 mg	Lok-Beta Pharmaceuticals (I) Pvt. Ltd.	28.11.2011	28.11.2016
Ritonavir	Ritonavir	Tabs, 100 mg	Makiz Pharma, Russia	11.01.2012	11.01.2017
Ritonavir	Ritonavir	Half-finished	Hetero Drugs Ltd, India	04.05.2010	n/a
Ritonavir	Ritonavir	n/a	Cdymax Pharma PVT LTD, India	29.12.2012	n/a
Ritonavir	Ritonavir -100	Caps, 100 mg	Hetero Drugs Ltd, India	13.04.2012	n/a
Saquinavir	Saquinavir Mesylate	n/a	Cdymax Pharma PVT LTD, India	16.07.2013	n/a
Stavudine	Stag	Caps, 30 mg	Hetero Drugs Ltd, India	09.03.2011	n/a
Stavudine	Stavudine	Caps, 30 mg	Obolenskoe Pharmaceutical Enterprise, Russia	21.07.2010	n/a
Stavudine	Stavudine	Caps, 30 mg	Obolenskoe Pharmaceutical Enterprise, Russia	21.07.2010	n/a
Stavudine	Stavudine	Powder substance	Hetero Labs Ltd, India	28.10.2009	n/a
Stavudine	Stavudine	Powder substance	Astrix Laboratories Ltd., India	13.11.2009	n/a
Stavudine	Stavudine	n/a	Shanghai Desano Chemical Pharmaceutical Co., Ltd., China	22.05.2013	n/a
Stavudine	Vudistav	Caps, 40 mg	Ranbaxy Laboratories Ltd, India	11.11.2011	n/a
Stavudine	Zerit	Caps, 30 mg	Bristol-Myers Squibb S.r.l., Italy	24.03.2009	n/a
Stavudine	Zerit	Caps, 30 mg	Bristol-Myers Squibb Co., France	24.03.2009	n/a
Stavudine	Zerit	Powder, 1 mg/ml	Bristol-Myers Squibb Co., USA	30.04.2009	n/a
Tenofovir	Tenofovir Disoproxil Fumarate	n/a	Hetero Labs Ltd., India	28.09.2011	n/a
Tenofovir	Viread	n/a	Gilead Sciences Ltd., USA	03.10.2011	03.10.2016
Tenofovir	Viread	n/a	Catalent Germany Schorndorf GmbH, Germany	03.10.2011	03.10.2016
Tenofovir	Tenofovir	Tabs	Hetero Labs Ltd., India	30.03.2010	n/a
Tenofovir	Tenofovir	Tabs, 300 mg	Hetero Labs Ltd., India	30.03.2010	n/a
Tenofovir	Tenofovir	n/a	Makiz Pharma Ltd., Russia	30.03.2010	n/a
Zidovudine	Azidothymidine	Caps, 100 mg	PJSC "Biopharma", Russia	09.06.2010	n/a
Zidovudine	Azimitem	n/a	OJSC "Pharmasyntez", Russia	11.07.2013	11.07.2018
Zidovudine	Retrovir	Solution, 10 mg/ml	Glaxo Operations UK Ltd., UK	19.12.2008	n/a

Table 15: ARV medicines registered in Russian Federation (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Zidovudine	Retrovir	Solution, 50 mg / 5 ml	GlaxoSmithKline Inc., Canada	31.05.2010	n/a
Zidovudine	Retrovir	Solution, 50 mg / 5 ml	GlaxoSmithKline Inc., Canada	28.05.2009	n/a
Zidovudine	Retrovir	Solution, 50 mg / 5 ml	GlaxoSmithKline Inc., Canada	28.05.2009	n/a
Zidovudine	Thymazidum	Powder substance	AZT Pharmaceutical Company, Russia	12.12.2008	n/a
Zidovudine	Thymazidum	Caps, 100 mg	AZT Pharma K.B., Russia	28.10.2009	n/a
Zidovudine	Thymazidum	Caps, 100 mg	AZT Pharma K.B., Russia	28.10.2009	n/a
Zidovudine	Viro-Z	Tabs, 300 mg	Ranbaxy Laboratories Ltd, India	13.08.2009	n/a
Zidovudine	Zido-H	Tabs, 300 mg	Hetero Drugs Ltd, India	04.05.2012	n/a
Zidovudine	Zidovirine	Caps, 100 mg	OJSC "Veropharm", Russia	18.05.2011	n/a
Zidovudine	Zidovudine	n/a	Zhejiang Xinhua Pharmaceutical Co., Ltd, China	07.08.2013	n/a
Zidovudine	Zidovudine	n/a	Anhui Biochem United Pharmaceutical Co., Ltd., China	07.08.2013	n/a
Zidovudine	Zidovudine	Tabs, 300 mg	Aurobindo Pharma Ltd. (India), Moscow Representative Office, Russia	14.02.2011	14.02.2016
Zidovudine	Zidovudine	Caps, 100 mg	Obolenskoe Pharmaceutical Enterprise, Russia	27.07.2010	n/a
Zidovudine	Zidovudine	Caps, 100 mg	Obolenskoe Pharmaceutical Enterprise, Russia	27.07.2010	n/a
Zidovudine	Zidovudine	Powder substance	Hetero Labs Ltd, India	09.11.2009	n/a
Zidovudine	Zidovudine	n/a	Tehnologiya Lekarstv, Ltd., Russia	17.04.2013	n/a
Zidovudine	Zidovudine	n/a	Shanghai Desano Chemical Pharmaceutical Co., Ltd., China	17.05.2013	n/a
Zidovudine	Zidovudine-Ferein	Caps, 100 mg	Bryntsalov A. ZAO	09.06.2009	n/a
FDCs					
Abacavir / Lamivudine / Zidovudine	Trizivir	Tabs	Glaxo Wellcome Operations, UK	25.05.2009	n/a
Emtricitabine / Tenfovir	Truvada	Tabs	Gilead Sciences Ltd., USA	29.09.2011	29.09.2016
Emtricitabine / Tenfovir	Truvada	n/a	Gilead Sciences Inc., USA	29.09.2011	29.09.2016

Table 15: ARV medicines registered in Russian Federation (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Lamivudine / Zidovudine	Combivir	Tabs, 150 mg / 300 mg	Glaxo Operations UK Ltd., UK	13.11.2009	n/a
Lamivudine / Zidovudine	Combivir	Tabs, 150 mg / 300 mg	Glaxo Operations UK Ltd., UK	13.11.2009	n/a
Lamivudine / Zidovudine	Combivir	n/a	Glaxo Operations UK Ltd., UK	13.11.2009	n/a
Lamivudine / Zidovudine	Virocomb	Tabs, 150 mg / 300 mg	Ranbaxy Laboratories Ltd, India	11.11.2011	11.11.2016
Lamivudine / Zidovudine / Nevirapine	Zidolam – N	Tabs, 150 mg / 200 mg / 300 mg	Hetero Drugs Ltd, India	02.07.2012	02.07.2017
Lamivudine / Zidovudine / Nevirapine	Zidolam – N	n/a	Hetero Drugs Ltd, India	02.07.2012	02.07.2017

Source: State Registry of Medicines (http://grls.rosminzdrav.ru/grls.aspx), as of 18 September 2013

Table 16: ARV medicines registered in the Republic of Uzbekistan

INN	Trade name	Dosage form	Company	Registration date	Validity
Single/boosted ARVs					
Abacavir sulfate	Abacavir sulfate	Tabs, 300 mg	Aurobindo Pharma Ltd., India	10.08.2012	n/a[115]
Abacavir sulfate	Abacavir sulfate	Tabs, 300 mg	Mylan Laboratories Ltd, India	08.10.2012	n/a
Abacavir	Ziagen	Tabs, 300 mg	Glaxo Operations UK Ltd, UK	15.02.2013	n/a
Didanosine	Didanosine	Caps, 400 mg	Aurobindo Pharma Ltd., India	03.02.2012	n/a
Efavirenz	Efavir 200	Caps, 200 mg	Cipla Ltd., India	29.12.2009	n/a
Efavirenz	Efavirenz	Tabs, 600 mg	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Efavirenz	Efavirenz	Tabs, 600 mg	Mylan Laboratories Ltd., India	08.10.2012	n/a
Efavirenz	Efcure- 600	Tabs, 600 mg	Emcure Pharmaceuticals Ltd., India	31.01.2011	n/a

115 The register published on the Ministry of Health website does not contain the date of registration expiration. But according to legislation of Uzbekistan, the period of registration validity is five years.

Table 16: ARV medicines registered in the Republic of Uzbekistan (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Lamivudine	Lamine	Solution, 50 mg / 5 ml	Jurabek Laboratories, Ltd., JV, Uzbekistan	25.03.2011	n/a
Lamivudine	Lamivudine	Solution, 10 mg/ml	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Lamivudine	Lamivudine	Tabs, 150 mg	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Lamivudine	Lamivudine	Tabs, 150 mg	Matrix Laboratories Ltd, India	08.10.2012	n/a
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Operations UK Ltd, UK; packed by GlaxoSmithKline Pharmaceuticals S.A., Poland	15.08.2008	n/a
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg	Abbott GmbH & Co. KG, Germany	16.01.2009	n/a
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	20.08.2010	n/a
Lopinavir / Ritonavir	Kaletra	Solution	Aesica Queenborough Ltd., UK	17.12.2010	n/a
Lopinavir / Ritonavir	Lopinavir 200 mg & Ritonavir 50 mg tablets	Tabs, 200 mg / 50 mg	Aurobindo Pharma Ltd, India	12.08.2011	n/a
Lopinavir, Ritonavir	Lopinavir / Ritonavir	Tabs, 200 mg / 50 mg	Matrix Laboratories Ltd, India	06.03.2009	n/a
Nelfinavir	Nelvir 250	Tabs, 250 mg	Cipla Ltd., India	29.12.2009	n/a
Nelfinavir	Viracept	Tabs, 250 mg	Roche Pharma SA, Spain, for F.Hoffmann-La Roche Ltd, Switzerland	17.01.2011	n/a
Nevirapine	Nevirapine	Tabs, 200 mg	Aurobindo Pharma Ltd., India	06.02.2012	n/a
Nevirapine	Nevirapine	Suspension, 50 mg / 5 ml	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Nevirapine	Nevirapine	Tabs, 200 mg	Mylan Laboratories Ltd, India	08.10.2012	n/a
Nevirapine	Viramune	Suspension, 50 mg / 5 ml	Boehringer Ingelheim International GmbH, Germany, manufactured by Boehringer Ingelheim Roxane Inc., USA	06.03.2009	n/a
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	06.04.2012	n/a
Ritonavir	Norvir	Caps, 100 mg	Aesica Queenborough Ltd, UK, and Catalent France Beinheim SA, France	17.12.2010	n/a
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany, for Abbott Laboratories SA, Switzerland	08.07.2011	n/a
Saquinavir	Invirase	Caps, 200 mg	F.Hoffmann-La Roche Ltd., Switzerland, manufactured by Roche Farma S.A., Spain	12.08.2011	n/a
Stavudine	Stavudine	Caps, 30 mg	Aurobindo Pharma Ltd., India	10.08.2012	n/a

Table 16: ARV medicines registered in the Republic of Uzbekistan (cont.)

INN	Trade name	Dosage form	Company	Registration date	Validity
Stavudine	Stavudine	Powder, 1 mg/ml	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Tenofovir disoproxil fumarate	Viread	Tabs, 300 mg	Gilead Sciences, Inc., USA, manufactured by Nycomed GmbH, Germany	14.02.2011	n/a
Zidovudine	Zidovudine	Tabs, 300 mg	Aurobindo Pharma Ltd., India	10.08.2012	n/a
Zidovudine	Zidovudine	Suspension, 50 mg / 5 ml	Aurobindo Pharma Ltd., India	10.08.2012	n/a
FDCs					
Emtricitabine / Tenofovir disoproxil fumarate	Emtricitabine / Tenofovir disoproxil fumarate	Tabs, 200 mg / 300 mg	Matrix Laboratories Ltd, India	06.03.2009	n/a
Emtricitabine / Tenofovir disoproxil fumarate	Truvada	Tabs, 200 mg / 300 mg	Gilead Sciences, Inc., USA, manufactured by Nycomed GmbH, Germany	14.02.2011	n/a
Lamivudine / Stavudine	Lamivudine / Stavudine	Tabs, 150 mg / 30 mg	Matrix Laboratories Ltd, India	06.03.2009	n/a
Lamivudine / Zidovudine	Combivir	Tabs, 150 mg / 300 mg	Glaxo Operations UK Ltd, UK	21.11.2008	n/a

Source: State registry of registered medicines in Uzbekistan (www.minzdrav.uz/en/services/registry/), as of 10 November 2013.

Annex 2. ARV procurements under Global Fund grants in Belarus, Tajikistan and Uzbekistan in 2012

Table 17: ARV procurement in 2012 under UNDP administered Global Fund grant in Belarus

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV (INN) spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	3TC	3TC 150 mg tablets	Pack (60 tablets)	Ranbaxy Laboratories Ltd	3,000	2.13	6,390	4/26/2012	7,708	17,218	2.23	1.46%	2.58	19,895
	3TC	3TC 150 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	2,708	2.30	6,228	8/23/2012						
	3TC	3TC 150 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	2,000	2.30	4,600	8/23/2012						
	3TC	3TC 10 mg/ml oral solution	Bottle (240 ml)	Cipla Ltd	515	1.32	680	4/26/2012	515	680	1.32	0.06%	1.53	785
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	1,562	12.49	19,509	8/23/2012	1,562	19,509	12.49	1.66%	14.43	22,542
	ABC	ABC 20 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	92	12.00	1,104	8/23/2012	92	1,104	12.00	0.09%	13.87	1,276
	ATV	ATV 300 mg tablets	Pack (30 tablets)	Emcure Pharmaceuticals Ltd	120	22.00	2,640	12/10/2012	120	2,640	22.00	0.22%	25.42	3,050
	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Cipla Ltd	735	3.14	2,308	4/26/2012	735	2,308	3.14	0.20%	3.63	2,667
	AZT	AZT 10 mg/ ml infusion solution	Box (5 bottles of 20 ml)	Glaxo SmithKline Ltd	25	35.12	878	4/26/2012	25	878	35.12	0.07%	40.58	1,014
	ddI	ddI 200 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	552	11.00	6,072	4/26/2012	18,512	212,388	11.47	18.06%	13.26	245,406
	ddI	ddI 200 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	448	11.00	4,928	4/26/2012						
	ddI	ddI 200 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	10,000	11.50	115,000	8/23/2012						
	ddI	ddI 200mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	7,512	11.50	86,388	8/23/2012						

Table 17: ARV procurement in 2012 under UNDP administered Global Fund grant in Belarus (cont.)

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV (INN) spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	DRV	DRV 300 mg tablets	Pack (120 tablets)	Janssen-Cilag International NV	198	696.00	137,808	4/26/2012	198	137,808	696.00	11.72%	804.20	159,232
	EFV	EFV 600 mg capsules	Pack (30 capsules)	Hetero Drugs Ltd	10,250	3.60	36,900	4/26/2012	30,348	107,243	3.53	9.12%	4.08	123,915
	EFV	EFV 600 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	10,098	3.50	35,343	8/23/2012						
	EFV	EFV 600 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	10,000	3.50	35,000	8/23/2012						
	LPV/r	LPV 200 mg + r 50mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	2,874	30.00	86,220	4/26/2012	7,711	206,064	26.72	17.53%	30.88	238,099
	LPV/r	LPV 200 mg + r 50mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	626	30.00	18,780	4/26/2012						
	LPV/r	LPV 200 mg + r 50mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	2,000	24.00	48,000	8/23/2012						
	LPV/r	LPV 200 mg + r 50mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	2,211	24.00	53,064	8/23/2012						
	LPV/r	LPV 80 mg + r 20mg/ml oral solution	Box (5 bottles of 60ml)	Abbot Laboratories Ltd	12	60.80	730	8/23/2012	12	730	60.80	0.06%	70.25	843
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	1,400	2.50	3,500	4/26/2012	6,253	15,390	2.46	1.31%	2.84	17,782
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	2,853	2.45	6,990	8/23/2012						
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	2,000	2.45	4,900	8/23/2012						
	NVP	NVP 10 mg/ ml oral suspension	Bottle (240 ml)	Aurobindo Pharma Ltd	242	1.95	472	8/23/2012	242	472	1.95	0.04%	2.25	545
	RAL	RAL 400 mg tablets	Pack (60 tablets)	Merck Sharp & Dohme Ltd	120	360.00	43,200	9/11/2012	120	43,200	360.00	3.67%	415.97	49,916
	RTV	RTV 100 mg tablets	Pack (30 tablets)	Mylan Laboratories Ltd	202	7.28	1,471	4/26/2012	202	1,471	7.28	0.13%	8.41	1,699

Table 17: ARV procurement in 2012 under UNDP administered Global Fund grant in Belarus (cont.)

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV (INN) spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	TDF	TDF 300 mg tablets	Pack (30 tablets)	Gilead Sciences, Inc.	850	36.00	30,600	4/26/2012	3,264	41,946	12.85	3.57%	14.85	48,467
	TDF	TDF 300 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	1,500	4.70	7,050	8/23/2012						
	TDF	TDF 300 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	914	4.70	4,296	8/23/2012						
FDCs	3TC/ ABC/ AZT	3TC 150 mg + ABC 300 mg + AZT 300 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	400	30.00	12,000	4/26/2012	565	16,620	29.42	1.41%	33.99	19,204
	3TC/ ABC/ AZT	3TC 150 mg + ABC 300 mg + AZT 300 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	165	28.00	4,620	4/26/2012						
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	8,500	7.85	66,725	4/26/2012	31,098	231,690	7.45	19.70%	8.61	267,710
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	11,000	7.30	80,300	8/23/2012						
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	11,598	7.30	84,665	8/23/2012						
	FTC/ TDF	FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Gilead Sciences, Inc.	1,650	54.00	89,100	4/26/2012	5,423	116,454	21.47	9.90%	24.81	134,558
	FTC/ TDF	FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	3,773	7.25	27,354	8/23/2012						
	Total									**1,175,813**		**100.00%**		**1,358,607**

Table 18: ARV procurement in 2012 under UNDP administered Global Fund grant in Tajikistan

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV (INN) spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	3TC	3TC 150 mg tablets	Pack (60 tablets)	Hetero Labs Ltd	307	2.30	706	10/2/2012	307	706	2.30	0.26%	3.21	985
	3TC	3TC 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	1,659	2.35	3,899	10/2/2012	1,659	3,899	2.35	1.44%	3.28	5,439
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	287	16.40	4,707	10/2/2012	287	4,707	16.40	1.74%	22.88	6,566
	ABC	ABC 20 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	301	12.00	3,612	10/2/2012	301	3,612	12.00	1.33%	16.74	5,039
	AZT	AZT 10 mg/ml oral solution	Bottle (100 ml)	Cipla Ltd	50	2.10	105	10/2/2012	806	2,222	2.76	0.82%	3.85	4,000
	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	756	2.80	2,117	10/2/2012						
	EFV	EFV 600 mg tablets	Pack (30 tablets)	Strides Arcolab Ltd	4,721	3.85	18,176	10/2/2012	14,721	56,676	3.85	20.94%	5.17	79,064
	EFV	EFV 600 mg tablets	Pack (30 tablets)	Strides Arcolab Ltd	10,000	3.85	38,500	30/09/12						
	EFV	EFV 200 mg tablets	Pack (90 tablets)	Strides Arcolab Ltd	100	9.30	930	30/09/12	359	3,339	9.30	1.23%	12.96	4,658
	EFV	EFV 200 mg tablets	Pack (90 tablets)	Strides Arcolab Ltd	259	9.30	2,409	10/2/2012						
	LPV/r	LPV 100 mg + r 20mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	100	10.28	1,028	10/2/2012	100	1,028	10.28	0.38%	14.34	1,434
	LPV/r	LPV 200 mg + r 50mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	1,064	36.00	38,304	10/2/2012	1,064	38,304	36.00	14.15%	50.23	53,435
	LPV/r	LPV 80 mg + r 20 mg/ml oral solution	Box (5 bottles of 60 ml)	Abbott Laboratories Ltd	98	60.80	5,958	10/2/2012	98	5,958	60.80	2.20%	84.82	8,312
	NVP	NVP 200 mg tablets	Container (60 tablets)	Strides Arcolab Ltd	1,813	2.40	4,351	10/2/2012	1,813	4,351	2.40	1.61%	3.35	6,070
	NVP	NVP 10 mg/ml oral suspension	Bottle (240 ml)	Aurobindo Pharma Ltd	924	1.95	1,802	10/2/2012	924	1,802	1.95	0.67%	2.72	2,514

Table 18: ARV procurement in 2012 under UNDP administered Global Fund grant in Tajikistan (cont.)

FDCs	3TC/ ABC	3TC 300 mg + ABC 600 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	100	22.00	2,200	10/2/2012	100	2,200	22.00	0.81%	30.69	3,069
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Ranbaxy Laboratories Ltd	10,055	7.85	78,932	10/2/2012	17,363	136,300	7.85	50.36%	10.95	190,141
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	7,308	7.85	57,368	10/2/2012						
	EFV/ FTC/ TDF	EFV 600 mg + FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Cipla Ltd	100	15.75	1,575	10/2/2012	100	1,575	15.75	0.58%	21.97	2,197
	FTC/ TDF	FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Aurobindo Pharma Ltd	455	8.75	3,981	10/2/2012	455	3,981	8.75	1.47%	12.21	5,554
	Total									**270,660**		**100.00%**		**377,576**

Table 19: ARV procurement in 2012 under UNDP administered Global Fund grant in Uzbekistan

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	3TC	3TC 150 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	5,800	2.40	13,920	1/14/2012	32,800	78,320	2.39	4.54%	2.84	93,134
	3TC	3TC 150 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	8,000	2.35	18,800	5/26/2012						
	3TC	3TC 150 mg tablets	Pack (60 tablets)	Mylan Laboratories Ltd	6,000	2.40	14,400	6/23/2012						
	3TC	3TC 150 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	13,000	2.40	31,200	10/13/2012						
	3TC	3TC 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	6,700	1.65	11,055	2/25/2012	10,700	17,655	1.65	1.02%	1.96	20,994
	3TC	3TC 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	4,000	1.65	6,600	1/14/2012						
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	900	15.00	13,500	1/7/2012	13,600	204,000	15.00	11.82%	17.84	242,585
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	1,200	15.00	18,000	1/2/2012						
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	2,500	15.00	37,500	5/26/2012						
	ABC	ABC 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	9,000	15.00	135,000	9/15/2012						
	ABC	ABC 20 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	1,200	13.00	15,600	4/19/2012	4,500	58,500	13.00	3.39%	15.46	69,565
	ABC	ABC 20 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	2,000	13.00	26,000	4/14/2012						
	ABC	ABC 20 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	1,300	13.00	16,900	5/26/2012						
	AZT	AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	4,000	7.15	28,600	3/12/2012	21,000	150,150	7.15	8.70%	8.50	178,550
	AZT	AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	17,000	7.15	121,550	11/9/2012						

Table 19: ARV procurement in 2012 under UNDP administered Global Fund grant in Uzbekistan (cont.)

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	3,000	1.85	5,550	2/4/2012	11,600	21,460	1.85	1.24%	2.20	25,519
	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	2,000	1.85	3,700	2/4/2012						
	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	3,600	1.85	6,660	2/3/2012						
	AZT	AZT 10 mg/ml oral solution	Bottle (240 ml)	Aurobindo Pharma Ltd	3,000	1.85	5,550	5/26/2012						
	d4T	d4T 30 mg capsules	Pack (60 capsules)	Aurobindo Pharma Ltd	3,600	2.00	7,200	2/3/2012	5,600	10,000	1.79	0.58%	2.12	11,891
	d4T	d4T 30 mg capsules	Pack (60 capsules)	Aurobindo Pharma Ltd	2,000	1.40	2,800	8/13/2012						
	d4T	d4T 1mg/ml oral solution	Bottle (200 ml)	Aurobindo Pharma Ltd	4,800	1.30	6,240	2/3/2012	9,564	12,433	1.30	0.72%	1.55	14,785
	d4T	d4T 1mg/ml oral solution	Bottle (200 ml)	Aurobindo Pharma Ltd	1,764	1.30	2,293	5/21/2012						
	d4T	d4T 1mg/ml oral solution	Bottle (200 ml)	Aurobindo Pharma Ltd	3,000	1.30	3,900	5/26/2012						
	ddI	ddI 400 mg capsules	Pack (30 capsules)	Matrix Laboratories Ltd	500	22.67	11,335	1/21/2012	1,900	43,073	22.67	2.50%	26.96	51,220
	ddI	ddI 400 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	600	22.67	13,602	5/26/2012						
	ddI	ddI 400 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	800	22.67	18,136	9/15/2012						
	EFV	EFV 200 mg capsules	Pack (90 capsules)	Aurobindo Pharma Ltd	2,000	9.00	18,000	2/4/2012	5,300	47,700	9.00	2.76%	10.70	56,722
	EFV	EFV 200 mg capsules	Pack (90 capsules)	Aurobindo Pharma Ltd	800	9.00	7,200	2/3/2012						
	EFV	EFV 200 mg capsules	Pack (90 capsules)	Aurobindo Pharma Ltd	2,500	9.00	22,500	5/26/2012						

Table 19: ARV procurement in 2012 under UNDP administered Global Fund grant in Uzbekistan (cont.)

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	EFV	EFV 50 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	4,000	2.00	8,000	2/27/2012	6,000	12,000	2.00	0.70%	2.38	14,270
	EFV	EFV 50 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	2,000	2.00	4,000	5/26/2012						
	EFV	EFV 600 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	6,000	4.00	24,000	5/26/2012	16,000	64,000	4.00	3.71%	4.76	76,105
	EFV	EFV 600 mg capsules	Pack (30 capsules)	Aurobindo Pharma Ltd	10,000	4.00	40,000	9/8/2012						
	LPV/r	LPV 200 mg + r 50 mg tablets	Pack (120 tablets)	Matrix Laboratories Ltd	1,600	33.00	52,800	1/21/2012	10,100	304,550	30.15	17.64%	35.86	362,153
	LPV/r	LPV 200 mg + r 50 mg tablets	Pack (120 tablets)	Mylan Laboratories Ltd	3,500	30.50	106,750	5/26/2012						
	LPV/r	LPV 200 mg + r 50 mg tablets	Pack (120 tablets)	Aurobindo Pharma Ltd	5,000	29.00	145,000	10/20/2012						
	LPV/r	LPV 80 mg + r 20 mg/ml oral solution	Box (5 bottles of 60 ml)	Aesica Queenborough Ltd	740	83.87	62,064	4/28/2012	2,780	233,159	83.87	13.51%	99.73	277,259
	LPV/r	LPV 80 mg + r 20 mg/ml oral solution	Box (5 bottles of 60 ml)	Aesica Queenborough Ltd	700	83.87	58,709	4/28/2012						
	LPV/r	LPV 80 mg + r 20 mg/ml oral solution	Box (5 bottles of 60 ml)	Abbott Laboratories Ltd	740	83.87	62,064	1/28/2012						
	LPV/r	LPV 80 mg + r 20 mg/ml oral solution	Box (5 bottles of 60 ml)	Abbott Laboratories Ltd	600	83.87	50,322	9/1/2012						
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	6,000	2.65	15,900	1/7/2012	26,000	62,400	2.40	3.61%	2.85	74,202
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	10,000	2.65	26,500	9/8/2012						
	NVP	NVP 200 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	10,000	2.00	20,000	10/20/2012						

Table 19: ARV procurement in 2012 under UNDP administered Global Fund grant in Uzbekistan (cont.)

	INN	Dosage form	Unit	Manufacturer	Quantity (units)	Unit cost (USD)	Total amount (USD)	Date of procurement	Total quantity per ARV (INN) in 2012 (units)	Total cost per ARV (INN) in 2012 (USD)	Average unit cost per ARV (INN) for 2012 (USD)	Share of total ARV spending in 2012	Average cost per ARV (INN) (price paid to manufacturer plus shipment costs) (USD)	Gross cost per ARV (INN) (amount paid to manufacturer plus shipment costs) (USD)
Single/ boosted ARVs	NVP	NVP 10 mg/ml oral suspension	Bottle (240ml)	Aurobindo Pharma Ltd	4,200	1.75	7,350	1/14/2012	14,200	24,880	1.75	1.44%	2.08	29,586
	NVP	NVP 10 mg/ml oral suspension	Bottle (240ml)	Aurobindo Pharma Ltd	2,000	1.75	3,500	1/14/2012						
	NVP	NVP 10 mg/ml oral suspension	Bottle (240ml)	Aurobindo Pharma Ltd	5,000	1.75	8,750	2/11/2012						
	NVP	NVP 10 mg/ml oral suspension	Bottle (240ml)	Aurobindo Pharma Ltd	3,000	1.76	5,280	5/26/2012						
FDCs	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	6,800	8.15	55,420	5/26/2012	31,800	247,670	7.79	14.35%	9.26	294,515
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Ranbaxy Laboratory Ltd	15,000	8.15	122,250	10/20/2012						
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	5,800	7.00	40,600	3/12/2012						
	3TC/ AZT	3TC 150 mg + AZT 300 mg tablets	Pack (60 tablets)	Aurobindo Pharma Ltd	4,200	7.00	29,400	3/12/2012						
	3TC/ EFV/ TDF	EFV 600 mg + 3TC 300 mg + TDF 300 mg tablets	Pack (30 tablets)	Mylan Laboratories Ltd	810	14.10	11,421	9/8/2012	810	11,421	14.10	0.66%	16.77	13,581
	3TC/ TDF	3TC 300 mg + TDF 300 mg tablets	Pack (30 tablets)	Mylan Laboratories Ltd	1,380	7.99	11,026	9/8/2012	1,380	11,026	7.99	0.64%	9.50	13,112
	EFV/ FTC/ TDF	EFV 600 mg + FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Mylan Laboratories Ltd	5,640	16.20	91,368	10/13/2012	5,640	91,368	16.20	5.29%	19.26	108,650
	FTC/ TDF	FTC 200 mg + TDF 300 mg tablets	Pack (30 tablets)	Mylan Laboratories Ltd	2,160	9.50	20,520	10/13/2012	2,160	20,520	9.50	1.19%	11.30	24,401
	Total									**1,726,285**		**100.00%**		**2,052,798**

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