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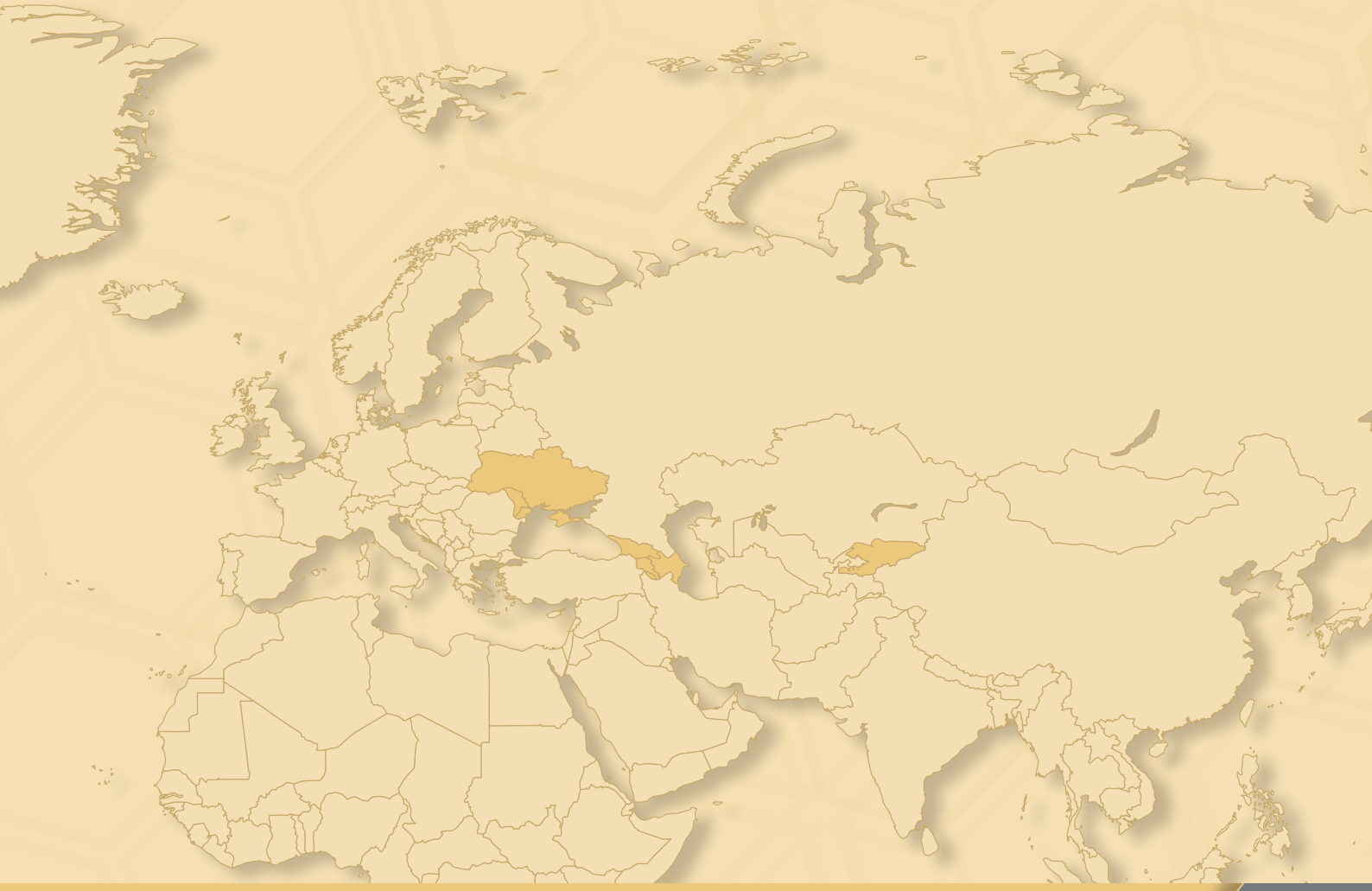
A sub-regional analytical report including Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova, and Ukraine



Sustainable Financing of National HIV Responses

Legal and regulatory frameworks for antiretroviral medicines and treatment in selected countries of Eastern Europe and Central Asia. A sub-regional analytical report including Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova, and Ukraine.

Sustainable Financing of National HIV Responses

Supplement to the main report on:
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.

Authors:
Timur Abdullaev, Boyan Konstantinov, Christoph Hamelmann

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Any omissions, inaccuracies and mistakes are responsibility solely of the authors. Please submit questions and comments to:
christoph.hamelmann@undp.org and **boyan.konstantinov@undp.org**

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Table of Contents

List of tables **4**

Acronyms and abbreviations **5**
Acronyms of ARV medicines **5**
Acknowledgments **6**
Executive summary **7**

1. INTRODUCTION **9**

2. OBJECTIVES AND METHODOLOGY **10**

3. ART GUIDELINES **11**
3.1 WHO ART guidelines 11
3.2 National ART guidelines in the study countries 13

4. GLOBAL AND REGIONAL PATENT REGIMES **22**
4.1. Paris Convention for the Protection of Industrial Property 22
4.2. Patent Cooperation Treaty 22
4.3. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) 23
4.4. Eurasian Patent Convention 24
4.5. EurAsEC, the Customs Union and the Eurasian Economic Union 24
4.6. Association Agreements with the EU 26
4.7. European Patent Convention 30

5. ANALYSIS OF IP REGULATORY FRAMEWORKS IN THE STUDY COUNTRIES **31**
5.1. Brief overview of the countries' legal systems 31
5.2. IP protection and flexibilities 31
5.3. Patent status of ARV medicines in the study countries 36

6. LICENSING AND REGISTRATION OF MEDICINES IN THE STUDY COUNTRIES **41**
6.1. Licensing of pharmaceutical activity 41
6.2. Registration of medicines 42
6.3. Registration status of ARV medicines in the study countries 45

7. PROCUREMENT SYSTEMS IN THE STUDY COUNTRIES **46**
7.1. Overview of countries' public procurement systems 46
7.1.1. Armenia 49
7.1.2. Azerbaijan 49
7.1.3. Georgia 49
7.1.4. Kyrgyzstan 49
7.1.5. Moldova 50
7.1.6. Ukraine 51
7.2. Procurement systems used within GFATM projects 51

8. CONCLUSIONS AND RECOMMENDATIONS **53**

Annexes **60**
Annex 1. ARV registration status in the study countries 60

List of tables

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 12
Table 2: National ART guidelines and protocols adopted in study countries 13
Table 3: Summary of regimens recommended in the study countries 14
Table 4: Status of the Paris Convention in the study countries 22
Table 5: Status of the PCT in the study countries 22
Table 6: Status of study countries' accession to WTO 23
Table 7: Status of study countries' accession to the EAPC 24
Table 8: EAPO patent maintenance fees, USD (as of May 2014) 25
Table 9: Status of study countries' accession to EurAsEC and Customs Union / EEU 26
Table 10: IP and related provisions in Association Agreements of Georgia, Moldova and Ukraine 27
Table 11: Patent laws of the study countries 31
Table 12: The status of countries in WTO, WIPO, EAPO, EurAsEC and EU (as of June 2014) 32
Table 13: IP provisions in the study countries and international/regional instruments (as of June 2014) 33
Table 14: Patent status of key ARVs in the study countries 37
Table 15: Key documents on licensing of pharmaceutical activities in study countries 41
Table 16: ARV medicines registered in the study countries grouped by generic/originator/both 45
Table 17: ARV medicines registered in Armenia 60
Table 18: ARV medicines registered in Azerbaijan 60
Table 19: ARV medicines registered in Georgia 61
Table 20: ARV medicines registered in Kyrgyzstan 63
Table 21: ARV medicines registered in Moldova 64
Table 22: ARV medicines registered in Ukraine 65

Acronyms and abbreviations

AA	Association agreement
AIDS	Acquired Immunodeficiency Syndrome
AMD	Armenian Drahm
ART	Antiretroviral therapy
ARV	Antiretroviral
AZN	Azerbaijani New Manat
bPI	Ritonavir-boosted protease inhibitor
CIS	Commonwealth of Independent States
DCFTA	Deep and comprehensive free trade area
EAPC	Eurasian Patent Convention
EAPO	Eurasian Patent Organisation
EEC	Eurasian Economic Commission
EECA	Eastern Europe and Central Asia
EEU	Eurasian Economic Union
EurAsEC	Eurasian Economic Community
EU	European Union
FDA	U.S. Food and Drug Administration
FDC	Fixed-dose combination
FTA	Free Trade Agreement
GEL	Georgian Lari
GFATM (GF)	Global Fund to fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
INN	International non-proprietary name
IP	Intellectual property
ISA	International Searching Authority
KGS	Kyrgyzstani Som
MDL	Moldovan Leu
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
SES	Single Economic Space
TB	Tuberculosis
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UAH	Ukrainian Hryvnia
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USD	United States Dollar
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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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 instrumental 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, most 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.

ART 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.

Within the framework of the regional project "Sustainable Financing of National HIV Responses", UNDP published a sub-regional report "Legal and regulatory frameworks for antiretroviral medicines and treatment in selected countries of the Commonwealth of Independent States" covering Belarus, Kazakhstan, Russian Federation, Tajikistan and Uzbekistan.[1] With the present report UNDP complements the work done so far, including several other UNDP efforts to tackle intellectual property (IP) rights and cost of treatment, such as a study on the nexus between pharmaceutical patents and prices which has been carried out at the UNDP Bureau for Policy and Programme Support

1 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan.* 2014.

(formerly – UNDP Bureau for Development Policy) in New York.[2]

The present report focuses on the analysis of critical factors affecting the affordability and accessibility of antiretroviral (ARV) medicines in Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova and Ukraine on the level of treatment guidelines, regulatory frameworks related to registration and licensing, 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.

2 UNDP. *Treating More for Less in Eastern Europe and Central Asia: A study of the Roles of Price, Patent and Drug Registration Statuses as Determinants of HIV Treatment Access*. New York, 2015.

1. INTRODUCTION

In 2014, UNDP Regional Support Centre for Europe and the CIS published the report on "Legal and regulatory frameworks for ARV medicines and treatment in selected CIS countries",[3] covering five countries of the region: Belarus, Kazakhstan, Russia, Tajikistan and Uzbekistan. The report was prepared as part of the regional project "Sustainable Financing of National HIV Responses".

The present supplementary report (hereinafter – the supplement) employs the same methodology to cover six more countries of the region: Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova and Ukraine. The supplement follows the structure of the first report on Belarus, Kazakhstan, Russian Federation, Tajikistan and Uzbekistan (hereinafter referred to as "the main report"). In order to avoid repetition, wherever possible, this supplement only summarizes information already presented in the main report. Given the inclusion of Georgia, a non-CIS state, in this analysis, the title of this supplement was modified to reflect its different scope.

Note to readers: This report is a result of a lengthy process of research and drafting, which was completed by mid-2014. However, during the time between report finalization and its preparing for publication there were certain changes in the political landscape of the region. So, in December 2014, Kyrgyzstan signed an agreement on joining of the Eurasian Economic Union in May 2015, and in January 2015 Armenia has officially become the fourth member of the Union. Also, in March 2015 Kyrgyzstan adopted a number of amendments to its patent law. Therefore, when reading this report, it has to be noted that the status of Armenia and Kyrgyzstan in the Eurasian Economic Union is given as of mid-2014, and that provisions of the Kyrgyzstan's 1998 patent law considered in this report have been changed.

3 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan.* 2014.

2. OBJECTIVES AND METHODOLOGY

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 and other 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;
- 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.

In order to achieve the above objectives, an extensive review and analysis of existing contextual frameworks were conducted, and country specific status of patent protection and registration of ARV medicines recommended by WHO and national ART guidelines was determined.

The review relied to a large extent on available published literature, policies and legislation, programmatic and internal institutional documentation.

3. ART GUIDELINES

3.1 WHO ART guidelines

To support ART delivery in national programmes and by treatment service providers, WHO has published guidelines for ART, primarily focused on a public health approach for resource-limited settings. First issued in 2002, these recommendations were updated in 2003, 2006, 2010, and, most recently, in 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,[4] and for infants and children,[5] but in 2013 it was decided to merge both into one document, the Consolidated Guidelines.[6]

The 2013 guidelines reflect important advances in HIV responses since 2010, including simple, safer, and if available once-daily, single-pill FDCs of ARV regimens; earlier start of ART; initiation of ART regardless of CD4 count for HIV-positive people with certain health conditions, HIV-positive partners in serodiscordant couples, pregnant and breastfeeding women and children younger than five years of age; and 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.

Table 1 below presents a summary of recommendations of 2010 and 2013 WHO guidelines in terms of ART for children and adults[7]. 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. 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.

> Countries should strive to amend their national ART guidelines and protocols in order to reflect the most recent WHO ART Guidelines. 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.

4 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/).

5 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).

6 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/).

7 Here and elsewhere, *children* refers to children and infants, and *adults* refers to adults and adolescents.

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	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	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			

8 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 six study countries.

Given that harmonization of national protocols with WHO guidelines requires considerable time and effort, by the time of completing of 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 WHO 2010 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
Armenia	Ordinance of the Minister of Health of the Republic of Armenia "On approval of the standards on HIV/AIDS treatment within the scope of state-guaranteed free health care services for the population," Ordinance No. 88-A of 23 January 2012
Azerbaijan	Clinical protocol on HIV/AIDS diagnosis and ART among adults and adolescents. Adopted by Collegium of the Ministry of Healthcare of the Republic of Azerbaijan (decision No 22 of 21 June 2013). Baku, 2013 *No national guidelines on ART among children exist.*
Georgia	Treatment and Care of HIV/AIDS Patients. Clinical guidelines. Tbilisi, 2013.
Kyrgyzstan	Antiretroviral therapy for adults and adolescents. Clinical protocol for healthcare facilities of primary, secondary and tertiary levels. Bishkek, 2013[9] Treatment and Care for Children with HIV. Clinical protocol for healthcare facilities of primary, secondary and tertiary levels. Bishkek, 2013[10]
Moldova	HIV-infection in adults and adolescents. National clinical protocol (No. PCN-211). Approved by Ministry of Health ordinance No. 417 of 19 May 2014[11] National guidelines on HIV and AIDS treatment and care. Ministry of Health of the Republic of Moldova, 2009[12, 13]
Ukraine	Clinical protocol on antiretroviral therapy for adults and adolescents. Kyiv, 2010.[14] Clinical protocol on antiretroviral therapy and carrying out medical supervision for children with HIV. Kyiv, 2007.[15]

9 Национальный клинический протокол "Антиретровирусная терапия у взрослых и подростков" для 1-3 уровней организаций здравоохранения. Утвержден Приказом МЗ КР №388 от 10 июля 2012 г.

10 Национальный клинический протокол «Лечение и помощь при ВИЧ-инфекции у детей» для 1-3 уровней организаций здравоохранения. Утвержден Приказом МЗ КР №111 от 01 января 2013 г.

11 Infecția cu HIV la adult și adolescent. Protocol clinic național (PCN-211). Aprobat prin ordinul Ministerului Sănătății al Republicii Moldova nr. 417 din.19.05.2014 "Cu privire la aprobarea Protocolului clinic național "Infecția cu HIV la adult și adolescent"" (http://old.ms.gov.md/_files/14791-PCN-211%2520Infectia%2520cu%2520HIV%2520la%2520adult%2520si%2520adolescent.pdf).

12 Ghid național de tratament și îngrijiri în infecția HIV și SIDA. Chișinău 2009.

13 It should be noted that the 2014 clinical protocol only covers HIV treatment in adults and adolescents, but does not address ART in children; these are still addressed by the 2009 national guidelines.

14 Клінічний протокол антиретровірусної терапії ВІЛ-інфекції у дорослих та підлітків. Затверджен наказом МОЗ України від 12.07.2010 №551 (http://moz.gov.ua/ua/portal/dn_20100712_551.html).

15 Клінічний протокол з антиретровірусного лікування та здійснення медичного спостереження за дітьми, хворими на ВІЛ-інфекцію. Затверджен наказом МОЗ України від 13.04.2007 № 182 (http://moz.gov.ua/ua/portal/dn_20070413_182.html)

Table 3: Summary of regimens recommended in the study countries

Treatment regimens	Categories of patients	National ART guidelines of Armenia			National ART guidelines of Azerbaijan			National ART guidelines of Georgia			National ART guidelines of Kyrgyzstan			National ART guidelines of Moldova			National ART guidelines of Ukraine		
		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	Adults	3TC	n/a	3TC/EFV/TDF[16]	3TC	n/a	3TC/EFV/TDF	3TC	n/a	3TC/EFV/TDF	3TC	n/a	3TC/EFV/TDF	3TC	n/a	3TC/EFV/TDF	3TC	3TC/ABC	3TC/EFV/TDF
		ABC		EFV/FTC/TDF	ABC*		EFV/FTC/TDF	ABC		EFV/FTC/TDF	ABC		EFV/FTC/TDF	ABC		3TC/NVP/TDF	ABC	3TC/ABC/AZT	3TC/TDF/LPV/r
		AZT		3TC/ABC/bPI	AZT		3TC/ABC/bPI	AZT		3TC/ABC/bPI	AZT		3TC/ABC/EFV	AZT		EFV/FTC/TDF	AZT	3TC/AZT	EFV/FTC/TDF
		EFV		3TC/ABC/EFV	EFV		3TC/ABC/EFV	EFV		3TC/ABC/EFV	EFV		3TC/ABC/LPV/r	EFV		FTC/NVP/TDF	EFV	EFV/FTC/TDF	FTC/TDF/LPV/r
		FTC		3TC/ABC/NVP	FTC		3TC/ABC/NVP	FTC		3TC/ABC/NVP	FTC		3TC/ABC/NVP	FTC		3TC/ABC/AZT	FTC	FTC/TDF	3TC/ABC/bPI
		NVP		3TC/AZT/bPI	NVP		3TC/AZT/bPI	NVP		3TC/AZT/bPI	LPV/r		3TC/AZT/EFV	LPV/r		3TC/ABC/EFV	LPV/r		3TC/ABC/EFV
		TDF		3TC/AZT/EFV	TDF		3TC/AZT/EFV	TDF		3TC/AZT/EFV	NVP		3TC/AZT/LPV/r	NVP		3TC/ABC/NVP	NVP		3TC/ABC/LPV/r
				3TC/AZT/NVP	bPIs**:		3TC/AZT/NVP	bPIs:		3TC/AZT/NVP	TDF		3TC/AZT/NVP	TDF		3TC/AZT/EFV	TDF		3TC/ABC/NVP
				3TC/NVP/TDF	ATV/r		3TC/NVP/TDF	ATV/r		3TC/NVP/TDF			3TC/NVP/LPV/r			3TC/AZT/NVP	Alt bPIs		3TC/AZT/bPI
				3TC/TDF/bPI	DRV/r		3TC/TDF/bPI	DRV/r		3TC/TDF/bPI			3TC/NVP/TDF			3TC/TDF/LPV/r	ATV/r		3TC/AZT/EFV
				ABC/EFV/FTC	LPV/r		ABC/EFV/FTC	LPV/r		ABC/FTC/bPI			ABC/EFV/FTC			ABC/AZT/FTC	FPV/r		3TC/AZT/LPV/r
				ABC/FTC/bPI	SQV/r		ABC/FTC/bPI			ABC/FTC/EFV			ABC/FTC/LPV/r			AZT/FTC/TDF			3TC/AZT/NVP
				ABC/FTC/NVP			ABC/FTC/NVP			ABC/FTC/NVP			ABC/FTC/NVP			FTC/TDF/LPV/r			3TC/NVP/TDF
				AZT/EFV/FTC			AZT/EFV/FTC			AZT/FTC/bPI			AZT/EFV/FTC						3TC/TDF/bPI
				AZT/FTC/bPI			AZT/FTC/bPI			AZT/FTC/EFV			AZT/FTC/LPV/r						FTC/NVP/TDF
				AZT/FTC/NVP			AZT/FTC/NVP			AZT/FTC/NVP			AZT/FTC/NVP						FTC/TDF/bPI
				FTC/NVP/TDF			FTC/NVP/TDF			FTC/NVP/TDF			FTC/NVP/LPV/r						
				FTC/TDF/bPI			FTC/TDF/bPI			FTC/TDF/bPI			FTC/NVP/TDF						

16 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 Armenia			National ART guidelines of Azerbaijan			National ART guidelines of Georgia			National ART guidelines of Kyrgyzstan			National ART guidelines of Moldova			National ART guidelines of Ukraine		
		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	Children	3TC		2 NRTIs + EFV	n/a	n/a	n/a	n/a	n/a	n/a	3TC	n/a	3TC/ABC/EFV	3TC	n/a	3TC/ABC/EFV	3TC	3TC/ABC/AZT	3TC/ABC/AZT
		ABC		2 NRTIs + LPV/r							ABC		3TC/ABC/LPV/r	ABC		3TC/ABC/NVP	ABC	3TC/AZT	3TC/AZT/EFV
		AZT		2 NRTIs + NVP							AZT		3TC/ABC/NVP	AZT		3TC/AZT/EFV	AZT	FTC/TDF	3TC/AZT/LPV/r
		EFV									ddI		2NRTIs+EFV	EFV		3TC/AZT/NVP	d4T		3TC/AZT/NFV
		LPV/r									EFV		2NRTIs+LPV/r	LPV/r		3TC/ABC/AZT	EFV		3TC/AZT/NVP
		NVP									FTC		2NRTIs+NVP	NVP		3TC/AZT/LPV/r	LPV/r		3TC/ABC/EFV
											LPV/r						NFV		3TC/ABC/LPV/r
											NVP						NVP		3TC/ABC/NFV
											TDF								3TC/ABC/NVP
																			3TC/d4T/EFV
																			3TC/d4T/LPV/r
																			3TC/d4T/NFV
																			3TC/d4T/NVP
Second line	Adults	3TC		3TC/TDF/DRV/r	3TC	n/a	3TC/TDF/LPV/r	3TC	n/a	3TC/TDF/ATV/r	3TC	n/a	3TC/TDF/LPV/r	3TC	n/a	3TC/AZT/LPV/r	3TC	3TC/ABC	3TC/ABC/AZT/bPI
		ABC		3TC/TDF/LPV/r	ABC		3TC/TDF/ATV/r	ABC		3TC/TDF/DRV/r	ABC		3TC/ABC/LPV/r	AZT		3TC/AZT/TDF/DRV/r	ABC	3TC/ABC/AZT	3TC/AZT/ddI/bPI
		AZT		AZT/ddI/DRV/r	ATV/r		3TC/TDF/DRV/r	ATV/r		3TC/TDF/LPV/r	AZT		AZT/ddI/LPV/r	ATV/r		3TC/AZT/TDF/LPV/r	AZT	3TC/AZT	3TC/AZT/TDF/bPI
		ddI		AZT/ddI/LPV/r	AZT		AZT/ddI/ATV/r	AZT		AZT/ddI/ATV/r	ddI		FTC/TDF/LPV/r	DRV/r		AZT/FTC/LPV/r	ddI	FTC/TDF	3TC/ddI/bPI
		DRV/r		FTC/TDF/DRV/r	ddI		AZT/ddI/DRV/r	ddI		AZT/ddI/DRV/r	FTC		3TC/AZT/LPV/r	FTC		FTC/TDF/LPV/r	FTC		3TC/TDF/bPI
		FTC		FTC/TDF/LPV/r	DRV/r		AZT/ddI/LPV/r	DRV/r		AZT/ddI/LPV/r	LPV/r		ABC/FTC/LPV/r	LPV/r		3TC/AZT/ATV/r	TDF		ABC/ddI/bPI
		LPV/r		3TC/ABC/DRV/r	FTC		FTC/TDF/ATV/r	FTC		FTC/TDF/ATV/r	TDF		AZT/FTC/LPV/r	TDF		3TC/AZT/TDF/ATV/r	bPIs:		AZT/FTC/TDF/bPI
		TDF		3TC/ABC/LPV/r	LPV/r		FTC/TDF/DRV/r	LPV/r		FTC/TDF/DRV/r						AZT/FTC/ATV/r	ATV/r		
				3TC/AZT/DRV/r	TDF		FTC/TDF/LPV/r	TDF		FTC/TDF/LPV/r						AZT/FTC/TDF/ATV/r	DRV/r		
				3TC/AZT/LPV/r			3TC/ABC/DRV/r			3TC/ABC/DRV/r						AZT/FTC/TDF/DRV/r	FPV/r		
				ABC/FTC/DRV/r			3TC/ABC/LPV/r			3TC/ABC/LPV/r						AZT/FTC/TDF/LPV/r	LPV/r		
				ABC/FTC/LPV/r			3TC/AZT/DRV/r			3TC/AZT/DRV/r						FTC/TDF/ATV/r	SQV/r		
				AZT/FTC/DRV/r			3TC/AZT/LPV/r			3TC/AZT/LPV/r									
				AZT/FTC/LPV/r			ABC/FTC/DRV/r			ABC/FTC/DRV/r									
							ABC/FTC/LPV/r			ABC/FTC/LPV/r									
							AZT/FTC/DRV/r			AZT/FTC/DRV/r									
							AZT/FTC/LPV/r			AZT/FTC/LPV/r									

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

Treatment regimens	Categories of patients	National ART guidelines of Armenia			National ART guidelines of Azerbaijan			National ART guidelines of Georgia			National ART guidelines of Kyrgyzstan			National ART guidelines of Moldova			National ART guidelines of Ukraine		
		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	Children	3TC		2 NRTIs + EFV	n/a	n/a	n/a	n/a	n/a	n/a	3TC	n/a	2NRTIs+bPI	3TC	n/a	3TC/ABC/LPV/r	ABC	n/a	ABC/ddI/LPV/r
		ABC		2 NRTIs + LPV/r							ABC		2NRTIs+NNRTI	ABC		ABC/ddI/LPV/r	AZT		AZT/ddI/LPV/r
		AZT		2 NRTIs + NVP							AZT			AZT		AZT/ddI/LPV/r	ddI		ddI/EFV/LPV/r
		ddI									ddI			ddI			EFV		ddI/NVP/LPV/r
		EFV									EFV			LPV/r			LPV/r		ABC/ddI/EFV
		LPV/r									FTC						NFV		ABC/ddI/NFV
		NVP									LPV/r						NVP		ABC/ddI/NVP
											NVP						SQV/r		ABC/ddI/SQV/r
											TDF								AZT/ddI/EFV
																			AZT/ddI/NFV
																			AZT/ddI/NVP
																			AZT/ddI/SQV/r

Notes:
* According to the Clinical protocol, ABC is not registered in Azerbaijan
** The Clinical protocol does not recommend any specific bPI, though provide a description of counter-indications. It is also mentioned that only LPV/r is registered in Azerbaijan

It should be noted that only Kyrgyzstan has its national guidelines accessible both in the Kyrgyz language and in Russian; the other study countries have their ART guidelines available only in their national languages, and not in English or Russian, which makes comparative analysis more complex.

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

In **Armenia**, ART for both adults and children is regulated by a 2012 Ordinance of the Minister of Health and therefore does not reflect the recommendations of the 2013 WHO Guidelines.

In terms of ART eligibility criteria, national guidelines of Armenia fall short of recommendations in the 2013 WHO Guidelines in that they recommend ART initiation at CD4 count ≤350 cells/mm^3 (≤500 cells/mm^3 in 2013 WHO Guidelines), in chronic HBV co-infected patients requiring treatment (WHO Guidelines recommend initiation of ART in all HBV co-infected individuals with CD4 ≤500 cells/mm^3 and regardless of CD4 cell count in the presence of severe chronic liver disease).

As to recommended regimens, the following differences can be noted between national and WHO Guidelines (2010 and 2013):

- Alternative first-line regimens for adults in national guidelines include combinations with bPIs, while WHO Guidelines – both 2010 and 2013 – reserve bPI-containing combinations for second line regimens;
- National guidelines recommend using ABC as part of alternative first- and second-line combinations for adults, which is not recommended by WHO Guidelines;
- In national guidelines, preferred second-line regimens for adults include ddI-containing combinations, while ddI is not recommended by WHO for preferred or alternative combinations;
- In the national guidelines, DRV/r is included in second-line preferred combinations, while in the 2010 WHO Guidelines it is part of alternative regimens, and in the 2013 WHO Guidelines, DRV/r-containing combinations are not among preferred and alternative second-line regimens.

It should be noted that national guidelines do not provide details of which specific NRTIs should be used in first-line regimens for children.

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. The existence of such a recommendation in Armenia's national guidelines could not be established during this research.

In order to be in line with the 2013 WHO Guidelines, national guidelines have to be reviewed so that the threshold for initiation of ART in both adults and children is lowered, regimens are revised and use of FDCs is explicitly recommended.

The Ministry of Health of **Azerbaijan** adopted clinical protocols on ART among adults and adolescents in 2013. On the website of the Ministry of Health there is no protocol or guidelines on ART for children; according to information from HIV service providers from civil society, practitioners use either 2013 WHO Guidelines or 2012 WHO clinical protocol for the European Region.[17] As it is discussed in Section 6, not all of the ARV medicines recommended by WHO are registered in Azerbaijan.

Azerbaijan's clinical protocol envisages higher threshold for ART initiation criteria: ≤350 cells/mm^3 at WHO clinical stage 1 and 2 (instead of ≤500 cells/mm^3,

17 HIV/AIDS treatment and care. Clinical protocols for the WHO European Region. 2012 Revisions. Protocol 11: HIV treatment and care for children. Available in English at: http://www.euro.who.int/__data/assets/pdf_file/0003/168393/Paediatric-Protocol-11-EN-2012-06-27.pdf?ua=1; in Russian: http://www.euro.who.int/__data/assets/pdf_file/0004/168394/Paediatric-Protocol11-RU-2012-06-27.pdf?ua=1.

as recommended in the 2013 WHO Guidelines). Also, the protocol's recommendation on initiation of ART in pregnant women (all pregnant women are eligible to ART regardless of CD4 count, but at CD4 count > 350 cells/mm^3 ART should be started after the second trimester) is not the same as the recommendation of 2013 WHO Guidelines to start lifelong ART in all HIV-positive pregnant women. Otherwise, the clinical protocol of Azerbaijan is in line with 2013 WHO Guidelines' ART initiation recommendations.

The following differences between the clinical protocol and WHO Guidelines (2010 and 2013) may be seen in terms of recommended first- and second-line ART:

- Alternative first-line regimens for adults in Azerbaijan's clinical protocol contain combinations with bPIs, while WHO Guidelines – both 2010 and 2013 – reserve bPI-containing combinations for second line regimens;
- The clinical protocol recommends using ABC as part of alternative first- and second-line combinations for adults, which is not recommended by WHO Guidelines;
- In the clinical protocol, preferred second-line regimens for adults include ddI-containing combinations, while ddI is not recommended by WHO for preferred or alternative combinations;
- In the clinical protocol, DRV/r is included in second-line preferred combinations, while in 2010 WHO Guidelines it is part of alternative regimens, and in 2013 WHO Guidelines, DRV/r-containing combinations are not among preferred and alternative second-line regimens;
- Even though the clinical protocol recommends a number of bPIs (ATV/r, DRV/r, LPV/r, SQV/r), it recognizes that the only bPI currently registered in the country is LPV/r.

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. The clinical protocol of Azerbaijan mentions the benefit of once-daily ARV regimens and FDCs, but this recommendation is not as strong as in the WHO Guidelines.

In order to be in line with 2013 WHO Guidelines, the clinical protocol has to be reviewed so that the threshold for initiation of ART in adults is lowered, regimens are revised and use of FDCs is explicitly recommended. Also, Azerbaijan is advised to develop national guidelines or a protocol on ART for children, so that practitioners have normative guidance on how to administer paediatric ART.

In **Georgia**, clinical guidelines on HIV treatment and care were adopted in 2013, and in terms of ART initiation criteria they are in line with 2013 WHO Guidelines. However, when comparing ART regimens, recommendations in Georgia's clinical guidelines are not fully in line with 2013 WHO Guidelines:

- Though WHO does not recommend using combinations with PIs as first-line for adults, these are recommended as alternative regimens in the national guidelines;
- The national guidelines recommend using ABC as part of alternative first-line combinations for adults, which is not recommended by WHO Guidelines;
- In the clinical guidelines, preferred second-line regimens for adults include ddI-containing combinations, while ddI is not recommended by WHO for preferred or alternative combinations;
- In the national guidelines, DRV/r is included in second-line preferred combinations, while in 2010 WHO Guidelines it is part of alternative regimens, and in 2013 WHO Guidelines, DRV/r-containing combinations are not among preferred and alternative second-line regimens.

Even though national guidelines are on "HIV/AIDS Patients", they seem not to have a section on ART for children. Therefore, paediatric ART formulations could not be considered.

According to information from Georgian HIV service providers from civil society, review of the guidelines has been planned for late 2014; it is therefore very important that it is brought in line with the 2013 WHO guidelines. In order to be in line with 2013 WHO Guidelines, new national guidelines have to be reviewed so that ART regimens are revised and use of FDCs is explicitly recommended. Also, it seems necessary to either include a chapter on paediatric

ART in the new guidelines, or to develop and approve separate guidelines on ART among children.

In **Kyrgyzstan**, the ART clinical protocols are relatively new (2012-2013), but they were approved before the adoption of 2013 WHO Guidelines, which explains discrepancies between the documents.

Regarding ART initiation for adults, Kyrgyzstan recommends starting ART at CD4 ≤350 cells/mm^3 (WHO Guidelines recommend initiation of ART at ≤500 cells/mm^3), in case of pregnancy – at CD4 ≤350 cells/mm^3 and for HIV-positive partners in serodiscordant couples – at CD4 count CD4 ≤350 cells/mm^3 (WHO recommendation is to start ART in all pregnant women and HIV-positive partners in serodiscordant couples regardless of their CD4 count). As to ART in children, the national protocol recommendation to start ART in all children under five years of age is the same as in 2013 WHO Guidelines; however, when it comes to children at the age of five and above, the national protocol recommends initiation of ART at CD4 count ≤350 cells/mm^3, while WHO recommendation is ≤500 cells/mm^3.

In terms of recommended treatments, comparison of Kyrgyzstan's clinical protocols with 2013 WHO Guidelines shows the following differences:

- Alternative first-line regimens for adults in the clinical protocol include combinations with LPV/r, while WHO Guidelines reserve bPI-containing combinations for second line regimens;
- The clinical protocol recommends using ABC as part of alternative first-line combinations for adults, which is not recommended by WHO Guidelines;
- The only bPI, which is recommended by Kyrgyzstan's clinical protocol as part of second-line regimens for adults is LPV/r, while WHO also recommends ATV/r;
- Kyrgyzstan's clinical protocol on adults recommends as preferred a ddI-containing combination as part of second-line ART, while ddI is not recommended by WHO for preferred or alternative combinations.

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. The Kyrgyzstan's clinical protocol on ART for adults mentions the benefit of once-daily ARV regimens and FDCs, but this recommendation is not as strong as in the WHO Guidelines. Besides, this recommendation is not at all found in the clinical protocol on ART for children.

In order to be in line with 2013 WHO Guidelines, clinical protocols have to be reviewed so that ART initiation threshold is lowered, ART regimens are revised and use of FDCs is explicitly recommended.

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.

In **Moldova**, national guidelines on HIV treatment and care were adopted in 2009; though the section on HIV treatment of adults and adolescents was replaced in 2014 with a clinical protocol on treatment of HIV in adolescents and adults, as of the time of completing this report the remaining part of the national guidelines seemed to be effective, including the section on ART for children. For this reason the recommendations in terms of ART initiation and regimens for adolescents and adults are closer to the latest WHO Guidelines, and those for children are rather outdated.

It has to be noted that regarding ART initiation criteria for adults, the clinical protocol (CP) now uses CDC clinical classification of HIV, and not that of WHO. So, instead of employing a four-stage classification, it applies a three-stage classification, with A for asymptomatic stage, B for symptomatic stage, and C for stage when patient shows AIDS-indicative

diseases. ART is recommended for all symptomatic patients with HIV (stages B and C) regardless of their viral load or CD4 count. The CP follows 2013 WHO Guidelines and recommends initiation of ART in asymptomatic patients (CDC stage A; WHO clinical stages 1 and 2) at CD4 cell count ≤500 cells/mm^3, for HIV-positive partners in serodiscordant couples and pregnant women regardless of their CD4 count and clinical stage. Furthermore, the CP exceeds the 2013 WHO Guidelines in terms of ART initiation for specific groups; for instance, ART should be started regardless of CD4 count, viral load and clinical stage in patients with hepatitis B and C (the recommendation of the 2013 WHO Guidelines is to start ART in individuals coinfected with HIV and HBV with evidence of severe chronic liver disease, and initiating ART among people coinfected with HIV and HCV should follow the same general principles as for general population of PLHIV) and for patients older than 50 years of age. Presence of Mycobacterium Tuberculosis is considered by the CP as an indication of clinical stage C, and therefore patients coinfected with TB (whether active or latent forms) seem to be eligible for ART regardless of immunological and virological indications.

In terms of ART initiation criteria for children, these are envisaged by the 2009 National Guidelines and are clearly outdated: ART is recommended for all children under 12 months of age, for all children with WHO clinical stage 4, and for children aged 12-35 months with CD4 count ≤750 cells/mm^3, children aged 36-59 months with CD4 count ≤350 cells/mm^3, and children aged five years and more with ≤200 cells/mm^3 (2013 WHO Guidelines recommend ART for all children under five years of age regardless of their CD4 count and for children of five years of age and older, if they have WHO clinical stage 3 and 4 or CD4 count ≤500 cells/mm^3).

Comparing ART regimens recommended by the CP/National Guidelines and those in 2013 WHO Guidelines reveals certain discrepancies:

- First-line regimens recommended by the CP are either standard or alternative; the CP does not have acceptable options or regimens for special circumstances – these are actually included in the 'alternative' regimens. That is why regimens considered in the 2013 WHO Guidelines as acceptable or recommended for special circumstances (such as triple NRTI combinations or bPI-containing regimens) are all listed among alternative regimens in the CP;
- First-line regimens recommended by the CP include ABC-containing combinations; this is not recommended WHO Guidelines;
- One of bPIs recommended by the CP for second-line regimens is DRV/r; while it was part of alternative combinations recommended by the 2010 WHO Guidelines, the 2013 Guidelines do not recommend using DRV/r as part of preferred or alternative regimens;
- For second-line treatment, the CP recommends quadruple combinations, while both preferred and alternative regimens recommended by the 2013 WHO Guidelines are triple combinations;[18]
- While WHO Guidelines recommend LPV/r-containing combinations as preferred first-line regimens for children, in national guidelines such combination is recommended as alternative;
- For second-line regimens for children, national guidelines recommend three preferred combinations and no alternative combinations. These do not include EFV- and NVP-containing combinations that are recommended by WHO, but do include two ddI-containing combinations, which are no longer recommended by 2013 WHO Guidelines.

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. While the national guidelines of Moldova recognized the benefit of once-daily ARV regimens and FDCs, this recommendation was well articulated only for adults and adolescents, and this section is now replaced with the 2014 CP, which does not contain such a recommendation. As to children, the respective section of the national guidelines does not mention the benefit of FDCs and does not contain a recommendation to use FDCs whenever possible.

18 Here and elsewhere in the report, ritonavir is not counted as an independent therapeutic component.

In order to be in line with 2013 WHO Guidelines, the 2014 CP should be amended so that the regimens are aligned with those recommended by the WHO, and the 2009 national guidelines have to be updated so that the threshold for initiation of ART in children is lowered and regimens are revised. Importantly, national ART guidelines have to explicitly recommend the use of age-appropriate FDCs and once-daily regimens both for adults and for children.

In **Ukraine** clinical protocol on ART in adults and adolescents was approved in 2010, and that on ART for children in 2007. While the clinical protocol on adults was approved in the same year as the previous revision of WHO Guidelines, that on children was adopted three years before the WHO issued its 2010 Guidelines.

In terms of ART initiation criteria, the threshold established by Ukrainian clinical protocols is higher than that of 2013 WHO Guidelines: ≤350 cells/mm^3 at WHO clinical stage 1 and 2 (instead of ≤500 cells/mm^3, as recommended in the 2013 WHO Guidelines). Also, unlike 2013 WHO Guidelines, clinical protocols of Ukraine do not envisage ART initiation for HIV-positive partners in serodiscordant couples. For children, recommendations of the clinical protocol are considerably different from 2013 WHO recommendations. So, national protocol recommends starting ART in children with WHO clinical stage 1 and 2 only at a certain level of CD4 count, while WHO recommends to initiate ART in all HIV-positive children under five years of age regardless of CD4 count and WHO clinical stage. For children over five years of age, 2013 WHO Guidelines recommend initiation of ART at WHO stage 3 or 4 or CD4 ≤500 cells/mm^3; according to the national protocol, ART should be started in children with WHO stage 3 or 4 or CD4 ≤200 cells/mm^3.

Comparing regimens recommended by Ukraine's clinical protocols and the WHO (2010 and 2013 Guidelines), the following differences can be seen:

- While WHO does not recommend using regimens with PIs as first-line for adults, these are recommended by Ukraine's clinical protocol both as preferred and alternative regimens;
- In the clinical protocol there are a number of first- and second-line combinations containing ABC for treatment of adults, which is not recommended by WHO;
- Among preferred second-line combinations for adults in Ukraine there are combinations consisting of four and even five therapeutic components, which is clearly more than standard three-component combinations recommended by WHO (four-component combinations are reserved for special circumstances only);
- Though NFV is not recommended by WHO for treatment of children, it is present in Ukraine's clinical protocol both in first- and second line regimens;
- Ukraine's clinical protocol contains additional PIs (FPV and SQV) for second-line regimens adults as compared to those recommended by the WHO.

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. While the clinical protocol on adults mentions specific FDCs and that for patients such combinations are more comfortable, this recommendation is not as strong as that of the 2013 WHO Guidelines. The protocol on ART in children mentions some FDCs that are available, but it does not have any specific recommendations regarding FDCs.

In order to be in line with 2013 WHO Guidelines, Ukraine should review its protocols so that the threshold for initiation of ART in both adults and children is lowered, regimens are revised and use of FDCs is explicitly recommended.

4. GLOBAL AND REGIONAL PATENT REGIMES

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.[19] Details of study countries' accession to the Paris Convention are given in Table 4 below.

Table 4: Status of the Paris Convention in the study countries

Country	Instrument	In force since
Armenia	Declaration of Continued Application: 1994	December 25, 1991
Azerbaijan	Accession: 1995	December 25, 1995
Georgia	Declaration of Continued Application: 1994	December 25, 1991
Kyrgyzstan	Declaration of Continued Application: 1994	December 25, 1991
Moldova	Declaration of Continued Application: 1993	December 25, 1991
Ukraine	Declaration of Continued Application: 1992	December 25, 1991

Source: WIPO website

The Convention applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models, trade names, geographical indications and the repression of unfair competition.

For more information on the Paris Convention see Section 4.1 of the main report.[20]

4.2 Patent Cooperation Treaty

The 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. All countries covered by the present study are parties to the PCT (see Table 5 below).

Table 5: Status of the PCT in the study countries

Country	Date on which country became bound by the PCT
Armenia	25 December 1991
Azerbaijan	25 December 1995
Georgia	25 December 1991
Kyrgyzstan	25 December 1991
Moldova	25 December 1991
Ukraine	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. It is then subjected to an "international search", carried out by the ISA and summarized in an "international search report". The ISA also prepares a written opinion on patentability. The procedure under the PCT has significant advantages for the applicant, the patent offices and the general public. For more

19 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.

20 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan*. 2014, p. 26.

information about the PCT see Section 4.2 of the main report.[21]

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

The TRIPS Agreement is part of the Law of the WTO. It 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.

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;
- allow for various forms of parallel imports depending on their exhaustion of rights regimes;
- apply general exceptions, such as early working for regulatory approval of generic pharmaceutical products or experimental use exceptions;
- make use of transition periods for developing countries and a longer, extendible transition period for least developed countries in particular.

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.

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. 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.

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.

Except Azerbaijan, all of the countries covered by the study are members of WTO (see Table 6 below).

Table 6: Status of study countries' accession to WTO

Country	Accession status
Armenia	Member since 2003
Azerbaijan	Negotiating accession
Georgia	Member since 2000
Kyrgyzstan	Member since 1998
Moldova	Member since 2001
Ukraine	Member since 2008

Source: WTO website

21 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan.* 2014, p. 27.

Table 7: Status of study countries' accession to the EAPC

Country	Signature	Ratification/Accession	Denunciation
Armenia	9 September 1994	27 November 1995	
Azerbaijan	9 September 1994	25 September 1995	
Georgia	9 September 1994	Not ratified	
Kyrgyzstan	9 September 1994	13 October 1995	
Moldova	9 September 1994	16 November 1995	26 April 2012
Ukraine	9 September 1994	Not ratified	

Source: EAPO website

For more information about the TRIPS Agreement, see Section 4.3 of the main report.[22]

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, including three countries covered by the present study: Armenia, Azerbaijan and Kyrgyzstan (see Table 7 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.[23]

The EAPC established the Eurasian Patent Organization (EAPO), based in Moscow. EAPO does not set its own patent maintenance fees, but charges fees that are applicable to maintenance of national patents in member states. Table 8 below shows patent maintenance fees for Armenia, Azerbaijan, Kyrgyzstan and Moldova.[24]

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. What it means in context of access to treatment is that these TRIPS-plus provisions, when enforced in national laws, could delay entry of and competition with generic ARV medicines in domestic markets, which typically leads to higher prices to ARVs. 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.

For more information about the EAPC, see Section 4.4 of the main report.[25]

4.5 EurAsEC, the Customs Union and the 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

22 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan*. 2014, p. 28.

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

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

25 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan.* 2014, p. 30.

Table 8: EAPO patent maintenance fees, USD (as of May 2014)

Year	Armenia	Azerbaijan[26]	Kyrgyzstan[27]	Moldova
1	-	-	-	137.0
2	48.2	-	-	137.0
3	48.2	12.7/63.7	120	137.0
4	60.2	20.4/102.0	150	137.0
5	60.2	28.0/140.2	180	137.0
6	72.3	35.7/178.5	200	411.0
7	72.3	43.3/216.7	240	411.0
8	91.6	51.0/255.0	300	411.0
9	91.6	58.6/293.2	360	411.0
10	115.7	66.3/331.5	360	411.0
11	115.7	76.5/382.5	480	684.9
12	139.8	86.7/433.5	480	684.9
13	139.8	96.9/484.4	720	684.9
14	163.9	107.1/535.4	720	684.9
15	163.9	117.3/586.4	720	684.9
16	192.8	127.5/637.4	840	958.9
17	192.8	137.7/688.4	840	958.9
18	241.0	147.9/739.4	840	958.9
19	241.0	158.1/790.4	960	958.9
20	241.0	168.3/841.4	960	958.9
Fees for maintenance of patents, extended under rule 16(5) of Patent Regulations				
21	313.3	181.0/905.2	1000	958.9
22	313.3	193.8/968.9	1050	958.9
23	385.6	206.5/1032.6	1100	958.9
24	385.6	219.3/1096.4	1150	958.9
25	385.6	232.0/1160.1	1200	958.9

Source: EAPO website (http://www.eapo.org/ru/documents/norm/tabposh.html – in Russian; as of May 2014, English page did not contain any numbers).
Note: fees are originally in USD for Armenia and Kyrgyzstan; fees for Azerbaijan (originally in AZN) and Moldova (in Euro) were calculated according to exchange rate as of May 15, 2014 (http://www.xe.com).

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. On 1 January 2010, the Customs Union of Belarus, Kazakhstan, and Russia came into existence. On 18 November 2011, the Presidents of Belarus, Kazakhstan, and Russia signed an agreement, setting a target

26 The price before slash is for individuals, organisations funded from the state budget and municipalities; the price after slash is for everybody else.

27 Individuals and not-for-profit organisations pay 10% of the fee; small-size enterprises pay 30% of the fee.

of establishing the Eurasian Union by 2015. The agreement included the roadmap for the future integration and established the Eurasian Commission and the Eurasian Economic Space, which started work on 1 January 2012. On 29 May 2014, Presidents of Belarus, Kazakhstan and Russia signed the Agreement on establishment of the Eurasian Economic Union, envisaging that the Union will go into effect on 1 January 2015. Armenia, Kyrgyzstan, Tajikistan and Uzbekistan have also expressed interest in joining. Moreover, in September 2013 the President of Armenia signed a roadmap of accession to the Customs Union; in October 2014 Presidents of Belarus, Kazakhstan, and Russia signed an agreement on Armenia's accession to the Eurasian Economic Union Treaty.[28] In May 2014 the government of Kyrgyzstan approved the first roadmap on the country's joining the Customs Union; in August 2014 the Presidents of Belarus, Kazakhstan and Russia signed the second version of the roadmap. Signing of the Agreement on Kyrgyzstan's entry in the Customs Union is expected to take place in December 2014.[29]

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.

Table 9: Status of study countries' accession to EurAsEC and Customs Union / EEU

Country	Status in EurAsEC	Status in Customs Union / EEU
Armenia	Observer since 2003	Non-member; roadmap of accession signed in 2013
Azerbaijan	-	-
Georgia	-	-
Kyrgyzstan	Member since 2001	Non-member; roadmap of accession signed in 2014
Moldova	Observer since 2002	-
Ukraine	Observer since 2002	-

For more information about the EurAsEC, Customs Union and the EEU, see Section 4.5 of the main report.[30]

4.6 Association Agreements with the EU

In June 2014, three of the study countries have ratified Association Agreements with the EU – Georgia,[31] Moldova[32] and Ukraine.[33] The Association Agreements (AA) include a Deep and Comprehensive Free Trade Area (DCFTA), promoting closer economic and political ties and envisaging alignment of the countries' regulatory systems with that of EU. Armenia finalized its negotiations on AA with the EU, including DCFTA, in July 2013. However, in view of Armenia's movement towards entry in the Customs Union of Russia, Belarus and Kazakhstan and the EEU, the AA, incompatible with membership in the Customs Union, was not signed.[34]

28 See, for instance: http://www.sputniknews.com/world/20141010/193914853/Armenia-Joins-Eurasian-Economic-Union.html, http://en.tengrinews.kz/politics_sub/Armenia-joins-Eurasian-Economic-Union-256806/.

29 See, for instance: http://en.itar-tass.com/economy/755491, http://www.sputniknews.com/world/20140830/192479271.html.

30 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan.* 2014, p. 33.

31 http://eeas.europa.eu/georgia/index_en.htm

32 http://eeas.europa.eu/moldova/index_en.htm

33 http://eeas.europa.eu/ukraine/index_en.htm

34 http://eeas.europa.eu/armenia/index_en.htm.

The three AAs have much in common in terms of structure and content, though some details vary. They all contain a chapter dealing specifically with IP issues ("Intellectual property rights"). The objectives of the chapter are to facilitate the production and commercialization of innovative and creative products between the country and the EU, and to achieve an adequate and effective level of protection and enforcement of IP rights. The comparison of some IP and related provisions in the AAs is shown in Table 10.

Table 10: IP and related provisions in Association Agreements of Georgia, Moldova and Ukraine

IP and related provisions	Association Agreement (AA)		
	Georgia	Moldova	Ukraine
Exhaustion regime	Regime of domestic or regional exhaustion of IP rights (Art. 152).	Regime of domestic or regional exhaustion of IP rights (Art. 279).	Free to establish its own regime for exhaustion of IP rights, subject to the provisions of the TRIPS Agreement (Art. 160).
Public health flexibilities	The Parties recognize the importance of the Doha Declaration, respect the Paragraph 6 Decision and contribute to its implementation (Art. 185).	The Parties recognize the importance of the Doha Declaration, respect the Paragraph 6 Decision and contribute to its implementation In interpreting and implementing the rights and obligations under AA's chapter on IP, the Parties ensure consistency with the Doha Declaration (Art. 313).	The Parties recognize the importance of the Doha Declaration, respect the Paragraph 6 Decision and contribute to its implementation In interpreting and implementing the rights and obligations under AA's chapter on IP, the Parties ensure consistency with the Doha Declaration (Art. 219).
Extension of patent protection	When a medicine is protected by a patent and was subject to registration procedure, a further period of protection should be provided for **up to five years**. In the case of medicines for which paediatric studies have been carried out, and provided that the results of those studies are reflected in the product information, a **further six months** extension has to be provided (Art. 186).	When a medicine is protected by a patent and was subject to registration procedure, a further period of protection should be provided for **up to five years**. In the case of medicines for which paediatric studies have been carried out, and provided that the results of those studies are reflected in the product information, a **further six months** extension has to be provided (Art. 314).	When a medicine is protected by a patent and was subject to registration procedure, a further period of protection should be provided for **up to five years**. In the case of medicines for which paediatric studies have been carried out, and provided that the results of those studies are reflected in the product information, a **further six months** extension has to be provided (Art. 220).
Data protection and exclusivity	**For at least six years** from the date of first authorization (registration) in one of the Parties, it should not be allowed for other applicants to market the same or a similar product, on the basis of the marketing authorisation granted to the applicant who had provided the test data or studies without his consent. This six year period may be extended to **a maximum of seven years** if, during the first six years after obtaining the initial authorisation, the holder obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies (Art. 187)	**For at least five years** from the date of first authorization (registration) in one of the Parties, it should not be allowed for other applicants to rely, directly or indirectly, on such data, without the consent of the person who submitted that data, in support of an application for marketing authorization of a medicine. **For at least seven years** from the date of authorization in a Party concerned, any subsequent application may not be granted, unless the subsequent applicant submits his/her own data or the data used for initial authorization with the consent of the person or entity who submitted that data. Products registered without submission of such data shall be removed from the market until the requirements are met. This seven-year period may be extended to **a maximum of eight years** if, during the first five years after obtaining the initial authorisation, the holder obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies. These provisions do not have retroactive effect and should not affect the marketing of medicines authorised before the entry into force of the AA (Art. 315)	When authorization (registration) of a medicine requires submission of test data or studies concerning the safety and efficacy of a medicine prior to granting registration, for **at least five years** from the date of the first approval, it should not be allowed for other applicants to market the same or a similar medicine on the basis of the registration granted to the applicant which had provided the test data or studies without his consent (Art. 222).

Table 10: IP and related provisions in Association Agreements of Georgia, Moldova and Ukraine (cont.)

IP and related provisions	Association Agreement (AA)		
	Georgia	Moldova	Ukraine
Approximation of legislation	Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of IP rights Timetable: the approximation with the provisions of the above Regulation, with the exception of Article 26, should be carried out within **three years** following the entry into force of the AA. The obligation on approximation to Regulation No 608/2013 in itself does not create any obligation on Georgia to apply measures where an IP right property is not protected under its substantive IP laws and regulations.	Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of IP rights Timetable: The approximation with the provisions of the above Regulation should be carried out by Moldova within **one year** following the entry into force of the AA.	Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs actions against goods suspected of infringing certain IP rights and the measures to be taken against goods found to have infringed such rights, without prejudice to the results of the current review of EU legislation on customs enforcement of IP rights. Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs actions against goods suspected of infringing certain IP rights and the measure to be taken against goods found to have infringed such rights. Timetable: the provisions of the above Regulations should be incorporated into Ukrainian law within three years following the entry into force of the AA.

Source: Texts of Association Agreements (http://eeas.europa.eu/georgia/pdf/eu-ge_aa-dcfta_en.pdf, http://eeas.europa.eu/moldova/pdf/eu-md_aa-dcfta_en.pdf, http://eeas.europa.eu/ukraine/docs/association_agreement_ukraine_2014_en.pdf)

The AAs require that both the countries and the EU (the Parties) ensure the adequate and effective implementation of the international agreements dealing with IP to which they are parties, including the TRIPS Agreement.

Association Agreements signed by Georgia, Moldova and Ukraine contain TRIPS-plus provisions, which may have negative impact on the countries' ability to access generic medicines, including ARVs. At the same time, the Association Agreements recognize the importance of the Doha Declaration and do not prevent countries from using TRIPS public health flexibilities.

One article of the chapter speaks specifically about patents and public health (art. 185 of the Georgia's AA, art. 313 of the Moldova's AA and art. 219 of the Ukraine's AA). The article envisages that the Parties have to recognize the importance of the Doha Declaration and to respect the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration.

At the same time, the AAs provide for patent extension (for up to five years) due to the time required to obtain market authorisation. Another extension is envisaged for paediatric medicines: "In the case of medicinal products for which paediatric studies have been carried out, and provided that results of those studies are reflected in the product information, the Parties shall provide for a further six months extension" (art. 186 of the Georgia's AA, art. 314 of the Moldova's AA and art. 220 of the Ukraine's AA).

Another TRIPS-plus provision is an article that envisages test data exclusivity (the TRIPS Agreement provides for test data protection, not exclusivity). Articles on data exclusivity read differently in the three AAs, but in general what they require is that the countries "implement a comprehensive system

to guarantee the confidentiality, non-disclosure and non- reliance of data submitted for the purpose of obtaining an authorisation to put a medicinal product on the market". Specifically in respect of Georgia and Moldova, AAs envisage that they need to "ensure that any required information that is submitted to obtain an authorisation to put a medicinal product on the market remains undisclosed to third parties and benefits from protection against unfair commercial use" (this provision is not present in the Ukraine's AA). For that purpose, countries shall not, for at least six years (Georgia) or five years (Ukraine) from the date of the first authorisation in one of the Parties, permit other applicants to market the same or a similar product, on the basis of the marketing authorisation granted to the applicant which had provided the test data or studies, unless the applicant which had provided the test data or studies has given his consent. Moldova's AA sets the timeframe differently:

"**(a)** during a period of at least five years, starting from the date of the grant of a marketing authorisation in the Party concerned, no person or entity, whether public or private, other than the person or entity who submitted such undisclosed data, shall be allowed to rely directly or indirectly on such data, without the explicit consent of the person or entity who submitted that data, in support of an application for the authorisation to put a medicinal product on the market;

(b) during a period of at least seven years, starting from the date of the grant of a marketing authorisation in the Party concerned, a marketing authorisation for any subsequent application shall not be granted, unless the subsequent applicant submits his/her own data, or data used with authorisation of the holder of the first authorisation, meeting the same requirements as in the case of the first authorisation. Products registered without submission of such data shall be removed from the market until the requirements are met."
The Georgia's and Moldova's AAs allow extension of the period of data exclusivity by one more year (to seven years in Georgia and eight years in Moldova) if, during the first six years (Georgia; five years for Moldova) after obtaining the initial authorisation, the holder obtains an authorisation for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with existing therapies.

The AAs foresee different regime for exhaustion of IP rights: for Georgia and Moldova the agreement is that they "provide for a regime of domestic or regional exhaustion of intellectual property rights", while Ukraine is "free to establish [its] own regime for exhaustion of intellectual property rights, subject to the provisions of the TRIPS Agreement". This gives Ukraine a comparative advantage vis-a-vis Georgia and Moldova, as Ukraine can establish international exhaustion regime and allow international parallel import of medicines if no other legislative restrictions exist.

Further, the AAs contain sections on enforcement of IP rights. The general obligation of the countries is that they reaffirm their commitments under the TRIPS Agreement (particularly Part III), and provide for a number of complementary measures, procedures and remedies necessary to ensure the enforcement of IP rights. These measures, procedures and remedies must be fair and equitable, and should not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. These measures and remedies must also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

The AAs also foresee border measures for goods violating IP rights; the Moldova's and Ukraine's AAs explicitly include here goods which infringe patents. This provision exceeds the minimum requirements of the TRIPS Agreement, which allows, but does not require, application of border measures to goods protected by patents.

Given that aligning of the countries' legal systems with the EU acquis requires some time, the Agreements foresee transition periods for approximation of legislations. In general, countries have one to three years to implement AA's IP related provisions and to ensure approximation of domestic legislation with EC Directives explicitly mentioned in the AAs. In case of some documents countries were given timelines: e.g. for the approximation with the provisions of Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights, Georgia has three years (Annex XIII), and Moldova has one year (Annex XXVI).

In general, association with the EU is expected to have considerable effect on IP protection and related processes in the three countries, including introduction of such TRIPS-plus provisions as test data exclusivity, which will very likely affect the access of the countries to generic medicines. While the AAs have already been agreed on, signed and now need to be implemented, the Agreements do not limit the opportunities of the countries to use TRIPS public health flexibilities, especially in view of the fact that the AAs respect the obligation to implement TRIPS Agreement and recognise the importance of the Doha Declaration on the TRIPS Agreement and Public Health. Also, countries that may consider association with the EU in the future should take into account potential negative consequences of TRIPS-plus IP-related provisions on access to treatment and cost of healthcare.

4.7 European Patent Convention

The Convention on the Grant of European Patents of 5 October 1973 – also known as the European Patent Convention (EPC) – establishes the European Patent Organization (EPO) and a system according to which European patents are granted. European patent are granted through a single procedure before the EPC. Applications may be filed in Munich, The Hague, or Berlin, or through patent offices of member states. European patents are nationally enforceable, and can also be revoked at national levels. Patent opposition is always post-grant and time-limited. While none of the study countries is party to the EPC, Moldova has signed an agreement with the EPO. Once the implementation of the agreement begins it will be possible for applicants and owners of European patents to have their patents recognized in Moldova.[35]

35 EPO, Simplifying Access to Patent Protection in Moldova, http://www.epo.org/news-issues/news/2013/20131021.html

5. ANALYSIS OF IP REGULATORY FRAMEWORKS IN THE STUDY COUNTRIES

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 Assembly of the CIS[36]: it develops 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 study countries.

All countries covered in this report except Ukraine have laws on normative legal acts, which specify hierarchy of legal documents. As a rule, legal acts of higher level (sometimes called legislative), including the constitution, codes and laws,[37] 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. The key requirement is that documents of a lower level do not contradict those of a higher level.

The main agencies in the field of public health are the ministries of health,[38] which are subordinate to national governments. 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.

36 This does not apply to Georgia, which is not part of the CIS.

37 In Armenia these include presidential decrees and government resolutions, in Georgia – presidential decrees,

38 In Georgia it is the Ministry of Healthcare, Labour and Social Protection.

5.2 IP protection and flexibilities

After gaining independence former Soviet republics started redefining their policies in respect of trade and IP. 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.

Table 11: Patent laws of the study countries

Country	Patent law (with amendments as of June 2014)
Armenia	Law of the Republic of Armenia "On Inventions, Utility Models and Industrial Designs" of 10 June 2008
Azerbaijan	Law of the Republic of Azerbaijan "On Patent", No. № 312-IQ of 10 June 1997
Georgia	Patent Law of the Republic of Georgia No. 1791-IIS of 5 February 1999
Kyrgyzstan	Patent Law of the Kyrgyz Republic No. 8 of 14 January 1998
Moldova	Law of the Republic of Moldova "On Protection of Inventions" No. 50-XVI of 7 March 2008
Ukraine	Law of Ukraine "On Protection of Rights for Inventions and Utility Models" No. 3769-XII of 15 December 1993

Accession to international and regional organizations, such as the WTO, WIPO, EAPO and EurAsEC and association with the EU also have a considerable effect on IP legislation of the countries. Table 12 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 12: The status of countries in WTO, WIPO, EAPO, EurAsEC and EU (as of June 2014)

Country	WTO	WIPO	EAPO	EurAsEC	EU
Armenia	Member	Member	Member	Observer (negotiating accession to the Customs Union)	Included in European Neighbourhood Policy and Eastern Partnership; Partnership and Cooperation Agreement
Azerbaijan	Observer (negotiating accession)	Member	Member	-	Included in European Neighbourhood Policy; Partnership and Cooperation Agreement
Georgia	Member	Member	-	-	Association Agreement (signed in June 2014)
Kyrgyzstan	Member	Member	Member	Member	Partnership and Cooperation Agreement
Moldova	Member	Member	Denounced EAPC	Observer	Association Agreement (signed in June 2014)
Ukraine	Member	Member	-	Observer	Association Agreement (signed in June 2014)

The WTO TRIPS Agreement offers 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.[39] This is 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). Some countries, such as Armenia and Moldova, have 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. Kyrgyzstan has received policy advice, reflected in its Strategy for IP development and the National Programme for IP development 2014-2016, which recommends some TRIPS-plus protection measures and does not always consider the country's status as a lower middle income country.

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

Table 13 below illustrates the status of integration of IP provisions in the study countries.

39 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).

Table 13: IP provisions in the study countries and international/regional instruments (as of June 2014)

	TRIPS Agreement	Armenia	Azerbaijan	Georgia	Kyrgyzstan	Moldova	Ukraine	EAPC
Patent duration	20 years	20 years (Art. 20(1) of the patent law)	20 years (Art. 2(2) of the patent law)	20 years (Art. 5(1) of the patent law)	20 years (Art. 4 of the patent law)	20 years (Art. 18(1) of the patent law)	20 years (Art. 6(4) of the patent law)	20 years
Patenting of new uses	Not required[40]	No	Yes (Art. 7(1) of the patent law)	Not clear[41]	Yes (Art. 5 of the patent law)	No	Yes (Art. 6(2) of the patent law)	No provision
Patent extensions	Not required	- Up to 5 years: immediately upon expiry of patent in case of war, natural disaster, etc.; - For pharmaceutical products: for period between date of filing the application on invention and date of obtaining authorization for putting the subject matter on the market, but not more than for 5 years (Art. 20 of the patent law)	No provisions	For medical products that require obtaining special permission: for period between the dates of applying to the patent office and the date of obtaining the permission, but not more than for 5 years (Art. 5(5) of the patent law)	Patents for pharmaceutical products may be extended for not more than for 5 years (Art. 4 of the patent law)	For medical and phytotherapeutic products having marketing permission, an additional certificate of protection may be issued for the product and its use for up to five years since the date of expiry of the patent (Arts. 69 and 71 of the patent law)	For products that require obtaining special permission (including medicines): for period between the dates of applying for the permission and the date of obtaining it, but not more than for 5 years (Article 6(4) of the patent law)	According to EAPC Patent Regulations, patent extension is possible if allowed by national laws, and for the period envisaged by those laws (Rule 16(5) of the EAPC Patent Regulations)
Exhaustion regime (parallel imports allowed when int'l)	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.	International (Art. 19 of the patent law)	Not clear, probably national (Art. 22 of the patent law)	International (Art. 52(a) of the patent law) Under AA, domestic or regional exhaustion regime should be introduced (art. 152)	Not clear, probably national (Art. 11 of the patent law)	National (Art. 20 of the patent law).	International (Arts. 28(2) and 31(3) of the patent law).	National (Rule 19 of the EAPC Patent Regulations)

40 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)

41 The Patent Law no longer contains provisions related to patenting of new uses of a known product (Art. 12(8), explicitly allowing it, was repealed), but this is implied in the Instruction on procedures related to drafting and filing Applications for Inventions and Utility Models and Granting a Patent (approved on 12 December 2011), which speaks about patenting the use of a product (e.g. in Art. 12(7)). Also, this is indicated on Georgian patent bureau web-site: http://www.sakpatenti.ge/index.php?lang_id=ENG&sec_id=5.

Table 13: IP provisions in the study countries and international/regional instruments (as of June 2014) (cont.)

	TRIPS Agreement	Armenia	Azerbaijan	Georgia	Kyrgyzstan	Moldova	Ukraine	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.	Compulsory license may be granted on conditions of non-exclusivity and equitable remuneration by court, when ▶ required by public interests, e.g. national security, healthcare or other vital sectors; ▶ patent owner or his licensee abuses patent rights; ▶ the invention has not been used or has been used unconscientiously during the period of 4 years from filing the application or 3 years from granting patent; ▶ patent holder does use, or does not sufficiently use, the patented invention, without a valid excuse, for 3 years since registration of the patent; ▶ unless there is emergency or state of war, there is a requirement to make efforts to conclude a license contract on reasonable commercial terms (Arts. 69 and 71 of the patent law)	▶ Use of patented invention without consent of the patent holder is allowed if it is in the interest of national security (with payment of "commensurate compensation"). ▶ Compulsory license may be granted by court on conditions of non-exclusivity, when the invention has not been used without valid excuse for 3 years since the grant of the patent, or if the use of patent was stopped for more than 3 years (Art. 20 of the patent law)	Government use: in emergency situations (natural disaster, catastrophe, etc.; Art. 52 of the patent law). Compulsory license: not envisaged for patents.	Government use: in emergency situations (Art. 13 of the patent law) Compulsory license: may be issued by court on conditions of payment of a commensurate compensation. The compulsory license may be granted to any person who wishes and is ready to use an invention if the invention has not been used or inadequately used in Kyrgyzstan within 3 years from the date of grant of the patent, and provided that the owner of rights has rejected the conclusion of the license agreement (Art. 12 of the patent law)	▶ may be issued by court on conditions of non-exclusivity and payment of a commensurate compensation ▶ may be granted to any person who wishes and is ready to use an invention if the invention has not been used or inadequately used in Moldova within 4 years since the application or within 3 years from the date of the grant of the patent, whichever expires last, and provided that it was impossible to get permission from patent owner on commercially acceptable terms and within reasonable period of time; ▶ may be issued in case of a national emergency or other emergency situation or for public use in not-for-profit purposes (Art. 28 of the patent law)	Government use: for purposes of protection of public health, national defence, environmental safety and other public interests. Compulsory license: ▶ may be issued by court on conditions of payment of a commensurate compensation; ▶ may be granted to any person who wishes and is ready to use an invention if the invention has not been used or inadequately used in Ukraine within 3 years from the date of publishing the data on granting a patent or from the date when the use of the invention was terminated, and provided that the owner of rights has rejected the conclusion of the license agreement (Article 30 of the patent law).	▶ 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).

Table 13: IP provisions in the study countries and international/regional instruments (as of June 2014) (cont.)

	TRIPS Agreement	Armenia	Azerbaijan	Georgia	Kyrgyzstan	Moldova	Ukraine	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).	▶ use for personal needs with no purpose to make profit; ▶ use as a subject of scientific research or scientific experiment; ▶ use for single preparation of medicaments in pharmacies based on physicians' prescriptions (Art. 17 of the patent law)	▶ use with no purpose to make profit; ▶ use as a subject of scientific research, scientific experiment or trial; ▶ use for single preparation of medicaments in pharmacies based on physicians' prescriptions (Art. 23 of the patent law).	▶ personal use with no purpose to make profit; ▶ use in emergency situations (natural disaster, catastrophe, etc.) (Art. 52 of the patent law)	▶ use for scientific or experimental purposes; ▶ use in emergency conditions (natural disaster, calamity, large-scale accident) subject to commensurate compensation to patent owner (Art. 11, 13(2) of the patent law)	▶ use in private sector in non-commercial purposes; ▶ use for experimental purposes; ▶ use for single preparation of medicaments in pharmacies based on physicians' prescriptions; ▶ if patent owner suffers damages due to such use of the patented invention, he is eligible to receive commensurate compensation (Art. 22 of the patent law).	▶ use without any commercial purpose; ▶ use for scientific or experimental purposes; ▶ use in emergency conditions (natural disaster, accident, epidemic etc.) with the notification of the patent owner as soon as possible and subject to commensurate compensation to patent owner (Art. 31(2) of the patent law).	▶ scientific research or experiment; ▶ one-time production of medicines in pharmacies by doctor's prescription; ▶ use for private not-for-profit purposes; ▶ use of a product after this product has been marketed by the patent owner himself or with his consent (Rule 19 of the EAPC Patent Regulations)
Regulatory exception (Bolar provision)	No provisions[42]	Art. 17 of the patent law allows use of patented products for the purpose of scientific research or scientific experiment.	Art. 23 of the patent law allows use of patented products for the purpose of trial.	No provisions	Art. 13 of the patent law allows use of patented products for the purpose of research and trials.	Art. 22 of the patent law allows use of the patented products for the purpose of experiment	Not clear[43]	No provisions
Test data exclusivity	Test data are protected under Art. 39.3.	Yes (Art. 16(7) of the law on protection of economic competition)	Test data are only exclusive in respect of inventions related to national security (Art. 30(7) of the patent law)	Test data are exclusive (Art. 4 of the law on medicines and pharmaceutical activity)	Yes (Art. 12 of the law on commercial secret)	Yes, unless required "for the protection of population" (Art. 12 of the law on commercial secret)	Yes, unless required "for the protection of population" (Art. 507 of the Civil Code)	No provisions

42 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.

43 On the one hand, Art. 31(2) of the Patent Law allows use of patented products for scientific purpose or experiment. On the other, the Law on Medicines (Art. 9) requires the applicant for registration of a patented medicine to submit a copy of the patent or license for production or sale of the medicine.

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 14 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 (e.g. EFV in Ukraine and NVP in Georgia44), have already expired. However, patents are still valid when it comes to specific formulations and FDCs. These include:

- hemisulphate salt of ABC (Eurasian patent EA001809, expires in 2018, and Ukrainian patent UA56231);
- 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; Georgian patent GE5083; Ukrainian patents UA85564 and UA89220);
- tablet formulation of RTV (Eurasian patent EA011924, expires in 2024; Ukrainian patent UA85564);
- combination of ABC with 3TC or FTC and AZT (Eurasian patent EA000626, expires in 2016; Georgian patent GE2467);
- combination of EFV/FTC/TDF (Eurasian patent EA017764, expires in 2026);
- combination of FTC/TDF (Eurasian patent EA015145, expires in 2024; Ukrainian patent UA81797).

> 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.

Eurasian patents listed above cover Armenia, Azerbaijan, Moldova and Kyrgyzstan. Even though Moldova is no longer party to the EAPC, it continues to recognize the patents above as they were granted before the date of EAPC denouncement. Still, Moldova is in a relatively advantaged position compared to the EAPC members covered by this study, and will be able to benefit from using generic versions of newer ARVs, which are and will be patented after Moldova denounced the EAPC.

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'.

44 Here and below, the status for all Georgian ARV patents is as of May 2012.

Table 14: Patent status of key ARVs in the study 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)	Armenia (as of February 2014)	Azerbaijan (as of February 2014)	Georgia (as of May 2012)	Kyrgyzstan (as of February 2014)	Moldova (as of February 2014)	Ukraine (as of February 2014)
3TC	Epivir	IAF Biochem GSK	EP0382526	Feb. 2010	No	No	Expired (GE1599)	No	No	No
crystal form			WO9221676	June 2012	No	No	Granted (GE1834)	No	No	Expired (UA41265)
liquid composition			WO9842321	2018	Granted (EA001990)	Granted (EA001990)	No	Granted (EA001990)	Granted (EA001990)	Granted (UA60328)
ABC	Ziagen	Wellcome (GSK)	WO9100282 EP0434450	June/Dec. 2010	No	No	No	No	No	Expired (UA29382)
hemisulphate salt			WO9852949	2018	Granted (EA001809)	Granted (EA001809)	Granted (GE2680)	Granted (EA001809)	Granted (EA001809)	Granted (UA56231)
composition for ped.use			WO9939691	2019	Granted (EA002916)	Granted (EA002916)	No	Granted (EA002916)	Granted (EA002916)	No
comb. w/ 3TC or FTC (and AZT)			WO9630025	2016	Granted (EA000626)	Granted (EA000626)	Granted (GE2647)	Granted (EA000626)	Granted (EA000626)	No
ATV	Reyataz	Novartis (BMS)	WO9740029	2017	Lapsed (EA001794)	Lapsed (EA001794)	No	Lapsed (EA001794)	Lapsed (EA001794)	No
bisulfate salt		BMS	WO9936404	2018	No	No	Granted (GE3026)	No	No	Granted (UA59432)
use in HIV therapy			WO03020206	2022	No	No	No	No	No	No
process			WO2005108349	2025	No	No	No	No	No	No
AZT	Retrovir	Glaxo Wellcome	US4724232	2006	No	No	No	No	No	No
AZT+3TC	Combivir	Glaxo Wellcome	WO9220344	May 2012	Expired (AM 858)	No	No	No	No	No
tablet formulation			WO9818477	May 2013	Lapsed (EA002437)	Lapsed (EA002437)	No	Lapsed (EA002437)	Lapsed (EA002437)	Withdrawn (UA64725)
d4T	Zerit	Yale Univ. (BMS)	EP0273277	Dec. 2007	No	No	No	No	No	No
ddI	Videx	US Gov (BMS)	WO8701284	2006	No	No	No	No	No	No
improved oral formulation		BMS	US5880106	July 2012	No	No	No	No	No	No
enteric-coated	Videx ec	BMS	WO9961002	2018	No	No	Granted (GE3014)	No	No	Granted (UA69413)

Table 14: Patent status of key ARVs in the study 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)	Armenia (as of February 2014)	Azerbaijan (as of February 2014)	Georgia (as of May 2012)	Kyrgyzstan (as of February 2014)	Moldova (as of February 2014)	Ukraine (as of February 2014)
DRV	Prezista	Searle, Monsanto	WO9404492	Aug. 2013	No	No	No	No	No	No
method of use		US Gov	WO9967417	2019	No	No	No	No	No	No
comb. w/ RTV		Tibotec	WO03049746	2022	No	No	No	No	No	No
pseudopolymorph / solvate form			WO03106461	2023	Granted (EA007120)	Granted (EA007120)	No	Granted (EA007120)	Granted (EA007120)	No
prep. of key intermediates			WO2005095410	2025	No	No	No	No	No	Granted (UA100835)
comb. w/ RTV & TDF			WO2006005720	2025	No	No	No	No	No	No
EFV	Stocrin/ Sustiva	Merck (MSD, BMS)	WO9403440	Aug. 2013	No	No	No	No	No	Granted (UA42699)
comb. w/ FTC & TDF	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	No	Granted (EA017764)	Granted (EA017764)	No
ETV	Intelence	Janssen (Tibotec)	WO0027825	2019	Granted (EA004049)	Granted (EA004049)	No	Granted (EA004049)	Granted (EA004049)	Granted (UA70966)
solid formulation			WO0122938	2020	Granted (EA005423)	Granted (EA005423)	Unknown	Granted (EA005423)	Granted (EA005423)	Granted (UA74797)
novel series		Tibotec	WO2006094930	2026	No	No	No	No	No	No
new forms			WO2006079656	2026	No	No	No	No	No	No
FPV	Lexiva	Vertex (GSK)	WO9933815	2018	Granted (EA003509)	Granted (EA003509)	Granted (GE2923)	Granted (EA003509)	Granted (EA003509)	Granted (UA72733)
calcium salt		GSK	WO0004033	2019	Lapsed (EA003191)	Lapsed (EA003191)	Withdrawn (GE3030)	Lapsed (EA003191)	Lapsed (EA003191)	No

Table 14: Patent status of key ARVs in the study 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)	Armenia (as of February 2014)	Azerbaijan (as of February 2014)	Georgia (as of May 2012)	Kyrgyzstan (as of February 2014)	Moldova (as of February 2014)	Ukraine (as of February 2014)
FTC	Emtriva	IAF Biochem	EP0382526	Feb. 2010	Expired (AM455)	No	Expired (GE1599)	Unknown[45]	No	No
		Emory Univ. (Gilead)	WO9111186 WO9214743	Jan. 2011/Feb. 2012	No	No	No	No	No	No
comb. w/ TDF	Truvada		WO2004064845	2024	Granted (EA015145)	Granted (EA015145)	No	Granted (EA015145)	Granted (EA015145)	Granted (UA81797)
comb. w/ TDF + RIL	Complera	Tibotec (Gilead)	WO2005021001	2024	Granted (EA014840)	Granted (EA014840)	No	Granted (EA014840)	Granted (EA014840)	No
comb w/ EFV + TDF	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	No	Granted (EA017764)	Granted (EA017764)	No
IDV	Crixivan	Merck	WO9309096 WO9422480	Nov. 2012/ March 2014	No	No	No	No	No	Expired (UA45945)
LPV	Kaletra	Abbott	WO9721685	2016	No	No	No	No	No	No
LPV/r Soft-gel caps			WO9822106	2017	No	No	No	No	No	No
LPV/r tablet formulation			WO2005039551	2024	Granted (EA011924)	Granted (EA011924)	No	Granted (EA011924)	Granted (EA011924)	Granted (UA85564)
			WO2006091529	2026	Granted (EA014446)	Granted (EA014446)	Granted (GE5083)	Granted (EA014446)	Granted (EA014446)	Granted (UA89220)
NFV	Viracept	Agouron Pharmaceuticals, Inc.	WO1995009843	Oct. 2014	No	Unknown	Unknown	Unknown	Granted (MD1507)	No
NVP	Viramune	Boehringer	EP0429987	Nov. 2010	No	No	Granted (GE3131)	No	No	No
hemihydrate formulation			WO9909990	2018	No	No	Granted (GE3799)	No	No	Granted (UA44370)
extended release formulation			WO2008154234	2028	Granted (EA018377)	Granted (EA018377)	No	Granted (EA018377)	Granted (EA018377)	Granted (UA97971)

45 As per information from Medicines Patent Pool database, as of March 2011, FTC was protected by patent KG219. At the time of writing of this report (February 2014), it was not possible to verify validity of the patent due to the fact that electronic database of patents of the State IP and Innovation Service of Kyrgyzstan (http://www.patent.kg/index.php/ru/invention/33-inventions/620-bazy-dannykh-v-razrabotke.html) was not functional.

Table 14: Patent status of key ARVs in the study 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)	Armenia (as of February 2014)	Azerbaijan (as of February 2014)	Georgia (as of May 2012)	Kyrgyzstan (as of February 2014)	Moldova (as of February 2014)	Ukraine (as of February 2014)
RAL	Isentress	Institute for Research in Mol. Biology, Italy, MSD	WO03035077	2022	Lapsed (EA007060)	Lapsed (EA007060)	No	Lapsed (EA007060)	Lapsed (EA007060)	Granted (UA77454)
Potassium salt			WO2006060712 WO2006060730	2025	Lapsed (EA012418)	Lapsed (EA012418)	No	Lapsed (EA012418)	Lapsed (EA012418)	Granted (UA87884)
RTV	Norvir	Abbott	WO9414436	Dec. 2013/2014	No	No	No	No	No	No
crystalline polymorph			WO0004016	2019	No	No	No	No	No	No
tablet formulation	Kaletra	Abbott	WO2005039551	2024	Granted (EA011924)	Granted (EA011924)	No	Granted (EA011924)	Granted (EA011924)	Granted (UA85564)
SQV	Fortovase	Hoffmann-La Roche	EP0432695	Dec. 2010	No	No	No	No	No	Expired (UA26029)
improved composition			WO9639142	2016	Lapsed (EA001413)	Granted (EA001413)	No	Granted (EA001413)	Lapsed (EA001413)	Granted (UA44316)
oral dosage form			WO2005004836	2024	Lapsed (EA015349)	Lapsed (EA015349)	No	Lapsed (EA015349)	Lapsed (EA015349)	Granted (UA81335)
TDF	Viread	Gilead	WO9905150	2018	No	No	No	No	No	No
ester prodrug			WO9804569	2017	No	No	No	No	No	No
comb. w/ FTC	Truvada		WO2004064845	2024	Granted (EA015145)	Granted (EA015145)	No	Granted (EA015145)	Granted (EA015145)	Granted (UA81797)
comb. w/ FTC + RIL	Complera	Tibotec (Gilead)	WO2005021001	2024	Granted (EA014840)	Granted (EA014840)	No	Granted (EA014840)	Granted (EA014840)	No
comb w/ EFV + FTC	Atripla	Gilead & BMS	WO2006135933	2026	Granted (EA017764)	Granted (EA017764)	No	Granted (EA017764)	Granted (EA017764)	No

Sources: Espacenet.com, Eurasian Patent Organization, Medicines Patent Pool, national patent offices, WIPO.
Note: 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 IN THE STUDY COUNTRIES

6.1 Licensing of pharmaceutical activity

In the EU and the U.S.A., 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* (in Azerbaijan and Georgia also called *authorization*) 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 and sell medicines; in Armenia and Ukraine a license is also needed to import pharmaceutical products. Such licenses are typically called licenses for pharmaceutical activity. Similarly, provision of medical services (so-called medical activity) also requires a license; for sale

Table 15: Key documents on licensing of pharmaceutical activities in study countries

Country	Documents (with amendments as of June 2014)
Armenia	Law of the Republic of Armenia "On Medicines", No. ZR-259 of 26 November 1998 Law of the Republic of Armenia "On Licensing", No. ZR-193 of 27 June 2001
Azerbaijan	Law of the Republic of Azerbaijan "On Medicines", No. 208-IIIQ of 22 December 2006 Decree of the President of the Republic of Azerbaijan "On additional measures in the area of issuance of authorization (license) for certain types of activities", No 510 of 29 December 2006 Decree of the President of the Republic of Azerbaijan "On improvement of rules for issuance of authorization (license) for certain types of activities", No 510 of 29 December 2006
Georgia	Law of Georgia "On Medicines and Pharmaceutical Activity", No. 659-IIc of 17 April 1997 Law of Georgia "On Grounds for Issuing Licenses and Permission for Entrepreneurial Activity", No. 1426-vc of 14 May 2002 Law of Georgia "On License and Authorization Fees", No. 2937-vc of 12 August 2003
Kyrgyzstan	Law of the Kyrgyz Republic "On Medicines", No. 91 of 30 April 2003 Law of the Kyrgyz Republic "On Licensing", No. 12 of 3 March 1997 Law of the Kyrgyz Republic "On Licensing-Permission System", No. 195 of 19 October 2013 Resolution of the Government of the Kyrgyz Republic "On Licensing of Certain Types of Activities", No. 260 of 31 May 2001.
Moldova	Law of the Republic of Moldova "On Pharmaceutical Activity", No. 1456 of 25 May 1993 Law of the Republic of Moldova "On Licensing of Certain Types of Activities", No. 451 of 30 July 2001 Regulations of the Ministry of Healthcare of the Republic of Moldova "On the Procedure of Issuing Licenses for Pharmaceutical Activity", No. 1307 of 13 July 1999
Ukraine	Law of Ukraine "On Medicines", No. 123/96-BP of 4 April 1996 Law of Ukraine "On Licensing of Certain Types of Economic Activity", No. 1775-III of 1 June 2000

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.

In order to obtain a license/authorization for pharmaceutical activity, an applicant typically needs to meet the following general criteria:[46]

- 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/authorization for production or importation of medicines, as of May 2014: in Azerbaijan 5500 AZN (7,011.7 USD), in Georgia 400 GEL (226 USD), in Kyrgyzstan 300 KGS (5.7 USD), in Moldova 1,800 MDL (133.5 USD), in Ukraine 1,254.54 UAH (106.7 USD).

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 legislation of all the selected countries, though in some countries (e.g. Azerbaijan, Georgia and Kyrgyzstan) 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 as exceptions, and one can expect that all countries will move towards uniform application of registration requirements to all medicines. The GFATM does not require ARVs procured with grants provided by this institution to be registered in the country, but requires for pharmaceutical products to "have been authorized" by national drug regulatory authority "in accordance with its standard practices for drug registration or other forms of authorization (such as authorizations for marketing or importation)".[47] Given that ad hoc waivers are a form of authorization, they are sufficient for medicines to be procured under the GFATM grants. 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. For example, in Armenia, Azerbaijan and Moldova not all of the recommended ARVs 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.[48] 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, 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.

46 Specific criteria vary from country to country.

47 Global Fund Quality Assurance Policy for Pharmaceutical Products (as amended and restated on 14 December 2010). http://www.theglobalfund.org/documents/psm/PSM_QAPharm_Policy_en/.

48 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 para. 4.5). As to the GFATM, it requires that the medicines procured within its grants are WHO prequalified (read more in para. 7.2).

Medicines can be exempt from registration procedures if they are:

- produced by pharmacies under physician's prescription (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova);
- imported for personal use (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Ukraine);
- imported for use as exhibition items (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Ukraine);
- imported for the purpose of preclinical and clinical trials (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Moldova, Ukraine);
- imported in case of epidemics, natural disasters or other emergencies, provided these medicines are registered in the country of origin (Armenia, Azerbaijan, Georgia, Kyrgyzstan, Ukraine);
- pharmaceutical substance imported in bulk for local production (Georgia, Moldova). It should be noted, however, that the medicine produced of that substance has to be registered before being marketed and used.

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.

In addition to standard registration procedure, there is a simplified or accelerated registration, which exists in Armenia, Georgia, Kyrgyzstan.

In **Armenia**, the maximum duration of the pre-registration expertise is 180 days. For medicinal products registered in one of the full member countries of European Union, the USA or Japan, expertise is carried out within maximum 30 days and does not include any laboratory examination.

In **Azerbaijan**, the registration procedure consists of several stages: preliminary expertise of documents (15 days), specialized expertise consisting of laboratory tests, review of normative and technical documentation and results of clinical and pharmacological trials (180 days for first registration and 90 days for re-registration), and, when required, additional expertise (30 days). In practice, the process is even longer, because of the formalities (e.g. signing a contract for specialised expertise or issuance of the registration certificate), in case the applicant is requested to provide additional documents, etc.

Georgia has two different registration regimes for medicines: recognition regime and national regime. The recognition regime may be applied for both innovative and generic pharmaceutical products already admitted into the relevant market by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries. The list of the above regulatory bodies is determined by the Resolution No. 188 of the Government of Georgia dated 22 October 2009 "On the List of State Bodies Regulating Other Countries' or Interstate Pharmaceutical Products."[49] The recognition regime is considerably easier and faster than the national regime.

According to the law on medicines, standard registration procedure in **Kyrgyzstan** may not take more than six months from the date of application. Simplified registration procedure is used for registration of generic medicine equivalent to an originator medicine, which is already registered in Kyrgyzstan, even if the generic was manufactured under a different technology and contains different additives. The duration of the simplified procedure is no longer than 1.5 months.

In **Moldova**, a standard registration procedure should not exceed 210 days from the date of submitting the application and payment of the fee. The procedure envisages several stages, including preliminary dossier review and specialised expertise, which includes quality control. The latter is not required at the stage of registration for medicines manufactured under GMP and registered in other countries, though for these medicines quality control is foreseen after the registration is granted (random control for medicines registered by the European Medicines Agency, in one of the countries of the European Economic Area, Switzerland, the USA, Canada, Japan or Australia, and

49 The List contains the following countries/authorities: EMA – European Medicines Agency; Australia; Austria; Belgium; Bulgaria; Canada; Cyprus; Czech Republic; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Iceland; Ireland; Italy; Japan; Korea; Latvia; Lithuania; Luxemburg; Malta; Netherlands; New Zealand; Norway; Poland; Portugal; Romania; Slovakia; Slovenia; Spain; Sweden; Switzerland; UK; USA.

per batch control for medicines registered in other countries).

In **Ukraine** the duration of the registration procedure depends on the quality of information proving efficacy, safety and quality of the medicine. The standard procedure includes initial review of the dossier and a specialised expertise. So, when the specialised expertise shows that there is sufficient evidence proving that the medicine meets the standards of efficacy, safety and quality, the medicine is registered. When it is found that information provided by the applicant is insufficient to draw conclusions on the medicine's efficacy, safety and quality profile, or on bioequivalence of the generic medicine to the originator medicine, additional expertise is carried out.

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 all study countries there is a requirement to pay a registration fee, which is considerably higher than the fee for obtaining a license. For instance, Armenia has fixed registration fees: as of February 2014, registration of the first pharmaceutical form and dosage strength of a generic medicine cost about 2,200 USD, each additional pharmaceutical form or each new indication – about 1,100 USD and each additional dosage strength – about 600 USD. In Ukraine, in order to register a medicine a company needs to cover the cost of the expertise and to pay a fee of 100 EUR per dosage form and 10 EUR per each additional dosage and additional package. In Kyrgyzstan there is a price list for registration of medicines, but according to the law on medicines the fee for registration may not exceed actual costs of the expertise. Unless there is a simplified procedure for registration that does not require carrying out full range of trials, when these have already been carried out in other countries, the expertise of the medicine is costly, which explains why pharmaceutical companies are so selective in terms of where and which products to register. It should be noted that according to Armenian legislation, for medicinal products of major therapeutic and public health interest intended for the treatment of serious or life threatening diseases or condition, the expertise for registration may be carried out at expense of state budget by the Government order. The list of such low demand but vital medicines is adopted by the Ministry of Health.

In all study countries, a registration is valid for five years and can be extended through re-registration. Legislation of all study countries envisages the deadlines (ranging from 90 to 120 days before expiry of registration), by when the manufacturer or distributor of the medicine needs to apply for re-registration. In this case, the re-registration procedures follow the steps of initial registration, but do not require laboratory tests, as long as the composition, dosage and other significant qualities of the medicine remain unchanged since its initial registration. If the deadline is missed, the re-registration may be carried under the standard registration procedure.

In addition to having a national regulatory framework for registration of medicines, Kyrgyzstan is a signatory to the *Agreement on Cooperation of Member States of Eurasian Economic Community Regarding the Circulation of Medicines (Pharmaceutical Compositions), Medical Products and Medical Instruments (Medical Equipment)*,[50] signed on 28 September 2012 by representatives of Belarus, Kazakhstan, Kyrgyzstan, Russia and Tajikistan.[51] As Armenia is moving towards joining the EurAsEC/EEU, one can expect that the country will also accede to this Agreement. The document contains the following important commitments:

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

51 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 No. 50-Z of 12 July 2013).

- 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 assign additional research, trials and inspections, when deemed necessary;
- to share information on identified unwanted side effects and decisions to recall medicines and medical products or limit their use.

It is worth mentioning 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*.[52] 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;
- the information provided in application instructions/package leaflet.

Even though these documents have not yet been fully implemented, one can be certain that further steps will be taken in the near future.

6.3 Registration status of ARV medicines in the study countries

All of the study countries provide online access to their registration databases. They allow a fast overview of which medicines are registered in the country, as well as details of their registration. Even though 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.

Grouping of ARVs being registered in the study countries by branded, generic or both shows considerable differences among the countries (see Table 16 below).

Table 16: ARV medicines registered in the study countries grouped by generic/originator/both

Country	ARVs registered		
	Originator	Generic	Both originator and generic
Armenia	LPV/r, NVP, RTV, TDF	-	-
Azerbaijan	3TC, DRV, LPV/r, RTV, TDF	3TC/AZT	FTC/TDF
Georgia	ABC, LPV/r, RAL, TDF; 3TC/ABC/AZT, FTC/TDF	3TC, AZT, d4T, EFV	NVP, RTV
Kyrgyzstan	RTV; FTC/TDF	ABC, AZT, d4T, ddI, EFV	3TC, LPV/r, NVP, TDF
Moldova	DRV, LPV/r, RTV, TDF; FTC/TDF	AZT, EFV, IDV; 3TC/d4T/NVP, 3TC/d4T, 3TC/AZT/NVP, 3TC/AZT	3TC
Ukraine	DRV, ETV, FPV, RAL; 3TC/ABC, 3TC/ABC/AZT,	d4T, ddI, IDV	3TC, ABC, AZT, EFV, LPV/r, NVP, RTV, TDF; 3TC/AZT, EFV/FTC/TDF, FTC/TDF

Registration status of ARV medicines in Armenia, Azerbaijan, Georgia, Moldova, Kyrgyzstan and Ukraine is shown in tables in Annex 1.

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

7. PROCUREMENT SYSTEMS IN THE STUDY COUNTRIES

7.1 Overview of countries' public procurement systems

For decades, study countries had been part of the Soviet Union, which had centralised systems of administration, including in the field of public procurements. After the collapse of the USSR, the newly independent states started reforming their procurements systems in a way to make them more efficient, transparent and de-centralised.

It is important to mention that public procurements, like some other economic areas, has been influenced by two different integration processes: development of EurAsEC and approximation with the EU. So, Armenia and Kyrgyzstan are moving towards joining the EurAsEC and Customs Union and the EEU, while Georgia, Moldova and Ukraine have signed association agreements with the EU.

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 Customs Union has an *Agreement on Public (Municipal) Procurements*, which entered into force on 1 January 2012.[53] Provisions of the Agreement are mandatory for the countries of the Union, 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;[54]
- 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.

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

54 This means that all states parties take measures to prevent, detect and stop violations of states parties' laws on procurements. For the purpose of ensuring the rights and interests of persons involved in state procurements, each state party identifies a state body responsible for oversight of procurements, resolving complaints, prevention of violations of the procurements legislation, keeping the registry of mala fide suppliers, etc.

For more information about the Agreement, see Section 7.1 of the main report.[55]

As to the *Association Agreements* (AA) of Georgia, Moldova and Ukraine with the EU, they all contain a chapter on public procurement. It envisages that the countries "recognise the contribution of transparent, non-discriminatory, competitive and open tendering to sustainable economic development and set as their objective the effective, reciprocal and gradual opening of their respective procurement markets". The chapter envisages mutual access to public procurement markets on the basis of the principle of national treatment at national, regional and local level for public contracts and concessions in the public sector. It provides for a gradual approximation of the public procurement legislations of the countries with the Union *acquis*[56] on public procurement, accompanied with an institutional reform and the creation of an efficient public procurement system based on the principles governing public procurement in the Union.

In terms of institutional background, the countries committed to establish/maintain an appropriate institutional framework and mechanisms necessary for the proper functioning of the public procurement system and the implementation of the provisions of the AA. In particular, in the framework of institutional reform, the countries agreed to designate:

(a) an executive body responsible for economic policy at central government level tasked with guaranteeing a coherent policy in all areas related to public procurement. Such a body will facilitate and coordinate the implementation of the public procurement chapter of the AA and guide the process of gradual approximation to the Union *acquis*; and

(b) an impartial and independent body tasked with the review of decisions taken by contracting authorities or entities during the award of contracts. In that context, 'independent' means that that body shall be a public authority which is separate from all contracting entities and economic operators. There should be a possibility to subject the decisions taken by that body to judicial review.

The chapter also contains an article on basic standards regulating the award of contracts (art. 144 of the Georgia's AA, art. 271 of the Moldova's AA, art. 151 of the Ukraine's AA). The first paragraph of the article sets the timeline for bringing national laws in compliance with a set of basic standards for the award of all contracts, which derive directly from the rules and principles of public procurement, as regulated in the EU *acquis* on public procurement, including the principles of non-discrimination, equal treatment, transparency and proportionality. The timeline is different for all the three countries: three years from the date of entry into force of the AA for Georgia, nine months for Moldova and six months for Ukraine.

Twenty years after gaining independence, on 15 September 2011, Armenia became the first country of the former Soviet Union to accede to the *WTO Agreement on Government Procurement* (GPA). The GPA is a plurilateral agreement within the framework of the WTO, meaning that not all WTO members are parties to the Agreement. Georgia, Kyrgyzstan, Moldova and Ukraine currently have observer status and are in the process of accession.

The fundamental aim of the GPA is to mutually open government procurement markets among its parties. The GPA is composed mainly of two parts: the text of the Agreement and parties' market access schedules of commitments. The text of the Agreement establishes rules requiring that open, fair and transparent conditions of competition be ensured in government procurement. However, these rules do not automatically apply to all procurement activities of each party. Rather, the coverage schedules play a critical role in determining whether a procurement activity is covered by the Agreement or not. Only those procurement activities that are carried out by covered entities purchasing listed goods, services or construction services of a value exceeding specified threshold values are covered by the Agreement.

The Parties continuously improve the document. The revised GPA, which entered into force on 6 April 2014, clearly sets out that, no later than three years after the

55 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan*. 2014, p. 53.

56 *Union acquis* (also *Community acquis or EU acquis*) refers to accumulated legislation, legal acts, and court decisions which constitute the body of European Union law.

entry into force of the revised GPA and periodically thereafter, the parties shall undertake further negotiations to progressively reduce and eliminate discriminatory measures and to achieve the greatest possible extension of the coverage. In this spirit, the GPA parties have also agreed to undertake a number of work programmes which will influence the future evolution of the Agreement.[57]

Another instrument that may affect access to medicines in the future is the *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, also referred to as the *MEDICRIME Convention*.

The Convention is not yet in force as not enough countries have ratified it. If it enters into force it will become a binding international instrument in the criminal law field on "counterfeiting" of medical products and similar crimes involving threats to public health. The proclaimed purpose of this Convention is to prevent and combat threats to public health by:

- providing for the criminalisation of certain acts;
- protecting the rights of victims of the offences established under the Convention;
- promoting national and international co-operation.

According to Article 3, the Convention concerns medical products whether they are protected under IP rights or not, or whether they are generic or not, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

To enter into force, the Convention needs five ratifications; as of the time of completing of this report, it was ratified by four countries: Hungary (9 January 2014), Moldova (14 August 2014), Spain (5 August 2013) and Ukraine (20 August 2012).

The provisions of the Medicrime Convention criminalize the "intentional manufacturing" of counterfeit products. However, the text defines "counterfeit" as "a false representation as regards identity and/or source", which is an overly broad definition. If applied, it could lead to the situation when unintentional false representation about a medicine could lead to criminal prosecution. While such accidents are rare they do happen (e.g. by unintentional mislabeling, or presence of contaminants) even with manufacturers who apply the highest manufacturing standards. Typically companies immediately recall such production and warn relevant authorities. Introducing criminal liability for unintentional mistakes is likely to have a detrimental effect on manufacturers, who may prefer not to enter markets where these provisions apply.

Also, there is a conflict between the definitions of "counterfeit" under the Convention and under national laws of countries in the EECA region, including the study countries, which might lead to conflation of generic medicines with substandard and falsified products. Again, this is likely to have a substantial detrimental effect on the generic industry and its presence on national markets.

Pooled procurement of pharmaceutical products, including ARV medicines, is a procurement instrument currently used under GFATM grants and in some regions around the world. Pooled procurement, also referred to as "group purchasing", or "group contracting", is a mechanism that allows achieving economies of sale and considerably lower costs per unit. As study countries will transit to national financing of ARV procurements, they may face a substantial increase in the cost of treatment due to significantly smaller volumes of medicines procured. This obstacle may be addressed by pooling procurements either by either creating new mechanisms, e.g. within CIS or Customs Union/Eurasian Economic Union, or by using existing pooled procurement systems, such as those offered by the UN and private sector. The latter option offers existing systems already in place. For instance, in December 2013 Uzbekistan contracted UNDP to access its pooled procurement mechanism, when the country made its first ARV procurement from the national budget. As to creating a new pooled procurement mechanism, in order for this mechanism to be used successfully, countries would need to harmonize their policies, treatment regimens and list of medicines, as well as quality, safety and efficacy control measures. If countries cannot achieve policy cohesion, standardization of medicines' lists, and secure finances,

57 More information about the GPA may be found on WTO website: http://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm.

as well as the establishment of one buying entity, pooled procurement may not be the best solution to lower cost of ARVs. Countries could combine pooled procurement with use of TRIPS Agreement flexibilities such as exhaustion of rights, or compulsory licensing.

7.1.1. Armenia

Public procurements in Armenia are regulated by the *Law "On Procurements"* of 22 December 2010, Civil Code and other relevant laws and bylaws. The Law establishes a general framework for procurement of goods, services and works for public aims.

Art. 17 of the law envisages the following methods of procurements: open procedure; competition-based dialogue; limited procedure; negotiation-based procedure. Open procedure is considered as the "main and preferred" one, also when it comes to procurement of medicines. For procurement of homogenous essential commodities for the amount not exceeding 20-fold amount of basic unit (one basic unit being equal to 1,000,000 AMD or about 2,420 USD), a simplified procurement procedure may be applied. Another relevant method is the negotiation procedure, used in emergency situations, when other methods cannot be applied in view of time constraints. Negotiation procedure may be initiated without prior announcement, when the required product may be only procured from one provider due to IP rights. However, this method has a considerable limitation: it is only used for procurements for the amount up to one basic unit.

7.1.2. Azerbaijan

The main document regulating public procurements in Azerbaijan is the *Law "On Public Procurements"* of 27 December 2001 No. 245-IIG, with further details envisaged by a number of other relevant laws and bylaws.

Articles 16 through 21 of the law envisage methods that can be used for public procurements: open tender; two-stage tender or request for proposals; tender with limited participation and closed tender; request for quotations; procurement from one source. According to art. 16, an open tender is the main procurement method; other methods can be used only when the procurement amount does not exceed one minimal unit (50,000 AZN or 63,750 USD) under circumstances, specifically described by articles 18-21. This is a comparatively high threshold, which means that a considerable part of the public procurements can be performed through methods other than open tenders. For example, procurement from a single source may be used when only one entity has exclusive rights for the goods to be procured; in cases of urgency, e.g. emergency situations, when time is not sufficient to use other methods of procurement, etc.

7.1.3. Georgia

Public procurements in Georgia are regulated by the *Law "On Public Procurements"* No. 1388-Ic of 20 April 2005, as well as by other laws and bylaws. The public procurement law provides general framework establishes principles of how public procurements are to be implemented in the country.

Chapter II of the law envisages the procurement methods: tender, price quotation, and single-source procurement. However, art. 10 requires that tender is used by default, unless there are grounds for using price quotation and procurement from the single source. So, price quotation may be used for procurement of goods and services for the amount not exceeding 50,000 GEL (as of May 2014, approximately 28,500 USD) by decision of the procurement entity. As to procurement from the single source, it may be done when expected cost of goods to be procured does not exceed 20,000 GEL (approximately 11,400 USD), when only one person has exclusive rights for the goods to be procured, in cases of extreme urgency, etc. Importantly, the law explicitly prohibits breaking procurements down into smaller pieces in order to avoid tendering procedure.

As per the Association Agreement with the EU, Georgia committed to ensure approximation of its legislation, including that in the public procurements are, to the EU standards. Therefore, within next years the country is expected to do a major review of its procurement legislation and procedures.

7.1.4. Kyrgyzstan

In Kyrgyzstan, the main law regulating public procurements is the *Law "On Public Procurements"* No. 69 of 24 May 2004, which establishes overall framework, and further details are found in other laws and bylaws.

According to the law, procurements may be carried out by the following methods: tender (with unlimited participation, with limited participation, two-stage), request for quotations, single-source procurements, electronic public procurements, electronic reverse auction. Tenders and electronic procurements are the preferred methods of procurements. These should be used when total amount of procurement equals to or exceeds maximum threshold levels (according to the Government Resolution "On approval of threshold levels for procurements of goods, works and services" No. 440 of 16 September 2005, maximum threshold level for the procurement of goods is 1,500,000 KGS or approximately 28,500 USD, as of May 2014).

It should be noted that procurement of medicines is regulated by the *Government Regulations "On centralized provision of healthcare organizations, working under the single payer system, with medicines and medical commodities"* approved by Government Resolution No. 322 of 10 June 2013.[58] According to this document, Kyrgyzstan has a centralized system for procurement of medicines. Public and municipal healthcare organizations, working under the single payer system, prepare the list of medicines that are required for the following year, and submit it to the Ministry of Health not later than three months before the beginning of the year. Based on the lists received from healthcare organizations, the Ministry of Health prepares the cumulative list of medicines that need to be procured for the following year, with regional and quarterly break-downs, and submits it to the Government's Compulsory Health Insurance Fund not later than two months before the beginning of the year. The Compulsory Health Insurance Fund then carries out centralized procurement of medicines in accordance with the requirements of the public procurements law.

It should be noted that as of the time of preparing of this report (May 2014), all ARV medicines in Kyrgyzstan were procured by the Global Fund project.

58 Положение «О централизованном обеспечении лекарственными средствами и изделиями медицинского назначения организаций здравоохранения, работающих в системе Единого плательщика», утвержденное постановлением Правительства Кыргызской Республики от 10 июня 2013 года № 322.

7.1.5. Moldova

Public procurements in Moldova are regulated by the *Law On Public Procurements* No. 96-XVI of 13 April 2007, other laws and bylaws.

The law envisages that public procurements may be carried out through the following procedures:

- open tenders
- limited participation tenders
- framework agreement
- competitive dialogue
- negotiation procedure
- single-source procurement
- request for quotations
- dynamic procurement systems
- electronic auction
- procurements through Universal Commodity Exchange.

Open tenders are considered as the main method of procurements, and other procurement procedures may be used only in situations explicitly foreseen by the law.

Regulations on procurements of medicines and other medical products for the needs of the system of healthcare approved by Government Resolution No. 568 of 10 September 2009 contain procedures that need to be followed when performing procurements of pharmaceuticals. So, heads of healthcare establishments define their needs in medicines and submit annual requests to the Ministry of Health by 1 July of the preceding year. The Ministry collects the requests and generates a cumulative request for medicines, which has to be submitted to the Agency on Medicines by 1 August 2014. Depending on the cost of the contracts to be concluded and specifics of procurement and use of medicines, the Agency may use one of the methods of procurements envisaged by the public procurements law. As per the Regulations, open tender is the method of preference; other methods may be used only in cases envisaged by the law. For instance, request for quotations may be used when estimated cost of procurement does not exceed 200,000 MDL (approximately 14,400 USD as of May 2014). Single-source procurement of medicines may be used only if no adequate offers were received within open tender procedure, due to maximum urgency or unexpected circumstances, and when there is only one entity that

has exclusive rights for the goods to be procured. When procuring medicines under single-source procurement procedure, the procuring entity must comply with requirements of article 53 of the public procurements law and provisions of the *Regulations on public procurements from a single source*, approved by Government Resolution No. 1407 of 10 December 2008. It should be noted, however, that as of the time of preparing of this report (May 2014), all ARV medicines in Moldova were procured by the Global Fund project.

As per the Association Agreement with the EU, Moldova committed to ensure approximation of its legislation, including that in the public procurements are, to the EU standards. Therefore, within next years the country is expected to do a major review of its procurement legislation and procedures.

7.1.6. Ukraine

Public procurements in Ukraine are carried out in accordance with the *Law "On Implementation of Public Procurements"* No. 1197-VII of 10 April 2014 (the newest law among the study countries), relevant laws and bylaws.

The law envisages the following procurement procedures:

- open tender
- two-stage tender
- request for quotations
- preliminary qualification of participants
- negotiations procedure.

Additionally, the law allows concluding fixed-term framework agreements, which need to meet the requirements envisaged for the above procedures.

Open tender is the main procurement procedure. In exceptional circumstances, such as procurement of goods which are objects of IP rights or extreme urgency of the procurement, procurement may be carried out through negotiations procedure.

Public procurements of medicines are regulated by *Resolution of the Cabinet of Ministers "On the procedure for procurement of medicines by healthcare institutions funded by the state budget"* No. 1071 of 5 September 1996. While the document does not contain any details as to the procedure itself, it has a list of medicines that may be procured by public healthcare facilities; it includes 3TC and 3TC-containing FTCs, ABC, ATV, AZT, d4T, ddI, DRV, EFV, ETV, IDV, NFV, NVP, RAL, RTV and RTV-containing FDCs, TDF and TDF-containing FDCs.

Where necessary, countries should reform their procurement regimes and cycles in order to ensure no stockouts, or shortages in supply take place. Reasonable stock availabilities, informed by previous experience and scientific projections, should always be maintained.

It should be noted that as per the Association Agreement with the EU, Ukraine committed to ensure approximation of its legislation, including that in the public procurements are, to the EU standards. Therefore, within next years the country is expected to do a major review of its procurement legislation and procedures.

7.2 Procurement systems used within GFATM projects

All study countries are currently 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.

Public procurements legislations often exclude procurements made within grants of international

organizations, including the GFATM, from their regulation (e.g. art. 2 of the Ukrainian law on public procurements specifically mentions Global Fund grants). 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"[59] and use a template[60] developed by the GFATM.

For more information about procurement systems used within Global Fund projects and their compliance with national systems, see Section 7.2 of the main report.[61]

59 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/).

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

61 UNDP. *Legal and Regulatory Frameworks for Antiretroviral Medicines and Treatment in Selected Countries of the CIS: Sub-regional Analytical Report including Belarus, Kazakhstan, Russia, Tajikistan, and Uzbekistan*. 2014, p. 61.

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.[62] Given the current dynamics of the HIV epidemic and the challenge of improving quality standards in line with recommendations of the 2013 WHO ART Guidelines, and also taking into account that the GFATM, the main external donor for ART in the region, announced more stringent eligibility criteria under its New Funding Model (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, and
- 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 registration
- 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 at national and international levels:

- Most 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 consideration the economic implications of such an update.

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

- Some countries continue to use first- and second-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 some countries, national health authorities have not adopted guidelines regulating ART for children.
- 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 guidelines' deviations or even outdated guidelines come at a cost and can be detrimental to the key objective of universal access to affordable quality treatment.
- While decisions are taken nationally, the CIS Council on HIV, TB and Malaria can be a 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.

Accession to international and regional organizations, such as the WTO, WIPO, EAPO and EurAsEC and association with the EU have a considerable effect on IP legislation of the countries.

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. 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. While countries have already introduced 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.
- Association Agreements signed by Georgia, Moldova and Ukraine, also contain TRIPS-plus provisions, which may have negative impact on the countries' ability to access generic medicines, including ARVs. At the same time, the AAs recognize the importance of the Doha Declaration and do not prevent countries from using TRIPS public health flexibilities.
- 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. When there are grounds to believe that the import of goods violates patent rights, 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 willful 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 pediatric 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' online patent databases are less transparent, information is sometimes incomplete; in some countries search options are limited and do not allow search by PCT application number. At the time of preparing the report (May 2014), Azerbaijan and Kyrgyzstan did not offer electronic access to patent databases.
- 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 should use the opportunities to discuss the development of IP in the EECA region through a public health perspective within the CIS Economic Council and the Inter-governmental Council on Legal Protection of IP, created in 2010. Inter-governmental agencies such as UNDP have the mandate to provide policy advice and technical assistance in this field and share experience from other countries and regions, including BRICS.

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.
- 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.

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

- 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.
- Moving to national procurements of ARV medicines is likely to have considerable implications in terms of costs per unit, as countries' demand is much lower than the volumes being procured under pooled procurement mechanisms used under GFATM grants. To overcome this, countries may consider creating new or using existing pooled procurement mechanisms.

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.[63]

63 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

If the Customs Union and the Single Economic Space are to expand, as it is envisioned by the concept of the EurAsEC, the levels of economic development of countries will become even more diverse with lower middle 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 transcontinental 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.

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

ART guidelines at national and international levels

- Countries should strive to amend their national ART guidelines and 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 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 and countries, which entered (or plan to enter) into free trade and association agreements with the EU, should benefit to the full from public health language in these agreements such as references to the TRIPS public health flexibilities and the Doha Declaration, while developing their national laws and policies.
- 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.

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.

- 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 not apply TRIPS-plus provisions regarding pharmaceuticals retroactively.
- 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 willful 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.

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 professional 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 registration

- Without compromising quality, safety, and efficacy, relevant authorities should ensure that licensing of pharmaceutical manufacturers, importers, sellers, etc. 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.
- 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 as well as the improvement of accuracy.
- Without compromising quality, safety, and efficacy relevant authorities should create incentives to register medicines in a fast and cost efficient manner, in order to secure access to the latest pharmaceutical products for the treatment of HIV and generally access to medicines.
- 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 medicine registries with a search function, 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.

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. Advice from relevant international organizations (including the Joint UN Team on AIDS) in the development of such legislation can be used.
- 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.
- To avoid a sharp rise in cost of ARVs after switching from pooled procurement mechanisms used under GFATM grants to national procurements, countries could consider pooling procurements by either using existing mechanisms (e.g. in the UN system), or, in longer term, explore opportunities for pooled procurement, in the context of the CIS, or the Customs Union/Eurasian Economic Union. In order for this mechanism to be used successfully, countries would need to harmonize their policies, treatment regimens and list of medicines, as well as quality, safety and efficacy control measures. Pooled procurement does not and should not prevent the use of the TRIPS Agreement public health flexibilities.

Annexes

Annex 1. ARV registration status in the study countries

Table 17: ARV medicines registered in Armenia

INN	Trade name	Dosage form	Manufacturer	Registration date[64]	Validity
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	18.02.2011	18.02.2016
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg	Abbott GmbH & Co. KG, Germany	07.12.2012	07.12.2017
Lopinavir / Ritonavir	Kaletra	Oral solution, 80 mg/ml + 20 mg/ml	Aesica Queenborough Ltd. for Abbott Laboratories Ltd, UK	26.10.2011	26.10.2016
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	28.12.2011	28.12.2016
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany	21.12.2010	21.12.2015
Tenofovir	Viread	Tabs, 300 mg	Gilead Sciences Ltd., Ireland	05.09.2014	05.09.2019

Source: List of registered medicines in Armenia (http://www.pharm.am/)

Table 18: ARV medicines registered in Azerbaijan

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity[65]
Single/boosted ARVs					
Darunavir	Prezista	400 mg, 600 mg, 800 mg	Janssen-Ortho LLC, USA	15.08.2014	15.08.2019
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Operations UK Ltd., UK / GlaxoSmithKline Pharmaceuticals S.A., Poland	13.05.2011	13.05.2016

64 Online database does not contain information about the date of registration; the dates provided in this table are calculated based on the registration term envisaged by the legislation (five years).

65 Online database does not contain information about the date of registration expiration; the dates provided in this table are calculated based on the registration term envisaged by the legislation (five years).

Table 18: ARV medicines registered in Azerbaijan (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	28.03.2012	28.03.2017
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany	28.03.2012	28.03.2017
Tenofovir	Viread	Tabs, 300 mg	Gilead Science Ltd, USA	06.06.2014	06.06.2014
FDCs					
Emtricitabine / Tenofovir	Emtricitabine & Tenofovir	Tabs, 200 mg / 300 mg	Hetero Drugs Ltd, India	16.05.2011	16.05.2016
Emtricitabine / Tenofovir	Truvada	Tabs, 200 mg / 300 mg	Gilead Science Ltd, USA	06.06.2014	06.06.2019
Lamivudine / Zidovudine	Lazid	Tabs, 150 mg / 300 mg	Emcure Pharmaceuticals Ltd., India	04.05.2009	04.05.2014

Sources: State registry of medicines of Azerbaijan (http://www.pharma.az/en/medicine-reg/3/32), Medical scientific-informational portal of Azerbaijan (http://www.medportal.az/ru/leksredstva/lekarstvennye-sredstva-zaregistrirovannye-v-azerbajdzhanskoj-respublike)

Table 19: ARV medicines registered in Georgia

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Single/boosted ARVs					
Abacavir	Ziagen 300 mg	Tabs, 300 mg	Glaxo Operations UK Ltd, UK	09.12.2009	09.12.2014
Efavirenz	Eferven	Tabs, 600 mg	Ranbaxy Laboratories Ltd, India	12.08.2013	12.08.2018
Efavirenz	Efavir 200	Caps, 200 mg	Cipla Ltd, India	14.06.2010	14.06.2015
Lamivudine	Lamivir	Tabs, 150 mg	Cipla Ltd, India	14.06.2010	14.06.2015
Lamivudine	Lamivir	Oral solution, 100 ml	Cipla Ltd, India	14.06.2010	14.06.2015
Lamivudine	Heptavir 150	Tabs, 150 mg	Hetero Drugs Ltd, India	14.12.2009	14.12.2014
Lopinavir / Ritonavir	Kaletra	Oral solution, 60 ml	Aesica Queenborough Ltd, UK	15.08.2014	14.06.2015[66]
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg	AbbVie Deutschland GmbH & Co. KG, Germany	19.03.2014	19.03.2019
Nevirapine	Viramune	Suspension, 50 mg / 5 ml	Boehringer Ingelheim Rocksan Inc, USA	29.02.2012	indefinite

66 Date as per registration database. There may be a mistake in either date of registration or registration expiration date, given that the standard term of registration is five years.

Table 19: ARV medicines registered in Georgia (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	20.02.2012	20.02.2017
Nevirapine	Nevivir	Tabs, 200 mg	Hetero Drugs Ltd, India	14.12.2009	14.12.2014
Raltegravir	Isentress	Tabs, 400 mg	Merck Sharp & Dohme B.V., The Netherlands	25.07.2014	25.07.2019
Ritonavir	Norvir	Tabs, 100 mg	AbbVie Deutschland GmbH & Co. KG, Germany	15.08.2014	06.12.2015[67]
Ritonavir	Ritomune-100	Caps, 100 mg	Cipla Ltd, India	14.06.2010	14.06.2015
Stavudine	Stag 30	Caps, 30 mg	Hetero Drugs Ltd, India	08.02.2010	08.02.2015
Stavudine	Stag 40	Caps, 40 mg	Hetero Drugs Ltd, India	08.02.2010	08.02.2015
Tenofovir	Viread	Tabs, 300 mg	Takeda GmbH, Germany	13.10.2014	13.10.2019
Zidovudine	Zidovir	Solution, 100 ml	Cipla Ltd, India	14.06.2010	14.06.2015
Zidovudine	Zidovir – 300	Tabs, 300 mg	Cipla Ltd, India	14.06.2010	14.06.2015
Zidovudine	Zido-H 300	Tabs, 300 mg	Hetero Drugs Ltd, India	21.12.2009	21.12.2014
FDCs					
Abacavir / Lamivudine / Zidovudine	Trizivir	Tabs	Glaxo Operations UK Ltd, UK	02.03.2010	02.03.2015
Emtricitabine / Tenofovir	Truvada	Tabs, 200 mg / 300 mg	Takeda GmbH, Germany	12.09.2014	12.09.2019

Source: State registry of medicines of Georgia (http://pharmacy.moh.gov.ge/Pages/Products.aspx)

67 Date as per registration database. There may be a mistake in either date of registration or registration expiration date, given that the standard term of registration is five years.

Table 20: ARV medicines registered in Kyrgyzstan

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity[68]
Single/boosted ARVs					
Abacavir	Abamat	Tabs, 300 mg	Matrix Laboratories Ltd., India	20.07.2010	20.07.2015
Didanosine	Didanosine	Caps, 200 mg	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
Didanosine	Didanosine	Caps, 200 mg	Matrix Laboratories Ltd., India	06.07.2011	06.07.2016
Didanosine	Didanosine	Caps, 400 mg	Matrix Laboratories Ltd., India	06.07.2011	06.07.2016
Efavirenz	Efavirenz	Tabs, 600 mg	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
Efavirenz	Efcure	Tabs, 600 mg	Emcure Pharmaceuticals Ltd., India	22.02.2010	22.02.2015
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Wellcome Operations UK Ltd., UK	13.07.2009	13.07.2014
Lamivudine	Lamivudine	Tabs, 150 mg	Aurobindo Pharma Ltd., India	10.07.2009	10.07.2014
Lamivudine	Lamivudine	Oral solution, 10 mg/ml	Aurobindo Pharma Ltd., India	10.07.2009	10.07.2014
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	22.02.2010	22.02.2015
Lopinavir / Ritonavir	Kaletra	Oral solution, 60 ml	Aesica Queenborough Ltd., UK	22.02.2010	22.02.2015
Lopinavir / Ritonavir	Lopinavir + Ritonavir	Tabs, 200 mg / 50 mg	Matrix Laboratories Ltd., India	13.07.2009	13.07.2014
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	08.07.2013	08.07.2018
Nevirapine	Nevirapine	Oral suspension, 50 mg / 5 ml	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany	19.01.2011	19.01.2016
Stavudine	Stavudine	Caps, 30 mg	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
Tenofovir	Tenofovir	Tabs, 300 mg	Matrix Laboratories Ltd., India	06.07.2011	06.07.2016
Tenofovir	Viread	Tabs, 300 mg	Gilead Sciences Inc., USA	19.01.2011	19.01.2016
Zidovudine	Zidovudine	Tabs, 300 mg	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
Zidovudine	Zidovudine	Solution, 50 mg / 5 ml	Aurobindo Pharma Ltd, India	10.07.2009	10.07.2014
FDCs					
Emtricitabine / Tenofovir	Truvada	Tabs, 200 mg / 300 mg	Gilead Sciences, Inc., USA	11.07.2009	11.07.2014

Source: State registry of medicines of Kyrgyzstan (http://www.pharm.kg/ru/registry)

68 The registry does not contain information about the term of registration validity. Dates in this column are based on the standard five-year validity term provided for in the legislation.

Table 21: ARV medicines registered in Moldova

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity[69]
Single/boosted ARVs					
Darunavir	Prezista	Tabs, 400 mg	Janssen Cilag SpA, Italia	28.05.2014	28.05.2019
Darunavir	Prezista	Tabs, 600 mg	Janssen Cilag SpA, Italia	28.05.2014	28.05.2019
Darunavir	Prezista	Tabs, 800 mg	Janssen Cilag SpA, Italia	28.05.2014	28.05.2019
Efavirenz	Estiva 600	Tabs, 600 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Indinavir	Indivir-400	Tabs, 400 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Lamivudine	Univudin	Caps, 100 mg	Universal-Farm SRL, Moldova	10.02.2012	10.02.2017
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Wellcome Operations UK Ltd, UK; GlaxoSmithKline Pharmaceuticals SA, Poland	08.04.2011	08.04.2016
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	Abbott GmbH & Co. KG, Germany	10.12.2009	10.12.2014
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg	Abbott GmbH & Co. KG, Germany	28.02.2013	28.02.2018
Ritonavir	Norvir	Tabs, 100 mg	Abbott GmbH & Co. KG, Germany	17.06.2011	17.06.2016
Tenofovir	Viread	Tabs, 300 mg	Gilead Sciences Ltd, Ireland	23.01.2013	23.01.2018
Zidovudine	Zidovudine	Caps, 100 mg	SC Balkan Pharmaceuticals SRL, Moldova	22.04.2013	22.04.2018
FDCs					
Emtricitabine / Tenofovir	Truvada	Tabs, 200 mg / 300 mg	Gilead Sciences Ltd, Ireland	28.02.2013	28.02.2018
Lamivudine / Nevirapine / Stavudine	Nevilast-30	Tabs, 150 mg / 200 mg / 30 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Lamivudine / Nevirapine / Stavudine	Nevilast-40	Tabs, 150 mg / 200 mg / 40 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Lamivudine / Stavudine	Lamistar-30	Tabs, 150 mg / 30 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Lamivudine / Zidovudine / Nevirapine	Zidolam-N	Tabs, 150 mg / 200 mg / 300 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015
Lamivudine / Zidovudine	Zidolam	Tabs, 150 mg / 300 mg	Hetero Drugs Ltd for NV Holding, India	07.09.2010	07.09.2015

Source: State registry of medicines of Moldova (http://infomed.amed.md/)

69 The registry does not contain information about the term of registration validity. Dates in this column are based on the standard five-year validity term provided for in the legislation.

Table 22: ARV medicines registered in Ukraine

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Single/boosted ARVs					
Abacavir	Abacavir sulfate	Tabs, 300 mg	Aurobindo Pharma Ltd., India	22.11.2013	22.11.2018
Abacavir	Abacavir sulfate	Tabs, 300 mg, in bulk	Aurobindo Pharma Ltd., India	22.11.2013	22.11.2018
Abacavir	Virol	Tabs, 300 mg	Ranbaxi Laboratories Ltd, India	21.12.2009	21.12.2014
Abacavir	Ziagen	Solution, 20 mg/ml	GlaxoSmithKline Inc., Canada	06.01.2011	06.01.2016
Abacavir	Ziagen	Tabs, 300 mg	Glaxo Operations UK Ltd, UK	06.01.2011	06.01.2016
Abacavir	Ziagen	Tabs, 300 mg, in bulk	Glaxo Operations UK Ltd, UK	06.01.2011	06.01.2016
Abacavir	Abacavir sulfate	Tabs, 300 mg	Hetero Labs Ltd., India	18.09.2014	18.09.2019
Abacavir	Abacavir sulfate	Tabs, 300 mg, in bulk	Hetero Labs Ltd., India	18.09.2014	18.09.2019
Darunavir	Prezista	Tabs, 75 mg	Janssen Cilag S.p.A., Italy; Janssen Ortho LLC, USA	06.01.2011	06.01.2016
Darunavir	Prezista	Tabs, 150 mg	Janssen Cilag S.p.A., Italy; Janssen Ortho LLC, USA	06.01.2011	06.01.2016
Darunavir	Prezista	Tabs, 300 mg	Janssen Cilag S.p.A., Italy; Janssen Ortho LLC, USA	25.10.2012	25.10.2017
Darunavir	Prezista	Tabs, 400 mg	Janssen Cilag S.p.A., Italy; Janssen Ortho LLC, USA	21.12.2009	21.12.2014
Darunavir	Prezista	Tabs, 600 mg	Janssen Cilag S.p.A., Italy; Janssen Ortho LLC, USA	21.12.2009	21.12.2014
Didanosine	Nisonadid	Caps, 125 mg	Mylan Laboratories Ltd, India	15.02.2010	15.02.2015
Didanosine	Nisonadid	Caps, 200 mg	Mylan Laboratories Ltd, India	15.02.2010	15.02.2015
Didanosine	Nisonadid	Caps, 250 mg	Mylan Laboratories Ltd, India	15.02.2010	15.02.2015
Didanosine	Nisonadid	Caps, 400 mg	Mylan Laboratories Ltd, India	15.02.2010	15.02.2015
Efavirenz	Efcure	Tabs, 600 mg	Lumiere Pharma Ltd., Ukraine	15.02.2010	15.02.2015
Efavirenz	Efamat	Tabs, 50 mg	Mylan Laboratories Ltd, India	17.03.2010	17.03.2015
Efavirenz	Efamat	Tabs, 100 mg	Mylan Laboratories Ltd, India	17.03.2010	17.03.2015
Efavirenz	Efamat	Tabs, 200 mg	Mylan Laboratories Ltd, India	17.03.2010	17.03.2015
Efavirenz	Efamat	Tabs, 600 mg	Mylan Laboratories Ltd, India	17.03.2010	17.03.2015
Efavirenz	Efcure-Zdorovya	Tabs, 600 mg	"Zdorovya" Pharmaceutical Company, Ukraine	29.10.2010	29.10.2015
Efavirenz	Efavirenz	Tabs, 200 mg	Strides Arcolab Ltd, India	12.04.2011	12.04.2016
Efavirenz	Efavirenz	Tabs, 200 mg, in bulk	Strides Arcolab Ltd, India	12.04.2011	12.04.2016

Table 22: ARV medicines registered in Ukraine (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Efavirenz	Efavirenz	Tabs, 600 mg	Strides Arcolab Ltd, India	12.04.2011	12.04.2016
Efavirenz	Efavirenz	Tabs, 600 mg, in bulk	Strides Arcolab Ltd, India	12.04.2011	12.04.2016
Efavirenz	Efavirenz	Caps, 50 mg	Aurobindo Pharma Ltd, India	22.11.2013	22.11.2018
Efavirenz	Efavirenz	Caps, 200 mg	Aurobindo Pharma Ltd, India	22.11.2013	22.11.2018
Efavirenz	Efavirenz	Caps, 200 mg, in bulk	Aurobindo Pharma Ltd, India	22.11.2013	22.11.2018
Efavirenz	Efavirenz	Tabs, 600 mg	Aurobindo Pharma Ltd, India	21.10.2013	21.10.2018
Efavirenz	Efavirenz	Tabs, 600 mg, in bulk	Aurobindo Pharma Ltd, India	21.10.2013	21.10.2018
Efavirenz	Stocrin	Tabs, 50 mg	Merck Sharp & Dohme B.V., Netherlands	25.11.2013	25.11.2018
Efavirenz	Stocrin	Tabs, 200 mg	Merck Sharp & Dohme B.V., Netherlands	25.11.2013	25.11.2018
Efavirenz	Stocrin	Tabs, 600 mg	Merck Sharp & Dohme B.V., Netherlands	25.11.2013	25.11.2018
Efavirenz	Eferven	Caps, 200 mg	Ranbaxi Laboratories Ltd, India	14.06.2013	14.06.2018
Efavirenz	Eferven	Tabs, 600 mg	Ranbaxi Laboratories Ltd, India	26.07.2013	26.07.2018
Efavirenz	Efcure	Tabs, 600 mg	Emcure Pharmaceuticals Ltd., India	28.10.2013	28.10.2018
Efavirenz	Efavir	Tabs, 600 mg	Cipla Ltd., India	10.07.2014	10.07.2019
Etravirine	Intelence	Tabs, 100 mg	Janssen-Cilag S.p.A., Italy	09.09.2014	09.09.2014
Fosamprenavir	Telzir	Suspension, 50 mg/ml	GlaxoSmithKline Inc., Canada	05.10.2011	05.10.2016
Fosamprenavir	Telzir	Tabs, 700 mg	Glaxo Operations UK Ltd., UK	03.10.2011	03.10.2016
Indinavir	Virodin	Caps, 400 mg	Ranbaxy Laboratories Ltd, India	21.12.2009	21.12.2014
Lamivudine	Zeffix	Solution, 5 mg/ml	GlaxoSmithKline Inc., Canada	07.04.2010	07.04.2015
Lamivudine	Zeffix	Tabs, 100 mg	Glaxo Operations UK Ltd., UK	07.04.2010	07.04.2015
Lamivudine	Lamivir	Oral solution, 50 mg/5 ml	Cipla Ltd., India	01.09.2010	01.09.2015
Lamivudine	Lamivudine	Oral solution, 10 mg/ml	"Tehnolog", Ukraine	08.05.2014	08.05.2019
Lamivudine	Lamivudine	Powder (substance)	Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd, China	19.06.2014	19.06.2019
Lamivudine	Lamivudine	Powder (substance)	Hetero Labs Ltd, India	31.10.2014	31.10.2019
Lamivudine	Lamivudine	Tabs, 150 mg	"Darnitsya" Pharmaceutical Firm, Ukraine	10.08.2011	10.08.2016
Lamivudine	Lamivudine	Tabs, 150 mg	Aurobindo Pharma Ltd., India	25.01.2012	25.01.2017
Lamivudine	Lamivudine	Powder (substance)	Mylan Laboratories Ltd, India	23.07.2012	23.07.2017

Table 22: ARV medicines registered in Ukraine (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Lamivudine	Epivir	Tabs, 150 mg	GlaxoSmithKline Pharmaceuticals C.A., Poland	14.06.2013	14.06.2018
Lamivudine	Epivir	Oral solution, 10 mg/ml	GlaxoSmithKline Inc., Canada	14.06.2013	14.06.2018
Lamivudine	Lamivir	Tabs, 150 mg	Cipla Ltd., India	23.09.2013	23.09.2018
Lamivudine	Virolam	Tabs, 150 mg	Ranbaxy Laboratories Ltd, India	28.05.2014	28.05.2019
Lopinavir / Ritonavir	Emletra	Tabs, 200 mg / 50 mg	Emcure Pharmaceuticals Ltd., India	14.11.2011	14.11.2016
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg	AbbVie Deutschland GmbH & Co. KG, Germany	08.06.2012	08.06.2017
Lopinavir / Ritonavir	Aluvia	Tabs, 200 mg / 50 mg, in bulk	AbbVie Deutschland GmbH & Co. KG, Germany	08.06.2012	08.06.2017
Lopinavir / Ritonavir	Aluvia	Tabs, 100 mg / 25 mg	AbbVie Deutschland GmbH & Co. KG, Germany	08.06.2012	08.06.2017
Lopinavir / Ritonavir	Kaletra	Oral solution, 80mg / 20 mg / ml	Aesica Queenborough Ltd., UK	08.06.2012	08.06.2017
Lopinavir / Ritonavir	Lopicip	Tabs, 200 mg / 50 mg	Cipla Ltd., India	23.05.2012	23.05.2017
Nevirapine	Nevimune	Oral suspension, 50 mg / 5 ml	Cipla Ltd., India	01.09.2010	01.09.2015
Nevirapine	Nevimune	Tabs, 200 mg	Cipla Ltd., India	01.09.2010	01.09.2015
Nevirapine	Nevirapine	Tabs, 200 mg	Strides Arcolab Ltd., India	12.04.2011	12.04.2016
Nevirapine	Nevirapine	Tabs, 200 mg, in bulk	Strides Arcolab Ltd., India	12.04.2011	12.04.2016
Nevirapine	Nevirapine bezvodniy	Substance (powder)	Hetero Labs Ltd, India	26.02.2014	26.02.2019
Nevirapine	Viramune	Tabs, 200 mg	Boehringer Ingelheim Ellas A.E., Greece	15.02.2010	15.02.2015
Nevirapine	Nevirapine	Tabs, 200 mg	"Darnitsya" Pharmaceutical Firm, Ukraine	12.04.2011	12.04.2016
Nevirapine	Nevirapine	Tabs, 200 mg	Aurobindo Pharma Ltd, India	25.01.2012	25.01.2017
Nevirapine	Nevirapine	Substance (powder)	Mylan Laboratories Ltd, India	31.08.2012	31.08.2017
Raltegravir	Isentress	Tabs, 400 mg	Merck Sharp & Dohme B.V., Netherlands	13.02.2014	13.02.2019
Ritonavir	Ritovir	Caps, 100 mg	Hetero Drugs Ltd, India	19.07.2012	19.07.2017
Ritonavir	Ritovir	Caps, 100 mg, in bulk	Hetero Drugs Ltd, India	19.07.2012	19.07.2017
Ritonavir	Norvir	Tabs, 100 mg	AbbVie Deutschland GmbH & Co. KG, Germany	09.07.2012	09.07.2017
Stavudine	Stavudine	Caps, 30 mg	Aurobindo Pharma Ltd, India	28.04.2012	28.04.2017

Table 22: ARV medicines registered in Ukraine (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Stavudine	Virostav	Caps, 30 mg	Ranbaxy Laboratories Ltd, India	26.02.2014	26.02.2019
Tenofovir	Tenohop	Tabs, 300 mg	Macleods Pharmaceuticals Ltd, India	04.10.2013	04.10.2018
Tenofovir	Tenvir	Tabs, 300 mg	Cipla Ltd., India	02.11.2012	02.11.2017
Tenofovir	Viread	Tabs, 300 mg	Gilead Sciences Ltd., Ireland; Nicomed GmbH, Germany	04.10.2013	04.10.2018
Zidovudine	Retrovir	Solution for infusions, 10 mg/ml	Glaxo Operations UK Ltd., UK	30.12.2013	30.12.2018
Zidovudine	Retrovir	Caps, 100 mg	Europharm SA, Romania	10.10.2014	10.10.2019
Zidovudine	Retrovir	Solution, 10 mg/ml	GlaxoSmithKline Inc., Canada	09.04.2013	09.04.2018
Zidovudine	Zidovir	Solution, 50mg / 5ml	Cipla Ltd., India	28.05.2014	28.05.2019
Zidovudine	Zidovir – 300	Tabs, 300 mg	Cipla Ltd., India	02.07.2012	02.07.2017
Zidovudine	Zidovudine	Substance (powder)	Zhejiang Xinhua Pharmaceutical Co., Ltd, China	01.03.2013	01.03.2018
Zidovudine	Zidovudine	Solution, 10 mg/ml	"Tehnolog", Ukraine	16.04.2014	16.04.2019
Zidovudine	Nardin	Solution, 200 mg/20 ml	"Yuriya Pharm", Ukraine	27.06.2014	27.06.2019
Zidovudine	Zidovudine	Substance (powder)	Hetero Labs Ltd, India	03.07.2014	03.07.2019
Zidovudine	Zidovudine	Caps, 100 mg	"Darnitsya" Pharmaceutical Firm, Ukraine	13.12.2010	13.12.2015
Zidovudine	Zidovudine	Caps, 250 mg	"Darnitsya" Pharmaceutical Firm, Ukraine	13.12.2010	13.12.2015
Zidovudine	Zidovudine	Tabs, 300 mg	Aurobindo Pharma Ltd, India	03.01.2012	03.01.2017
Zidovudine	Zidovudine	Substance (powder)	Mylan Laboratories Ltd, India	23.07.2012	23.07.2017
Zidovudine	Viro-Z	Tabs, 300 mg	Ranbaxy Laboratories Ltd, India	23.09.2013	23.09.2018
FDCs					
Abacavir / Lamivudine	Kivexa	Tabs, 600 mg / 300 mg	Glaxo Operations UK Ltd, UK	29.10.2010	29.10.2015
Abacavir / Lamivudine	Kivexa	Tabs, 600 mg / 300 mg, in bulk	Glaxo Operations UK Ltd, UK	29.10.2010	29.10.2015
Abacavir / Lamivudine / Zidovudine	Trizivir	Tabs, 300 mg / 150 mg / 300 mg	Glaxo Operations UK Ltd, UK	14.11.2011	14.11.2016
Efavirenz / Emtricitabine / Tenofovir	Atripla	Tabs, 600 mg / 200 mg / 300 mg	Gilead Sciences Inc., USA	30.12.2009	30.12.2014

Table 22: ARV medicines registered in Ukraine (cont.)

INN	Trade name	Dosage form	Manufacturer	Registration date	Validity
Efavirenz / Emtricitabine / Tenofovir	Viradey	Tabs, 600 mg / 200 mg / 300 mg	Cipla Ltd., India	28.03.2014	28.03.2019
Emtricitabine / Tenofovir	Tenvir – Em	Tabs, 200 mg / 300 mg	Cipla Ltd., India	11.11.2011	11.11.2016
Emtricitabine / Tenofovir	Truvada	Tabs, 200 mg / 300 mg	Gilead Sciences Ltd., Ireland	05.07.2013	05.07.2018
Emtricitabine / Tenofovir	Tenohop – E	Tabs, 200 mg / 300 mg	Macleods Pharmaceuticals Ltd, India	04.10.2013	04.10.2018
Emtricitabine / Tenofovir	Emtricitabine Tenofovir	Tabs, 200 mg / 300 mg	Hetero Labs Ltd, India	18.09.2014	18.09.2019
Emtricitabine / Tenofovir	Emtricitabine Tenofovir	Tabs, 200 mg / 300 mg	Hetero Labs Ltd,, India	18.09.2014	18.09.2019
Lamivudine / Nevirapine / Zidovudine	Duovir – N	Tabs, 150 mg / 200 mg / 300 mg /	Cipla Ltd, India	26.02.2014	26.02.2019
Lamivudine / Nevirapine / Zidovudine	Lamivudine, Zidovudine, Nevirapine	Tabs, 150 mg / 200 mg / 300 mg /	Aurobindo Pharma Ltd, India	26.02.2014	26.02.2019
Lamivudine / Zidovudine	Lazid	Tabs, 150 mg / 300 mg	Lumiere Pharma Ltd., Ukraine	15.02.2010	15.02.2015
Lamivudine / Zidovudine	Zovilam	Tabs, 30 mg / 60 mg	Mylan Laboratories Ltd, India	03.12.2010	03.12.2015
Lamivudine / Zidovudine	Zovilam	Tabs, 150 mg / 300 mg	Mylan Laboratories Ltd, India	03.12.2010	03.12.2015
Lamivudine / Zidovudine	Combivir	Tabs, 150 mg / 300 mg	Glaxo Operations UK Ltd., UK	18.09.2014	18.09.2014
Lamivudine / Zidovudine	Lamivudine 150 mg & Zidovudine 300 mg	Tabs, 150 mg / 300 mg	Aurobindo Pharma Ltd, India	23.02.2012	23.02.2017
Lamivudine / Zidovudine	Duovir	Tabs, 150 mg / 300 mg	Cipla Ltd., India	06.09.2013	06.09.2018
Lamivudine / Zidovudine	Virocomb	Tabs, 150 mg / 300 mg	Ranbaxi Laboratories Ltd, India	02.08.2013	02.08.2018
Lamivudine / Zidovudine	Cobmivudine	Tabs, 150 mg / 300 mg	"Darnitsya" Pharmaceutical Firm, Ukraine	02.04.2014	02.04.2019
Lamivudine / Zidovudine	Lazid	Tabs, 150 mg / 300 mg	Emcure Pharmaceuticals Ltd., India	30.05.2014	30.05.2019
Lamivudine / Zidovudine	Lazid	Tabs, 150 mg / 300 mg, in bulk	Emcure Pharmaceuticals Ltd., India	30.05.2014	30.05.2014

Source: State registry of medicines of Ukraine (http://drlz.kiev.ua/)

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