


ECUO CONCEPTION ON ACCESS TO TREATMENT



International charitable organization "East Europe and Central Asia Union of People Living with HIV" on the use of modern drugs in the HIV treatment in Eastern Europe and Central Asia, as a mandatory condition to end the epidemic in our region

2017

Position Statement has been developed on initiative of East Europe and Central Asia Union of People Living with HIV (ECUO) within the Regional Program "Partnership for Equitable Access to HIV Care Continuum in EECA" with financial support of Global Fund to Fight AIDS, Tuberculosis and Malaria.

■ ■ We, the International charitable organization “East Europe and Central Asia Union of People Living with HIV” (ECUO) being a regional “network of networks” that unites the community of people living with HIV (PLHIV) from 15 countries in Eastern Europe and Central Asia (EECA):

■ **STATE THE FACT** that today, when the world marks reduction of new HIV cases and AIDS-related deaths, the EECA region is the only region that has not achieved the Millennium Development Goals, namely Goal 6: “... combat the spread of HIV/AIDS and begun to reverse the spread of HIV/AIDS.”

■ **CONSIDER** that PLHIV in our region have the right to access to modern HIV drugs, allowing to reach the Sustainable Development Goals by 2030 in the solution of global challenges, namely Goal 3: “...ensure healthy lives and promote well-being for all at all ages” in accordance with the resolution of the UN member states, the intention to combat the epidemic of HIV/AIDS and TB by 2030.

■ **WELCOME** the Minsk Statement of the Ministries of Health of the countries in Eastern Europe and Central Asia:

■ Participants of the Minsk Statement, the representatives of the Ministries of Health of Armenia, Republic of Azerbaijan, Republic of Belarus, Georgia, Republic of Moldova, Republic of Kazakhstan, the Kyrgyz Republic, the Russian Federation, Tajikistan, Turkmenistan, Uzbekistan and Ukraine, in their intention to improve access to quality antiretroviral, TB and hepatitis drugs in the countries of the Eastern Europe and Central Asia region.

■ “HIV and TB: treatment for all,” in particular, paragraph 6, which stresses the importance of access to modern drugs while ensuring the human right to health and the intention to use the existing tools to reduce price to save lives in the countries of our region.

■ **SUPPORT** the UNAIDS strategy for 2016-2020 “Acceleration towards “Y “zero”: 90-90- 90”

■ ■ **STRONGLY ENCOURAGE** all interested parties to direct their efforts to increase access to modern HIV treatment, namely:

WHO, UNAIDS, INTERNATIONAL ORGANIZATIONS:

- integrate the principles of the “patient-oriented approach” in the treatment guidelines for our region. High standards of HIV/AIDS treatment (including clinical research on resistance to ARV drugs and viral load) are the unified approach for all people in the world;
- hold economic analysis to compare the total cost of the comprehensive HIV treatment process and its results, and to include in the calculation the price for carrying analysis on viral load, resistance to ARV drugs, the price of ARVs, logistics costs, value of the transfer to new treatment regimens, side effects from drugs, etc. to define the “real” cost efficiency at all stages of the care continuum.

NATIONAL GOVERNMENTS:

- review the regulatory framework aiming to expand access to modern HIV drugs, simplify the registration procedure for new HIV drugs, registered in countries with a rigid regulatory system (Switzerland, USA, UK, Japan, Canada and/or for those prequalified by WHO);
- jointly with the leading manufacturers of ARV, TB and hepatitis drugs to consider the ability to localize production of these drugs in the EECA countries;
- pay attention to the fact that treatment interruption or change in regimens without due medical justification results in the emergence of resistant forms of the virus that will lead to a new loop of epidemics and the need to increase budgets for diagnosis, treatment, care and support for people living with HIV;
- stop discriminating PLHIV by transferring them to other treatment regimens without due medical research, including resistance test and viral load analysis, thereby worsening the life quality of people undergoing treatment;
- develop and approve the long-term national programs aimed at providing affordable and quality services for the prevention and treatment, care and support of HIV, TB and viral hepatitis in the EECA, and **RECOGNIZE**, that costs on the material, human and financial resources needed to address the issues of public health, are to be considered not as expenditures but as **INVESTMENTS** which allow ending the spread of HIV/AIDS, TB and VH in the EECA countries.

MINISTRIES OF HEALTH, THE PROFESSIONAL AND SCIENTIFIC COMMUNITY OF COUNTRIES:

- consider the inclusion of a wider application of modern HIV drugs into the national treatment protocols, aiming their wider application, and the expansion of interaction with leading international professional health and governmental organizations (DHHC, EACS, IAS-USA, BHIVA, GeSIDA and other).

PROCUREMENT AGENCIES:

- negotiate a cost reduction for modern HIV, TB and hepatitis drugs, and expand the use of reduction mechanism during ARV procurements.

PHARMACEUTICAL COMPANIES-BRANDS:

- cancel the effect of patents for modern ARV drugs and/or reduce the price, as well as register these medicines in the EECA countries, where they are not presented.

PHARMACEUTICAL COMPANIES-GENERIC:

- contribute to the early meeting the needs of patients taking ARV drugs, by producing the generic forms of branded drugs, as well as register them in the EECA countries aiming to increase the competition, resulting in a significant price decline.

MEDICAL PATENT POOL:

- negotiate with patent holders to transmit the patents in open access, patent pool, and expand the level of involvement of the community members in the negotiations process, including the use of experience and tools of ECUO on the EECA CAB platform.

PLHIV COMMUNITIES AND HIV ACTIVISTS:

- advocate on the national level the expansion of access to modern and vital drugs to treat HIV, TB and VH; initiate a review of treatment protocols for HIV, TB and VH; demand the registration of these drugs, which will expand access to modern ARV treatment; improve the literacy of the communities regarding treatment of HIV/AIDS, TB and VH.

WE HEREBY DECLARE that we will focus our efforts on expanding access to modern drugs to treat HIV, TB and VH by negotiating with all stakeholders, and will do everything to overcome all barriers in ensuring access for all those who need treatment using modern drugs, taking into account the need to achieve an optimal cost-efficient treatment, including the use of existing tools to reduce prices, but not only this, to achieve the goals of the UNAIDS Strategy 90-90-90, save the lives of PLHIV and combat the HIV epidemic in the EECA region, by doing the following:

- ➡ Advocating the use of various procurement mechanisms, including international mechanisms and pooled procurement mechanism;
- ➡ Support transparent price negotiations with the suppliers of ARV, TB and hepatitis drugs, including the possibility of working directly with pharmaceuticals manufacturers;
- ➡ Support manufacturers of ARV, TB and hepatitis drugs in the EECA countries, in production of modern drugs and receipt of WHO prequalification;
- ➡ Advocacy of long-term state programs aimed at provision of available and quality services on prevention and treatment, care and support for people living with HIV, TB and VH in the countries of EECA region.

THE CONCEPT OF THE ECUO GROUNDS ON THE FOLLOWING FACTS:

FACT 1. THE CHALLENGE OF THE HIV/AIDS EPIDEMIC GROWTH IN THE EECA REGION IS THE CHALLENGE OF THE LAST DECADE.

In 2010, at the XVIII International Conference on HIV/AIDS in Vienna, Austria, the PLHIV communities from 15 countries of the Eastern Europe and Central Asia, and ECUO as a regional partner, drew international attention to the critical situation of growth of HIV/AIDS epidemic in the EECA countries by holding an information campaign “not so much of us are dying, but we are dying faster!”¹.

At the high level meeting on HIV/AIDS in the framework of the UN General Assembly in New York, on June 8-10, 2016, the networks of communities in Eastern Europe and Central Asia prepared the report “Eastern Europe and Central Asia: do not leave without an answer” to draw the attention of the leaders of the countries and the world community to the disastrous situation in the region. The report was initiated and prepared by the East Europe and Central Asia Union of People Living with HIV (ECUO)), jointly with all regional networks of communities in the EECA region: the Eurasian Network of People Who Use Drugs (ENPUD), the Eurasian Coalition on Male Health (ECOM), the Eurasian Harm Reduction Network (EHRN), the Eurasian Women's AIDS Network (EWAN), the European AIDS Treatment Group (EATG), the International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru), the Sex Workers' Rights Advocacy Network (SWAN). The communities claimed openly that while the whole world is celebrating the decline in HIV prevalence and AIDS related mortality, in Eastern Europe and Central Asia, the detection of new HIV cases and mortality continue to increase. There were proposed the recommendations that will catch up with the rest of the world towards the end of the AIDS epidemic and achievement of the Sustainable Development Goals by 2030².

Within the framework of the United Nations General Assembly, Michel Kazatchkine, the UN Special Envoy for HIV/AIDS in the EECA region, jointly with representatives of civil society, in particular ECUO, initiated a meeting with the Ministers of Health of the UN member states in the EECA region to discuss counteractions to combat the HIV/AIDS epidemic, paid attention of government officials to the deplorable situation in the region, based on the data from the report “Eastern Europe and Central Asia: do not leave without an answer,” prepared by the civil society networks under the initiative of “East Europe and Central Asia Union of People Living with HIV” (ECUO)³.

¹ <http://ecuo.org/nas-umiraet-menshe-no-my-umiraem-bystree/>

² The report of regional networks “Eastern Europe and Central Asia: do not leave without an answer!” <http://ecuo.org/wp-content/uploads/2016/07/position-doc-fin-rus.pdf>

³ <http://ecuo.org/vstrecha-s-ministrami-zdravoohraneni-ya-stran-uchastnikov-oon-regiona-vetsa-v-nyu-jorke/>

Later, at the 21st International AIDS Conference - AIDS 2016, held on July 18-22 in Durban, South Africa, the representatives of the region and ECUO, in particular, once again reported on the issue of HIV/AIDS in EECA, about the need to ensure quality transition to public funding, drug interruptions, non-transparent mechanism, purchases at unreasonably high prices, and drew attention to the report of the regional networks “EECA: do not leave without an answer!”⁴.

FACT 2. EECA IS THE ONLY REGION IN THE WORLD WITH A GROWING HIV/AIDS EPIDEMIC

While worldwide there is a steady decline in the number of new HIV cases and AIDS-related deaths, the Eastern Europe and Central Asia remain the only region where the Millennium Development Goals have not been achieved, namely Goal 6 - combat the spread of HIV/AIDS and begun to reverse the spread of HIV/AIDS.”⁵.

According to the latest UNAIDS report, “Ending AIDS. Progress towards the 90-90-90 target,” the number of newly registered HIV cases is growing in the EECA region, as well as AIDS related deaths. According to UNAIDS/WHO/EuroCDC, as of 2016, 190,000 [160,000-220,000] people living with HIV were newly identified in the region, the total number of new HIV cases increased by 60% compared to 2010, while in the world, the scaling up of treatment has reduced the annual number of new HIV cases by 16% compared to 2010. Access to treatment in the EECA region is one of the lowest in the world and equals 28%. The AIDS-related deaths reported in the EECA region have increased by 38%, while in the world, AIDS-related deaths fell by almost a half (48%).⁶

FACT 3. AN EFFECTIVE, PROVEN WAY TO PREVENT AND TREAT HIV INFECTION IS ART

Antiretroviral therapy (ART) is by far the only effective way to stop the progression of HIV infection in the human body. ART reduces the number of deaths from diseases caused and not caused by AIDS in PLHIV, reduces the probability of mother-to-child transmission of HIV, discordant couples, is an effective method of preventing the spread of HIV by any transmission route and an effective way of reducing new HIV infection at an early start and ensuring broad access to treatment. ART allows reaching UNAIDS goal **90-90-90**⁷ and occupies a central position and plays a key role in combination with other effective measures of the "combined" prevention.

⁴ <http://ecuo.org/mezhdunarodnaya-konferentsiya-aids-2016-obzor-i-rezultaty-uchastiya-vtso-lzhv/>

⁵ “Millennium Development Goals: report 2015,” p.44 (UN)

⁶ Global AIDS Update 2017 “Ending AIDS. Progress towards the 90-90-90 target” UNAIDS http://www.unaids.org/sites/default/files/media_asset/UNAIDS_2017_ENDINGAIDS_Slides_en.pdf

⁷ UNAIDS strategy for 2016-2021 http://www.unaids.org/sites/default/files/media_asset/unaidstrategy_2016-2021_ru.pdf

FACT 4. IT IS IMPOSSIBLE TO ACHIEVE THE GOALS OF THE UNAIDS STRATEGY 90-90-90 AND END THE EPIDEMIC IN THE EECA REGION, IF NOT TAKING INTO ACCOUNT THE LIFE QUALITY OF PATIENTS

Today, we observe an increase in the total number of PLHIV, they live longer, but the number of concomitant diseases increases due to the prolonged use of ARV drugs and due to aging of PLHIV. It is necessary to introduce new approaches aimed at improving the life quality and health of PLHIV. It is evident that modern methods of treatment provide access to HIV/AIDS care continuum for the majority of PLHIV, but many other health issues remain unresolved. It is impossible to achieve the goals of the UNAIDS Strategy for 2016-2021, without taking into account the life quality of patients referred to in the multilateral initiative of HIV Outcomes: Beyond viral suppression⁸⁹.

FACT 5. APPROACHES TO HIV TREATMENT

To date, modern HIV treatment regimens, recommended by the U.S. Department of Health and Human Services (DHHC)¹⁰, by the European AIDS Clinical Society (EACS)¹¹, and the International Antiviral Society (IAS-USA)¹² provide the following: high antiviral activity; safety and good tolerance; simple dosing regimen; minimum restrictions on food and liquid intake; a low incidence of antiretroviral resistance; low variability of pharmacokinetics and a few undesirable drug-drug interactions. The recommended ART regimens improve therapeutic indicators and significantly improve the life quality of PLHIV.

The patient treatment regimens, recommended by WHO, ensure basic ARV therapy requirements, differ significantly from the recommended treatment regimens of international professional and governmental organizations (DHHC, EACS, IAS-USA) (see Picture 1).

⁸ <http://ecuo.org/novye-politicheskie-prioritety-dlya-vich-hiv-outcomes-beyond-viral-suppression/#1498913158125-9bc8f8d7-44da>

⁹ <http://ecuo.org/novye-politicheskie-prioritety-po-vich-dolgovremennoe-zdorove-soputstvuyushhie-zabolevaniya-i-ustojchivost-sistemy-zdravoohraneniya-otchet-o-vstrechi-v-bryussele/>

¹⁰ "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents" U.S. Department of Health and Human Services <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/>

¹¹ "Guidelines Version 8.2 January 2017" European AIDS Clinical Society http://www.eacsociety.org/files/guidelines_8.2-english.pdf

¹² Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2016 Recommendations of the International Antiviral Society–USA Panel <http://jamanetwork.com/journals/jama/fullarticle/2533073>

Picture 1

2016: MODERN RECOMMENDATIONS FOR HIV TREATMENT FOR ADULTS, INCLUDING NEW WHO APPROACH									
DHHS, 2016		EACS, 2016		IAS-USA, 2016		WHO, 2016		WHO, 2016 ALTERNATIVE	
ABC/3TC	DTG	ABC/3TC/DTG		ABC/3TC	DTG	TDF+3TC (or FTC)	EFV	TDF+3TC (or FTC) DTG	
TDF (TAF)/FTC	DTG EVG/c RAL	TDF/FTC	DTG EVG/c RAL	TAF/FTC*	DTG EVG/c RAL			TDF+3TC (or FTC)	EFV or NVP
	DRV/r	TDF/FTC	DRV/r DRV/c	ALTERNATIVE					
				TDF(TAF) /FTC	DRV/r				
				ABC/3TC	DRV/r				
		TDF/FTC	RPV**	TDF(TAF) /FTC	RPV**			AZT+3TC	
				TDF/FTC	EFV				
* if TAF/FTC unavailable, possible switch to TDF + FTC or 3TC									
** Only at viral load>1000000 mol/ml									

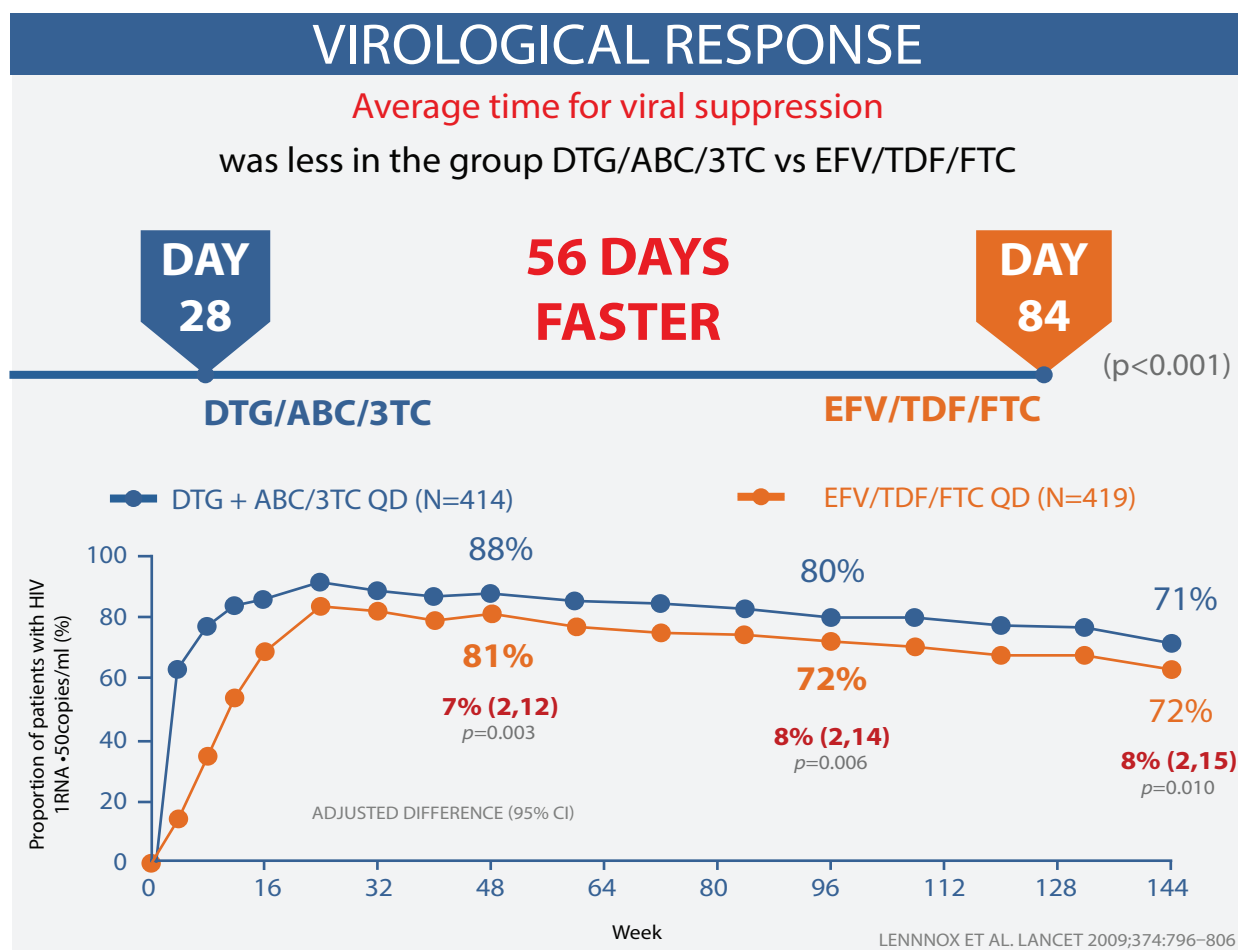
FACT 6. THE EFFECTIVENESS OF INTEGRASE INHIBITORS

It is important to note that INI (integrase inhibitors) have shown their effectiveness, having the highest and fastest viral suppression rates, compared to PI (protease inhibitors/reinforced) and NNRTIs (non-nucleoside reverse transcriptase inhibitors) that used to be the core drugs, as the third “key” component of the complex ART regimen in combination with NNRTIs-base.

Let's stress that the “key” component of the complex ART regimen is associated with higher long-term efficiency, better portability, lower risks of antiretroviral resistance, better pharmacokinetics and fewer undesirable drug-drug interactions.

Moreover, the integrase inhibitors are generally better tolerated, and some of them can act as co-medicines with other nucleoside analogues, allowing to create a potent, well tolerated medicine in the form of a single pill once a day, which makes it possible to reduce the viral load, create high adherence, and eventually, allows the health care system to save money and improve the life quality of patients.

Picture 2¹⁴



¹³ <http://www.who.int/hiv/pub/toolkits/transition-to-new-arv/en/>

¹⁴ Lennnox et al. Lancet 2009;374:796-806



FACT 7. HIGHLY RESTRICTED ACCESS TO INTEGRASE INHIBITORS IN THE EECA REGION

At the same time, according to the collected ECUO data, the number PLHIV, who had the ability to take ARVs of integrase inhibitor (INI) class in 13 countries of the EECA (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Tajikistan, Uzbekistan, Ukraine and Estonia) was less than 200 people at the end of 2015! According to the results of monitoring access to drugs, conducted by ECUO in 2015 and reflected in the ART database for the EECA region (arv.ecuo.org), the drugs of integrase inhibitors class were purchased for the state funds in Latvia, Lithuania, Poland, Ukraine, Estonia and the Russian Federation, and for the Global Fund budget in Armenia, Belarus and Georgia in very limited quantities in 2015.

For instance, in Georgia 120 packs of the drug Isentress 400mg (Raltegravir) 60 Tablets/Pack (RAL) were procured, which equals a 10-year course for 5876 registered HIV/AIDS cases in Georgia in 2015¹⁵, in Belarus – 112 packages considering that at the end of 2015 - 7392 people were receiving ART in Belarus, and 63493 packages were purchased in Russia, about 5300 annual courses, considering that the number of reported HIV cases among the citizens of Russia is more than 1 mln. 167 thousand people.



FACT 8. THERE IS AN EXPERIENCE IN REDUCING THE COST OF ART

Following the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, it is allowed to use the compulsory licensing mechanism for patented pharmaceutical products, providing access for the countries (members of the WTO in need) to the necessary generic drugs produced in other countries. This mechanism has been used successfully in developing countries, thus allowed to significantly reduce the price of ARV drugs. Despite a widespread compulsory licensing in the world, region the proposed mechanism is not used in the EECA region.

In 2016, the company «ViiV Healthcare» and the Medicines Patent Pool reported an expansion of the joint licensing agreement to provide access to new antiretroviral drug - Dolutegravir, DTG, for all low-income countries¹⁶.

As a result, at the beginning of 2017, seven countries of Eastern Europe and Central Asia: Georgia, Kyrgyzstan, Tajikistan, Moldova, Armenia, Ukraine and Uzbekistan, got an opportunity to procure generic drugs containing the active component “Dolutegravir” from manufacturers who have received sub-license of Medicines Patent Pool¹⁷. At the same time, the license does not work in other countries of our region.

¹⁵ http://www.aidscenter.ge/epidsituation_eng.html

¹⁶ http://www.medicinespatentpool.org/viiv-mpp_extend-licence-for-dtg-in-all-lower-mics/

¹⁷ Licence agreement between ViiV HEALTHCARE COMPANY and THE MEDICINES PATENT POOL FOUNDATION, <http://www.medicinespatentpool.org/wp-content/uploads/Amended-and-Restated-ViiV-MPPF-Adult-Headlicence-dated-22-April-2016-Executed-copy.pdf>

**COUNTRIES OF EASTERN EUROPE AND CENTRAL ASIA ARE EUROPE!
IN EUROPE, THERE SHOULD BE NO DOUBLE STANDARDS IN THE
TREATMENT AND DISCRIMINATION OF HIV-POSITIVE PEOPLE
IN ACCESS TO THE ENTIRE CARE CONTINUUM!**

For notes

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