

Access to HCV treatment in Eastern Europe and Central Asia.

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Overview

- Introduction
- HIV and HCV in the Eastern Europe and Central Asia
- Civil society's role in scaling up access to HCV diagnostics and treatment
- Survey on the progress made
- Remaining challenges
- Conclusions and recommendations

HIV and HCV in EECA:

- EECA - the fastest growing HIV/AIDS epidemic in the world.
- HIV infections in EECA increased by 57% with Russia responsible for 80% of the new cases (UNAIDS report).
- More than 11 M people infected with HCV (based on country estimates)
- 80% - in Russia, Ukraine and Uzbekistan
- Injecting drug use is one of the main driving forces of the epidemic.

Key challenges

- Low awareness
- No national strategies
- No funding for treatment
- High prices for treatment
- No political will

Awareness raising and mobilization

- awareness raising campaigns
- patients' schools
- educational programs and training for harm reduction clients, medical professionals, social workers and police officers
- establishing networks to advocates, patients, lawyers
- data and information collection, reporting to government

Advocacy campaigns aimed at:

- developing national treatment programs and treatment guidelines
- allocation of funds
- price reduction for diagnostics and treatment
- IP work

Testing and treatment programs

- testing campaigns to identify HCV-antibody positive (awareness raising, evidence based advocacy, referring to clinics)
- treatment programs and integration of HCV services in harm reduction programs

Introduction of the survey

Purpose of the overview:

- identify key aspects of the hepatitis B and C epidemics and response in EECA;
- outline advocacy tools and activities of NGOs and community-based groups;
- identify gaps in response;
- provide recommendations to the key stakeholders.

Methods:

- data collected through questionnaires;
- 11 NGOs in 11 countries: Armenia, Azerbaijan, Belorussia, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine and Uzbekistan;
- information was cross-referenced with open-source information;
- WHO viral hepatitis treatment protocols were used.
- Additional patent information was obtained from Medicines Patent Pool (MedsPal)

Results:

Data and information was consolidated into the report . “Hepatitis C in Eastern Europe and Central Asia: civil society response to the epidemic” (as for November 2016 report is available at www.aph.org.ua or direct [link](#)).

Estimations for HIV, HCV and HBV

Country estimates, (% if other doesn't indicated)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
- HIV	n/a (2482 total of HIV+ people)	n/a (4955 total of HIV+ people)	0,14 (total 18 864 HIV+ people)	19,3 per 100 000 (total of 6204 HIV+ people)	n/a (23485 total of HIV+ people)	n/a (5877 total of HIV+ people)	129,04 per 100 000 people (8557 total of HIV+ people)	1% (up to 1,5 million HIV+ people)	57.2 cases per 100,000 population (6558 total of HIV+ people)	0,9% (313,3 per 100 000 people, total 300 453 of HIV+ people)	n/a (total of HIV+ people 30 340)
- HBV	1,8	2- 8	14% of all hepatitis incidence cases	20,1 per 100 000 people		6,6	2-7	1-5	0,04	1,5-2	n/a
- HCV	4	3,2	2-3	5,4	1,2	4	1,4 per 100 000 people	4,4	0,01	8	6,5
Co-infections prevalence among general population, %											
HIV/HCV	15,9	58,8	50-60	48	n/a (number of people 7288)	80	37	27	25,6	25	n/a
HIV/HBV	2,2	n/a	n/a	n/a	n/a (number of people 259)	n/a	10	5,2-7,3	n/a	7	n/a
Among PWID											
HCV	31	62,8	70-95	44-69	N/a (number of people 5982)	60,61	35,3-65,4	69	22,7 %	55,9	20,9
HBV	n/a	10,1	0,1	2	7,9	56	4,1-12,4	9	2	4,5	n/a
HIV/HCV		60	70	73,4	85-89	23	45,6	up to 98		16,9	n/a
HIV/HBV				8,5		n/a	10	n/a		1,8	n/a

HIV, HCV and HBV in EECA

- HCV prevalence among general population ranges from 0,01% (Tajikistan) to 8% (Ukraine).
- HCV/HIV co-infection rate varies from 13,9% (Armenia) to 80% (Kyrgyzstan)
- HCV prevalence among PWID is high: > 60% in 6 countries (Azerbaijan, Belarus, Georgia, Kyrgyzstan, Moldova, Russia)
- HBV prevalence is lower than HCV prevalence. The highest reported rate is 6,6% in Kazakhstan.
- Key affected populations: PWID, PLHIV, medical workers, blood/tissue recipients.

Prevalence in PWIDs

- HCV prevalence in PWIDs (>50%):
 - Up to 95% - Belarus
 - Up to 69% Georgia and Russia
 - Up to 65% Moldova
 - 62,8% Azerbaijan
 - 60,61% Kyrgyzstan
 - 55,9% Ukraine

Availability of HCV Treatment Guidelines in EECA countries (February 2017)

Country	Date	Key treatment schemes	Comments
Armenia		PEG-IFN/RBV	According to information received from the respondent, WHO HCV guidelines are used. PWID are not prioritized.
Azerbaijan	2009	PEG-IFN/RBV	Guidelines will be updated
Belarus	2015	SOF/PEG-IFN/RBV, SIM/PEG-IFN/RBV, SOF/LDV±RBV, 3D±RBV, SOF/SMV±RBV, SOF/DCV±RBV, SOF±RBV, SMV/PEG-IFN/RBV	Guidelines available here
Georgia	2015	SOF/PEG-IFN±RBV, SOF/LDV±RBV	The SOF-based regimen is mentioned in the national program, launched in April 2015
Kazakhstan	2015	PEG-IFN/RBV, SMV/PEG-IFN/RBV; 3D is a recommended interferon-free regimen; BOC and TPV are no more preferred options	Recommended by the Expert Council of the Republican Center of Healthcare Development of the Ministry of Health and Social Development of the Republic of Kazakhstan dated December 10, 2015, Protocol No. 19
Kyrgyzstan	2017	SOF/DCV, SOF/LED, SOF±RBV	Guidelines available here
Moldova	2015	SOF/DCV±RBV, SOF/LDV±RBV, SOF/SMV±RBV; 3D±RBV; SOF/PEG-IFN±RBV, SOF/RBV, SMV/PEG-IFN/RBV	Guidelines available here
Russia	2017	SOF/PEG-IFN/RBV, SIM/PEG-IFN/RBV, 3D±RBV, SOF/SMV±RBV, SOF/DCV±RBV, SMV/PEG-IFN/RBV, DCV/ASV/PEG-IFN/RBV, DCV/ASV, NPV/PEG-IFN/RBV/RTV	Guidelines are available here
Tajikistan	2015	n/a	Russian guidelines are referred for HCV treatment.
Ukraine	2016	PEG-IFN/RBV (alternative regimen), SOF/PEG-IFN/RBV, SOF/LDV±RBV, 3D±RBV, SOF/SMV, SOF/SMV/RBV, SMV/PEG-IFN/RBV: SOF/RBV (genotype 2 – 12 weeks, genotype 3 – 24 weeks); BOC and TPV are no more recommended as preferred options	Approved by Order of the MoH of Ukraine 18.07.2016 No 729
Uzbekistan	2013	Alfa interferon	To be revised in 2018 or upon emergence of new evidence. Simeprevir delivered as humanitarian aid.

DAA-based treatment regimens are included into guidelines in Belarus, Georgia, Kazakhstan, Moldova, Russia, Ukraine. DAAs are not included but used for treatment in Tajikistan, Uzbekistan and Azerbaijan.

Registration of HCV medicines

Country	Peg-interferon	sofosbuvir	sofosbuvir generic	sofosbuvir / ledipasvir	sofosbuvir / ledipasvir generic	Sofosbuvir/ velpatasvir	Sofosbuvir/ velpatasvir (generic)	daclatasvir	daclatasvir generic	Elbasvir/ grazoprevir	ombitasvir/ paritaprevir/ ritonavir/ dasabuvir (Viekira Pak)	ombitasvir/ paritaprevir/ ritonavir	dasabuvir	simeprevir	Asunaprevir	Narlaprevir
Armenia	X															
Azerbaijan	X		2X								X			X		
Belarus	X		2X								X					
Georgia	X	X		X												
Kazakhstan	3X		2X	X					pending		X			X		
Kyrgyzstan	2X		6X	X	4X				X							
Moldova	X		3x						x			X	X	X		
Russia	X	X						X			X			X	X	X
Tajikistan	X		X													
Ukraine	X	X		X							X	X	X	X		
Uzbekistan	X		X													

Registration of one or more second-generation DAAs is reported in 10 (91%) of 11 countries.

e.g, in Uzbekistan, the absence of registration (SOF/LED,DAC) does not limit the sale of generics at commercial market (Gilead and MPP/BMS VL).

Prices for HCV treatment

Lowest drug prices in surveyed countries - USD per vial/pack

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Country	Peg-interferon (PEGINF-ALPHA-2a 180 mg)	sofosbuvir	sofosbuvir generic	sofosbuvir/ ledipasvir	sofosbuvir/ ledipasvir generic	daclatasvir	daclatasvir generic	ombitasvir/ paritaprevir/ ritonavir/ dasabuvir	ombitasvir/ paritaprevir/ ritonavir	dasabuvir	simeprevir	Ribavirin	Lowest available price for DAA-based 12 w treatment course
Armenia	175 P												
Azerbaijan	100R		365 R					5000 P (per 112 tablets)				7,3R (60 tablets)	2360,7
Belarus	187,2 P		<u>800</u>					4620,6 P (per 112 tablets)				3,5 P (30 tabs)	4705,9
Georgia	free of charges	free of charges		free of charges								free of charges	free of charges
Kazakhstan	163,16 G			6704 G				99,77 G (per pack)				free of charges	20 112
Kyrgyzstan	183P		152 P	319 P			60 P					9,4 (per 30 tabs)	636
Moldova	140,38 R		350 R			262 R			14639,64 R	1272,57 R	8468,42 R	53,02 R (per 168 tabs)	2893,62
Russia	114,83 P					1830 P		5106 P			3459 R, 3012 P	19 R (per 60 tabs)	15 318
Tajikistan	140		145										
Ukraine	127,08 R	250 G		300 G							512,9 P	3,69 P (per 30 tabs)	2336,73
Uzbekistan			109 P		144 P		60 P					4,6 P (per 30 tabs)	507

The lowest price (109 USD) for generic SOF is reported in Uzbekistan. The highest price (6704 USD, currently negotiating with Gilead) is reported in Kazakhstan.

Price for SOF-based 12w treatment course in Belarus may reach 5 000 USD (if the 800 USD price will be agreed).

Prices for HCV diagnostics

Full diagnostics:

Georgia: average price = USD 199,5.

70% covered by state for financially disadvantaged citizens. 30% for other population groups.

Ukraine: average price = USD 55 (50% discount, fibro scan not included), USD 98.2 (price without discount).

Fibro scan = from USD 33 to USD 69

PCR (quantitative) price:

- **Kyrgyzstan:**

USD 36 (general public)

Ukraine:

free for PWIDs and other KPs (Alliance treatment program)

USD 23 (out of Alliance agreement)

In most countries of EECA, diagnostics remain unaffordable for majority of the population

Availability of HCV treatment programs

- Available in Armenia, Azerbaijan, Georgia, Belarus, Kazakhstan, Moldova, Ukraine, Tajikistan, Uzbekistan.
- Different funding sources – national and local programs, donor programs, donations.
- State-funded programs: in Armenia (acute viral hepatitis infections), Azerbaijan (HCV), Georgia (HCV), Belarus (HCV), Kazakhstan, Moldova (hepatitis B,C,D), Ukraine (HCV,HBV), Tajikistan (HBV).
- Donor-funded programs available in Georgia, Kazakhstan, Kyrgyzstan, Ukraine, Uzbekistan (GF, MdM, MSF, Abbvie, etc)
- 20-25 thousand people receive HCV treatment annually under national programs in EECA region.

Less than 1% of people in need received treatment.

National and Donor-Driven HCV Treatment Programs

Country	National Hepatitis program/ separate legislative acts	Key risk groups which are prioritized for treatment	Number of people (received treatment from state)	Comments	Donor program	Number of people
Armenia	-	PLHIV	Absolute number unknown.	Treatment provided due to the general health policies	-	-
Azerbaijan	+	Without limitation	Absolute number unknown.	Quantity of people on treatment is not limited by the state program	-	-
Belarus	-	Treatment is free of charges for children and post-transplantation patients	Absolute number unknown.	Treatment provided due to the general health policies	-	-
Georgia	+	Without limitation	20 000 people annually during 10 years	Up to 20 000 000 GEL (about 8,3 mln USD from local and regional budgets for support diagnostic and service)	+	> 200
Kazakhstan	-	All patients with CHCV with compensated liver diseases	Average number of people who received hepatitis B and c treatment is 1200/year	Treatment provided due to the general health policies	+	20
Kyrgyzstan	-	PLHIV	Up to 100 annually	Treatment provided in the frames of National HIV response program.	+	Up to 100
Moldova	+	n/a	In 2016 was announced to increase the number of treatment courses to 3000 per year (hepatitis B,C,D)	-	-	-
Russia	-	Prioritized for treatment: people with >F2 fibrosis, PWID, woman who planned pregnancy, HIV/ HCV co-infected.	In 2016, 8792 people received treatment. Number of patients who expected to receive 48-week course of PEG-IFN in 2017 is 540 and 290 treatment courses of SMV.	Government announced HCV treatment procurement for total amount over 4,6 mln USD	-	-
Tajikistan	-	n/a	n/a	n/a	-	-
Ukraine	+	Prioritized for treatment: people with >F2 fibrosis, PWID, woman who planned pregnancy, HIV/ HCV co-infected, people with extrahepatic syndroms, these who have frequent contacts with infected people	n/a	Government announced HCV treatment procurement of DAAs (SOF, SOF/LED, 3D) which may cover up to 10 000 treatment courses	+	Alliance program up to 2000
Uzbekistan	-	-	-	National treatment program is expected in 2017	+	> 200

Access to HCV services (testing, diagnostics, treatment).

Is it possible in your country:	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
1) get tested for HCV and/or HBV anonymously	no	yes	yes (paid). Free of charges - with passport	yes	yes	yes (paid)	no	yes (paid)	no	yes	yes (paid)
2) compulsory testing for certain categories of population	no	no	yes	no	yes	yes	no	yes	yes	no	yes
- medical workers			+		+	+		+	+	+ (recommended)	+
- KPs	+ recommended		+			+		+		+ (recommended)	
- people who got invasive procedures			+		+	+		+		+ (recommended)	
3) to get the diagnostics free of charges (for HIV - positive people, KPs)	yes	yes	yes	70% of diagnostics cost covered by state for financially disadvantaged citizens	yes	no (unaffordable price)	yes	yes (for co-infection)	yes	no (unaffordable price)	yes, for PLHIV
4) receive treatment for free (for HIV - positive people, KPs)	yes (for PLHIV with HBV/HIV co-infection only)	yes	yes (for people under 18 y.o. and these who had liver transplantation)	yes	yes	only for PLHIV	yes	yes (for HIV)	no	yes	only for PLHIV in donor-funded program

Armenia, Moldova and Tajikistan reported absence of anonymous testing; Armenia, Belarus, Kyrgyzstan, Tajikistan, Russia and Uzbekistan (6/11 countries) reported limited or no access to treatment for key populations.

Access to HCV drugs. Voluntary Licenses

Voluntary licenses .

Country	Gilead VL	BMS (MPP VL)	MSD, Pegintron (USD 40 per vial),
Armenia	No	No	No
Azerbaijan	No	Yes	No
Belarus	No	No	No
Georgia	No	Yes	No
Kazakhstan	No	No	No
Kyrgyzstan	Yes	No	Yes
Moldova	No	No	No
Tajikistan	Yes	No	Yes
Russia	No	No	No
Ukraine	No	No	No
Uzbekistan	Yes	Yes	No

Gilead VL: Kyrgyzstan, Tajikistan, Uzbekistan.

MPP/BMS VL: Azerbaijan, Georgia, Uzbekistan.

Uzbekistan benefits from both VL agreement (Gilead and MPP/BMS), price for 12w treatment course (SOF+DAC generics) is 507 USD

In 2015-2016, patent oppositions for sofosbuvir were filed in Russia and Ukraine (results pending).

- After over a year of court litigation, in 2017, Ministry of Health of Ukraine approved an out-of-court settlement between Gilead and the state. Gilead included Ukraine into Global Access Program, offering Sovaldi at 250 USD and Harvoni 300 USD per pack under Ukrainian public procurement programs.
- In Russia, the patent for sofosbuvir was opposed by NGO “Humanitarian action”, the last court session was in March 2017 (results pending at the time of presentation).

Market for unregistered DAAs imported for personal use

- 2015 -2016, buyers' clubs - for generic DAAs (sofosbuvir, sofosbuvir/ledipasvir, daclatasvir) mainly originating from India and Egypt.
- patients prefer to take personal responsibility for purchasing drugs in India or Egypt and import them for personal (relatively lower price).
- Delivery of generics through “buyers ‘clubs” was reported in Belarus, Kazakhstan, Russia, Ukraine.
- In Belarus, the buyers’ club is reported as the main procurement source for treatment (in-country registered price for DAAs is higher than the price of imported generics)

- High prices for diagnostics and treatment
- Lack of national programs and limited funding
- Obsolete treatment regimens (inf-based therapy, TEL, Boceprevir still used - obsolete treatment guidelines)
- Extremely limited or no access to treatment for PWIDs (criminal and/or administrative responsibility for personal use of drugs without intent to sell is applied in 11/11 (100%) of surveyed countries)

Next steps

Recommendations for CSOs:

- Continue raising awareness among the stakeholders
- Continue mobilizing communities
- Advocate for effective national strategies
- Advocate for price reduction for diagnostics and treatment (applying different strategies including the use of TRIPS flexibilities)
- Advocate for accelerated registration of DAAs
- Strengthen cooperation between civil society and government
- Ensure community involvement at all levels of response to the epidemics
- Advocate for harm reduction policies e.g. decriminalization of drug users (possession for personal use)
- Ensure state funding to scale up harm reduction services including OST and NSP.
- Integrate HCV services into harm reduction (simple service delivery model, peer support, HBV vaccination) driven by CSOs.

Steps required from other stakeholders

Pharmaceutical companies:

- price reduction for treatment courses and testing, registration of drugs and diagnostic products
- VL agreements
- access programs, demonstration project. NO anti-diversion measures.

National authorities

- national viral hepatitis policies/strategies (prevention, testing, treatment and care)
- sufficient funding for implementing national programs and plans.
- reliable surveillance system both for hepatitis B and C, including key populations
- continue HBV vaccination of general and vulnerable populations
- development and update of testing, treatment and care guidelines (following WHO, EASL and AASLD recommendations)
- Include KPs into treatment guidelines and providing treatment to them

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Thank you!

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