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HEPATITIS B C

in Eastern Europe and Central Asia:

Response to the epidemic.

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Abbreviations

AASLD	American Association for the Study of Liver Diseases
Anti-HCV	HCV antibodies
ART	Antiretroviral Therapy
BMS	Bristol-Myers Squibb
CAB	Community Advisory Board
CSO	Civil society organization
EASL	European Association for the Study of the Liver
DAA	Direct Acting Antivirals
EAPO	Eurasian Patent Organization
EECA	Eastern Europe and Central Asia
EECA CAB	Eastern European and Central Asian Community Advisory Board
EHRN	Eurasian Harm Reduction Network
GeCAB	Georgian Community Advisory Board
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNI	Gross National Income
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
I-MAK	Initiative for Medicines, Access, & Knowledge
ITPC	International Treatment Preparedness Coalition
LMIC	Low and Middle Income Countries
MARP	Most-at-risk Population
MdM	Médecins du Monde/Doctors of the World
MoH	Ministry of Health
MSD	Merck Sharp & Dohme
MSF	Médecins Sans Frontières/Doctors without Borders

NGO	Non-governmental organization
OSF	Open Society Foundations
OST	Opioid Substitution Therapy
PI	Protease Inhibitors
PLHIV	People living with HIV
PWID	People who inject drugs
RF	Russian Federation
TRIPS Rights	The Agreement on Trade-Related Aspects of Intellectual Property
UNAIDS	Joint United Nations Program on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

Abbreviations for drugs

3D – dasabuvir; ombitasvir, paritaprevir boosted with ritonavir

BOC – boceprevir

cePEG-IFN – cepeginterferon alpha-2b

DAS – dasabuvir

DCV – daclatasvir

OMB – ombitasvir

PEG-IFN – pegylated interferon

PTV/r – paritaprevir/ritonavir

RBV – ribavirin

SMV – simeprevir

SOF – sofosbuvir

SOF/LDV – sofosbuvir/ledipasvir

SOF/LDV – sofosbuvir/velpatasvir

TPV – telaprevir

NPV – narlaprevir

3TC – lamivudine

ETV – entecavir

LdT – telbivudine

ADV – adefovir

FTC - emtricitabine

TAF – tenofovir alafenamide fumarate

TFV – tenofovir

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Introduction and Background

Introduction

The purpose of this report is to provide an overview of key aspects of the hepatitis B and C (HBV and HCV) epidemic and response by governments and civil societies in Eastern Europe and Central Asia (EECA). It also outlines tools and activities for civil activists and non-government organizations (NGOs) working on expanding access to HBV and HCV treatment in the region. Currently there is a strong global movement towards elimination of viral hepatitises. It is essential that this analysis be available, to ensure that the EECA region is included in global strategies being developed to provide universal access to innovative curative treatment regimens currently in the pipeline.

The overview summarizes data from 11 EECA countries (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine and Uzbekistan) with a focus on availability of HBV and HCV medicines, treatment guidelines, national/donor treatment programs, and civil society involvement in the epidemic response. It also offers possible approaches and steps that could be taken by NGOs to improve access to HCV treatment.

Background

Worldwide, 96% of all hepatitis-related mortality is caused by HBV and HCV. WHO's Global Hepatitis Report published in April 2017 provides a new estimate of epidemiological data. Total HBV prevalence is estimated at up to 257 million people, with chronic HCV at 71 million. The highest HCV prevalence rates are noted in the Eastern Mediterranean and European regions of WHO. It should be stressed that an estimated 95% of people with HCV are unaware of their infection. Due to limited or no access to prevention and harm reduction programs, people who inject drugs (PWID) remain the driving force behind the epidemic in some regions. It should also be noted that a significant share of medical injections — 5% of the total — also remain unsafe.

Although drugs capable of curing more than 95% of infected people exist, the epidemic has not been stopped because access to them is very limited. In 2015, only 8% of people diagnosed with HBV received treatment. Less than 500,000 (<1%) people diagnosed with HCV gained access to highly efficient medications — direct-acting antivirals (DAAs). **The number of new infections substantially exceeds the number of people who have received treatment.**

Access to DAAs remains problematic for people living with HIV (36.7 million), among whom estimated prevalence of HBV is 2.7 million and of HCV, 2.3 million. WHO includes people with HIV/hepatitis co-infection in the category of people requiring priority access to treatment, since HIV provokes fast progress of diseases caused by hepatitis viruses, especially types B and C.

According to WHO estimates, up to 14 million people with HCV and about 15 million people with HBV live in the WHO European region, while 11 million people with HCV live in Eastern Europe and Central Asia (EECA). Countries in EECA region demonstrate high growth rates of HIV (57% in 2010–2015) and the highest share of HIV-positive people with serological indicators of HCV (27%). One reason for this is low accessibility of prevention and harm reduction services for PWID. In some parts of EECA, prevalence of HIV/HCV

co-infection among PWID may reach 98%. Low ART coverage in the region (less than 21%) suggests increased mortality rates among most-at-risk groups, including PLHIV with HIV/viral hepatitis co-infection. Lack of data on diseases caused by HCV or HBV recorded on death certificates is characteristic for most EECA countries, but results of the few conducted studies show that HBV-related mortality among PWID aged up to 30 may be as high as 80%.

Change in the treatment paradigm

For a long time the standard of care for HCV was a 48-week course of a combination of injectable pegylated interferon (PEG-IFN) and oral ribavirin (RBV). DAAs have allowed treatment to be shortened to 12 weeks, improving sustained virologic response (over 90%) and significantly reducing adverse effects. The current trend followed by manufacturers of DAAs involves cutting treatment duration to 6 to 8 weeks and using pan-genotypic DAAs without PEG-INF.

WHO recommends that tenofovir and entecavir therapy be used to suppress replication of HBV, as these are the strongest anti-HBV drugs. But in most people this treatment does not cure the infection, and HBV treatment must be life-long.

Key viral hepatitis-related documents

World Health Organization

1) Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection, (2014, updated April 2016)
2) Guidelines for the Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection (March 2015)

These guidelines are intended mainly for healthcare policy makers; government officials; specialists responsible for developing programs for screening, care and treatment of HCV and HBV, and healthcare providers.

The guidelines set forth simplified approaches to provision of care to people with chronic hepatitis B and C, particularly in settings with limited resources.

The new version of the guidelines for hepatitis C includes the recommendation to use DAAs instead of PEG-INF+RBV therapy, though it does not rule out that PEG-INF may sometimes be combined with DAAs.

The guidelines were developed with the participation of several international NGOs: Treatment Action Group (TAG); International Network of People Who Use Drugs (InPUD); Médecins du Monde *(*MdM); Women and Harm Reduction International Network; World Hepatitis Alliance, and Médecins Sans Frontières (MSF), as well as the Alliance for Public Health (Alliance) and the Eurasian Harm Reduction Network (EHRN) from the EECA region.

3) Global Health Sector Strategy on Viral Hepatitis

In 2016, the World Health Assembly adopted the first global health sector strategy on viral hepatitis until 2030. This strategy is aimed at fighting all five types of hepatitis (A, B, C, D, and E), with emphasis on viral hepatitis B and C considering their public health significance. Countries which have signed the strategy have committed to eliminating hepatitis B and C, with 90% diagnosed cases of chronic hepatitis C and 80% of people covered with HCV treatment.

The strategy includes harm reduction targets up to 2030, including use of safe injecting equipment. WHO recommends distributing 300 sterile needles and syringes per year per

individual injecting drugs. Safer injecting equipment is recommended to cover 90% of all injections performed in both healthcare institutions and community settings. Opioid Substitution Therapy (OST) is included in the strategy, but without quantitative targets. Ninety percent coverage with HBV vaccination til 2030, including vaccination of newborns, is recommended.

Representatives of MSF, TAG, EHRN, the Alliance and other organizations contributed to the WHO Strategic and Technical Advisory Committee for Viral Hepatitis, which was in charge of developing the global strategy. Experience in implementing treatment programs piloted by the Alliance in EECA was taken into account in preparing the global strategy recommendations.

4) Action plan on viral hepatitis in the European region in 2016–2021 (approved at the 66th session of the WHO Regional Committee for Europe in September 2016)

The action plan sets regional control indicators and targets covering the whole continuum of services related to viral hepatitis. It suggests priority actions for member states, supported by WHO activities, under five strategic directions: information for focused action, interventions for impact, delivering for equity, financing for stability, and innovation for acceleration.

European Association for the Study of the Liver (EASL)

1) Clinical Practice Guidelines: Management of Chronic Hepatitis B Virus Infection (2017)
2) Recommendations on Treatment of Hepatitis C (2016)

EASL clinical practice guidelines help doctors and other healthcare providers, as well as patients and stakeholders, in making clinical decisions by describing a number of common approaches to diagnostics, treatment and prevention of specific liver diseases.

American Association for the Study of Liver Diseases (AASLD)

AASLD produce and publish evidence-based guidelines developed and updated regularly by a committee of experts. The guidelines include recommendations of preferred approaches to the diagnostic, therapeutic and preventative aspects of care for people with liver diseases, including those infected with viral hepatitis. The guidelines are intended primarily for general practitioners, hepatologists or other healthcare professionals working in the field of liver diseases. The guidelines take into account specifics of different age groups of patients, as well as management of pregnancy.

Key partners

Besides WHO, the strategy to eliminate the epidemic has been embraced by major international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF), Unitaid, Open Society Foundations (OSF), and AIDS Fonds. International NGOs Treatment Action Group, International Network of People Who Use Drugs, Médecins du Monde, Women and Harm Reduction International Network, World Hepatitis Alliance, and Médecins Sans Frontières play an important role. In EECA countries, NGOs are the driving force of the national response to the epidemic. NGOs contribute not just by providing services, but by advocating for changes to legislation and immediate participation in developing strategies and action plans at the international, national and local level. NGOs actively support development and marketing authorization of new drugs, reduction of medication prices, implementation of treatment programs, development and implementation of guidelines, increased funding, and so on.

Methodology

The data presented in this overview have been collected through questionnaires sent to NGO representatives in 11 countries of the EECA region (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Ukraine, Russia and Uzbekistan) and compared with information found in public sources.

Questionnaire topics included HCV and HBV disease burden; prevalence among the general population, PWID and PLHIV; registered drugs and prices; HCV treatment guidelines, and national and donor programs. Respondents were asked to provide a brief description of HCV and HBV work done by NGOs at national and local level, and to describe accessibility of prevention and treatment services.

Most data concern the period of January to April 2017. As of the time of report publication, some information might be outdated.

For the purpose of unification of price information, the report authors suggested that respondents indicate prices of medications in US dollars.

To analyze treatment guidelines and calculate prices for therapy, the authors used the HCV treatment guidelines issued by the European Association for the Study of the Liver in the edition available on the EASL website as of May 2016, as well as the WHO guidelines of April 2016.

HCV and HBV Epidemic Data

EECA countries tend to lack a well-developed, reliable system of epidemiological surveillance of viral hepatitis, and screening campaigns or other measures aimed at regular detection of infection cases in the general population and/or vulnerable groups.

The data given in table 1 are in some instances based on results of local studies (some of which were conducted with support from non-government organizations), or data announced by experts or state officials, or WHO data.

According to table 1, prevalence of HCV in the general population varies from 8% in Ukraine to 0.01% in Tajikistan. The highest estimated prevalence of HBV, according to national experts, is 8% (in Uzbekistan). Low prevalence in Tajikistan is more likely to be a sign of unreliable epidemic surveillance than of a small number of people with HCV.

HIV prevalence varies from 0.2% (Armenia, Azerbaijan, Kazakhstan, Kyrgyzstan, Uzbekistan) to 1% in Russia, primarily due to critically low coverage with prevention and harm reduction services. PWID are the most-at-risk group in all 11 countries of the study. Key populations besides PWID include people living with HIV, medical workers, men having sex with men (MSM), commercial sex workers (CSW), prisoners, haemodialysis patients, and blood transfusion recipients.

The estimated number of PWID in the region may reach 3.1 million, including 1.8 million in Russia. HCV prevalence among PWID varies from 20.9% in Uzbekistan to 95% in Belarus. At the same time, HBV prevalence among PWID in Belarus is 0.1%, while in Kyrgyzstan it may reach 56%. Needle and syringe exchange programs are present in all 11 countries, but the coverage and reach of services differ greatly. In Ukraine there were 1,643 needle and syringe exchange sites as of the end of 2016. In Russia, after reduction of funding from the Global Fund, there were 60 needle and syringe exchange sites in 2011[1]. According to the respondent, there may now be fewer than 10 sites.

PWID enjoy very limited access to prevention, diagnostics and treatment of viral hepatitis, HIV and TB. The main hindrance to access is excessive criminalization and discrimination of PWID in the EECA region. All the studied countries impose administrative or criminal sanctions for possession of narcotic substances for individual consumption without the intent to sell. Punitive legislation and policies have led to excessively high rates of imprisonment in EECA countries: 455 per 100,000 people in Russia, 335 per 100,000 people in Belarus, 281 per 100,000 in Georgia, 275 per 100,000 in Kazakhstan, 236 per 100,000 in Azerbaijan, and 212 per 100,00 in Moldova. **The world average ratio of incarceration is 146 per 100,000 people**. PWID are estimated to comprise about a third of all incarcerated people in some EECA countries (31.9% in Azerbaijan, 30.4% in Kyrgyzstan), and almost half in others (48.7% in Ukraine). Prevalence of hepatitis C in prisons in Ukraine is 60.2%, in Kyrgyzstan it is 49.7%, and in Azerbaijan, 38.2%[2]. These data show that limited access to prevention programs and increased risk of going to jail,

[1] https://www.google.com.ua/url?sa=t&rct=j&q=&esrc=s&source=web&cd=9&cad=rja&uact=8&ved=0ahUKEwibvaOl34XVAhVJG5oKHU9nDlYQFghbMAg&url=https%3A%2F%2Fwww.unodc.org%2Fdocuments%2Fbalticstates%2F%2FEventsPresentations%2FManagement_HR_Programmes%2FOrganization_management.doc&usg=AFQjCNExbKd0eVvBJyOizqCEwZo6MCTkog

[2] https://www.google.com.ua/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&cad=rja&uact=8&ved=0ahUKEwiQ-aK1huvUAhWla5oKHX2HDAYQFgg7MAQ&url=http%3A%2F%2Fwww.uiphp.org.ua%2Fmedia%2F1620&usg=AFQjCNHghfHl7cYMuyVyxez3C4KXg2StoA

where prevalence of HCV is many times higher than among the general population, make PWID one of the groups most vulnerable to infection with hepatitis, HIV or tuberculosis.

HCV prevalence among the total number of people with HIV varies from 13.9% in Armenia to 80% in Kyrgyzstan. Prevalence of HBV among people with HIV and in the general population is much lower than that of HCV.

Table 1. Epidemiologic data for 11 EECA countries

	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzberkistan
Estimated WHO/UNAIDS prevalence, %											
HIV	0.2	0.2	0.6	0.4	0.2	0.2	0.6	n/a	0.3	0.9	0.2
HBV	n/a	n/a	n/a	n/a	1–5	n/a	n/a	1–5	<5	1–5	>10
HCV	n/a	n/a	n/a	3–5	1–3	n/a	n/a	1–3	<1	>5	>5
Country estimates, (%, unless otherwise indicated)											
HIV	n/a (2,482 total HIV+ people)	n/a (4,955 total HIV+ people)	0.14 (18,864 total HIV+ people)	19.3 per 100,000 population (6,204 total HIV+ people)	n/a (23,485 total HIV+ people)	n/a (5,877 total HIV+ people)	129.04 per 100,000 population (8,557 total HIV+ people)	1% (up to 1.5 million HIV+ people)	57.2 per 100,000 population	0.9 (300,453 total HIV+ people)	n/a (30,340 total HIV+ people)
HBV	1.8	2–8	14% of all hepatitis incidence cases	20.1 per 100, 000 population	3–4	6.6	2–7	1–5	n/a	1.5–2	8
HCV	4	3.2	2–3	5.4	1.2	4	1.67 per 100,000 population	4.4	n/a	8	4.5
Co-infections prevalence, %											
HIV/HCV	13.9	58.8	50–60	48	n/a (7,288 total number of people)	80	37	27	25.6	25	n/a
HIV/HBV	2.2	n/a	n/a	n/a	n/a (259 total number of people)	n/a	10	5.2–7.3	n/a	7	n/a
Among PWID											
HCV	31	62.8	70–95	69	n/a (5,982 total number of people)	60.61	35.3–65.4	69	22.7–49.3%	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	25
HIV/HBV				8.5		n/a	10	n/a		1.8	n/a
HBV vaccination policy	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

According to table 2, there may be over 11.5 million people infected with HCV and more than 6 million people with HBV.

Table 2. Absolute number of people who may be infected with HBV or HCV in EECA

Country	Population	HCV prevalence (%)	Estimated number of people living with HCV (or anti-HCV)	HBV prevalence (%)	Estimated number of people living with HBV (or anti-HBV)
Armenia	2,994,520 as of 01.02.2017 National Statistical Service http://www.armstat.am/	4%	120,000	1.8%	< 54,000
Azerbaijan	9,810,000 as of 2017 http://www.stat.gov.az/source/demography/ap/indexen.php	3.2%	300,800	2–8%	196,000
Belarus	9,498,600 as of 01.04.2017 National Statistics Committee of Belarus http://www.belstat.gov.by/	2.0–3.0%	250,000 MoH data, 2015: 47,000	n/a	190,000
Georgia	3,718,200 as of 01.01.2017 http://geostat.ge/index.php?action=page&p_id=473&lang=eng	5.4%	200,000	2–3% National Center for Disease Control: 20.1 per 100,000 people	74,400
Kazakhstan	17,754,000 as of 01.01.2017 http://www.stat.gov.kz	1.2%	255,000–510,000	3–4%	532,000
Kyrgyzstan	6,140,200 as of 01.01.2016 http://www.stat.kg/ru/statistics/naselenie/	4%	220,000	6.6%	405,250
Moldova	3,553,100 as of 01.01.2016 http://www.statistica.md/newsview.php?l=ru&idc=168&id=5156	1.4 per 100,000 people	60,000–142,000 National Healthcare Management Center 2012: 9,411 official number	2–7%	71,000
Russia	146,800,000 as of 01.01.2017 Rosstat	about 4%	Russian Federal service Rospotrebnadzor: 5.9 million	1–5%	1,468,000
Tajikistan	8,547,000 as of 01.01.2016 http://www.stat.tj	2.3%*	< 200 000		
Ukraine	42,371,996 as of 1.03.2017 http://www.ukrstat.gov.ua/	5%[3]	2,135,400 Estimates: http://moz.gov.ua/ua/portal/pre_20140728_d.html; clinical guidelines	1.5–2%	635,570
Uzbekistan	31,575,300 as of 01.01.2016 http://www.stat.uz/statinfo/demograficheskie-dannye	6.5%[4]	1,800,000	8%	2,526,000
			Overall estimate: 11,441,200 people		**Overall estimate: 6,152,200 people**

[3] In a recently published article by Hope et al. HCV antibody prevalence in Ukraine was estimated at 12%. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891474/

[4] Ibid. prevalence of anti-HCV in Kyrgyzstan indicated at 13.1%.

Treatment Guidelines

HCV treatment guidelines

At present, recommended HCV treatment regimens use mainly second generation DAAs, in line with generally accepted standards for treatment of hepatitis C defined particularly in the guidelines of the American Association for the Study of Liver Diseases (AASLD), the European Association for the Study of the Liver (EASL) as revised in 2015[5], and WHO as revised in 2016[6]. According to information collected for the report, second generation DAAs are recommended in protocols of 7 out of 11 countries.

In some countries, such as Armenia and Tajikistan, respondents were unable to find publicly accessible information about HCV treatment guidelines. In Armenia, WHO HCV treatment protocols are used. According to the respondent in Tajikistan, work is underway to develop and adopt a new treatment protocol. The absence of a nationally approved treatment protocol does not exclude use of DAAs to treat HCV. In particular, this option is available through import of medications for patients' own use, including through a buyer's club.

EECA countries have been actively updating HCV treatment protocols and training medical personnel, in part spurred on by NGOs. In Ukraine, Kyrgyzstan and Kazakhstan (and possibly other countries) NGO representatives have joined expert committees developing guidelines. International organizations such as WHO, AASLD and EASL often involve NGOs in providing services to patients, and patient organizations in the work of expert groups developing guidelines.

Table 3. HCV treatment guidelines in EECA countries

Country	Year of adoption	Key treatment regimens	Notes
Armenia		PEG-INF/RBV	According to the respondent, WHO guidelines on HCV are used
Azerbaijan	2009	PEG-INF/RBV	Recommendations will be updated
Belarus	2015	SOF/PEG-INF/RBV, SIM/PEG-INF/RBV, SOF/LDV±RBV, 3D±RBV, SOF/SMV±RBV, SOF/DCV±RBV, SOF±RBV, SMV/PEG-INF/RBV	Recommendations will be updated
Georgia	2015	SOF/PEG-INF±RBV, SOF/LDV±RBV	SOF-based regimen is indicated in the national program implemented since April 2015
Kazakhstan	2017	3D, SOF/LED, SOF/DCV, SOF/VEL, SOF/RBV	Recommended by the Expert Council of the Republican Healthcare Development Center of the Ministry of Health and Social Development of Kazakhstan, Protocol no. 21 dated 12.05.2017
Kyrgyzstan	2017	SOF/DCV, SOF/LED, SOF±RBV	www.med.kg;
Moldova	2015	SOF/DCV±RBV, SOF/LDV±RBV, SOF/SMV±RBV; 3D±RBV; SOF/PEG-INF±RBV, SOF/RBV, SMV/PEG-INF/RBV	Order no. 1035 dated 31.12.2015, published 2016
Russia	2017	SOF/PEG-INF/RBV, SIM/PEG-INF/RBV, 3D±RBV, SOF/SMV±RBV, SOF/DCV±RBV, SMV/PEG-INF/RBV, DCV/ASV/PEG-INF/RBV, DCV/ASV, NPV/PEG-INF/RBV/RTV	Recommendations for diagnostics and treatment of HCV in adults

[5] A new edition was adopted in September 2016, please see easl.eu.

[6] http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-policy/ru/

Tajikistan		n/a	n/a
Ukraine	2016	PEG-INF/RBV (alternative regimen), SOF/PEG-INF/RBV, SOF/LDV±RBV, 3D±RBV, SOF/SMV, SOF/SMV/RBV, SMV/PEG-INF/RBV: SOF/RBV (2–12 weeks genotype, 3–24 weeks genotype); BOC and TPV are not recommended anymore as preferred options	Approved by Order of the MoH of Ukraine no. 729, dated 18.07.2016
Uzbekistan	2013	Alpha-interferon	Will be revised in 2018 or upon availability of new evidence

HBV treatment guidelines

In many countries (Kyrgyzstan, Moldova, Uzbekistan) HBV treatment guidelines do not comprise a separate clinical protocol, but are included in a general protocol for treatment of viral hepatitis. In some cases recommendations are included in a general protocol for treatment of infectious diseases (Belarus) or in an HIV/viral hepatitis co-infection treatment protocol (Armenia).

In Kazakhstan and Ukraine, the HBV treatment protocol is a separate document containing many recommendations concerning treatment as well as detection of HBV in vulnerable populations, diagnostics and monitoring of HBV patients.

Table 4. HBV treatment guidelines in EECA countries

Country	Protocol	Notes
Armenia	+	HIV/HBV co-infection treatment protocol
Azerbaijan	+	General protocol for treatment of viral hepatitis
Belarus	+	General protocol for infectious diseases
Georgia	n/a	n/a
Kazakhstan	+	Clinical protocol for diagnostics and treatment of HBV in adults. PEG-INF, TDF, ETV
Kyrgyzstan	+	Diagnostics, treatment and prevention of hepatitis B, C and D. Clinical protocol for all tiers of healthcare
Moldova	+	National clinical protocol for treatment of hepatitis B and D in adult patients
Russia	+	Clinical recommendations of the Russian Gastroenterologic Association and Russian Society for Liver Studies on diagnostics and treatment of HBV in adult patients*, 2014 http://www.gastro-j.ru/files/_2014_3_s8_1406993670.pdf
Tajikistan	n/a	n/a
Ukraine	+	Unified clinical protocol of primary, secondary and tertiary care “Viral Hepatitis B”
Uzbekistan	+	Clinical protocol for chronic hepatitis

*Not adopted by the Ministry of Health of the Russian Federation

Drug Registration and Pricing

Methodology

Drug registration data in EECA is mainly taken from state pharmaceutical registers (as of March 2017). Information about prices of drugs used to treat HCV and HBV was taken from government programs, drug registries, or the commercial sector. Where these resources were unavailable, additional information was received via non-government organizations operating in specific countries. Prices refer to the period of January to March 2017.

The data presented provide only a very basic picture of the overall treatment pricing landscape in the region. Prices per unit may not be indicative of the projected price for the whole treatment course, as pharmaceutical companies tend to offer special pricing policies (such as “buy one, get one free”). In a number of the research countries, prices for medicines are not publicly available. Information had to be gathered through personal communication, which can cause bias.

Another important factor to take into consideration is currency fluctuations in most countries of the region. In order to simplify the price comparison between countries, prices in national currencies have been converted into US dollars.

HEPATITIS C

Registration

As of March–April 2017, certain DAAs were registered in most countries of the region. Drugs allowing provision of interferon-free treatment are registered in at least 10 out of 11 countries covered by the study. The authors note considerable progress in the number of registered DAAs in the last two years.

Accessibility of second generation generic DAAs was also analyzed. DAAs (both brand-name and generic) are registered in at least 10 countries of the region; generic drugs are officially registered in at least seven countries (Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan).

Table 5. HCV DAAs accessibility in EECA countries

	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
PEG-INF	X	X	X	X	X	X	X	X	X	X	X
SOF				X				X		X	
SOF generic		2x	2x		2x	6x	3x		X		X
SOF/LDV				X	X	X				X	
SOF/LDV generic						6x					
SOF/VEL											

SOF/VEL generic											
DCV								X			
DCV generic						X	X				
3D (Viekira Pak)		X	X		X			X		X	
OMB/ PTV/r							X			X	
DAS							X			X	
SMV		X			X		X	X		X	

X — at least one registered medication available;
The number by the "x" stands for the number of generic versions of the drug registered in the country

Market for unregistered DAAs imported for personal use

In the last few years, a so-called buyer's club has developed for generic DAAs (sofosbuvir, sofosbuvir/ledipasvir, daclatasvir, sofosbuvir/velpatasvir) mainly originating in India and Egypt. According to information received from NGOs, patients prefer to take personal responsibility for purchasing drugs in India, Egypt or Bangladesh and import them for personal use because of their relatively low price.

This practice of procuring drugs for personal use occurs in Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia, Uzbekistan and Ukraine. This is because these drugs are much cheaper than registered generics, and are readily available.

Prices

The analysis demonstrates a **considerable differences in prices for DAAs** in the countries of the region. Prices for generics also vary significantly.

The lowest price of generic sofosbuvir (USD 109) is in Uzbekistan.

The highest price of brand-name sofosbuvir (USD 6,704), as of the time of reporting, was discussed with a manufacturer in Kazakhstan.

In Ukraine and Georgia these drugs are provided free of charge under treatment programs supported by donors or governments. Price comparison of simeprevir (no generic version available) ranges from USD 3,459 per package in Russia to USD 8,468 per package in Moldova.

A package of the combination of ombitasvir, paritaprevir, ritonavir and dasabuvir costs USD 4,620 in Belarus, USD 5,000 in Azerbaijan and USD 5,120 in Russia.

Prices of generic sofosbuvir vary. In Uzbekistan it costs USD 109; in Kyrgyzstan it starts at USD 319 per bottle. The highest price — USD 800 – was observed in Belarus. Belarus plans to start producing a local generic version of sofosbuvir (the drug itself will be manufactured in Egypt, then dispensed and packaged in Belarus). Marketing this generic is expected to significantly reduce the price of sofosbuvir.The price of sofosbuvir on the market of *unregistered drugs imported for personal use* is USD 130 per bottle in Uzbekistan; supply to Ukraine or Belarus costs from USD 155 per bottle.

Table 6. Prices of HCV drugs in EECA countries

	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
PEG-IFN	175 P	100 R	187.2 P	Free	163.2 G	183 P	140.38 P	114.83 P	140	127.08 R	
SOF	250*			250* Free	6704 G	250*	250*		250*	250* G	
SOF generic		365 R	630			152 P	350 R		145		109 P
SOF/LDV	300*			300* Free		319 P, 300*	300*		300*	300* G	
SOF/LDV generic											144 P
SOF/VEL	300*			300*		300*	300*		300*	300*	
SOF/VEL generic											
DCV								1830 P			
DCV generic						60 P	262 R				60 P
3D (Viekira Pak)		5000 P (per 112 tablets)	4620.6 P (per 112 tablets)		99.77 G per pack			5120 P			
OMB/ PTV/r							14639.64 R				
DAS							1272.57 R				
SMV							8468.42 R	3459 R, 3012 P		512.9 P	
RBV		7.3 R (60 tablets)	3.5 P (30 tablets)	Free	Free	9.4 P (per 30 tablets)	53.02 R (per 168 tablets)	19 R (per 60 tablets)		3.69 P (per 30 tablets)	4.6 P (per 30 tablets)
Lowest available price of a 12-week DAA treatment course		1866.3	4705.9	Free	16763	636	1836	15318		2336.73	507
		SOF/PEG-INF/RBV	SOF/PEG-INF/RBV		3D	SOF/DCV	SOF/DCV	3D		SOF/PEG-INF/RBV	SOF/DCV

*price under accessibility program implemented by Gilead, but this price does not mean actual availability of the drug in private pharmacies

P – commercial market price
G – government procurement price
R – price in the drugs registry

HCV diagnostics

In most of the countries of research the price of diagnostics is extremely high, and thus unaffordable for the general population. For example, in Ukraine the average price of procedures required for a diagnosis is USD 98.2. The situation is alleviated by an agreement between NGOs and diagnostic laboratories which envisages 50% discount for patients (the agreement does not include elastography). A fibroscan costs USD 33–69. Participants of treatment programs run by the Alliance for Public Health can receive diagnostic services free of charge. In Georgia, the average price of a similar diagnostic package is USD 199.5. Patients in Georgia may have diagnostics partially covered by the state program (70% of the cost of diagnostics covered for people in difficult financial situations, 30% for other categories). In Kyrgyzstan, the cost of qPCR is USD 36, while in Ukraine it is USD 23 (without discount). Price is one of the main barriers to detection of the infection and ensuring access to treatment.

HEPATITIS B

Registration

In most of the countries, the main HBV drugs — such as tenofovir — are registered. For example, in Armenia lamivudine is provided to PLHIV under a Global Fund ART program, but buying it to treat HBV is problematic. Table 7 contains data on registration of HBV drugs in EECA countries.

Table 7. Registration of antivirals to treat HBV in the EECA region

	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
3TC		X	X					X		X	
3TC generic		X	X		X	X	X			X	X
LdT			X							X	
LdT generic					X						
ETV								X	X		
ETV generic					X	X		X			
TDF		X	X			X		X		X	
TDF generic			X		X	X	X	X		X	X
ADV											
ADV generic											
FTC			X			X	X			X	
FTC generic			X			X		X		X	X
TAF											

Prices

Drug prices vary depending on country and availability of generics on the market. The prices of drugs are listed in table 8.

Table 8. Average prices of HBV antivirals in EECA countries (USD)

	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
3TC		21.17	77.88–83.61					2 R		4.7	
LdT										267–360.8	
ETV						87			59	196–260	
TDF			64.6–95.86				40	18 R		70	26.7
ADV										700–737	

HCV Drugs Access Policy and Intellectual Property Rights

This section contains the result of analysis of voluntary licences and other pharmaceutical company strategies aimed at improving access to HCV treatment in the EECA region. Of the 11 countries studied, only three (Kyrgyzstan, Tajikistan and Uzbekistan) are included in the accessibility program implemented by the manufacturer of brand-name sofosbuvir. Although Ukraine is not on the list of countries covered by the program, the Alliance for Public Health was able to negotiate the lowest price for sofosbuvir in 2014 (USD 900 per course); the price of sofosbuvir and sofosbuvir/ledipasvir combination was subsequently reduced to USD 250 and USD 300 respectively following a settlement between Gilead and the Ministry of Health of Ukraine. Joint work by state agencies and NGOs enabled Armenia, Georgia, Moldova and Ukraine to be covered by a special pricing policy for brand-name HCV drugs: sofosbuvir at USD 250 per package, sofosbuvir/ledipasvir at USD 300 per package, and sofosbuvir/velpatasvir at USD 300 per package[7].

Azerbaijan, Georgia and Uzbekistan are included in the list of countries that are parties to a settlement between BMS and the Medicines Patent Pool. Five countries (Azerbaijan, Belarus, Kazakhstan, Russia and Ukraine) have been included in a settlement between the Medicines Patent Pool and generic manufacturer Pharco. The settlement stipulates access to ravidasvir antiviral for participating countries.

Table 9. Voluntary licenses and programs offered by pharmaceutical companies to provide access to DAAs and PEG-INF in EECA countries. April 2017

Country	Sofosbuvir sofosbuvir/ledipasvir	daclatasvir license status/patent status	Ravidasvir	
			DNDI /Presidio	MPP/Pharco
Armenia	no	no/no	yes	
Azerbaijan	no	yes/withdrawn		yes
Belarus	no	no/no		yes
Georgia	no	yes/not filed		
Kazakhstan	no	no/no		yes
Kyrgyzstan	yes	no/no	yes	
Moldova	no	no/no	yes	
Tajikistan	yes	no/no	yes	
Russia	no	no/yes		yes
Ukraine	no	no/no		yes
Uzbekistan	yes	yes/not filed		

In addition to voluntary licenses, Georgia runs a national program on HCV eradication (see section on national treatment programs). Two countries – Kyrgyzstan and Tajikistan – were included in the special MSD program of peginterferon-alpha-2b price decrease (USD 40 per vial). Pegintron, which was not registered in Kyrgyzstan for a long time, was finally registered after the beginning of this program.

[7] http://gilead.com/~/media/files/pdfs/other/chronic%20hepatitis%20c%20medicines%20pricing%20-%20september%202016.pdf

Analysis shows that high prices are often the result of monopolies, with existing patents giving companies an exclusive right to market their drugs. However, NGOs are actively working to eliminate barriers to access to treatment related to intellectual property rights. Besides patent law optimization and introduction of mechanisms enabling countries to avoid patent barriers, priorities for NGOs include analyzing patent landscapes and opposing patents which prevent cheaper generic drugs from entering the market.

NGOs in several countries have successfully opposed patents for a number of ARV drugs for treating HIV[8], as well as patents for PEG-IFN and sofosbuvir for treating HCV[9]. There is now an active movement aimed at opposing patents for DAAs, mainly sofosbuvir which is the backbone of most preferred HCV treatment regimens. On 5 October 2016, information was published about the partial revocation of one of the key patents on sofosbuvir (patent on the pro-drug form) in the EU, in response to opposition filed by Médecins du Monde[10]. In 2017, the pro-drug form of sofosbuvir was opposed in China at the initiative of I-MAK, while in Russia the patent for sofosbuvir substance was opposed with support from the International Treatment Preparedness Coalition in EECA (ITPCru). Also in Russia, the Chamber for Patent Disputes has ruled to revoke the patent for entecavir, a drug used to treat HBV. The expert group decision states that the patent does not meet the patentability criterion of involving an inventive step. There have been attempts to oppose the sofosbuvir patent in Ukraine, but no positive ruling has been made so far.

Opposing patents may positively influence further opposition of similar patents in other countries.

In addition to legal objections to patents or patent applications, civil society organizations can take other actions to remove intellectual property barriers. The International Treatment Preparedness Coalition (ITPC) submitted a request to the competent authorities to issue a compulsory license for sofosbuvir and other DAAs in Russia[11]. In Kyrgyzstan, largely due to NGOs, amendments were recently introduced to laws on intellectual property, taking into account the legal flexibilities of TRIPS[12], which were largely initiated because of the complicated situation with anti-hepatitis drugs.

The Medicines Patent Pool in 2016 announced the launch of MedsPal (http://medspal.org), an online platform providing information about patents and licenses for the main medicines used for HCV and TB treatment, and for ART. Information on EECA countries covered by the present study is available on the website.

[8] See, for instance, The Critical Role of Civil Society in Shaping the Market for Antiretroviral Therapy and Direct-Acting Antivirals, available online at http://www.i-mak.org/civil-society/

[9] See, for instance, Kaplan, K. Activist Strategies for Increasing Access to Treatment in Low- and Middle-Income Countries. pp. 21–22, available online at: http://hepcoalition.org/advocate/advocacy-tools/article/activist-strategies-for-increasing

[10] http://itpcru.org/2016/10/05/vrachi-mira-patent-na-sofosbuvir-v-es-chastichno-annulirovan/

[11] http://itpcru.org/2015/04/16/analiticheskaya-zapiska-o-prinuditelnyh-litsenziyah-na-preparaty-v-rf/

[12] See, for example, http://zdorovie.akipress.org/news:19576

National and Donor-Driven HCV Treatment Programs

National HCV treatment programs are being implemented, in one form or another, in Ukraine, Russia, Georgia and Moldova. A treatment program is planned in Uzbekistan. It is expected that HCV DAAs may soon be provided to patients in Belarus. Nevertheless, only 1% of the estimated number of people living with HCV in the region are receiving treatment.

The treatment program in Armenia started in 2017, for which the main source of sofosbuvir is 3,000 packages donated by the Georgian government, equal to 1,000 standard treatment courses. Thanks to work by the NGO Armenian Network of Positive People, PLHIV were included in the treatment program. Despite the donation, only people who were able to buy daklatasvir and/or ribavirin and pay for diagnostics could take part in the program. Belarus received a similar donation of 1,500 vials of sofosbuvir, equalling 500 standard treatment courses, from the Georgian government.

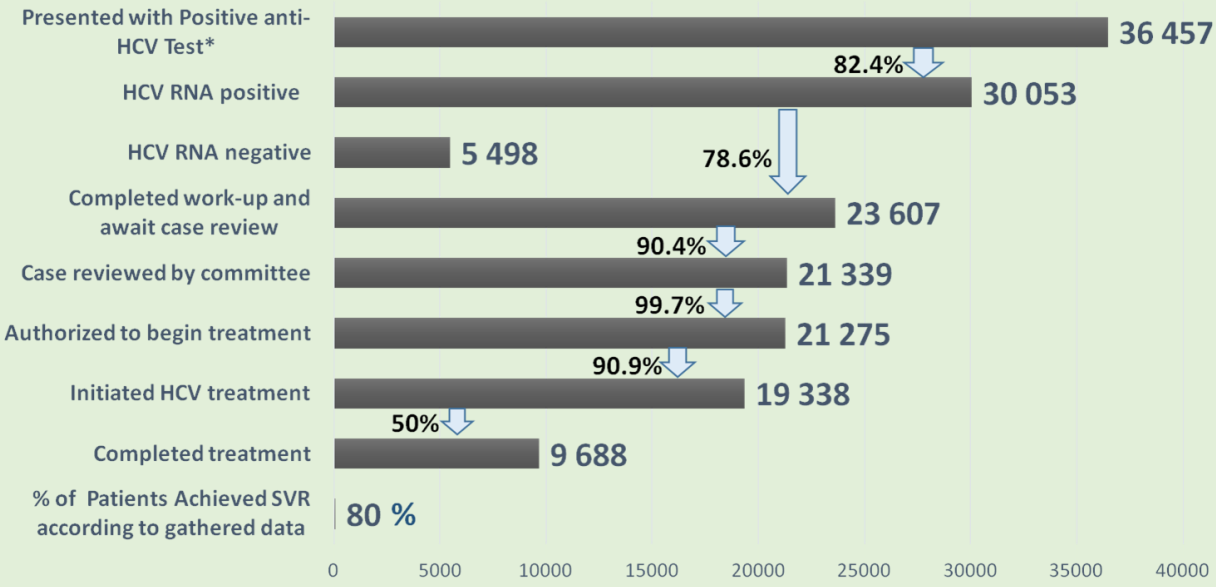
Detailed information about the state program in Azerbaijan is currently unavailable. However, according to the respondent, the state program sets no limits on the number of people provided with treatment.

Georgia launched a national program to fight HCV in 2014. Since April 2015, under the State HCV Elimination Program up to 5000 patients received free medications and partial diagnostics (there are different HCV diagnostics programs in different cities) as the first part of the programme. Sofosbuvir and sofosbuvir/ledipasvir under the state program are provided by Gilead. Priority is given to patients with F3–F4 stage fibrosis. From the second half of 2016 the second stage of the program was launched, under which 20,000 patients will receive access to therapy each year over 10 years. There is also a program in Georgia to diagnose, prevent and treat HCV in prisons, and a program to diagnose and treat HCV in Adzharia region implemented with financial support from the local budget.

GEORGIA. Case study of a state-implemented treatment program	
Prevalence of HCV (RNA) in the country (2015)	5.4%
Estimated prevalence among citizens over 18	150,300 people
Most-at-risk populations	PWID, medical workers, MSM
HCV prevalence among most-at-risk populations	PWID: 57–74% MSM: 7.1%–18.9% medical workers:5%
Treatment programs: 1) State HCV Elimination Program. 2) Program to diagnose, prevent and treat HCV in prisons. 3) Program to diagnose and treat HCV in Adzharia region. 4) Donor program for treatment and social support supported by Medecins du Monde. Planned annual treatment coverage: > 20,000 people. 2020 goals: ✓ 90% of people living with HCV are diagnosed ✓ 95% of those diagnosed receive treatment ✓ 95% of those who have received treatment are cured Strategies: • Strategy 1 — Promotion of advocacy, raising awareness and knowledge, facilitation of partnerships to mobilize HCV-related resources	

- Strategy 2 — Prevention of HCV transmission
- Strategy 3 — Identification of people infected with HCV
- Strategy 4 — Improvement of laboratory diagnostics of HCV
- Strategy 5 — Providing treatment and care to patients with HCV
- Strategy 6 — Improvement of the HCV epidemic surveillance system

HCV treatment cascade as of 28 April 2015–30 September 2016



*Data from a presentation by Mr. Amiran Gamkrelidze, director, National Center for Disease Control and Public Health, Georgia

In Moldova the current National Program of Combating Viral Hepatitis B, C and D for 2012–2016 stipulates treatment with sofosbuvir/daklatasvir combination of at least 3,000 patients annually. The Ministry of Health claims this is approximately seven times more patients than were previously supported by the state with the same amount of funding, a result made possible through introduction of generics.

In Ukraine, the State Social Program of Prevention, Diagnostics and Treatment of Viral Hepatitis (approved in April 2013) ran until 2016. The program is now finished, but a DAA procurement and provision component has been included in the general state healthcare program. The Alliance for Public Health and other NGOs are actively advocating for development of a viral hepatitis elimination plan. The Alliance in collaboration with the Ministry of Health is working on implementation of alternative treatment provision models with effective DAAs for HCV positive people. It is expected that MoH activities and reform of the healthcare sector will be in line with updated WHO guidelines and take into account the main provisions and recommendations of the WHO Global Strategy for Viral Hepatitis.

UKRAINE. Case study of an NGO-implemented treatment program	
Prevalence of HCV (RNA) in the country (2015)	Different estimates suggest 8–12%
Estimated prevalence among citizens over 18	n/a

Most-at-risk populations	PWID, MSM, commercial sex workers, blood/organs recipients, haemodialysis patients, medical workers, prisoners, children of HCV or HBV-positive mothers, people receiving medical or dental care.
HCV prevalence among most-at-risk populations	Bio-behavioral studies conducted by the Alliance show the following patterns of prevalence among: *PWID* HCV — 55.9% HIV/HCV — 16.9% HIV/HBV — 1.8% *MSM* HIV/HCV — 0.7% HIV/HBV — 0.4% *commercial sex workers:* HIV/HCV — 4.5% HIV/HBV — 0.3%
Advocacy campaign and treatment program In 2012 the Alliance initiated the advocacy campaign “Demand treatment!". Main results of the campaign are: a State Program for Viral Hepatitis developed, approved and partially financed; guidelines on treatment of viral hepatitis including DAAs developed; MARPs included in the treatment protocol; more than 15 regional programs for HCV treatment approved; DAAs included in the state nomenclature of medications to be procured using state budget funds; DAAs procured for state and some regional programs in 2016. The Alliance for Public Health negotiated the world’s lowest prices (as of 2014) with the manufacturer of brand-name sofosbuvir for a pilot treatment program in Ukraine; this price became the procurement benchmark. In 2015 the Alliance launched the first program of sofosbuvir treatment for HCV in Ukraine supported by the Global Fund. The program includes provision of free of charge diagnostics and treatment to most-at-risk populations. Under the Alliance’s treatment program, more than 1,770 representatives of MARPs received DAA treatment. Coverage of more than 2,000 people is planned by the end of 2017. HIV-positive people make up 74.5% of patients, of whom 72.3% are receiving ART. A total of 74% of patients are PWID, 9% of whom are receiving OST. As of 01.07.2017, access to treatment was provided to more than 1,870 people, with a success rate of 94.4%. More than 38,000 people from vulnerable populations were rapid-tested for HCV and HBV antibodies, and more than 150 doctors were trained on treatment with DAAs. Advocacy from the Alliance and support from international partners led to inclusion of sofosbuvir in the List of Vital Drugs in Ukraine. Currently the Alliance is working with the Ministry of Health of Ukraine on development of a viral hepatitis elimination plan.	

In Kazakhstan, Belarus and Russia, HCV therapy provision is regulated by separate legislative acts.

In Kazakhstan diagnostics and treatment of viral hepatitis is provided on the basis of the Constitution of the Republic of Kazakhstan, Article 29, paragraph 2, on the right of citizens to a guaranteed amount of medical assistance.

In Belarus HCV treatment is provided free of charge to people under 18 or who have had a liver transplant (without age restrictions) according to Regulation 25 dated 04.04.2014. The main access to treatment listed by the respondent is buying DAAs for personal use through a

buyer's club. Access to treatment may be extended to 500 more citizens using sofosbuvir courses donated by the Georgian government.

In Russia HCV patients are provided with drugs mainly at the expense of the following sources: federal budget funds to provide medicines to separate categories of citizens; RF subjects' healthcare development programs; target programs for RF subjects combating viral hepatitis, funds allocated within the framework of obligatory health insurance (OHI). According to the report of the International Treatment Preparedness Coalition, in 2016 state-funded therapy could be provided to less than 0.2% of the total estimated number of HCV patients and about 1.5% of registered patients. Of them, DAA-based therapy could be provided to less than 0.1% of the total estimated number of patients and about 0.5% of registered patients. Because sofosbuvir is not actually available on the market (despite being a registered drug), an important factor making treatment accessible is purchase of drugs for personal use, like in Belarus. The cost of therapy with unregistered generics of sofosbuvir+daklatasvir allowed for import for personal use was about USD 500 (less than 30,000 rubles) at the time of report-writing. This is approximately 30 times cheaper than non-interferon regimens using brand-name drugs.

In Kyrgyzstan, HCV treatment for PLHIV has been included in the draft state program on HIV, and development of a new national program of treatment and diagnostics of HCV and/or HBV is underway. This program will include free treatment of HCV for PLHIV and children.

According to minutes of the meeting of the Republican Emergency Anti-epidemic Commission of Uzbekistan, the Ministry of Health and the Ministry of Finance are to provide 3,500 patients with modern drugs to treat HCV in the country in 2017 (starting approximately in August 2017).

In Tajikistan treatment of hepatitis is envisaged by the law "On Protection of the Population" dated 22.04.2003. However, clear mechanisms for its provision are not indicated. According to the respondent, the country is developing a separate viral hepatitis law.

Armenia, Georgia, Belarus, Kazakhstan, Kyrgyzstan, Ukraine and Uzbekistan are among countries receiving donor support for procurement of drugs and tests to treat HCV.

In Kyrgyzstan, the Global Fund program for 2016–2017 stipulates funding for diagnostics for PWID, SW and MSM.

In terms of donor-driven HCV treatment programs, Ukraine has the largest HCV treatment program supported by the Global Fund. The program is implemented in several stages involving 25 health facilities in 19 regions of Ukraine. Treatment is planned for at least 2,000 patients by the end of 2017. HCV treatment has been integrated into already operational harm reduction programs with coverage of more than 300,000 clients. Prices for GF-funded procurement, as a result of negotiations between the Alliance and the manufacturer of brand-name sofosbuvir, served as a benchmark for the state treatment program in Ukraine. Advocacy by the Alliance and the effectiveness of the treatment program led to inclusion of DAAs into the Unified Treatment Guidelines and the list of drugs to be procured within national and local budgets.

Table 10. National and donor HCV treatment programs in EECA countries

Country	National programs/ laws	Vulnerable populations assigned priority treatment	Number of patients receiving government-funded treatment	Notes	Donor programs	Donor	No. of patients
Armenia	-	People living with HIV	Absolute number unknown	Treatment provided under general health policy	+	Government of Georgia and Gilead	1000
Azerbaijan	+	No data	Absolute number unknown	Number of people receiving treatment is not restricted in the state program	-		-
Belarus	-	Treatment is free for children and transplant patients	Absolute number unknown	Treatment provided under general health policy	+	Government of Georgia and Gilead	500
Georgia	+	No limits	20,000 per year over 10 years	About USD 8.3 mln from local and regional budgets to support diagnostics and service programs	+	MdM	> 200
Kazakhstan	-	All HCV patients with compensated liver diseases	Average number of people having received treatment of HBV and HCV is 1,200 per year	Treatment provided under general health policy	+	AbbVie	20
Kyrgyzstan	-	People living with HIV	Up to 100 a year	Treatment provided under the National HIV Program	+	GF	About 100
Moldova	+	n/a	In 2016 increase in the number of treatment courses to 3,000 a year (hepatitis B, C, and D) was announced	Treatment provided under general health policy	-		-
Russia	-	n/a	8,792 in 2016. The number of patients waiting to receive a 48-week PEG-IFN course in 2017 was 540, for SMV course — 290.	The government announced procurement of USD 4.6 mln-worth of HCV courses in 2017	-		-
Tajikistan	-	n/a	n/a	n/a	-		-

Ukraine	+	People with F2 stage fibrosis, women planning pregnancy, HIV/HCV co-infected, people with extrahepatic syndromes, medical workers	n/a	The government announced procurement of HCV drugs (SOF, SOF / LED, 3D) that may cover up to 10,000 treatment courses	+	GF and Gilead	About 2,000 (Alliance programs)
Uzbekistan	-/+		Planned treatment for 3,500 HCV patients until the end of the year	National treatment program expected to be ready in 2017	+	MSF	> 200

Availability of hepatitis services (diagnostics and treatment)

In many countries of research, access to diagnostics and treatment remains an acute problem. For example, in Belarus free testing is provided only to those patients who can produce a passport. In Armenia, Moldova and Tajikistan, no anonymous testing is available.

In some countries, such as Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, and Uzbekistan, mandatory testing/detection of viral hepatitis is practiced for certain populations.

Another major problem is treatment accessibility for key populations. Six out of the 11 researched countries (Armenia, Belarus, Kyrgyzstan, Russia, Tajikistan and Uzbekistan) reported limited or no access to treatment for key populations.

Table 11. Access to hepatitis services in EECA countries

Does your country permit:	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
1) Anonymous testing for HCV and/or HBV	no	yes	yes (paid). Non-anonymous testing is free	yes	yes	yes (paid)	no	yes (paid)	no	yes	yes (paid)
2) Mandatory testing for certain populations	no	no	yes	yes	yes	yes	no	yes	yes	no	yes
- Medical workers			+		+	+		+	+	+ (recommended)	+

- Key populations	+ (recommended)		+			+		+		+ (recommended)	
- People who have undergone invasive procedures			+		+	+		+		+ (recommended)	
3) Free diagnostics (for HIV-positive people, key populations)	yes	yes	yes	70% of the cost of diagnostics for people in difficult financial situations is covered by the state	yes	no (unaffordable)	yes	yes (co-infection)	yes	no (unaffordable)	only for PLHIV
4) Free treatment (for HIV-positive people, key populations)	yes (for PLHIV with HBV/HIV co-infection only)	yes	yes (for people under 18 and those who have had a liver transplant)	yes	yes	only for PLHIV	yes	only for PLHIV	no	yes	only for PLHIV under a donor-sponsored program

EECA Civil Society Involvement in HCV Response

NGOs are the main driving force behind the HBV and HCV epidemic response in terms of policy making, protection of patients' rights, and service provision in EECA countries. In this part of the report, NGOs' hepatitis-related activities in the EECA region are discussed. The authors believe that NGO best practices should be systemized, recorded and made available to other organizations.

In this report, NGO work is structured according to the following criteria:

- Mobilization and advocacy, testing and treatment programs
- Raising awareness of access to viral hepatitis treatment
- Policy change
- Training doctors and social workers on integrating effective models of medical and social support of patients with hepatitis
- Organization of national campaigns to inform the public and decision makers about different problems in the response to the viral hepatitis epidemic

A good example of an effective educational campaign is the HCV awareness-raising campaign conducted by Georgian NGOs over several years, which made HCV a priority for the government. The campaign involved working with journalists, bloggers and celebrities in Georgia in order to heighten visibility of the topic in the media. After the government of Georgia announced the launch of a large-scale state HCV treatment program, a number of major events took place: developing new treatment guidelines, training medical personnel, conducting systematic work with patients, monitoring treatment programs, etc. The Open Society Foundation in Georgia, in close cooperation with the Georgian Harm Reduction Network, patient organizations New Vector and Hepa+, and regional organizations mobilized and coordinated activists, experts and advocacy leaders. Efforts were made to strengthen the capacity of civil and professional communities, and coordinate a working group comprised of representatives of public authorities, patient organizations and international donors.

In Ukraine the Alliance for Public Health has been conducting an all-Ukrainian advocacy campaign "Demand treatment!" since 2012. The campaign is unparalleled in its involvement of the non-government sector and its effectiveness.
During campaign implementation, more than 100 advocacy events were held all around Ukraine. Events on World Hepatitis Day included large-scale screening among the general population to raise public and official awareness of the epidemic nationwide. About 18,000 people took rapid tests in all regional centers of Ukraine, with an average positive rapid test result of 8–9%.

In 2013 the Alliance initiated the first Ukrainian HCV treatment program, and in April 2015 it launched the first program of treatment with a DAA — sofosbuvir — for vulnerable groups in Ukraine. Treatment guidelines developed by the Alliance for these programs now form the basis of the National HCV Treatment Guidelines. One of the main achievements of the program was the drug procurement precedent of USD 300 per package. Effective cooperation between the Alliance and the MoH, and the treatment program's effectiveness, led to inclusion of sofosbuvir in the National Register of Medicines and the Unified Guidelines for Prevention, Diagnostics and Treatment of Viral Hepatitis in Ukraine, as well as the list of drugs to be procured within national and local budgets. More than 150 doctors were trained in using DAAs in treatment.

In Kyrgyzstan, the main initiator of ensuring accessibility of HCV treatment is the Partner Network association and the Coalition for Access to Medicines formed of 15 NGOs. They were actively involved in adoption of new clinical guidelines on treatment of parenteral hepatitis, including HCV, in 2016–2017. The guidelines are based on the latest WHO recommendations and indicate DAAs as the main HCV treatment drugs. Advocacy and negotiations with distributors allowed reduction of the market price of sofosbuvir to USD 150 per bottle. A wide range of DAAs have been registered, and several brand names of daklatasvir are now undergoing registration. All DAAs included in the clinical guidelines were also included in the List of Vital Medicines (approval pending at the time of report writing). HCV treatment for PLHIV was included in the draft National HIV Program for 2017–2021. Annual treatment provision is planned for 100 PLHIV free of charge, using funds provided by the GF or the state budget. At the same time, development of a national hepatitis program is ongoing with WHO support.

Mobilization of NGOs, activists, stakeholders and the general public with regard to access to HCV testing and treatment.

Measures taken in one form or another in EECA countries include:

- Uniting, mobilizing and training activists supporting improvement of access to treatment.
- Informing the general public; eradicating myths about the incurability of HCV, etc.

Conducting assessments on HCV response in the region:

- Assessment of access to treatment for representatives of vulnerable groups and the general public.
- Review of access to diagnostics and treatment. Assessment of medication registration, review of pricing policies in the region.
- Assessment of the country's financial responsibility in terms of provision of funding and testing, level of funding for HCV testing and treatment programs, etc.
- NGO monitoring of prices and stock lists of state procurement.

Several examples of such studies conducted in EECA countries are given below[13]:

The Alliance for Public Health and the International Treatment Preparedness Coalition prepared the report "Hepatitis C in Eastern Europe and Central Asia: Epidemic and Response".

A report on accessibility of HCV treatment in Russia in 2016 was published by the International Treatment Preparedness Coalition in 2017.

A report on the HCV epidemic in Kyrgyzstan was produced by the harm reduction program association Partner Network, the Harm Reduction Network and Adilet Legal Clinic.

Organization of meetings and round tables between stakeholders (representatives of pharmaceutical companies, NGOs, and the public sector) to discuss access to medications for diagnostics and treatment of viral hepatitis.

[13] This list is not complete.

- Armenia: joint press-conferences and round tables with Ministry of Health representatives, infectious disease doctors and hepatitis patients.
- Belarus: a meeting of the Eastern European and Central Asian Community Advisory Board (EECA CAB) was used to conduct negotiations with Gilead and Cipla. A representative of the Belarus Community of PLHIV asked the manufacturer of brand name sofosbuvir to include Belarus in the access program and to change the approach to assessment and decision-making on inclusion of countries into the program.
- Kazakhstan: meetings with the Ministry of Health leadership are held regularly, as are meetings with pharmaceutical companies to expand access to treatment through reduction of the cost of medicines used to treat HCV and HBV.

The Eastern European and Central Asian Community Advisory Board has so far held more than 10 regional meetings on HIV and HCV treatment access with the following companies: MSD, Janssen, AbbVie, Cipla, Gilead, BMS, Biocad and Pharmasintez[14]. The meetings were dedicated mostly to accessibility of diagnostics and treatment, medication prices and registration status, clinical trials in EECA countries and early access programs as a tool to ensure access to unregistered drugs.

At EECA CAB meetings, regional activists have repeatedly voiced their concern that pharmaceutical companies holding the rights to boceprevir and telaprevir would delay registration and promotion of new drugs in order to maximize profits from old ones. This happened in Russia, when the company applied to include telaprevir and simeprevir into the List of Vital Medicines, after which telaprevir was added to the list, while simeprevir was not. The company used a market segmentation strategy by cutting telaprevir prices, which led to the simeprevir application being rejected because of its high price. Activists protested against the inclusion of telaprevir in the List of Vital Medicines both in the framework of EECA CAB and by sending open letters. During the last consideration process, the Commission for the List of Vital Medicines approved inclusion of simeprevir and exclusion of telaprevir.

Organizing protest campaigns aimed at reversing/changing the policies of pharmaceutical companies, governments, donor organizations and other stakeholders restricting or hindering access to HCV testing and treatment.

Activities take the form of open letters and petitions, collecting signatures, flash-mobs on social media, street protests, etc. Good examples are campaigns aimed at reducing costs of HCV medications, advocacy for adoption of state treatment programs, and participation in intersectoral committees on development and/or revision of guidelines on HCV prevention, testing, treatment and care.

For example, in Kazakhstan, the AGEP'C Foundation participated in revision of the National HCV Treatment Guidelines (new edition, 2017). In Georgia, NGOs now cooperate with the Ministry of Health on revision of the current HCV guidelines. In Ukraine and Kyrgyzstan NGOs have contributed to development of recently adopted guidelines. In Ukraine, NGO representatives participate in the HCV working group under the Ministry of Health of Ukraine and take active part in developing strategic documents and policies on HCV.

[14] The minutes of the meetings are available at: eeca-cab.org

Such activities are common to other countries of the region, including Moldova, Kyrgyzstan, Azerbaijan, etc. In Belarus, after patient organizations submitted an open letter to the president, an order was issued to provide HCV treatment free of charge to people under 18[15].

In Ukraine, the Alliance for Public Health holds an annual event on World Hepatitis Day (July 28) within the framework of the "Demand Treatment!" campaign. The event involves testing the general public for HCV, and distributing information materials and fliers offering a discount for laboratory testing. In 2012–2013 advocacy events aimed at getting the National Program of Treatment of Viral Hepatitis approved included, beside the traditional testing, an information campaign in the media, collection of signatures for a petition to the president and government, engaging international and local experts, public activities, and allegorical presentation of the problem. Following the advocacy campaign, the state program was approved in 2013.

All around EECA, groups of patients in Armenia, Georgia, Kyrgyzstan, Latvia, Moldova, Russia and Ukraine held events and protests on World Hepatitis Day in order to raise awareness among key decision-makers, demanding that governments improve access to treatment and pharmaceutical companies reduce prices.

Efforts to overcome patent barriers hindering access to HCV treatment.

In most of the countries, NGOs have already started working on this issue. In Russia, ITPC prepared and disseminated a brief on the possibility and feasibility of mandatory licenses for vital medications in the RF, including HCV medications. Also in Russia, with ITPC's support one sofosbuvir patent was challenged. In Kyrgyzstan, mostly due to NGO efforts, amendments to intellectual property legislation were adopted taking account of the legal flexibilities of TRIPS. In Moldova, a claim was filed to the Intellectual Property Agency against provision of a patent for application a 2014 0035 (wo2013/040492) for sofosbuvir due to absence of an inventive step. Also in Moldova, NGOs initiated a letter to BMS and MPP requesting inclusion of Moldova in the area of voluntary licenses for daklatasvir, and asked the Ministry of Health to support the open letter to MPP on behalf of the government.

Implementing HCV testing, treatment and care projects with a link to harm reduction programs; integrating HCV into harm reduction programs.

Over the last 10 years the main agency combating HIV/AIDS in EECA countries has been the non-government sector. As a result NGOs have gained significant experience in providing services related to HIV and associated diseases, contributing substantially to existing harm reduction programs, viral hepatitis work, and advocacy.

Overall, EECA NGOs have contributed to the following achievements in the field of fighting viral hepatitis:

- Improved access to treatment and diagnostics of viral hepatitis
- Drawing the attention of decision makers to the problem
- Collecting epidemiologic data on viral hepatitis
- Development and implementation of guidelines on treatment of viral hepatitis
- Development and implementation of national treatment programs
- Initiation of pilot treatment programs for vulnerable groups

[15] http://news.tut.by/health/343769.html

- Changes in pharmaceutical company policies towards faster registration of drugs and price reduction in EECA countries
- Increased awareness of different aspects of viral hepatitis among patients and the general population, and increased mobilization of community and patient organizations around treatment access

Findings and Suggestions Regarding Civil Society Involvement in the Response to the Epidemic of Viral Hepatitis in EECA

- The number of registered DAAs, including generics, has significantly increased in several countries.

- There is a stable trend of shifting towards using DAAs instead of pegylated interferon in the countries where DAAs have been registered.

- Prices for DAAs have decreased gradually, mainly due to introduction of generics; however, the average HCV therapy price still remains high compared to the average income level, and even more so compared to the income level among vulnerable groups.

- Government funding of viral hepatitis treatment remains extremely low. The number of people receiving treatment at the expense of state programs is insufficient considering the estimated number of people living with viral hepatitis.

- The number of people receiving therapy in certain countries at the expense of the state (Georgia, etc.) or donor programs (Ukraine) is increasing.

- In a number of countries, HCV treatment guidelines are being updated to include second-generation DAAs. With the update of WHO protocols and their translation into Russian, protocols update is expected in other countries.

- In a number of countries (Russia, Ukraine, Moldova), civil society organizations are actively opposing DAA patents.

Key Conclusions and Recommendations

- An epidemic surveillance system for viral hepatitis in the general population and key vulnerable groups should be established.
- NGOs can contribute to improving the quality of data on the epidemic by, among other things:
  - ✓ conducting screening studies to assess incidence/prevalence of viral hepatitis in most-at-risk populations
  - ✓ raising awareness about the lack of data through public events/cooperation with mass media
- According to available data, there are high prevalence rates of viral hepatitis among PWID and PLHIV in EECA countries.
- NGOs can integrate hepatitis services into projects focused on PWID and PLHIV, including harm reduction projects. Viral hepatitis diagnostics and treatment are part of the WHO/UNODC/UNAIDS comprehensive package of interventions for HIV prevention, treatment and care for PWID[16].
- NGOs can monitor cases of PWID denied HCV treatment and care services, work to gain access in those cases, and create legal precedents with media coverage if and when appropriate.
- It is recommended to document cases where PWID are denied hepatitis-related services and disseminate research results among decision makers.

[16] http://www.drugsandalcohol.ie/19190/1/IDUTechnical_Guide_2012_Revision.pdf

- It is recommended to mobilize vulnerable groups and facilitate inclusion of PWID into state programs and guidelines on prevention and treatment of viral hepatitis.
- NGOs should advocate for increasing the number of people receiving treatment on government programs. According to research results, treatment uptake is likely to be around 1% or less of the estimated number of people living with HCV. However, it is worth noting a considerable increase in treatment coverage (both percentage and absolute numbers) in certain countries (Georgia, Ukraine).
- NGOs should advocate for reduction of prices of medications to treat viral hepatitis, through direct meetings with stakeholders and indirectly through media pressure.
- Second generation DAAs sofosbuvir (original or biosimilar), sofosbuvir/ledipasvir, simeprevir, 3D, daclatasvir, etc. are registered and used mainly in countries where HCV treatment programs of one sort or another are implemented, or where adoption of these programs is actively supported by civil society.
- NGOs should regularly monitor the drug registration landscape in countries and keep decision makers informed, also through the mass media.
- NGOs should put pressure on pharmaceutical companies and governments to speed up registration of newer drugs.
- NGOs should establish partner relations with leading international NGOs for implementation of projects aimed at opposing patent barriers to improve access to affordable and high quality generic/biosimilar drugs.
- NGOs should explore TRIPS flexibilities[17] to remove intellectual property barriers. NGOs can call on national governments to use these mechanisms or implement them independently[18]. Examples include opposing patents and pushing governments to issue compulsory licenses for the import or production of medicines.
- NGOs should advocate for registration of biosimilar drugs retaining the proper quality control mechanisms.
- Due to the introduction of generic DAAs, prices for HCV therapy in a number of countries have considerably decreased compared to previous years. Nonetheless, prices for officially registered HCV drugs remain high compared to the average income level in the countries covered by this study. An important, and in some cases the main opportunity for patients to access DAAs is the market of unregistered drugs supplied for personal use.
- NGOs should conduct regular price monitoring for viral hepatitis drugs to identify the lowest prices and disseminate this information among the widest possible circle of stakeholders.
- NGOs should conduct active information campaigns in the media to put pressure on pharmaceutical companies to reduce prices.
- NGOs should push governments to disclose prices, volumes and other important parameters of treatment programs to enable evaluation by independent experts.
- NGO representatives should take part in development of national policies (programs, treatment guidelines etc.).

[17] TRIPS flexibilities refer to options in the TRIPS agreement enabling countries to achieve a balance between intellectual property rights protection and specific development priorities, including the attainment of national public health objectives. This includes the liberty to determine the grounds for issuing compulsory licenses and for ordering government use, to allow parallel import, to set stricter patentability criteria, to allow third parties to oppose patents, etc.
[18] Very recently in Kyrgyzstan, largely owing to the efforts of a civil society organization, amendments to the law on intellectual property were introduced, taking into account TRIPS flexibilities. See, for example, http://zdorovie.akipress.org/news:19576

- NGOs can initiate and advocate for consideration of joint procurement of drugs, including viral hepatitis drugs, in order to achieve price reduction, e.g. within the Customs Union.
- NGOs should work with governments to ensure lower generic prices, in particular through introducing respective changes to the national regulatory framework.
- In a number of countries (Ukraine, Kazakhstan, Moldova), HCV treatment recommendations are being approximated to the guidelines of WHO, EASL and AASLD on HCV medicines. The same protocols contain recommendations on discontinuing the use of telaprevir and boceprevir.
- However, in some countries national viral hepatitis treatment guidelines are not approved or have not been updated for many years. In countries where HCV and/or HBV treatment guidelines are not available, NGOs should put pressure on the respective government and academic bodies to initiate the process of guidelines development and implementation.
- NGO representatives should seek opportunities to engage in the work of national committees responsible for developing viral hepatitis treatment guidelines. NGOs should also ensure that the interests of key populations, such as PWID, are taken into account.
- NGOs should closely monitor updates in the guidelines of leading international healthcare organizations and, where appropriate, advocate revision of national guidelines. EECA NGOs should participate in advocacy activities related to revision of WHO guidelines.
- Donor-driven HCV projects have contributed to launching government programs in at least two countries of the region (Ukraine, Georgia).
- NGOs should advocate for including testing, vaccination (HBV) and treatment of viral hepatitis in applications to donor organizations focusing on key groups, though taking into account the needs of the general population.
- They should also document and disseminate their best advocacy and service practices in the field of viral hepatitis.

ANNEX 1. USEFUL RESOURCES

HCV Treatment Guidelines:

1. WHO Guidelines for the Screening, Care and Treatment of Persons with Chronic Hepatitis C Infection. World Health Organization, April 2016.
2. Recommendations for Testing, Managing and Treating Hepatitis C. American Association for The Study of Liver Diseases.
3. Recommendations on Treatment of Hepatitis C. EASL HCV Treatment Recommendations.

Policy Documents:

1. Prevention and Control of Viral Hepatitis C Infection. Framework for Global Action, 2012.
2. The World Health Assembly Hepatitis Resolution, 2014.

Scientific Research

1. Minimum costs for producing Hepatitis C Direct Acting Antivirals, for use in large-scale treatment access programs in developing countries. By Andrew Hill, et al.
2. Expanding Access to Treatment for Hepatitis C in Resource-Limited Settings: Lessons from HIV/AIDS. Paper by Nathan Ford (MSF), et al.

Civil Society Reports:

1. HCV Pipeline Report. By Treatment Action Group.
2. New Treatments for Hepatitis C virus: Strategies for Achieving Universal Access. MdM.
3. Nobody Left Behind. The Importance of Integrating People Who Inject Drugs Into HCV Treatment Programmes. MdM and INPUD.
4. The Critical Role of Civil Society in Shaping the Market for Antiretroviral Therapy and Direct-Acting Antivirals, available online at: http://www.i-mak.org/civil-society/
5. Activist Strategies for Increasing Access to Treatment in Low- and Middle-Income Countries. By Karyn Kaplan, available online at: http://hepcoalition.org/advocate/advocacy-tools/article/activist-strategies-for-increasing
6. Pills Cost Pennies, Greed Costs Lives. First Hepatitis C Virus World CAB Report.
7. Minutes of the meetings of the Eastern European and Central Asia Community Advisory Board. http://eeca-cab.org/en/
8. Current Situation Regarding Access to Hepatitis C Treatment in Eastern Europe and Central Asia. Eurasian Harm Reduction Network.

9. Between the Past and the Future. Access to Drugs for Treating HCV in Russia in 2015. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (in Russian).