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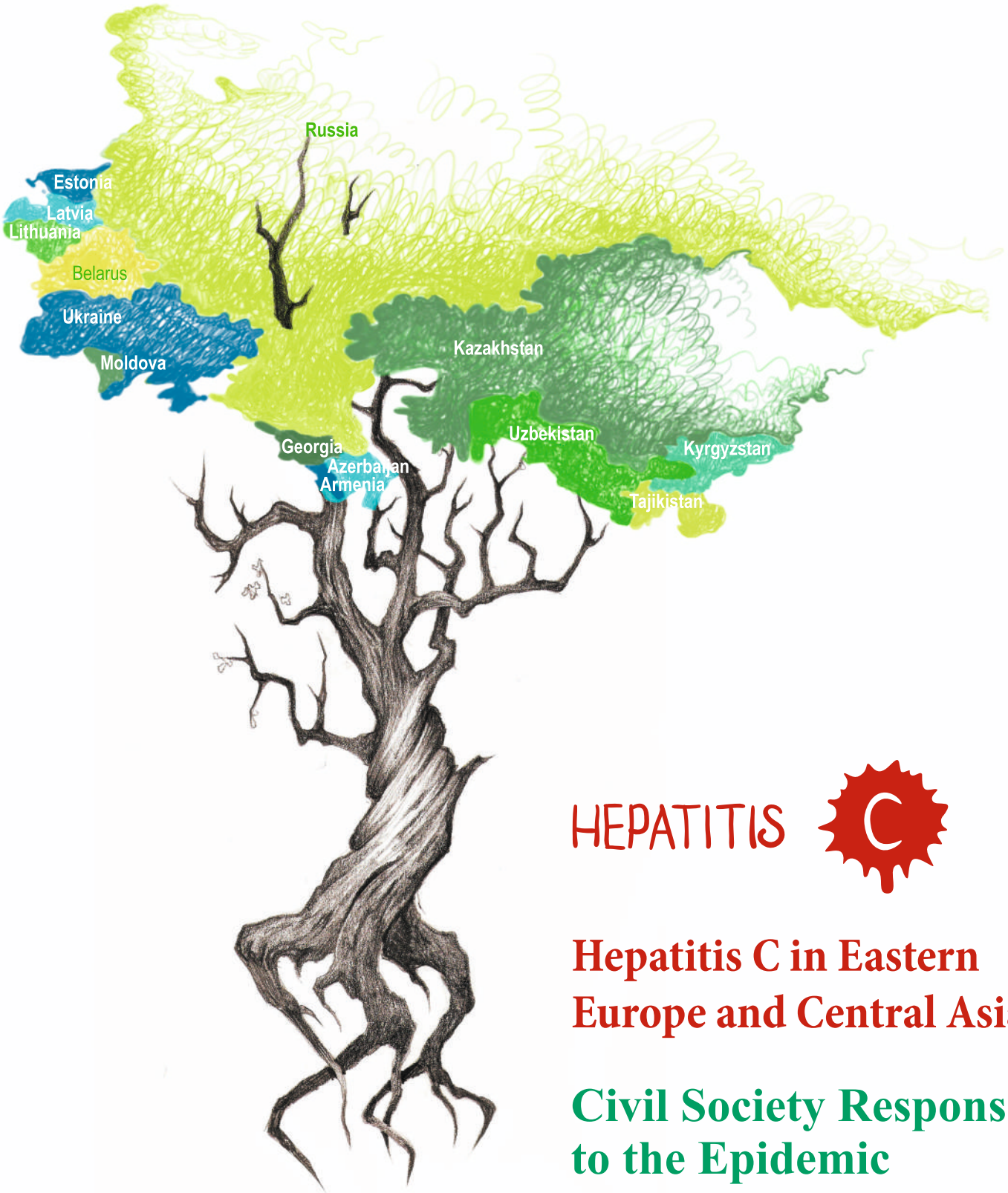

HEPATITIS C

Hepatitis C in Eastern Europe and Central Asia

Civil Society Response to the Epidemic

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The mention of any international non-proprietary or trade names does not mean that the authors give them preference, or conversely, do not recommend them. The references made to any treatment regimen in this report should, under no circumstances, be taken as an alternative to consulting with a licensed medical specialist.

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Acronyms

Anti-HCV	HCV antibodies
ART	Antiretroviral Therapy
BMS	Bristol-Myers Squibb
CAB	Community Advisory Board
CSO	Civil Society Organization
DAA	Direct Acting Antivirals
EECA	Eastern Europe and Central Asia
EECA CAB	Community Advisory Board in Eastern Europe and Central Asia
EHRN	Eurasian Harm Reduction Network
EAPO	Eurasian Patent Organization
GeCAB	Community Advisory Board of Georgia
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNI	Gross National Income
HCV	Hepatitis C Virus
I-MAK	Initiative for Medicines, Access, & Knowledge
LMIC	Low and Middle Income Countries
MdM	Médecins du Monde/Doctors of the World
MSD	Merck Sharp & Dohme Corp.
MSF	Médecins Sans Frontières / Doctors without Borders
OSF	Open Society Foundations
PI	Protease Inhibitors
PLHIV	People Living with HIV
PWID	People Who Inject Drugs
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
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

SIM – simeprevir

SOF – sofosbuvir

SOF/LDV – sofosbuvir/ledipasvir

TPV – telaprevir

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Introduction and Background

Introduction

The purpose of this report is to provide an overview of some of the key aspects of the hepatitis C (HCV) epidemic and response in Eastern Europe and Central Asia (EECA). It also outlines tools and activities for civil society organizations (CSOs) and community-based groups working on expanding access to HCV treatment in the region. Right now, there is a strong global movement towards elimination of the HCV epidemic, and it is essential to have this analysis available to ensure the EECA region is not left out while global strategies are being developed to provide universal access to innovative curative treatment regimens that are 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 HCV medicines, HCV treatment guidelines, national/donor HCV treatment programs, and civil society involvement in the HCV response. It also offers possible approaches and steps that could be taken by CSOs to improve access to HCV treatment.

Background

The World Health Organization estimates that more than 185 million people in the world live with chronic HCV infection. According to the most recent analysis, HCV is responsible for approximately 700,000 deaths globally each year[1]. EECA combined account for approximately **9.1** million people living with HCV, which is around 5% of the entire global number of HCV-positive people[2]. The estimated HCV prevalence in Eastern Europe and Central Asia is **2.9%** and **3.8%** of the total population, respectively[3]. As reported in previous overviews[4], the epidemic in many countries of the region has strongly affected marginalized populations, such as people who inject drugs (PWID), with some studies reporting a striking prevalence of up to 90% among groups of injecting drug users in certain settings[5]. With the widespread use of antiretroviral therapy (ART), which reduces the risk of HIV-associated opportunistic infections, HCV-related liver diseases are becoming the leading cause of death among people living with HIV[6]. People living with HIV (PLHIV) are more vulnerable to HCV as HIV accelerates the progression of HCV, especially in people with a low CD4 count[7]. The region of EECA has a relatively low ART coverage of 21% according

[1] Global, regional, and national age-specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2015; 385: 117-71
[2] WHO. Guidelines for the screening, care and treatment of persons with hepatitis C infection, p.25. April, 2014. Available online at: http://who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/
[3] Ibid.
[4] Eurasian Harm Reduction Network. Current Situation Regarding Access to Hepatitis C Treatment in Eastern Europe and Central Asia. 2013. Available online at: http://idhdp.com/mediaimport/33100/ehrn_hepatitis_c_treatment_access_in_eeca.pdf
[5] Paintsil et al. Hepatitis C virus infection among drug injectors in St Petersburg, Russia: social and molecular epidemiology of an endemic infection. 2009. Society for the Study of Addiction.
[6] WHO. Guidelines for the screening, care and treatment of persons with hepatitis C infection, p. 28.
[7] WHO. Guidelines for the screening, care and treatment of persons with hepatitis C infection, p. 28.

to UNAIDS[8], which aggravates the risks associated with HCV for PLHIV in the region. The issue of HCV has recently received considerable attention at a global level. Below is a brief summary of achievements in this area that have happened over the course of the last 2-3 years.

Change in the treatment paradigm. For a long time, the standard of care has been a combination of injectable pegylated interferon (PEG-IFN) with oral ribavirin (RBV). This regimen is characterized by modest cure rates varying significantly across genotypes, complex treatment administration, as well as hard-to-tolerate side effects. The first-generation direct acting antivirals (DAAs) – protease inhibitors boceprevir and telaprevir – were registered in 2011 and improved cure rates in previously hard-to-treat populations with genotype 1 HCV infection. These drugs, however, still had to be given with PEG-IFN/RBV and increased the cost greatly. Second-generation DAAs, first of which were registered in 2013, have significantly increased cure rates as compared to the PEG-IFN/RBV regimen. In clinical trials, combinations of these drugs have led to cure rates of up to 100 percent, regardless of HCV treatment history, cirrhosis, host genotype, and HIV-coinfection[9]. In addition, the safety profile of the new DAAs is far better than that of interferon-based treatment, and the DAA-based regimens are much easier to administer and to monitor. In fact, the industry is developing so fast that the first-generation DAAs (the protease inhibitors boceprevir and telaprevir) are no longer recommended as a preferred option in the EU and US due to lower cure rates and higher toxicity as compared to "second-generation" DAAs.

Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection were released by WHO in 2014. The Guidelines are intended mainly for policy-makers, government officials, specialists responsible for developing programs for the screening, care and treatment of persons with HCV infection, as well as for healthcare providers. The guidelines have a focus on low- and middle-income countries. Among those who contributed to the development of the document, there were representatives of CSOs working in the field of treatment access, including Treatment Action Group, the International Network of People Who Use Drugs, Médicins du Monde (MdM), Women and Harm Reduction International Network, World Hepatitis Alliance, and Médicins Sans Frontières (MSF). Among the CSOs from the EECA region, there were representatives of the International HIV/AIDS Alliance in Ukraine and Eurasian Harm Reduction Network (EHRN).

World Health Assembly Resolution on Hepatitis, 2014. On May 22, 2014, the World Health Assembly – the decision-making body of the World Health Organization – passed a resolution on viral hepatitis[10], which committed the WHO and United Nations (UN) member states to urgent action to address the global hepatitis pandemic, including that of HCV. The resolution urged Member States, among other things, to develop and implement coordinated multi-sectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context and to promote the involvement of civil society in all aspects of preventing, diagnosing and treating viral hepatitis. In addition,

[8] http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/factsheet
[9] An overview of the studies can be found, for instance, in the Pipeline Report by Treatment Action Group. Available online at: http://www.pipelinereport.org/
[10] Sixty-seventh World Health Assembly. WHA67.6 Hepatitis. Available online at: http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R6-en.pdf

Member States were encouraged to consider the use of different administrative and legal tools (in the form of laws, decrees, *etc.*) in order to expand access to treatment.

Large international donors have become involved in the issue of hepatitis C. Several current projects funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) have HCV testing and treatment components. Among the countries of the EECA region, the most notable examples of GF-funded HCV projects are in Ukraine and Georgia. Also, other donors, such as UNITAID, Open Society Foundations (OSF) and AIDS Fonds, have started to support projects with a focus on HIV/HCV coinfection. In the EECA region, the activities of the HCV-related projects supported by UNITAID mainly cover Ukraine, with OSF and AIDS Fonds funding HCV-related advocacy activities in Georgia, Kyrgyzstan, Russia, and Ukraine.

The issue of pricing for the new hepatitis C drugs has been widely discussed by various stakeholders. For a number of years, the exorbitantly high prices for PEG-IFN were constantly discussed at various events and in many reports related to HCV treatment access. The first protease inhibitors, boceprevir and telaprevir, were priced between USD 30,000 and USD 40,000 per course of treatment in the U.S. and EU, or even higher[11]; importantly, these sums did not include the price for PEG-IFN and RBV that had to be taken in combination with boceprevir and telaprevir. One of the first second-generation DAAs, sofosbuvir, was approved by the FDA and priced by Gilead, its producer, at the level of USD 84,000 for 12 weeks of therapy in the US[12]. This price did not include the price for additional medicines to be taken in combination with sofosbuvir (PEG-IFN, ribavirin or other DAAs depending on the regimen). Such exorbitant pricing caused a wave of publications in the most influential international media which drew the attention of, and led to, discussions among politicians, payers, and other decision-makers about the pricing issues and actions taken in this regard, such as the US Senate hearing on the price of sofosbuvir (Sovaldi)[13]. Many of the publications were initiated by CSOs who have been at the vanguard of the fight for affordable prices for HCV drugs. Different coalitions and alliances have been established, with one of the most prominent examples being the HepCoalition uniting, among others, such organizations as Treatment Action Group, International Treatment Preparedness Coalition (ITPC), Médicins du Monde, Médicins sans Frontières, the International HIV/AIDS Alliance in Ukraine, *etc*.

The HCV agenda has largely been driven by CSOs who have not only engaged in service provision but have also initiated changes in the regulatory framework and the adoption of strategies and operational plans on the international, national and local level. CSOs have worked in the field of development and registration of newer drugs, drug price reduction, the implementation of treatment programs, guideline development and introduction, increased funding, *etc*. The region of EECA has not been an exception, with a number of organizations contributing to global activities and carrying out work on the regional, national and local levels. The achievements in the field of HCV in EECA (treatment coverage expansion through increased awareness about HCV issues, availability of new drugs, the launch of treatment guidelines, government and donor programs, and) will serve as a solid platform for future efforts at all levels.

[11] http://www.bloomberg.com/news/articles/2011-04-03/merck-j-j-s-new-hepatitis-c-treatments-fetch-31-000-in-france
[12] http://www.bloomberg.com/news/articles/2014-01-27/at-84-000-gilead-hepatitis-c-drug-sets-off-payer-revolt
[13] http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf (PDF)

Methodology

The data presented in the overview has been collected through questionnaires sent to CSO representatives in 11 countries of the EECA region and with the help of in-depth interviews with these representatives, and then validated, whenever possible, using publicly available sources. The low- and middle-income countries include Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Ukraine, and Uzbekistan. The high-income country: Russia. In the sections related to drug registration and pricing, some references are made to the Baltic States, including Estonia, Latvia, and Lithuania.

When collecting the data, the task was to see what kind of information about the selected elements of the HCV epidemic response is available to CSOs and can be used by CSOs in their advocacy activities. A questionnaire was used, with items related to the HCV disease burden, prevalence among the general population, PWID and PLHIV; registered drugs and prices; HCV treatment guidelines, and national and donor programs.

Based on the answers received, interviews were conducted in order to obtain more detailed information on certain aspects. Respondents were also asked to provide a brief description of the HCV work carried out by CSOs at the national and local levels, with a focus on advocacy work.

The respondents are CSO representatives having experience in the field of hepatitis and HIV advocacy and research (1-2 organizations per country). Wherever possible, data obtained through questionnaires was validated using open-source data (drug registers, price registers, texts of treatment guidelines, publications in scientific journal, mass media, *etc.*).

The data collected were mainly from June-August 2015; some information may already be outdated at the time of the publication.

To harmonize the prices for HCV drugs, an average exchange rate (USD – local currency) was used for August 2015 based on oanda.com, except for the cases when the respondents recommended using a different exchange rate relating to a specific period of time.

To analyze HCV treatment guidelines and to calculate prices for triple therapy or IFN-free therapy, the authors used the latest edition of the guidelines issued by the European Association for the Study of the Liver (see Annex 2).

The authors plan to publish such overviews on a regular basis (at least annually) to enable ongoing monitoring of trends in the HCV response and to identify the priority areas for the future HCV work of CSOs.

The focus of this report is on the treatment component; however, the same methodology can be applied to other aspects of the HCV response (such as prevention and testing), and, possibly, to other diseases.

HCV Epidemiology and Data

The World Health Organization (WHO) estimates that the two regions (Eastern Europe and Central Asia) account for approximately 9.1 million people living with HCV, which is around 5% of the total number of people living with HCV globally. The HCV prevalence in Eastern Europe and Central Asia is 2.9% and 3.8%, respectively.

Among the countries of the report where statistics were available, the highest reported HCV prevalence is in Georgia (6.7%), whereas the lowest – in Kazakhstan (1-3%). In terms of the absolute number of people living with HCV, the largest figures have been reported in Russia (up to 5 million), Uzbekistan (1.8 million) and Ukraine[14] (1.2 million). Considering the maximum figures, the total estimated number of people with HCV in 11 countries covered by the research may be up to 10 million, with about the half of them living in Russia, and 80% – in three countries (Russia, Uzbekistan and Ukraine).

Table 1, below, also contains information about HCV prevalence for two groups at high risk of HCV, namely PWID and PLHIV. The figures of HCV prevalence among PWID were up to 70-95% (Belarus), 74% (Georgia), 69% (Russia), 65% (Moldova), and 62.8% (Azerbaijan). In some countries, the information available indicates a high prevalence of HCV among HIV-positive people (80% in Kyrgyzstan, 58% in Azerbaijan, 48% in Georgia).

It must be noted that the estimates in the table are in a number of cases based on the results of small-scale studies, some implemented with the support of CSOs, or estimates made by experts or government officials. The respondents were asked to provide data on the prevalence of chronic HCV; however, in some cases, it is difficult to verify this, and the prevalence data can rely on studies of the prevalence of HCV antibodies. HCV prevalence among PLHIV is in some cases calculated based on the number of people registered with HIV/HCV coinfection. The risk groups have been identified by the respondents.

The issue of establishing adequate national-level HCV surveillance systems needs considerable development. Despite some progress made in this area, most countries of the region still need to invest considerable resources into HCV surveillance. Among the countries of research, only in Kazakhstan the representatives of CSOs received from the Ministry of Health detailed information about the registered number of people with chronic HCV infection. According to mass media, Russia is currently launching a registry of patients with viral hepatitis, containing, in particular, detailed clinical data, including the estimate of the stage of fibrosis, coinfections, and required treatment, but to the authors' knowledge, such registry has not been finalized as of the date of this overview publication.[15]

[14] According to some recent publications, anti-HCV prevalence in Ukraine may be up to 12%; this information will be analyzed and included in the next edition of this report.
[15] http://ria-ami.ru/read/9854

Table 1. HCV Epidemiology in 11 EECA countries

Country	Prevalence (%)	Estimated number of people living with HCV (or anti-HCV)	Estimated HCV prevalence/burden among PLHIV	Estimated prevalence/burden among PWID	Key populations
Armenia	4.0%	120,000	17.89%	52.6%	Migrants, PWID
	Interview with the hepatologist of the National Infectious Disease Clinic, available online at https://www.youtube.com/watch?v=d556US-dyuE	Official data are not available or not accessible	Based on the data provided by the AIDS Centre (2014)	Behavioral and Biological Research in the Republic of Armenia, 2012	
Azerbaijan	3.2%	300,800	58.8%	62.8%	PWID
	Estimated; using the population figures and the estimates provided	Chief Gastroenterologist of Azerbaijan, 2013. According to the Ministry of Health, there were 181 people registered with hepatitis C in 2013.	UNGASS 2012-2013 Global AIDS Response Progress Report	Respondent	Respondent
Belarus	2%-3%	250,000	n/a	70-95%	PWID
	Estimated; using the population figures and the number provided by the Ministry of Health (MoH)	MoH Data, 2015, First Open Hepatitis Forum; 47,000 – official figure		According to the drug control monitoring data of the Republican Scientific and Practical Center for Mental Health http://naviny.by/rubrics/society/2013/07/25/ic_news_116_421694/	Respondent
Georgia	6.7%	200,000	48%	57%-74%	PWID, MSM, health workers
	Prevalence of Hepatitis C, HIV, and Risk Behaviors for Blood-Borne Infections: A Population-Based Survey of the Adult Population of T'bilisi, Republic of Georgia. J Urban Health. 2006 Mar; 83(2):289-298; new data will be available end of 2015	Ibid	Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC), 2011	BSS Report – Characteristics, high-risk behaviors and knowledge of STI/HIV, and prevalence of HIV, syphilis and hepatitis among injecting drug users in Batumi, Tbilisi and Kutaisi, Georgia 2002-2006; USAID funded STI/HIV Prevention project	
Kazakhstan	1.5% - 3%	255,000-510,000	44.86%	% not available, 6,049 people	
	Data of the MoH	As of 31.12.14, there were 36,254 people in the national register of people with hepatitis B and/or C (official Letter of the Ministry of Health of Kazakhstan)	Ibid (based on the number of registered HIV+ cases) 7,284 of 16,318 people living with HIV in Kazakhstan	Ibid	
Kyrgyzstan	4%	220,857	80%	45.2%	
	"Overview of the situation with viral hepatitis C in Kyrgyz Republic", Association "Partner Network", 2015 (unpublished)	Ibid. According to the official statistics, in 2014 there were 3,023 HCV cases registered	Ibid	Ibid	

Country	Prevalence (%)	Estimated number of people living with HCV (or anti-HCV)	Estimated HCV prevalence/burden among PLHIV	Estimated prevalence/burden among PWID	Key populations
Moldova	1.7%-4%	60,000 – 142,000	45.6%	35.3% - 65.4%	PWID
	Respondents	National Centre for Health Management, 2012, official number: 9,411	Respondent	IBBS 2012 has been done in 4 sites, through respondent-driven sampling	
Russia	About 4%	5,000,000	At least 27%	69%	PWID
	Report of the International Treatment Preparedness Coalition http://itpcru.org/2015/08/03/lechenie-gepatita-s-v-rf-staroe-novoe-nedostupnoe/	Rospotrebnadzor Reference Center of Viral Hepatitis Monitoring	At least 200,000 of registered patients; according to the official data received from health institutions in 45 entities of the RF	Report of Andrey Rylkov Foundation http://en.rylkov-fond.org/wp-content/uploads/2014/07/ARF-HCV-report-2013-final_eng.pdf	Ibid
Tajikistan	3.8%*	320,000	25.6%	22.7% - 49.3%	PWID
	*No official data, estimated prevalence in CA Central Asia		Epidemiologic Survey 2014; sample – 2,200 PWID; data refers to HIV+ PWID only	Lowest – ibid; the highest estimate (49.3%) refers to the study conducted by NGO “SPIN PLUS”, sample – 300 PWID.	
Ukraine	3%[16]	1,200,000	n/a	55%	PWID; hemophiliacs, hemodialysis; MSM; PMTCT
	No official data, MOH operates using WHO estimated data	Estimated; http://moz.gov.ua/ua/portal/pre_20140728_d.html; clinical guidelines		Alliance Ukraine data http://www.aidsalliance.org.ua/ru/library/our/2014/arep14/zvit%20IDU_obl_eng.pdf,p 15	According to Standardized clinical protocol (2014)
Uzbekistan	6.5%[17]	1,800,000	n/a	36%	Health workers, PWID, patients receiving invasive treatment
	No official data, the number is given in the study of Andrew Hill: Hill A, Khoo S, Fortunak J, et al. Minimum costs for producing hepatitis C direct-acting antivirals for use in largescale treatment access programs in developing countries. Clin Infect Dis. 2014 Apr;58(7):928-36. doi: 10.1093/cid/ciu012			2007 Epidemiologic Survey, as stated by the respondent	

*Here and hereinafter the data from Kazakhstan have been provided by the Public Fund Antihepatitis C

[16] WHO now refers to the article by Hope et al, citing the prevalence of anti-HCV of up to 12%. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891474/
[17] In the same article, the prevalence of anti-HCV in Uzbekistan is estimated at the level of 13.1%. This data will be analyzed and included in the next revision of this report.

Accessibility of HCV Drugs

Until recently, the standard of care for HCV globally was a combination of PEG-IFN (either alpha-2a or alpha-2b) and ribavirin (RBV). The HCV drug market has been characterized by exorbitantly high prices for PEG-IFN, largely due to the unavailability of biosimilar drugs. In 2011, the first direct-acting antivirals (DAAs) for treating HCV, protease inhibitors (PI) telaprevir (TPV) and boceprevir (BOC), were registered first in the US and EU. They allowed increasing the cure rate for the most complicated genotype 1 by approximately 20%. However, they had additional side effects, they were used only against genotype 1, and they did not eliminate the need for PEG-IFN/RBV.

Since 2013, second-generation DAAs have been registered in the US, EU and other countries of the world (including the EECA region), which were characterized, among other things, with higher cure rates and more favorable safety profile:

- Simeprevir (SMV), protease inhibitor (*Olysio*, Sovriad in Russia);
- Daclatasvir (DCV), NS5A inhibitor (*Daklinza*);
- Asunaprevir (ASV), protease inhibitor (*Sunvepra*);
- Sofosbuvir (SOF), NS5B polymerase inhibitor (*Sovaldi*);
- Fixed-Dose Combination of sofosbuvir and ledipasvir (LDV) (*Harvoni*);
- Combination of protease inhibitor paritaprevir boosted by ritonavir (PTV/r) and co-formulated with the polymerase inhibitor dasabuvir (DAS) (in one pill), alongside NS5A inhibitor ombitasvir (OMB) (*Viekirax* and *Exviera* in EU, in Russia the whole combination is marketed under trade name *Viekira Pak*).

Some of these drugs are currently being used in combination with pegylated interferon and ribavirin; however, all-oral combination DAA therapy is already available in the US and EU and is recommended by the respective American and European guidelines. References to the international guidelines on HCV diagnostics and treatment are attached in Annex 2.

Registration

The research found that out of the 11 countries of the region, in three (Kyrgyzstan, Tajikistan, Uzbekistan) so far no DAAs have been registered (or data on their registration is not available) (Figure 1). According to the data available, sofosbuvir, which is the basis of most treatment regimens recommended by the EASL, is registered in Georgia (original drug under Sovaldi brand) and in Azerbaijan (generic); at the time of the report finalization, SOF was registered in Ukraine. In Georgia, another drug is registered, which is the combination of sofosbuvir/ledipasvir (*Harvoni*). Simeprevir, also recommended by the EASL for HCV treatment as a component of combination therapy, is registered in Kazakhstan, Russia, Azerbaijan, and Ukraine. Besides, the combination of ombitasvir; dasabuvir, paritaprevir and ritonavir (Viekira Pak) is registered in Russia as well as the drugs daclatasvir (Daklinza) and asunaprevir (Sunvepra), used in combination (Figure 1). According to the data provided by our respondent, in Kyrgyzstan two generic versions of

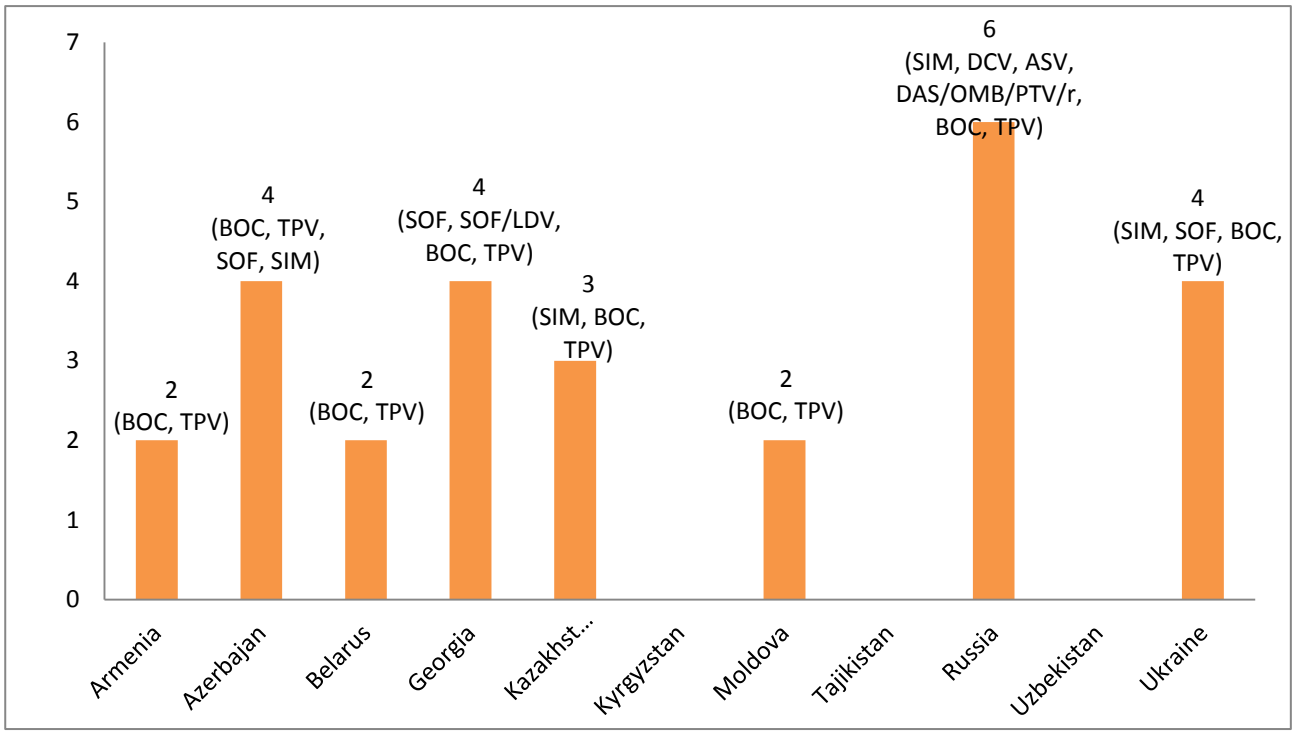
sofosbuvir (produced by Natco and produced in Egypt) are in the process of registration, with relevant applications submitted at the end of August 2015.

Notably, **second-generation DAAs are mostly registered in the countries with some HCV treatment programs running**. Thus, in 2015 Georgia announced the launch of a large-scale treatment program with state support[18], and the government of Kazakhstan has been providing free HCV treatment since 2010 within the state-funded program. National treatment programs were initiated in Ukraine (2014) and Azerbaijan (2015). In Russia, for at least 5 years HCV drugs have been provided free of charge within various programs to certain patient groups (including HIV/HCV co-infected patients). More detailed information is provided in the section on national and donor treatment programs.

Boceprevir and telaprevir, which are no longer recommended as preferred options for treating HCV (see Section on HCV Treatment Guidelines below) are registered in most research countries. It is important to note that in some countries of the world pharmaceutical companies have already announced withdrawal of these drugs from the market[19].

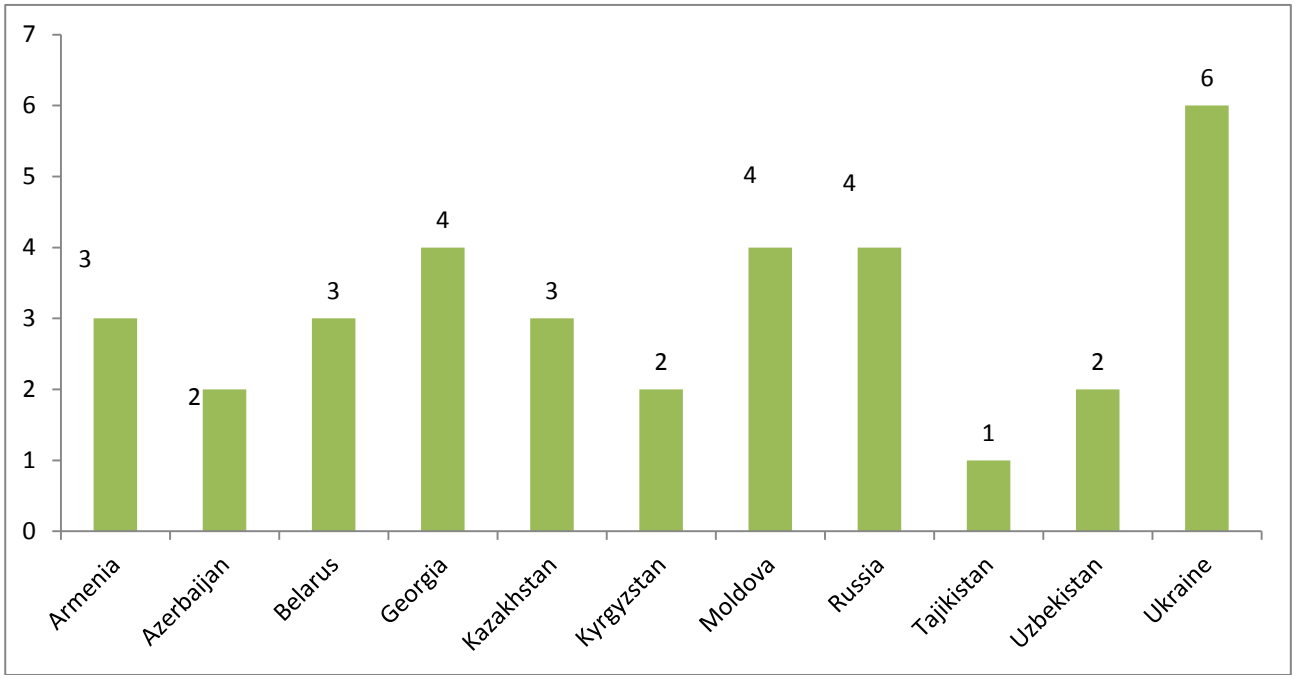
The availability of PEG-IFN is better as compared to new DAAs (Figure 2). Besides the original drugs PEG-IFN alpha-2a (Pegasys) and alpha-2b (PegIntron), a range of bio-similar products is available in the countries of research, as well as a novel drug peg-interferon alpha-2b, marketed under the brand name Algeron.

Table 2 summarizes information on registration status of HCV medicines in the studied EECA countries



[18] http://newsgeorgia.ru/politics/20150115/217282160.html
[19] http://www.firstwordpharma.com/node/1258918

Figure 1. Registration status of DAAs in the countries of EECA



Note: the numbers refer to the number of registered trade names, either brand or biosimilar

Figure 2. Registration Status of PEG-IFN in the countries of EECA

Table 2. Registration of HCV drugs in EECA countries

International Non-Proprietary Name	Armenia	Azer-baijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan	EU*
Gross National Income, USD[20]	3,810	7,590	7,340	3,720	11,670	1,250	2,550	13,210	1,060	3,560	2,090	-
Sofosbuvir (Sovaldi)				Yes						Yes		Yes
Sofosbuvir (Grateziano, European Egyptian Pharm, Inc.)		Yes				Application						
Simeprevir		Yes			Yes			Yes		Yes		Yes
Sofosbuvir/ledipasvir				Yes								Yes
Daclatasvir								Yes				Yes
Asunaprevir								Yes				
Dasabuvir								Yes*[21]				Yes
Ombitasvir/paritaprevir/ritonavir												Yes
Boceprevir	Yes	Yes	Yes	Yes	Yes		Yes	Yes		Yes		Yes
Telaprevir[22]	Yes	Yes	Yes	Yes	Yes		Yes	Yes		Yes		Yes
PEG-IFN ALPHA-2a (Pegasys) 180	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
135 µg					Yes		Yes	Yes		Yes		
90 µg							Yes					
PEGFERON				Yes						Yes		
Pegnano180 µg/0,5 ml/Nanogen Pharmaceutical Biotechnology Company Ltd./Vietnam							Yes					
PEG-IFN ALPHA-2b (PegIntron)[23]		Yes	Yes	Yes				Yes			Yes	Yes
50 µg	Yes				Yes		Yes	Yes		Yes		
80 µg					Yes		Yes	Yes		Yes		

[20] GNI per capita in 2014, Atlas method, USD, http://data.worldbank.org/indicator/NY.GNP.PCAP.CD
[21] *Dasabuvir and ombitasvir/paritaprevir/ritonavir are registered in Russia as a combination drug “Viekira Pak”
[22] The data on registration of telaprevir and simeprevir have been verified, in particular, with the data presented by the company at the meeting of EECA CAB in May 2015 http://eeca.cab/wp-content/uploads/2015/08/Janssen_27_05_2015_final.pdf
[23] In case no info is available on the specific dosages of PEG-IFN alpha-2b, “yes” is put in this column.

International Non-Proprietary Name	Armenia	Azer-baijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan	EU*
100 µg					Yes		Yes	Yes		Yes		
120 µg					Yes		Yes	Yes		Yes		
150 µg							Yes	Yes		Yes		
Peginferon-RUS, Rus-Med Exports Private Limited/ Virchow, India												
100 µg							Yes					
80 µg							Yes					
PEG-IFN ALPHA-2b (Alphapeg)										Yes		
UNITRON										Yes		
PEG-IFN ALPHA-2b (PegAltevir)[24]								Yes		Yes		
CePEG-IFN Alpha-2b (Algeron)	Yes		Yes	Yes	Yes	Yes		Yes				
Ribavirin[25]	Yes							Yes	Yes			
Ribavirin (Copegus)		Yes	Yes			Yes	Yes			Yes	Yes	
Ribavirin (Rebetol)		Yes			Yes		Yes	Yes		Yes		Yes
Ribavirin (generic)			Yes		Yes	Yes		Yes		Yes		

Registries of Drugs:

- Armenia – http://www.moh.am/?section=static_pages/index&id=585#
- Azerbaijan – http://www.pharma.az/az/
- Belarus – http://www.rceth.by/Refbank/reestr_lekarstvennih_sredstv/results
- Georgia – www.mis.ge
- Kazakhstan – http://www.dari.kz/category/search_prep
- Kyrgyzstan – n/a
- Moldova – http://nomenclator.amed.md/
- Russia – http://grls.rosminzdrav.ru/
- Tajikistan – n/a
- Ukraine – http://www.drlz.kiev.ua/
- Uzbekistan – http://www.med.uz/services/registry/other.php

[24] Data on cePEG-IFN were verified with the info in the minutes of the meeting of EECA CAB with Biocad, May 28, 2015
[25] For some countries, trade names for ribavirin were not available.

Pricing

This section summarizes the information about prices for various HCV drugs. The data has been mostly taken from government programs (marked as GP in Table 3) and drug registries (marked as R in Table 3), or refers to the commercial sector (marked as C in Table 3). Prices in the donor programs are cited in the section *HCV Treatment Programs*.

As a reference, gross national income (GNI) per capita of countries as per the classification of the World Bank is cited. The prices refer to the period of June-August 2015. Wherever possible, the source of information is provided so that CSOs can update the data on a regular basis.

The data presented should be interpreted with caution and are given to provide a very basic picture of the overall HCV 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 (for example, "buy one, get one for free")[26]. These pricing policies have not been analyzed. Registered prices are, as a rule, lower than the prices at which the drugs are available commercially.

In a number of the research countries, prices for medicines are not publicly available. Information had to be accessed 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, the prices in national currencies have been converted into US dollars, either at the average rate for August 2015 given at oanda.com (unless a different time period is indicated), or at the rate used by country representatives. The exchange rates are indicated below the table.

The analysis demonstrated **considerable differences in prices for DAAs and PEG-IFN/RBV** in the countries of the region. The highest prices for DAAs were observed in the Baltic States. Thus, the maximum price for the combination drug sofosbuvir/ledipasvir in Latvia is USD 87,165 for a 12-week treatment course. The highest price for sofosbuvir in Latvia is USD 77,830 for a 12-week treatment course. Within the national HCV treatment programs or HCV treatment programs implemented with donor support (Georgia and Ukraine), sofosbuvir is available free of charge. The price for a generic version of sofosbuvir in Azerbaijan at the commercial market is USD 2,700 for a 12-week course of treatment. According to many respondents, a significant number of patients prefer to purchase DAAs not registered in their countries from India or China due to cost considerations.

The lowest price for PEG-IFN in the region is around USD 2,500 per 48 weeks of treatment (not taking into account ribavirin). In a number of countries (Belarus, Kazakhstan, Russia) an innovative drug, cepeginterferon alpha-2b (Algeron) is available at a price of around USD 5,000 for 48 weeks of treatment within the so-called "Towards Cure" program (in Russia this drug is also available to patients within various treatment programs). In Moldova and Ukraine, a range of biosimilar products are registered, as a rule, at prices lower than prices for brand products (generally, within the range USD 5,000 – USD 10,000 per 48 weeks of treatment). As noted above, registered prices may not necessarily reflect the prices in the commercial market. Importantly, the prices above do not include ribavirin. Ribavirin, as it has

[26] See, for instance, the minutes of the meeting between representatives of CS organizations and Roche in December 2013, St. Petersburg. Available online at: http://eeca-cab.org/media/2014/01/13/meeting_minutes_eeca_cab_roche_101213_rus_final.pdf

been stated by several country representatives (for instance, Tajikistan and Kazakhstan), can be provided free of charge through special access programs. It is also available commercially in several countries, with prices per 48 weeks of treatment ranging significantly, starting from USD 250 up to almost USD 3,500. During the meetings of EECA Community Advisory Board (CAB), representatives of patients' organizations said that when purchasing biosimilar versions of PEG-IFN ribavirin would have to be procured at full commercial price, and so the total price for the treatment course with biosimilar drugs would have been higher than the price for a treatment course with an original drug[27].

In government treatment programs, prices for PEG-IFN range from 85 (Ukraine) and 93 (Georgia) to 158 (Russia) USD per vial. In Georgia and Ukraine, the price for 48 weeks of PEG-IFN in government treatment programs is in the range of 4 – 4.7 thousand USD. DAAs are provided by the government in Georgia (SOF, donation) and in Russia (11,500 – 20,500 depending on the drug, regimen and region, see table below).

In general, the current prices remain exorbitantly high within the context of the GNI per capita and average income, even for the treatment regimen with PEG-IFN and ribavirin, which is no longer recommended as the preferred treatment option according to international standards.

It is important to be reminded that many DAAs, including boceprevir and telaprevir registered in most EECA countries, must be combined with PEG-IFN and ribavirin. Sofosbuvir and simeprevir, in the absence of other DAAs, must also be combined with PEG-IFN/RBV with a different duration depending on the genotype (for instance, 24 weeks of SOF with RBV or 12 weeks of SOF/PEG-IFN/RBV).[28] **Consequently, the price for the full treatment regimen based on either boceprevir or telaprevir should also include the price of PEG-IFN and ribavirin for up to 48 weeks of treatment according to the therapy regimen**. For example, the price for the combination of SMV and PEG-IFN/RBV in Russia is approximately USD13,780 (out-of-pocket, "Towards Cure" program, valid only for SMV in combination with cePEG-IFN). The approximate prices for the full HCV treatment regimens in some EECA countries are stated in Table 4. For those regimens, the authors of the report tried to take into account special discounts offered by pharmaceutical companies. Information about such discount programs was by study respondents.

[27] http://eeca.cab/wp-content/uploads/2015/08/Biocad_28_05_2015_FINAL.pdf
[28] Different treatment regimens are described in detail in the guidelines referred to in the Section "Useful Resources".

Table 3. Prices in USD for HCV drugs in the EECA countries as of August 2015

International Non-Proprietary Name	Armenia	Azerbai-jan	Belarus	Georgia	Kazakh-stan[29]	Kyr-gyzstan	Latvia	Lithuania	Moldova	Tajiki-stan	Russia	Uzbek-istan	Ukraine[30]	Estonia
Sofosbuvir		2,700* (C)		n/a (C), 0 (GP)			77,830 (C)	74,295 (C)					0* (GF)	
Sofosbuvir / ledipasvir				n/a (C), 0 (GP)			87,165 (C)	90,549 (C)						
Simeprevir							36,193 (C)	55,722 (C)			10,482-22,486 (C), 15,174-20,419 (GP)			
Asunaprevir											11,500 (GP)[31]			
Daclatasvir														
Dasabuvir							5,441 (C)				12,416 (GP), 15,860 (C)			
Ombitasvir/ paritaprevir/ritonavir							62,423 (C)							
Dasabuvir							5,441 (C)							
Boceprevir	n/a		12,100[32] (C)	36,960[33] (C)	31,844 (C)		53,115 (C)	47,773 (C)	33,098 (R)		11,280-22,973 (C), 13,219 (GP)		22,385 (R)	40,480
Telaprevir	35,772 (C)		n/a	n/a[34]	28,423 (C)		37,699 (C)	26,688 (C)	25,712 (R)		8,535-20,693 (C), 11,219 (GP)		10,776 (C[35])	36,540
PEG-IFN ALPHA-2a (Pegasys) 180	305-329 (C)	205 (C)	238 (C)	241 (C)	256 (C), 265 (GP)	231 (C)	217*	297/265/ 255*	156 (R), 220-229 (C)	200 (C)	138-194 (C), 151 (GP)	280-350 (C)	138 (R), 125 – 200 (C)[36], 105 (GP[37])	260

[29] Data provided by Foundation Antihepatitis C.
[30] Data provided by the International HIV/AIDS Alliance in Ukraine.
[31] Based on the tender announced in Moscow region in September 2015, price for 24 weeks of combination of daclatasvir and asunaprevir.
[32] The price for boceprevir in Belarus was reduced three times by the day of publication of this overview, from USD 33,000 to USD 12,100 per 44-week course of treatment.
[33] The price indicated was USD 10 per one pill.
[34] At the time of research, the product was not available on the market.
[35] The price for telaprevir was declared by Janssen at the meeting with EECA CAB (May 2015), USD 898 for 42 pills, minutes of the meeting are available at the website of EECA CAB: http://eeca.cab/wp-content/uploads/2015/08/Janssen_27_05_2015_final.pdf
[36] These prices may refer to different types of PEG-IFN. The prices at the commercial market of Ukraine were difficult to harmonize due to a very wide range of prices.

International Non-Proprietary Name	Armenia	Azerbai-jan	Belarus	Georgia	Kazakh-stan[29]	Kyr-gyzstan	Latvia	Lithuania	Moldova	Tajiki-stan	Russia	Uzbek-istan	Ukraine[30]	Estonia
135 µg							194		126 (R)				101 (R)	210
90 µg							154*		89 (R)				94 (R)	
PEGFERON				93 (GP)									131.3 (R)	
PEG-IFN ALPHA-2b (PegIntron)[38]		252 (C)	99 (C)									280-350 (C)	85 (GP)	
50 µg	200 (C)				245 (GP)		100*		95 (R)		-		133 (R)	112
80 µg					277 (GP)		161*		197 (R)		154 (C), 148 (GP)		134 (R)	175
100 µg					321 (C), 316 (GP)		201*		189 (R)		130-168 (C), 158 (GP)		137 (R)	217
120 µg				139 (C)	362 (C), 370 (GP)		240*		227 (R)		161-168 (C), 143 (GP)		139 (R)	260
150 µg							300*				161 (C), 151 (C)		143 (R)	322
PEG-IFN ALPHA-2b (Alphapeg)														
80 µg													57 (R)	
100 µg													59.2 (R)	
120 µg													61.34 (R)	
150 µg													64.33 (R)	
PEG-IFN ALPHA-2b (UNITRON)														
50 µg													131.3 (R)	
80 µg													131.3 (R)	
100 µg													131.3 (R)	
120 µg													131.3 (R)	
150 µg													131.3 (R)	
Peginferon-RUS,														

[37] Exchange rate of November 2014.
[38] In case no info is available on the specific dosages of PEG-IFN alpha-2b, the price is given in this column.

International Non-Proprietary Name	Armenia	Azerbai-jan	Belarus	Georgia	Kazakh-stan[29]	Kyr-gyzstan	Latvia	Lithuania	Moldova	Tajiki-stan	Russia	Uzbek-istan	Ukraine[30]	Estonia
Rus-Med Exports Private Limited/ Virchow India														
100 µg									185 (R)					
80 µg									167 (R)					
CePEG-IFN Alpha-2b (Algeron)														
80			86* (C)		97* (C)									
100			90* (C)		100* (C)						86-91 (C), 88 (GP)			
120			91* (C)		104* (C)						91-102 (C), 93 (GP)			
160			96* (C)		109* (C)						96-128 (C), 123 (GP)			
200			100* (C)		114* (C)						87-100 (C), 99 (GP)			
Ribavirin											760 (R)[39]			
Ribavirin (Copegus)			600 (C)						543 (R)			1440 (C)	254	8,410
Ribavirin (Rebetol)									3,540 (R)				550	8,448
Ribavirin (generic)			291 (C)		908* (C)								504[40]	

* C – commercial, GP – government program, R – registered., GF – Global Fund
* Price for pegylated interferon are given per one vial.
* Prices for direct-acting antivirals are given for a course of treatment: 44 weeks for boceprevir, 12 weeks for telaprevir.
* Prices for ribavirin are converted to 48 weeks (1,680 tablets). 1,000 – 1,200 mg of ribavirin must be taken daily over the treatment course.
* Generic sofosbuvir, Grateziano, European Egyptian Pharm, Inc., is available only if ordered from a distributor.
* The price for Algeron is stated subject to purchase of 4 vials within the program “Towards Cure”.
* For Lithuania, the price for Pegasys 180 µg is stated subject to purchase of 1 syringe/ set of 4 vials/ set of 4 vials + Copegus 200 mg, 168 pills
* For Latvia, the price for Pegasys 90 µg and 180 µg is stated subject to purchase of a set of 4 vials + Copegus 200 mg, 168 pills; the price for PegIntron 50, 80, 100, 120, 150 µg is stated subject to purchase of a set of 4 vials + Rebetol 200 mg, 140 pills. For antivirals, the maximum price offered in drug stores is stated.
* In Ukraine, sofosbuvir is available within the project implemented by the International HIV/AIDS Alliance in Ukraine supported by the Global Fund; within the pilot project, in 2015-2016 2,000 people will get access to the drug, including patients with HIV/HCV coinfection, people who use drugs and members of other vulnerable populations; in 2016-2017, it is expected that the program will be expanded to include 5,000 patients.

[39] Many generics available; the price given refers to the last registered price.
[40] A range of generics available; the price in the table refers to the lowest price.

Sources of Information:

Armenia	http://www.danapharm.com/r/import-eksport/registraciya-lekarstv-v-armenii
Azerbaijan	Private sector prices, communication with the country representative; no information could be accessed online
Belarus	http://apteka.103.by/ (accessed on February 6, 2015, the website accumulates prices from different drugstores in the country; prices change every day)
Georgia	Hotline Farmadepo (commercial prices), http://www.moh.gov.ge/index.php?lang_id=GEO&sec_id=380 (government program, USD 93 per vial)
Estonia	www.sm.ee/sites/default/files/content-editors/eesmargid_ja_tegevused/Tervis/Ravimid/hinnakokkulepped_01.08.2015.xls
Kazakhstan	http://www.sk-pharma.kz
Latvia	http://www.apvienibahiv.lv/docs/729/2015_dazadi/KZS_ARV_VHC_2015(4).xls
Lithuania	http://www.sam.lt/go.php/lit/Kompensuojamieji-vaistai-ir-medicinos-pagalbos-priemones
Moldova	http://amed.md/
Russia	http://grls.rosminzdrav.ru
Tajikistan	Private sector prices, communication with the country representative; no information could be accessed online; the price includes ribavirin
Ukraine	Official register: http://www.moz.gov.ua/ua/portal/register_prices_drugs/
Uzbekistan	No information could be accessed online; unified national hotline +998711401919

Exchange Rates

Country	USD/Local currency	
Armenia	478,206	
Azerbaijan	1,0484	
Belarus	16 1150,2	
Georgia	2,3191	
Kazakhstan	203,462	
Kyrgyzstan	62,1844	
Moldova	1,08 – EUR/USD	Some prices for Moldova are given in EUR in the register, others are given in USD; the register is dated March 31, 2015
Russia	65,2353	
Tajikistan	6,2691	
Ukraine	Due to currency fluctuations, the exchange rate is given at the time of the contract or as indicated in the register.	
Uzbekistan	2571,64	
Euro	0,8990	

oanda.com Average rate for 01/08/2015-30/08/2015

Table 4. Prices for treatment regimens with DAAs in some EECA countries (projected out-of-pocket)

Treatment course	Armenia*	Azerbaijan	Belarus	Georgia	Latvia[41]	Russia	Ukraine
Simeprevir + PEG-IFN + RBV, 12 (24 weeks)	-	-	-	-	36,193 + 50*24 = **37,393**	**13,780**[42]	-
Sofosbuvir + PEG-IFN + RBV, 12 weeks	-	2,700 + 205*12 = **5,160**	-	Free of charge	77,830 + 50*12 + 0 = **78,430**	-	-
Sofosbuvir + RBV, 24 weeks	-	-	-	-	-	-	-
Ombitasvir/paritaprevir/ritonavir + dasabuvir, 12 weeks	-	-	-	-	62,423 + 5,441 = **67,864**	**15,860**	-
Sofosbuvir/ledipasvir, 12 weeks	-	-	-		**87,165**	-	-
Sofosbuvir + simeprevir, 12 weeks	-	-	-	-	77,830 + 36,193= **114,023**	-	-
Sofosbuvir + daclatasvir, 12 weeks	-	-	-	-	-	-	-
Boceprevir + PEG-IFN + RBV, (28 weeks)	-	-	12,100 + 90*28 + 170 = **14,790**	-	-	-	-
Telaprevir + PEG-IFN + RBV, (24 weeks)	35,772 + 305*24= **43,092**	-	-	-	-	-	10 776 + 3000 + 127 = **13 903**

[41] Patient co-payment in Latvia for PEG-IFN is 25% (200USD – price for PEG-IFN alpha-2b 100 μg. In other cases when the price for RBV is not taken into account it is considered to be provided free of charge. Prices in Latvia do not include RBV (info not available).
[42] This price is valid only for the program “Towards Cure” for the combination of simeprevir and cePEG-IFN (Algeron); RBV price – 380 USD (24 weeks).

Access Programs

Many pharmaceutical companies implement so-called access programs, offering drugs to certain countries at special prices, which are, as a rule, considerably lower than in other counties. Currently only several companies provided information about programs of access to drugs for HCV treatment. The data for EECA counties are summarized in Table 5 and Figure 3 below. Taking into account that only 3 (Kyrgyzstan, Tajikistan and Uzbekistan) out of 11 countries of research are included in the access programs of BMS and Gilead, and given the HCV burden estimates above, only 24% of people living with HCV in these 11 countries will have access to generic DAAs produced under the license of these brand companies.

Importantly, inclusion of countries into the access programs does not mean that drugs are at the moment physically available in the country. Thus, the drug PegIntron has not yet been registered in Kyrgyzstan, which raised a discussion between CSOs and company representatives at the most recent meeting of EECA CAB. As noted above in the section about registration status, no DAAs are currently registered in Kyrgyzstan, Tajikistan and Uzbekistan (in Kyrgyzstan, the registration application for a generic sofosbuvir is pending).

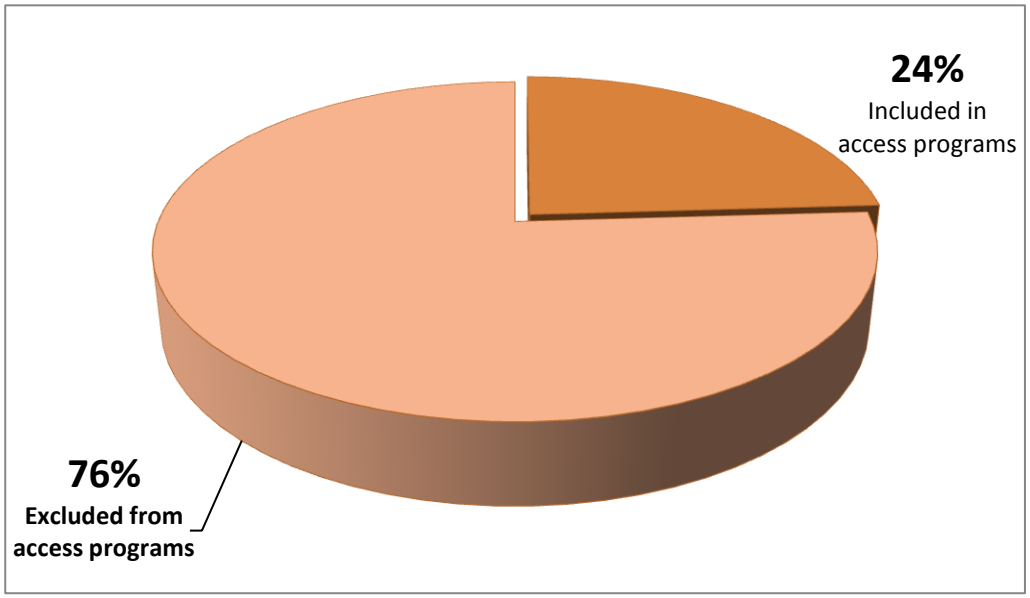


Figure 3. Coverage of Treatment Access Programs of Gilead and BMS in 11 EECA countries

Table 5. Voluntary Licenses and programs offered by pharmaceutical companies to provide access to DAAs and PEG-IFN in EECA countries. January 2015.

Country	GNI	Gilead[43] Voluntary license	BMS[44]	MSD, PegIntron (USD 40 per vial), 57 countries[45]
Armenia	3,810	No	No	No
Azerbaijan	7,590	No	No	No
Belarus	7,340	No	No	No
Georgia	3,720	No	No	No
Kazakhstan	11,670	No	No	No
Kyrgyzstan	1,250	Yes	Yes	Yes
Moldova	2,550	No	No	No
Tajikistan	1,060	Yes	Yes	Yes
Russia	13,210	No	No	No
Ukraine	3,960	No	No	No
Uzbekistan	1,900	Yes	Yes	No

[43] http://www.gilead.com/ /media/Files/pdfs/other/HCVGenericAgreementFactSheet.pdf
[44] http://www.bms.com/responsibility/access-to-medicines/Pages/HCV-developing-world-strategy.aspx
[45] Minutes of the meeting between EECA CAB and MSD in 2014, available online: //eeca-cab.org/en/2010/05/06/merck-sharp-dohme/

Patents

High prices can often be caused by monopolies due to the existing patents for drugs giving companies an exclusive right to market their drugs. In the field of HIV, CSOs have long been actively working to eliminate the barriers in access to treatment issues related to intellectual property rights (patents). Besides patent law optimization and introduction of mechanisms enabling countries to avoid patent barriers, one of the priorities for CSOs has been analyzing patent landscapes and opposing patents which prevent cheaper generic (biosimilar) drugs from entering the market. Research shows that the new expensive second-generation DAAs can be produced at the cost of approximately USD 100 per 12 weeks course of treatment[46].

CSOs in several countries have successfully opposed patents for a number of ARV drugs for treating HIV[47], as well as PEG-IFN for treating HCV[48]. Now, there is an active movement aimed at opposing patents for DAAs, mainly sofosbuvir, which is the backbone of most preferred HCV treatment regimens. Patent oppositions have already been filed in India (one of the patents revoked[49]), the EU, Brazil and many other countries. In Russia, the Treatment Preparedness Coalition and the Charitable Foundation "Humanitarian Action" opposed a patent for a pro-drug form of sofosbuvir[50]. Besides, Treatment Preparedness Coalition submitted a request to the competent authorities to issue a compulsory license for sofosbuvir and other DAAs in Russia. In Ukraine, the patent for sofosbuvir was opposed by the All-Ukrainian Network of People Living with HIV. In Kyrgyzstan, largely due to the efforts of CSOs amendments were recently introduced into the laws on intellectual property, taking into account the legal flexibilities of TRIPS[51]. The Egyptian producer of sofosbuvir submitted an application for the registration of a generic drug, based on the possibility of international exhaustion.

WHO experts have recently prepared an analysis of patents for a number of DAAs. This paper covers some EECA countries (Russia, Ukraine, and Georgia) as well as the Eurasian Patent Organization[52] (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, and Turkmenistan). The results of this analysis in the countries of EECA are summarized in Table 6 below. In addition, the table contains data about patents for PEG-IFN alpha-2a (Pegasys) and PEG-IFN alpha-2b (PegIntron) based on the results of the research carried out by the Initiative for Medicine, Access and Knowledge (I-MAK).

[46] Hill et al. Minimum costs for producing Hepatitis C Direct Acting Antivirals, for use in large-scale treatment access programs in developing countries. 2014. Available online at: http://cid.oxfordjournals.org/content/early/2014/01/06/cid.ciu012.full.pdf+html
[47] 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/
[48] 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
[49] http://www.ip-watch.org/2015/01/14/key-hepatitis-c-patent-rejected-in-india-for-lack-of-novelty-inventive-step/
[50] http://itpcru.org/2015/05/20/obshhestvennye-organizatsii-osparivayut-patent-na-sofosbuvir-v-rossii/
[51] See, for instance, http://zdorovie.akipress.org/news:19576
[52] http://www.eapo.org/en/

Table 6. Patents and patent applications for DAAs[53] and PEG-IFN[54] in certain EECA countries, including the Eurasian Patent Organization (EAPO)

Drug	EAPO	Georgia	Moldova[55]	Kazakhstan	Kyrgyzstan	Russia	Ukraine
ABT-450	n/a	n/a	n/a	n/a	n/a	Issued RU2475494C2	n/a
Daclatasvir	Issued: EA15756B1, EA17173B1, EA17348B1, EA018152B1 + Applications: EA201270555A1 and EA201390155A1	n/a	n/a	n/a	n/a	Issued RU015756	n/a
Dasabuvir	Applications: EA201390128A1 and EA201390130A1	n/a	n/a	n/a	n/a	Applications: RU2010114827A, RU2010114828A	n/a
Ledipasvir	Applications: EA201190259A1, EA201490853A1, EA201490854A1, EA201490588A1	n/a	n/a	n/a	n/a	n/a	Application: UA201113524
Ombitasvir	Applications: EA201170401A1, EA201300495A1, EA201291394A1, EA201390538A1	n/a	n/a	n/a	n/a	n/a	Issued UA201103926 + Application: UA201305877
Simeprevir	Issued: EA15131B1, EA12410B1, Applications: EA201291042A1, EA201170456A1	n/a	n/a	n/a	n/a	Issued RU2483067C2 + Applications: RU2011130895A, RU2012143977, RU2009132660A, RU2011139325A	Application: UA201102963
Sofosbuvir	Applications: EA201290988A1, EA201290993A1, EA201171417A1, EA201370186A1, EA201490588A1, EA201390576A1, EA201390133A1, EA201190110A1	No applications found	Applications: WO2013/040492 and WO2013/082003	Applications: EA201490806; EA201171417; EA201290993; EA201370186; EA201490588; EA201490903; EA201290988	n/a	Issued: RU2358979C2, RU2478104C2 , Application: RU2012152811A	Applications: UA201306068A, UA201301999A
PEG-IFN alpha-2a	No data	1 patent	n/a	n/a	1 patent	3 patents	1 patent
PEG-IFN alpha-2b	No data	Not found	n/a	n/a	Not found	Not found	Not found

[53] The WHO analysis of patents for antiviral drugs is available online at: http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/

[54] See the full analysis by I-MAK at http://essentialdrugpatents.com/hepcdatabase.php

[55] The data for Moldova and Kazakhstan were received within the project of the Treatment Preparedness Coalition to eliminate the barriers related to the intellectual property by the community of patients with support of the AIDS Fonds.

HCV Treatment Guidelines

In order to determine the current standard of care for HCV treatment in the world, American Association for the Study of Liver Diseases (AASLD), European Association for the Study of the Liver (EASL) and WHO guidelines were analyzed. It turns out that all these documents recommend regimens based on second-generation DAAs as preferred therapy options.

The guidelines in the 11 countries of research mostly recommend PEG-IFN/RBV or a triple combination of boceprevir/telaprevir and PEG-IFN/RBV as a preferred choice for treating HCV, even if these drugs are not available in the country (for instance, Kyrgyzstan).

The guidelines in Russia recommend triple therapy using protease inhibitors as a standard for treatment of HCV genotype 1, allowing the use of standard interferon in combination with ribavirin for the treatment of HCV genotypes 2 and 3 under certain conditions. As of the date of most recent update of the guidelines, the 3D regimen as well as the drugs daclatasvir and asunaprevir were not registered in Russia, SOF and SOF/LDV were also not registered, when this overview was prepared.

In Georgia, the use of sofosbuvir in combination with PEG-IFN/RBV is stipulated in the national treatment program.

Some guidelines mention second-generation DAAs (Kyrgyzstan – simperevir and sofosbuvir) as future treatment options.

In terms of the approval dates, among the research countries, Kazakhstan (2015), Ukraine and Kyrgyzstan (2014) have newly adopted guidelines. The guidelines in Georgia, according to country respondents, are soon to be adopted in 2015 with inclusion of DAAs. Belarus, according to country respondents, refers to guidelines approved back in 2006 when no DAAs were available; the guidelines are expected to be updated in 2015. The guidelines in Azerbaijan were approved in 2009, when DAAs were not available either; there is some information that those guidelines are to be updated in 2015 with the inclusion of DAAs.

Some countries, like Armenia and Tajikistan, still have no HCV treatment guidelines, according to the data available; while Tajikistan, according to the country respondent, refers to Russian guidelines.

The Ukrainian guidelines mention representatives of CSOs among the authors, including representatives of the International HIV/AIDS Alliance in Ukraine, Patients of Ukraine, the All-Ukrainian Network of People Living with HIV and Stop-Hepatitis. In other countries, such as Kyrgyzstan and Kazakhstan, CSOs have also been included in the expert committee responsible for the development of the guidelines. The practice of including CSOs working with patients and patient organizations into guideline expert panels is widely used at the international level, in particular in WHO, AASLD, and EASL.

Table 7. HCV Guidelines in the Countries of EECA

Country	Title	Date	Standard of Care, 1st Line	DAAs	Comments
Armenia	N/A				Only HIV/HCV co-infection guidelines available; adapted from WHO guidelines
Azerbaijan	Clinical Guidelines for the Treatment of HCV	2009	PEG-IFN/RBV	PIs as a future option	To be revised in 2015 with inclusion of DAAs
Belarus		2006	PEG-IFN/RBV	No	Revision planned for 2015 according to the respondent
Georgia		2011	PEG-IFN/RBV SOF/PEG-IFN	(see Comments)	Next revision is expected in 2015 with inclusion of sofosbuvir; The SOF-based regimen is mentioned in the national program, launched in April 2015
Kazakhstan	Clinical Guidelines for Diagnostics and Treatment of Chronic HCV in Adults	2015	PEG-IFN/RBV	Triple therapy with protease inhibitors (BOC/TPV)	
Kyrgyzstan	Clinical Guidelines on Testing, Treatment and Prevention of Viral Hepatitis C in Kyrgyz Republic	2014	PEG-IFN/RBV; Triple therapy (BOC/TPV)	SOF and SMV are mentioned	www.med.kg
Moldova	Chronic Hepatitis C in Adults, National Clinical Guidelines	2012	PEG-IFN/RBV	Triple therapy; BOC or TPV	
Russia	Guidelines on Testing and Treatment of Hepatitis C in Adults	2014	Triple therapy PI/PEG-IFN/RBV for genotype 1, PEG-IFN/RBV	TPV, BOC, SMV	After approval of the recent version, such drugs have been registered as 3D, DCV, ASV
Tajikistan	N/A				HIV/HCV coinfection guidelines available; Russian guidelines are used for HCV treatment
Ukraine	Unified Clinical Guidelines for Primary and Secondary (Specialized) Healthcare Services for Adults and Children Infected with Viral Hepatitis C	2014	PEG-IFN/RBV or IFN/RBV (e.g., children)	Triple therapy; BOC/TPV	

Uzbekistan	Clinical Guidelines for Diagnostics, Treatment and Prevention of Chronic Hepatitis in Adults in Primary Healthcare	2013	PEG-IFN/RBV	No	Revision planned for 2018 or in case new evidence emerges

References:

- Azerbaijan – http://isim.az/upload/File/reports/19_Hepatit_C.pdf
- Kazakhstan – not available online
- Georgia – http://www.moh.gov.ge/files/01_GEO/jann_sistema/gaidlaini/gaidlain-protokol/105.1.pdf
- Kyrgyzstan – Order#479 of 25.08.2014; www.med.kg
- Moldova – http://old.ms.gov.md/_files/12490-PCN%2520HCV%2520C__31_07_2112_FINAL%2521.pdf
- Russia - http://www.rsls.ru/ru/for-specialists/recommendations/20-recomend-3
- Ukraine – http://www.dec.gov.ua/mtd/reestr_e.html; the required guidelines can be found at the end of the list

National and Donor-Driven HCV Treatment Programs

The issue of insufficient government funding for treating HCV has been high on the agenda of treatment access advocates for a number of years now, including the EECA region. Large-scale public campaigns have been launched and are ongoing in many countries of the region, including Ukraine, Russia, Georgia, and Moldova. Despite revolutionary progress made in the field of HCV therapeutics, the funds allocated for HCV treatment programs in the face of exorbitantly high prices for HCV drugs are simply not enough to cover the need.

Also, CSOs globally have been pressurizing large international donors, such as the GF and UNITAID, to provide funding for HCV. Following public pressure[56], UNITAID included HCV in the context of HIV-coinfection in its strategy. At least one project with an HCV component, which includes an EECA country (MSF, Ukraine) was supported by UNITAID in 2014[57]. The Global Fund is currently funding several HCV projects in EECA countries (mainly in Ukraine and Georgia).

Among the countries included in the research, Georgia, Kazakhstan, Moldova, Russia, and Ukraine have certain HCV treatment programs; also, Georgia and Ukraine are among the countries receiving donor support for purchasing items for HCV testing and treatment. These testing and treatment programs are implemented within Global Fund grants. In Kazakhstan the government committed to providing care to people living with HCV free of charge. In Kyrgyzstan, the national HCV program does not cover the cost of treatment, but currently a new program is being developed, which is expected to include treatment for some groups of patients, including people living with HIV and children. Azerbaijan, according to the media, will soon be launching an HCV treatment program[58] using a biosimilar drug produced in Ukraine. In April 2015, Georgia launched a large-scale HCV eradication project with the use of DAAs (SOF-based regimen)[59]. The data on the coverage of patients within this project will be soon available.

The total number of people who received treatment within national treatment programs in the 11 countries of research was very roughly estimated at 10,000 people in 2014 (with the majority of people in Kazakhstan and Russia, in Russia the therapy is based on PEG-IFN and ribavirin not taking into account standard interferons). **This is approximately 1% of the estimated number of people living with HCV in the countries of research.**

In terms of donor-driven HCV treatment programs, Ukraine and Georgia have the largest HCV treatment components within the grants supported by the GF, with 145 OST patients with HIV/HCV coinfection already treated in Ukraine in 2013-2014 with PEG-IFN and ribavirin within the program implemented by the International HIV/AIDS Alliance in Ukraine. In Georgia, funds were allocated annually for approximately 110 people for the period of 5 years (2011-2015). In 2015, 1,500 people from key populations in Ukraine will be treated with SOF-based regimens[60].

[56] http://www.treatmentactiongroup.org/HCV/unitaid-letter
[57] http://www.unitaid.eu/en/resources/press-centre/releases/1352-unitaid-approves-grants-of-160-million
[58] http://www.1news.az/society/20150206033844002.html
[59] http://georgianpress.ru/sociumm/41037-preparatyi-dlya-lecheniya-gepatita-s-postupyat-v-gruziyu-v-kontse-etoy-nedeli.html
[60] http://www.aidsalliance.org.ua/ru/news/pdf/02.04.15/Scaling_up_access_to_hcv_tx_in_Ukraine_FINAL_ENG.pdf

The prices set in the procurement programs within the GF grants as a result of negotiations with the GF and pharmaceutical companies (for instance, USD 4,800 in the International HIV/AIDS Alliance in Ukraine procurement program) have been used as a benchmark for the government program adopted in Ukraine.

Table 8. National Treatment Programs in the Countries of EECA

Country	Title (or indication of availability)	Amount	Number of people	Comment
Armenia	N/A	N/A	N/A	Order #3128-A of 28.12.2012; list of diseases and situations in which healthcare services are provided for free; acute hepatitis is included.
Azerbaijan	National program	N/A	N/A	There is information in the media that 500 people will be treated using federal money by the Ministry of Health in 2015.
Belarus	According to Decree No 249 of February 21, 2014, free HCV treatment is provided for persons aged under 18 years.	N/A	N/A	
Georgia		Data not available; USD9,680,000 (20,000,000 LARI) are estimated as out-of-pocket expenses in the government discount program for 2015	10,000 people planned for treatment at USD93 per vial. First stage of the HCV eradication program launched in April 2015 with preference given to patients with F3-F4 for 5,000 patients; SOF/PEG-IFN/RBV, SOF/RBV	http://www.moh.gov.ge/index.php?lang_id=GEO&sec_id=380 http://www.moh.gov.ge/index.php?lang_id=GEO&sec_id=29&info_id=2365
	National Program of testing, treatment and prevention in prisons		180 prisoners have completed treatment; 134 currently on treatment	http://www.mcla.gov.ge/ka/RegulationLaws
Kazakhstan	National Treatment Program since 2010; HCV is included into the List of Socially Significant Diseases	~USD16,443,000 (3,045,000,000) - 2014; ~USD15,865,200 (2,938,000,000) - 2015	1,250+(150) - 2014; 1,037+(95) – planned for 2015	The figure in brackets in the column “Number of People” refers to children.
Kyrgyzstan	Targeted Program “Viral Hepatitis”		N/A	A program is being prepared to cover certain groups (people living with HIV, children) with treatment services
Moldova	Yes	No data of the actual spending available	300 patients are planned per year; an estimated number of around 400 patients have received treatment so far	http://cnsp.md/wp-content/uploads/2014/07/HG_90-2012_Program_national_combaterea_hepatitelor.pdf
Russia	Funds for treatment and diagnostics are allocated from various sources	At least USD50 million in 2014	Up to 8,800 patients depending on the duration of treatment course in 2014	Data received based on the monitoring of the official site of public procurement
Tajikistan	N/A			
Ukraine	Yes, 4-year program, since 2014	~USD5,270,000 (UAH61,031,637.40) for 2014 (average rate for 2014)	Approximately 1,100 treatment courses in 2014 (Alliance Ukraine data)	The order of MoH of Ukraine of 02.04.2014 N 233 http://zakon1.rada.gov.ua/laws/show/637-2013-%D0%BF; http://moz.gov.ua/ua/portal/?title=%F0%EE%E7%EF%EE%E4%B3%EB+%E3%E5%EF+2014+2015
Uzbekistan	N/A			

Table 9. Donor Programs in the Countries of EECA

Country	Donor	Amount, treatment and/or number of people	Comment
Armenia	N/A	N/A	
Azerbaijan	N/A	N/A	
Belarus		N/A	
Georgia	Global Fund	550 patients during 5 years	Running since 2011.
Kazakhstan		N/A	
Kyrgyzstan	Global Fund	The current proposal includes diagnostics for 8,000 PWID annually.	Diagnostics was included as part of the GF grant for 2011-2014, but excluded later on.
Moldova	N/A	N/A	
Russia	N/A	N/A	
Tajikistan	Global Fund	54-62 people over the period 2013-2014	Within Round 8 GF, HCV treatment was offered to patients with HIV/HCV coinfection.
Ukraine	Global Fund	130 HIV/HCV co-infected PWID treated in 2013-2014; 1,500 to be treated with SOF in 2015; USD900 for 12 weeks of sofosbuvir, USD4,800 for 48 weeks PEG-IFN; implemented by Alliance Ukraine; first disbursement allowed putting 250 people on treatment.	
Uzbekistan	N/A	N/A	

EECA Civil Society Involvement in HCV Work

For several years, CSOs in EECA have been involved in HCV work, in policy-making, patients' rights protection and service provision; many have used the experience of their work in the field of HIV and harm reduction and transferred it to HCV. The section below summarizes and categorizes some of the activities implemented. All the organizations doing HCV projects are encouraged to share their best practices through the communication channels available (social media, listservs, *etc*.) and to ask international organizations, such as WHO, to document and share such practices. We tried to group the activities below according to the following framework: awareness-raising, mobilization, advocacy, testing and treatment programs.

Implementing projects aimed at raising awareness about HCV access issues and changing policy in this field, such as:

- Initiating publications in the mass media to bring into focus various aspects related to HCV;
- Producing educational videos about various aspects of HCV work, such as the importance of testing, treatment, and an overview of new drugs available;
- Organizing the so-called "patient schools" for people living with HCV on different clinical and legal aspects of treatment, including access issues; and,
- Organizing national-level public campaigns to draw the attention of the general public and decision-makers to various gaps in the HCV response.

In Georgia, a group of CSOs (including the Georgian Harm Reduction Network, OSF Georgia, GeCAB, Médicins du Monde, Hepa+, New Vector, and others) have for a number of years been implementing awareness-raising campaigns related to HCV aimed at decision-makers and the general public. The campaign involved celebrities and was widely covered in the national media, including TV and radio. Finally, the government of Georgia announced a large-scale HCV government treatment program[61].

In Ukraine, the International HIV/AIDS Alliance in Ukraine launched a national campaign, "We Demand Treatment", uniting more than 90 CSOs and around 300 activists, experts and patient groups from all over Ukraine. Launched in 2012, the campaign was designed to raise awareness about

[61] http://www.natap.org/2014/HCV/021014_01.htm

HCV issues among the general public and key populations, generate demand for testing and treatment, and to push the government of Ukraine to adopt a national HCV treatment program, as well as to allocate funds for it. Within the framework of this campaign, several HCV testing projects across most regions of Ukraine have been, and are still being implemented. The results were widely used in advocacy and awareness-raising activities. In addition, in 2012-2014 large-scale public events were held. The campaign resulted in the approval of the State Hepatitis Program and 8 regional/local programs for combating HCV (hepatitis programs), allocation of funds from state budget and local budgets in 8 out of 27 regions of Ukraine, approval of HCV treatment guidelines, price reduction for HCV diagnostics by 2 times and price reduction for HCV treatment by 2.5 times (less than USD 5,000 for 48 weeks). At the end of 2013, due to the considerable price reduction for diagnostics and treatment (PEG-INF/ribavirin), Alliance has been successful in securing GF resources to start the first HCV treatment program in 10 regions of Ukraine for an initial 130 HIV/HCV co-infected PWID. In April 2015, Alliance Ukraine launched the first program of treatment using the regimen with sofosbuvir. The first 250 patients are patients with HIV/HCV coinfection and PWID. The second wave (September) will include 500 patients, in particular with mono-infection. Before the end of the year, it is expected to treat up to 1,500 patients, and in 2016-2017 it is planned to expand the program to other countries.

Mobilizing patient organizations and the general public around the issue of access to HCV testing and treatment. Activities in this field include:

- Establishing networks of individuals/organizations advocating for improved access to treatment; and,

- Developing and implementing sign-on campaigns to demand better access to treatment.

In 2012, the Eurasian Harm Reduction Network (EHRN) launched the so-called HCV Treatment Waiting List sign-on campaign to document the gap in access to HCV treatment and to mobilize the patient community in the region around the issue of high prices for HCV medicines. The list was signed by over 6,000 people and sent to different decision-makers in the countries of the region.

In 2013, a campaign was organized in EECA to collect signatures under the letter addressed to pharmaceutical companies with a demand to reduce prices for 48 weeks of PEG-IFN treatment to USD2,000. The letter was signed by 83 organizations from 12 countries[62]. As a result, a meeting with representatives of the headquarters of one of the companies was organized.

[62] http://eeca-cab.org/en/2013/08/19/83-organizacii-potrebovali-snizheniya-ceny-na-lechenie-gepatita-s/

In 2015, the linking organizations of the International HIV/AIDS Alliance, including the HIV/AIDS Alliance in Ukraine, launched the Unite to Eliminate Hep C: Know It, Test It, Treat It campaign aiming at drawing attention of decision-makers and the general public to the issue of HCV and to the need to act jointly in order to eliminate the HCV epidemic. So far, the campaign has been supported by over 21,000 people and by many organizations, including those in the region of EECA.

Carrying out research aimed at identifying gaps in the current HCV response. The areas in which CSOs have been conducting research include:

- inadequate HCV treatment access for vulnerable groups and for the general population;
- diagnostics and medicines pricing/registration landscape in different countries; and,
- the level of funding allocated for HCV testing and treatment programs, *etc*.

Several examples of research in the field of HCV in EECA countries are listed below[63]:

- A policy brief prepared by the Eurasian Harm Reduction Network entitled *"Current Situation Regarding Access to Hepatitis C Treatment in Eastern Europe and Central Asia"*, 2012[64];
- A report about the HCV epidemic in Russia by the Andrey Rylkov Foundation entitled, *"Hepatitis C in Russia: an Epidemic of Negligence"*[65];
- A report about the epidemic of HCV in Russia with a focus on the procurement and provision of HCV drugs prepared by the Treatment Preparedness Coalition[66]; and,
- A report about the HCV epidemic in Kyrgyzstan prepared by the Kyrgyz Harm Reduction Network, Partnership Network Association and Adilet Legal Clinic.

[63] This list is not exhaustive; the authors of this report apologize for omitting other important pieces of research.
[64] http://www.harm-reduction.org/sites/default/files/pdf/hep_c_policy_brief_update_en_edited_3.pdf
[65] http://en.rylkov-fond.org/blog/hcv/hcvrus/
[66] http://itpcru.org/2014/04/29/otchet-dostup-k-preparatam-dlya-lecheniya-gepatita-s-v-rossii-v-2013-godu/

Organizing meetings between headquarters of pharmaceutical companies and CSOs to discuss HCV treatment access issues

The practice of organizing the patient community advisory boards to discuss clinical aspects and access policy is used all over the world, in particular in the EECA region. The Eastern European and Central Asian Community Advisory Board (EECA CAB) has so far held 5 regional meetings with a focus on HCV treatment access with the following companies: MSD, Janssen, AbbVie, Gilead, and BMS, respectively[67]. The meetings were mainly focused on pricing, registration status, clinical trials and early access programs as a way of providing access to unregistered drugs. In 2015, national community advisory board meetings were held in Moldova and Kazakhstan; a community advisory board meeting at the level of the Baltic States was held in Latvia. The agenda of these meetings included issues related to HCV treatment access.

More than once, concerns were voiced at the meetings of EECA CAB and by the activists of the region that pharmaceutical companies owning the rights to boceprevir and telaprevir will delay the registration and marketing of new drugs, trying to maximize profit from selling the older medicines. This is what happened in Russia, when the company submitted an application to include telaprevir and simeprevir into the List of Vital and Essential Medicines, and as a result telaprevir was included into the list, and simeprevir was not[68]. The company applied a market segmentation strategy by significantly reducing the prices for telaprevir, which led to the application for simeprevir being declined due to the high cost of the drug. After that, within the activities of EECA CAB and in open letters activists opposed to the inclusion of telaprevir into the List of Vital and Essential Medicines. During the most recent revision of the list, the commission approved inclusion of simeprevir into the list and exclusion of telaprevir.

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

These campaigns have been aimed at reducing prices for treatment, pushing the government to adopt government treatment programs, *etc*. The activities take the form of open letters and petitions, sign-on campaigns, flash-mobs on social media, street protests, *etc*.

In Ukraine, Patients of Ukraine (formerly UCAB), held several campaigns aimed at improving the HCV response, such as “The Condemned”[69] street protest held in order to push the government to adopt the national HCV treatment program.

In Moldova, Initiativa Pozitiva, together with a number of other patient’s organizations and networks, initiated a funeral ceremony for more than 300,000

[67] The minutes of the meetings are available online at eeca-cab.org
[68] http://government.ru/docs/16428/
[69] http://patients.org.ua/en/hvori-na-gepatit-otrimuyut-likuvannya-za-derzhavnij-kosht/

people with HCV who, according to the message of the activists, became victims of indifference and corruption in the system. More than a hundred people gathered to express their dissatisfaction with the policies of the Ministry of Health, the Ministry of Finance, the National Agency of Medicines and Medical Devices as well as pharmaceutical companies. On July 28, 2014, more than 20 activists from the League of People Living with HIV, and the CAB in Moldova, held a protest in front of the office of the pharmaceutical company, Roche, demanding a price reduction for ”Pegasys”.

Across the EECA region, patient groups in Armenia, Georgia, Kyrgyzstan, Latvia, Moldova, Russia, and Ukraine have held protests dedicated to the World Hepatitis Day (observed annually on July 28), demanding better access to treatment from their governments and lower prices from pharmaceutical companies[70].

Taking part in cross-sectoral committees responsible for the HCV prevention, treatment, testing and care guidelines development and/or revision. In several countries of research, CSOs have pushed relevant authorities to develop/revise HCV treatment guidelines and taken part in such processes. In Kazakhstan, the non-profit organization Antihepatitis C took part in the revision of HCV treatment guidelines (new edition – 2015). In Ukraine and Kyrgyzstan, CSOs have also contributed to the development of the newly adopted guidelines. In Georgia, CSOs are now working with the Ministry of Health to revise the current version of the guidelines.

Partnering with governments to develop national HCV strategies, programs and plans. In Georgia and Ukraine, CSOs have actively advocated and contributed to the development of national treatment programs. Similar activities are now happening in other countries of the region, including Moldova, Kyrgyzstan, Azerbaijan, etc. In Belarus, following an open letter sent by patient organizations to the President, a Decree was issued stipulating free HCV treatment for children aged under 18 years[71].

Efforts aimed at overcoming patent barriers hindering the access to HCV treatment. At stated above, CSOs in a number of EECA countries have already started taking actions

[70] An overview of some protest actions can be found in the blog of Patients in Control http://packontrol.livejournal.com/14569.html (Russian only).
[71] http://news.tut.by/health/343769.html

in this area. Thus, in Ukraine and Russia patents for sofosbuvir were opposed, and in Russia the Treatment Preparedness Coalition developed and distributed a memorandum concerning the possibility and viability of issuing compulsory licenses for essential drugs, in particular to treat HCV, in the Russian Federation. Kyrgyzstan, largely due to the efforts of CSOs, recently approved amendments to the laws on intellectual property, taking into account legal TRIPS flexibilities. It is expected that similar activities may be initiated in other countries of the region, where intellectual property issues may aggravate the access to medicines (e.g., Belarus, Kazakhstan, Moldova, *etc*.)

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

CSOs in EECA have gained considerable experience of providing services related to HIV and coinfections (drug dependence, tuberculosis, etc.), including testing and treatment services. Some organizations have extended this area of work to HCV. Their positive practices can be used as a basis for developing this field.

As a result of advocacy efforts, the International HIV/AIDS Alliance in Ukraine (Alliance Ukraine) managed to reduce the price for PEG-IFN to USD 4,800 per 48 weeks of treatment and agree with the GF allocation of the grant funds to purchase drugs for the first in Ukraine HCV treatment program, which enabled delivering services to 145 OST patients with HIV/HCV coinfection. This price was subsequently used as a benchmark for the government procurement program. In 2015, Alliance Ukraine launched a sofosbuvir-based treatment program at the negotiated price of USD900 per 12 weeks of treatment and agreed with the GF procurement of drugs for first 250 patients. This became possible due to a significant decrease in the price for medicines as a result of negotiations of Alliance Ukraine with pharmaceutical companies. The program will be expanded to include 1,500 patients in 2015, and further in 2016-2017. The HCV treatment component was integrated into the existing harm reduction services run by Alliance Ukraine with total coverage of over 270,000 clients.

Overall, CSOs in the EECA region have contributed to the following achievements in the field of HCV:

- Development and implementation of national treatment programs;
- Initiating pilot treatment programs for vulnerable groups;
- Data collection about HCV epidemiology;
- Development and implementation of HCV treatment guidelines;
- Changes in the policies of pharmaceutical companies towards faster registration of drugs and price reduction in EECA countries;
- Increased awareness about different aspects of HCV among patients and general population and increased mobilization of patient organizations around the issue of treatment access.

Findings and Suggestions Regarding Civil Society Involvement into HCV Work in EECA

Data about HCV prevalence/incidence and the burden of HCV among the general population and key groups is limited and hard to obtain. In terms of HCV, the healthcare systems of the countries of research are still characterized by poor surveillance systems and absence of patient registers. In some research countries, official HCV epidemiology data is not available (either non-existent or not published). In some cases, the data is based on the results of small-scale studies conducted several years ago.

CSOs can contribute to improving the quantity and quality of the data on the HCV epidemiology in the following ways, including, but not limited to:

- Implementing studies on HCV incidence/prevalence in key populations; and,
- Raising awareness about the lack of data through public events/cooperation with mass media.

High HCV prevalence among people who inject drugs and people living with HIV according to the data available.

- CSOs can integrate HCV services (testing, counseling and treatment) into projects focused on PWID and PLHIV (such as harm reduction projects). Viral hepatitis diagnostics and treatment is part of the WHO/UNODC/UNAIDS comprehensive package of interventions for HIV prevention, treatment and care for PWID[72];
- Monitor cases when PWID are denied HCV treatment and care services, work to gain access for those cases, and create legal precedents with coverage in the media if and when appropriate;
- Document cases when PWID are denied HCV services and disseminate results of the research among decision-makers; and,
- Work on including PWID into national HCV prevention and treatment programs and guidelines.

The number of people treated within the government programs is disproportionately small in relation to the total number of people living with HCV in the countries of research. According to the results of the research, the treatment uptake is likely to be around 1% of the estimated number of people living with HCV or even less.

- CSOs should advocate for the increased political commitment and funding for HCV treatment and reduction of prices for HCV medications through direct meetings with stakeholders and indirectly, through mass media pressure.

Limited availability of DAAs in the EECA countries in terms of registration. Only a few countries of the region can boast registration of DAAs; mostly, these are first-

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

generation protease inhibitors boceprevir and telaprevir, no longer recommended by international treatment guidelines as preferred options. Second-wave DAAs (sofosbuvir, simeprevir, 3D etc.) are registered in countries which have introduced HCV treatment programs.

- CSOs should:
    - Regularly monitor drug registration landscape in the countries and inform the decision-makers about the results, also through mass media; and,
    - Pressurize pharmaceutical companies and governments to speed up registration of newer drugs. Such work can be conducted through the CABs described in the section above.

Limited availability of biosimilar/generic drugs in some countries of research.

- CSOs should partner with the leading international civil society organizations to implement projects aimed at opposing patent barriers to improve access to affordable quality biosimilar/generic drugs. Such projects are already ongoing in some countries of the region, including Kyrgyzstan, Ukraine, Moldova, Kazakhstan, Georgia and Russia.

- CSOs should study opportunities provided by flexibilities in the the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[73] to eliminate intellectual property barriers to affordable treatment. CSOs can either push governments to implement these mechanisms or use these mechanisms themselves[74]. Examples include opposing patents and pushing the governments to issue compulsory licenses for the import or production of medicines.

- CSOs should work with governments to ensure generic prices are significantly lower than brand product prices, in particular through introducing respective changes into the national regulatory framework.

- CSOs should conduct negotiations with relevant authorities to create enabling conditions for the registration of generic drugs with retention of the mechanisms of proper quality control.

Prices for key HCV medications remain high as compared to the average level of income in the countries of research.

- CSOs should conduct regular monitoring of prices for HCV drugs. The results of this monitoring should be made public in local currency and US dollar equivalent to allow for harmonization and should be updated regularly (at least once a year) to serve as a basis for advocacy.

[73] 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*.
[74] Very recently, in Kyrgyzstan, largely owing to the efforts of the civil society organization, amendments to the law on intellectual property were introduced, taking into account the TRIPS flexibilities. See, for example, **http://zdorovie.akipress.org/news:19576**

- CSOs should draw the attention of different stakeholders to the issue of exorbitant prices through publications in the mass media, pressurizing pharmaceutical companies to reduce prices.

- CSOs should push the governments to disclose prices, volumes and other important parameters of the treatment programs to enable evaluation by independent experts.

- CSO representatives should be part of the supervisory boards/committees within the national treatment programs.

- CSOs can take part in discussions and/or initiate consideration of the question of joint procurement of drugs, including HCV drugs, in order to achieve price reduction, *e.g*. within the Customs Union.

In the countries of the region, HCV treatment guidelines lag behind WHO, AASLD and EASL guidelines in terms of treatment regimens. Some countries have not yet adopted HCV treatment guidelines.

- In the countries where HCV treatment guidelines are not available, CSOs should pressurize the respective government bodies and academic societies to initiate the process of guidelines development and implementation.

- Representatives of CSOs should seek opportunities for engaging in the work of national committees responsible for HCV guidelines development; CSOs should also ensure interests of key populations, such as PWID, are taken into account, when developing the guidelines.

- CSOs should closely monitor updates in the guidelines of the leading international healthcare organizations and, wherever appropriate, advocate revision of the national guidelines.

- CSOs of the EECA region should participate in advocacy activities related to the revision of WHO guidelines.

Donor-driven HCV projects have contributed to launching government programs in at least two countries of the region (Ukraine, Georgia).

- CSOs should consider including HCV testing and treatment components into their proposals, primarily with a focus on key affected populations, but also taking into account the needs of the general population.

- Best practices of CSO-led HCV testing and treatment programs should be document-ed and disseminated throughout the EECA region and at the international level.

ANNEX 1. COUNTRY PROFILES

Armenia

Prevalence: 4% (about 120 thousand).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 305 per PEG-IFN vial.

National program: data not available.

Clinical guidelines: data not available.

Donor-driven programs: data not available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access.

Potential areas of activities[75]: raising the HCV issue in general, raising the issue of the lack of reliable statistics, pilot testing and treatment programs, registration of second-generation DAAs and working towards price reduction, national HCV treatment guidelines, initiating the development of the national plans for viral hepatitis with inclusion of HCV prevention and treatment programs, taking into account the needs of key populations.

Azerbaijan

Prevalence: 3.2% (about 300 thousand).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 205 per PEG-IFN vial, from USD 2,700 per 12 weeks of sofosbuvir treatment.

National program: launched in 2015, includes PEG-IFN/RBV; no data is available on the coverage and funding.

Clinical guidelines: 2009, to be updated with inclusion of DAAs.

Donor-driven programs: no data available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): generic sofosbuvir registered.

[75] Hereinafter the list is not exhaustive

Potential areas of activities: scaling up the national HCV treatment program, taking into account the needs of key affected populations, engagement of CSO representatives into its implementation, inclusion of second-generation DAAs (sofosbuvir) into the national program, revision of the HCV treatment guidelines, in particular with participation of CSOs, registration of other second-generation DAAs and efforts to reduce prices for drugs.

Belarus

Prevalence: 2-3% (about 250 thousand).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 86 per PEG-IFN vial.

National program: patients under 18 years of age receive treatment free of charge.

Clinical guidelines: 2006.

Donor-driven programs: data not available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access.

Potential areas of activities: raising the issue of HCV in general, initiating development of the national viral hepatitis prevention and treatment program (with focus on HCV), taking into account the needs of key affected populations with participation of CSOs, revision of HCV treatment guidelines with participation of CSOs, registration of second-generation DAAs, efforts to reduce prices for drugs, and overcoming patent barriers, if necessary.

Georgia

Prevalence: 6.7% (about 200 thousand).

Current treatment standard: SOF/PEG-IFN/RBV within the national program.

Treatment cost: free of charge within the national program.

National program: implemented since 2014.

Clinical guidelines: 2011, to be revised in 2015.

Donor-driven programs: Global Fund, since 2011.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): available (sofosbuvir, planned sofosbuvir/ledipasvir within the national program).

Potential areas of activities: maximum expansion and improvement of the national program, taking into account the needs of key affected populations with participation of CSOs, inclusion of other combinations of DAAs (sofosbuvir/daclatasvir) into the national program, revision of the national HCV treatment guidelines with involvement of CSOs.

Kazakhstan

Prevalence: 1.5-3% (255-510 thousand).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 97 per PEG-IFN vial.

National program: since 2010, treatment is provided free of charge within the current laws (about 1,000 patients annually).

Clinical guidelines: 2015.

Donor-driven programs: limited corporate donations.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): simeprevir registered.

Potential areas of activities: registration of second-generation DAAs and efforts to reduce prices for drugs, overcoming patent barriers, if necessary, inclusion of second-generation DAAs into the national treatment program.

Kyrgyzstan

Prevalence: 4% (about 220 thousand).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 230 per PEG-IFN vial.

National program: implemented since 2012, but does not cover treatment.

Clinical guidelines: 2015, not approved as of the date of report preparation.

Donor-driven programs: diagnostics within the GF programs.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access, the country is included into Gilead and BMS access programs.

Potential areas of activities: inclusion of HCV prevention and treatment components into the national program, in particular for key affected populations, efforts to register second-generation DAAs (in particular within the existing license agreements) and include DAAs

into the national treatment program, using the opportunities offered by patent laws to scale up access to drugs.

Moldova

Prevalence: 1.7-4% (60-142 thousand people).

Current treatment standard: PEG-IFN/RBV.

Treatment cost: registered prices start from USD 95 per PEG-IFN vial.

National program: available, with coverage of around 300 patients a year, yet no accurate data is available.

Clinical guidelines: 2012.

Donor-driven programs: no data available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access.

Potential areas of activities: expansion of the national treatment program, registration of new DAAs, inclusion of DAAs into the national treatment program, efforts to reduce prices for drugs, overcoming patent barriers, if necessary, to scale up access to drugs, revision of the national HCV treatment guidelines

Russia

Prevalence: 4% (5-5.8 million).

Current treatment standard: PEG-IFN/RBV, for genotype 1 triple therapy with the use of DAAs is recommended.

Treatment cost: from USD 88 per PEG-IFN vial, from USD 10,000 to 15,000 for a treatment course with DAAs in the commercial market and within treatment programs.

National program: at least USD 50 million allocated from various sources to procure drugs.

Clinical guidelines: 2014.

Donor-driven programs: no data available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): registered daclatasvir, asunaprevir, ombitasvir/paritaprevir/ritonavir + dasabuvir, simeprevir. Limited amounts are procured within various treatment programs.

Potential areas of activities: initiating the development of national plans for viral hepatitis with inclusion of HCV prevention and treatment programs, taking into account the needs of key affected populations, facilitating approval of the register of HCV patients, registration of new DAAs and efforts to reduce prices for them, overcoming patent barriers, if necessary, to scale up access to drugs.

Tajikistan

Prevalence: no data available (3.8 – prevalence in Central Asia)

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 200 per PEG-IFN vial (including RBV).

National program: no data available.

Clinical guidelines: 2014 Russian guidelines are used.

Donor-driven programs: no data available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access, the country is included into Gilead and BMS access programs.

Potential areas of activities: raising the HCV issue in general, raising the issue of the lack of reliable statistics, piloting HCV testing and treatment programs, initiating discussions on the development and adoption of the national viral hepatitis prevention and treatment program (with a focus on HCV), registration of new DAAs (in particular, within the existing license agreements), efforts to reduce prices for drugs.

Ukraine

Prevalence: 3% (1.2 million), according to some sources prevalence of anti-HCV up to 12%

Current treatment standard: PEG-IFN/RBV, sofosbuvir (within the GF program), the use of sofosbuvir within the national program is being discussed.

Treatment cost: from USD 60 for PEG-IFN vial, sofosbuvir is provided free of charge to a limited number of patients within the GF grant, the cost of triple therapy with first-generation DAAs (telaprevir) starts from USD 10,000 in the commercial market

National program: since 2014.

Clinical guidelines: 2014.

Donor-driven programs: GF-supported program run by the International HIV/AIDS Alliance in Ukraine.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): sofosbuvir is available within the GF-supported program run by the International HIV/AIDS Alliance in Ukraine.

Potential areas of activities: scale up of national and regional programs with engagement of key affected populations, inclusion of new DAAs into the national treatment program, registration of new DAAs and reduction of prices for the drugs, overcoming patent barriers, if necessary, revision of the national HCV treatment guidelines, expansion of diagnostic and treatment program for key affected populations with support of international donors.

Uzbekistan

Prevalence: 6.5% (about 1.8 million), according to some sources prevalence of anti-HCV of up to 13.1%.

Current treatment standard: PEG-IFN/RBV.

Treatment cost: from USD 280 per PEG-IFN vial.

National program: no data available.

Clinical guidelines: 2013.

Donor-driven programs: no data available.

Access to second-generation DAAs (sofosbuvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir, dasabuvir): no access or limited access, the country is included into the Gilead and BMS access programs.

Potential areas of activities: raising the HCV issue in general, piloting HCV testing and treatment programs, initiating discussions on the development and adoption of the national viral hepatitis prevention and treatment program (with a focus on HCV), registration of DAAs (in particular, within the existing license agreements), efforts to reduce prices for drugs, revision of the national HCV treatment guidelines.

Quotations:

Aibar Sultangaziev, Partner Network, Kyrgyzstan:

“Nobody at all has access to free treatment in Kyrgyzstan. The situation may be reversed only with a national hepatitis program. So far, a working group has been established at the Ministry of Health to develop such a program, which will hopefully include free treatment for children, PLHIV and other most vulnerable populations”.

Aleksandrs Molokovskis, Association HIV.LV, Latvia

“The current situation with only 75% compensation of the cost of pegylated interferon is not normal. We are very satisfied with the government decision to allocate additional target

funding in the amount of EUR 4 million, staring from 2016, to reimburse for the cost of HCV drugs and hope that the Parliament will approve this decision. We also hope that the Ministry of Health will use this money to cover treatment with innovative effective medicines, but, at the same time, we would like to express our concern that even the expected introduction of 90% reimbursement of the cost of those drugs will not better the lot of the patients significantly due to the high prices".

Dmitry Proskurnin, Together Against Hepatitis, Belarus

"The access to hepatitis C treatment in Belarus is very low. The prices are very high, and if we talk about the "new" drugs, only boceprevir and telaprevir are available. What should be done to change the situation? First of all, we need to have a patient register so that we understand how many people need treatment and so that this issue is made public. Also, it is important to have a member of the patients' community as an observer in the commission for hepatitis at the Ministry of Health, so that we could inform people and make comments on all questions and solutions".

Sergey Biryukov, NGO "AGEP'C (ANTIGEPAPTIT'C)", Kazakhstan

The program of free HCV treatment has been implemented in Kazakhstan since 2010, with an average of 1,000-1,200 people receiving treatment annually, which is clearly not enough to ensure the comprehensive coverage of all HCV patients with treatment. It is estimated that the HCV prevalence in Kazakhstan may range from 1.5% to 3%. First of all, it is necessary to eliminate all restrictions on allocation of state budget funds to provide treatment to all people in Kazakhstan living with HCV within the guaranteed volume of free medical aid. All divisions to determine the priority in treatment based on the stage of fibrosis should be eliminated, which will also reduce the corruption component in allocation of the expensive HCV drugs. Registration of new HCV treatment drugs and their introduction into the national guidelines should be accelerated. Permanent negotiations should be held with the producers of new, original HCV drugs on scaling up access to treatment, in particular through early access, clinical studies, humanitarian programs, and also through reducing the cost of produced drugs. Simultaneously, efforts should be undertaken to register the generic forms of HCV drugs in the country.

Ludmila Maistat, International HIV/AIDS Alliance in Ukraine

"The role of civil society in scaling up the access to HCV treatment is paramount. The civil society not only initiates awareness-raising campaigns, it also offers testing and treatment services, showing an example to the Ministry of Health. To eliminate the epidemic, all stakeholders should unite their efforts. Governments should develop HCV treatment programs and guidelines in line with the WHO recommendations, allocate the necessary funds to implement prevention, testing and treatment programs, and also take the necessary steps to provide treatment to all those who need it, in particular using TRIPS flexibilities. Pharmaceutical companies, from their side, should not capitalize on the epidemic – they should reduce prices for their drugs and should not delay their registration".

ANNEX 2. USEFUL RESOURCES

HCV Treatment Guidelines:

1. Guidelines for the screening, care and treatment of persons living with hepatitis C infection. World Health Organization.
2. Recommendations for Testing, Managing and Treating Hepatitis C. American Association for The Study of Liver Diseases.
3. Recommendations on Treatment of Hepatitis C. European Association for the Study of the Liver Diseases.

Policy Documents:

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

Scientific Research

6. 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.
7. 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:

8. HCV Pipeline Report. By Treatment Action Group.
9. New Treatments for Hepatitis C virus: Strategies for Achieving Universal Access. By MdM.
10. Nobody Left Behind. The Importance of Integrating People Who Inject Drugs Into HCV Treatment Programmes. MdM and INPUD.
11. 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/
12. 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
13. Pills cost pennies, greed costs lives. First Hepatitis C Virus World Community Advisory Board Report.
14. Minutes of the meetings of the Eastern European and Central Asia Community Advisory Board. http://eeca-cab.org/en/
15. Eurasian Harm Reduction Network. Current Situation Regarding Access to Hepatitis C Treatment in Eastern Europe and Central Asia
16. Access to Drugs for Treating HCV in Russia in 2013. International Treatment Preparedness Coalition in Eastern Europe and Central Asia.