Alliance for Public Health

ITPC ru
Международная коалиция по готовности к лечению
Восточная Европа и Центральная Азия

AllianceCentre
for HIV, Hepatitis C and Drug Use

ACCESS®
HCV TREATMENT

UNITE TO ELIMINATE hepC
KNOW IT, TEST IT, TREAT IT




HEPATITIS C

# Hepatitis C in Eastern Europe and Central Asia

## Civil Society Response to the Epidemic

**Authors:** Ludmila Maistat, Sergey Golovin, Nataliya Kravchenko, Tatyana Khan, Kseniya Babikhina.

**Reviewers:** Denis Godlevskiy (AIDS Healthcare Foundation), Karyn Kaplan (Treatment Action Group), Pauline Londeix (Access), Antons Mozalevskis (WHO Regional Office for Europe), Aleksandrs Molokovskis (Society "Association HIV.LV"), Dasha Ocheret (Eurasian Harm Reduction Network), Graham Shaw (independent consultant), and Raminta Stuikyte (independent consultant).

**Acknowledgements:**
We would like to thank the following people, without whom this overview would have been impossible: Akmal Aliyev (Community of People Living with HIV, Uzbekistan), Anait Arutiunyan (NGO Armenian Network of Positive People), Tatyana Barnard (ICF Alliance for Public Health), Stela Bivol (PAS Center, Moldova), Sergey Biryukov (NGO AGEP'C, Kazakhstan), Pascal Boulet (Medicines Patent Pool), Kiromiddin Gulov (Equal Opportunities CSO, Tajikistan), Pulod Jamolov (NGO SPIN plus, Tajikistan), Yuliya Dragunova (Treatment Preparedness Coalition, Russia), Ihor Kilchevskyi (League of People Living with HIV, Moldova), Sergey Kondratiuk (All-Ukrainian Network of PLWH), Aleksandr Kurashov (Positive Initiative, Moldova), Saida Mamedli (Research Institute of Obstetrics and Gynecology, Baku, Azerbaijan), Zulfia Mustafaeva (NGO Legal Development and Democracy, Azerbaijan), Ehtiram Pashaev (NGO To Fight AIDS Azerbaijan), Dmitry Proskurnin (Together Against Hepatitis, Belarus), Paata Sabelashvili (independent consultant, Georgia), Rita Seicas (PAS Center, Moldova), Aibar Sultangaziev (Partner Network, Kyrgyzstan), Sergey Tolstolychenko (Youth for the Right to Life, Moldova), Ludmila Trukhan (Belarus NGO Positive Movement), Liudmyla Untura (league of People Living with HIV, Moldova), Kamila Fatyhova (Uzbekistan), Sergey Fillippovych (ICF Alliance for Public Health), Mari Chokheli (Open Society Foundation, Georgia).

**Disclaimer**:
The information contained in this report has been taken from public sources. The authors do not guarantee 100% accuracy of the data obtained from third parties and, likewise, might not share the opinions of third parties cited in this report. The authors do not carry any responsibility for the use or interpretation of data, conclusions and recommendations presented in this report by third parties. The conclusions and recommendations contained in this report express the points of view of the report authors which might not coincide with views held by other interested parties. This document will be regularly updated. The authors reserve the right not to publicly announce all changes made to the document. The current version of the document is available on the websites http://www.aph.org.ua and itpcru.org (http://itpcru.org/2015/04/22/12505/).

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. 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.

Updated: June 2016. Comments can be sent to: tatyana.khan@itpcru.org, Maistat@aph.org.ua, kravchenko@aph.org.ua, kbabikhina@itpcru.org.

**Recommended citation:** Hepatitis C in Eastern Europe and Central Asia. Civil Society Response to the Epidemic, Alliance for Public Health, International Treatment Preparedness Coalition in Eastern Europe and Central Asia, June 2016.

**Translation**: the original Russian version of the report has been translated by the Alliance for Public Health. In case of discrepancies between the Russian and the English version the Russian version shall prevail.

**Abbreviations**

| | |
|---|---|
| Anti-HCV | HCV antibodies |
| ART | Antiretroviral Therapy |
| BMS | Bristol-Myers Squibb |
| CAB | Community Advisory Board |
| CSO | Civil society organization |
| DAA | Direct Acting Antivirals |
| EAPO | Eurasian Patent Organization |
| EECA | Eastern Europe and Central Asia |
| EECA CAB | Community Advisory Board in Eastern Europe and Central Asia |
| EHRN | Eurasian Harm Reduction Network |
| 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 |
| NGO | Non-governmental organization |
| 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

NPV – narlaprevir

OMB – ombitasvir

PEG-IFN – pegylated interferon

PTV/r – paritaprevir/ritonavir

RBV – ribavirin

SMV – simeprevir

SOF – sofosbuvir

SOF/LDV – sofosbuvir/ledipasvir

TPV – telaprevir

# Table of Contents


Introduction and Background ..... 6

Introduction ..... 6

Background ..... 6

Methodology ..... 10

HCV Epidemic Data ..... 11

Registration and Pricing for HCV Drugs ..... 16

Registration ..... 16

Prices ..... 20

HCV Drugs Access Policy and Intellectual Property Rights ..... 27

HCV Treatment Guidelines ..... 32

National and Donor-Driven HCV Treatment Programs ..... 35

EECA Civil Society Involvement in HCV Work ..... 40

Findings and Suggestions Regarding Civil Society Involvement in HCV Work in EECA ..... 47

Key changes in comparison with the previous edition of the report (summer–autumn 2015) ..... 47

Key conclusions with recommendations ..... 47

Quotes about Access ..... 51

ANNEX 1. USEFUL RESOURCES ..... 53

# Introduction and Background

## *Introduction*

The purpose of this report is to provide an overview of 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. It is essential that this analysis is available to ensure that the EECA region is not left out of global strategies being developed to provide universal access to innovative curative treatment regimens currently in the pipeline.

The overview summarizes data from 11 EECA countries (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine and Uzbekistan) with a focus on availability of 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*

According to the latest estimates of the World Health Organization (WHO), about 80 million people worldwide live with chronic viral hepatitis C (HCV), while 110 million people have antibodies to HCV. This figure is significantly lower than that reported earlier (130–150 million) which, in WHO experts' opinion, is due to the improvement of HCV test quality (fewer false positive results), as well as a decrease in HCV morbidity.

However, the HCV epidemic continues to have a huge detrimental effect on public health. According to study data, 700,000 people worldwide die each year of HCV-related diseases[1]. Countries in Eastern Europe and Central Asia together account for approximately **11.3** million people living with antibodies to HCV (6.8 and 4.5 million in each region respectively), and about 6.6 million people with chronic hepatitis C (4.7 and 1.9 million respectively; viremia levels of 69% and 43% respectively)[2]. The estimated HCV prevalence in Eastern Europe and Central Asia is **3.3%** and **5.4%** 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

[1] Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Updated version, April 2016, p.11. http://apps.who.int/iris/bitstream/10665/205035/1/9789241549615_eng.pdf?ua=1

[2] Ibid, p. 19

[3] Ibid, p. 19

[4] European Harm Reduction Network. Current situation regarding access to hepatitis C treatment in Eastern Europe and Central Asia. 2013. Available 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] Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, p.24.

low CD4 count[7]. The EECA region has relatively low ART coverage of 21% according to UNAIDS[8], which aggravates the risks associated with HCV for PLHIV.

The issue of HCV has recently received considerable attention globally. Below is a brief summary of achievements in this area over the course of the last 2–3 years.

**Change in the treatment paradigm.** For a long time the standard of care was 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, and hard-to-tolerate side effects. 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, the first of which were registered in 2013, have significantly increased cure rates as compared to PEG-IFN/RBV and PI/PEG-IFN/RBV regimens. In clinical trials, combinations of these drugs have led to cure rates of up to 100%, 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 DAA-based regimens are much easier to administer and monitor. In fact, the industry is developing so fast that first-generation DAAs (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.

Currently about 10 DAAs of three classes (polymerase inhibitors, protease inhibitors and NS5A inhibitors) are registered in the world, including fixed-dose combinations. Among them are sofosbuvir, sofosbuvir/ledipasvir, sofosbuvir/velpatasvir, daclatasvir, simeprevir, ombitasvir/paritaprevir/ritonavir/dasabuvir (dasabuvir and ombitasvir/paritaprevir/ritonabir are also registered separately), grazoprevir/elbasvir, asunaprevir, and narlaprevir. In the nearest future a few more medicines that have proved highly effective in clinical trials are to be registered.

**Guidelines for Screening, Care and Treatment of Persons with Hepatitis C Infection were released by WHO in 2014 and updated in April 2016.** The guidelines are intended mainly for policy-makers; government officials; specialists responsible for developing programs for screening, care and treatment of persons with HCV infection, and healthcare providers. The guidelines focus on low and middle-income countries. In spring 2016 the guidelines were updated to account for new data on DAAs.

Among those who contributed to development of the first version of the guidelines were representatives of CSOs working in the field of treatment access, including Treatment Action Group, the International Network of People Who Use Drugs (INPUD), Médicins du Monde (MdM), Women and Harm Reduction International Network, World Hepatitis Alliance, and Médicins Sans Frontières (MSF).

Among CSOs from the EECA region were representatives of the International HIV/AIDS Alliance in Ukraine (now Alliance for Public Health) and Eurasian Harm Reduction Network (EHRN).

[7] Ibid.

[8] http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/factsheet

[9] Overview of the trials is available, for example, in the report by Treatment Action Group. Available online at: http://www.pipelinereport.org/

**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 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 involvement of civil society in all aspects of preventing, diagnosing and treating viral hepatitis. In addition, member states were encouraged to consider the use of different administrative and legal tools (in the form of laws, decrees, etc.) to expand access to treatment.

**Global Strategy for Viral Hepatitis.** In May 2016, the 69th session of the World Health Assembly was held, which adopted the first Global Strategy for Viral Hepatitis, setting the goal to eliminate viral hepatitis B and C till 2030.

For the countries who signed the Strategy it means commitment to eliminate hepatitis B and C till the end of 2030, including 90% diagnosed cases of chronic hepatitis C and 80% people covered with HCV treatment. Besides, the Strategy includes targets in the area of harm reduction and using safe injecting equipment. Thus, WHO recommends distributing sterile needles and syringes among people who inject drugs in the amount of 300 pieces a year per one drug user – target up to 2030. It is suggested to use safer injecting equipment, which should cover 90% of all injections performed both in healthcare institutions and in community settings. Opioid substitution treatment is included to the text, but there are no quantitative targets set forth in this area so far. It is also important to mention HBV vaccination, with the coverage of 90% till 2030, including vaccination of newborns. Representatives of MSF, TAG, EHRN, Alliance for Public Health and other organizations took part in the activities of the WHO Strategic and Technical Advisory Committee for Viral Hepatitis, which was in charge of developing the Global Strategy. The experience of implementing treatment programs piloted by Alliance in EECA was taken into account when preparing recommendations of the Global Strategy.

In September 2016, it is planned to present the WHO action plan on viral hepatitis in the European region in 2016-2021 for approval at the 66th session of the WHO Regional Committee for Europe. The action plan is developed by the Advisory Committee comprising of the representatives of governmental authorities of WHO member states, civil society, and organizations implementing research in the area of viral hepatitis. The action plans are based on recommendations defined in the Global Strategy. The main goal of action plans' approval is to ensure specific suggestions and actions to implement the objectives of the Global Strategy at the country level. Draft plans have been developed, taking into account best practices and expertise of the countries, leading elimination of hepatitis C in the region.

**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) include HCV testing and treatment components. In the EECA region, the most notable examples of GF-funded HCV projects are in Ukraine and Georgia. 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 HCV-related

[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

projects supported by UNITAID mainly cover Ukraine, with OSF and Aids Fonds funding HCV-related advocacy activities in Georgia, Kyrgyzstan, Russia and Ukraine.

**Pricing for new hepatitis C drugs has been widely discussed by various stakeholders.** For a number of years, the exorbitantly high prices for PEG-IFN have been 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 US 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 USD 84,000 for 12 weeks of therapy in the US[12]. This price did not include the cost of additional medicines to be taken in combination with sofosbuvir (PEG-IFN, ribavirin or other DAAs depending on the regimen).

Such exorbitant pricing provoked a wave of publications in influential international media. This attracted attention and led to discussions among politicians and decision-makers about pricing issues and actions to be taken in this regard, such as a US Senate hearing on the price of sofosbuvir (Sovaldi)[13]. Many publications were initiated by CSOs who have been at the vanguard of the fight for affordable HCV drugs. Different coalitions and alliances have been established, one of the most prominent being the HepCoalition which unites, among others, Treatment Action Group, International Treatment Preparedness Coalition (ITPC), Médicins du Monde, Médicins sans Frontières, and the Alliance for Public Health. Largely due to vigorous pressure from civil society, prices for DAAs have started to decrease. The price for a 12-week treatment course of generic DAAs manufactured by Indian, Egyptian, Pakistani or Bangladeshi companies starts from about USD 500. This tendency towards price decrease on the commercial market and governmental programs can be observed in the EECA region as well.

The HCV agenda has been largely driven by CSOs which have not only engaged in service provision but initiated changes in the regulatory framework and adoption of strategies and operational plans on international, national and local level. CSOs have worked on development and registration of newer drugs, drug price reduction, implementation of treatment programs, guideline development and introduction, increased funding, etc. The EECA region has not been an exception, with a number of organizations contributing to global activities and carrying out work on regional, national and local level. Achievements in the field of HCV in EECA (treatment coverage expansion through increased awareness about HCV issues; access to new drugs; the launch of treatment guidelines, government and donor programs, and so on) serve as a solid platform for future work 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 this overview have been collected through questionnaires sent to CSO representatives in 11 countries of the EECA region (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Ukraine, Russia and Uzbekistan). In the sections related to drug registration and pricing, some references are made to the Baltic States of Estonia, Latvia, and Lithuania.

When collecting data, the task was to see what kind of information about selected elements of the HCV epidemic response is available and can be used by CSOs in their advocacy activities. The questionnaire included 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 to obtain more detailed information. Respondents were also asked to provide a brief description of HCV work carried out by CSOs at national and local level, with a focus on advocacy.

The respondents are CSO representatives with experience in the field of hepatitis and HIV advocacy and research (1–3 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 journals, mass media, etc.).

The data collected were mainly from January–June 2016; some information may already be outdated by the time of publication.

To harmonize prices for HCV drugs, an average exchange rate (USD – local currency) was used for 2016 based on calc.ru, except for cases when respondents quoted USD price data.

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

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 identify priority areas for future HCV work by 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 Epidemic Data

As mentioned above, according to WHO data there are about 11 million people living with antibodies to HCV in EECA countries, and about 6.6 million people with chronic viral hepatitis C (the average prevalence of chronic HCV is about 2.3% according to WHO data). Among the countries covered by the report where statistics are available, the highest reported HCV prevalence is in Georgia (7.5%), and 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] (2.1 million). Considering the maximum figures, the total estimated number of people with HCV in 11 countries covered by the research may be up to 12 million, with about half of them living in Russia and 80% in three countries (Russia, Uzbekistan and Ukraine). These data correlate with the anti-HCV prevalence data used by WHO in the current HCV treatment guidelines. In separate studies focused on Ukraine and Uzbekistan, higher prevalence data are used (see notes to the table).

Table 1 below also contains information about HCV prevalence among two groups at high risk of HCV: PWID and PLHIV. The figures for HCV prevalence among PWID are up to 70–95% (Belarus), 74% (Georgia), 69% (Russia), 65% (Moldova), and 62.8% (Azerbaijan). In some countries, the available information indicates a high prevalence of HCV among HIV-positive people (80% in Kyrgyzstan, 58% in Azerbaijan, and 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 on estimates made by experts or government officials. 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 establishment of adequate national 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 under research, only CSO representatives in Kazakhstan received from the Ministry of Health detailed information about the registered number of people with chronic HCV infection. According to media reports, Russia is currently launching a registry of patients with viral hepatitis, containing detailed clinical data including estimates of the stage of fibrosis, coinfections, and required treatment. But to the authors' knowledge, such a registry has not been finalized as of this overview's 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 | Population data for 2016 | Prevalence (%) | Estimated number of people living with HCV (or HCV antibodies) |
|---|---|---|---|
| **Armenia** | 2,994,400 | 4.0% | **120,000** |
| | As per data of the National Statistical Service of the Republic of Armenia, 01.04.2016 http://www.armstat.am/ | Interview with the hepatologist of the National Infectious Diseases Clinic: https://www.youtube.com/watch?v=d556US-dyuE | Official data are lacking or unavailable |
| **Azerbaijan** | 9,705,600 | 3.2% | **300,800** |
| | As of 2016 http://www.stat.gov.az/source/demography/ap/indexen.php | Estimated number based on the population size and assumptions | Chief Gastroenterologist of Azerbaijan, 2013. According to the Ministry of Health, there were 181 people registered with hepatitis C in 2013. |
| **Belarus** | 9,498,700 | 2.0–3.0% | **250,000** |
| | As of 01.04.2016 National Statistical Committee of Belarus http://www.belstat.gov.by/ | 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 |
| **Georgia** | 3,720,400 | 7.5 % | **208,800** |
| | As of 01.01.2016 http://geostat.ge/index.php?action=page&p_id=473&lang=eng | HCV Seroprevalence Survey in Georgia. National Center for Disease Control and Public Health | Ibid. |
| **Kazakhstan** | 17,753,200 | 1.5–3.0% | **255,000–510,000** |
| | As of 01.05.2016 http://www.stat.gov.kz | MoH data | 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) |
| **Kyrgyzstan** | 6,019,500 | 4% | **About 220,000** |
| | As of 01.01.2016 http://www.stat.kg/ru/statistics/naselenie/ | "Overview of the situation with viral hepatitis C in Kyrgyz Republic", Association "Partner Network", 2015 (unpublished) | Ibid. According to official statistics, in 2014 there were 3,023 registered HCV cases |

| Country | Population data for 2016 | Prevalence (%) | Estimated number of people living with HCV (or HCV antibodies) |
|---|---|---|---|
| **Moldova** | 3,553,100 | 1.7–4.0% | **60,000–142,000** |
| | As of 01.01.2016<br>http://www.statistica.md/newsview.php?l=ru&idc=168&id=5156 | Respondents | National Centre for Health Management, 2012, official number: 9,411 |
| **Russia** | 146,544,710 | About 4% | **5.9 million** |
| | as of 01.01.2016<br>according to Rosstat data | Report of the International Treatment Preparedness Coalition<br>http://itpcru.org/2015/08/03/lechenie-gepatita-s-v-rf-staroe-novoe-nedostupnoe/ | Rospotrebnadzor Reference Center of Viral Hepatitis Monitoring |
| **Tajikistan** | 8,547,000 | 2.3%* | **About 200,000** |
| | As of 01.01.2016<br>http://www.stat.tj | * No official data, estimated prevalence in Central Asia | |
| **Ukraine** | 42,708,647 | 5%[16] | **2,135,400** |
| | As of 01.04.2016<br>http://www.ukrstat.gov.ua/ | No official data, MOH operates using WHO estimated data | Estimated data: http://moz.gov.ua/ua/portal/pre_20140728_d.html; clinical guidelines |
| **Uzbekistan** | 31,575,300 | 6.5%[17] | **1,800,000** |
| | As of 01.01.2016<br>http://www.stat.uz/statinfo/demograficheskie-dannye | 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 large scale treatment access programs in developing countries. Clin Infect Dis. 2014 Apr;58(7):928-36. doi: 10.1093/cid/ciu012 | |
| **TOTAL (maximum figures)** | | | **11,787,000** |

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%.

## Table 2. Estimated HCV prevalence among PWID and PLHIV in 11 EECA countries, data of separate studies

| Country | Estimated HCV prevalence/burden among PLHIV | Estimated prevalence/burden among PWID | Key risk groups |
|---|---|---|---|
| **Armenia** | 17.89% (of all registered PLHIV, 3.9% prevalence among PLHIV as of the time of report drafting) | 52.1% | Migrants, PWID |
| | Based on National AIDS Center data (as of late 2015) | Behavioral and Biological Research in the Republic of Armenia, 2014, only Yerevan data | |
| **Azerbaijan** | 58.8% | 62.8% | PWID |
| | UNGASS 2012–2013 Global AIDS Response Progress Report | Respondent | Respondent |
| **Belarus** | n/a | 70–95% | PWID |
| | | 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** | 48% | 57–74% | PWID, MSM, medical staff |
| | Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC), 2011, 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** | 44.86% | % n/a, 6,049 people | |
| | Ibid (based on the number of registered HIV+ cases) 7284 of 16,318 people living with HIV in Kazakhstan | Ibid. | |
| **Kyrgyzstan** | 80% | 45.2% | |
| | Ibid. | Ibid. | |

| Country | Estimated HCV prevalence/burden among PLHIV | Estimated prevalence/burden among PWID | Key risk groups |
|---|---|---|---|
| **Moldova** | 45.6% | 35.3–65.4% | PWID |
| | Respondent | IBBS 2012 has been done in 4 sites, through respondent-driven sampling | |
| **Russia** | At least 27% | 69% | PWID |
| | At least 200,000 registered patients; according to 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** | 25.6% | 22.7–49.3% | PWID |
| | 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** | n/a | 55% | PWID; patients with hemophilia, patients on hemodialysis, MSM, PMTCT |
| | | Alliance for Public Health data http://www.aidsalliance.org.ua/ru/library/our/2014/arep14/zvit%20IDU_obl_eng.pdf стр. 15 | According to Standardized clinical protocol approved in 2014 |
| **Uzbekistan** | n/a | 36% | Medical staff, PWID, patients undergoing invasive procedures |
| | | Epidemiological surveillance of 2007, indicated by the respondent | |

* Hereafter Kazakhstan data are represented by the AGEP' C (ANTIGEPAPTIT'C) foundation.

# Registration and Pricing for HCV Drugs

## Methodology

Drug registration data in the EECA is mainly taken from state pharmaceutical registers. If these resources are unavailable, additional information was received via patient organizations operating in specific countries.

Data are mostly taken from government programs (marked as GP in Table 3) and drug registries (marked as R in Table 3), or refer to the commercial sector (marked as C in Table 3). Prices in donor programs are cited in the section *HCV Treatment Programs*.

As a reference, country gross national income (GNI) per capita as per the classification of the World Bank is cited. Prices refer to the period of May–June 2016. Wherever possible, the source of information is provided so that CSOs can update 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 (such as “buy one, get one free”). These pricing policies have not been analyzed. 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 June 2016 (unless other time period is specified) given at calc.ru, or at the rate used by country representatives. Exchange rates are indicated below the table.

### *Registration*

**It was found in the course of the study that as of June 2016 certain DAAs are registered in most countries of the region.** Moreover, drugs allowing provision of interferon-free treatment are registered in at least 8 of 11 countries covered by the study. The authors note considerable progress in the number of registered DAAs as compared to autumn 2015.

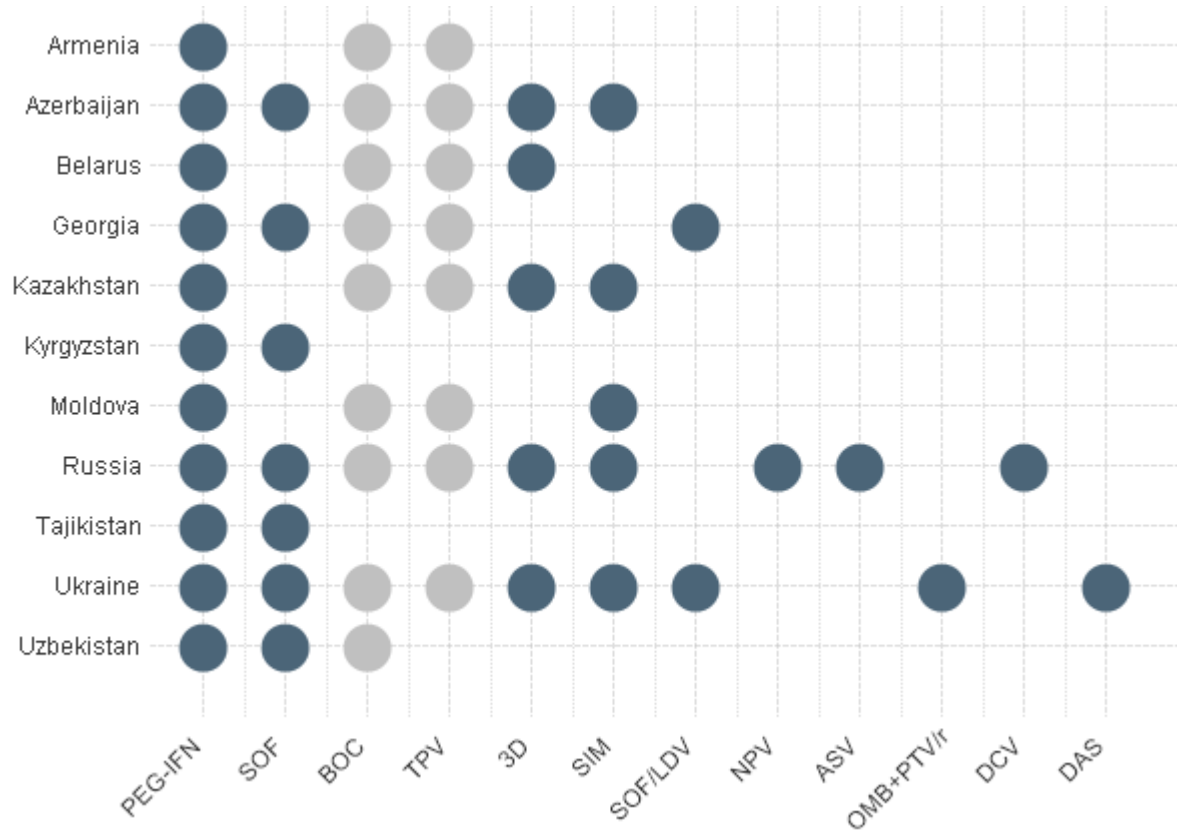



*Figure 1. HCV DAAs accessibility in EECA countries*

## Sofosbuvir

**Recommendations: EASL, AASLD, WHO**
Sofosbuvir, which is the basis of most treatment regimens (Sovaldi or generic), is registered in at least seven countries of the EECA region covered by the study: Azerbaijan, Georgia, Kyrgyzstan, Russia, Tajikistan, Uzbekistan, and Ukraine.

## Sofosbuvir/ledipasvir

**Recommendations: EASL, AASLD, WHO**
Combined drug sofosbuvir/ledipasvir (Harvoni) is registered in at least two countries (Georgia and Ukraine). At the moment of report writing, in Kyrgyzstan an application has been submitted for registration of both original and generic drug. In Kazakhstan, the drug is also undergoing registration, according to the respondent.

## Daclatasvir

**Recommended: EASL, AASLD, WHO**
Daclatasvir (Daclinza), in combination with sofosbuvir forming a universal regimen to treat HCV genotype 1-6, is registered in Russia as of the moment of report writing. In Kyrgyzstan, an application for the generic version has been submitted.

In early 2016 drug manufacturer Bristol-Myers Squibb signed an agreement with the Medicines Patent Pool (MPP) allowing manufacture and sale of generic daclatasvir without royalty payments in 112 low-income countries, including three EECA countries: Georgia, Azerbaijan and Ukraine.

### Asunaprevir

**Recommended: not mentioned**
Asunaprevir (Sunvepra) from Bristol-Myers Squibb, recommended for use together with daclatasvir to treat HCV genotype 1, is registered in Russia as of the moment of report update.

### Ombitasvir; paritaprevir; ritonavir and dasabuvir

**Recommended: EASL, AASLD, WHO**
The combination of ombitasvir, dasabuvir, paritaprevir and ritonavir (Viekira Pak) is registered in at least five countries of the region (Azerbaijan, Belarus, Kazakhstan, Russia and Ukraine). Separate combinations of this drug, Viekirax and Exviera, are registered in Ukraine. In Belarus these drugs are available on the market through a special permission from the Ministry of Health. According to patient organizations, these drugs were imported in a limited quantity according to a decision of the Ministry of Health after a petition was made.

### Simeprevir

**Recommended: EASL, AASLD, WHO**
As of the moment of report update, simeprevir is registered in at least five countries of the region: Azerbaijan, Kazakhstan, Moldova, Russia, and Ukraine. In Ukraine, despite registration and presence in the national guidelines, the drug remains unavailable and is not used for HCV treatment in clinical practice. In Uzbekistan, the drug is available through a humanitarian aid program.

### Narlaprevir

**Recommendations: not mentioned**

Narlaprevir (Narlaprevir, manufacturer R-Pharm) was registered in Russia in May 2016. narlaprevir is recommended for treatment of HCV genotype 1 and must be used only in combination with pegylated interferon, ribavirin and ritonavir.

### Telaprevir and boceprevir

**Recommendations: not recommended as preferred options**

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. According to information from partner organizations, these drugs are not actually used for HCV treatment anymore and are absent from the commercial market in most of the countries (Azerbaijan, Armenia, Belarus, Russia, Ukraine).

### Pegylated interferon (peginterferon)

**Recommended in combination with DAAs only.**
Peginterferon is accessible in all surveyed EECA countries. In addition to the original drugs (Pegasys, PegIntron), biosimilar versions or an innovative cepeginterferon alpha-2b (Algeron)

are available in most countries of the region. In Ukraine at least six trade names of different types of peginterferon are registered, in Moldova and Russia, four drugs are registered. It should be noted that in some countries the registered trade names are actually unavailable. For example, cepeginterferom alpha-2b (Algeron) is registered in Armenia and Kyrgyzstan but absent from pharmacies at the time of report writing.

### *Biosimilar versions of DAAs*

Access to biosimilar forms of second generation DAAs was also analyzed (at the time of report writing generic versions were available only for sofosbuvir, sofosbuvir/ledipasvir and daclatasvir). DAAs (both brands and generics) are registered in at least seven countries of the region, with generics officially registered in at least five countries (Azerbaijan, Kyrgyzstan, Tajikistan, Uzbekistan and Ukraine).

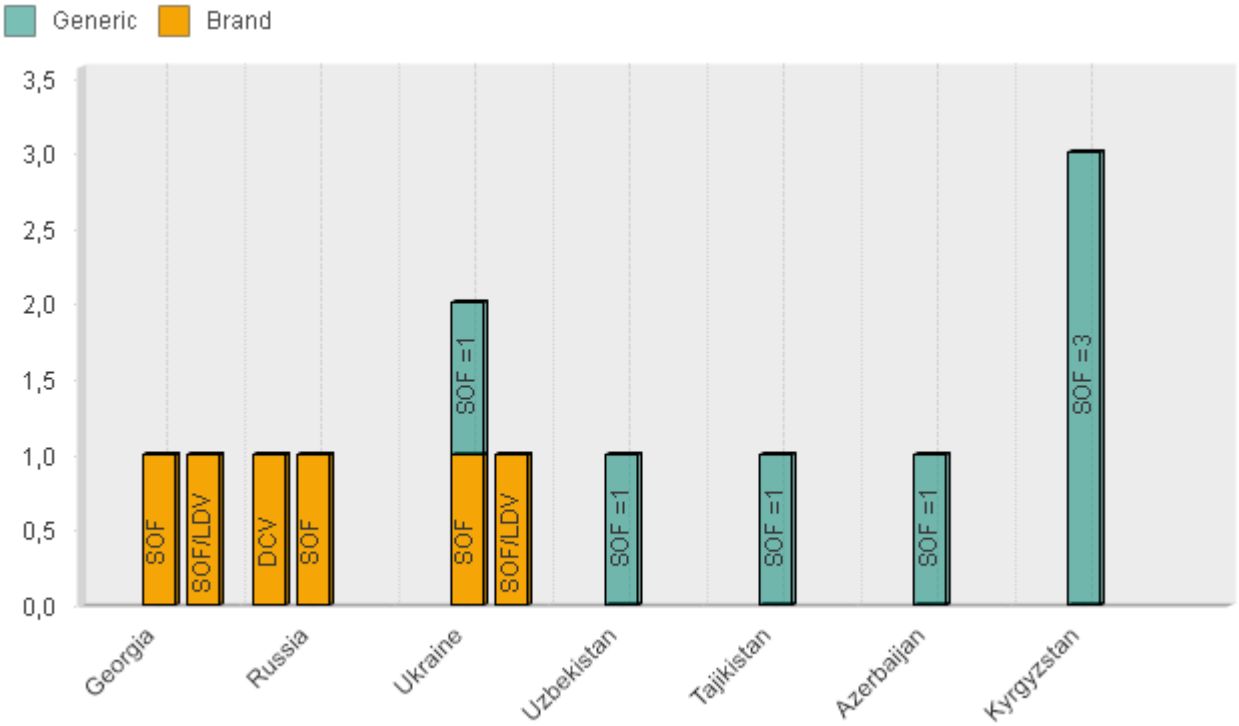



*Figure 2. Generics and original drugs in EECA countries. Second generation DAAs*

## Market for unregistered DAAs imported for personal use

From late 2015 to early 2016 in the EECA region a so-called "buyers' club" rapidly developed for generic DAAs (sofosbuvir, sofosbuvir/ledipasvir, daclatasvir) mainly originating from India and Egypt. based on CSO information, patients prefer to take personal responsibility for purchasing drugs in India or Egypt and import them for personal use because of their relatively low price. Information about such purchase of generics was received from Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia, Uzbekistan, and Ukraine. Despite the market availability of registered drugs, direct procurement of generics from India and Egypt continues. This is because the registered price for DAAs is higher than the price of generics imported for personal use from Egypt and India. For example, the difference between the registered price for generic sofosbuvir in Uzbekistan and the price in India is up to USD 150 per bottle. The situation in Ukraine is the same (see Prices section below).

## *Prices*

### Antivirals

The analysis demonstrates considerable differences in prices for DAAs in the countries of the region. The highest prices for DAAs were observed in the Baltic States. Thus, the maximum price of sofosbuvir in Lithuania (original drug Sovaldi) is USD 74,304 for a 12-week treatment course (USD 24,768 per bottle). The price of combination drug sofosbuvir/ledipasvir (Harvoni) in Latvia is USD 73,041 per 12-week course (USD 24,347 per bottle). Within national HCV treatment programs or HCV treatment programs implemented with donor support (Georgia and Ukraine), sofosbuvir is available free of charge. For Russia the price of the original drug is unknown at the moment of report writing because it is not yet registered in the country. If we compare prices for simeprevir which has no generic version, in Estonia the registered price is USD 12,181 per one package (USD 36,543 per 12-week course), in Russia it is USD 3159 per 1 package and USD 9,477 per 12-week course, and in Moldova, USD 8,469 per package and USD 25,407 per 12-week course.

The highest price for the combination of ombitasvir, paritaprevir, ritonavir and dasabuvir is registered in Baltic countries. In Estonia the combined price for the combination of all these drugs is USD 17,175 per 1 package (USD 51,525 per 12-week course). In Belarus the cost of this combination is USD 5583 per package (USD 16,749 per course).

The generic version of sofosbuvir is much cheaper. In Uzbekistan the sofosbuvir price is USD 275 per bottle (USD 825 per 12-week course), in Kyrgyzstan it costs from USD 260 (USD 780 per 12-week course), in Ukraine USD 935 (USD 2805 per 12-week course), while in Azerbaijan it costs USD 600 (USD 1800 per 12-week course).

The price of sofosbuvir on the market of *unregistered drugs imported for personal use* is USD 130 per bottle in Uzbekistan; supply to Ukraine and Belarus costs from USD 155 per bottle. In Ukrainian pharmacies Hepcinat drug is promoted at prices from USD 400 per bottle.

The price of generics supplied to Russia is presented below. It is important to note that the actual price may differ from the supply prices to other EECA countries in connection with complicated import procedures and other factors.

| Drug | Price per package, $ | Country | Manufacturer |
|---|---|---|---|
| **Sofosbuvir** | 150–220 | INDIA | Hepcinat NATCO, MyHep MYLAN, Sofovir HETERO, etc. |
| | 180 | EGYPT | Grateziano, European Egyptian Pharm Inc., Sofolanork, Mash, etc. |
| | $3200 per 1 kg | CHINA | |
| **Daclatasvir** | 110–130 | INDIA | Natdac, NATCO, DaclaHep, HETERO, etc. |
| | 70 | EGYPT | Daclavirocyrl, Marcyrl, Daclanork, Mash, etc. |
| | $4000 per 1 kg | CHINA | |
| **Sofosbuvir/ledipasvir** | 310–390 | INDIA | Ledifos, HETERO, Hepcinat LP, NATCO, MyHep LVIR, MYLAN, etc. |
| | 180 | EGYPT | Heterosofir, Pharmed HealthCare |

## Pegylated interferon

Pegylated interferon prices also significantly depend on the region. The lowest price for a biosimilar peginterferon 48-week course is USD 3,038 (Alfapeg 80 mcg, Ukraine). In Russia the minimum peginterferon price is about USD 3,456 per 48-week course (Algeron, 80 mcg).
On average, the range of registered prices for the original drug Pegasys, 180 mcg, in the EECA region is USD 5,700–2,600 per 48-week course, and Pegintron 120 mcg costs USD 5300–13,300.

As noted above, registered prices may not necessarily reflect prices on the commercial market.

Importantly, the prices above do not include ribavirin. Ribavirin, according to several country representatives (Tajikistan, Kazakhstan, Azerbaijan, Armenia), 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 from USD 250 up to almost USD 3,500.

As a conclusion on price dynamics, it is first of all important to note the significant price decrease for DAA regimens in a number of EECA countries in comparison to 2015, due to introduction of generics. Peginterferon prices are also decreasing, although at a slower pace. In general, despite this tendency, current prices on the commercial market and in governmental programs generally remain very high compared to GNI per capita and average income level in the countries. According to interviews in the countries studied, the main method of gaining access to new, highly efficient DAAs is to purchase generics not registered in the countries and import them for personal use.

## Table 3. Registration and prices in USD for HCV drugs in EECA countries

| INN | Armenia | Azerbaijan | Moldova | Georgia | Uzbekistan | Tajikistan | Kyrgyzstan | Kazakhstan | Belarus | Ukraine | Russia | Estonia | Latvia | Lithuania |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **GNI (USD)** | **4020** | **7600** | **2650** | **4490** | **2090** | **1080** | **1250** | **11850** | **7340** | **3560** | **13220** | **-** | **-** | **-** |
| PEGINF-ALPHA-2a Pegasys 180* | 171–213 (C) | 208 (R) | 154 (R) | n/a | 121 (C) | n/a | 183 (C) | 161 (GP) | 225–266 (C) | 127.1 (R), 180 (C) | 151 (GP) | 263 (R) | 219 (*) | 203 (*) |
| 135 mcg | | 196 (R) | 126 (R) | | 112 (C) | | | | 191–226 (C) | 92.22 (R), 156,5 (C) | n/a | 212 (R) | 196 (*) | |
| 90 mcg | | 128 (R) | 83 (R) | | | | | | | 93.74(R), 145l.91 (C) | n/a | | 156 (*) | |
| PEGINF-ALPHA-2a (biosimilar) | | | n/a (Optipeg, Pegnano) | | | | | | | 131.3 (R), 160 (C) – PEGFERON | | | | |
| PEGINF-AlPHA-2b (Pegintron) | 150–252 (C) | | | 0 (GP) | | | | | | | | | | |
| 50 mcg | | 122 (R) | n/a | | 100 (C) | | | 152 (GP) | 124 (C) | 133 (R), 147(C) | 151 (GP) | 113 (R) | 102 (*) | 91 (*) |
| 80 mcg | | 159 (R) | 194 (R) | | n/a | | | 156 (GP) | 112 (C) | 134 (R), 88.3 (C) | 139 (GP) | 177 (R) | 162 (*) | 145 (*) |
| 100 mcg | | 167 (R) | n/a | | 197 (C) | | | 188 (GP) | 112 (C) | 138 (R), 88.l21 (C) | 146 (GP) | 220 (R) | 203 (*) | 182 (*) |
| 120 mcg | | 277(R) | n/a | | n/a | | | 212 (GP) | 112 (C) | 139 (R), 89.15 (C) | 146 (GP) | 263 (R) | 243 (*) | 217 (*) |
| 150 mcg | | 349 (R) | n/a | | n/a | | | | 136–180 (C) | 143(R), 90.1 (C) | 151 (GP) | 325 (R) | 304 (*) | 217(*) |
| PEGINF-ALPHA-2b (biosimilar) | | | Peginferon-RUS | | | | | | | Sylatron, Unitron, AlfaPeg* | PegAltevir | | | |
| 50 mcg | | | n/a | | | | | | | | 160 (R) | | | |
| 80 mcg | | | | | | | | | | 63.31 (R), | 146 (GP) | | | |
| 100 mcg | | | n/a | | | | | | | 65.7(R), 91.45 (C) | 149 (GP) | | | |
| 120 mcg | | | | | | | | | | 68 (R), 88.54 (C) | 129 (GP) | | | |
| 150 mcg | | | | | | | | | | 71.4 (R), 97.59 (C) | 144 (GP) | | | |
| CePEGINF-Alpha-2b (Algeron) | n/a | | | n/a | | | n/a | n/a | | | | | | |
| 80 mcg | | | | | | | | n/a | n/a | | 72 (GP) | | | |
| 100 mcg | | | | | | | | n/a | 81 (C) | | 78 (GP) | | | |
| 120 mcg | | | | | | | | n/a | 83 (C) | | 89 (GP) | | | |
| 160 mcg | | | | | | | | n/a | 87 (C) | | 110 (GP) | | | |
| 200 mcg | | | | | | | | n/a | 91 (C) | | 89 (GP)* | | | |
| RBV | | | | 0 (GP) | | n/a | 15,79 (C) | | | | | | | |

| INN | Armenia | Azerbaijan | Moldova | Georgia | Uzbekistan | Tajikistan | Kyrgyzstan | Kazakhstan | Belarus | Ukraine | Russia | Estonia | Latvia | Lithuania |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| RBV (Copegus)<br>168 tablets | 21*4=84 (C) | | 53 (R) | | 8*4=32 (C) | | | | n/a | 43.35 (R), 39.1 (C) | n/a | 850 (R) | | 825 (C) |
| RBV (Rebetol)<br>140 tablets | 84 (C) | | 292 (R) | | 38 (C) | | | | n/a | 55 (R), 68 (C) | 68 (R) | 711 (R) | | 900 (C) |
| RBV (generic) | | | | | 24 tablets – 3 (C) | | | 30 tablets – 0,1 (R) | 30 tablets 4 (C) | 30.57(R), 38 (C) * Virorib (100 tablets) | 60 tablets – 13 (R) | | | |
| BOC (Viktrelis)<br>336 tablets 200 mg | n/a | n/a | n/a | n/a | n/a | | | n/a | n/a | 2035(R), 1770 (C) | 1160 (GP), 1067 (C) | 3718 (R) | n/a | 4 344 (C) |
| TPV (Incivo)<br>168 tablets 375 mg | 1694*4= 6776 (C) | n/a | 2143*4= 8571 (R) | n/a | | | | n/a | n/a | 898.05*4=3592.2 (R), 3938 (C) | 3158 (R) | n/a | 12 568 (C) | 9635 (*), 11008 (C) |
| NPV (Narlaprevir)<br>100 mg | | | | | | | | | | | n/a | | | |
| SMV (Olisio/Sovriad)<br>28 tablets 150 mg | | 2667 (C) | 8469 (R) | | | | | n/a | | 7630.52 (C) | 3159 (R), 3031 (C) | 12 181 (R) | 12 065 (C) | 18 576 (C) |
| SOF (Sovaldi)<br>28 tablets 400 mg | | | | 0 (GP) | | | | | | 0 (GF) | n/a | n/a | 21 701 (C) | 24 768 (C) |
| SOF (Hepcinat, Sofgen, Grateziano, Virso)<br>28 tablets 400 mg | | 600 (C) | | | 275 (C) - Virso | Virso | 260,315,450 (C) | | 1 kg – 25000$, API - Ruyuan Hec Pharm Co. Ltd., China | 1000 (R), 935.l7 (C) – Grateziano | | | | |
| SOF/LDV (Harvoni)<br>28 tablets, 400 mg/90 mg | | | | 0 (P) | | | Application for original and generic | | | 0 (GF) | | n/a | 24 347 (C) | 30 186 (C) |
| DSV (Daclinza)<br>28 tablets, 60 mg | | | | | | | Application for generic | | | | 1789 (GP), 1855 (C) | n/a | n/a | n/a * |
| ASV (Sunvepra)<br>56 tablets 100 mg | | | | | | | | | | | 179 (GP), 196 (C) | | | |
| 3D (Viekiera Pak)*<br>112 tablets (56+56) | | 5000 (C) | | | | | | n/a | 9000* | n/a | 4427 (GP), 4968 (C) | | | |
| DAS (Exviera)<br>56 tablets | | | Application | | | | | | 447 (C) | n/a | | 1386 (R) | 1 617 (C) | 1 717 (C) |
| OMB+PTV/r (Viekirax)<br>56 tablets | | | Application | | | | | | 5136 (C) | n/a | | 15 789 (R) | 18 549 (C) | 19 450 (C) |

*The countries where the drugs in question are registered are marked in green. 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 1 package; prices for ribavirin are given for 1 package.
* For Lithuania, the price for Pegasys 180 mcg 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 mcg and 180 mcg 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 mcg is stated subject to purchase of a set of 4 vials + Rebetol 200 mg, 140 pills. For antivirals, the maximum price offered in pharmacies is stated.
*For Ukraine the price for generic Peginterferon alpha 2-b is indicated for Alfapeg. 3D drug is registered under the trade name Vimvi, DAS – Virelakir, OMB+PTV/r – Vilvio.
*For Belarus the price for Viekiera Pak is given as stated during registration.
*Info about DCV in Lithuania has been obtained directly from BMS http://eeca.cab/2016/07/04/voprosy-ot-vetsa-kaba-k-kompanii-bms-iyun-2016-goda/

## Sources of information:

| Country | Registration | Prices |
|---|---|---|
| **Armenia** | http://www.moh.am/?section=static_pages/index&id=585 | Private sector prices, communication with the country representative; no information could be accessed online |
| **Azerbaijan** | pharma.az<br>Communication with country representative | - http://www.tariffcouncil.gov.az/documents/DVA.pdf<br>- Communication with country representative |
| **Moldova** | http://nomenclator.amed.md/, interviews with country representatives | http://amed.md/ |
| **Georgia** | www.mis.ge | - Communication with country representative |
| **Uzbekistan** | http://www.med.uz/<br>Communication with country representative | Communication with the country representative; no information could be accessed online |
| **Tajikistan** | Communication with the country representative and mailing list information; no information could be accessed online itpcru@googlegroups.com | Communication with the country representative; no information could be accessed online |
| **Kyrgyzstan** | Communication with the country representative; no information could be accessed online | http://www.apteka24.kg/<br>Communication with the country representative |
| **Kazakhstan** | http://www.dari.kz/category/search_prep | http://www.sk-pharma.kz |
| **Belarus** | http://www.rceth.by/Refbank/reestr_lekarstvennih_sredstv/results | http://apteka.103.by/ (as of May 2016, website collects price proposals from different pharmacies, information is updated daily) |
| **Ukraine** | http://www.drlz.com.ua/ | Official register: http://www.moz.gov.ua/ua/portal/register_prices_drugs/ (as of 01.06.2016)<br>http://tabletki.ua/ |
| **Russia** | Register of registered drugs<br>http://grls.rosminzdrav.ru/Default.aspx | http://grls.rosminzdrav.ru/Default.aspx,<br>http://aptekamos.ru/apteka/<br>Communication with the country representative |
| **Estonia** | Register of registered drugs http://193.40.10.165/register/register.php?keel=eng&inim_vet=inim | www.sm.ee/sites/default/files/content-editors/eesmargid_ja_tegevused/Tervis/Ravimid/hinnakokkulepped_01.05.2016.xls |
| **Latvia** | Register of registered drugs<br>https://www.zva.gov.lv/?id=673&sa=673&top=334 | http://www.apvienibahiv.lv/docs/729/2015_dazadi/KZS_ARV_VHC_2016.xls<br>https://www.zva.gov.lv/?id=588&top=588&sa=111 |
| **Lithuania** | Register of registered drugs http://195.182.66.169:8080/idrug-public-app/search/mode/compensated.8 | http://www.vaistai.lt/ |

**Exchange rate**

| Country | USD/local currency |
|---|---|
| Armenia | 480 |
| Azerbaijan | 1.5. Information partially presented in USD |
| Moldova | 1.11 – EUR/USD prices in the register for certain drugs are indicated in Euro, for others in USD. Register date – 31.05.2016 |
| Georgia | 2.2 |
| Uzbekistan | Information presented in USD |
| Tajikistan | Information presented in USD |
| Kyrgyzstan | Information presented in USD |
| Kazakhstan | 330 |
| Belarus | 19,881 |
| Ukraine | 25.22 |
| Russia | 65.66 Average rate of May 2016 http://www.cbr.ru/ |
| Euro | 0.89 |

The pricing table does not include telaprevir and boceprevir containing regimens as they are practically excluded from clinical practice and are not recommended as preferred options. To calculate peginterferon prices the price for Pegasys 180 mcg was used which is the most popular in clinical practice according to information from patients and monitoring of state procurements.

## Table 4. Estimated prices for treatment regimens with registered DAAs in some EECA countries (projected out-of-pocket for patients)

| Course | Azerbaijan | Moldova | Belarus | Georgia | Russia | Uzbekistan | Latvia | Ukraine |
|---|---|---|---|---|---|---|---|---|
| **Simeprevir + PEG-IFN + RBV*, 12 (24 weeks)** | 2667*3+208*24= **12,992** | 8,469*3+174*24 = **29,664** | - | - | **9,338*** | - | - | - |
| **Sofosbuvir + PEG-IFN + RBV, 12 weeks** | 600*3+208*12= **4,296** | - | - | free of charge | - | 275*3+ 121*12+ 18*3 = **2,331** | 21918*3 +50*12+0 = **65,703** | free of charge |
| **Sofosbuvir + RBV, 24 weeks** | | - | - | - | - | - | - | - |
| **Ombitasvir/paritaprevir/ritonavir + dasabuvir, 12 weeks** | 5000*3 = **15,000** | - | 5,136*3+ 447*3= **16,749** | - | 4,427*3= **13,281** | - | - | - |
| **Sofosbuvir/ledipasvir, 12 weeks** | - | - | | free of charge | - | - | - | planned to be free of charge |
| **Sofosbuvir + simeprevir, 12 weeks** | 600*3+2667*3= **9,800** | - | | - | - | - | - | - |
| **Sofosbuvir + daclatasvir, 12 weeks** | 2667*3+208*24= **12,992** | | | | | | | |

*This price is relevant for the "Course to recovery" program if one purchases the combination of simeprevir and cepeginterferon-alpha-2b (Algern); ribavirin price is USD 182 (24 weeks).

# HCV Drugs Access Policy and Intellectual Property Rights

High prices are often caused by monopolies, due to existing patents giving companies an exclusive right to market their drugs. In the field of HIV, CSOs have long been actively working to eliminate barriers to access to treatment related to intellectual property rights (patents). Besides patent law optimization and introduction of mechanisms enabling countries to avoid patent barriers, priorities for CSOs have 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-week course of treatment[18].

The report authors carried out a brief analysis of voluntary licenses and other strategies of pharmaceutical companies to improve access to HCV treatment drugs in EECA. The analysis showed that only 5 out of 11 researched countries are covered with voluntary licensing agreements concluded between BMS and Gilead with the MPP and directly with generic manufacturers (see table below). Meanwhile, as the table shows, the coverage areas of these agreements do not fully overlap, while the original version of the BMS access program (not available on the company website anymore) regarding EECA countries coincided with the Gilead license coverage area.

In addition to voluntary licenses, it is necessary to also mention that Georgia runs a national program on HCV eradication (see section on National Treatment Programs). Moreover, two countries – Kyrgyzstan and Tajikistan – were included in the special MSD program of peginterferon-alpha price decrease (USD 40 per vial). It is important to note that Pegintron was not registered in Kyrgyzstan for a long time, even after the start of this program, and civil society representatives reiterated this fact during meetings with company representatives.

[18] Hill et al. Minimum costs for producing Hepatitis C Direct Acting Antivirals, for use in large-scale treatment access programs in developing countries. 2014. Translation available online at: http://itpcru.org/2013/07/16/dostup-k-novym-preparatam-dlya-lecheniya-gepatita-s-100-dollarov-za-kurs-realnost/

## Table 5. Voluntary licenses and programs offered by pharmaceutical companies to provide access to DAAs and PEG-IFN in EECA countries. May 2016.

| Country | Gilead[19] Voluntary license | BMS[20] | MSD, Pegintron (USD 40 per vial), 57 countries[21] |
|---|---|---|---|
| Armenia | No | No | No |
| Azerbaijan | No | Yes | No |
| Belarus | No | No | No |
| Georgia | No* | Yes | No |
| Kazakhstan | No | No | No |
| Kyrgyzstan | Yes | No | Yes |
| Moldova | No | No | No |
| Tajikistan | Yes | No | Yes |
| Russia | No | No | No |
| Ukraine | No | No | No |
| Uzbekistan | Yes | Yes | No |

In many countries CSOs are compelled to take vigorous action to remove patent barriers. CSOs in several countries have successfully opposed patents for a number of ARV drugs for treating HIV[22], as well as PEG-IFN for treating HCV[23]. There is now an active movement aimed at opposing patents for DAAs, mainly sofosbuvir which is the backbone of most preferred HCV treatment regimens.

In the EECA region legal objections to patents for antiviral drugs to treat HCV have been filed in Russia and Ukraine:

- In Russia, the Treatment Preparedness Coalition and the Charitable Foundation Humanitarian Action opposed a patent for a pro-drug form of sofosbuvir (RU2478104)[24]. As of the moment of report publication there have been two hearings in the Patent Dispute

[19] http://www.gilead.com/ /media/Files/pdfs/other/HCVGenericAgreementFactSheet.pdf

[20] http://www.medicinespatentpool.org/wp-content/uploads/MPP-HCV-License-Agreement-BMS-FINAL_Web_.pdf

[21] Protocol of the EECA CAB meeting with MSD in 2014, available online://eeca-cab.org/en/2010/05/06/merck-sharp-dohme/

[22] 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/

[23] 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

[24] http://itpcru.org/2015/05/20/obshhestvennye-organizatsii-osparivayut-patent-na-sofosbuvir-v-rossii/

Chamber (in January and March 2016). Based on the results of the hearings the chamber decided to uphold the patent validity. This decision will be challenged by patient organizations in court. Consequently Pharmasintez pharmaceutical company filed an objection to the same patent. The first hearing in the Patent Dispute Chamber is scheduled for September 2016.

- In Ukraine on April 30, 2015 the All-Ukrainian Network of PLWH submitted to Ukrpatent a legal objection to the application from Gilead №a201212444 («Nucleoside phosporamidates»). To date Ukrpatent has made two preliminary decisions to refuse issuing a patent based on remarks received from the applicant and repeated opposition from the network. The applicant's response to the current refusal is expected in late May 2016; the PLWH network is planning to submit another objection depending on the content of the response. Ukrpatent's final decision is expected by late summer 2016. In February and March 2016 the Network of PLWH submitted two more objections with regard to application No. a201403617 "Hepatitis C treatment ways"[25].

In addition to legal objections to patents or patent applications, CSOs can take other action to remove intellectual property barriers. The Treatment Preparedness Coalition submitted a request to the competent authorities to issue a compulsory license for sofosbuvir and other DAAs in Russia[26]. In Kyrgyzstan, largely due to CSOs, amendments were recently introduced into laws on intellectual property, taking into account the legal flexibilities of TRIPS[27], which were largely initiated because of the complicated situation with anti-hepatitis drugs.

To facilitate work on intellectual property rights and hepatitis therapy, WHO experts have recently prepared an analysis of patents for a number of DAAs which covers, inter alia, several EECA countries (Russia, Ukraine, Georgia). It also covers the patents of the Eurasian Patent Organization (EAPO)[28], which covers Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, and Turkmenistan. Moldova left the EAPO on April 26, 2012; since April 27, 2012 the agreement between the Government of Moldova and the EAPO is valid for legal protection of inventions on the territory of Moldova after denunciation of the Eurasian Patent Convention by the Republic of Moldova.

The results of this EECA analysis are summarized in Table 6 below, taking into account analysis of the EAPO site in May 2016, on which basis several updates were made to the table compared to the original WHO analysis. In addition, the table contains data about patents for PEG-IFN alpha-2a (Pegasys) and PEG-IFN alpha-2b (PegIntron) based on results of research carried out by the Initiative for Medicine, Access and Knowledge (I-MAK). In addition, it represents data received in the course of implementing a project on removal of patent barriers in the EECA region supported by Aids Fonds (Kazakhstan, Moldova), as well as data received directly from the All-Ukrainian Network of PLWH and the MPP.

25 Information received directly from the All-Ukrainian Network of PLWH

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

27 See, for example, http://zdorovie.akipress.org/news:19576

28 http://www.eapo.org/ru/

## Table 6. Patents and patent applications for DAAs[29] and PEG-IFN[30] in certain EECA countries, including the Eurasian Patent Organization (EAPO)

| Drug | EAPO | Georgia | Moldova[31] | Kazakhstan | Kyrgyzstan | Russia | Ukraine |
|---|---|---|---|---|---|---|---|
| ABT-450 | n/a | n/a | n/a | n/a | n/a | Issued patent RU2475494 C2 | Issued patent UA109532 |
| DCV | Issued: EA15756B1, EA17173B1, EA17348B1, EA018152B1 (supported for RF only (eapo.org)**: EA022303** (application EA201270555A1, supported for all EAPO countries and Moldova), application EA201390155A1 | Applications were not submitted according to the Agreement with MPP | See EAPO | See EAPO | See EAPO | Issued RU015756 + see ЕАПО | Lacking, the international application time has expired |
| DAS | Applications: EA201390128A1 и EA201390130A1 | n/a | n/a | n/a | n/a | Applications: RU2010114827A, RU2010114828A | Issued patent UA104995 |
| LDV | Issued: EA021974 (application EA201190259A1, supported for all EAPO countries and Moldova); applications EA201490853A1, EA201490854A1, EA201490588A1 | No applications submitted | See EAPO | See EAPO | See EAPO | See EAPO | Issued UA108610 (application UA201113524) UA201403617, UA201413049 |
| OMB | Issued EA 020031 (application EA201170401A1, supported for all EAPO countries and Moldova, except for Tajikistan); applications EA201300495A1, EA201291394A1, EA201390538A1 | n/a | See EAPO | See EAPO | See EAPO | See EAPO | Issued UA201103926 – patent № UA103052<br>Application: UA201305877<br>Application UA201300334 – patent issued UA105434;<br>Application UA201306152 – patent issued UA108904 |
| SMV | Issued: EA15131B1 (valid for Russia), EA12410B1 (currently valid for the territory of Russia and Kazakhstan), applications: EA201291042A1, EA201170456A1 | n/a | See EAPO | See EAPO | See EAPO | Issued RU2483067 C2, also see EAPO + applications: RU2011130895A, RU2012143977, RU2009132660A, | Application: UA201102963 |

[29] WHO analysis is available at: http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/

[30] I-MAK analysis is available at: http://essentialdrugpatents.com/hepcdatabase.php

[31] Information for Moldova and Kazakhstan is received within the framework of the project of the Treatment Preparedness Coalition on removal of IP barriers by the patient community, supported by Aids Fonds.

| Drug | EAPO | Georgia | Moldova[31] | Kazakhstan | Kyrgyzstan | Russia | Ukraine |
|---|---|---|---|---|---|---|---|
| | | | | | | RU2011139 325A | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| SOF | applications: EA201290988A1, EA201290993A1, EA201171417A1, EA201370186A1, EA201490588A1, EA201390576A1, EA201390133A1, EA201190110A1 | Applications not found | Applications: WO2013/040492 andWO2013/082003 | Applications: EA201490806; EA201171417; EA201290993; EA201370186; EA201490588; EA201490903; EA201290988 | n/a | Issued: RU2358979C2, RU2478104C2 , application: RU2012152811A | Applications: UA201212444, UA201311603, UA201405757, UA201306068A – issued secondary patent № UA110354, UA201301999A, UA201110568 – issued secondary patent UA110093 |
| PEG-IFN-alpha-2a | n/a | 1 patent | n/a | n/a | 1 patent | 3 patents | 1 patent |
| PEG-IFN alpha-2b | n/a | not found | n/a | n/a | Not found | Not found | Not found |

# HCV Treatment Guidelines

In order to determine the current world standard of care for HCV treatment, American Association for the Study of Liver Diseases (AASLD), European Association for the Study of the Liver (EASL) and WHO guidelines of 2016[32] were analyzed. It turns out that all these documents recommend regimens based on second-generation DAAs as preferred therapy options.

According to updated information, second-generation DAAs as priority interferon-free regimen options are recommended in the guidelines for Ukraine (updated version of 2015) and Kazakhstan (updated version of 2015). It is also important to note that in the current guidelines of these countries boceprevir and telaprevir are no more recommended as preferred therapy options, reflecting the latest recommendations of WHO, AASLD and EASL.

The guidelines in Russia (2014) recommend triple therapy using protease inhibitors as a standard for treatment of HCV genotype 1 (simeprevir, boceprevir and telaprevir), allowing the use of standard interferon in combination with ribavirin for the treatment of HCV genotypes 2 and 3 under certain conditions. The 3D regimen is recommended as a preferred option for treatment of patients with HCV/HIV co-infection according to the national HIV treatment guidelines.

In Georgia, the use of sofosbuvir in combination with PEG-IFN/RBV is stipulated in the national treatment program. The updated guidelines, according to the respondent, will include sofosbuvir and sofosbuvir/ledipasvir-containing regimens.

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

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

It is important to note that recently, due in part to the active work of NGOs, HCV treatment protocols in EECA countries are being updated. The latest guidelines are dated 2015 (Ukraine, Kazakhstan), while in 2016 updated guidelines are expected in Georgia, Azerbaijan, Belarus, Kyrgyzstan, and the Russian Federation.

In Ukraine, Kyrgyzstan and Kazakhstan (and possibly other countries) CSOs have also been included in expert committees responsible for development of guidelines. The practice of including CSOs working with patients and patient organizations into guideline expert panels is widely found at international level, in particular in WHO, AASLD, and EASL. Translation of the 2016 WHO guidelines for HCV treatment was prepared with participation of the Treatment Preparedness Coalition.

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

## Table 7. HCV guidelines in the countries of EECA

| Country | Name | Date | Key treatment schemes | Comments |
|---|---|---|---|---|
| Armenia | n/a | | | Only HIV/HCV co-infection guidelines available; adapted from WHO guidelines. According to information received from the respondent, WHO HCV guidelines are used. |
| Azerbaijan | Clinical Guidelines for the Treatment of HCV | 2009 | PEG-IFN/RBV<br>PIs as a future option | To be revised in 2016 to include DAAs |
| Belarus | | 2006 | PEG-IFN/RBV<br>No | According to the respondent, to be revised in 2016 |
| Georgia | | 2011 | PEG-IFN/RBV<br>SOF/PEG-IFN* (not in the 2011 guidelines) *(see comments) | Next revision is expected in 2016; sofosbuvir and sofosbuvir/ledipasvir will be included.<br>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, SMV/PEG-IFN/RBV; 3D is a recommended interferon-free regimen; BOC and TPV are no more preferred options | Recommended by the Expert Council of the Republican Center of Healthcare Development of the Ministry of Health and Social Development of the Republic of Kazakhstan dated December 10, 2015, Protocol No. 19 |
| Kyrgyzstan | Clinical Guidelines on Testing, Treatment and Prevention of Viral Hepatitis C in Kyrgyz Republic | 2014 | PEG-IFN/RBV;<br>Triple therapy (BOC/TPV)<br>SOF and SMV are mentioned | the document is currently unavailable, the new version will be published on the website www.med.kg |
| Moldova | Chronic Hepatitis C in Adults, National Clinical Guidelines | 2012 | PEG-IFN/RBV<br>Triple therapy; BOC or TPV | |
| Russia | Guidelines on Testing and Treatment of Hepatitis C in Adults | 2014 | Triple therapy IP/PEG-IFN/RBV for genotype 1, PEG-IFN/RBV<br>TPV, BOC, SMV; 3D is the preferred HIV/HCV treatment regimen according to HIUV treatment protocols. | After approval of the last version, such drugs as 3D, DCV, ASV, SOF, NPV have been registered. Guidelines are being updated. |

| Country | Name | Date | Key treatment schemes | Comments |
|---|---|---|---|---|
| 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 | 2015 | PEG-IFN/RBV, SOF/PEG-IFN/RBV, SOF/SMV, SOF/SMV/RBV, SMV/PEG-IFN/RBV: SOF/RBV (genotype 2 – 12 weeks, genotype 3 – 24 weeks); BOC and TPV are no more recommended as preferred options | Approved by Order of the MoH of Ukraine 04.11.2015 № 723 |
| Uzbekistan | Clinical Guidelines for Diagnostics, Treatment and Prevention of Chronic Hepatitis in Adults in Primary Healthcare | 2013 | PEG-IFN/RBV | To be revised in 2018 or upon emergence of new evidence |

## Links:

- Azerbaijan: http://isim.az/upload/File/reports/19_Hepatit_C.pdf
- Kazakhstan: http://online.zakon.kz/Document/?doc_id=32246498 (2014 version, 2015 version will be published shortly)
- Georgia - http://www.moh.gov.ge/files/01_GEO/jann_sistema/gaidlaini/gaidlain-protokol/105.1.pdf
- Kyrgyzstan – Order No. 479 dated 25.08.2014; updated version will be published on the website www.med.kg
- Moldova: http://old.ms.gov.md/_files/12490-PCN%2520HCV%2520C_31_07_2112_FINAL%2521.pdf
- Russia: http://rsls.ru/images/Рекомендации_по_диагностике_и_лечению_зрослых_больных_гепатитом_С.pdf
- Ukraine: www.dec.gov.ua/mtd/dodatki/2015_723VirysGepatitC/2015_723_YKPMD_vgC.doc

# National and Donor-Driven HCV Treatment Programs

According to respondents and data from open sources, national HCV treatment programs are being implemented in Ukraine, Russia, Georgia and Moldova.

Detailed information about the state program in Azerbaijan is unfortunately currently unavailable. According to the respondent and the media, patients receive Ukraferon and ribavirin within the program's framework.

Georgia launched a large-scale HCV eradication project in 2015. It envisages funding for diagnostics and service provision for patients with HCV, as well as procurement of PEG-IFN and ribavirin. Gilead provides sofosbuvir and sofosbuvir/ledipasvir within the framework of the state program. Priority is given to patients with F3–F4 stage fibrosis. From the second half of 2016 the second stage of the program will be launched, within the framework of which 20,000 patients will receive access to therapy during 10 years.

In Moldova the current National Program of Combating Viral Hepatitis B, C and D for 2012–2016 stipulates treatment of not less than 300 patients annually. Data on actual implementation of the program are not available.

In Ukraine under the operating State Social Program of Prevention, Diagnostics and Treatment of Viral Hepatitis till 2016 (approved in April 2013) treatment is planned for not less than 30% of people with viral hepatitis B and C. Alliance for Public Health in collaboration with the Ministry of Health works on developing the National Program for the period of 2017-2021. It is expected that the Program will be in line with the updated WHO guidelines and will take into account the main provisions and recommendations of the WHO Global Strategy for Viral Hepatitis.

In Kazakhstan, Belarus and Russia separate national programs for treatment of viral hepatitis are absent as such, but HCV therapy provision is regulated by separate legislative acts.

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

In Belarus HCV treatment is provided free of charge to persons under 18 according to Regulation 249 dated 21.02.2014.

In Russia HCV patients are provided with drugs mainly at the expense of the following sources: federal budget funds to provide medicines to separate categories of citizens; RF subjects' healthcare development programs; target programs for RF subjects' healthcare development, funds allocated within the framework of obligatory health insurance (OHI).

In Kyrgyzstan development of a new national program is underway which will include treatment for separate groups of patients, including PLHIV and children.

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

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

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

In Ukraine in 2015 ICF Alliance for Public Health launched a pilot program for HCV treatment with sofosbuvir with GF support, including free diagnostics and treatment for vulnerable groups. Participants of the first stage of the program were 93% PLWH, of whom 94% were on ART; 80% of patients were PWID, and 8% of them substitution therapy patients. A total of 15% of participants in the program's first stage had previous experience of failed treatment with 2-component PEG-IFN and ribavirin regimen. As of the end of May 2016 more than 780 individuals had obtained access to treatment, with cure rates of 92%.

According to information on the website of the Soglom Avlod Uchun foundation, in Uzbekistan in 2015 AmeriCares (USA) humanitarian cargo was supplied in the form of simeprevir antiviral to the amount of USD 8 million, which was fully handed over to the Virology Research Institute of the Ministry of Health of Uzbekistan. More detailed information is not available.

The total number of people who received HCV therapy in 2015 within the framework of different programs in 11 countries is roughly **up to 20,000** depending on the duration of the treatment course. Data on Russia are based on information on the amount of procured drugs and not actually provided treatment. It is also important to note that the data on Russia do not include people who received therapy with standard interferons which are still being actively used in clinical practice. In absolute numbers the most patients were treated in Georgia, Kazakhstan, Ukraine and Russia. **20,000 people is less than 1% of the estimated number of people with HCV in the countries of research.**

In terms of donor-driven HCV treatment programs, Ukraine has the largest HCV treatment components within grants supported by the GF. Since 2015 there has been a DAAs treatment program in the country for vulnerable groups, implemented by ICF Alliance for Public Health. The program is implemented in several stages engaging 19 health facilities. By the end of 2016 treatment is planned for not less than 1,500 patients, with expanded numbers of participants in 2017. HCV treatment has been integrated into already operational harm reduction programs with coverage of 270,000 clients. Prices for GF-funded procurement as a result of negotiations between the GF and pharmaceutical companies (for example, USD 2025 for a 12-week course of SOF/PEG-IFN/RBV within the Alliance for Public Health treatment program), served as a benchmark for the state treatment program in Ukraine. The advocacy efforts of Alliance and high efficiency of the treatment program allowed to include DAAs into the Unified Treatment Guidelines and the List of Drugs to be Procured within the National and Local Budgets.

## Table 8. National treatment programs in the countries of EECA

| Country | Title (or indicate whether it exists) | Amount | Number of people | Comment |
|---|---|---|---|---|
| Armenia | Absent | not allocated | 0 | 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 | Ukraferon, ribavirin drugs are provided within the national program |
| 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 | The state supports patients at hospitalization, providing two free PEG-IFN-alpha-2b, but the rest is provided at the expense of the patient |
| Georgia | State program on eradication of hepatitis operates from April 2015 | Total amount of funds envisaged within the framework of the state program, in particular, for procurement of HCV treatment drugs, is about LARI 20 million (for diagnostics, research and services, as well as procurement of ribavirin and interferons). Sofosbuvir and sofosbuvir/ledipasvir are provided by Gilead free of charge. | Priority treatment of patients with F3–F4. As of March 2016 about 6100 patients are treated within the program; free access to sofosbuvir, sofosbuvir/ledipasvir, pegylated interferon, ribavirin. In the second half of June 2016 launch of the second stage of the program is planned – 200,000 patients in 10 years. Annually 20 000 patients will gain access to therapy. Partial funding of diagnostics from local budgets is stipulated. | Link to the State HCV Program: http://www.moh.gov.ge/index.php?lang_id=GEO&sec_id=691 |
| | State program of testing, treatment, prevention in jails | n/a | In 2014–2015 about 400 persons obtained treatment at the expense of state program funds | - |
| Kazakhstan | A national hepatitis treatment program in the Republic of Kazakhstan is absent. Diagnostics and treatment are provided on the basis of the Constitution of RC, Art. 29, para. 2 on the right of citizens for a guaranteed amount of free medical assistance (GAFMA). The disease has a socially dangerous status. | Total scope of funds within the GAFMA, in particular, for HCV medicines: 2015 – 2938 million tenge; 2016 – 3435 million tenge. | 2015 – 1037 adults and 95 children; for 2016 treatment of 1247 adults and 80 children is planned. | - |
| Kyrgyzstan | State program is lacking, under development | 0 | n/a | - |

| | | | | |
|---|---|---|---|---|
| Moldova | National program to combat viral hepatitis B, C and D for 2012–2016 | Actual expenditures data are not available. The state compensates treatment at the expense of the national medical insurance office for 300 persons per year. | Annual provision of antiviral treatment for adults and children with chronic viral hepatitis and cirrhosis caused by viral hepatitis B, C and D – not less than 300 patients with viral hepatitis B, 300 – with viral hepatitis C and 100 – with viral hepatitis D. | For 2012–2016 LEI 720 000 000 are planned for the expenditure item "Detection, treatment and hospitalization of patients".<br>Link to the national program:<br>http://lex.justice.md/viewdoc.php?action=view&view=doc&id=342219&lang= |
| Russia | Funds for treatment and diagnostics are allocated from various sources | Total amount of funds spent for HCV medicines in 2015 is RUB 2,685,911,303.72. | Number of patients who could potentially have received treatment with a 48-week course of PEG-IFN in 2015 was 4885 persons or 10,000 for the 24-week course. 990 persons could have been treated with DAAs. | Data are based on official state procurement website monitoring |
| Tajikistan | National program is absent | n/a | n/a | Treatment is stipulated by Law of the RT "On public health protection" dated 22.04.2003 .No.19, dated 28.02.2004 no. 13, dated 28.12.2005 No. 138 ("all patients with infectious or viral diseases shall be entitled to free assistance and help in the respective medical facilities of the RT"). According to respondents, a separate law on hepatitis is being developed.<br>RT government decree dated 1.07.2011 No. 331 on approval of the list of work, fulfillment of which involves exposure to infectious diseases, including hepatitis: ensuring access to free testing, vaccination and treatment. MoH and Ministry of Social protection are the responsible implementers. There is also a regulation of the Ministry of Health and Ministry of Social Policy dated 27.12.2014, No.1119 "On the Prevention of Infectious Diseases", indicating prevention, diagnostics and treatment of HCV". |
| Ukraine | State Social Program of Prevention, Diagnostics and Treatment of Viral Hepatitis for the period to 2016, approved in April 2013. | Forecast amounts in the regulations of the Cabinet of Ministers of Ukraine for treatment and prevention for patients with viral hepatitis B and C in 2015 is UAH 398 516 400, in 2015 UAH 425 510 800.<br>Information about actual funding is not available. | Based on regional health departments' data for November–December 2015 treatment was provided to 1575 people at the expense of the state budget and to 83 persons at the expense of oblast budgets. In total 1658 persons. Treatment at the expense of oblast budgets and the state budget was provided to 157 PLHIV. | Resolution of the Cabinet of Ministers of Ukraine dated 29.04.2013 No. 637<br>http://zakon3.rada.gov.ua/laws/show/637-2013-n/page |
| Uzbekistan | n/a | n/a | n/a | - |

## Table 9. Donor programs in the countries of EECA

| Country | Donor | Amount, treatment and/or number of people | Comment |
|---|---|---|---|
| Armenia | Absent | 0 | |
| Azerbaijan | n/a | n/a | |
| Belarus | n/a | n/a | |
| Georgia | Gilead pharmaceutical company | Sofosbuvir and sofosbuvir/ledipasvir are provided free of charge for implementation of the state HCV program | For 20,000 patients in 10 years |
| Kazakhstan | Absent | 0 | |
| Kyrgyzstan | Global Fund | Free diagnostics for 8,000 persons annually | Funding is envisaged for diagnostics for PWID, SW, MSM in the GF grant for 2016–2017. Contracts are being concluded with private laboratories with regard to payment for diagnostics. |
| Moldova | Absent | 0 | |
| Russia | Absent | 0 | |
| Tajikistan | Absent | 0 | |
| Ukraine | Global Fund since 2015 | The program is implemented by ICF Alliance for Public Health. Within the framework of Stage 1 of the program (April 2015 to January 2016) treatment was provided to 450 patients. Within the framework of implementation of the second stage of the program as of May 1, 2016 782 patients obtained access to treatment in 19 health facilities. Selection of patients continues: in May–June 2016 another 360 persons are planned to be included in the project. | Diagnostics and treatment for representatives of vulnerable groups are provided free of charge. By the end of 2016 treatment of no fewer than1,500 patients is planned; in 2017 plans are to increase the number of program participants. HCV treatment component has been integrated into already operating harm reduction programs with total coverage exceeding 270,000 clients. |
| Ukraine | European Union, since 2015, project "Poltava region for IDPs" | Within the framework of a project for patients with HBV and HCV more than UAH 1.5 million is announced for implementation of the components of an oblast social program of hepatitis treatment. | |
| Uzbekistan | n/a | n/a | |

# EECA Civil Society Involvement in HCV Work

For several years, CSOs in EECA have been involved in tackling the HCV epidemic through policy making, patients' rights protection and service provision. Many have transferred their experience working in HIV and harm reduction to HCV. The section below summarizes and categorizes some implemented activities. All organizations implementing HCV projects are encouraged to share best practices through available communication channels (social media, mailing lists, etc.) and to ask international organizations such as WHO to document and share such practices. The activities below are grouped according to the following framework: awareness-raising, mobilization, advocacy, testing and treatment programs.

**Implementing projects aimed at raising awareness of HCV treatment access and changing policy in this field:**

- Initiating publications in the mass media to bring into focus various aspects related to HCV;

- Producing educational videos about various aspects of HCV, such as the importance of testing and treatment, and an overview of available new drugs;

- Organizing "patient schools" for people living with HCV on different clinical and legal aspects of treatment, including access issues;

- Organizing training for doctors and social workers for integration of efficient models of medico-social support for patients with HCV.

> 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. In 2015–2016 active work was carried out in the framework of a working group, including: development of new treatment protocols; training for doctors; awareness raising for people with HCV within "patient schools"; direct preparation of an HCV eradication program and treatment programs monitoring, etc.

- Organizing national public campaigns to draw public and decision makers' attention to gaps in the HCV response.

**In Ukraine,** in April 2015 ICF Alliance for Public Health launched a new treatment program using direct-acting antiretroviral sofosbuvir to treat vulnerable group representatives, achieving price reduction and creating a precedent of drug procurement at the price of USD 300 per package. Currently this price is the upper benchmark for sofosbuvir procurement at the expense of local and oblast budgets. Due to efficient cooperation between the Alliance and the MoH of Ukraine, and the effectiveness of the Alliance's treatment programs, sofosbuvir was included in the state register of pharmaceuticals and the unified guidelines on prevention, diagnostics and treatment of viral hepatitis in Ukraine, as well as the list of medicines which can be procured at the expense of oblast budgets and state treatment programs.
Within the framework of the all-Ukrainian advocacy campaign "We Demand Treatment!" in 2015 the Alliance held a national annual event on World Hepatitis Day. Testing was performed among the military personnel involved in the armed conflict in eastern Ukraine, soldiers who were mobilized and receiving treatment. In total 4,300 people were tested, with 3.9% of them receiving positive results. In the course of testing, TNS company carried out a sociological survey among those tested and discovered numerous risk factors for acquiring socially dangerous diseases among military personnel involved in the armed conflict in eastern Ukraine. This campaign gave momentum to cooperation between the Alliance and the Ministry of Defense of Ukraine to develop prevention of socially dangerous diseases in war conditions and provide treatment with DAAs to patients with HCV.

**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;
- Developing and implementing campaigns collecting signatures to demand better access to treatment.

**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;
- the level of funding allocated for HCV testing and treatment programs.

Several examples of research in the field of HCV in EECA countries are listed below[33]:

[33] This list is not exhaustive.

- 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[34];

- A report about the HCV epidemic in Russia by the Andrey Rylkov Foundation entitled, *"Hepatitis C in Russia: an Epidemic of Negligence"*[35];

- A report about the epidemic of HCV in Russia with a focus on procurement and provision of HCV drugs prepared by the Treatment Preparedness Coalition[36];

- A report about the HCV epidemic in Kyrgyzstan prepared by the Kyrgyz Harm Reduction Network, Partnership Network Association and Adilet Legal Clinic.

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

The practice of organizing 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 five regional meetings on HIV and HCV treatment access with the following companies: MSD, Janssen, AbbVie, Gilead, BMS, Biocad and Pharmasintez[37]. 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.

[34] http://www.harm-reduction.org/sites/default/files/pdf/hep_c_policy_brief_update_en_edited_3.pdf

[35] http://en.rylkov-fond.org/blog/hcv/hcvrus/

[36] http://itpcru.org/2016/07/14/mezhdu-proshlym-i-budushhim-analiz-gosudarstvennyh-zakupok-preparatov-dlya-lecheniya-gepatita-s-v-rf-v-2015/

[37] The minutes of the meetings are available online at eeca-cab.org

More than once, concerns have been voiced at the meetings of EECA CAB and by activists in the region that pharmaceutical companies owning the rights to boceprevir and telaprevir will delay registration and marketing of new drugs, trying to maximize profit from selling older medicines. This is what happened in Russia, when a 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 but simeprevir was not. 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. Through the activities of EECA CAB and open letters, activists opposed 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 or 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. Activities take the form of open letters and petitions, collecting signatures, flash-mobs on social media, street protests, etc.






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

**In Kyrgyzstan** representatives of the Partner Network organization are participating in writing the state HCV program, and advocating for writing and approving new treatment standards including DAAs based on the latest WHO recommendations. They actively cooperate with the media to draw attention to the problem of hepatitis and access to treatment in the country.

**Partnering with governments to develop national HCV strategies, programs and plans**. In Georgia and Ukraine, CSOs have actively advocated for and contributed to the development of national treatment programs. Similar activities are now happening in other countries of the region, including Moldova, Kyrgyzstan and Azerbaijan. 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[38].

**In Ukraine** ICF Alliance for Public Health within the framework of the "We Demand Treatment!" campaign conducts an annual event for World Hepatitis Day which includes general population testing for HCV, and distribution of information materials and discount coupons for laboratory diagnostics. Events are aimed at increasing popular awareness of the routes of HCV transmission and diagnostics and access to HCV treatment; attracting public attention to the problems of access to treatment, and encouraging the government to fund and integrate at national level a successful diagnostics and care model piloted by the Alliance among vulnerable populations.

The Patients of Ukraine organization (previously UCAB), conducted several events advocating for improvement of the HCV response in Ukraine. Among them the street protest "The Doomed" called on the government to approve a national treatment program.

**In Moldova** Positive Initiative organization together with a number of other patient organizations and networks carried out a protest in the form of a funeral ceremony for 300,000 people with HCV who fell victim to indifference and corruption in the system, according to activists. On July 28, 2014 more than 300 representatives of the League of PLWH and the Consultative Advisory Board of Patients in Moldova carried out a protest near Roche's office demanding that the company decrease the price for Pegasys.

**In the entire EECA** groups of patients in Armenia, Georgia, Kyrgyzstan, Latvia, Moldova, Russia and Ukraine held protests related to World Hepatitis Day (July 28), demanding that their governments provide access to treatment, and pharmaceutical companies decrease prices for drugs.

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

**Efforts aimed at overcoming patent barriers hindering access to HCV treatment.**

At stated above, CSOs in a number of EECA countries have already started taking action in this area. 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 laws on intellectual property, taking into account legal TRIPS flexibilities. Similar activities can be expected in other countries of the region where intellectual property issues may aggravate access to medicines (e.g., Belarus, Kazakhstan, Moldova, etc.)

**Implementing HCV testing, treatment and care projects with a link 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.

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

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

As a result of advocacy efforts, the Alliance for Public Health managed to reduce the price for PEG-IFN to USD 4,800 per 48 weeks of treatment and agree with the GF to allocate grant funds to purchase drugs for the first Ukrainian HCV treatment program, which enabled delivering services to 132 OST patients with HIV/HCV co-infection. This price was subsequently used as a benchmark for the government procurement program. In 2015, Alliance launched a sofosbuvir-based treatment program at the negotiated price of USD 900 per 12 weeks of treatment and agreed with the GF procurement of drugs for the first 250 patients. This became possible due to a significant decrease in the price for medicines as a result of negotiations between the Alliance and 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 existing harm reduction services run by Alliance with total coverage of over 270,000 clients. Based on results of the Alliance program's implementation, sofosbuvir was included in the nomenclature of medicines for viral hepatitis treatment and in 2016 the MoH, through the system of UNDP bidding procurements, managed to procure sofosbuvir for the treatment of patients within the framework of the state program.

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

## *Key changes in comparison with the previous edition of the report (summer–autumn 2015)*

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

- Generally, the prices for DAAs and pegylated interferon decreased, the DAAs prices mainly due to the introduction of generics; however, the average HCV therapy prices still remain high compared to the average income level and GNI;

- The number of people receiving treatment at the expense of the state programs remains very low in comparison to the estimated number of people living with HCV; meanwhile, the number of people receiving therapy in certain countries at the expense of the state and the donor programs (Ukraine) is increasing; the number of persons receiving DAAs is increasing;

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

- In a number of countries (Russia, Ukraine), civil society organizations started active work on opposing DAA patents.

## *Key conclusions with recommendations*

**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, data is based on the results of small-scale studies conducted several years ago. In a number of countries work on collection of relevant epidemiological information is underway (including Georgia, Russia and Ukraine).

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

- Implementing studies on HCV incidence/prevalence in key populations;

- 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 available data**.

- 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[39].

- 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 research among decision-makers.

- Work on including PWID into national HCV prevention and treatment programs and guidelines.

**The number of people treated within government programs is disproportionately small in relation to the total number of people living with HCV in the countries of research.** According to research results, treatment uptake is likely to be around 1% or less of the estimated number of people living with HCV. *Meanwhile, it is worth noting considerable increase in treatment coverage in percentage and absolute numbers in certain countries (Georgia, Ukraine)*.

- CSOs should advocate for 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.

**Access to DAAs in terms of registration of drugs in the EECA countries has considerably increased in comparison with 2015; however, there are countries where this access is limited.** Second generation DAAs (sofosbuvir, original or biosimilar), sofosbuvir/ledipasvir, simeprevir, 3D, daclatasvir, etc. are registered and used mainly in countries where HCV treatment programs of one sort or another are implemented, or where adoption of these programs is actively supported by the patient community (Kyrgyzstan). Work on initiating DAAs registration among the countries covered by this study should be intensified in Moldova, Armenia, Tajikistan, Uzbekistan and Azerbaijan. In EECA countries access to biosimilar HCV drugs has improved (analogues of pegylated interferons alpha-2a and 2b, as well as cepeginterferon alpha-2b).

- CSOs should regularly monitor drug registration landscape in countries and inform decision-makers of the results, also through mass media.

- CSOs should put pressure on pharmaceutical companies and governments to speed up registration of newer drugs. Such work can be conducted through the CABs described in the section above.

- CSOs should establish partner relations with leading international CSOs for implementation of projects aimed at opposing patent barriers to improve access to affordable and high quality generic/biosimilar drugs. These projects are already

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

implemented in several countries of the region, including Kyrgyzstan, Ukraine, Moldova, Kazakhstan, Georgia and Russia.

- CSOs should explore TRIPS flexibilities[40] to remove intellectual property barriers. CSOs can call on national governments to use these mechanisms or implement them independently[41]. Examples include opposing patents and pushing governments to issue compulsory licenses for the import or production of medicines.

- CSOs should negotiate with the respective bodies to establish favorable conditions to register biosimilar drugs retaining the proper quality control mechanisms.

**Due to the introduction of generic DAAs the prices for HCV therapy in a number of countries considerably decreased in comparison with previous years. However, prices for officially registered HCV drugs remain high compared to the average income level in the countries covered by this study. The key opportunity for patients to access DAAs is the market of unregistered drugs supplied for personal use.**

- CSOs should conduct regular monitoring of prices for HCV drugs in their own and other countries to identify the lowest prices and disseminate this information among the widest possible circle of stakeholders. 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.

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

- CSO representatives should be part of supervisory boards/committees within 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.

- 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 make sure that the possibility to import drugs not registered in the country for personal use based on medical indications is stipulated in laws and regulations.

**In a number of countries (Ukraine, Kazakhstan) HCV treatment recommendations are being approximated to the guidelines of the WHO, EASL and AASLD on HCV**

[40] 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.

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

**medicines. The same protocols contain recommendations on discontinuing the use of telaprevir and boceprevir. However, in some countries national HCV treatment guidelines are not approved or have not been updated for many years.**

- In countries where HCV treatment guidelines are not available, CSOs should put pressure on the respective government and academic bodies 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 the interests of key populations, such as PWID, are taken into account when developing guidelines.

- CSOs should closely monitor updates in the guidelines of leading international healthcare organizations and, where appropriate, advocate revision of 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). Active work on initiation of a similar program in Kyrgyzstan with the involvement of NGOs is being conducted.**

- 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 documented and disseminated throughout the EECA region and at the international level.

# Quotes about Access

**Aybar Sultangaziev, Partner Network, Kyrgyzstan:**



"Access to treatment is determined by several factors, including physical availability and economic affordability. Currently the physical availability of HCV medicines has greatly improved. Sofosbuvir manufactured in India or Egypt is available on the market. In the nearest future the registration of daclatasvir and sofosbuvir/ledipasvir will start, and then virtually all the range of newest medicines will be registered in the country. And the price is relatively affordable compared to other countries. Meanwhile, the state does not allocate funds for procurement of these medicines, especially for vulnerable groups including PLWH, medical specialists and children. Now the process of developing a state program and clinical guidelines including new drugs has accelerated, and we expect that in 2017–2018 Kyrgyzstan citizens will be able to receive affordable treatment".

**Mari Chokheli, Open Society Foundation, Georgia**



"Since the second half of June 2016 initiation of the second stage of the program on HCV eradication in Georgia is planned, within the framework of which about 20,000 patients annually over 10 years will have access to treatment; partial funding of diagnostics is stipulated in several districts of Georgia.

Compared to 2010 the situation with access to treatment has rapidly improved. The HCV eradication plan in Georgia may become real if several important steps are taken: implementation of effective prevention measures, including expansion of harm reduction programs, improved drug policy to increase the diagnostics rate of new cases, and increased funding for diagnostics and treatment monitoring of HCV in Georgia".

**Anait Arutiunyan, Armenian Network of Positive People, Armenia**



"In Armenia, pegylated interferon and ribavirin are registered. New generation drugs are not registered. They are present on the market, imported illegally by individuals; these are mainly Indian generics. As for the cost, the price of pegylated interferons remains high; generics are more affordable. It is very important that the country takes certain steps. Currently we have no national program on Hepatitis. We need to strengthen epidemiological surveillance, and develop joint action aimed at decreasing the burden of disease. It's not true that people receive no treatment at all in Armenia, but the accessibility of drugs is not fully ensured. The government should undertake responsibility for providing treatment to people".

**Sergey Biryukov, SF AGEP'C (ANTIGEPAPTIT'C), Kazakhstan**



"Unfortunately, the situation with access to HCV treatment is far from satisfactory. Thousands of people get diagnosed, barely one thousand get treated; there are about 40,000 people on the waiting list.

What could be done to improve the situation? It is necessary to have fully-fledged screening. It is necessary to develop a clear long-term national program on combating HCV with clear indicators for achieving its goals. We should start negotiations with the leading manufacturers of original drugs to decrease drug

prices within the developed country program. Georgian experience in this respect shows that this is possible. It's necessary to simultaneously allow and start registration in the country of generics used for HCV treatment".

**Ludmila Maistat, Alliance for Public Health, Ukraine**



"Eradication of HCV in EECA countries is impossible without ensuring access to diagnostics and treatment for vulnerable groups, because it's the use of injecting drugs which is the driving force of the epidemic. Fulfilling the recommendations of WHO and the European Association for the Study of the Liver entails inclusion of representatives of vulnerable groups in HCV testing and treatment programs, which is important to consider while shaping national plans and programs to overcome the epidemic. The Alliance for Public Health in partnership with the MoH of Ukraine ensures treatment for the most vulnerable groups; pilots efficient models and forms the basis for considerable expansion of access to diagnostics and treatment for everybody who needs it; achieves decrease of diagnostics and treatment prices; increases people's awareness, and carries out regular training for doctors and social workers. The successful experience of the Alliance's treatment program implementation was taken into account while shaping the WHO Global Viral Hepatitis Strategy. It is also worth noting that on condition of sufficient funding, decrease of DAA prices, and ensured access to quality generics, EECA countries have a solid chance to implement this strategy, dramatically increasing accessibility of innovative treatment and thus curbing the HCV epidemic in the region".

# ANNEX 1. USEFUL RESOURCES

**HCV Treatment Guidelines:**

1. WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. World Health Organization, April 2016
2. Recommendations for Testing, Managing and Treating Hepatitis C. American Association for The Study of Liver Diseases.
3. Recommendations on Treatment of Hepatitis C. EASL HCV Treatment Recommendations.

**Policy Documents:**

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

**Scientific Research**

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

**Civil Society Reports:**

1. HCV Pipeline Report. By Treatment Action Group.
2. New Treatments for Hepatitis C virus: Strategies for Achieving Universal Access. By MdM.
3. Nobody Left Behind. The Importance of Integrating People Who Inject Drugs Into HCV Treatment Programmes. MdM and INPUD.
4. The Critical Role of Civil Society in Shaping the Market for Antiretroviral Therapy and Direct-Acting Antivirals, available online at: http://www.i-mak.org/civil-society/
5. Activist Strategies for Increasing Access to Treatment in Low- and Middle-Income Countries by Karyn Kaplan, available online at: http://hepcoalition.org/advocate/advocacy-tools/article/activist-strategies-for-increasing
6. Pills cost pennies, greed costs lives. First Hepatitis C Virus World CAB Report.
7. Minutes of the meetings of the Eastern European and Central Asia Community Advisory Board. http://eeca-cab.org/en/
8. Eurasian Harm Reduction Network. Current Situation Regarding Access to Hepatitis C Treatment in Eastern Europe and Central Asia
9. Between the Past and the Future. Access to Drugs for Treating HCV in Russia in 2015. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (in Russian).