

Current situation regarding access to hepatitis C treatment in Eastern Europe and Central Asia

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Acronyms and abbreviations

AASLD = American Association for the Study of Liver Diseases
EASL = European Association for the Study of the Liver

EUROPEAN ASSOCIATION for the Study
EECA = Eastern Europe and Central Asia
EHRN = Eurasian Harm Reduction Network

Global Fund = Global Fund to Fight AIDS, Tuberculosis and Malaria

HCV = hepatitis C virus

IDU = injecting drug user

PLHIV = people living with HIV

WHO = World Health Organization

Note on text: All URLs (website addresses) listed were valid as of 1 November 2012.

1. Introduction and overview

Hepatitis C is often referred to as a "hidden" epidemic because it receives far less attention and resources than other potentially deadly viral illnesses, such as HIV infection, and a relatively small share of people living with it are aware of the fact. Yet it is a major health concern, given that perhaps 150 million to 170 million people worldwide (if not more) are thought to be living with the hepatitis C virus (HCV). It is increasingly clear as well that epidemics of viral hepatitis C represent a growing public health catastrophe in most countries of Eastern Europe and Central Asia (EECA). The true extent of the epidemics is difficult to gauge because surveillance systems for HCV are not in place in many EECA countries and treatment demand is not well documented. According to rough estimates, HCV prevalence in the general population is as high as 4 percent in Kyrgyzstan and 6.9 percent in Georgiaⁱⁱ; in comparison, in no country of the region is HIV prevalence assumed to be much higher than 1 percent.

Existing evidence indicates, moreover, that hepatitis C is an especially serious health concern among certain socially, economically and legally marginalized populations. Most notably, HCV prevalence among the region's injecting drug users (IDUs) is among the highest in the world, iii ranging from 10 percent to 96 percent. Rates remain high in part because treatment access for members of the population is extremely limited. The significant concentration of hepatitis C among IDUs has wide-ranging public health consequences for a number of reasons, including the fact that rates of injecting drug use in most EECA countries are also among the world's highest.

More targeted and effective efforts to prevent and treat HCV infection are needed throughout the region in order to safeguard individuals' health and lives and prevent further spread of this often-deadly virus. Representatives and policy makers from all sectors—public, private and non-governmental—need to better understand the human and financial costs of failing to act responsibly and comprehensively.

One necessary change concerns greater awareness of optimal hepatitis C treatment. The term "standard of care" refers to evidence-based, internationally recognized treatment regimens that are most successful in clearing the hepatitis C virus from patients. For the past decade, the standard treatment for chronic hepatitis C infection has been a combination regimen comprising pegylated interferon and ribavirin. Recent developments indicate that the standard of care is in the process of changing, however. Most notably, the use a different kind of drug, protease inhibitors, has been shown to improve response rates when added to the existing two-drug combination. Many researchers anticipate eventually being able to achieve excellent treatment outcomes in regimens that do not contain interferons, although that may be several years in the future.

These ongoing developments offer great hope to people living with hepatitis C in EECA. Yet most still have limited or no access to the longstanding standard of care treatment, and healthcare providers in some of the region's nations continue to prescribe suboptimal regimens. It is inexcusable that some practitioners and policy makers champion such methods in the face of clear evidence showing they are inadequate. All involved in hepatitis C treatment in the region and can and should do better.

1.1 About this policy brief

This policy brief summarizes key findings from an assessment of hepatitis C treatment accessibility in EECA undertaken by the Eurasian Harm Reduction Network (EHRN). It also refers to recommendations from the World Health Organization (WHO) on how to support national governments and affected communities in order to improve hepatitis C treatment access.

The EHRN mapping was conducted from October to December 2011 in six countries of Eastern Europe and Central Asia (EECA): Georgia, Kazakhstan, Kyrgyzstan, Lithuania, Russia and Ukraine. The main goal of the mapping was to assess access to pegylated interferon and ribavirin, a combination that at the time of the mapping was the internationally recognized standard for hepatitis C treatment. Hassed on the mapping's findings, EHRN has formulated recommendations on how to remove the identified barriers to access and improve the situation. These recommendations target both international stakeholders, including WHO and multinational pharmaceutical companies, as well as national ones (e.g., governments, national health agencies, doctors and community based organizations). The recommendations are grouped by category and thus listed at the end of each of the three main sections of this report (Sections 2, 3 and 4).

The mapping consisted of two main elements:

- analysis of official documents, including legal acts and protocols related to HCV diagnostic and treatment, national hepatitis C programmes and strategies (where they exist), and information related to the registration of medicines to treat hepatitis C; and
- interviews with key informants in each country, including patients, people who use drugs, doctors, and providers of harm reduction services.

1.2 Main findings from the mapping

The mapping results showed that the most significant barrier to hepatitis C treatment access is the extremely high price of pegylated interferon. In every country surveyed, that element of the combination treatment regimen is unaffordable both to EECA governments (which provide most health services in their countries through public-sector facilities) and to patients. Other findings underscore the lack of attention and effort given to addressing this high-cost obstacle. Most notably, governments do not consider hepatitis C to be a public health threat, and therefore there is little political will or interest in taking aggressive action to confront it. Also, in all six countries surveyed:

- there are no specific national programmes/strategies on hepatitis C;
- the quality of treatment offered is substandard due to the lack of treatment guidelines prioritizing up-todate internationally recognized hepatitis C diagnostics and treatment protocols;
- inadequate information is available as to HCV prevalence and treatment demand due to weak or non-existent surveillance systems;
- HCV testing access and uptake are extremely low; and
- awareness of hepatitis C, including risk factors and treatment, is limited among both healthcare providers and patients.

2. National hepatitis C policies

Most governments in the six-country survey area do not consider hepatitis C to be a public health priority. Nevertheless, political commitment is increasing, with most governments now indicating they want to do something. This development stems in part from a WHO resolution on viral hepatitis (from 2010) that recognizes the global impact of hepatitis C and urges the allocation of dedicated resources to combat it.vii

To date, though, programmes in the EECA region are poor in quality and content and still have little to no budgetary allocation. None of the six countries assessed has a specific national programme on hepatitis C, and thus all lag far behind places such as Australia and Scotland that have internationally recognized examples of good practice. However, some countries in the region recently have begun to introduce guidance for national policies on viral hepatitis, including hepatitis C (see Table 1).

Table 1 National frameworks to coordinate domestic hepatitis C activities

Country	Framework	Comments	Technical assistance requested from WHO in 2010 ^{xi}
Georgia	None	None	 Awareness raising Increasing access to treatment Delivery of vaccination Developing goals for the prevention and control of hepatitis B and hepatitis C Developing tools to assess the effectiveness of interventions Surveillance
Kazakhstan	Government programme for healthcare development in the Republic of Kazakhstan - "Salamaty Kazakhstan" for 2011–2015, dated 29 November 2010 ^{xii}	A government programme introduced by decree. This government health programme contains a section dedicated to hepatitis C	No request was submitted
Kyrgyzstan	Targeted programme of the Ministry of Health, "Prevention and treatment of viral hepatitis in the Kyrgyz Republic for 2011–2015"xiii	A programme of the Ministry of Health, introduced by the Ministry of Health	 Awareness raising Increasing access to treatment Delivery of vaccination Developing goals for the prevention and control of hepatitis B and hepatitis C Developing tools to assess the effectiveness of interventions Surveillance

<u> </u>			
Country	Framework	Comments	Technical assistance requested from WHO in 2010 ^{xi}
Lithuania	None ^{xiv}	None ^{xiv}	 Increasing access to treatment Developing tools to assess the effectiveness of interventions
Russia	Federal targeted programme for socially significant diseases for 2007–2012 ^{XV}	A government programme introduced by decree. Hepatitis C-related issues are discussed in the subprogramme "Viral hepatitis"	 Awareness raising Increasing access to treatment
Ukraine	Concept note for a government programme for the prevention, diagnosis and treatment of viral hepatitis through 2016 ^{xvi}	Waiting approval from the Cabinet of Ministers	 Increasing access to treatment Delivery of vaccination Developing goals for the prevention and control of hepatitis B and hepatitis C Developing tools to assess the effectiveness of interventions Surveillance

It is important to stress that the existence of a national framework or programme on viral hepatitis does not necessarily correlate with greater access to hepatitis C treatment. Limited or non-existent improvement in access can result from the low quality of national programmes, including imprecise targets and indicators; lack of an action plan; and insufficient budget to achieve targets.

Targets in the countries' national hepatitis C programmes/frameworks are usually formulated as "to decrease viral hepatitis B and C prevalence".xvii Yet these targets will be difficult to meet, especially in the short term. The main reason is that the majority of people living with hepatitis C in EECA are not aware of their status; therefore, incidence and prevalence will rise along with increased access to HCV testing, which is needed to expand treatment coverage. Thus, while beneficial to recipients, effective implementation of the programmes will lead to an increase rather than a decrease in reported prevalence. This has to be understood at the stage of programme planning. Decreasing prevalence is a long-term goal, but the prevalence indicator should be avoided or used cautiously in assessing programmes during the first years of programme implementation.

Despite the high HCV transmission rates among IDUs in all EECA countries, xviii only in rare exceptions are there specific interventions targeting members of the injecting drug population. One, the Kyrgyzstan programme, includes the following language: "Reducing hepatitis morbidity among injecting drug users and codependent persons including the implementation of harm reduction measures". The intervention's impact is questionable, though, because no government funding is allocated to undertake measures to undertake it. The Russian and Kazakhstan programmes do not list people who inject drugs as a target group, and harm reduction activities are not mentioned in them either.

Moreover, the lists of indicators and activities in the Russia, Kazakhstan and Kyrgyzstan programmes

emphasize epidemiological control measures; hepatitis C treatment activities are not specified in a detailed fashion. Another example of insufficient indicators is "Reduction in the incidence of acute hepatitis C per 100,000 people" (the Russian and Kazakhstan programmes). xix Also, combining the indicators for hepatitis B and C, as is done in the Russian programme and the Ukrainian concept note, does not allow for monitoring the effectiveness of hepatitis C prevention and treatment activities because prevention measures for the two viruses are drastically different. For example, there is an effective vaccine to prevent hepatitis B, but there is no vaccine for hepatitis C.

Perhaps unsurprisingly, given its size, Russia has allocated the largest amount of **funding** from the state budget for viral hepatitis programmes.** Yet it is also an exception in that it has targeted funding for hepatitis C activities. In the other countries whose hepatitis C strategies were assessed by EHRN, activities are not supported by specific funding from state budgets. With the exception of Russia, none of the disease-specific programme budgets that were analyzed contains a budget line dedicated specifically to hepatitis C treatment, and it is not possible to determine the number of people who are receiving hepatitis C treatment through the programmes or how much money is actually being spent—or is expected to be spent—for treatment. This lack of clarity is likely to have negative cost-effectiveness implications. If the amount allocated for future purchases of hepatitis C commodities, including medicines, were specified in its national hepatitis C framework, a government could have greater price-negotiating leverage with pharmaceutical companies based on lower unit prices for guaranteed large volume purchases.

Recommendations regarding hepatitis C programmes and frameworks

- Governments in EECA countries should develop national hepatitis C programmes or integrate hepatitis C components into existing health policy frameworks. Those programmes and components should:
 - include as a target the reduction of actual prevalence, or prevalence estimates (not number of reported cases or reported prevalence);
 - specify objectives to reduce the risk of transmission of HCV among drug users through harm reduction measures and to increase access to hepatitis C treatment;
 - develop specific indicators to i) assess progress in activities aimed at reducing transmission through drug injecting, and ii) provide HCV testing and standard of care treatment for chronic hepatitis C;
 - design an action plan to achieve the priorities listed above; and
 - determine funding levels in accordance with the action plan, including separate budget lines for prevention among key populations (including harm reduction programmes) and for the procurement of hepatitis C diagnostics and treatment.
- WHO should provide technical support to EECA governments developing hepatitis C programmes. The agency should promote its technical target-setting guidexxi as a tool to set relevant, achievable and measurable objectives and indicators for hepatitis in national HIV and other programmes.

3. Hepatitis C treatment guidelines (protocols)

In addition to their main objective—to provide doctors and patients with guidance in taking clinical decisions—diagnostics and treatment protocols can serve as an instrument of treatment quality control. Also, protocols can i) provide grounds for reimbursement of treatment expenses from state healthcare systems or medical insurance schemes, and ii) inform procurement of relevant medical products. From an advocacy perspective, another advantage of having an official national treatment protocol is that it can help to defend, in courts, the right to health care for people living with hepatitis C. In other words, a comprehensive protocol can strengthen a patient's position in the justice system if he or she seeks legal redress after being excluded from a hepatitis C treatment programme or if the patient's care is mismanaged.

In Russia and Kyrgyzstan there are **no state-approved hepatitis C treatment protocols**; in Ukraine, meanwhile, the treatment protocol covers only HIV/HCV co-infection. These gaps limit the quality of hepatitis C care and put patients at risk of developing severe liver disease. They therefore lead to lower life quality and higher mortality rates among people with hepatitis C.

In 2009, I asked my doctor to prescribe me treatment for hepatitis C due to the sharp deterioration of my health. Both diagnostic services and treatment were provided with poor quality and no regard to evidence-based and internationally accepted recommendations for hepatitis C treatment. I was not offered HCV genotype or viral load tests, a liver biopsy or a fibroscan. I was not offered treatment for hepatitis C with pegylated interferon in combination with ribavirin, which is the international standard for hepatitis C treatment. Instead, I was recommended to buy expensive food supplements, which hadn't undergone clinical trials and could damage my health. I didn't get recommendations about hepatitis C prevention or, in fact, any counselling at all.

The above quote is from a submission to the Global Commission on HIV and the Law made by a female Russian patient in May 2011. Four months later, she was diagnosed, outside Russia, with HCV 1 genotype, 3rd stage of liver fibrosis and enrolled into treatment (also abroad) with pegylated interferon and ribavirin.

In the hepatitis C treatment protocols or treatment recommendations analyzed in the six countries, xxii **illicit drug use is not an exclusion criterion** for treatment. Yet at the same time, those protocols do not provide recommendations on specifics of management of HCV infection among IDUs—as is done, for example, through the American Association for the Study of Liver Diseases (AASLD). xxiii The gaps in the EECA approach heighten the potential for denying hepatitis C treatment for those who inject drugs. They also substantially decrease the usefulness of protocols as a basis for effective treatment advocacy.

It is virtually impossible to obtain hepatitis C treatment for patients diagnosed with drug dependency. Medical specialists justify this by claiming that such patients' adherence to treatment will be low and that treatment interruptions are possible at any point, which in their opinion means that expensive drugs will be thrown out the window. Two of my clients were able to receive hepatitis C treatment but they kept their drug dependency a secret for fear of being denied treatment.

Interview with a social worker, Kaliningrad, Russia

Inconsistencies have been identified in the protocols/recommendations in regards to pre-treatment **diagnostics**. For example, the Kazakhstan protocol does not recommend viral load and genotype testing prior to treatment uptake even though these tests are essential in making decisions on drug dosage and length of treatment. This is a major oversight for many reasons. For one, international treatment guidelines state that effectively treating genotype 1 requires a lengthier course of treatment and higher dose of ribavirin. Also, according to recent international recommendations, a liver biopsy should not be mandatory, and thus a patient's unwillingness to undergo this in-patient, complicated and painful procedure should not be a barrier to treatment.**

Weanwhile, the Lithuanian and Kazakhstan treatment protocols do not recommend fibroscans or other alternatives to a biopsy, as international guidelines suggest.

Hepatitis C treatment with **pegylated interferon and ribavirin** is a standard of care recommended by WHO,

AASLD and European Association for the Study of the Liver (EASL) guidelines.** EECA treatment protocols recommend that treatment regimen, but in the case of Russia and Lithuania, for example, the protocols also allow the use of linear interferon treatment even though studies from almost a decade ago showed that it is considerably less effective in clearing the virus than its pegylated counterpart.xxvi Also, Russian and Kazakhstan protocols recommend other medications—phosphogliv in Russia and ursodesoxicholic acid in Kazakhstan—that are of questionable value because their therapeutic effects have not been sufficiently proven as per international standards.

Myself, I do not prescribe herbal drugs or food supplements because I don't think they are effective for treating patients with hepatitis C. Those who do not get pegylated interferon and ribavirin, I prescribe Ronkoleikin and

This is a citation with a hepatitis treatment doctor in Almaty, Kazakhstan. Ronkoleikin is not a specific anti-hepatitis C treatment and has not been recommended by EASL or AASLD treatment guidelines. Interal is a brand-name version of linear interferon.

Hepatitis C treatment often leads to significant side effects which need specific management and may require dosage correction and, in some cases, discontinuation of treatment. Side effects may also decrease treatment adherence and, accordingly, treatment outcomes. XXVII Yet the Kazakhstan and Lithuanian protocols do not provide recommendations on treatment side effects, whereas the Russian protocol offers a general mention of psychological side effects only.

Similar to other lengthy treatment procedures, hepatitis C treatment requires the active participation and vigilance of patients, and adherence plays a critical role in treatment outcome. XXVIII None of the analyzed protocols include information or other language focused on adherence and care support, including counselling on treatment adherence or on living with hepatitis C. The Russian protocol mentions adherence issues only in the section on HIV/HCV co-infection. Moreover, none of the protocols recommend integration of hepatitis C treatment with other services such as opioid substitution treatment or HIV and TB treatment. Also not mentioned anywhere is peer counselling, which is considered essential for improved outcomes in many countries and contexts.

Recommendations regarding hepatitis C protocols

- WHO and other international stakeholders, including networks of people living with HIV and/or hepatitis C, should urge and support governments to adopt national hepatitis C treatment guidelines (protocols) that provide guidance on how to diagnose and treat hepatitis C in accordance with up-todate scientific evidence and international best practices. Patients in the region deserve access to the best quality treatment; therefore, protocols should change in response to new information and revised clinical-management guidelines from leading international organizations.
- To facilitate the process of developing/improving national treatment protocols, WHO should take the lead in developing model hepatitis C diagnostic and treatment guidelines for resource-limited settings. The model guidelines should:
 - encourage hepatitis C treatment for people who use drugs by highlighting evidence-based interventions to increase their access and adherence to treatment as well as integration of hepatitis C treatment with opioid substitution, HIV and TB treatments;
 - provide clear guidance on the choice of diagnostic procedures and treatment options proven to be clinically effective, safe and cost-effective;
 - provide explicit guidance on side-effects management; and
 - highlight the need for counselling and peer counselling for people who receive treatment and provide recommendations on how to increase treatment adherence.

4. Treatment costs: who pays and what price?

The major barrier to hepatitis C treatment access in EECA (as well as most other places in the world) is the high price of pegylated interferon, one of the components of the internationally recognized standard of care treatment regimen for hepatitis C. The prohibitive cost of pegylated interferon makes the most effective treatment options unaffordable to both patients and national governments in many countries, including in EECA.

The drug's high cost will remain a challenge for the foreseeable future because pegylated interferon is also an integral part of relatively a new triple-combination therapy regimen that significantly increases treatment effectiveness and decrease duration of treatment.** That regimen is expected to eventually be recommended as the standard of care worldwide upon broader regulatory approval of one or both of the protease inhibitors (boceprevir and telaprevir) that will be used along with pegylated interferon and ribavirin. It is currently difficult if not impossible to estimate the eventual prices of the protease inhibitors in most of EECA, although their use will undoubtedly increase the overall cost of treatment.** What is clear now, though, is that the high prices charged for pegylated interferon make greater access to treatment unaffordable to all but a few in need.

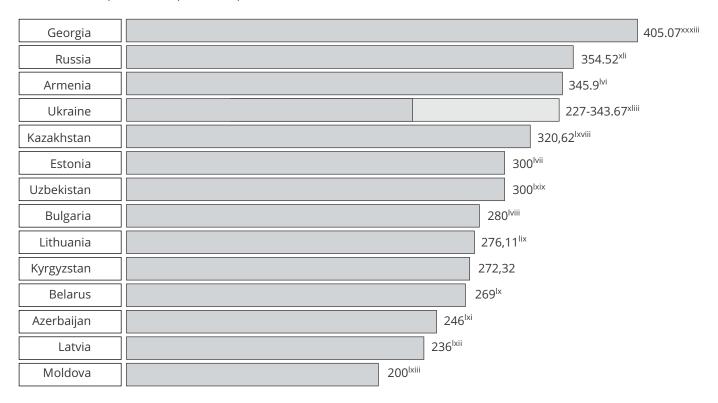
Table 2. Comparison of prices for Pegasys and PegIntron for 48 weeks of treatment

Note: 48 weeks of treatment is recommended for patients diagnosed with HCV genotype 1, the most prevalent genotype in EECA. Pegasys and PegIntron are the brand-name versions of pegylated interferon made by, respectively, Roche and Merck. Unless specified otherwise, the prices are based on mapping undertaken from October to December 2011. Fluctuations in exchange rates may have caused prices in dollar terms to vary somewhat. "N/a" is noted when information was unavailable.

Pegasys						
Country	Government purchase price for 1 vial, in \$	Government purchase price over 48 weeks, in \$	Retail price per ampule, in \$	Cost per patient based on retail price over 48 weeks, in \$ (if covered by patient)		
Georgia	149.70 ^{xxxii}	7,185.63	405.07 ^{xxxiii}	19,443.31		
Kazakhstan	385.14 ^{xxxiv}	18,486.72	320.62 ^{xxxv}	15,390		
Kyrgyzstan	not procured ^{xxxvi}	not procured	272.32 ^{xxxvii}	13,071.38		
Lithuania	275.58 ^{xxxviii}	13,227.97	276.11 ^{xxxix}	13,253.19		
Russia	309.89 ^{xl}	14,874.81	354.52 ^{xli}	17,016.77		
Ukraine	not procured ^{xlii}	not procured	227.30 – 343.67 ^{xliii}	10,190.17 - 16,496.28		
PegIntron 1	PegIntron 120 mg					
Country	Government purchase price for 1 vial, in \$	Government purchase price over 48 weeks, in \$	Retail price per ampule, in \$	Cost per patient based on retail price over 48 weeks, in \$ (if covered by patient)		
Country Georgia	purchase price	purchase price over		on retail price over 48 weeks, in \$ (if covered		
	purchase price for 1 vial, in \$	purchase price over 48 weeks, in \$	per ampule, in \$	on retail price over 48 weeks, in \$ (if covered by patient)		
Georgia	purchase price for 1 vial, in \$	purchase price over 48 weeks, in \$ 6,960.00	per ampule, in \$	on retail price over 48 weeks, in \$ (if covered by patient) 15,520.96		
Georgia Kazakhstan	purchase price for 1 vial, in \$ 145.00 ^{xliv} 371.90 ^{xlvi} – 384 ^{xlvii}	purchase price over 48 weeks, in \$ 6,960.00 17,851.03	per ampule, in \$ 323.35 ^{xlv} 392.13 ^{xlviii}	on retail price over 48 weeks, in \$ (if covered by patient) 15,520.96 18,822.24		
Georgia Kazakhstan Kyrgyzstan ^{xlix}	purchase price for 1 vial, in \$ 145.00 ^{xliv} 371.90 ^{xlvi} – 384 ^{xlvii} not procured	purchase price over 48 weeks, in \$ 6,960.00 17,851.03 not procured	per ampule, in \$ 323.35 ^{xlv} 392.13 ^{xlviii} n/a	on retail price over 48 weeks, in \$ (if covered by patient) 15,520.96 18,822.24 n/a		

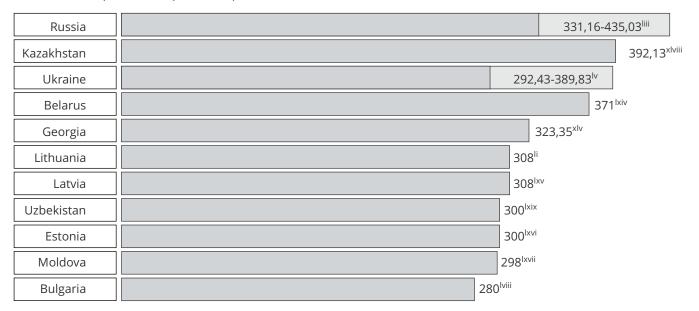
Graphic 1. Variance of Pegasys retail price per ampule in CEECA, in \$

Note: Graphics include mapping updates from Bulgaria, Estonia, Armenia, Azerbaijan, Belorussia, Latvia, Uzbekistan, and Moldova. Updates took place in September – November, 2012.



Graphic 2. Variance of PegIntron retail price per ampule in CEECA, in \$

Note: Graphics include mapping updates from Bulgaria, Estonia, Armenia, Azerbaijan, Belorussia, Latvia, Uzbekistan, and Moldova. Updates took place in September – November, 2012.



Prices for pegylated interferon vary significantly, particularly in state procurement, even for same version of the medicine. For example, data from the Kazakhstan governmental procurement information system show that the government pays nearly three times as much for the medicine as does its counterpart in Georgia. More than half the **price reduction** for PegIntron in Georgia was achieved through a government tender announced to procure hepatitis C medication for people living with HIV (PLHIV) in the framework of programme supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). In Lithuania, where hepatitis C treatment costs are covered through the health insurance system, the price of pegylated interferon is more than 10 percent lower than in Russia and Kazakhstan, where governments purchase pegylated interferon through national health programmes.

The variations are significant, but the price-reduction efforts have not had as dramatic an effect in comparison with the steep decline in HIV treatment prices after the introduction of **generic** antiretroviral drugs (ARVs). The annual cost per patient of some anti-HIV regimens fell by more than 95 percent in many countries, from more than \$10,000 in 2000 to little more than \$100 a decade later. Such an impact is not likely in the short term in regards to hepatitis C treatment because of a lack of readily available generic versions of pegylated interferon. So far, only one generic version has been registered in the region (*Mili Healthcare* in Ukraine), and its product is not yet on the market. In Russia, a local pharmaceutical company recently started a trial of a generic pegylated interferon version to the cases extensive analysis is likely to be needed to ensure quality and effectiveness, thus further delaying their possible availability. WHO guidance and leadership will be needed in this effort, which is particularly critical because pegylated interferon is a biological product (and thus more complex and difficult to produce than drugs such as ARVs). For the time being, therefore, substantial price reductions in hepatitis C treatment regimens will be difficult to secure.

With the exception of Lithuania, where treatment is covered by national health insurance fund, access to hepatitis C treatment is restricted in all countries covered by this EHRN assessment. There are a few different reasons for such limitations. In some countries, governments have requested **funding from international donors** (as Georgia has done from the Global Fund and as Ukraine did previously from the World Bank) to cover only a small share of overall treatment need—specifically people co-infected with HIV/HCV. In others, governments allocate insufficient funding to purchase hepatitis C treatment **through non-transparent schemes**—as in Russia, where the majority of people in need are still not enrolled in treatment. In Kyrgyzstan hepatitis C treatment is available only for patients who can cover all costs **out-of-pocket**, and thus most people in need are unable to cover the high price.

The cost of pegylated interferon is the most significant yet not the only expense associated with hepatitis C treatment. **Costs of diagnostic procedures and medication for side effects** may also present a barrier for both treatment enrolment and its successful completion.

I was told to pay for my tests at the following prices: viral genotyping and quantifiable PCR, 1,600 rubles (\$52); a visit to an infectious disease specialist, 350 rubles (\$11); viral load monitoring every three months, 1,109 rubles (\$36) each time; and two qualitative PCR tests, 450 rubles (\$14.50) each. I don't know where to find this money: currently I am unemployed, and my only relative is my retired mother who is drinking.

Interview with a person living with HIV and HCV in Tver, Russia

Table 3. Hepatitis C-related costs-sharing among governments, patients and international donors (for 2011)

Note: The information in this table is based on interviews conducted with serviceproviders and patients by EHRN in November and December 2011; it should be considered as valid only as per that time. "N/a" is noted when information was unavailable.

	Georgia	Kazakhstan	Kyrgyzstan
Antibody testing	Patient pays Exceptions: i) IDUs/clients of Global Fund supported needle-exchange programmes; ii) citizens of Tbilisi, where tests are provided free of charge by a pharmaceutical company	Patient pays Exceptions: PLHIV, children	Patient pays Exceptions: IDUs and prison inmates through needle-exchange/prison programmes supported by the Global Fund
PCR (viral load)	Patient pays Exception: People co- infected with HIV and HCV who get treatment through the Global Fund Round 9 programme	Patient pays	Patient pays
PCR (genotype)	Patient pays Exception: People co- infected with HIV and HCV who get treatment through the Global Fund Round 9 programme	Patient pays	Patient pays
Biochemical blood test	N/a	N/a	Patient pays
Hormones test	N/a	N/a	Patient pays
Liver biopsy	N/a	N/a	Patient pays
Fibroscan	N/a	N/a	Patient pays
Hepatitis B vaccination	N/a	N/a	Patient pays
Pegylated interferon	Patient pays Exception: People co- infected with HIV and HCV who get treatment through the Global Fund Round 9 programme	Patient pays In 2010 the government agreed to pay for the medicine, but as of December of that year the majority of clients continued to be charged for the costs	Patient pays
Ribavirin	Provided by pharmaceutical companies free of charge		Patient pays
Antidepressants	Patient pays	Patient pays	Patient pays

	Lithuania	Russia	Ukraine
Antibody testing	Patient pays	Patient or state health insurance pays, depending on the region	Patient pays Exception: IDUs/clients of needle-exchange programmes supported by the Global Fund
PCR (viral load)	State health insurance pays Exception: The insurance scheme does not cover unemployed individuals, thereby excluding a large share of drug users	Patient pays	Patient pays
PCR (genotype)	State health insurance pays Exception: The insurance scheme does not cover unemployed individuals, thereby excluding a large share of drug users	Patient pays	Patient pays
Biochemical blood test	State health insurance pays Exception: The insurance scheme does not cover unemployed individuals, thereby excluding a large share of drug users	State health insurance pays	N/a
Hormones test	Patient pays	Patient pays	N/a
Liver biopsy	Patient and state health insurance jointly pay Exception: The insurance scheme does not cover unemployed individuals, thereby excluding a large share of drug users	N/a	N/a
Fibroscan	Service not available	Patient pays	N/a
Hepatitis B vaccination	Patient pays	Patient pays	Patient pays
Pegylated interferon	State health insurance pays Exception: The insurance scheme does not cover unemployed individuals, thereby excluding a large share of drug users	Patient pays Exceptions: PLHIV (covered by National Priority Health Programme), and only occasionally people without HIV	Patient pays Exception: Around 10 persons with HIV/HCV co- infection were enrolled into treatment free of charge, covered by the government, in 2012

Recommendations regarding cost of treatment and diagnostics

- The international community should support EECA governments in their efforts to reduce the cost of hepatitis C treatment prices. External assistance is needed given the lingering economic crisis and shortages of international funding, including resource shortfalls at the Global Fund. In light of these challenges, prospects appear bleak for identifying substantial new funding to improve access to hepatitis C testing and treatment in EECA.
- National governments should provide diagnostics and treatment for hepatitis C free of charge using relevant schemes of reimbursement from national health budget or health insurance systems. Governments of low-income countries should request international and bilateral donors to start pilot programmes to provide standard of care treatment to all people living with hepatitis C in need, including those co-infected with HIV.
- National governments should seek to initiate an open dialogue with Merck and Roche, the two multinational pharmaceutical companies that make pegylated interferon, with the goal of obtaining significant price reductions for purchases of the medicines.
- WHO should prioritize the issue of availability of hepatitis C treatment at affordable cost by:
 - including pegylated interferon and ribavirin in the WHO Model List of Essential Medicines;
 - including pegylated interferon in the WHO List of Prequalified Medicinal Products;
 - reviewing its standard of care treatment guidelines to ensure that the most effective regimens are recommended as quickly as possible, including triple-combination therapies that add a protease inhibitor;
 - harmonizing guidelines for development of bio-similar products and quickly yet thoroughly assessing the quality of generic drugs; and
 - developing and scaling up the infrastructure for treating hepatitis C, in preparation for interferon-sparing (shorter course) and interferon-free regimens that are currently in development.

5. Conclusion

The findings from the 2011 EHRN mapping underscore the major challenges regarding access to effective, affordable hepatitis C treatment and diagnostics in the EECA region. New and improved regimens are being developed around the world that will greatly improve treatment outcomes. However, the majority of patients in need in the region still have limited (if any) access to the standard of care treatment regimen that has been included in internationally recommended guidelines for the past several years.

Governments ignore the public health consequences at their peril. Most people infected with HCV are unaware of their situation. If and when they become ill and need care, the cost to public-sector facilities will be substantial and long-running. The most cost-effective approach to the looming epidemic is to develop and implement improved surveillance and testing programmes that help move people into treatment when they need it. Such efforts should be accompanied by strengthened efforts to reduce the cost of treatment by, most notably, working to cut the cost of pegylated interferon.

The mapping findings also reinforce the importance of human rights in healthcare provision. The beneficial impact (both in terms of financial costs and individual health) of the diagnostics and treatment aspects of hepatitis C programming can be heightened by policies providing comprehensive harm reduction services to IDUs and others most at risk for contracting HCV. As the primary providers of health care in the region, governments will save costs in the long run by working with community-based groups to provide appropriate care and services to those most in need as early as possible. By doing so, they can also form important and powerful alliances with patients and community groups, thereby increasing the potential for addressing hepatitis C over time.

- ¹ For example, the World Health Organization (WHO) states the following on its website: "About 150 million people are chronically infected with hepatitis C virus, and more than 350,000 people die every year from hepatitis C-related liver diseases." Available at www.who.int/mediacentre/factsheets/fs164/en/index.html (accessed 12 November 2012). The U.S. government's Centers for Disease Control and Prevention (CDC) give a similar estimate for hepatitis C-related deaths, but estimate the number of people living with HCV to be higher, around 170 million. Available at www.cdc.gov/features/dshepatitisawareness/index.html#References (accessed 12 November 2012).
- ii Butsashvili M et al. Prevalence of hepatitis B, hepatitis C, syphilis and HIV in Georgian blood donors. Eur J Epidemiol. 2001;17(7):693-5.
- iii Hoover, J. (2009). Shining a light on a hidden epidemic: why and how civil society advocates can support the expansion of hepatitis C treatment in Eastern Europe and Central Asia. Retrieved from www.soros.org/initiatives/health/focus/access/articles_publications/publications/hepc_20090821/light_20
- 090821.pdf. Also: Aceijas, C., & Rhodes, T. (2007). Global estimates of prevalence of HCV infection among injecting drug users. International Journal of Drug Policy, 18:352-58
- iv Aceijas, C., & Rhodes, T. (2007). Global estimates of prevalence of HCV infection among injecting drug users. International Journal of Drug Policy, 18:352-58.
- $^{\mathrm{V}}$ EHRN (2011). Call for action: reduce prices for hepatitis C treatment. Available at www.harm-reduction.org/images/stories/documents/hcv_call_for_action.pdf.
- ^{vi} Since the mapping took place, some of the world's leading guidelines-setting organizations have updated their best-practice treatment guidelines to include a protease inhibitor, either boceprevir or telaprevir. (See, for example: www.hivandhepatitis.com/hepatitis-c-topics/hcv-treatment/3292-aasld-hepatitis-c-treatment-guidelines-updated-to-include-boceprevir-and-telaprevir.) Other leading organizations had not changed their clinical practice guidelines for managing HCV infection as of October 2012, including the European Association for the Study of the Liver (EASL). (Its most recent guidelines were published in 2011 and are available at www.easl.eu/assets/application/files/4a7bd873f9cccbf_file.pdf.) For the purposes of this report, the term "standard of care" refers to the combination of pegylated interferon plus ribavirin. It is assumed that access to this regimen, which remains limited in the EECA countries assessed, is a stepping-stone to ultimately achieving access to a triple-combination regimen in the future.
- $^{\rm vii} \ {\it See for example: www.worldhepatitis alliance.org/Policy/WHO_Resolution.aspx.}$
- viii Correlation Working Group on Hepatitis C (2011). Hepatitis C among people who use drugs: Key messages from practitioners. Available at www.correlation.net.org/hepatitis/index.php?option=com_content&view=article&id=12&Itemid=13.
- $^{\mathrm{ix}}$ See for example: www.health.gov.au/internet/publications/publishing.nsf/Content/ohp-national-strategies-2010-hcv-l.
- $^{\rm x}$ See for example: www.scotland.gov.uk/Resource/Doc/222750/0059978.pdf.
- x^{i} Information may be found at the website of the World Hepatitis Alliance: www.worldhepatitis alliance.org/Policy/2010PolicyReport.aspx.
- xii State health development program of the RK "Salamatty Kazakhstan" for 2011-2015 years Available in Russian at http://ru.government.kz/resources/docs/doc19.
- xiii State Programme on Prevention of HIV Epidemic and Its Socio-economic Consequences in the Kyrgyz Republic for 20012-16. Available in Russian at www.aids.gov.kg/doc/StateProgram_HIV_21-sep-2011_draft_ru.pdf.
- x^{iv} There are, however, some elements related to hepatitis C integrated in horizontal health programmes—for example, the Program on Improvement of Public Health.
- xv Decree of the Government of the Russian Federaion on May 10 2007 N 280 on the Federal Target Program "Prevention and control of social diseases (2007-2012)" (government decrees of 18.02.2008N 95, from 02.06.2008 N 423 of 09.04.2009 N 319, from 06.04.2011 N 254). Available in Russian: http://fcp.economy.gov.ru/cgi-bin/cis/fcp.cgi/Fcp/View/2010/214.
- xvi Concept project of the "State targeted social program on prevention, diagnostics and treatment of viral hepatitis until 2012" Available in Ukrainian at http://hepatit.org.ua/ofitsioz/proekt-kontseptsiyi-derzhavnoyi-tsilovoyi-sotsialnoyi-programi-z-profilaktiki-diagnostiki-ta-likuvannya-virusnih-gepatitiv-na-period-do-2016-roku/.
- xvii For example, the programmes in Russia and Kyrgyzstan noted in Table 1.
- xviii Aceijas, C., & Rhodes, T. (2007). Global estimates of prevalence of HCV infection among injecting drug users. International Journal of Drug Policy, 18:352-58.
- xix Acute hepatitis C has clinical manifestations (symptoms) only in 10-15% of cases, and consequently most people with acute HCV infection do not come into contact with healthcare facilities. This situation is further complicated because the share of people who have symptoms of acute hepatitis C and seek medical aid differs in various social categories. For example, it is known that IDUs, who make up a majority of people living with hepatitis C in EECA, are among those least likely to seek care for acute conditions.
- xxx Decree of the Government of the Russian Federaion on May 10 2007 N 280 on the Federal Target Program "Prevention and control of social diseases (2007-2012)" (government decrees of 18.02.2008N 95, from 02.06.2008 N 423 of 09.04.2009 N 319, from 06.04.2011 N 254). Available in Russian: http://fcp.economy.gov.ru/cgi-bin/cis/fcp.cgi/Fcp/View/2010/214.
- xxi WHO, UNODC, UNAIDS (2009). Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, pp. 32-35. Available at www.who.int/hiv/pub/idu/idu_target_setting_guide.pdf.
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- xxiii Ghany, M.G, Strader D.B, Thomas D.L et al. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1361-62.
- xxiv Ibid.
- xxv As noted earlier in this policy brief, the mapping that underpinned this policy brief took place when the uniform standard of care for treating HCV infection was a combination regimen comprising pegylated interferon and ribavirin. Since then, the U.S. Food and Drug Administration (FDA) has approved the use of two protease inhibitors, boceprevir or telaprevir, for use as part of a triple-combination treatment in which one of them is added to the existing two-drug regimen. The AASLD now considers this triple-combination regimen to be the standard of care. Other treatment guidelines, including those of the EASL, were not changed as of October 2012—but it is expected they will be if and when the two protease inhibitors are approved by relevant regulators.
- xxvi Shepherd, J et al(2004). Pegylated interferon alpha-2a and -2b in combination with ribavirin in the treatment of chronic hepatitis C: a systematic review and economic evaluation. Health Technology Assessment, 8, (39), 1-140.
- xxvii Ghany, M.G, Strader D.B, Thomas D.L et al. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1361-62; McGowan C.E, Fried M.W. Barriers to hepatitis C treatment. Liver Int. 2012;32Suppl 1:151-6; Manns M.P et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. Lancet. 2001;358(9286):958-65.
- xxviii Weiss, J.J et al (2011). Adherence to medication for chronic hepatitis C building on the model of human immuno deficiency virus antiretroviral adherence research. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC3102513/.
- xxix As noted elsewhere in this policy brief, triple therapy is based on using pegylated interferon, ribavirin and a protease inhibitor (telaprevir or bocapervir). See: Zeuzem, S et al M. (2011). Telaprevir for retreatment of HCV infection. The New England Journal of Medicine, 364(25): 2417-2428.
- xox Recent developments in Latvia give some idea of what the additional costs might be for triple-combination treatment. The multinational companies that make telaprevir (Janssen Pharmaceuticals) and boceprevir (Merck Sharp & Dohme Corp.) submitted applications to include the drugs on the list of reimbursable medicines through the public health system. Based on these preliminary submissions, four weeks of treatment with boceprevir could cost around €4,000 (US\$5,080), with telaprevir even more expensive. Such prices indicate that these drugs alone could cost at least €48,000 (US\$61,000) if taken over a 48-week period. This would more than double the cost of treatment through ribavirin and pegylated interferon alone, a combination that is already prohibitively expensive in most of the region.
- xxxii European Association for the Study of the Liver (EASL), (2011). EASL clinical practice guidelines: management of hepatitis C virus infection. Journal of Hepatology, 55: 245-264.
- xxxiii Prices for governmental tender in 2009 (for prison inmates).
- xxxiii Communication with Paata Sabalashvili, programme manager at the Georgian Harm Reduction Network, on 26 January 2012.
- xxxiv As per http://goszakup.gov.kz/app/index.php/kz/publics/plans/point/10687140 (in Russian), yet it should be noted that this is the only mention of a Pegasys governmental purchase (tender) for 2011.

- xxxv Communication with Sergey Biryukov from the NGO "AGEP'C" on 10 October 2012.
- xxxvi The Kyrgyzstan government does not purchase Pegasys.
- xxxvii Average pharmacy retail price. Source: EHRN (2012) Access to hepatitis C treatment in Kyrgyzstan, upcoming.
- xxxxviii List of reimbursable medicines 2011 approved by the health minister (order No V-312, April 1, 2011); source: www.vlk.lt/vlk/files/2011/kv/201108VaistuKainynas.pdf (in
- xl According to www.drugreg.ru/Bases/ (in Russian), this is the maximum price for governmental wholesale purchase for the Moscow region (accessed 17 November 2011). The same price was given in Moscow tenders for November/December 2011. The new price list can be downloaded at www.rlsnet.ru/prmoni.htm (in Russian).
- xli Information obtained from an Internet pharmacy (http://smed.ru/price/65776/#article), accessed on 26 December 2011 (in Russian).
- xlii In 2011, when mapping for the report underpinning this policy brief took place, there was no centralized purchase in Ukraine.
- xiiii As per http://medbrowse.com.ua/pegasis-cena/ukraina, accessed 23 January 2012 (in Russian).
- $^{\mbox{\scriptsize xliv}}$ Price specified in winning Global Fund programme tender in 2011.
- xlv Interview with a patient.
- xlvi This is the official distributor price, according to a response to a request from EHRN, December 2011.
- xlvii As per http://goszakup.gov.kz/app/index.php/kz/publics/plans/point/7245054 (in Russian).
- xlviii Communication with Sergey Biryukov from the NGO "AGEP'C" on 10 October 2012.
- xlix PegIntron is not available in Kyrgyzstan.
- List of reimbursable medicines 2011 approved by of the health minister (order No V-312, April 1, 2011); source: www.vlk.lt/vlk/files/2011/kv/201108VaistuKainynas.pdf (in Lithuanian).
- iii According to www.drugreg.ru/Bases/ (in Russian) , this is the maximum price for governmental wholesale purchase for the Moscow region (accessed 17 November 2011). The same price was given in Moscow tenders for November/December 2011. The new price list can be downloaded at www.rlsnet.ru/prmoni.htm (in Russian).
- iii Information obtained from an Internet pharmacy www.onko-help.ru/_pegintron, www.rlsnet.ru/tn_index_id_16794.htm (accessed on 23 January 2012); verified by www.drugreg.ru/Bases/. (All links are in Russian.)
- liv In 2011, when mapping for the report underpinning this policy brief took place, there was no centralized purchase in Ukraine.
- N As per http://medbrowse.com.ua/pegintron-120-cena/ukraina and www.pegintron.kiev.ua/ (both in Russian), verified in interview with representatives of harm reduction programmes.
- l^{ivi} Communication with Anahit Harutyunyan, "Positive People Armenian Network" on 2012 10 12
- lvii http://www.raviminfo.ee/apthkiri.php?atc=L03AB11&apteek=?®ioon=01, access on 2 November 2012
- ^{Iviii} Communication with Martin Georgiev, European Liver Patient Association on 13 November, 2012
- lix List of reimbursable medicines 2011 approved by the health minister (order No V-312, April 1, 2011); source: www.vlk.lt/vlk/files/2011/kv/201108VaistuKainynas.pdf
- 1x http://tabletka.by/result1.php?tlec=%D0%BF%D0%B5%D0%B3%D0%B0%D1%81%D0%B8%D1%81&ns=0&srcreg=1&srctype=1®ion=-23&x=15&y=20, accessed on 10 October 2012
- ^{lxi} Communication with Zulfiyya Mustafaeva, Legal Development and Democracy on 2012 10 12)
- lxii http://www.apvienibahiv.lv/docs/729/2012_dazadi/KZS_HIV_HCV_ARV_2012.xls, accessed on 10 October 2012
- lxiii http://www.ms.go v.md/ru/ministry/regtsenrusproizvod/catalogregtsenrus
- lxiv http://tabletka.by/result1.php?tlec=%D0%9F%D0%B5%D0%B3%D0%B8%D0%BD%D1%82%D1%80%D0%BE%D0%BD&ns=0&srcreg=1&srctype=1®ion=-23&x=19&y=8, accessed on 10 October 2012
- http://www.apvienibahiv.lv/docs/729/2012_dazadi/KZS_HIV_HCV_ARV_2012.xls, accessed on 10 October 2012
- ${}^{lxvi}\ http://www.raviminfo.ee/apthkiri.php?atc=L03AB10\&apteek=?\®ioon=01, access on 2\ November\ 2012$
- lxvii http://www.ms.gov.md/ru/ministry/regtsenrusproizvod/catalogregtsenrus
- ^{lxviii} Communication with Sergey Biryukov, NGO "AGEP'C" on 2012 10 10
- lxix Communication with Sergey Uchayev, Uzbekistan Association of People Living with HIV/AIDS on 2012 10 12
- lxx EHRN (2011). Call for action: reduce prices for hepatitis C treatment. Available at www.harm-reduction.org/images/stories/documents/hcv_call_for_action.pdf.
- lxxi As per http://biocad.ru/138/256/347, http://biocad.ru/139/189 (in Russian).
- lpc-ru (2011) Россия на пути к всеобщемудоступу: междувластью и эпидемией (Russia on its way to the universal access: between authority and epidemics). Available in Russian at http://itpcru.org/netcat_files/10/196/Alternative_report_2011ru.pdf.



Eurasian Harm Reduction Network (EHRN) is a regional network of harm reduction programs and their allies from across 29 countries in the region of Central and Eastern Europe and Central Asia (CEECA). Together, we work to advocate for the universal human rights of people who use drugs, and to protect their lives and health.

The Network unites over 350 institutional and individual members, tapping into a wealth of regional best practices, expertise and resources in harm reduction, drug policy reform, HIV/AIDS, TB, HCV, and overdose prevention. As a regional network, EHRN plays a key role as a liaison between local, national and international organizations. EHRN ensures that regional needs receive appropriate representation in international and regional forums, and helps build capacity for service provision and advocacy at the national level. EHRN draws on international good practice models and on its knowledge about local realities to produce technical support tailored to regional experiences and needs. Finally, EHRN builds consensus among national organizations and drug user community groups, helping them to amplify their voices, exchange skills and join forces in advocacy campaigns.

Since 2008 EHRN hosts the Civil Society Action Team (CSAT) in CEECA. CSAT is a civil society-led global initiative that coordinates, brokers and advocates for technical support to civil society organizations implementing or seeking grants from the Global Fund to Fight AIDS, TB and Malaria.

Become an EHRN Member: EHRN invites organizations and individuals to become part of the Network. Membership applications may be completed online at: www.harm-reduction.org/become-a-member.

Eurasian Harm Reduction Network (EHRN)

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hep C waiting list

I am joining the list for one of the following reasons:

- I live with hepatitis C and can't access treatment.
- I want those living with hepatitis C to receive high-quality treatment.
- I want my government and the pharmaceutical industry to make treatment affordable and stop the hepatitis C epidemic.

We, people living with hepatitis C and their families, representatives of the public sector and of civil society organizations, are signing up for the Hepatitis C Treatment Waiting List to demand affordable, high-quality hepatitis C treatment. Governments can't afford not to treat hepatitis C, but we can't afford the treatment. The cost of pegylated interferon (PEG-INF) - the key component of today's most effective hepatitis C treatment - makes it inaccessible for the majority of those who need it. Merck and Roche, the pharmaceutical giants that produce PEG-INF, keep the price for the average 48-week treatment course at unaffordable and unacceptable level for most people.

We all live in communities affected by hepatitis C, though the majority of people infected with the virus have not yet been diagnosed. Without treatment, hepatitis C can lead to cirrhosis and liver cancer. If governments do not make testing and high-quality treatment accessible to those in need, thousands of people with hepatitis C will die.

We demand that Merck and Roche reduce the price of PEG-INF so that middle- and low-income countries can afford hepatitis C treatment. It is the social responsibility of Merck and Roche to reduce the treatment price to a fair level and stop making millions of dollars while allowing thousands to die.

We demand that national governments allocate funds for hepatitis C treatment, monitor the quality and coverage of hepatitis C treatment, and negotiate price reductions for PEG-INF.

The Hepatitis C Treatment Waiting List holds our governments and the pharmaceutical industry accountable. As the list gets longer, we show our governments, Merck, and Roche the evergrowing demand for effective and accessible hepatitis C treatment. This is more than a symbolic act of solidarity with people living with hepatitis C - it is a collective action directed at those who make decisions about the lives and health of people in our communities. The waiting list will be used in open dialogue with governments and pharmaceutical companies, on the national level and internationally.

you can join Hepatitis C Treatment List: www.harm-reduction.org/petitions/

