



Call for Action:

Reduce Prices for Hepatitis C Treatment

July 28th 2011 marks World Hepatitis Day. The World Health Organization (WHO) refers to hepatitis C (HCV) as a “viral time bomb” due to the remarkable toll in worldwide infections and the extent of time it takes for HCV to become symptomatic. Globally, between 130-170 million people are chronically infected with HCV (WHO, 2011). Eastern Europe and Central Asia (EECA) have carried the brunt of HCV infections with approximately 10 million people living with HCV in the region (Hoover, 2009).

Unlike hepatitis A and B, a vaccine for HCV does not exist. As a result, every year 3-4 million people are infected with the virus (WHO, 2011). However, there is a cure for HCV. With new developments in HCV treatment, there is optimism for a substantial decline in HCV prevalence. Yet, access to HCV treatment for lower middle-income countries, such as most countries in EECA, is severely limited by high drug prices. HCV antivirals are extremely costly for governments let alone the individuals in EECA where the average household monthly wages and salaries per capita range from US \$277* in Ukraine to US \$564† in Kazakhstan. The HCV treatment market is currently regulated by two pharmaceutical companies – Merck and Roche – who keep the price between 10,749 – 16,123 USD at average for one course of treatment. Globally, inaccessibility to HCV treatment has contributed to liver cirrhosis among 50% of people living with the disease and liver cancer among 5% of those living with the disease. Furthermore, 350,000 people per year needlessly die from these and more HCV-related diseases (WHO, 2011).

Reducing HCV treatment prices is possible with the advocacy and pressure of governments, international entities, and civil society. National HCV protocols and programs are essential for effective price reduction negotiation with pharmaceutical companies. If pressure is effectively placed on governments to utilize various price reduction strategies, pharmaceutical companies will be more likely to offer cheaper prices. Price reduction for HIV antiretroviral drugs has made strides in the past decade thanks to the voice and pressure of civil society, AIDS activists, and governments. The same must be done in order to deliver HCV treatment to the millions of people living with HCV today.

Hepatitis C Prevalence in EECA

The EECA region has been gravely affected by an overwhelming incidence of HCV transmitted through injecting drugs with shared unsterilized equipment (Acejas & Rhodes, 2007). Up to 96% of people who inject drugs in Russia are HCV-infected (Gyarmathy et al, 2009; Rhodes et al, 2006; UNODC, 2011). In Latvia, about 74% of people who inject drugs are HCV infected (ENCCA, 2009).

* State Statistics Service of Ukraine, 2011

† The Agency of Statistics of the Republic of Kazakhstan, 2011

Reduce Prices for HCV Treatment

In Georgia, the overall HCV prevalence is 6.7%; while in Kazakhstan, 3.1% of the population is living with HCV (Lazarus, Shete, Eramova, Merkinaite, & Matic, 2007). The spread of HCV in the EECA region creates a dire situation that must be addressed promptly by providing accessible and affordable HCV treatment.

HCV Treatment

In many cases HCV can be treated and cured. Unlike HIV, lifelong treatment is not required; HCV is treated within 24-48 weeks, depending on a combination of viral and host factors (Lagging et al, 2008). HCV genotype 1 is the most common in EECA (European Association for the Study of the Liver (EASL), 2011). Each genotype requires a different treatment regimen. However, all include HCV treatments with pegylated interferon (marketed as Pegasys and PegIntron) and ribavirin (marketed as Copegus and Rebetol).

Unfortunately, extremely high prices make the current standard of care – a combination of pegylated interferon and ribavirin – inaccessible to most people in EECA. *Table 1* demonstrates the disparity in Average Monthly Wages and Salaries per capita and the cost of HCV treatment in 5 select countries of the region.

Table 1. EECA Comparative prices for brand medications, in US Dollars

Prices for HCV medications					
Price USD	Ukraine	Georgia	Latvia**	Russia	Kazakhstan
Pegasys+Copegus (Roche) – 24 weeks	6,000-8,400	6,975	7,169	7,167	9,041
Schering Plough/Merck) – 24 weeks	7,500	8,295	8,134**	6,611	8,712
Pegasys+Copegus (Roche) – 48 weeks	12,000-16,800*	13,950	14,338	14,334	18,082
Schering Plough/Merck) – 48 weeks	15,000	16,590	16,268**	13,222	17,424
Average Household Monthly Wages and Salaries per capita (2010)	277 ¹	316 ^{2***}	818 ³	620 ^{4***}	564 ⁵

NOTE: Prices in the table are based on a rapid assessment provided by EHRN in 2011 and may need further verification. Information comes from EHRN country focal points and is based on their oral communication with pharmaceutical companies if other source is not mentioned.

*The price in Ukraine depends on whether it is provided with free ribavirin or not.

** Base prices retrieved from The Center for Economics in Riga, Latvia

***2009 Data

1 State Statistics Service of Ukraine, 2011

2 Geostat, 2011

3 Central Statistical Bureau of Latvia, 2011

4 Russian Federation Federal State Statistics Service, 2011

5 The Agency of Statistics of the Republic of Kazakhstan, 2011

Competitive pricing of generic HIV antiretroviral drugs helped to significantly reduce costs of HIV treatment and increase its accessibility. Drug manufacturing competition contributed to HIV antiretroviral drug prices dropping from US \$10,000 in 2000 to US \$116 in 2010 (WHO, 2010). Generic ribavirin is registered in a number of EECA countries, but it does not significantly decrease HCV treatment price. In Russia, generic ribavirin helps to reduce price for a 24 week treatment course to approximately 140 USD. It is pegylated interferon that makes treatment so expensive, and generic pegylated interferon is not yet available.

Recent Developments

Since May 2011, two HCV protease inhibitors, boceprevir and telaprevir, have been approved to treat people with HCV genotype 1. Boceprevir (marketed as Victrelis) was recently approved by the European Medicine Agency (EMA) and now goes through a registration process in the countries of the European Union. Telaprevir (marketed as Incivo) has just recently received a positive opinion from the EMA Committee for Medicinal Products for Human Use and is expected to be approved soon (European Medicines Agency (EMA), 2011).

The upcoming standard of care for people with HCV genotype 1 is triple combination therapy, with pegylated interferon, ribavirin and a protease inhibitor. The triple combination therapy can shorten the duration of HCV treatment, and increase cure rates in people with HCV genotype 1 to up to 80% (Zeuzem et al, 2011). Nevertheless, adding a protease inhibitor to the treatment regimen will increase the price to more than 45,000 USD. As the most prevalent HCV genotype in EECA is 1, the new triple combination therapy must be made available and affordable in the region.

Making HCV Treatment Available

An important step towards making treatment available is to adopt a national HCV program. The only national HCV programs across the EECA region are in Kazakhstan and Russia. Ukraine is in the process of developing a national HCV program. In Russia, only HIV/HCV co-infected individuals are treated for HCV, HCV treatment does not have a separate budget line within the national program; and the number of treatment courses are determined upon residual funds from the HIV treatment budget.

HCV medications need to be registered with national pharmaceutical regulation authorities so that these products can be imported into countries to facilitate treatment access. Registering HCV medications is an important step for governmental preparedness to scale up treatment access. HCV treatment must be incorporated into the List of Essential Medicines, thereby allowing medication to be procured through government tenders. If WHO includes HCV drugs into its Model List of Essential Medicines, it can facilitate the process on the national level.

National HCV programs need to cover all types of interventions including HCV prevention, diagnostics and treatment and set clear and achievable targets. Funding allocated for treatment can help to start the dialogue on price reduction with the pharmaceutical companies.

It is vital that national programs focus on most-at-risk populations, particularly injecting drugs users. The national programs should provide resources for harm reduction interventions as well as HCV treatment for vulnerable groups. There is enough evidence that HCV infection in active drug users can be successfully treated with pegylated interferon and ribavirin (Backmund, Reimer, Meyer, Gerlach, & Zachoval, 2005; Robaey & Buntinx, 2005).

One of objectives of a national program can be to adopt HCV treatment protocols. The World Health Organization (WHO) can be requested to provide technical support to governments on treatment protocols.

Call for Action

Mobilize civil society to demand affordable and accessible HCV treatment

Begin a HCV treatment price reduction dialogue by becoming more self-informed and educating the harm reduction community on the high prices of HCV treatment. Document facts of denial of HCV testing and treatment. Frame access to HCV treatment as a human right. Network and build alliances with HCV treatment price reduction advocates including human rights and harm reduction organizations and activists, and people living with HIV and/or HCV; and those impacted by drugs.

Advocate for national HCV programs

Put pressure on governments to develop and implement a national HCV program. Make sure that adequate funding is allocated for treatment of injecting drug users. Accumulate international expertise for HCV national protocol development.

Advocate for WHO leadership in improving access to HCV treatment

Put pressure on WHO to ensure it takes the lead in making HCV treatment universally available. Demand technical support from WHO in developing national HCV programs and treatment protocols. Demand inclusion of HCV drugs in the WHO Model List of Essential Medicines.

Study intellectual property regulations and prepare to negotiate HCV treatment prices when generics become available

Study intellectual property legislation and strategize country-specific actions to make sure generic HCV drugs are registered for when they become available.

**Follow EHRN's HCV Treatment Advocacy Efforts at
www.harm-reduction.org**

References

- Aceijas, C., & Rhodes, T. (2007). Global estimates of prevalence of HCV infection among injecting drug users. *International Journal of Drug Policy*, 18:352-58.
- The Agency of Statistics of the Republic of Kazakhstan. (2011). *Latest Data*. [Data File]. Retrieved from <http://www.eng.stat.kz/Pages/default.aspx>.
- Backmund, M., Reimer, J., Meyer, K., Gerlach, J. T., & Zachoval, R. (2005). Hepatitis C virus infection and injection drug users: Prevention, risk factors, and treatment. *Clinical Infectious Diseases*, 40(5), 330–335.
- The Center for Health Economics. (2011). *Kompensējamo zāļu A un B saraksts, kas stājas spēkā ar 2011.gada 1.jūliju*. [Data File]. Retrieved from <http://vec.gov.lv/uploads/files/4e0c2f08c26e0.pdf>.
- The Central Bureau of Statistics. (2011). *Average monthly wages and salaries of employees, by months*. [Data File]. Retrieved from <http://www.csb.gov.lv/en/statistikas-temas/wages-and-salaries-key-indicators-30608.html>.
- Enserink, M. (2011). First specific drugs raise hopes for hepatitis c. *Science*, 332: 159-160.
- European Center for Disease Prevention and Control (ECDC). (2010). *Surveillance and prevention of hepatitis B and C in Europe*. Retrieved from cdc.europa.eu/en/publications/.../101012_TER_HepBandC_survey.pdf
- 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.
- European Medicines Agency (EMA). 2011. *Incivo*. Retrieved from http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002313/WC500109199.pdf
- GeoStat. (2011). *Wages*. [Data file]. Retrieved from http://www.geostat.ge/index.php?action=page&p_id=149&lang=eng.
- Gyarmathy, V.A., Li, N., Tobin, K., Hoffman, I., ... Latkin, C. (2009). Correlates of unsafe equipment sharing among injecting drug users in St. Petersburg, Russia. *European Addiction Research* 15(3): 163–70.
- 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 http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/hepc_20090821/light_20090821.pdf.
- Lagging, M., Langeland, N., Pedersen, C., Farkkila, M., Buhl, M., Morch, K., ...NORDynamIC Study Group. (2008). Randomized comparison of 12 or 24 weeks of peginterferon alpha-2a and ribavirin in chronic hepatitis C virus genotype 2/3 infection. *Hepatology* 47 (6): 1837–45. [doi:10.1002/hep.22253](https://doi.org/10.1002/hep.22253)
- Lazarus, J., Shete, P., Eramova, I., Merinaite, S., & Matic, S. (2007). HIV/hepatitis coinfection in eastern Europe and new pan-European approaches to hepatitis prevention and management. *International Journal of Drug Policy*, 18: 426-432.
- National Statistical Committee. (2011). [Data File]. Retrieved from <http://212.42.101.124:1041/stat1.kg/>.

Reduce Prices for HCV Treatment

Rhodes, T., Platt, L., Maximova, S., Koshkina, E., Latishevskaya, N., Hickman, M., Parry, J. (2006). Prevalence of HIV, hepatitis C and syphilis among injecting drug users in Russia: a multi-city study. *Addiction*, 101:252-266. doi:10.1111/j.1360-0443.2006.01317.x

Robaeys, G., & Buntinx, F. (2005). Treatment of hepatitis C viral infections in substance abusers: Guidelines on hepatitis c management in patients infected after substance abuse. *Acta Gastro-enterologica Belgica*, 68(1): 55–67

Russian Federation Federal State Statistics Service. (2011). *Average monthly nominal accrued wages of employees of organizations oby kinds of economic activities*. [Data File]. Retrieved from http://www.gks.ru/bgd/regl/b10_12/IssWWW.exe/stg/d01/07-07.htm.

State Statistics Service of Ukraine. (2011). *Basic indicators of social and economic development of Ukraine*. [Data File]. Retrieved from <http://www.ukrstat.gov.ua/>.

United Nations Office on Drugs and Crime (UNODC). (2011). *World drug report 2011*. New York: UNODC. Retrieved from http://www.unodc.org/documents/data-and-analysis/WDR2011/World_Drug_Report_2011_ebook.pdf

World Health Organization (WHO). (2011). *Hepatitis c*. [Factsheet]. Retrieved from <http://www.who.int/mediacentre/factsheets/fs164/en/index.html>.

World Hepatitis Alliance (WHA). (2010). *Viral Hepatitis: Global Policy*. Retrieved from http://www.worldhepatitisalliance.org/Libraries/Campaign_Materials/Viral_Hepatitis_Global_Policy.sflb.ashx.

Zeuzem, S., Andreone, P., Pol, S., Lawitz, E., Diago, M., Roberts, S.,...Beumont, M. (2011). Telaprevir for retreatment of HCV infection. *The New England Journal of Medicine*, 364(25): 2417-2428.