

THE VOICE OF HARM REDUCTION

Hepatitis C Edition, November 2012

At least 160 million people are living with chronic hepatitis C virus (HCV). Each year, it kills more than 350,000 people.

Time of Change: Global Movement Towards Access to Hepatitis C Treatment

By *Karyn Kaplan and Tracy Swan*,
Treatment Action Group (TAG)

In 2010, the XVIII International AIDS Conference featured an unprecedented session on HCV treatment access, with speakers from Brazil, India, Ukraine and the US. Since then, advocacy efforts have gained momentum on numerous fronts. A global movement has begun. Creative advocacy initiatives are in full swing, from Georgia to India; several are highlighted below.

• **The Eurasian Harm Reduction Network (EHRN)** began a **Hepatitis C Treatment Waiting List**, which has been signed by more than 5000 people. The Waiting List demands affordable HCV treatment. On World Hepatitis Day (July 28, 2012), the Waiting List was delivered to the World Health Organization (WHO) and two pharmaceutical companies, Merck and Hoffman - La Roche. Both companies produce pegylated interferon (PEG-IFN) and hold a monopoly, keeping prices prohibitively high (at least 15,000 USD per treatment course).

• **Thai AIDS Treatment Group (TTAG)** invited **New York's Treatment Action Group (TAG)** to Bangkok, to help map out a strategy documenting local availability of HCV diagnostics and



Karyn Kaplan, Treatment Action Group (TAG)

treatment, identify barriers specific to people who inject drugs and people living with HIV/AIDS, and create an **activist-focused and peer-driven educational curriculum**. The curriculum inspired a national movement, which led to HCV treatment access under Thailand's universal healthcare.

▪ **Egypt** has the highest HCV prevalence; over 15% of the population was infected inadvertently through a vaccination campaign. In 2007, the **government committed to treating as many people as possible**. Since then, more than 200,000 people have been treated. **Egypt was able to negotiate a massive price reduction from Merck and Roche**, who agreed to sell their pegylated interferon for approximately 2,000 USD per 48-week course. Availability of a locally produced pegylated interferon gave the Egyptian government the muscle they needed to leverage a better price from the multinational companies.

▪ At the XIX International AIDS Conference in 2012, **activists from around the world met to share needs, advocacy experiences and strategies**. They agreed to the **Washington Call, which has been signed by over 100 organizations**. The "Call" demands that intergovernmental agencies, governments, the pharmaceutical industry and donors ramp up support to address HCV.

▪ In **India**, the Sankalp Rehabilitation Trust **filed a post grant opposition to Roche's patent claim of 2006 on pegylated interferon**, claiming Roche's product patent was illegitimate given that the technology was not new.



Tracy Swan, Treatment Action Group (TAG)

The Trust won the case and the Intellectual Property Appellate Board (IPAB) has revoked a patent granted in India to Roche for Pegasys and held that a patients' group can challenge the validity of granted patents.

While HCV continues to wreak havoc on the lives of poor people, people living with HIV/AIDS, and people who inject drugs, groups like EHRN and TAG are rising to the challenge. Activists are coming together to share information, challenge patent and pricing barriers, demand action on the parts of governments to address the diagnostic and treatment needs of their people, and anticipate new treatments in the pipeline. EHRN, TAG and others hope you will join us to make our aspirations for our communities a reality!

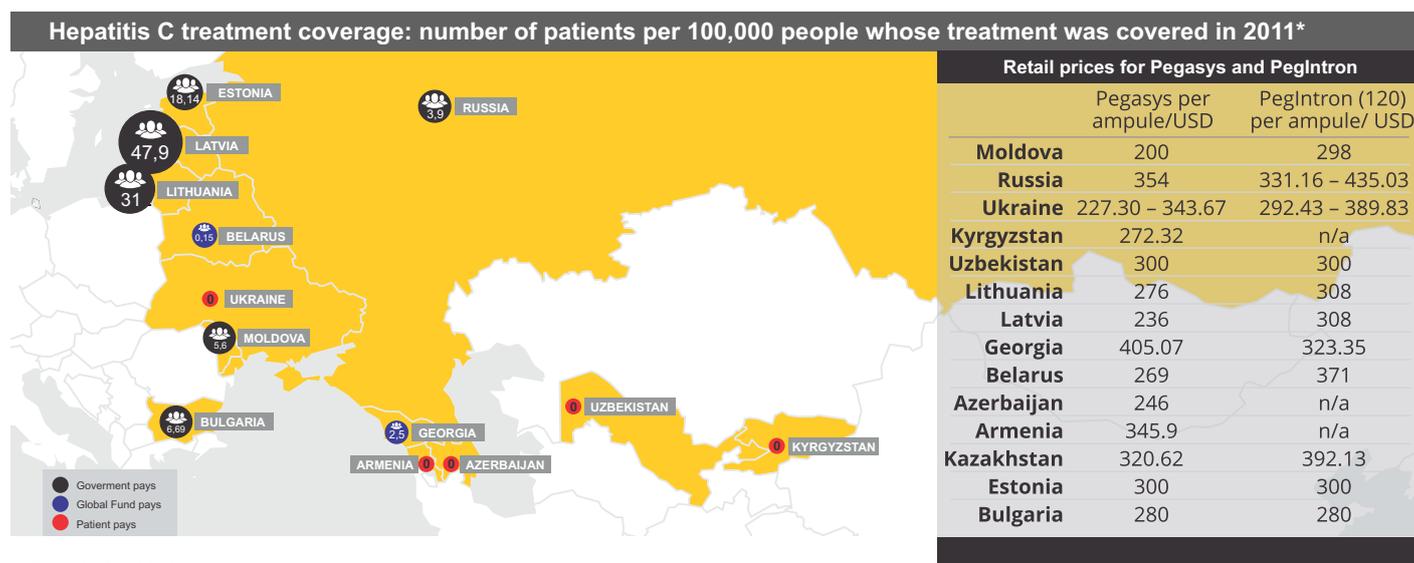
Inside this issue:

<i>Time of Change: Global Movement Towards Access to Hepatitis C Treatment</i>	1
<i>Hepatitis C treatment mapping in EECA</i>	2
<i>Hepatitis C treatment waiting list</i>	3
<i>Local initiatives</i>	3
<i>Being heard</i>	5
<i>Reducing the Price of Hepatitis C Treatment: Mission Possible</i>	6
<i>EHRN: who we are</i>	8

Hepatitis C treatment mapping in EECA

In October – December, 2011, EHRN mapped hepatitis C treatment accessibility in 6 countries of the region: Russia, Ukraine, Kazakhstan, Kyrgyzstan, Lithuania and Georgia.

Mapping results showed that **access to hepatitis C treatment** with pegylated interferon and ribavirin – today's internationally recognized hepatitis C treatment standard– **is very limited**. Extremely high prices make it unaffordable both for EECA governments and for patients.



KEY FINDINGS:

- Hepatitis C is not on the political agenda: no EECA country mapped has a specific national programme on hepatitis C
- Governments do not fund hepatitis C treatment: there are no national hepatitis C treatment targets and budget allocations
- Low quality of treatment due to lack of treatment guidelines commensurate with up-to-date internationally recognized HCV diagnostic and treatment guidelines
- True prevalence of HCV is not known and treatment demand is not documented due to poor or nonexistent surveillance systems
- Low level of awareness both among physicians and patients about hepatitis C treatment literacy

* 2010 in Estonia

Advocacy agenda

ASK GOVERNMENT:

- To develop national hepatitis C strategy / programme in cooperation with hepatitis C treatment activists
- To ensure hepatitis C treatment funding from national budget
- To develop hepatitis C treatment protocols in accordance with international standards
- To develop hepatitis C surveillance system
- To increase hepatitis C testing among most at-risk populations

ASK INTERNATIONAL DONORS

- To establish hepatitis C treatment funding programs

ASK PHARMACEUTICAL COMPANIES:

- To reduce hepatitis C treatment price to 2000 USD for a 48-week treatment course

ASK WORLD HEALTH ORGANIZATION:

- To take a leading role in hepatitis C treatment price reduction by adding pegylated interferon and ribavirin to the WHO Essential Medicines List and to the WHO list of prequalified medicinal products
- To harmonize guidelines for development of bio-similar products and quickly yet thoroughly assess the quality of generic drugs
- To develop treatment guidelines for limited resource settings
- To set targets on treatment availability
- To ask member states to report on HCV prevalence and treatment availability

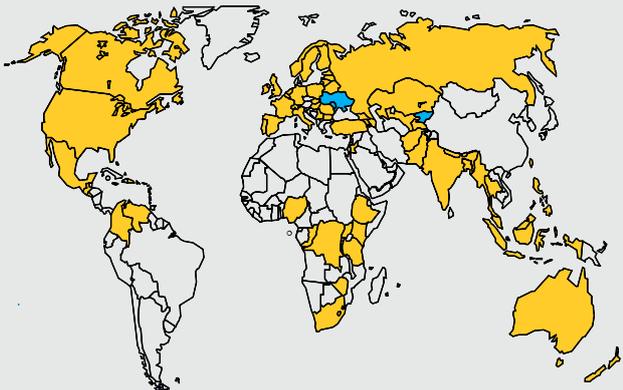
REGIONAL HIGHLIGHTS

Hepatitis C treatment waiting list

Patients around the world demand hepatitis C treatment

In order to document hepatitis C treatment demand and to mobilize communities and their allies around hepatitis C treatment price reduction, in July 2012 EHRN launched the campaign "Hepatitis C Treatment Waiting List". Close to 6000 people from 70 countries signed the petition.

Campaign coverage



Top 3 countries: **Ukraine** (over 3000 signatures) **Kyrgyzstan** (over 1500 signatures) **Moldova** (over 500 signatures)



Visit <http://harm-reduction.org/petitions/> and **sign the petition**

If you want to implement the campaign in your country and **create your national hepatitis C treatment waiting list**, contact Erika Matuizaite: erika@harm-reduction.org

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 an unaffordable and unacceptable level for most people.

Local initiatives

On World Hepatitis Day and around it national advocates run access to hepatitis C treatment campaigns in their countries.

UKRAINE: We demand high quality and affordable hepatitis C treatment for everybody who needs it!

Campaign messages to Government

Provide reliable statistical information on HCV morbidity and spread!
Recognize HCV epidemic in Ukraine!
Approve national program on viral hepatitis!
Approve treatment protocol compliant with international standards!
Ensure state procurement of high quality and safe medicines!

Since May 2012, the International HIV/AIDS Alliance in Ukraine has been implementing a national hepatitis C treatment advocacy campaign. **49 NGOs from 40 cities (22 of 27 oblasts) joined the campaign so far.** The goal of the campaign is to create an informational basis for enhancing the efficiency of advocacy activities of the community **aimed at approval of the state program and oblast programs on viral hepatitis and allocation of budget funds for hepatitis C diagnostics and treatment.** The campaign includes a range of activities: press conferences, round tables, working meetings, gathering of signatures for the open letter to Prime Minister and gathering applications from patients with HCV to regional/oblast healthcare departments. On

REGIONAL HIGHLIGHTS

World Hepatitis Day, July 28, events included street distribution of informational material (booklets, advocacy leaflets), a flash mob, hepatitis C testing, and Living Libraries.

Key achievements of the campaign:

- Gathered over 6000 signatures demanding hepatitis C treatment
- Gathered 350 applications from patients living with HCV to oblast healthcare departments
- Made arrangements with Pharmasco and Synevo laboratories to decrease price by 30% and 50% for diagnostic tests and to provide free rapid tests
- 2 oblasts allocated funds from state budget for social advertising on hepatitis C issues
- Hepatitis C programmes approved in 6 oblasts
- Schools for hepatitis C patients started to operate in 5 oblasts
- Established first coordination council on hepatitis C issues in Ukraine

For more information: Ludmila Maistat, International HIV/AIDS Alliance in Ukraine, maistat@aimsalliance.org.ua

GEORGIA: The value of life is higher than the cost of hepatitis C treatment. Patients need treatment now!

The Georgian Harm Reduction Network has run various hepatitis C treatment campaigns since 2011. The main goal of the campaign on World Hepatitis Day, July 28, 2012, was to increase access to treatment by **demanding a pilot treatment plan for 1000 patients during the first year**. A roundtable with policy makers was organized to present the waiting list and a pilot treatment plan. A range of street actions on World Hepatitis Day took place: gathering of signatures from people living with HCV to stress that they are ready to receive treatment, and an obstacle race symbolizing the unacceptably high cost of treatment. **A letter to all registered political parties running for parliamentary elections in 2012** was sent. The letter asks for **support for state financing for an hepatitis C pilot treatment plan (GEL 15 mln) if candidates are elected to Parliament**.

Key achievements of the campaign:

- Discussion of HCV included in public discourse: more than 10 talk-shows on radio and TV addressed the issue in detail
- Minister of Health, President, and MPs publicly acknowledged the problem and expressed readiness to formulate a policy response
- Several political parties selected the topic for inclusion in their pre-election campaign
- Tbilisi city hall launched a free screening program

For more information: Paata Sabelashvili, Georgian Harm Reduction Network, psabelashvili@hrn.ge

MOLDOVA: Selling a kidney to cure a liver!

Since July 2012 Moldavian NGO "Credinta" has been implementing a national Hepatitis C Treatment Waiting List campaign. The goal of the campaign is to mobilize the community living with HCV and their allies around access to hepatitis C treatment. In cooperation with harm reduction service providers and other organizations working with representatives of vulnerable groups or during the street actions, signatures were collected in the whole country.



Key achievements of the campaign:

- Almost 500 signatures collected for the Moldavian Hepatitis C Treatment Waiting List
- Mobilized community of PLWHIV from western, eastern and southern parts of the country
- National listserv devoted to HCV topic created

For more information: Denis Maruha, "Credinta", maruha78@gmail.com

BEING HEARD

In August 2012, Svetlana Laskova from Uzbekistan approached the Eurasian Harm Reduction Network (EHRN) requesting help getting medicines for her daughter's hepatitis C treatment. Svetlana's daughter Marina is undergoing 48-week hepatitis C treatment in Uzbekistan, and in order to complete it successfully she needs another 16 ampules of pegylated interferon which her family can't afford to buy because of the extremely high price.

With EHRN's assistance Svetlana prepared and distributed a letter to the two pharmaceutical companies producing pegylated interferon, Merck and Roche. Please find below Svetlana's letter:

Dear Sir/Madam,

If you have children, then I'm sure I don't have to explain a parent's anguish when they realize that they can't help their own child. The life of my only daughter is in your hands, and I turn to you hoping for compassion and kindness.

10 years ago there was a tragedy in our family. My then 18-year old daughter, Marina Murtashaeva, had a stillbirth 5 months into her pregnancy. During her surgery Marina experienced internal bleeding and needed an urgent blood transfusion. Four donors responded to the call for help and my daughter miraculously survived. However, a month and a half after the surgery, it was discovered that she contracted HCV (1b) through the blood transfusion. At the time of the surgery Marina's life was in great danger, every minute mattered and the donated blood was not screened for any infectious agents.

We were told that HCV is a chronic and incurable condition, that Marina's health will continue to deteriorate over the coming years, and that the only thing we can do is administer supportive treatment with hepaprotectors. For the next 8 years Marina had not received any treatment

with the exception of Hemodez (later replaced with saline infusions) and Essentiale Forte. Two years ago, following another check-up, Marina was strongly advised to begin treatment as there was a sharp increase in her viral load. That's when we found out that there is a treatment for HCV. However our newly found hope quickly turned to despair after we learned that the cost of treatment with Pegasys and Ribavirin in Uzbekistan is roughly \$20-25,000. We didn't have that much money and how could we? Marina's husband makes about \$100 a month, the country struggles with widespread unemployment. Marina can't find a job and has to take care of her young child.

Yet something needed to be done, so I moved to Moscow to work as a nanny for \$500 a month. Thanks to this, but mostly, thanks to the donations from three different Russian charity foundations, we were able to procure 30 ampules of Pegintron and 9 ampules of Pegasys. In the beginning of 2012 my daughter finally started her long-awaited treatment. In the course of 3 months she received 14 injections with Pegasys. When Marina's HCV test results came back negative, her doctor decided to end the treatment. Looking back, it's clear that that decision was premature. A month and a half later Marina's test results showed that her viral load was higher than prior to starting treatment. The doctors concluded that she needed to begin a new course of 48 injections.

This is what Marina is doing right now. She can't afford to interrupt this course of treatment. She has 15 ampules left from her first treatment attempt. We turned to our relatives and friends, took on large amounts of debt to purchase another 17 ampules. But to complete the full course of treatment we need another 16 ampules, which altogether cost more than \$6000. We have enough medicine to last us until February. I don't know what to do after that. Our family has no savings left, no one to borrow from anymore—and a single dose of the

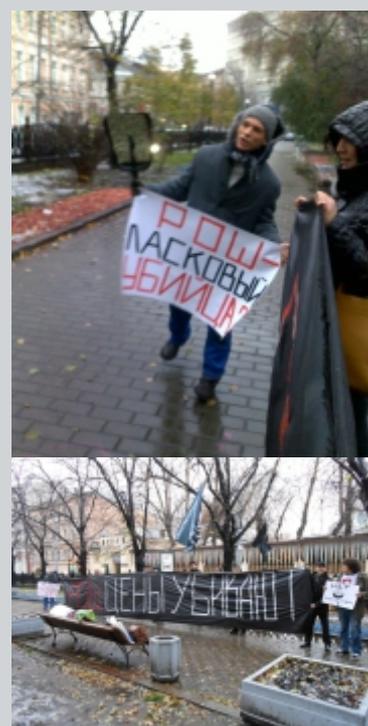
medication costs a bit more than my monthly salary...

Dear drug makers! On behalf of thousands of mothers whose children are living with hepatitis C, I'm appealing to you to reduce the treatment costs for this potentially fatal disease, so that most people living on a middle income could access these lifesaving medications. And I'm asking you to give me the chance to purchase the remaining 16 ampules for my daughter for \$1,000—a price I can afford to pay.

I continue to hope that justice will prevail and that my daughter, who, like millions of other young people throughout the world, is suffering through no fault of her own, will get her lifesaving treatment at an affordable price.

Svetlana Laskova, Marina Muratshaeva's mother.

On October 31, 2012, 15 activists held a protest in front of the office of Roche, demanding a 7-fold price reduction for their hepatitis C medicine Pegasys



Reducing the Price of Hepatitis C Treatment: Mission Possible

Sergey Golovin, ITPCru

Hepatitis C virus (or an abbreviation - HCV) is sometimes referred to as a "gentle murderer", because of its way of "sleeping" in the body for years without showing any symptoms. The epidemic of this disease evolved relatively unnoticed until it had become a global problem, with more than 170 million people living with HCV. Treatment exists - so it possible to defeat the virus? Yes, with two big "buts": the effectiveness of currently available drugs is approximately 50%, and the price of medication is not always affordable even for people residing in "rich" countries. Very few people can afford to pay approximately 15,000 dollars per one year course of therapy, with an average 50% recovery rate.

Because of the high cost and uncertain results even governments often cannot afford to buy drugs to treat hepatitis C. In countries where the medical insurance system is not well developed, patients still rely either on limited government programs or on their own wallets.

One country, however, stands out. This country is Egypt - a sort of reserve of low prices for pegylated interferon (the main component of hepatitis treatment). The cost of peginterferon in this country is about \$2,000, which is 6 times lower than the average price in the rest of the world. Of course, many people (except, perhaps, pharmaceutical companies) would like to see these outlandish prices spread to other regions. What makes Egypt so special? And how can we use this experience to reduce the price of hepatitis therapy in all countries?

In brief, the history is as follows: Egypt

is notorious for its exceptionally high HCV rates and mortality associated with liver diseases. In the early 2000s, in this country with a population of over 60 million, the prevalence of HCV according to various estimates ranged from 7.8% to 13%. Some sources give higher estimates. In many countries even 1% HCV prevalence is already a disaster of national significance. The main cause of infection is medical treatment with injections, in particular, treatment for Schistosomiasis. Egypt is different, for example, from Ukraine and Russia, where according to experts the key HCV transmission risk factor is injecting drug use.

The situation in Egypt reached a point where something had to be done. In 2008, a comprehensive long-term program to combat viral hepatitis for a period of five years was released. This program, developed with the participation of several ministries, UN agencies (including WHO), and research centers and universities, stated four priorities: monitoring, prevention, care and treatment for patients, and research.

The program was ambitious: according to estimates, in the framework of this program almost 190,000 patients received HCV-related care. The Government of Egypt also set an ambitious goal: to provide hepatitis C treatment for 20% of people in need of treatment by 2012.

At that time, treatment coverage was only 2% of 600,000 people living with HCV. In other words, the state communicated to manufacturers that it is ready to cover the cost of more than 150,000 courses of therapy in five years (taking into account forecasts that by 2012 the number of people in

need of treatment was to increase).

The volume of drugs the government was to purchase was to serve as a very strong argument in price negotiations.

HCV treatment price reduction was explicitly stated as one of the components of the state program. We can compare the situation in Egypt to the situation in Russia, where the hepatitis C situation is also challenging. In 2012, the Russian government spent approximately 45 million USD on hepatitis treatment (the Egyptian government spends on its entire program approximately 80 million USD per year). The quantity of drugs purchased in 2012 as part of the federal program should provide treatment for at least 4,000 patients. In addition, the 2012 budget has decreased more than 1.5 times compared with 2011.

But let us return to Egypt. In addition to the comprehensive national program, there was another factor - an unusual situation in the hepatitis C drug market. The situation is unusual because of the presence of competition. Typically, pharmaceutical markets are characterized by inelastic demand and a high degree of monopolization, because it is extremely difficult to enter these markets. In the case of hepatitis C, this rule is observed by almost 100%. But in Egypt, the strong monopoly of the two major producers of pegylated interferon - Merck, Sharpe and Dohme (MSD) (peginterferon alfa 2b, PegIntron®) and Roche (peginterferon alfa-2a, Pegasys®) is cracking. In 2004, a third player - Minapharm - appeared on the market; this company had already been working for several decades in Egypt. Minapharm registered a drug under the brand name Reiferon Retard®. This is a new pegylated interferon alfa-2a,

AROUND THE WORLD

derived from the yeast *Hansenula*. Minapharm's originally proposed price was about four times lower than that of Roche and MSD, and, according to the company representatives, the company quickly won almost half of the commercial market. This strategy eventually forced major peginterferon manufacturers to open up to negotiations and consider price reduction. For example, according to the Egyptian Initiative for individual rights (EIPR), Roche reduced its price from 480 to 250 Egyptian pounds per vial (2011). In 2011, Minapharm supplied the Health

Insurance Organization (HIO) with hepatitis treatment drugs at a price of 220 Egyptian pounds per vial.

This competition resulted in a significant reduction of the average annual hepatitis treatment course cost, to about \$2,000.

In some regions of the world, this treatment can cost up to \$20,000. And what about the patent? In most countries pegylated interferon, produced by Roche and MSD, is protected by patents, and other companies

cannot produce analogues of these drugs (called biosimilar drugs). But technically, Reiferon Retard is not quite a biosimilar drug. The company managed to obtain a license for the mode of production before the patent rules tightened a few years ago after the introduction of new provisions relating to international trade. Since Minapharm still does not attempt to deliver its product to other countries, and uses it only for the domestic market, the issue of patent protection does not arise.

Let us talk about how the Egyptian experience can be used to reduce prices. The first step is to show that the epidemic exists. Not all countries have data on how many people are living with hepatitis C, not to mention the number of people in urgent need of treatment. The "gentle murderer" is quietly doing its dirty work, while officials fail to act. Second is political will. Egypt shows that political will can translate into an explicit, comprehensive long-term program of hepatitis C treatment. Third, it is important to enable other participants to enter the market with high quality analogues of existing drugs, as well as with new, more effective drugs. And, of course, we should not forget about the role of civil society. The more people claim the right to treatment and life, the harder it is for companies to keep repeating the standard excuses to justify the deadly high cost of drugs.

Demand hepatitis C treatment for Egyptian prices!

ACKNOWLEDGEMENTS

On July 9-12, 2013, Vilnius (Lithuania) will host the International Harm Reduction Conference (IHRA) 2013. For the first time there will be a Russian track in the conference. One of the 6 regional sessions will be devoted to hepatitis C. We encourage you to submit an abstract and contribute to hepatitis C policy in the EECA region. The deadline for submission of abstracts is December 15. For more information: russian.abstracts@harm-reduction.org

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 was established in 1997 and is governed by its Steering Committee. The Steering Committee is formed of elected representatives from CEECA sub-regions and community of people who use drugs. In 2001, the Steering Committee established the Secretariat, which is based in Lithuania and carries out the programmatic and administrative activities of the Network. EHRN holds a Special Consultative NGO Status with the Economic and Social Council of the United Nations (ECOSOC).

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.

For more information on how to get involved:

Follow cutting-edge drug development information at: HIV-HCV-TB Pipeline Report, Treatment Action Group (TAG): <http://www.pipelinerreport.org>

Eurasian Harm Reduction Network (EHRN): <http://www.harm-reduction.org>

Sign the "HCV Treatment Access Waiting List" at: <http://harm-reduction.org/petitions/>

The "Washington Call" is available in 6 languages, including Russian, at: <http://www.medecinsdumonde.org/Nos-Combats/Campagnes/Washington-Call-for-access-to-HCV-diagnostics-treatment-and-care-for-all>

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

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