



**Strategies to Increase Access to Hepatitis
C Treatment: A Question of Price or Public
Health? Study based on the situation in
the Eastern European selected countries
Russia, Ukraine and Georgia**

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Executive Summary

Hepatitis C virus (HCV) infection is becoming an utmost global health concern. Worldwide there are 185 million people estimated to be infected with HCV (3% of the world's population). Described as a “viral time bomb” by the WHO, there is a lack of epidemiological data and most infected people are unaware of their status. The virus is transmitted parentally by infected blood, affecting marginalized groups of people who inject drugs (PWID) and people infected with HIV, resulting in 350,000 liver-related deaths a year.

Even though the treatment landscape for chronic HCV is experiencing a revolution since the emergence of the new direct antiviral agents (DAAs) with cure rates exceeding 90%, these new drugs are expected to be priced out of reach in Low and Middle Income Countries (LMICs) where most affected people live. The current standard treatment in most of these countries is the combination of pegylated interferon (PEG-IFN) and ribavirin that depending on the genotype, cures less than half of treated patients with important side effects. Moreover, PEG-IFN still remains inaccessible to most patients and their countries' health systems.

Eastern Europe encompasses a relevant volume of HCV infected people, applicable data, governments with relevant power to take action and initiation of civil society mobilization. This study aims at finding strategies to increase access to HCV treatment throughout the review of the current situation regarding HCV treatment in three selected countries: Russia, Ukraine and Georgia.

The first part of the paper reports the natural history, epidemiology and global burden of HCV, and it is followed by the analysis of the three countries regarding treatment costs, government procurements, how many treatment regimens are potentially available at the moment, and the commitment of governments and civil society toward hepatitis C. This analysis has been developed according to available data and communications with national organizations and patients groups' leaders.

The discussion part entails different advocacy strategies that are currently adopted by national and international NGOs and activists to increase access to HCV treatment from different perspectives. Relevant people involved in this concern from different fields—from academia, to WHO and medical community—have been interviewed in order to engage the discussion and ultimately build a number of recommendations to change the political agenda generating a debate on how to increase access such as the creation of competition and the importance of activism.

The accessibility issues in Easter Europe described in this report are only the tip of the iceberg of a much bigger problem: the high prices of the new generation of highly effective medicines to treat and cure hepatitis C, are starting to cause accessibility problems even in fully developed countries. In the US the price of Sofosbuvir is US\$85,000-110,000 and some insurance companies have decided to ration the medicine for specific patients. Furthermore, at the time of publication of this report, countries such as Spain had just negotiated an agreement with Gilead, the producer of Sovaldi, for which it would pay around 25,000 Euros per treatment. In Spain there are an estimated 700,000 people infected, and the government has only earmarked 124,000 Euros for the purchase of the new treatment. Therefore, if no solution is found, only 5,000 patients out of 700,000 will be able to access the treatment, a situation that could be repeated in other European countries, which could create a real public health problem also in the developed world.

Introduction

Globally, it is estimated that 185 million people are infected, which represents a three per cent of the world's population. Often referred by researchers and policymakers as the “hidden or silent” epidemic, reliable data on global burden remains scarce due to limited surveillance and to that extent the global epidemic is still unclear.

HCV is transmitted parentally by infected blood and the most common route of transmission is the practice of unsafe injections. Additional routes include inadequate sterilization of medical equipment, unscreened blood and blood products, and most rarely, sexual transmission and vertical transmission mother-to-child. The natural course of the infection is usually asymptomatic but when the virus persists in the liver, the so-called chronic HCV infection, it can lead to liver cirrhosis, liver-related cancers and transplants. Overall, estimates indicate that 350,000 deaths annually are due to HCV-related causes.

Global burden of HCV with a focus on Eastern Europe

Even though the major burden of the infection is in LMICs, the global prevalence varies geographically. The most recent epidemiological review appointed Africa and the Middle East as the regions with the higher HCV infection prevalence (>3.5%) whereas Europe reported an intermediate-to-high prevalence (>2.5%). In the specific case of Eastern Europe, there is an overall prevalence of 2.9% that represents more than 6.2 million people.

Furthermore, HCV prevalence is highly present among certain socially, economically and legally marginalized populations, such as high-risk vulnerable groups of people who inject drugs (PWID) who reside principally in Eastern Europe and Asia. The prevalence of HCV infection in the European Union ranges from 45% to >90% in people who inject drugs, and annual incidence rates are 6–40%. There is also a generalised concern in areas where HIV is highly prevalent, especially in Africa. Estimations suggest that between 4 and 5 million people are currently HIV/HCV co-infected. In addition, HIV has a strong impact on hepatitis C, causing higher rates of chronicity and accelerating the disease progression and mortality.

For the purpose of this work 3 countries from the Eastern European region¹ will be studied regarding HCV epidemiology and access to treatment, including the Federation of Russia (hereafter Russia), Ukraine and Georgia. Prevalence figures in the 3 countries selected goes beyond 3.5%, which is the established threshold of high HCV prevalence.

¹United Nations Regional Groups of Member States. Available at: www.un.org/depts/DGACM/RegionalGroups.shtml

HCV genotype distribution

The HCV genetic variation has not only epidemiological relevance, but also has therapeutic importance. HCV has six mostly common genotypes (designated 1–6) along with many subtypes (designated a, b, c, etc.) and they present a diverse geographical distribution. While HCV genotypes 1, 2 and 3 are worldwide spread, genotypes 4, 5 and 6 usually appear in specific regions. In this context and according to the recently released clinical practice guidelines from the European Association for the Study of the Liver (EASL) regarding the management of the hepatitis C infection, genotype 1 is the most prevalent globally, with a higher proportion of subtype 1b in Europe, and genotype 3a is highly prevalent among the European population of PWID.

Genotype 4 is found predominantly in Africa and the Middle East—that being due to the particular case of Egypt, which presents the world's highest hepatitis C prevalence, induced through use of non-sterile injection equipment in a nationwide schistosomiasis eradication campaign. Genotype 5 is almost exclusively found in South Africa, while genotype 6 is endemic in Southeast Asia, Hong Kong and Southern China.

Current treatment recommendations

Most LMICs do not have a well-structured national program on hepatitis and when available, the related clinical guidelines are usually incomplete. The WHO has recently released the first-ever guidelines for the evaluation and management of hepatitis C. Importantly, the WHO will be working with countries to introduce the guidelines as part of their national treatment programmes². The WHO support will include assistance to make the new treatments available and consideration of all possible avenues to make them affordable for all. There are additional relevant clinical guidelines, including the one from AASLD³, constantly being updated, and the EASL published in early 2014. These guidelines, however, may not take into consideration resource-limited settings.

According to the WHO guidelines, it is recommended that the standard of care (SOC) for chronic HCV infection should be the administration of PEG-IFN in combination with RBV. The duration of the treatment varies depending on the genotype, degree of fibrosis or cirrhosis, and HIV co-infection, and it is recommended for as long as 48 weeks both for people infected with HCV as well as for those with HIV/HCV co-infection who present genotype 1. This period remains subject to change depending on the virological response (SVR).

Other recommended therapies by the WHO include the triple combination of PEG-INF and RBV together with Telaprevir or Boceprevir—first generation DAAs—suggested for adults with genotype 1 rather than PEG-INF/RBV alone. Although the treatment shows better SVR results, the side effects are still considerable. Thus, it would require appropriate clinical equipment apart from the supervision of experienced clinicians, and the duration can oscillate between 24 to 48 weeks depending on the response. The availability and cost of DAAs varies depending on the country and may affect the adherence to treatment, especially in LICs.

²WHO. Available at: www.who.int/mediacentre/news/releases/2014/hepatitis-guidelines/en/

³AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org

Finally, the new generation of DAAs —with Sofosbuvir (Gilead) as example of an already approved product— prove to be more tolerable aside from presenting SVR rates above 90%, a shorter treatment duration (12-24 weeks) and most important, being able to be administered without PEG-IFN in some cases depending on the genotype and the clinical condition. The WHO Guidelines Development Group, however, could not take into account resource settings in this case, as the price of these new drugs remains not officially available except for the case of the US —where Sofosbuvir is priced at US\$ 84,000.⁴

It is likely that PEG-IFN will remain the backbone of HCV treatment in LMICs until several barriers to access new drugs against HCV are overcome. PEG-IFN is priced out of reach for most people and for their governments in these countries. Two pharmaceutical companies—Roche and Merck—retain the duopoly of the brand-named PEG-IFN around the world: Roche produces Pegasys® and Merck, Peginteron®. The expiration of all remaining patents on the first generation of biological medicines is opening new hopes for the availability of more affordable copies of PEG-IFN, the so-called bio-generics or biosimilars, which in analogy to the small chemical generic medicines would lead to market competition, lower prices and wider and more affordable access for patients.

The EMA⁵, followed by the US FDA⁶ and other regulatory bodies from high income and emerging countries like Brazil and India, have developed specific guidelines on how to establish biosimilarity and obtain market authorisation. Biosimilar requirements do not include all elements of the complete dossier for the approval of a new biological medicine. However, the “abbreviated approval pathway” in all available Biosimilar Guidelines is much more comprehensive than for small chemical generics and includes a set of preclinical and clinical comparative studies with the reference biologic that are out of reach for most (generic) manufactures and have not been particularly effective in promoting increased access to affordable biological medicines.

The latest emergence of DAAs has not only increased the cure rates but also the tolerability, apart from presenting a reduction of the treatment duration. Hence, highly effective and tolerable innovations mark the beginning of a new era regarding HCV therapies. However, access to standard and new treatments remains low in LMICs. Registration in countries, adaptation of national clinical guidelines, countries’ budget allocation, Ministries of Health negotiations with concerned pharmaceutical companies for national procurement are mandatory before people suffering HCV will get adequate treatments. This work aims at revising the current situation regarding access to HCV treatment in Russia, Ukraine and Georgia and to discuss strategies from different perspectives to increase access.

⁴www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/

⁵Available at: www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001811.jsp&mid=WC0b01ac058004d5c1

⁶Available at: www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm

Methodology

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- In this study, Russia, Ukraine and Georgia are considered Eastern European countries according to the UN Regional Groups of Member States.
 - Regarding literature, peer reviewed publications, reports, briefing papers published and unpublished internal documents have been reviewed (total database over 50 files).
 - The HCV treatment recommendations are based on the WHO guidelines.
 - For the analysis of the three countries, health statistics have been taken from the World Bank and the WHO (Global Health Observatory Data Repository) websites, and HCV treatment information has been extracted from national NGOs reports and email communications.
 - The discussion is based on the other's section information and the interviews undertaken with diverse stakeholders involved in hepatitis C from different fields: academia, WHO, philanthropy, national and international NGOs and medical community.
 - Unfortunately, although having contacted Gilead through different ways —phone, website inquiry and email—, there has not been proper feedback from their part.
 - All interviews and communications were conducted during May-June 2014.

Countries Analysis

Until the new DAAs is available, the major barrier to access HCV treatment in many parts of the world is the high price of PEG-IFN, one of the integral components of the standardized drug therapies to combat HCV infection. This is especially notable in resource-limited settings where interferon-free therapies are not yet a reachable option as it is occurring in the case of Russia, Ukraine and Georgia. In recent years, the average retail price for PEG-IFN in these countries was US\$ 15,000 and the average government purchase price was US\$ 9,500.

Russia

Considered a high-income country, Russia generally presents low health indicators when compared with other emerging economies and there are abysmal differences in health outcomes across regions. The general government expenditure on health was the 10.3% of the total federal budget in 2012 and it represented the 61% of the total expenditure on health of the country.⁷

With a total population of 143 million, 5 million people are estimated to be HCV infected. HCV epidemiological data available is heterogeneous and accurate statistics are not available due to the lack of a united system to collect and analyse information related to the HCV epidemic. Hepatitis C appears in the lists of socially significant diseases and diseases posing danger to others since 2012, and selected HCV medicines can be provided to certain groups of people who have the right to receive governmental social assistance. Surprisingly, there is no federal law supporting the fight against hepatitis C as opposed to the fight against HIV —since 1995—, and TB —since 2001—, both establishing free treatment and testing for patients.

The Russian EML includes some HCV medicines (standard IFN, PEG-IFN and RBV) and the government regulates their maximum selling price. The sum allegedly allocated for the procurement of drugs to treat HIV, HBV and HCV in 2014 is approximately US\$400 million, thus, it is not possible to foresee the amount that will be specifically allocated to procure HCV drugs. Included in the regional target-oriented programs, healthcare administrators can purchase some HCV drugs to that extent, including the first generation of DAAs: Boceprevir, Telaprevir and Simeprevir.

Based on the latest study regarding access to HCV treatment in Russia, over 2012-13 a total of US\$47 million was spent by the government on PEG-IFN procurements, resulting in a total of 176,345 vials purchased to treat 3,700 patients in 48-week regimens. Prices for one and the same drug within a region varied 1.5 times in some regions. Besides, US\$ 4.8 million were allocated to purchase Telaprevir and Boceprevir that could potentially treat 120 patients.

⁷WHO. Available at: <http://apps.who.int/gho/data/node.country.country-RUS>

In a meeting held at the Community Advisory Board in EECA with HCV drug manufacturers in July 2012, it was stated that the main obstacle hindering access to HCV is the speculative pricing policy of pharmaceutical companies.⁸ At the moment, there are speculations around the willingness of the government to start implementing a separate National Hepatitis C Program with a well-detailed budget for treatment, testing and prevention. As for the new generation of DAAs, some sources appoint that Sofosbuvir will be registered in Russia in mid 2015.⁹

“The key priorities in our HCV treatment access advocacy include the price reduction of drugs, to create a separate National Hepatitis C Program and to increase treatment coverage, including people who inject drugs”

Sergey Golovin (ITPCru).

Ukraine

Although facing profound political conflicts since early 2014, Ukraine has been suffering a recurrent health crisis for a long time.¹⁰ The health system started a discrete reform in 2011 and last statistics indicated that the general government expenditure on health was 11.5% from the total budget. The general government expenditure on health from the total budget was 54.9%, thus, almost 50% came from the private sector.¹¹

From a total population of 45.53 million, it is estimated that 4.7 million people are HCV infected in Ukraine, which stands out as the country with the highest prevalence rates in Eastern Europe -three times higher than the world’s average-. However, the government of Ukraine did not procure PEG-IFN before 2013 leaving no option to the patients but to pay their treatment out of pocket. Of course when the prices were ranging from US\$ 10,000 to 18,000, very few could afford to receive it. The situation remained the same until the egregious achievement in September 2013, when the MoH announced a national HCV program to commit to the procurement of at least 13,000 courses totalling US\$ 65 million by 2015. That was stimulated right after the Global Fund and Ukraine Alliance worked together to acquire reduced prices for a single 48-week course of PEG-IFN and RBV treatment –US\$ 5,000 instead of the previous US\$ 13,200- which established a benchmark for the government.¹²

Despite of the recent political instability, the government has committed to continuing the procurement this year, with a budget allocated to HCV medicines equal to US\$8 million, which is more than in 2013. Approximately 16,000 patients could be potentially treated within this budget.¹³ Moreover, MSF was awarded a grant by UNITAID to procure HCV treatment —which will include DAAs— in several countries including Ukraine, where they procure treatment to HIV/HCV co-infected patients.¹⁴

“Our organization will talk to Gilead on including Ukraine on the list of countries with special price for Sofosbuvir. We will also advocate for the development of the next National HCV Program in 2015”

Inna Boyko (Patients of Ukraine).

⁸<http://eeca-cab.org/en/2012/06/14/vstrecha-soveshatelnogo-soobshestva-pacientov-regiona-veca-po-dostupu-k-lecheniyu-gepatita-s/>

⁹Email communication with Sergey Golovin (ITPCru).

¹⁰World Bank. Available at: www.worldbank.org/content/dam/Worldbank/document/Ukraine-Snapshot.pdf

¹¹WHO. Available at: <http://apps.who.int/gho/data/node.country.country-UKR>

¹²The Global Fund. Available at: www.theglobalfund.org/en/blog/2013-10-08_Hepatitis_C_Treatment_in_Ukraine_A_Victory_For_Patients/

¹³Email communication with Inna Boyko. (Patients of Ukraine)

¹⁴UNITAID. www.unitaid.org/en/resources/press-centre/releases/1352-unitaid-approves-grants-of-160-million

Georgia

Georgia is a MIC and its health indicators seem to present a steady improvement, however private expenditures on health remain a challenge in the sector.¹⁵ Total private health expenditures have significantly increased in recent years, representing the 82% in 2012, whereas only 18% came from public financing.¹⁶ At the moment the country is rapidly moving toward achieving universal health insurance coverage, thus trying to improve the financial protection of its citizens.

Georgia has a total population of 4.358 million, from which an estimated 200,000 people live with HCV. The prevalence is two times higher than the world's average and the cost for treatment used to be one of the highest in the region. Since then, civil society organizations in the country have focused on increasing access to hepatitis C treatment, price reduction, and developing and implementation of Hepatitis National programs. In January 2013, the Ministry of Corrections and Legal Assistance supported civil society groups in the process of developing a national program. Moreover, in June 2013 the government adopted a pilot program to procure treatment in prisons and the MoH committed to work on the National program, which is awaiting budget provision from the government.

The prison program included a condition to the pharmaceutical company Roche to procure 10,000 treatment courses for out of pocket sale at the same price. As a result, PEG-IFN price was reduced from US\$246 to 93 per vial (60% reduction). Treatment price includes RBV, distribution, administration and cold chain storage. Furthermore, in March 2014, the Georgian Centre for Disease Control and Public Health and the American CDC started to cooperate and have been discussing models for updating epidemiological data and the design to implement a possible HCV elimination program.¹⁷

In May 2014, the Ministry of Labour, Health and Social Affairs adopted a decree to create a working group for the design of an HCV elimination plan. The working group will be divided in two subgroups; a Negotiation Group to negotiate prices with the pharmaceutical companies that produce the new DAAs, and an Expert Group that will work on the elimination program.

“Official negotiations with Gilead have not started yet but I have applied to be on the Negotiation Group to speed up the process”

Paata Sabelashvili (Georgian Harm Reduction Network).

¹⁵WORLD BANK. www.worldbank.org/content/dam/Worldbank/document/Georgia-Snapshot.pdf

¹⁶WHO. <http://apps.who.int/gho/data/node.country.country-GEO>

¹⁷Email communication with Paata Sabelashvili (Georgian Harm Reduction Network).

Discussion: Strategies to increase access from different perspectives

Having reviewed the current situation of Russia, Ukraine and Georgia regarding access to HCV treatment, and although facing some differences, the three countries share a similar scenario: high presence of groups of PWID and high HCV prevalence, weakness or absence of national programs dedicated to HCV, former Soviet Union governments with disorganized health systems and political will to some extent, civil society starting mobilizations, lack of access to treatment due to high prices and unavailability of new DAAs. Therefore, which could possibly be the strategies to increase access to HCV treatment?

The WHO not only issued the first guidelines for hepatitis C last April but also recently inaugurated a new department for hepatitis and the 67th World Health Assembly that took place last May at the WHO headquarters passed the resolution in relation to hepatitis and improving the health of patients with viral hepatitis.¹⁸ It is expected that these guidelines will also provide a framework for the development or strengthening of hepatitis C treatment programmes in low and middle-income countries.

These are all steps forward towards addressing the viral disease, increasing awareness globally and serve as tools for national NGOs and patients associations to advocate locally. However, considering HCV is a curable disease and preventing the disease liver progression is of high public health value, there is an imperative to increase access to HCV treatment aligned with the need to improve the mechanisms for epidemiological monitoring.

Despite the fact that new generation of direct antiviral agents can cure the majority of people affected by HCV, pegylated interferon and ribavirin are and will stay the standard treatment for lower and middle income countries, due to the excessive prices of more recently developed drugs. However, treatment with pegylated interferon is also unaffordable for most Ministries of Health and for patients suffering HCV in LMICs. Pegylated interferon is one of the oldest biologics developed for which multiple follow-on exist but for the time being none has been assessed and approved within current regulatory framework for biosimilars, leading to continued monopoly pricing and access challenges in the developing world.

Several groups of HCV patients in HCV affected countries are advocating for regulatory experts to find innovative strategies to promote and assess the development of affordable, safe, effective and quality pegylated interferon biosimilars, by clarifying the risk-benefit analysis taking into account the cost of development as well as the price in human lives of having no access at all.

¹⁸WHA67. Available at: http://apps.who.int/gb/e/e_wha67.html. Accessed June 5, 2014.

“The new guidelines’ recommendations still contain PEG-IFN because it is the only option that exists in most LMICs. However, the long-term future treatment for HCV will be DAAs and the guidelines are expected to be updated every 2 years to include the new treatments,”

Nathan Ford (WHO).

The next WHO Expert Committee on Selection and Use of Essential Medicines is expected to meet by April 2015.¹⁹ Relevant applications related to new DAAs are foreseen to be submitted by manufacturers and/or other organizations, so, it will be an important period for advocacy and technical work.

Civil society organizations, as seen in the case of Georgia, play a crucial role in advocating for the access to essential life-saving medicines in many countries. In the case of HCV, many organizations have started to tackle the issue in recent years.²⁰ They are the international voice for HCV patients and have the technical expertise to pressure governments and decision makers. Then, one question arises: how should advocacy be addressed in order to make treatment available and face the public health crisis?

The HCV treatment currently available in Russia, Ukraine and Georgia includes PEG-IFN, and even if some price reductions have been achieved in selected countries, it still remains too high for most patients living in these countries. Thus, additional efforts are painfully needed to reduce pricing with Merck and Roche as well as advocating with regulatory authorities to define a pathway for biosimilar assessment that takes into consideration the access perspective.

Despite the demonstration that large-scale manufacture of two or three drug combinations of HCV DAAs is feasible, with minimum target prices of US\$100-250 per 12 week treatment course, current pricing information of second generation DAAs are likely to be exorbitant and limit treatment access. New DAAs are expected to be available not before 2 to 5 years in these countries. It takes time to register new medicines, more in these countries where the system is highly bureaucratic. It will then take time and creative strategies to make DAAs available widely and affordably.

“We have and we are advocating for new drugs but let’s not drop the ball on PEG-IFN because it is curing patients in these countries now,”

Els Torreale (OSF).

Funding agencies such as the Global Fund and UNITAID procure some treatment for HIV/HCV co-infected patients. Even though that mainly serves to treat a handful of HCV mono-infected patients that is not going to make a big difference, it can be a catalyst in order to make governments react, as happened in the case of Ukraine. The counterpart is that these agencies are primarily oriented towards HIV/AIDS, TB and malaria and it is unlikely that they would widely include HCV. Moreover, international generosity seems to be decreasing.

Currently, there is not an international financing mechanism for HCV treatment, thus its purchase solely remains in the direct commitment and possibilities of the states alone.

The HIV/AIDS experience in reducing treatment prices from more than US\$ 20.000 in the 90s²¹ to less than US\$ 100 may seem similar to the situation with hepatitis C treatment today. It is true on a principle basis; however, there are relevant differences to considerate. First of all, HCV

¹⁹WHO. www.who.int/selection_medicines/committees/en/

²⁰<http://www.treatmentactiongroup.org/press/2013-pipeline-report>

²¹Schwartländer B, Grubb I, Perriens J. The 10-year struggle to provide antiretroviral treatment to people with HIV in the developing world. *Lancet*. 2006 Aug 5;368(9534):541-6. Review.

prevalence is five times that of HIV and a large proportion of infected people remain unaware of their status. The greatest challenge is around strengthening the global advocacy on HCV to pressure governments, international decision makers and the participation of the pharmaceutical industry.

Moreover, the rather poor social mobilization on hepatitis C at an international level compared with AIDS could be due to the false perception of indolent course of HCV. The inclusion of new DAAs in the WHO Model List of Essential Medicines could greatly help increasing access to HCV treatment as well as countries using all the provisions permissible under international law to protect the public health aligned with local production and/or compulsory licenses. In addition, the low pricing scenario which allowed more than 10 million people living with AIDS to have access to treatment by 2012, proved to work for first line AIDS treatment 15 years ago but the world could not reproduce the same success for the second line treatment that remains unaffordable.²²

Finally, it is unclear how many international and national donors will commit to fund hepatitis C treatment as opposed to other diseases. The hepatitis C epidemic is prevalent in MICs not eligible to international funds and mainly affecting vulnerable groups currently not covered by health insurance schemes, and not able to afford such exorbitant prices out of pocket.

“I am convinced that the current efforts from civil society and medical community together with the UN, can lead to significant reduction in prices. It will take some time but it will happen,”

Michel Kazatchkine (UN special envoy for HIV/AIDS in EECA).

At the moment, there is a patent opposition for Sofosbuvir in India where Gilead had started the registration procedure of its new drug, which claims that Sofosbuvir is not innovative enough.²³ If the patent office decides that Gilead cannot get the patent, the process could then lead to court as the Novartis case. Many activists support patent opposition, and they see it as replicable to a number of other countries.

“We facilitate the filing of patent oppositions, helping to produce patent landscapes, and enabling international lawyers to work with lawyers in different countries to engage in oppositions,”

Rohit Malpani (MSF).

The preferred strategy of most pharmaceuticals is to negotiate tiered pricing in MICs and voluntary licensing in LICs. During the first HCV World Community Advisory Board (CAB), Gilead announced a list of 60 countries that will have a special price for Sofosbuvir. In theory then, these licenses will leave out 77.5 million people with HCV in LMICs from the access of Sofosbuvir.

“In April Karyn Kaplan –also activist from TAG–, worked closely with our colleagues to hold the first demonstration at an hepatitis C scientific meeting– EASL, to protest the price of Sofosbuvir,”

Tracy Swan (TAG).

Towards seeking guidance and expert opinion on the development of an R&D-based strategy and prepare a draft Target Product Profile for a timely, affordable, and efficacious treatment for hepatitis C, DNDi convened an Expert Consultative meeting on hepatitis C in Geneva, Switzerland, on March 18th 2014.²⁴

²²UNAIDS: www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/20130923_FactSheet_Global_en.pdf

²³<http://spicyip.com/2013/11/i-mak-files-pre-grant-opposition-against-gileads-anti-viral-drug-sofosbuvir.html>

²⁴Personal communication from Graciela Diap MD, DNDi associate staff.

Conclusions and Recommendations

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- While it is curable, the vast majority of people living with hepatitis C reside in low- and middle-income countries where treatment is virtually inaccessible entailing a public health problem. Current treatment is expensive and in most cases depends on the economic resources of the patients instead of relying on the capacity of the health systems.
 - In line with the newly developed WHO Guidelines, proactive support is urgently needed for policy-makers, government officials, and others working in low and middle-income countries that are developing programmes for the screening, care and treatment of persons with HCV infection.
 - The field of HCV therapy is evolving rapidly and current trends indicate that the era of shorter, interferon free, fixed-dose combination, single pill regimes with high rates of success and good tolerability are near. The prospect is that it will be many years before the new drugs are rolled out to all who need them because high prices of these treatments exclude most of the affected people.
 - Regulatory efforts are required for assessing and market affordable versions of pegylated interferon to treat HCV in LMICs until new generation of HCV drugs are universally available and affordable.
 - International commitments should force the creation of a competitive market for generic companies to manufacture affordable treatments for HCV (DAAs), applying similar strategies as for HIV/AIDS.
 - The rates and most importantly the reasons of barriers to treatment in chronic HCV patients vary widely among countries. Although The Global Fund for TB, AIDS, and Malaria is providing some marginal resources for co-infected patients, there is no such thing as a global initiative to promote the natural increase of HCV treatments.
 - To scale up access to hepatitis C treatment, attention is required both to the millions in need now who can benefit from PEG-IFN if made more affordable, as well as to make available the new oral drugs widely and affordably, which will likely take some time and may require a combination of strategies.
 - Considering the cases studied in Russia, Ukraine and Georgia and the discussion of different strategies it is ultimately recommended:

- Activism to increase political responsibility.
- Country-specific national strategies.
- Resource allocation and implementation of global management policies.
- Patent opposition.
- Insist on generic production.
- Local production and/or compulsory licenses and other arrangements permissible under international law to protect public health.
- A bid to globalize the problem

Acronyms and abbreviations

AASL	American Association for the Study of the Liver
CDC	Center for disease Control
DAA	Direct Anti-viral Agent
DNDi	Drugs for Neglected Diseases initiative
EASL	European Association for the Study of the Liver
EECA	Eastern Europe and Central Asia
EMA	European Medicines Agency
EML	Essential Medicines List
FDA	Food and Drug Administration
GHRN	Georgian Harm Reduction Program
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIC	High Income Country
HIV/AIDS	Human Immunodeficiency Virus/Acquired immunodeficiency Syndrome
ITPCru	International Treatment Preparedness Coalition Russia
LIC	Low Income Country
LMICs	Low and Middle Income Countries
MIC	Middle Income Country
MoH	Ministry of Health
MSF	Médecines Sans Frontières
NGO	Non-Governmental Organization
OSF	Open Society Foundations
PEG-IFN	Pegylated Interferon
PWID	People Who Inject Drugs
RBV	Ribavirin
R&D	Research and Development
SOC	Standard of Care
SVR	Sustained Virological Response
TAG	Treatment Action Group
TB	Tuberculosis
UN	United Nations
US	United States
WHO	World Health Organization

- 1** Wiktor S., Nguyen T., Clark N., Easterbrook P., Vitoria M. and SA. WHO Guidelines for the screening, care and treatment of persons with hepatitis c infection. 2014;(April). Available at: www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/.
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