REPORT #2

DYING AT THESE PRICES:
GENERIC HCV CURE DENIED

mapCrowd
Online global data on hepatitis C

DIRECT ACTING GENERICS
YES WE CURE

July 2016
Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS. For more information, please visit www.treatmentactiongroup.org

Present in France and in 64 countries, Médecins du Monde is an independent international movement of activists who provide care, testify, and accompany social change. From our 255 innovative medical programs and advocacy based on facts, we place people who are excluded and their communities in the capacity to access health while fighting for universal access to care. For more information, please visit www.medecinsdumonde.org

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Hepatitis C Virus (HCV) elimination never seemed so close, yet the road ahead is precarious for the 80 million chronically infected people worldwide.¹ The HCV deaths-related toll -- approximately 700,000 persons every year -- grows more unbearable each day as stakeholders pass on major opportunities to escalate the response to the epidemic. Effective national elimination policies and programs need monitoring and surveillance. However, accurate and meaningful data is too often unavailable.

mapCrowd is an online crowdsourcing platform created by Médecins du Monde (MdM) and Treatment Action Group (TAG), designed to help collect and share up-to-date HCV information. Since mapCrowd was launched earlier this year, many reached out to participate, contribute and access data on HCV worldwide. The platform now displays a consistent dataset on HCV for more than 40 countries, building further on an expanding network of contributors. It includes data uploaded by HCV advocates across the globe, as well as current scientific and institutional information, presenting national epidemiological, diagnostic, treatment and policy data, and contact information for local HCV organizations. mapCrowd data is available at mapcrowd.org for free; users can access interactive charts, graphs and maps, and download the full mapCrowd dataset.

mapCrowd connects contributors and users from around the world, to share valuable information. HCV experts and advocates who join mapCrowd will enhance international HCV advocacy networks and, through sharing national data, will shed light on current conditions in their own countries. mapCrowd will continually incorporate data from new countries, and provide a regular stream of updates on developments in the global HCV epidemic.

In late 2013, new direct-acting antivirals (DAAs) for the treatment of hepatitis C were launched worldwide. New treatment regimens - combining DAAs and interferon-free - are now being prescribed. They have shown to cure over 90% of people with HCV, often in 12 weeks, with limited side-effects. Thus, they revolutionized hepatitis C treatment. Prospects of an HCV-free world have never been so attainable in our lifetimes. Unfortunately, the price of new regimens remains the main barrier to access for a vast majority of people with HCV around the world.

Latest analysis of mapCrowd data paints a contrasting picture of the road to HCV elimination.

**High-income countries: The rationing game**

According to data collected in mapCrowd, 14 out of 17 countries in Western Europe set up treatment restrictions for people with HCV within their territory. Most of the time, DAAs are limited to those exhibiting the most severe conditions. These restrictive policies are mainly due to high prices charged for treatments: DAA combinations’ prices range from US$25,000 to US$75,000. As a consequence, none of the countries allow general practitioners to prescribe DAAs, which was generally the practice for previous treatment with pegylated-interferon.

On the other side of the Atlantic, the United States adopted rationing policies, while HCV is shown to be killing more people than any other infectious disease nationwide. DAA combinations are sold between US$54,600 and US$83,319 across the US, and coverage by insurance is erratic.

**HCV generics: Free the cure!**

The ongoing battle for generics access sounds sadly familiar. It was the case for antiretroviral (ARV) treatments, and the availability of generics is key to reduce treatment prices. Competition among manufacturers creates pressure to reducing costs throughout the production process, resulting in general downward trends in prices.

Using data collected in mapCrowd, the case for generics’ effects on treatment prices is demonstrated once again. Out of 13 countries, we can establish an average price for branded sofosbuvir (Gilead’s Sovaldi®) at US$38,154 when no generic competition exists. By comparison, the mean price for the same branded sofosbuvir sets at US$2,023 in 5 countries where generics are also available on the market. Beyond this reducing effect on the prices of branded drugs, generics are also a viable alternative for people with HCV to access life-saving treatment. The average price for generic versions of sofosbuvir is US$921, while the generic version of daclatasvir drops to US$241.

As these prices are continuously decreasing where generic competition is effective, the best prices might be still ahead, as the «Rapidly falling costs for new hepatitis C DAAs: Potential for universal access fair price» study (led by Dr. Andrew Hill)
powerfully demonstrates. They recently updated their lowest projected cost of production and retail price for sofosbuvir and daclatasvir generic versions to US$62 and US$14, respectively.

Generics can be introduced on the market using legal tools, such as compulsory licenses and patent oppositions. Moreover, generics’ safety and efficacy is already being documented, revealing performances similar to branded versions of the treatment course. With all these tools at decision-makers’ disposal, there should be no time wasted before engaging meaningfully with programs to eliminate HCV infection.

**Treatment uptake: Political will knocked off course by drug pricing**

Targets discussed by the international community toward HCV elimination are still far from reach. In mapCrowd countries with data available, treatment uptake in 2015 ranges from 0.13% (Malaysia) to 8.4% (the United States). The highly anticipated treatments scale-up, following the DAA therapeutic revolution, is evidently slower than expected. Treatment access dynamics, deeply intertwined with drug pricing, depend on the ability of States and health authorities, alongside civil society, to set up aggressive drug pricing strategies to widen the number of persons treated. Between 2013 and 2015, Pakistan, for example, achieved similar treatment uptake progression as France, which was once considered leading in the field of HCV treatment access worldwide.

**People who inject drugs: Highest burden, lowest uptake**

While people who inject drugs face the highest burden for HCV infection, they are more frequently excluded from prevention and treatment. HCV elimination cannot be conceived without enhancing access to diagnosis and treatments for those most at risk of being infected. Although these dynamics are well documented, treatment uptake among people who inject drugs remains very low. Stigma and criminalization act as powerful restrictions to access life-saving care and treatments. Yet the case for access to treatments for people who inject drugs is currently being emphasized. Preliminary results from a project implemented with Médecins du Monde in Georgia show promising outcomes. In a peer-support intervention -- designed to facilitate the access of people who inject drugs to a national HCV elimination program -- 98.8% of participants completed treatment with very good adherence.

So far, the cohort reached a 90.1% cure rate with an undetectable viral load at week 12 after treatment. Similar programs using harm reduction approaches can continually make an impact in curbing HCV rates.
The data and key findings highlighted in this report and on the mapCrowd website originate from a combination of scientific publications and field-based sources. mapCrowd relies on a network of national HCV experts and advocates, or “mapCrowders,” who act as focal points for data collection. Most mapCrowders are affiliated with non-governmental organizations (NGOs). They are selected for their expertise in HCV advocacy and their capacity to obtain country-level information from a variety of sources. To supplement their contributions, mapCrowd also incorporates data gathered from a literature review of peer-reviewed medical journals, expert reports and institutional research.

Since mapCrowd was launched in February 2016, HCV experts and advocates were granted access to their respective country profile, upon review of their background and ability to gather relevant data. mapCrowders were then able to update online data on HCV at the national level according to their research and network. In some cases, respondents reported that data was hard to obtain or only partially available (such as data on yearly national treatment uptake). Where possible, mapCrowders worked with ministries of health to obtain the most up-to-date information and complete missing data.

### mapCrowd Data Sources

#### General Country Information
- The World Bank Open Data (http://data.worldbank.org)

#### HCV Epidemiological Data
- mapCrowders

#### HCV Diagnostics
- mapCrowders

#### HCV Treatment
- mapCrowders

#### HCV Policy
- mapCrowders

#### Organizations
- mapCrowders
I. HIGH-INCOME COUNTRIES: THE RATIONING GAME

In Western Europe, regarded as a high-income region although economic disparities exist, new DAAs are registered and protected by patents throughout the region. In 14 out of 17 countries examined, high-priced DAAs resulted in restrictions to access. Taking many forms, from eligibility criteria to reimbursement level, astonishing disparities within the region show a lack of coordination on strategizing the response to the epidemic at the European level.

Restrictions on access

Germany, the Netherlands and Portugal are the only countries opposing no restrictions for people with HCV in treatment guidelines. However, in practice, universal access is not guaranteed. For instance, in 2015, Portugal initiated a policy granting universal access to HCV treatments; however, geographical disparities still remain for effective access. The people who are at most risk of HCV transmission, namely people who inject drugs and prisoners, still face very low uptake.

Other countries make recommendations in national guidelines to include specific populations, but effective access is compromised. While in Greece people who use drugs are not restricted from accessing treatment, they must be enrolled in a drug treatment-related program to obtain life-saving medicines. In France, after a harsh battle to demand universal access for new regimens of treatments, there have been recent announcements for the gradual inclusion of so-called vulnerable populations in treatment access programs. However, the modalities for effective access are still unclear.

Who can prescribe?

Prescription mechanisms can have a positive effect on increasing treatment uptake nationwide. New treatments, such as DAAs, allow for the expanding the scope of prescribing practitioners, given the simplification in follow-up and administration. However, to this day, prescribing is still limited to specialists in Western Europe, with few exception in sight.

Except for Germany, where general practitioners can prescribe DAAs, liver specialists and infectious disease doctors are the generally designated prescribing practitioners. A patient could access HCV treatment from both types of doctors in Greece, Ireland, France, and Italy, which are the latest countries to have an additional option of internists for prescribing. Meanwhile, a patient would be limited to waiting for an appointment with a liver specialist in Belgium, and could turn only to an infectious disease doctor in Sweden.
Treatment uptake in the US, with a focus on people who inject drugs

MapCrowd data gives rough estimates on the number of people with HCV treated each year, approximately 125,000 (in 2014) and 260,000 (in 2015). About 40-60% of people who inject drugs (PWID) have chronic HCV. Of these people, only 1-2% are treated each year in the US. The increase in treatment uptake between 2014 and 2015 can be attributed to new, better tolerated, effective DAAs on the market, as opposed to previous treatments which had greater side effects and lower efficacy.

However, due to stigma, discrimination, poor linkage to care, and a significant majority of people who inject drugs not knowing their status, HCV-related mortality has been increasing. HCV is now killing more people than any other infectious disease in the US. This indicates that people living with HCV are not accessing antiviral therapy and achieving the sustained viral response (SVR) of a cure. A study found that only 19% of people with hepatitis C and 16% of HIV/HCV co-infected patients were eligible for and received treatment; 13% and 11%, respectively, completed therapy; and 3% and 6%, respectively, were cured.

Drug pricing for DAAs in the US

Table1. Drug pricing for DAAs in the US

<table>
<thead>
<tr>
<th>DAA Treatment</th>
<th>Average cost of 12-week course (in USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daclatasvir (Daklinza*)</td>
<td>63,000</td>
</tr>
<tr>
<td>Elbasvir-Grazoprevir (Zepatier*)</td>
<td>54,600</td>
</tr>
<tr>
<td>Ombitasvir-Paritaprevir-Ritonavir (Technivie*)</td>
<td>76,653</td>
</tr>
<tr>
<td>Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir</td>
<td>83,319</td>
</tr>
<tr>
<td></td>
<td>(Viekira Pak*)</td>
</tr>
<tr>
<td>Simprevir (Olysio*)</td>
<td>66,360</td>
</tr>
<tr>
<td>Sofosbuvir-Ledipasvir (Harvoni*)</td>
<td>72,765</td>
</tr>
<tr>
<td>Sofosbuvir (Sovaldi*)</td>
<td>64,680</td>
</tr>
<tr>
<td>Sofosbuvir-Velpatasvir (Epclusa*)</td>
<td>74,760</td>
</tr>
</tbody>
</table>

A frayed safety net and complex patchwork of restrictions limit access to DAAs

In the United States, access to DAAs against HCV depends on:

- Type of insurance (publicly funded or private);
- Military service;
- Geography and strength of healthcare network in each state;
- HIV status;
- Disease progression;
- Previous or current alcohol and drug use.

The “Big Four” federal public payers have the greatest purchasing power and receive the largest discounts on the latest DAAs: Veterans Administration, Department of Defense, US Coast Guard, and Indian Health Service. For senior citizens, Medicare Part D insurance must include at least one DAA on their formularies. However, individual supplemental co-insurance determines out-of-pocket costs for seniors, which can range from under US$700 to over US$10,000. The Veterans Administration provides DAAs for all covered veterans, but navigating the system can be cumbersome and time-consuming, with waiting lists for months.
As part of federal health insurance reform under the Affordable Care Act (ACA), 32 of 50 states have expanded publicly funded Medicaid coverage for low-income US citizens and residents to include those making up to 30% of US GNI (or US$16,243/year in 2015). States that did not expand Medicaid coverage created a situation in which the population’s income is too high to qualify, but too low for people to be able to afford subsidized, private insurance through the ACA. This lack of coverage leaves behind at least 2.9 million people; the poorest people in the poorest states are more likely to be infected by HCV.

Restrictions put in place by public and private payers are incoherent with American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL) HCV treatment guidelines, particularly states’ sobriety requirements, and can be seen as ways to avoid paying the high price tags for the latest DAAs. Patient groups, medical professionals, clinical researchers, and other health advocates have mobilized state and nationwide responses to lift treatment restrictions and expand access.

In response to advocates’ demands, threats of lawsuits, and pressure from state Attorneys General, Medicaid programs in Delaware, Florida, Massachusetts, and New York no longer restrict DAA coverage to recipients with late stage fibrosis/cirrhosis. In 19 states, individuals co-infected with HIV have access to DAAs through Medicaid, but 10 of those states require undetectable levels of HIV to access HCV treatment. Untreated HCV in HIV co-infected people accelerates disease progression and other health issues, such as liver cancer and cirrhosis. Curing cases of HCV can improve health outcomes for people living with HIV who are co-infected.

Additional levels of complexity – and barriers – persist despite these recent changes. For example, in New York State, expanded access only applies to Medicaid recipients in Fee-for-Service programs (about 10% of those on Medicaid), whereas the vast majority of recipients are covered under Managed Care Organizations (MCOs), a different payment model. Restrictions based on previous or current alcohol and drug use remain in place for New York MCO recipients. The seven largest private insurers in New York State cover treatment at all disease stages, with no restrictions on active drug and alcohol use. Restrictions barring active drug and alcohol users from receiving DAAs continue in at least 30 states.

Even where legal challenges have been successful, access lags. In Washington State, a federal judge ruled in favor of Medicaid coverage for all HCV patients, but implementation has not begun to date. One private insurer operating in 14 states covers DAAs for all HCV patients, and another one offers HCV drugs nationwide, but only through specialty pharmacies. Out-of-pocket costs for private insurers vary and all require prior approval.
**Additional access issues for special populations**

In addition to people who do not qualify for publicly funded Medicaid insurance or those who struggle to pay out-of-pocket costs, prisoners and undocumented people comprise key populations who are infected with HCV and do not have access to treatment.

**Prisoners**

The US has the largest prison population in the world, with over 2.2 million adults in prisons and jails. Of these, 10% are detained in federal prisons, 57% in state prisons, and 33% in county or municipal jails. The Federal Bureau of Prisons (BOP) Evaluation and Management of Chronic HCV Infection guides assessment and treatment of federal prisoners and serves as the model for many state prison systems. The BOP recommends voluntary testing for all sentenced and long-term inmates. All HCV antibody positive individuals should be evaluated for cirrhosis and receive quantitative RNA viral load testing to confirm active infection.

Patients in the prison system are treated according to priority criteria:

- Priority 1 (highest level) - Cirrhosis, liver transplant recipient or candidate, comorbidity, HCC, chronic kidney disease (GFR <30 mL/min) or dialysis, receiving immunosuppressant therapy for a comorbid condition or those already on treatment.
- Priority 2 - Stage 3 fibrosis, HIV or HBV co-infection, chronic kidney disease (GFR 30-59 mL/min), comorbid liver disease.
- Priority 3 - Stage 2 fibrosis, diabetes or porphyria cutanea tarda.
- Priority 4 - All other patients.

All these patients must have more than 18 months of life expectancy, demonstrated ability to adhere to treatment, and avoid “risky behaviors.” Approved treatments in the prison medical formulary include: daclatasvir + sofosbuvir, Zepatier, Harvoni, Viekira Pak, sofosbuvir + simeprevir, sofosbuvir + ribavirin.

According to the National Hepatitis Corrections Network, states are free to determine their own guidelines, with many modeling their guidelines on the BOP. Prisoners have a right to adequate medical care, but the burden remains on prisoners themselves to demonstrate that prison officials have acted with “deliberate indifference to serious medical needs” when there has been a denial of care. A key US Supreme Court ruling considered whether a medical issue would be treated by a reasonable doctor; if daily activities are impacted; and whether the prisoner is experiencing chronic, substantial pain. In addition, some states charge prisoners for medical care.

Individuals who have already initiated HCV treatment when arrested or detained are held in county or municipal jails. Some local jails, such as Rikers Island in New York City, have expressed commitments to continue treatment for all detainees.

**Undocumented migrants**

An estimated 11 million undocumented migrants live in the United States, including 30,000 people in detention centers awaiting deportation. Despite contributing to publicly funded social safety net programs through sales taxes and via illegally purchased social security numbers provided to employers, these individuals are excluded by law from Medicare, Medicaid and subsidized private health insurance under the ACA. New York and California have recently expanded publicly funded health insurance to include low-income residents regardless of federal immigration status. It is difficult to obtain accurate HCV-related data among undocumented migrants, but concerted efforts by the medical community must be taken to ensure their access to treatment and prevent HCV transmission.
II. HCV GENERICS: FREE THE CURE!

Direct-Acting Antiviral (DAA) regimens have shown cure rates above 90%. Highly effective, safe and tolerable, they do not require intensive monitoring. This creates an opportunity for the global elimination of hepatitis C. However, due to the exorbitant prices charged for DAAs, a tiny fragment of people with HCV actually access these life-saving drugs (see page 17). The main barrier to HCV treatment access, across all country contexts, remains price. The availability of generic drugs alongside originator manufacturers’ competition has been—and continues to be—the most efficient way to dramatically bring down drug prices (see “Lessons Learned from HIV” section).

The impact of generics on general drug pricing is clearly revealed when examining the data collected, to date, from mapCrowd on the lowest prices for sofosbuvir and daclatasvir worldwide, including both the branded and generic versions when available on national markets. For a person who seeks care in the United States, it costs over 500 times as much as for a person who seeks care in Pakistan to receive a similar dosage of sofosbuvir. This is particularly due to the availability of generics on the market and competition between manufacturers to reduce costs.

Table 2. Prices of sofosbuvir for 12 weeks in mapCrowd countries, 2016 (USD)

Table 3. Prices of daclatasvir for 12 weeks in mapCrowd countries, 2016 (USD)

The price of generics still doesn’t make a difference if access is prohibited in a country by provisions in free trade agreements, including intellectual property mechanisms that go beyond the TRIPS Agreement. Fortunately, a range of legal tools exist and should be used wherever possible to increase access to HCV treatments.

At the core of the generics production process are active pharmaceutical ingredients (API). However, licensing is one of the stumbling blocks in the battle for “the fair price”, which can be reached with generics as reasonable alternatives. In addition, clear of the price obstacle, the issue of safety and efficacy of DAAS generics remains. While waiting for World Health Organization (WHO) prequalification for sofosbuvir and daclatasvir (which is currently underway), Dr. James Freeman led a trial that establishes similar safety and efficacy performances for generic and brand-name drug regimens.
HCV CURE AND THE FAIR PRICE

Since the new generation of DAAs emerged in 2013, the pharmaceutical industry have justified their exorbitant prices based on intellectual property ownership, market mechanisms, and the financial implications of R&D processes. We need a reality check on production costs for generic versions of DAAs if we are going to achieve universal access to HCV treatment. Significant work has been conducted over the past few years on this issue by a team of researchers led by Dr. Andrew Hill. These findings establish that production costs for generics are constantly diminishing because competition between manufacturers and amongst API providers inevitably sets off a downward pricing trend. Based on the analysis and projections from available trading data on API and generic DAAs produced and/or exported, the evidence establishes a “fair price,” taking into account a reasonable profit margin for incentives, as well as costs relative to product marketing. Interestingly enough, this fair price is far from those charged at the moment by pharmaceutical companies, even in countries included in negotiated discount programs.


As production efficiency improves, product pricing historically decreases. The per-kilogram cost of the active pharmaceutical ingredient is a key determinant of the price of a generic. Hill and colleagues observed the evolution of the API prices between January 2016 and June 2016, and estimated sustainable generic prices of DAAS, especially for sofosbuvir and daclatasvir by analyzing the costs of production. The prices of Indian sofosbuvir and daclatasvir API exports were extracted from Indian import-export logs (www.infodriveindia.com).

Cost-based generic price of sofosbuvir (12 weeks)

- Cost of API = $1,094/kg
- API per 12 weeks = $37
- Formulated drug = $40
- Packaging = $0.35/month
- Profit margin = 50%
- Final generic price = $62

Cost-based generic price of daclatasvir (12 weeks)

- Cost of API = $998/kg
- API per 12 weeks = $5
- Formulated drug = $8
- Packaging = $0.35/month
- Profit margin = 50%
- Final generic price = $14

Target prices for generic sofosbuvir and daclatasvir were calculated by a validated algorithm, taking into account the additional costs of drug production: a 40% mark-up for formulation, US$0.35 per month for packaging, and a 50% profit margin were added to per-pill API cost. The calculation assumed market competition and optimization of production processes.

In the first half of 2016, 10.2 tons of sofosbuvir (equivalent to 303,000 12-week treatment courses), and 5,443 kg of daclatasvir (1,080,000 courses) were exported from India. API prices decreased throughout this time frame. API prices by the end of May 2016 were sofosbuvir US$1,094/kg and daclatasvir US$998/kg.

HCV DAAs production costs are falling rapidly. 12-week treatments of sofosbuvir can be manufactured for US$62 and daclatasvir US$14, all including a 50% profit margin. Bioequivalence studies and efficacy data from treatment programs may be required to validate the quality of new generic DAA supplies.

The Fair Price: The Road Ahead

The latest update to the study, presented in Durban at the 21st International AIDS Conference in 2016, highlighted prospects for additional price reductions. A generic combination of sofosbuvir/daclatasvir could be sold at US$76, while still being profitable for manufacturers, and representing close to 1% of the current US retail price for a treatment course of the branded version. These estimated prices constitute useful markers to assert the imperative of universal access to treatment.
Patent monopolies on medicine have come under criticism because it enables brand name–drug companies (originators) to sell their drugs at astoundingly high prices, essentially preventing generic competition for 20 years, at a minimum. Due to monopolistic pricing methods, access to current HCV treatment is virtually nonexistent for most people living with hepatitis C, although the infection is treatable and curable with the new generation of DAAs. Even in high-income countries, access to these life-saving treatments is severely limited (see page 8).

Neither tiered-pricing nor voluntary licensing strategies (both widely used by originator companies) have prevented monopolies. In practice, the restrictive terms of these agreements have severely delayed or impaired the use of legal tools, such as compulsory licences and patent oppositions, by governments, civil society organizations and generic manufacturers.

Lessons learned from HIV

In the 2000s, the introduction of antiretroviral (ARV) generic competition transformed the access landscape for people living with HIV in low and middle-income countries. In 2000, less than one million people were on ARVs. Civil society pressure and use of compulsory licenses by countries like Brazil and Thailand, enabled generic ARV production and scaled up HIV/AIDS programmes. Within a decade, this competition helped reduce the price of first-line HIV drugs by 99%, from US$10,000 to under US$100 per person per year, thereby putting 17 million people living with HIV on treatment in 2015.

Compulsory license (CL) is a legal tool made available by the TRIPS Agreement to WTO Member States to overcome patent barriers when regarded as necessary. Through compulsory licensing, governments can allow generic producers to manufacture a patented medicine without the consent of the patent owner, in exchange of royalties granted to the patent owner as a compensation. Compulsory license can be used to allow importation of generic drugs to a country without manufacturing capacities – in that case a CL will need to be issued in both exporting and importing Countries if patents exist. Compulsory licensing can act as an essential public health safeguard to overcome misuse of intellectual property rights by patent holders. Several United Nations bodies, including the World Health Organization, recommended the use of CL to overcome high prices and improve access to medicines.\textsuperscript{18} CLs have been used by several countries – including EU Member States - to reduce prices of medicines and to improve access for their populations. In 2007, Brazil issued a compulsory license for efavirenz (a WHO recommended first-line ARV). This resulted in five-year savings, which exceeded US$103 million.

CLs are legal mechanisms that can be used to promote access to new HCV medicines, as recommended by the World Health Assembly in 2014.\textsuperscript{19} Yet no compulsory license has been issued, to date. Countries may fear political backlash, such as trade sanctions or other punitive measures, (e.g. Special 301 Report issued by the U.S. Trade Representative) or pressure from pharmaceutical companies.\textsuperscript{20}

Lessons learned from HIV

In the 2000s, the introduction of antiretroviral (ARV) generic competition transformed the access landscape for people living with HIV in low and middle-income countries. In 2000, less than one million people were on ARVs. Civil society pressure and use of compulsory licenses by countries like Brazil and Thailand, enabled generic ARV production and scaled up HIV/AIDS programmes. Within a decade, this competition helped reduce the price of first-line HIV drugs by 99%, from US$10,000 to under US$100 per person per year, thereby putting 17 million people living with HIV on treatment in 2015.

Compulsory license (CL) is a legal tool made available by the TRIPS Agreement to WTO Member States to overcome patent barriers when regarded as necessary. Through compulsory licensing, governments can allow generic producers to manufacture a patented medicine without the consent of the patent owner, in exchange of royalties granted to the patent owner as a compensation. Compulsory license can be used to allow importation of generic drugs to a country without manufacturing capacities – in that case a CL will need to be issued in both exporting and importing Countries if patents exist. Compulsory licensing can act as an essential public health safeguard to overcome misuse of intellectual property rights by patent holders. Several United Nations bodies, including the World Health Organization, recommended the use of CL to overcome high prices and improve access to medicines.\textsuperscript{18} CLs have been used by several countries – including EU Member States - to reduce prices of medicines and to improve access for their populations. In 2007, Brazil issued a compulsory license for efavirenz (a WHO recommended first-line ARV). This resulted in five-year savings, which exceeded US$103 million.

CLs are legal mechanisms that can be used to promote access to new HCV medicines, as recommended by the World Health Assembly in 2014.\textsuperscript{19} Yet no compulsory license has been issued, to date. Countries may fear political backlash, such as trade sanctions or other punitive measures, (e.g. Special 301 Report issued by the U.S. Trade Representative) or pressure from pharmaceutical companies.\textsuperscript{20}

\textbf{What is a patent?}

A patent is an exclusive intellectual property right that can be granted to the inventor of certain novelty under national (or in some cases regional) law for a certain period of time. Under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the term of patent is 20 years, at a minimum. Without the consent of the patent holder, another person cannot make, sell, offer for sale, use, or import the invention.

\textbf{What is a generic?}

A generic drug is identical–or bioequivalent–to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Generic drugs are usually manufactured if there is no patent or if the patent has expired.

\textbf{In the field of hepatitis C, we also need to ensure that affordable versions of HCV generic drugs reach markets as soon as possible by using and promoting these legal tools.} At this rate, with another 13-17 years of patent monopolies, we can anticipate an estimated 10.5 million HCV-related deaths by 2030.
**Patent Oppositions**

“Globally, there is a growing movement to remove artificial barriers to health that drug companies create when they seek illegitimate patents. Patents are rights that governments confer to products proven to be novel, nonobvious and useful. But too often, pharmaceutical companies increase profits through exclusive claims on science that is already in the public domain. Lawyers, scientists and health advocates are pushing to end drug companies’ abuse of patents and remove obstacles to vital hepatitis C treatment.”

Priti Radhakrishnan (I-Mak)

Not all inventions deserve to be patented. The World Trade Organization’s TRIPS Agreement indicates that to deserve a patent an invention must be new, involve an inventive step, and be useful – but national legislations can add on further patentability criterias.

A patent opposition is a recourse by which any interested party (i.e civil society organizations) can contest the validity of a patent regarding patentability criterias. The procedure can occur before the patent is granted (pre-grant opposition) or after it is granted (post-grant opposition), but not all national legislations allow such procedures.

A successful patent opposition results in patent invalidation, creating the opportunity for generic drug competition, thereby bringing down drug prices. This legal mechanism has already been used by civil society in Brazil, India, as well as in the United States to get abusive patents removed.

Patent oppositions are not only used by civil society organisations to improve access to medicine, in fact most of patent oppositions are led by pharmaceutical companies to oppose their competitors patents.

**Chronology of Patent Oppositions on sofosbuvir**

**Why target sofosbuvir?** Gilead’s DAA, sofosbuvir is currently the strongest “backbone” drug of many oral HCV regimens. It can be used—with other drugs—for treating all HCV genotypes.

In January 2015, the application for a Gilead’s patent on sofosbuvir is first rejected by the Indian Patent Office as lacking inventiveness and novelty. Gilead has appealed the decision.

On February 11, 2015: Médecins du Monde filed a patent opposition on sofosbuvir to the European Patent Office (EPO) – a patent cooperation mechanism which has been created by the European Patent Convention signed by 38 European Countries. A successful opposition at this level automatically revokes the patent in all the Member States. The MdM filing at the EPO is a post-grant opposition; the opposition procedure does not affect the patent enforcement until a decision is taken.

May 2, 2015: Three civil society groups challenge Bristol-Myers Squibb’s pending patent application on daclatasvir before the Delhi Patent Office.

April –May 2015: I-MAK, Grupo de Trabalho sobre Propriedade Intelectual (GTPI), All-Ukrainian Network of People Living with HIV/AIDS, International Treatment Preparedness Coalition, and Fundación Grupo Efecto Positivo (Fundación GEP) have filed a series of coordinated patent challenges on sofosbuvir in their respective countries: China, Brazil, Russia, Argentina and Ukraine. In June 2015, Gilead’s patent application has been rejected in China and Ukraine has made two preliminary decisions to refuse issuing a patent on sofosbuvir, its final decision is expected by late summer 2016.

May 10, 2016, Indian patent office contradicted its 2015 decision and granted the patent. The patent office dismissed all pre-grant oppositions. I-MAK is considering appealing against the decision. A second key patent application on sofosbuvir is pending at the Indian Patent Office, and has been opposed by patient and public interest groups.

October 4 and 5, 2016: Oral proceedings at the European Patent Office in Munich, following the patent opposition filed by Médecins du Monde in February 2015.
SAFETY AND EFFICACY OF GENERICS DAAs,
THE REDEMPTION TRIAL

In most countries where HCV DAAs are available, including those considered as high income, restrictions to access are set up to prevent the bankruptcy of national health systems. Yet, generic versions of sofosbuvir, ledipasvir, and daclatasvir are being mass produced. The latest expected price that is calculated for DAAs and forecasts the generics of sofosbuvir could be sold for about 1% of the current US branded version retail price (see p13). However, access, distribution, and retail of generics remain as sticking points when negotiating international trade agreements and IP provisions, as patent monopolies and exorbitant pricing policies represent major barriers to access treatments. While people living with HCV are facing limited access to treatment (i.e., through restrictive treatment eligibility criteria, highly expensive out-of-pocket treatment, among social stigma, discrimination, and other barriers), as individuals they have been seeking out more affordable generic alternatives abroad.

Grey areas can be explored to allow individuals to access generics produced abroad for domestic use, even outside authorizing agreements with the patent holder. Namely, TRIPS Agreement Article 60 grants authorization for individuals to carry or have delivered generics version of patented drugs for personal use, within their domestic territory. In accordance with this provision Australia, the UK, and numerous legally authorized persons can import a three-month supply of medication.

TRIPS Agreement Article 60: De Minimis Imports
This article states, “Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travelers’ personal luggage or sent in small consignments.”

Dr. James Freeman is an Australian consultant physician involved in telemedicine, and he has been decisive in setting up FixHepC, an online buyers’ club to import small quantities of DAAs in a non-commercial capacity. FixHepC was launched as a pilot in March 2015 and scaled up in August 2015 after his first patients reached sustained viral response (SVR). The online platform supports people with HCV on all the continents to ensure the quality of generics bought online, as well as provides legal advice for them to operate lawfully. Patients on HCV treatment can also receive advice and exchange information.

Furthermore, people who are self-importing generic versions of DAAs are invited to take part in a clinical trial, which aims at assessing the safety profile and efficacy of their medications (see below). Intermediary results of this study have been released in early 2016, which confirm that treatment with legally imported generic DAAs led to high SVR rates — similar to those seen in the Phase 3 trials of branded treatments.

REDEMPTION Trial (Reviewing DAA Efficacy Managing Patient Treatment In Online Neighbourhoods)
Design: observational cohort
Schedule: July 2015 – June 2017

Population: Patients around the world chronically infected with HCV, aged 18 to 82, and who are choosing to self-import generic versions of the Direct Acting Antivirals sofosbuvir, ledipasvir and daclatasvir from countries like China, India and Bangladesh are invited to participate. A sample size of 10,000 people is expected.

Goals and outcomes: The primary goal is to assess the efficacy and safety of the generic medications used by the patient, and for which no clinical evaluation has been done. Sustained virological response at 4 weeks after the end of treatment (SVR4) is used to assess the efficacy of the treatment. The safety profile assessed by occurrence of side effects during treatment. A secondary goal is to answer efficacy questions for which there is currently insufficient trial data available (promising treatment combinations with no reliable data in some genotypes).

Methods: Generic DAAs are first evaluated for biochemical quality using HPLC, NMR and Mass Spectrometry. Patients are enrolled on an intention to treat basis via the fixhepc.com website and are assisted in making a personal importation of affordably priced medication. Patients are assessed pre-treatment, during treatment, and then for SVR (cure) following treatment using a telemedicine platform.

Interim analysis on the first patients enrolled: Among the 448 first patients enrolled, most were genotype 1 (63.9%), and about one third had cirrhosis. Biochemical quality of the generics assessed was satisfying. SVR4 was reached by 94.2% of the first 137 patients having completed the treatment. No new or unknown side effects were reported, three patients temporarily decompensated their cirrhosis, and four patients died, all from hepatocellular carcinoma (including 1 prior to treatment start).

Millions of people diagnosed with HCV throughout the world still face heavy restriction in accessing the new molecules, documenting quality and efficacy of DAAs generics is of the outmost importance in building the case for universal access to HCV treatment.
In 2013, the therapeutic revolution represented by the introduction of new DAAs on the market opened new prospects for people living with the hepatitis C virus (HCV). Used in combination, they achieve higher cure rates in a shorter period than previous generation of treatments and offer excellent tolerance for people with HCV.

With an eye towards an HCV-free world, WHO set ambitious targets for treatment coverage, aiming to treat 80% of chronically infected people by 2030 in order to achieve the overall goal of HCV elimination in the medium term. Upon closer examination, comparing available data on treatment access since 2013 across various countries reveals that health systems generally regarded as constrained or uneven (e.g. Georgia, Pakistan) have achieved substantial progress towards these goals when compared to their counterparts in high-income countries (e.g. France).

France vs. Pakistan: Elimination, Drug Pricing and Political Will

To further explore the dynamics of treatment access globally, a comparison between two contrasting systems in France and Pakistan has been conducted to shed light on the key measures and processes leading to greater advancements in HCV elimination. Between 2013 and 2015, Pakistan multiplied yearly treatment uptake by 2.5 times, while France, (WHO’s top rank health system), is only reaching back its 2007-level of persons treated annually.

### General information

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<thead>
<tr>
<th></th>
<th>Pakistan</th>
<th>France</th>
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<tbody>
<tr>
<td>Population (in millions of inhabitants)</td>
<td>183.13</td>
<td>66.2</td>
</tr>
<tr>
<td>Population ages 15-64, total (in millions of inhabitants)</td>
<td>115.41</td>
<td>42.06</td>
</tr>
<tr>
<td>GNI per capita/month (in US$)</td>
<td>118</td>
<td>3,589</td>
</tr>
<tr>
<td>Nurses and midwives (per 1,000 people)</td>
<td>0.55</td>
<td>9.3</td>
</tr>
<tr>
<td>Physicians (per 1,000 people)</td>
<td>0.81</td>
<td>3.38</td>
</tr>
<tr>
<td>Health expenditure, public (% of government expenditure)</td>
<td>4.7%</td>
<td>15.8%</td>
</tr>
<tr>
<td>Health expenditure, total (% of GDP)</td>
<td>2.8%</td>
<td>11.7%</td>
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<tr>
<td>Out-of-pocket health expenditure (% of total expenditure on health)</td>
<td>55%</td>
<td>7%</td>
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### HCV Burden

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<tr>
<th></th>
<th>Pakistan</th>
<th>France</th>
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<tr>
<td>Estimated adult prevalence of HCV (antibody) overall</td>
<td>4.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Estimated number of viremic adults</td>
<td>6,576,000</td>
<td>392,000</td>
</tr>
<tr>
<td>Genotype distribution</td>
<td>GT1 11.9%, GT2 3.4%, GT3 79.0%, GT4, 5.2%</td>
<td>GT1 59.0%, GT2 10.5%, GT3 20.6%, GT4, 9.1%, GT5 2.6%</td>
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### Access to diagnosis and treatment

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<tr>
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<th>Pakistan</th>
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<tr>
<td>Minimal cost of a basic HCV assessment package (USD)</td>
<td>260.4 USD (220% of monthly GNI)</td>
<td>129 USD (3.6% of monthly GNI)</td>
</tr>
<tr>
<td>Lab. Antibody testing - 7.6</td>
<td>Lab. Antibody testing - 16</td>
<td></td>
</tr>
<tr>
<td>Viral load – 52.2</td>
<td>Viral load - 62</td>
<td></td>
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<tr>
<td>Genotyping – 73.6</td>
<td>Genotyping - 17</td>
<td></td>
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<tr>
<td>Fibroscan – 125</td>
<td>Fibroscan - 34</td>
<td></td>
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<tr>
<td>Cost of available treatments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard IFN – 64</td>
<td>Pegylated IFN (48 weeks) – 5,528</td>
<td></td>
</tr>
<tr>
<td>Pegylated IFN (48 weeks) – 1,632</td>
<td>Sofosbuvir, Sova (12 weeks) – 46,300</td>
<td></td>
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<tr>
<td>Sofosbuvir, Sova (12 weeks) – 900</td>
<td>Simeprevir, Olysio (12 weeks) – 23,700</td>
<td></td>
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<tr>
<td>Sofosbuvir, Sova (12 weeks) – 126</td>
<td>Dadavafir, Daklinza (12 weeks) – 28,850</td>
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<tr>
<td></td>
<td>Harvoni (combo) (12 weeks) – 52,000</td>
<td></td>
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<tr>
<td></td>
<td>Vekirac/Exviera (combo) (12 weeks) – 43,095</td>
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Treatment uptake in France declined from 2007, with a significant drop in 2013, when treatment initiations were being postponed awaiting introduction of upcoming DAAs treatments. Progression since 2013 is rather a catch-up phenomenon than an actual scale-up of HCV treatments.
HCV prevalence in France is 1/6th that of Pakistan. France has had access to the new DAAs since 2014. Treatment costs can reach US$150,300 in some cases, and they are reimbursed by the national social security system. Still, only physicians specialized in hepatology or infectious diseases are allowed to prescribe HCV treatment, and individual access is decided upon through multidisciplinary committee meetings. Until recently, HCV treatments were only prescribed to people with fibrosis stages of severe F2 to F4. A decree from the Ministry of Health extended access to patients with non-severe F2, who have been transplanted or who are waiting for a transplant, as well as so-called vulnerable populations, whichever their fibrosis stages (i.e. people who use drugs, prisoners, and women planning to become pregnant). Migrants and persons contaminated through a transfusion might also sparingly access treatment through the ongoing multidisciplinary committee system. A second decree announcing open access to all people with HCV is expected later in 2016. However, universal access will not become effective until 2017. The limited capacity of specialized consultation slots is used by French health authorities to explain the slow growth in the number of people accessing HCV treatment. In the end, over-priced DAAs, which place a heavy financial burden on an overstretched social security system, have led to restricted treatment access. Once leading worldwide regarding HCV treatment access, France is currently experiencing considerable delays in treatment of diagnosed persons.

With an estimated 6.5 million chronically infected adults, Pakistan has the second highest burden of HCV infection in the world, after China. Until recently, both standard interferon and Peginterferon were used for treatment, in combination with ribavirin. Pakistan entered Gilead’s Global Access Program for Sovaldi, allowing them to receive a heavily discounted price of US$300 per month. The drug was formally registered in March 2015, and used either in combination with ribavirin for 24 weeks or with ribavirin and Peginterferon for 12 weeks. A variety of strategies have since been deployed by health authorities to reduce the costs of DAA treatments, including:

- Regional tenders, resulting in a price of US$80 for generic sofosbuvir in Punjab; and
- Opening competition to unlicensed Active Pharmaceutical Ingredients (API) producers to lower the costs of raw materials used for in-country production of generic drugs.

Beyond pricing policies, any Pakistani physician can prescribe HCV drugs, and access is granted to every diagnosed patient regardless of fibrosis severity. Illustrating the political will and determination of the government towards eliminating HCV, ambitious targets have been set at the national level, to treat 510,000 people with HCV each year between 2016 and 2030, representing a 7.75% projected treatment uptake per year. However, the road ahead is neither straight nor smooth for Pakistan to reach such bold targets. Ensuring drug quality is essential to ensure DAA benefits can be sustained. The ability of any physician to prescribe DAAs must be coupled with reinforced trainings to avoid unnecessary prescriptions and facilitate adherence to treatment. Ultimately, additional treatment strategies will have to be made available to emerging difficult-to-treat HCV patients. Genotype 3 carriers with prior treatment exposure as well as cirrhosis, appearing mainly in tertiary health centers, will require combinations of DAAs that are not accessible, to date, in Pakistan.

Notwithstanding the numerous barriers and challenges Pakistan health system will face on the road toward HCV elimination, political will and resolution on creating the conditions of universal access to the new generation of treatments appear to be obvious decisive provisions for any proclaimed HCV elimination intentions. Namely, access to generics of DAAs, and the price reduction that comes with their introduction to the market, alongside non-discriminatory treatment access, represent prerequisites for a sustained and fair policy.
Although they generally carry a substantial part of the HCV epidemic, treatment uptake among people who inject drugs (PWID) tends to be very low. Worldwide, there is an estimated 12.19 million (range: 8.48-21.46 million) people who inject drugs, of whom an estimated 8 million live with chronic hepatitis. The development of simple, tolerable and highly effective direct-acting antiviral (DAA) therapies is a significant game changer! However, people who inject drugs might remain excluded if governments, healthcare workers, service organizations, and community members do not take stronger actions to dismantle the multiple barriers to treatment they face, particularly in low- and middle-income countries (LMICs). Beyond drug pricing, treatment access is significantly impeded by criminalization and systemic discrimination, averse national policies and healthcare workers’ reluctance to provide care to people who inject drugs pose as the major obstacles to equal access to HCV treatment.

East and South-East Asia and Eastern Europe are particularly affected by the HCV epidemic among people who inject drugs. For example, in the countries of the former Soviet Union, HCV prevalence in the general population ranges from 1.3 to 11.3%. In this region, people who inject drugs bear a disproportionately heavy burden, with up to 92% of antibodies carriers in some countries (see Table 5).

According to mapCrowd data, about 1.5 million (or 15%) of people who inject drugs in the former Soviet Union are chronically infected with HCV, accounting for 19% of infected PWID worldwide.

If specific measures are taken, people who inject drugs can achieve adherence to and outcomes from HCV treatment comparable to other patients. The evidence does not support concerns that people who inject drugs who have been cured of HCV contribute to high re-infection rates. Legal, medical, and community efforts require focus on prevention and continual support to ensure those who have been cured can remain free of the virus. To tackle and reverse the HCV epidemic, particularly in a period when we have a cure, people who inject drugs must be centrally included in targeted and general (i.e. age cohort screening) HCV treatment programs.

Harm Reduction Approach Essential to HCV Treatment Program in Georgia

To an even greater extent than in its neighbors, Georgia faces very high HCV rates with a concentrated epidemic among people who inject drugs. In this context, people who inject drugs have limited access to harm reduction services, and experience enormous stigma and reluctance to seek healthcare. These factors can lead to advanced disease progression, if left unchecked.
According to a recent nationwide population-based survey, hepatitis C prevalence is around 7% in the general population, with an estimated 25.6% of prevalent cases among people who inject drugs. A study conducted among People who inject drugs in 2012 found 82% were chronically infected -- 24.4% of whom had advanced liver fibrosis. Until 2015, treatment uptake in general was very poor, with only 0.5% of chronically infected people accessing PegInterferon/Ribavirin each year.

National policies have greatly evolved since 2011 when the Ministry of Health recognized HCV as a major public health concern. Community mobilization and civil society-led advocacy work have been driving the public health response. Since the arrival of sofosbuvir, Georgian health authorities have negotiated with Gilead to provide treatment as part of an ambitious National HCV Elimination Plan, supported by the US Center for Disease Control and Prevention. These discussions have been successful: an emergency phase kicked off in mid-May 2015 to initially provide 5,000 free courses of sofosbuvir intended for people with advanced liver fibrosis. Additional courses of DAAs from the same producer are negotiated step-by-step. The second phase of the elimination plan is in the process of being refined, which aims to make Georgia an HCV-free zone through universal access to prevention, diagnosis and treatment. In May 2016, approximately 9,000 (36%) of the 250,000 chronically infected persons had initiated treatment, reaching an 83.3% cure rate for those having achieved SVR12 (sustained viral response 12 weeks after completion of treatment).

In 2011, Médecins du Monde in partnership with New Vector, a self-support organization, opened a harm reduction project in the capital, Tbilisi. On one hand, the partners provide medical and harm reduction services to injecting drug users to focus on containing HCV. On the other, they undertake advocacy efforts to improve people’s access to health and to fight criminalization of this population.

Since May 2015, Médecins du Monde, in collaboration with New Vector and the Health Research Union, is implementing a peer-support intervention to facilitate the access and retention of people who inject drugs in the national program and to prevent reinfection after treatment. Over a six-month period, 554 PWID were screened at the harm reduction center, of whom 244 are chronically infected with advanced liver fibrosis and had started HCV treatment. Presently, 98.8% of participants of this operational research project managed to complete treatment with very good adherence. Individuals reported significant reduction in behaviors at risk for HCV transmission between the start and end of treatment. By mid-June, the cohort had reached a 90.1% cure rate with an undetectable viral load at week 12 after treatment (of the 141 SVR12 results available to date). These are preliminary findings and more definitive results are expected to be released in September 2016.

The work of MdM and New Vector has been instrumental in convincing health authorities that people who inject drugs can be successfully treated, when associated with harm reduction services to which they are accustomed. In the short term, additional harm reduction centers intend to replicate these results. However, the effectiveness of this ambitious public health intervention might suffer from the lack of therapeutic alternatives, such as treatment combination with daclatasvir for difficult-to-treat patients, if the national guidelines and registration processes keep on focusing principally on DAAs produced by Gilead only.

Georgia has already achieved significant work for rolling out its HCV elimination plan, but will have to overcome a few setbacks to become the first country to eliminate hepatitis C. Firstly, anti-diversion measures imposed by the direct-acting antivirals (DAA) originator company raise ethical concerns, as they require an array of controls that most decentralized health centers do not have the means to implement - in addition to being an obvious violation of medical confidentiality.

Today Georgia has, by far, the most ambitious national HCV plan of all low- and middle-income countries. Although major hurdles exist, including discrimination and stigma in seeking healthcare services, a civil society sector still emerging, and reliance on one producers of DAAs, Georgia has the potential to reverse the HCV epidemic nationwide and to serve as a ‘best practice’ model for the rest of the region.

| Table 6. HCV treatment cascade for 100 people starting treatment in Georgia

Preliminary results from a treatment program among PWID in Tbilisi

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<thead>
<tr>
<th></th>
<th>General population*</th>
<th>PWID supported by the MdM/New Vector project**</th>
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<tbody>
<tr>
<td>Start treatment</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Finish treatment</td>
<td>97.3</td>
<td>98.8</td>
</tr>
<tr>
<td>Cured</td>
<td>81.1</td>
<td>89.0</td>
</tr>
</tbody>
</table>

*From Ministry of health data of May 2016: 9124 treatment start, 234 early treatment stop, and 83.3% of SVR12  
**From MdM preliminary data of mid-June 2016: 244 treatment start, 3 early treatment stop, and 90.1% of SVR12
REFERENCES

Map1 Treatment Rationing in Western Europe

Sources related to DAA prices/reimbursement: mapCrowders and external sources:


6. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is an agreement to which World Trade Organization members must adhere to which they must adapt their national laws.

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mapCrowd aims to enhance HCV information and advocacy worldwide. This report aims at highlighting recent HCV developments with comprehensive, up-to-date data. At the same time, this growing network of advocates will more easily be able to share knowledge and mobilize information supporting their advocacy. People with HCV, those who work in public health and development, and the larger international health community all stand to benefit from mapCrowd’s continued growth.

To accomplish this, we are seeking to identify and enlist more qualified HCV experts to join the mapCrowd project on a voluntary basis. Ideal mapCrowder candidates will be strongly involved in HCV advocacy work in their respective countries, or have a medical or public health background. As data are often highly limited or difficult to obtain, we are looking for candidates who have a strong network of local contacts and a capacity to support national level data collection on a range of topic areas.

Why become a mapCrowder?
There are numerous benefits to participating in the mapCrowd project. As a mapCrowder, you will have the opportunity to:
- Contribute valuable information that will advance global understanding of the HCV epidemic, lead to an informed response, and enhance advocacy efforts around the world,
- Connect with a growing, international network of HCV experts and activists,
- Develop and maintain national-level contacts that can support data collection and estimations,
- Raise the visibility of your organization and its mission and objectives.

How do I join?
If you are interested in becoming a mapCrowder, please visit:

http://mapcrowd.org/en/inscription

As more mapCrowders join, the stronger mapCrowd will be at generating data that highlights and helps break down barriers to HCV testing and treatment around the world. Findings based on these data will be presented and publicized in future annual reports.
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