

THE CRITICAL ROLE OF CIVIL SOCIETY IN SHAPING THE MARKET FOR ANTIRETROVIRAL THERAPY AND DIRECT-ACTING ANTIRETROVIRALS

The objective of this document is to demonstrate to UNITAID that civil society is an essential partner in expanding drug access. We first articulate how civil society – in particular people living with and affected by HIV/AIDS – helped shape the market for antiretroviral (ARV) drugs in low- and middle-income countries (LMICs). We then describe the critical need for UNITAID to support civil society interventions that will similarly impact treatment access for the hepatitis C virus (HCV), followed by specific recommendations for UNITAID to move in this direction.

Despite the millions of HIV-positive people having access to life-saving antiretroviral therapy (ART), co-infection with HCV has become a threat to their health and survival. Liver disease caused by HCV is now a leading cause of illness and death among HIV-positive people. UNITAID is poised to change the course of history by shaping the market for direct-acting antivirals (DAAs), safe and effective oral drugs that can cure HCV in just a few months regardless of HIV status. However, these DAAs are priced far out of reach for 80% of people living with HCV in LMICs. Civil society involvement is integral to achieving UNITAID's market-shaping objectives for DAAs, including demand creation, price reductions and ultimately achieving universal access.

SUMMARY RECOMMENDATIONS

We urge UNITAID and other leading health institutions to engage civil society organizations (CSOs) as key partners in market shaping for DAAs from the outset of interventions, including the following actions:

- **Include people living with HIV and HCV, and people who use drugs (PWID), in all decision-making for HIV/HCV co-infection:** As codified in the Denver Principles,¹ directly-affected communities need to be involved at every level of policy and program decision-making, serve on boards of key stakeholder organizations, and be included in all HIV and HCV forums to share their experiences and expertise.
- **Fund interventions that target criminalized and marginalized populations:** Significant structural barriers such as stigma, discrimination and punitive laws and policies impede or prevent access to HIV and HCV treatment for key at-risk populations, including PWID. Investment in removing these structural barriers through civil society's community-led work is an investment in market shaping and universal access.
- **Dramatically increase funding for civil society interventions:** Civil society has held a prominent and often a leadership role in successful market shaping and treatment strategies for HIV. We urge UNITAID to develop a strategy for HCV that meaningfully includes CSOs, and to actively solicit and support the development of proposals from CSOs through technical assistance, to most effectively and efficiently drive access to treatment. In addition, we urge UNITAID to expand the types of interventions it funds – particularly with respect to the advocacy work that will be essential to national and global prioritization of HCV. This will be particularly important in middle-income countries (MICs), many of which are being excluded from voluntary licenses on DAAs that will keep prices out of reach without further intervention.

¹ http://data.unaids.org/Public/externaldocument/2007/gipa1983denverprinciples_en.pdf

INTRODUCTION

In the early days of the HIV/AIDS epidemic, global health leaders believed that treatment in developing countries was not feasible; yet today 13 million people are on life-saving ART in LMICs. This was made possible by an ecosystem of actors, including donors, global policymakers, national governments and nongovernmental organizations (NGOs). However, the essential role of civil society is often excluded from the official narrative about market shaping and scale-up of ART. In particular, networks of people living with HIV (PLHIV) and key affected populations played a critical role in making the epidemic a national and international public health priority and driving access to and affordability of ART. Going forward, these groups must be involved in any market shaping response.

Civil society's role expands far beyond advocacy. Its technical expertise has been integral to removing barriers to medicines access, driving and shaping research agendas, and creating momentum for policy and programmatic changes at the national and global levels. Many CSOs laid the foundation for demand creation, treatment literacy, service delivery and drug affordability for HIV/AIDS, creating a strong base from which other institutions were able to scale up treatment programs. Without civil society's work, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) would not have been established. **It was civil society's work that catalyzed and made possible the rapid treatment scale-up achieved by major global health actors** including the GFATM, The United States President's Emergency Plan for AIDS Relief (PEPFAR), UNAIDS, the World Health Organization (WHO), UNITAID and the Clinton Health Access Initiative (CHAI).

While civil society does more than advocacy, it is important to recognize that advocacy is amongst its most impactful work. Despite UNITAID's historic reluctance to fund advocacy and the perception that its impact cannot be measured, **advocacy has sustained the largest gains in the ARV access movement by creating the enabling environment for generic drug access.** This impact is reflected in the cost savings of generic treatment to date catalyzed by civil society's advocacy (see **Boxes 2 and 3**). Importantly, civil society groups are uniquely positioned to conduct high-impact advocacy because of their approach to promoting health as a human right and ability to represent affected populations.

BY BETTER UNDERSTANDING THE IMPACT OF ALL OF CIVIL SOCIETY'S CONTRIBUTIONS – INCLUDING TECHNICAL, LEGAL AND MARKET-SHAPING ACTIVITIES AS WELL AS ADVOCACY – UNITAID CAN MORE EFFECTIVELY IDENTIFY THE HIGHEST-LEVERAGE INVESTMENTS FOR INCREASING ACCESS TO HCV TREATMENT FOR PEOPLE WITH HIV/HCV CO-INFECTION.

The sections that follow outline and provide numerous examples of the ways in which civil society's engagement has and continues to shape the market for HIV/AIDS medicines, and can similarly impact the new market for HCV drugs.

BOX 1: DEFINING CIVIL SOCIETY

Civil society is broadly understood as non-governmental, not-for-profit organizations formed by people around a common interest; it includes a wide range of organizations, networks, associations, community groups and movements.³

Examples:

- **People living with HIV/HCV and treatment advocates:** Delhi Network of Positive People, Red Latinoamericana por el Acceso a Medicamentos.
- **Key affected populations and their organizations:** Eurasian Harm Reduction Network, the Global Forum on MSM & HIV, Thai Drug Users Network.
- **Implementing partners:** Médecins du Monde, Médecins Sans Frontières
- **Technical and legal advocates:** I-MAK, Treatment Action Group

While there is often a perceived distinction between PLHIV networks and technical organizations, PLHIV and their advocates have built strong expertise and now lead work as experts. To illustrate, PLHIV networks often take the lead on technical advocacy, as was the case for the Treatment Action Campaign and the Asia-Pacific Network of People Living with HIV spearheading patent law reform.

³ <http://www.who.int/trade/glossary/story006/en/>.

² E.g. Men who have sex with men, sex workers, and people who inject drugs

DEMAND GENERATION

Civil society has been instrumental in establishing and sustaining ARV demand in LMICs – including by catalyzing national treatment programs, determining priority medicines, and systematically addressing market barriers to sustainable ART access. Specific examples of these activities are presented below.

Accelerating drug development

CSOs such as Treatment Action Group (TAG) focused on development and optimization of antiretroviral agents and strategies, pushing for ethical, clinically relevant and inclusive trials through work with regulatory agencies, research networks and pharmaceutical companies. They subsequently advocated for the results of these trials to be reflected in national and global guidelines panels. This work showcases the technical, evidence-based advocacy that is a necessary precursor to demand creation.

Creating markets in LMICs

In the early years of the HIV/AIDS epidemic, LMIC governments, donors and global policymakers began providing treatment only as a response to well-organized patient demand. Communities living with HIV/AIDS and their advocates catalyzed this response by establishing treatment literacy and delivery programs, through which they effectively lobbied national governments to respond to the epidemic.

Community-led HIV/AIDS treatment literacy ensured that PLHIV possessed multiple levels of knowledge about ART: in-depth clinical understanding, legal and human rights, global and national policy-making, and pricing and supply-chain barriers. Empowered with this technical knowledge, PLHIV across the globe began seeking treatment and successfully pushing national governments to make ART a public health priority – thereby creating a market for ARVs.

- In South Africa, the Treatment Action Campaign (TAC) played an integral role in securing a universal public AIDS treatment program, now one of the world's largest.
- Brazilian civil society was at the forefront of creating the country's free universal treatment program, including through raising public awareness, establishing the national health system, and securing the right to health under the Constitution.⁴

- The Thai Network of People Living with HIV/AIDS (TNP+) and the AIDS Access Foundation were essential to the passage of the National Health Insurance Act by the government, resulting in the Universal Coverage Scheme that provides healthcare services including ART to all Thais at no cost.

As these initiatives grew from community to national level responses, global networks such as the International Treatment Preparedness Coalition (ITPC) were created to coordinate this work across countries. This allowed for the pooling of knowledge and sharing of best practices, including with countries that did not have robust civil society groups, as well as the formation of a global coalition that could more successfully push for global policy and funding changes.

As a parallel effort, CSOs such as Médecins Sans Frontières (MSF) and Médecins du Monde (MDM) started in-country diagnostic and treatment programs (see **Service delivery** below), providing not only health services but also evidence that treatment programs were feasible in resource-poor settings. They also facilitated procurement of drugs for these programs, catalyzing the creation of a larger market.

Setting national and global priorities

Both national and global priorities for HIV have been influenced by the technical inputs and advocacy of civil society groups, resulting in increased demand for the most effective ARVs.

Civil society has played an important role in setting global commitment goals and targets at the United Nations (UN) General Assembly Special Session and subsequent high-level meetings. Similarly, civil society has advocated for budget commitments nationally and internationally. For example, TAC successfully convinced and worked with the South African government to commit to treating HIV as well as reforming the tendering system.

Civil society groups have also been instrumental in ensuring that global- and national-level treatment guidelines and essential medicines lists (EMLs) include ARVs, as inclusion in such policies is a prerequisite for ARV funding and procurement. For example, Health Action International and MSF were

⁴ Intellectual property rights and access to ARV medicines: Civil society resistance in the global south. Rio de Janeiro: ABIA, 2009.

key advocates for inclusion of ARVs on the WHO EML, which countries use to inform their national EMLs. In addition, civil society groups like TAG have served on panels to establish and update WHO and national treatment guidelines for HIV. In many countries (e.g. Argentina and Ukraine), networks of PLHIV sit on the Ministry of Health (MoH) committee to assist in setting clinical guidelines for ART.

These activities have been critical in ensuring that ARV demand consolidates around the most important products, allowing volume growth that leads to price reductions. Another key example of this is the Stavudine Phaseout Campaign spearheaded by the Delhi Network of Positive People (DNP+) in India. Although the WHO recommended the phase out of stavudine (d4t) — a first line ARV with significant and irreversible side effects — several developing countries did not implement this recommendation for many years. Indian CSOs filed evidence of the use and effects of stavudine with the Supreme Court of India, after which a stavudine phase-out plan was jointly agreed upon between the Indian government and CSOs under direction from the Court.

Ensuring continued access

Once national and global policies and programs were in place, civil society continued working to ensure uninterrupted ARV treatment scale-up by systematically addressing access barriers in the market, particularly for marginalized and high-risk communities. This work has been vital in keeping the ARV market healthy, sustainable and patient-centered.

For example: In Argentina, Brazil, and India, civil society groups successfully **used the legal system to ensure treatment**. When the Argentinian fiscal crisis devalued local currency in 2002, the health budget was cut by two-thirds. The Argentinean Network of Positive People through Centro de Estudios Legales y Sociales filed a lawsuit, which resulted in a mandate that the MoH continue provision of ARV treatment for its citizens. In Brazil, CSOs filed several judicial cases that led to the adoption of a federal law assuring the right to free and universal access to HIV/AIDS treatment in 1996. In India, networks of PLHIV and the Lawyers Collective (LC) successfully used the courts to ensure treatment provision to vulnerable communities such as prisoners.

In other countries, CSOs have played an important role in addressing other supply chain and access barriers:

- Country networks of the Asia-Pacific Network of People Living with HIV (APN+) regularly **monitor stock-outs** throughout the region using a dual-prong strategy following suppliers and patients. Using state- and district-level networks and patient-initiated mechanisms, they track reporting of stock-outs at ART clinics and serve as a bridge to policymakers to expeditiously address the problems. Similar initiatives have been undertaken by DNP+ in India and in South Africa through the Stop Stockouts campaign.⁵
- In Russia, ITPCru engages in **treatment surveillance** through an elaborate community-based monitoring system, including monitoring procurement, pricing and stock-outs. In the Eastern European/Central Asian region, ITPCru also follows originator company behavior to **press for in-country registration** when it was needed.

DRUG AFFORDABILITY AND INTELLECTUAL PROPERTY (IP) BARRIERS TO ACCESS

ART was so costly in the early days of the HIV/AIDS epidemic that developing countries could not afford to implement treatment programs. During the 1990s, the World Bank and other development agencies advised developing countries to focus on prevention over treatment because of high treatment costs. This would not have changed without the efforts of a variety of civil society actors who employed law reform and IP-related strategies to achieve large-scale generic competition for HIV/AIDS medicines.

Generic competition has proven to be the only way to create universal, affordable and sustainable treatment access. While some pharmaceutical companies have more access-friendly policies, branded drugs are generally priced out of reach for developing countries. Generic competition helped reduce the price of first-line HIV drugs by 99% within a decade, from US\$10,000 to under US\$100 per person per year.⁶

A key strategy used by civil society to achieve generic drug access is **strategic litigation**. CSOs in many countries have established legal standing to file patent challenges (see **Box 2**) and conducted other strategic litigation to expand ART access.

⁵ <http://stockouts.org>

⁶ Médecins Sans Frontières. *Untangling the Web of Antiretroviral Price Reductions*. 17th ed. July 2014.

For example:

- Grupo de Trabalho sobre Propriedade Intelectual (GTPI/Rebrip), a consortium of NGOs in Brazil, filed a case at the Brazilian Supreme Court that is currently pending on over 1,100 pipeline patent applications that may curtail access to ARVs and other drugs.
- In India, the LC and Cancer Patients Aid Association won a Supreme Court case in 2013 that upheld a key public-health safeguard in the patent law, ensuring access to countless lifesaving drugs.
- South African groups, supported by the global community of CSOs, protested a case filed by 39 pharmaceutical companies challenging South Africa's amendments to allow for cheaper generic drugs, in addition to filing their own legal intervention at the competition commission. Ultimately, this resulted in South Africa obtaining more affordable ARVs and scaling up their domestic treatment program.

Civil society actors have used other strategies as well to sustain generic competition and achieve price reductions in the ARV market:

- **Reforming IP laws to include public health safeguards:** CSOs such as GTPI/Rebrip, TAC and LC helped LMICs reform their patent laws to include public health-oriented provisions – such as stricter patentability standards and mechanisms for patent oppositions and compulsory licensing – and to exclude TRIPS-plus measures from national law.
- **Market monitoring on IP-related issues:** Several groups have monitored and disseminated information to influence policy and improve transparency in the ARV market. For example, the Consumer Project on Technology's website (now keionline.org) was relied upon as a leading source of information about patent law developments for policymakers and the media across the world. Another example is MSF's annual "Untangling the Web" report, which brings transparency to ARV originator and generic pricing.
- **Global technical advocacy on trade-related issues:** Organizations such as the Third World Network, Health Gap, Public Citizen and Act Up-Paris have done highly technical advocacy at the global level and with American and European policy-makers to extend the TRIPS transition period for LDCs and prevent passage of overly restrictive trade agreements that have a detrimental impact on the public health.

- **Direct supplier negotiations:** CSOs have played a critical role in convincing generic drug suppliers to enter ARV product markets and publicly pressuring originators to lower their prices. To illustrate, the All-Ukrainian Network of People Living with HIV serves as one of the leading procurement agencies in Ukraine, negotiating price reductions from originators, advising on MoH ARV procurement and influencing generic behavior in the market. In 2009, Merck initiated patent litigation against Indian generic suppliers of efavirenz to halt imports to Ukraine. The Network conducted rounds of negotiations with Merck, ultimately resulting in non-enforcement of its patent and continued supply of generic efavirenz.⁷

BOX 2: PATENT OPPOSITIONS

In 2005, civil society successfully ensured that India's new patent system included public health safeguards, which allowed for patents to be challenged and prohibited re-patenting of known substances. Civil society actors including I-MAK, DNP+, LC and MSF were then able to file patent challenges that enabled generic production of four key ARVs: tenofovir, lopinavir/ritonavir, abacavir, and nevirapine syrup. Generic drug suppliers then began to file their own patent challenges on ARVs after civil society set these precedents and held trainings for generic companies on how to file oppositions. Because India supplies generic drugs to most of the developing world, this has resulted in annual savings of >\$100 million for global purchases of these medicines.⁸ **Enabling continued generic production of these drugs in India made it possible for actors like GFATM, CHAI and UNITAID to scale-up ART access to 13M people in LMICs.**

Patent challenges are now strategically used by civil society groups across the world to remove barriers to treatment scale-up and allow for generic market entry. In addition to their technical expertise, civil society's community mobilization and advocacy work has made these patent opposition victories possible; without such work, there would not be sufficient public awareness and pressure to counter the well-funded pharmaceutical industry lobby and convince patent offices, courts and governments to act in the interests of patients.

⁸ I-MAK ARV Impact Analysis: Abacavir, Lopinavir/Ritonavir and Nevirapine Syrup. I-MAK, April 2011.

⁷ See <http://i-base.info/world-cab/> and <http://www.treatmentactiongroup.org/hcv/publications/wcab-report-2014>

BOX 3: STRATEGIC ADVOCACY, DOMESTIC PRODUCTION AND COMPULSORY LICENSES

In addition to supporting generic competition, civil society has used other strategies to lower ARV prices, including negotiating deep discounts with branded suppliers and promoting domestic ARV production. Brazil and Thailand's dramatic reduction in AIDS-related morbidity and mortality is the result of these strategies. For example, a government price negotiation committee for the Thai universal health care plan was formed as a response to advocacy from TNP+. In 2006, the Thai government issued compulsory licenses for ARVs after multiple unsuccessful negotiations with originator companies. Thailand was then able to domestically produce and import several generic ARVs, greatly reducing drug prices and increasing the number of people treated. On two ARVs alone, it is estimated that the Thai government saved US \$140 million from 2008-2011.⁹

In Brazil, civil society groups played an essential role in influencing the government to use the national public laboratories as leverage in negotiations with pharmaceutical companies. By strategically estimating the price of local production and using the potential for compulsory licenses as leverage, the Brazilian government was able to negotiate significant price reductions. Civil society catalyzed these outcomes through public demonstrations and technical analysis, including an in-depth analysis of the capacity of Brazilian drug manufacturers and a petition to the court to issue compulsory licenses. Ultimately, Brazil realized cost savings of over US \$100 million over five years by issuing a compulsory license on one ARV.¹⁰

⁹ Compulsory Licensing: Budget Impact and Cost Saving, presentation by Thailand's National Health Security Office, available on file with the AIDS ACCESS Foundation.

¹⁰ Viegas Neves da Silva F, Hallal R, Guimarães A.

Compulsory licence and access to medicines: economic savings of efavirenz in Brazil. The 19th International AIDS Conference. Washington, D.C. 22-27 July 2012.

SERVICE DELIVERY

Civil society and members of affected communities developed many of the early care and support models due to a lack of international response to the HIV/AIDS epidemic, both in the United States and internationally. These programs, built by affected individuals and frontline healthcare workers, not only pioneered care in many countries, but also initiated care that was patient-centered and sensitive to the needs of different populations.

Because of this, community-driven programs have often been more successful in meeting patient needs, especially for marginalized and criminalized populations that have low levels of treatment access. For example, treatment access for PWID who are living with HIV/AIDS is 4% globally and is similarly low for other criminalized communities.¹¹ **With assistance from large donors such as PEPFAR and the GFATM, community-driven service delivery has been able to increase reach and expand access that would have been either impossible or significantly delayed if driven by the public sector alone.**

For example:

- The AIDS Support Organization, an indigenous HIV/AIDS service initiative in Uganda, pioneered non-public response to the epidemic in the country. What began as a small informal group of volunteers grew into one of the largest institutions providing the most comprehensive HIV prevention, care and support services with the assistance of PEPFAR funding.
- In Thailand, Thai Drug Users Network (TDN) submitted a groundbreaking proposal directly to the GFATM, bypassing the traditional government-led process due to the government's inaction. TDN and three additional community-based organizations were granted US\$1.3 million over three years to develop and scale up community-based needle and syringe programs and HIV services.
- Globally, community advocates also monitor treatment to improve quality of care at the local level. ITPC publishes the "Missing the Target" report, which monitors the delivery of HIV services in-country and advocates for change. As a result, critical gaps in the HIV response are exposed earlier and people are empowered to advocate for timely and relevant solutions.

Similar to HIV/AIDS, and because of co-infection with HIV/AIDS, HCV disproportionately affects marginalized and criminalized populations – in particular, MSM, prisoners and PWID (it is estimated that 10 out of 16 million PWID globally are HCV antibody-positive¹²). **CSOs – particularly those led by and working with affected communities – are better positioned than large institutions to reach high-risk and disproportionately impacted populations, and must be engaged to create and advocate for patient-centered services.** These models must be built from the ground up to be more successful in meeting patients' needs, as was done for HIV/AIDS.

¹¹ Mathers, BM, Degenhardt L, Hammad A, et al. HIV prevention, treatment, and care services for people who inject drugs: a systematic review of global, regional, and national coverage. *The Lancet* 2010;375(9719):1014 – 1028.

¹² Nelson PK, Mathers BM, Cowie B, Hagan H, Des Jarlais D, Horyniak D, et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews. *The Lancet*. 2011;378:571–83

SHAPING THE HCV MARKET

HCV is a leading cause of illness and death amongst HIV positive people. As a result, the global response to HIV is interdependent with the response to HCV. Learning from the history of the HIV/AIDS epidemic, it is critical to involve civil society – particularly people with HCV, PLHIV and PWID – in HCV treatment scale-up.

Accelerating drug development

Civil society is well placed in drug development. Community Advisory Boards (CABs), comprised of people living with and at risk for HIV and HCV, meet with pharmaceutical companies and research networks to inform drug development and treatment strategy trials for HIV, HCV, tuberculosis and other prevalent co-infections. CABs push for essential, clinically and geographically relevant research on medicines and their implementation; these are inclusive of high-prevalence populations and those with the most urgent need for treatment. For example, CABs have been at the forefront of the demand for more thorough drug-drug interaction studies with DAAs, ARVs, opioid substitution treatment and other commonly used medications to facilitate safe and effective HCV treatment.

Civil society representatives work at each stage of drug development, with regulatory agencies, protocol teams, research networks, and guidelines panels. Civil society representatives can provide unbiased recommendations for the optimal products and regimens for resource-limited settings based both on scientific rationale and knowledge of local, national, regional and global needs.

Creating markets

To address HCV among people living with HIV, stakeholders at all levels must be aware of the burden of disease and understand how it is diagnosed and treated. Although an estimated 170 million people have chronic HCV, most have not been diagnosed and only 1-5% have been treated.^{13,14} Community-led HCV treatment literacy initiatives are essential to creating demand by increasing awareness and mobilizing PLHIV to seek testing, care and treatment for HCV co-infection. This can help strengthen health systems, including through task-shifting responsibilities (e.g. adherence

counseling) to affected communities, as well as by providing accountability and oversight through pressure on health systems and governments to perform.

Civil society groups will be at the forefront of community mobilization, testing efforts and treatment literacy, including by engaging in direct negotiations with drug companies through CABs; raising public awareness; and creating patient-centered treatment programs. This work is already being done in Georgia, Ukraine, and several other countries but needs to scale across LMICs.

Setting priorities

Numerous obstacles to eradication of HIV/HCV remain that require international political leadership: weak national surveillance systems; an absence of costed national plans and treatment guidelines; and a dramatic shortfall in funding to meet the needs of the global HCV pandemic.¹⁵ CSOs can mobilize international funding organizations to channel resources to the most pressing needs. Advocacy by CSOs can put the urgent need for HCV treatment on the global health agenda and help shape the response at the global and national levels.

For example:

- Civil society groups took over the plenary session at the 9th International Congress on AIDS in Asia and the Pacific in 2009, which successfully put HCV treatment on the agenda of several international aid agencies and institutions.
- The “Missing” campaign was initiated by MDM, Act Up Basel, International Network of People who Use Drugs (INPUD), TAG and APN+ to hold WHO Director-General Margaret Chan accountable to respond to the HCV pandemic. In response to this campaign, the WHO established a permanent Strategic and Technical Advisory Committee on Viral Hepatitis; held a broad civil society consultation on HCV and established a permanent Civil Society Reference Group; issued a call to action to scale-up the global HCV response; and released HCV screening and treatment guidelines.¹⁶

¹³ Dore GJ, Ward J, Thursz M. Hepatitis C disease burden and strategies to manage the burden. *J Viral Hepat* 2014; 21(Suppl 1):1-4.

¹⁴ Mohd HK, Groeger J, Flaxman AD, Wiersma ST. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. *Hepatology*. 2013;57(4):1333–42.

¹⁵ Kaplan K. *Activist Strategies for Increasing Access to HCV Treatment in Low- and Middle-Income Countries*. Treatment Action Group, 2015.

- The civil society groups TAG, INPUD, MSF and Alliance-Ukraine participated in global target-setting as members of the WHO's Strategic and Technical Advisory Committee. Some of these organizations were also consulted during the creation of the first HCV treatment guidelines in December 2013. TAG is helping to identify the optimal DAAs for use in HIV/HCV co-infection and participates in the development of HCV treatment guidelines with WHO. CSOs also continue to work to ensure the inclusion of certain products (e.g. new DAAs) on the WHO's EML.
- Finally, CSOs have helped determine the health priorities of their countries by participating in the development of national HCV treatment policies and guidelines. In Thailand, informed community members advocated to have HCV treatment with pegylated interferon and ribavirin added to the national EML and the health benefit package of the Universal Coverage Scheme, allowing HCV treatment access at no cost. They also worked to remove discriminatory policies that excluded key populations including people with HIV from receiving treatment.

Ensuring continued access

Civil society effectively advocates for urgent measures and longer-term policy improvements to address gaps in the health system, which they are well-positioned to do given their extensive networks and ability to reach marginalized populations. In addition, CSOs act as "watchdogs" for the global response by monitoring the WHO's HCV policies and guidelines, participating in UN meetings and holding governments and UN agencies accountable to their commitments. Civil society engagement also ensures that a broad range of actors are represented in decision-making, including people living with HIV/HCV, PWID, technical experts and advocates.

Drug affordability

DAAs can be mass-produced affordably. While a 12-week DAA regimen currently costs more than US \$90,000 in the United States, the regimen can be produced sustainably for a few hundred dollars by generic suppliers.¹⁷

Building on lessons from the ART scale-up experience, civil society groups have started to remove IP barriers and accelerate generic DAA entry

through the use of TRIPS flexibilities (e.g. monitoring patent examination, patent oppositions and compulsory licensing). Patent challenges on key DAAs have been filed thus far by I-MAK, DNP+, Sankalp, LC, APN+ and MDM. Similar to the experience for ARVs, generic suppliers have now followed suit with their own patent challenges.

Civil society groups also share information about originator negotiations with governments, initiate public pressure on companies and governments, encourage generic manufacturers to enter the market, and serve as a market monitor on patents and pricing.

- Since the first DAAs were approved in the United States in late 2013, CSOs such as TAG, MDM, INPUD, and Act Up-Basel have garnered significant press coverage in publicly denouncing the high prices set by originator companies – including at key scientific conferences like The International Liver Congress, AIDS 2014 in Melbourne, and the 2014 Conference on Retroviruses and Opportunistic Infections.
- In March 2014, MDM published "New treatments for Hepatitis C virus: strategies for universal access" showing that the HCV pandemic was concentrated in MICs and that none of the strategies undertaken by originator companies were enabling access to these new treatments. National level advocacy complements this work: in countries like Georgia and Ukraine, advocacy for price reductions helped drive government efforts to negotiate with originators and establish treatment programs, particularly for prisoners.

Service delivery

Involving people with HIV, HCV and PWID in service delivery maximizes effectiveness of limited human resources and helps reach marginalized, disproportionately impacted communities. Given the simplicity of DAA regimen administration and reductions in burdensome monitoring, task shifting to less specialized workers (including people with HIV/HCV) can greatly enhance service delivery in resource-limited settings. Implementing partners such as MSF and MDM also play a significant role by demonstrating the feasibility and effectiveness of treatment programs, laying the foundation for treatment scale-up on a larger scale.

¹⁶ <http://www.hepcoalition.org/advocate/campaigns/missing/article/missing>.

¹⁷ van de Ven N, Fortunak J, Simmons B, et al. Minimum target prices for production of direct-acting antivirals and associated diagnostics to combat hepatitis C virus. *Hepatology* 2015;61:1174-1182.

¹⁸ Londeix P with Forette C. New Treatments for Hepatitis C Virus: Strategies for Achieving Universal Access. *Médecins du Monde*, March 2014.

CONCLUSION

Across multiple countries and types of interventions, civil society groups have demonstrated their ability to drive improvements in treatment access and outcomes for HIV/AIDS. As UNITAID enters the DAA market, it should seek to replicate these gains for HCV by leveraging civil society's potency and specific capabilities. This is particularly true while HCV treatment programs are still in the inception phase, when it is most critical to use high-impact advocacy to make treatment scale-up a national and global priority. Civil society is uniquely positioned to do this given its representation of patients globally and approach to promoting health as a human right.

UNITAID and other leading health institutions such as the WHO should engage CSOs (and in particular people living with HIV/HCV, PWID, and other disproportionately affected communities) as key partners in market shaping from the outset of DAA market interventions. We urge UNITAID to take the following specific actions:

- **Include PLHIV/HCV and PWID in all decision-making for HIV/HCV co-infection:** As codified in the Denver Principles¹⁹, directly-affected communities need to be involved at every level of policy and program decision-making, serve on boards of key stakeholder organizations, and be included in all HIV and HCV forums to share their experiences and expertise.
- **Fund interventions that target criminalized and marginalized populations:** Significant structural barriers such as stigma, discrimination and punitive laws and policies impede or prevent access to HIV treatment for key at-risk populations, including PWID. Based on experience with barriers to HIV treatment for PWID, it is likely that this heavily stigmatized community will continue to face barriers to HCV treatment access, despite carrying a disproportionately high burden of the epidemic and having a high risk of infection.²⁰ For the market to become equitable and treatment outcomes to be optimized, these structural factors need to be addressed. When communities are driven underground, they are not actively participating in and leading efforts to create demand at the national level, nor are they receiving treatment. Investment in removing these structural barriers through civil society's community-led work is an investment in market shaping and universal access.
- **Dramatically increase funding for civil society interventions:** Civil society has held a prominent and often a leadership role in successful market shaping and treatment strategies for HIV. To maximize outcomes for HIV/HCV co-infection, significantly increased funding will be needed for their work in creating markets and ensuring access. We therefore urge UNITAID to develop a strategy for HCV which meaningfully includes CSOs, and to actively solicit proposals from CSOs to most effectively and efficiently drive access to treatment.

To do so, we encourage UNITAID and other funders to work in partnership with CSOs to develop appropriate frameworks for measuring impact. As seen from the India case study in Box 2, financial and treatment impact of civil society interventions can be measured, though requires some flexibility as the impact is not always immediately realized. In addition, we urge UNITAID to expand the types of interventions it funds – particularly with respect to the advocacy work that will be essential to national and global prioritization of HCV.

Supporting civil society groups is particularly important in MICs. Voluntary licensing trends in the DAA market thus far, notably those of Gilead Sciences and Bristol Myers Squibb, indicate that many MICs with high HCV burden are being excluded from licenses and will be forced to pay significantly higher prices than low-income countries, despite similarly constrained health budgets. To achieve the greatest levels of treatment access, UNITAID should provide parallel support to civil society's technical and advocacy strategies to ensure that access to generic, affordable DAAs can be a reality in MICs and all developing countries.

¹⁹ http://data.unaids.org/Pub/externaldocument/2007/gipa1983denverprinciples_en.pdf.

²⁰ Médecins du Monde and International Network of People who Use Drugs. Nobody left behind- the importance of integrating people who inject drugs into HCV treatment programs: Arguments from a human rights and public health perspective. 2014

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