

ACCESS CHALLENGES FOR HIV TREATMENT

Among People Living with HIV
and Key Populations in
Middle-Income Countries

POLICY BRIEF // OCTOBER 2013



Acronyms

ACTA	Anti-Counterfeiting Trade Agreement
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
EPA	Economic Partnership Agreement
EU	European Union
FTA	Free Trade Agreement
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
ICESCR	International Convention on Economic, Social and Cultural Rights
IP	Intellectual Property
MDG	Millennium Development Goal
MICs	Middle Income Countries
MSM	Men Who Have Sex With Men
NCDs	Non-Communicable Diseases
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People Living with HIV
PMTCT	Preventing Mother-to-Child Transmission
PWID	People Who Inject Drugs
SW	Sex Workers
TG	Trans-gender Persons
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Program on HIV/AIDS
WHO	World Health Organization
WTO	World Trade Organization

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BACKGROUND

More than two billion people in middle-income countries (MICs) lack access to essential medicines. Medicines are expensive, and consume 25 to 65 percent of the total private and public spending on health, and 60 to 90 percent of household expenditure in MICs.¹ In the public sector, there is poor availability of medicines and patients are forced to purchase medicines from the private market. The Global Burden of Diseases 2010 study shows that MICs rather than experiencing a classic ‘epidemiological transition’ in which infectious diseases dissipate and non-communicable diseases (NCD) emerge, are facing a ‘dual burden’ in which infectious diseases are still prevalent, especially HIV, viral hepatitis and tuberculosis, while NCD rates are rising.² Access to affordable medicines³ is therefore of central importance in ensuring universal access to health care in these countries.

Middle-income countries (MICs) are facing a crisis of containing costs for treating people living with HIV. These countries carry a high burden of HIV, and transmission of the virus is often concentrated amongst key populations: people who inject drug (PWID), men who have sex with men (MSM), sex workers (SW), transgender (TG), prisoners and migrants. The highest numbers and the highest prevalence of PWID with HIV are in East and Southeast Asia (17 percent), Eastern Europe (27 percent), and Latin America (29 percent). HIV prevalence is on average 13 times higher among MSM compared to the general population. In most parts of the world, sex workers experience higher prevalence of HIV than the general population. Access to treatment can be a challenge for key populations given the structural barriers such as laws and legislation that criminalize their behavior, stigma and discrimination, and lack of general acceptance in society. But even when such barriers are overcome, medicines including ARVs may not be available (‘stocked out’), largely because of the high costs as well as poor procurement and distribution system. The high cost of medicines are often the reasons governments claimed to have prevented them from including or limiting access to treatment as part of the public health insurance or social security system. Moreover, a country’s ability to pay is not always commensurate to willingness to pay especially when it involves key populations.

Treatment for people living with HIV is life-long, and long-term survival depends on continuous access to newer and more potent ARVs, including more robust first-line drug

1. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. “Medicine prices, availability, and affordability in 36 developing countries and middle-income countries: a secondary analysis.” *Lancet*. 2009. 373(9659):240-249.

2. Global Burden of Disease Study 2010. *The Lancet*. 13 December 2012. As noted by the editors, “GBD 2010 consists of seven articles, each containing a wealth of data on different aspects of the study including data for different countries and world regions, men and women, and different age groups.” Available at: www.thelancet.com/themed/global-burden-of-disease

3. For the purpose of this paper these include medications, vaccines, diagnostics and other medical products.

combinations with fewer side effects. For key populations living with HIV, a simpler, less toxic treatment and with less potential for drug-drug interactions (such as with female hormones or injecting drugs) would encourage greater uptake and result in improved adherence. As HIV is constantly mutating, resistance will eventually develop. People living with HIV in MICs need access to affordable second-line and third-line regimens. Access to medicines for people living with HIV is not only limited to ARVs but may also include treatment that is affordable for other illnesses including HIV co-infections such as hepatitis C, drug resistant tuberculosis, sexually transmitted diseases, cancer drugs including vaccines for human papillomavirus, and basic antibiotics to fight off other infections. Therefore, as people living with HIV are aging they need access to affordable medicines to manage their own non-HIV related chronic diseases similar to the rest of the population.

The right to medicines is an integral part of the right to health. While the global community has repeatedly made commitments to secure affordable medicines for all, this promise runs counter to the prevailing economic and trade interests that view medicines as investments and commodities from which to extract maximum profit. In this next decade, governments will need to decide whether essential life-saving medicines for HIV, TB and malaria as well as for NCDs and infectious diseases are for protecting the profits of corporations or for protecting persons' health.

This policy brief examines the challenges to affordable HIV treatment access in MICs amongst people living with HIV (PLHIV) and key populations.⁴ **Section 1** presents the global commitments to securing affordable treatment and the right to health. **Section 2** identifies four key barriers – pricing and patents, intellectual property regimes, regulatory environment, and lack of investment in science and technology – that affect access to affordable essential medicines. **Section 3** reviews present and future HIV treatment access situation and the global commitments to scaling up treatment access. The last section, **section 4**, provides a set of recommendations on how to reconcile the interests of currently prevailing parallel value streams that are working in opposition, namely trade-related rights and human rights, in the wider context of health equity and ethical responsibility. The policy brief is interspersed with examples of national and international campaigns by PLHIV networks and key population communities to illustrate the real-life impact of, and fight for, treatment access.

4. Box 1 provides a set of definitions related to income measures, key populations, and pharmaceuticals that is used throughout the paper.

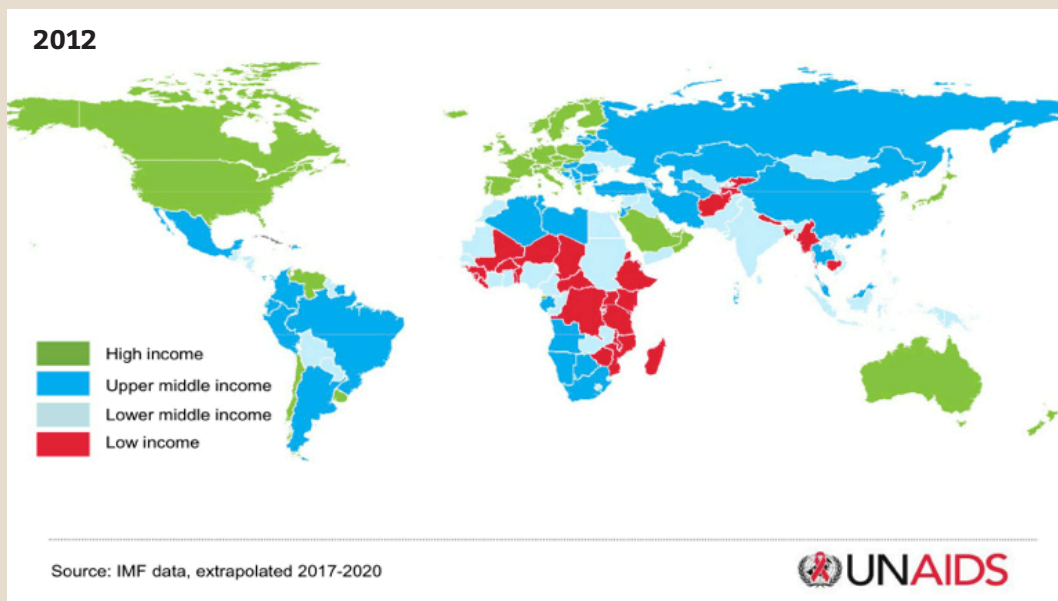
Box 1: Terminology

Income classification

For the purposes of the paper, middle-income countries refers to lower and upper middle-income countries as classified by the World Bank based on gross national income (GNI). In earlier World Bank publications GNI was referred to as the gross domestic product. Countries are classified in the following manner:

- Countries with GNI less <\$1,026 are **low-income** and there are 36 countries in this grouping.
- Countries with GNI from \$1,027 and <\$4,035 are **lower middle-income** countries and there are 54 countries in this grouping
- Countries with GNI from \$4,036 and <\$12,475 are **upper middle-income** countries and there are 54 countries in this grouping

UNAIDS provides an illustration of this mapping based on income.



Key populations

Key populations are defined by UNAIDS as those in which vulnerability and high risk converge in being infected or affected by HIV, and whose involvement is vital for an effective and sustainable response. Key populations include people living with HIV, their partners and families, people who sell or buy sex, men who have sex with men, transgender persons, persons who inject drugs, orphans and other vulnerable children, certain categories of migrants and displaced people, and prisoners. For the purposes of this paper, the focus is on PLHIV, PWID, MSM and SW.

Pharmaceuticals terms from Health Action International

Generic medicine: A pharmaceutical product comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use; interchangeable with the originator brand product, manufactured with or without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. These medicines are identical with the innovator product, but cost significantly less.

Originator or innovator medicine: A product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization and usually has a brand name, but it may vary between countries. These medicines developed by a company are usually protected by a patent owned by the company, and are usually more expensive.



Men who have sex with men and structural barriers to access

The Global Forum on MSM & HIV (MSMGF) conducted its second biennial Global Men's Health and Rights study (GMHR), which included both a global online survey component of 5,779 from 165 countries and focus group discussion component. The 2012 GMHR aimed to identify barriers and facilitators that affect access to HIV services for men who have sex with men (MSM), and to place access to HIV services in the broader context of sexual health and lived experiences of MSM globally. According to the results structural barriers at the policy and cultural level played a central role in hindering access to prevention technologies and treatment. MSM in MICs had difficulty accessing prevention tools such as condoms, lubricants, and HIV testing. Access to treatment was observed at 40 percent, but respondents noted that homophobia and stigma and discrimination often delayed, interrupted and altogether thwarted the onset of treatment. Criminalization of homosexuality provided a pretext for extortion, blackmail, and violence aimed at MSM.

Discrimination on the part of health care providers was especially damaging, causing men to delay or avoid treatment for HIV and other sexually transmitted infections. The impact of structural barriers trickled down to the interpersonal and individual level, leading to social alienation, poor mental health outcomes, and further declines in access to services and health-seeking behaviors.

Source: The Global Forum on MSM and HIV, "Access to HIV Prevention and Treatment for Men Who Have Sex with Men: Findings from the 2012 Global Men's Health and Rights Study (GMHR)." 2013, MSMGF.

SECTION 1

THE RIGHT TO HEALTH AND AFFORDABLE MEDICINES⁵

Access to affordable medicines, including HIV treatment, is of central importance in healthcare and in improving health outcomes. It is also a fundamental element in achieving the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health that is enshrined in global legally binding treaties. The right to health is recognized in the 1948 Universal Declaration of Human Rights and the 1966 International Covenant on Economic, Social, and Cultural Rights, the Convention on the Elimination of All Forms of Racial Discrimination (1965), by the constitution of the World Health Organization (WHO) (1946) and several other documents protecting specific groups such as workers and migrant workers, prisoners, the disabled and mentally ill. Over 100 countries also include health provisions in their constitutions. In addition, the United Nations General Assembly has, since 2001, committed to access to affordable treatment as part of its political commitment to halting and reversing the HIV epidemic and mitigating its impact.⁶ In 2011, the 193 governments of the UN committed to a target of 15 million people living with HIV on ARV by 2015, and recognized the critical importance of affordable medicines in scaling up access.

In 1977, WHO launched its first Model List of Essential Medicines, setting the stage for the 1978 *Alma-Ata Declaration on Health for All* that listed essential medicines as one of eight components of primary health care and a social goal of the highest possible level of health. In the 17th edition, essential medicines are defined as those drugs that satisfy the health care needs of the majority of the population, and should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.⁷ Access to essential medicines is also one of the five indicators identified by the UN High Commissioner for Human Rights to measure progress in the progressive realization of the right to the highest attainable standard of health.

Access to medicines is a prerequisite to achieving several of the Millennium Development Goals (MDGs), namely reducing child mortality (MDG4), improving maternal health (MDG5), and combating HIV/AIDS, malaria and other diseases (MDG6), and is specifically stated in MDG target 8E which makes a global commitment to ensuring access to affordable essential

5. This section is based on the following two publications: Hogerzeil, H V and Mirza Z. *The World Medicine Situation: Access to Essential Medicines as Part of the Right to Health*. WHO, Geneva. 2011. Toebes, B. *The Right to Health as a Human Right in International Law*. Intereentia. Antwerp. 1999.

6. Text of the three UNGA Political Declaration on HIV (2001, 2006, and 2011) are available at: www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2001declarationofcommitmentonhivaids/ Zaidi S. Treatment Access and the 2011 Political Declaration. *In Focus*. APCASO with ITPC. December 2011. Volume 2. Available at: [www.itpcglobal.org/atomic-documents/11057/20000/APCASO%20inFocus%20Vol%202%20-%20Treatment%20Access_Revised%20Prefinal%20Lay-out%20lighter%20red%20\(1\).pdf](http://www.itpcglobal.org/atomic-documents/11057/20000/APCASO%20inFocus%20Vol%202%20-%20Treatment%20Access_Revised%20Prefinal%20Lay-out%20lighter%20red%20(1).pdf)

7. World Health Organization. WHO Model List of Essential Medicines. 17th Edition. 2011. WHO. Available at: http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf

drugs is achieved by 2015. The post-2015 development agenda, currently under discussion, is aiming to set up more ambitious health targets, emphasizing equity, addressing trade agreements, and achieving universal health coverage.⁸

While the right to health and access to essential medicines are globally recognized, achieving them is primarily the responsibility of governments. The human rights framework looks at three duties of the state regarding a human right: the duty to respect, the duty to protect, and the duty to fulfill.⁹

- To **respect** a right means refraining from interfering with the enjoyment of the right.
- To **protect** the right means enacting laws that create mechanisms to prevent violation of the right by state authorities or by non-state actors. This protection is to be granted equally to all.
- To **fulfil** the right means to take active steps to put in place institutions and procedures, including the allocation of resources to enable people to enjoy the right. A rights-based approach develops the capacity of duty-bearers to meet their obligations and encourages rights holders to claim their rights.

Inequitable access is viewed as government failure and can be, and has been, subject to litigation in domestic courts and international committees and courts.¹⁰ In addition to these state obligations, access to medicine depends on government actions in the following four aspects:

- **Availability** – products are developed or existing products are adapted for local use and are on hand through public or private sector;
- **Accessibility** – consumers know how to properly consume the product;
- **Affordability** – patients and health care providers can purchase the product within their means (or reasonably priced); and
- **Acceptability** (Quality) – products work as intended, and are efficacious and safe.

The right to health is firmly embedded in a globally agreed upon human rights framework. But in spite of this, more than two billion persons in MICs lack access to essential medicines including seven million people living with HIV, many of whom are key populations.

Access to medicines is a basic human right – with a focus on equity, solidarity, and justice – and not a just a form of charity or commodities from which multinational companies can

8. The World We Want. High Level Dialogue on Health in the Post 2015 Development Agenda. Meeting Report. Gaborone. 4–6 March 2013.

9. General Comment No. 3 of the Committee on Economic, Social and Cultural Rights provides an authoritative interpretation of the right to health. The right to respect is considered an obligation of conduct, as opposed to obligations of result, which relate to the right to protect and fulfil. ICESCR Comment, General Comment No. 3. 1990.

10. New models of collaboration including international solidarity between northern and southern HIV activists, especially in the case of South Africa, effectively used rights-based civic actions to ensure access to treatment for HIV/AIDS. Subsequently, HIV activists have used legal strategies and community mobilization including demonstrations to ensure access to treatment for patients in many countries. ESCR-Net provides caselaw on health that includes domestic cases as well as use international law on health. Available at: http://www.escr-net.org/caselaw-database/view/filter?field_summary_value=&field_forum_value=&field_country_tid=All&field_thematic_focus_tid=2344

extract unreasonable amount of profits/income simply from control of a monopoly.¹¹ The challenge that arises is how to effectively use the human rights framework to address the problems and adverse health impact of the parallel framework of trade and intellectual property rights discussed in the next section.



Sex workers and mobilizing for access

Globally, sex workers of all genders experience unacceptable levels of exclusion from and violations by HIV programs. For sex workers living with HIV this includes widespread inequitable access to treatment, care and support programs. Harm reduction commodities, including condoms, lubricants, needles and syringes, and pre-exposure prophylaxis are often inaccessible to sex workers because their profession is criminalized and stigmatized, leading to widespread discrimination including in health settings. However, sex workers in all parts of the world have taken control of their status as a key affected population and have mobilized their communities locally, nationally and globally to demand better HIV prevention programming and equal access to treatment, care and support.

UNAIDS and UNFPA in collaboration with the Asia-Pacific Network of Sex Workers (APNSW), recently published a collection on innovative approaches to HIV and sex work. This publication highlights the key elements of a comprehensive response to HIV in the context of sex work and documents good practice case studies of sex worker-led programs in the Asia and Pacific region. These case studies highlight the importance of advocacy and leadership building amongst sex workers and document the importance of collective mobilization in demanding appropriate care, treatment and support for sex workers.

APNSW has played a critical role since 1994 in mobilizing sex workers on critical issues such as decriminalization of sex work, unethical drug trials with sex workers as subject, promoting access to health care for sex workers, and most recently organizing against the free trade agreements that aim to undermine the supply of ARVs. The role of community networks in advocacy on the right to medicines is critical in facilitating access to treatment through awareness, education, outreach, and creating community care and local safety nets and spaces for sex workers to develop collective action. Veshya Anyay Mukti Parishad (VAMP) is a registered collective of 5,000 female sex workers in India using a rights-based approach to empower and collectivize sex workers and is noted as an example of good practice amongst many other sex worker-led organizations in Asia and the Pacific region.

Source: APNSW, UNAIDS, and UNFPA. *The HIV and Sex Work Collection: Innovative responses in Asia and the Pacific*. (2012). www.apnsw.org on FTA see: <http://apnsw.wordpress.com/2013/04/08/wnu-organises-protest-in-phnom-penh-against-eu-india-free-trade-agreement/>

SECTION 2

BARRIERS TO AFFORDABLE MEDICINES



This section focuses on pricing, patents, and trade-related treaties affecting access to affordable medicines for people living with HIV and key populations. It also touches upon the regulatory environment and scientific and technological capacity as these topics are also important but outside the scope of this paper.

There are manifold reasons why essential medicines are not affordable in MICs, and even in high-income countries medicines costs can consume a significant percentage of the healthcare budget.¹² The lack of availability of medicines particularly in the public sector is an important barrier to access, but the most visible cause of why people who need life-saving medicines do not get the treatment they need is due to high prices. Medicines, particularly newer medicines needed for second and third line HIV treatment, the treatment of hepatitis C and for NCDs are expensive because of strong intellectual property protections that result in monopolies. In MICs with functioning health systems and insurance schemes, medicines can account for nearly half of the total health expenditure¹³ And, in the public sector medicines may be free but availability and accessibility can be poor forcing patients to purchase medicines from the private market at much higher prices.¹⁴

In MICs, the high cost of medicines is often the reason claimed by governments for not including, or limiting access to, treatment as part of the public health insurance or social security system. Individuals are forced to purchase medicines in the private market and as a result incur high out-of-pocket expenditures for medicines.¹⁵ Even in the case of HIV treatment, access to older generation ART (lamivudine, stavudine, and nevirapine) costs significantly less (\$52 per person per year) than the newer WHO recommended treatment regimens that include tenofovir and cost over \$100 per person per year.¹⁶ Despite WHO's recommendations to phase out stavudine (d4T)-based regimens because of their long-term side effects, governments have been nervous about switching over to newer treatment options given the costs. The costs of diagnostic and monitoring tools are also expensive, further limiting access.

People living with HIV, key populations and broader civil societies have often pressured its government to bring down the prices of medicines, but countries that have attempted

12. EpiAnalysis. U.S. versus European Healthcare Costs: the data. 18 July 2012. Available at: <http://epianalysis.wordpress.com/2012/07/18/usversuseurope/>

13. Lu Y, Hernandez P, Abegunde D, Edejer T. "Medicines Expenditures" in *The World Medicines Situation 2011*. World Health Organization. (2011). Geneva.

14. Cameron A, Ewen M, Auton M, Abegunde D. "Medicine prices, availability, and affordability" in *The World Medicine Situation 2011*. World Health Organization. (2011). Geneva.

15. World Health Organization. *The World Medicine Situation 2011*. Geneva. 2011. WHO.

16. MSF Access Campaign. *Untangling the Web*. 15th Edition. July 2012. MSF.

this have come under economic and political pressure from wealthy countries and the pharmaceutical industry.¹⁷

WTO and the globalization of patent rules

Prior to the creation of the World Trade Organization (WTO) in 1994, medicines were not widely subject to patents in developing countries, allowing local pharmaceutical manufacturers to develop generic versions of drugs as well as local manufacturing capacity. Generic medicines are identical copies of originator products and significantly less expensive to produce. But with the formation of the WTO, any country that wanted to participate in global trade had to also sign the Agreement on Trade-Related Intellectual Property Rights (TRIPS). TRIPS requires WTO member countries to grant a minimum of 20 years' of patent protection on all processes and products, without distinction of whether or not the products are life-saving or life prolonging medicines or luxury items. It also requires the protection of originator data against unfair commercial use.

Developing countries were given a period of time to become TRIPS compliant and all these countries are now enforcing intellectual property on medicines as required by the WTO rules. Countries classified by the UN as Least Developed Countries (LDCs) who are WTO members had till 2013 to comply with TRIPS and till 2016 to enforce patents on pharmaceutical products. LDCs have now secured with considerable support from global civil society a further extension to comply with TRIPS by 2021. The deadline to enforce pharmaceutical patents scheduled to expire in 2016 is similarly likely to be further extended.¹⁸

While the stated intention of TRIPS, according to its defenders in developed countries, was to encourage innovation and balance the rights of patent holders and consumers, it instead created international, legally protected monopolies that limited competition resulting in higher costs of medicines.¹⁹ The high price of medicines became associated with a system of patents that prevented competition and created monopolies by conferring exclusive rights to the pharmaceutical company that invented the product, thereby precluding others from making, using, selling, or importing the patented drug.²⁰ Originator pharmaceutical companies claim that patent protection was necessary for research and development (R&D) of new products, and high prices of medicines were a return on that investment.²¹ However, companies have failed to disclose their expenses related to bringing a new product to market, and independent analysis has revealed that marketing was the biggest expense

17. Berkman A, Garcia J, Munoz-Laboy M, et al. "A critical analysis of the Brazilian response to HIV/AIDS: lessons learned for controlling and mitigating the epidemic in developing countries." *Public Health Matters*. (2005). 95(7):1162-1172.

18. The LDC request for an extension to becoming TRIPS compliant was is being forcefully opposed by the U.S and the EU. See Carter Z. TRIPS exemption opposed by Obama Administration, threatening cost spike for drugs in poorest nations. *Huffington Post*. May 20, 2013. Available at: www.huffingtonpost.com/2013/05/20/trips-obama-administration_n_3306992.html

19. Smith R D, Correa C, and Oh C. "Trade, TRIPS and Public Health." *The Lancet*. (2009). 373(9664):684-91.

20. Scherer F M. The Pharmaceutical Industry: Prices and Progress. *New England Journal of Medicine*. (26 August 2004). 351(9):927-932.

21. Correa, M. "Ownership of knowledge – the role of patents in pharmaceutical R&D." *Bulletin of WHO*. (2004). 82:784-790.

incurred by the pharmaceutical industry with originator companies spending twice as much on advertising and promotion as compared to R&D.²²

Originator companies also focused on products that were emulations of other products on the market, labeled as “me too” with little added value to health. Companies were also inclined to extend patent monopolies through minor alterations to existing products (either formulation or process) and file a new patent for such alterations. These low-risk incremental innovations, known as “evergreening”, on already existing products are an expensive undertaking given the clinical trial process. Originator companies also filed for a new patent when an existing product turned out to be effective in treatment for other diseases, new use patent. For instance, the first drug ever to be approved for the treatment of HIV, zidovudine (AZT), was originally a cancer medicine. On discovering its additional use for HIV, a patent for a new use was filed on the drug in the late 1980s even though the drug itself was synthesized in the 1960s.

Overall these practices have led to less innovation, less health impact but an increasingly more expensive drug.²³

TRIPS and the HIV movement

The WTO’s intellectual property regime based on the commercial interests of developed countries developed in parallel with the growing HIV epidemic that was taking an increasingly devastating toll on MICs. South Africa was home to the largest numbers of PLHIV and when the new democratic post-apartheid government amended its Medicines Act to make generic medicines more easily accessible, 41 pharmaceutical companies sued the government claiming that it violated TRIPS. The case led to national and global protests against the actions of the companies. It was also at this time that community activism in the developing world put access to affordable ARVs on the international stage - first at the 2000 AIDS Conference in Durban and then through a legal brief filed on behalf of communities in South Africa for treatment access.²⁴

Meanwhile, activism on the other side of the ocean over the patent on stavudine developed by Yale University researchers came to a head when students, researchers, and access advocates pressured university administrators to renegotiate the license with Bristol Myers Squibb to ensure that generic versions of the medicine would be available in developing countries.²⁵ In 2001, CIPLA, an Indian generic manufacturing company, produced a fixed-dose combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP) for \$350 per person per year, making treatment affordable, simplified and sustainable for people living

22. Gagnon, M A and Lexchin, J. “The cost of pushing pills: A new estimate of pharmaceutical promotion in expenditures the United States.” *Plos Medicines* (2008), 5(1):29-33.

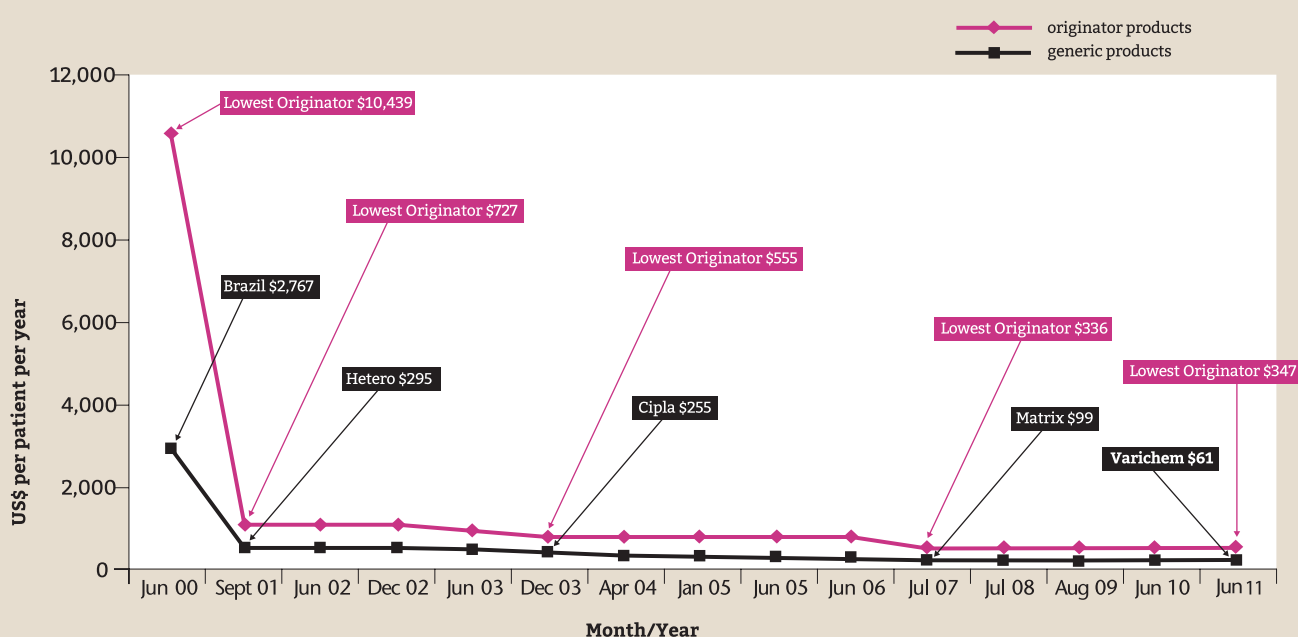
23. Boldrin, M and Levine, D K. “The case against patents.” *Journal of Economic Perspectives*. Winter 2013. 27(1):3-22. The authors arguing for reforming the current patent system as it is damaging public health by raising the cost of prescription drugs, while failing to generate a plethora of innovative new treatments for life-saving diseases. Furthermore, they advocate for rules prior to the Bayh-Dole Act of 1980 according to which the results of federally subsidized should not lead patents but be available to all market participants.

24. Heywood M., “South Africa’s Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health.” *Journal of Human Rights Practice*. 1(1):14-36.

25. Borger J and Boseley S. “Campus revolt challenges Yale over \$40 million AIDS drug deal.” Published in *The Guardian* on March 13, 2001. Available at: www.commondreams.org/headlines.shtml/headlines01/0313-01.htm

with HIV in MICs.²⁶ As of 2008, Indian made generic ARVs accounted for 80% of global purchases of adult ARVs and close to 90% of pediatric ARVs in low and middle income countries.²⁷

Generic competition as a catalyst for price reductions. The fall in the price of the first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000



Source: MSF access campaign

The first generation of first-line ARVs dropped by 99 percent in the past decade because the pre-2005 the current intellectual property (IP) regime had not been adopted by countries including India that supplies most of the world's generics. As a result over 9 million PLHIV now have access to ARVs, a twenty-fold increase since 2003. Nonetheless, global commitments promise to put another 6 million persons on HIV treatment by 2015 while a great number more are eligible to start treatment. Many PLHIV have been on first-line ARVs for nearly 10-years and require second-line or third-line ARVs.

Crucially, India, also a member of the WTO is now TRIPS compliant and granting patents on newer medicines. It is unlikely that Indian companies will be able to manufacture and export new generic ARVs, and the fact that originator companies have been aggressively patenting ARVs in MICs is but a pointer towards future direction. Given the standardized IP regime it is unlikely that prices for ARVs will drop dramatically in the future unless the medicine is no longer patent protected and unless governments are willing to take the necessary policy measures to ensure access to affordable generic medicines.

26. The same fixed-dose combination in 2012 June cost about \$56 ppy, but new WHO guidelines recognizing the terrible side-effects of stavudine have recommended that it be discontinued. MSF Access Campaign. Untangling the Web. 15th Edition. MSF.

27. Waning B, Diedrichsen E, Moon S. "A lifeline to treatment: The role of Indian generic manufacturers in supplying to antiretroviral medicines to developing countries." *Journal of International AIDS Society*. (2010). 13(35).

Using TRIPS flexibilities to ensure access to medicines

Global outrage over the case filed by multinational companies against the South African government not only led to the case being withdrawn by the companies, it also prompted a meeting of all WTO members in Doha in November 2001 to discuss the impact of the TRIPS Agreement on access to medicines. The resulting 'Doha Declaration on the TRIPS Agreement and Public Health' signed by all WTO member countries stated, *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

TRIPS created a standard patent regime but it allowed for certain "flexibilities" permitting developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies. The use of compulsory licensing (CL), parallel importation, and Bolar provisions are forms of flexibilities that protect access to treatment (see Box 2 for details). These mechanisms were reaffirmed by the 2001 Doha Declaration on Public Health with its goal is promoting access to medicines for all.²⁸ This unprecedented political commitment by WTO members elevated the protection of public health to the international trade agenda.

TRIPS flexibilities have been difficult to use in practice, but when implemented have achieved significant progress in ensuring access to affordable treatment. The simplest flexibility, even if politically contentious, is a CL where governments permit the manufacture, use or sale of a medicine, without the consent of the patent owner for the domestic market and subject to certain conditions, for export to other developing and least developed countries as well. Since 1995 there have only been a few instances of CLs being issued in 17 countries and most have involved medicines for HIV.²⁹ Countries that have issued CLs, especially those that have local manufacturing capacity, have faced backlash from wealthy governments in the form of real or threatened trade sanctions and their originator companies who have retaliated against the issue of CL with the refusal to distribute other medicines.³⁰ However, the availability of generics as a result of CLs has led

28. See UNAIDS, UNDP, WHO. Policy Brief: Using TRIPS Flexibilities to Improve Access to HIV Treatment. Available at: www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

29. Beal R and Kuhn R. Trends in compulsory license of pharmaceuticals since the Doha Declaration: A database analysis. *PlosMedicines*. (Jan 2012). 9(1):1-7. Compulsory licenses have been issued for 16 HIV/AIDS drugs, 4 for communicable diseases (2 anthrax and 2 for flu) and 5 for NCDs (of which 4 for cancer and 1 for viagra). On 9th March, India issued the first compulsory license for kidney and liver cancer drug Nexavar produced by Bayer to Natco, an Indian generic company. Bayer appealed the decision, and most recent court ruling decided that Bayer should receive royalties of 7 percent up from 6 percent. Available at: www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/

30. After Thailand issued a CL in 2006 for generic version of Abbott's Kaletra. The company undertook an aggressive attack against the Thai government from accusing them of "stealing" intellectual property to punitive measures such as cancelling plans to sell seven new medicines including a heat-stable version of lopinavir/ritonavir requiring no refrigeration. Abbott also cut the price for more than 40 countries and demanded that Thailand repeal the CL if it wanted benefits from the discount. See: Ford N, Wilson D, Chaves G C, et al. "Sustaining access to antiretroviral therapy in the less developed world: lessons from Brazil and Thailand." *AIDS*. (2007). 21(Suppl 4): S21-29.

Box 2: Defining TRIPS flexibilities

Compulsory licenses: Issued in the form of an order by competent administrative or judicial authority allows for the use of a patent-protected invention by the government or third parties without the consent of the patent-holder who receives adequate compensation in the form of a royalty. According to the Doha Declaration, WTO members can determine the grounds upon which to issue a CL.

Parallel imports: Companies offer differential pricing for medicines across countries. This means that an intermediary can purchase medicines from one country at lower prices and resell it another country without the permission of the patent owner. Once the patent owner has been rewarded through the first sale or distribution of the product, then the right has been “exhausted”. But because of a complicated set of regulations, this mechanism is difficult to apply.

Bolar provision/regular exception: Allows for the manufacturer of generic drugs to use patented invention to obtain marketing approval for example from the public health authorities before the patent expires. This permits a generic product to enter the market more quickly after patent expiry, facilitating access to cheaper medicines.

Source: UNAIDS, UNDP, WHO. Policy Brief: Using TRIPS Flexibilities to Improve Access to HIV Treatment. Available at: www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

to considerable savings. For instance in the case of Thailand, of almost \$370 million over five years.³¹

Last year in an unprecedented move Indonesia issued CLs on seven ARVs and one hepatitis B medicine. When fully implemented, the introduction of widespread generic competition will generate big cost savings. At the same time China overhauled part of its intellectual property laws to allow local production of patented drugs during state emergencies, unusual circumstances or in the interests of the public.³² This amendment to China’s patent laws, led to Gilead offering certain concessions, including offering China a substantial donation of tenofovir, an ARV, to treat not only HIV but also hepatitis B.³³ However, the price for tenofovir did not drop. China is the largest emerging market for pharmaceuticals with a population of 1.3 billion, with 13 percent already 60 plus years old creating a market for NCDs that are expensive to treat.

31. Mohara A, Yamabhai I, Kakanang C., et al. “Impact of the introduction of government use licenses on the drug expenditures on seven medicines in Thailand.” *Value in Health*. (2012). 15:595-599. See also Yamabhai I, Mohara A, Tantivess S, et al. “Government use licenses in Thailand: an assessment of the health and economic impact.” *Globalization and Health*. (2011). 7:28. Nunn A, Da Fonseca E, and Gruskin S. Changing global essential medicines norms in improving access to AIDS treatment: lessons from Brazil. *Global Public Health*. (2009). 4(2):131-149.

32. Bigg M. Indonesia acts to over-ride patents on HIV drugs. Reuters. (12 Oct. 2012). Available at: www.reuters.com/article/2012/10/12/us-indonesia-hiv-idUSBRE89B00620121012

33. Paul Cawthorne, coordinator, MSF Access Campaign in Asia. Personal communication. Summer 2012.

Examples of compulsory licensing for pharmaceuticals worldwide

Year	Country	Products	Type	Results
2002	Zimbabwe	Any drug used for the treatment of HIV/AIDS	Emergency	The average price of ARVs dropped from \$30 to \$50 per month to just over \$15 a month, cutting the price by at least 50%.
2003	Malaysia	3 ARVs: ddI; AZT; 3TC + AZT (Combivir)	Govt use	Average cost reduction of about 81% per patient per month; number of patients treated by public services increased from 1,500 to 4,000.
2004	Mozambique	3 ARVs: 3TC; d4T; and NVP	Extreme Emergency	
2004	Zambia	ARV: 3TC + d4T + AZT	Extreme Emergency	
2004, 2007, 2012	Indonesia	2004 – 2 ARVs: NVP; 3TC 2007 – 3 ARVs: NVP; 3TC; and EFV 2012 – Seven ARVs + Hep B: EVF; ABC; ddI; LPV/RTV; TDF; TDF+ FTC; and TDF+ FTC+ EFV	Govt use	About 2,000 patients received free access to ARVs after first two licenses.
2005	Eritrea	ARVs	Emergency, Govt use	
2005	Ghana	ARVs	Emergency, Govt use	Annual price for ARVs dropped by 50%.
2005, 2006, 2007	Italy	2005 – antibiotic combination: 2006 – migraine drug sumatriptan succinate 2007 – prostate cancer: finasteride, a treatment for prostate hypertrophy, prostate cancer and male baldness	Anti-competitive practices	
2006, 2007, 2008	Thailand	2006 – 1 ARV: EFV 2007 – 2 ARVs + cardiovascular: LPV/RTV; and clopidogrel 2008 cancer treatments: docetaxel; erlotinib; letrozol; (ultimately the imatinib CL was not needed due to the successful negotiations with patent holders)	Govt use	The price of EFV was reduced by seven times; LPV/RTV by 75%; clopidogrel by 91%; docetaxel by 24 times; letrozol by 70 times. After the CL, Abbott cut the price of lpv/r by more than 55% for over 40 countries for low and middle-income countries. Patients accessing LPV/r tripled in 2008. By 2010, the number of patients receiving EFV increased from 4,539 to 29,360 in Thailand.
2007	Brazil	EFV	Govt use	CL produced immediate savings of US\$31.5 million.
2009, 2010, 2012	Ecuador	2010 – ARV: RTV 2012 – ARV: ABC+3TC		30% reduced price offer for ritonavir.
2012	India	Sorafenib (drug against kidney and liver cancer)		It is estimated that the price of the drugs will be reduced by 97% from US\$5,500 to US\$ 175 per patient per month.

Legend: 3TC= lamivudine | ABC= abacavir | AZT= zidovudine | d4t= stavudine | ddI= didanosine | EVF= efavirenz | FTC= emtricitabine | LPV= lopinavir
NVP= nevirapine | RTV= ritonavir | TDF= tenofovir

Source: Public Citizens Global Access to Medicines Program. www.citizen.org/access

Civil society has played a critical role in ensuring that governments in MICs enact pro-health safeguards in their intellectual property laws and have been at the forefront of several legal battles aiming to balance public interest and intellectual property. In India, Thailand and Brazil, civil society groups and PLHIV networks have successfully opposed patents and patent applications on key medicines including ARVs. A crucial health safeguard included in India's patent law by Indian legislators to restrict evergreening patents – Section 3(d) has been under attack by multinational companies and developed countries alike. A global campaign supporting Indian groups in extensive litigation by Swiss MNC Novartis that challenged and tried to weaken these safeguards received a huge victory in April 2013 when the Indian Supreme Court upheld a strong interpretation of Section 3(d). Restrictions on evergreening have been adopted in Argentina and Zanzibar and are being considered in Brazil and South Africa.

The use of TRIPS flexibilities is critical for increasing access to affordable treatment. However, their use has been limited in many developing countries. One reason for this is because many countries lack of supportive legal environments including an informed judiciary in which to prepare and file compulsory licenses or to draft strong patent laws or to amend existing patent laws. Countries also require technical and administrative resources to assess patents and negotiate with patent holders.

Free Trade Agreements undermining access to medicines

Governments in MICs are not always well prepared to address the challenges to public health posed by TRIPS, but an even greater threat to treatment access is emanating from wealthy countries of the north, primarily the U.S. and the European Union. These countries are pressuring developing countries into signing bilateral and regional free trade agreements (FTAs) and economic partnership agreements (EPAs) that include provisions that mandate even greater IP protection than is required under TRIPS. Thus these agreements have been labeled as “TRIPS- plus”. The provisions contained in these non-transparent and secretly negotiated trade agreements restrict the use of TRIPS flexibilities and require the adoption of measures that greatly limit production and distribution of generic medicines.

For example, TRIPS-plus FTAs and EPAs generally include clauses to extend patent terms beyond the twenty-year minimum required by TRIPS, limit the use of CLs, and require data exclusivity that restricts the use of clinical data by national drug regulatory authorities to approve generic production for a certain time period (between five to twelve years). Ongoing negotiations by the US on the Trans-Pacific Partnership Agreement (TPPA) with multiple developing countries also seek to prevent countries from restricting evergreening or allowing pre-grant oppositions. The EU meanwhile is negotiating EPAs with key MICs like India, Thailand, Indonesia, the Philippines, Vietnam and others seeking to impose TRIPS-plus provisions on these countries, many of whom have significant generic production capacity. These FTAs and EPAs also contain “investment” provisions that would allow MNCs to sue developing country governments in private, secret arbitration on the grounds that the expected profits from their intellectual property have been reduced by the implementation of pro-health policies.

There is significant evidence that essential medicines are much more expensive in countries that have signed TRIPS-plus agreements.³⁴ Thai academics studying the Thailand-USA FTA currently under negotiation estimated that medicines prices would increase by 32 percent and the domestic industry would lose over three million US dollars, and they conclude that IPR protection of pharmaceutical should be excluded.³⁵

The integrity of affordable medicines is also under threat from stronger intellectual property (IP) enforcement measures. The Anti-Counterfeiting Trade Agreement (ACTA), negotiated secretly amongst a handful of high-income countries led by the U.S. is based on the flawed premise that stricter enforcement of IP is the best remedy to protect patients from sub-standard and fraudulent medicines.³⁶ ACTA purposely conflates legitimate generic drugs with counterfeit medicines. This IP enforcement agenda is complex, and includes a range of partners from the national level to international agencies such as the World Customs Union and the World Health Organization. It is yet another threat to affordable access as legitimate generic medicines can be seized while in transit. However, last year activists globally mobilized and successfully defeated the ratification of ACTA in the

34. Oxfam. “All Costs, No Benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines.” March 22, 2007. www.oxfam.org/en/policy/bp102_jordan_us_fta Ellen Shaffer and Joseph Brenner. “A Trade Agreement’s Impact on Access to Generic Drugs.” *Journal of Health Affairs*. September/October 2009 vol. 28 no. 5. <http://content.healthaffairs.org/content/28/5/w957.abstract>

35. Kessomboon N, Limpananont J, Kulsomboon V, Maleewong U, Eksaengsri A and Paothong P. “Impact on access to medicines from TRIPS-plus: a case study of Thai-US FTA.” *Southeast Asia Journal of Tropical Medicines and Public Health*. 2010. 41(3):667-677.

36. Baker, B K. “ACTA – Risks of Third-Party Enforcement for Access to Medicines.” *Am U Int’l Law Review*. 2011. 26(3):579-99.

European Parliament.³⁷ Eight countries – Australia, Canada, Japan, Morocco New Zealand, Singapore, South Korea and the United States – are currently signatory to ACTA.

TRIPS-plus IP enforcement measures have emerged through several forums and also feature in FTA negotiations. They have also made their appearance through laws in several African countries. In 2012, the Constitutional Court of Kenya, in a challenge filed by people living with HIV struck down provisions of an anti-counterfeiting law on the grounds that it would negatively impact access to generic medicines and therefore violate the Constitutionally recognised right to life.³⁸

Governments should resist attempts that use anti-counterfeiting laws and legislations to label generic medicines as sub-standard and fake medicines and respond to public sentiment.³⁹ Instead of adopting TRIPS-plus IP enforcement laws that in fact threaten access to generic medicines, countries should focus on strengthening their drug regulatory authorities (DRA) which have a complex and less well understood impact on access to medicines.⁴⁰ Regulatory systems are central to health systems as they govern pharmaceutical safety and efficacy, market access, price controls, and distribution. The system is responsible for entry of a drug and thus must be balanced with the public health needs of the population. The WHO recognizes four interlocking factors – rational selection of medicines, affordable prices, sustainable financing and reliable and health and system – that are critical for functioning regulatory framework and advocates that the creation of an effective DRA is crucial for oversight.⁴¹

Effective regulatory systems are important for ensuring the quality of generics and building consumer confidence especially in situations where the patient may perceive that they are receiving a lesser quality product (or in cases where generics are being equated to fake medicines such as in Eastern Africa).⁴² While sole responsibility of regulation lies with the government, there is potential for considerable influence by other players. The regulatory environment is also emerging as critical for the manufacturing of biological products that are complex molecules produced inside living cells. Access to affordable biologics, and in particular to bio-similars, is going to be a major challenge for all countries given pricing and regulatory system.

37. Daily Caller. Activists present anti-ACTA petition to the EU. Available at: <http://dailycaller.com/2012/02/28/activists-present-anti-acta-petition-to-eu/?print=1>

38. Patricia Asero Ochieng v. The Attorney General, High Court of Kenya, Petition No. 409 of 2009.

39. UN General Assembly. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Expert Consultation on Access to Medicines as a Fundamental Component of the Right to Health. A/HRC/17/43. Geneva. 16 March 2011.

40. Rågo, L. and Santos, B. Drug Regulation: History, Present and Future. In *Drug Benefits and Risks: International Textbook of Clinical Pharmacology*, revised 2nd edition Edited by C.J. van Boxtel, B. Santoso and I.R. Edwards. IOS Press and Uppsala Monitoring Centre, 2008. Gray, A. Access to Medicines and Drug Regulation in Developing Countries: a Resource Guide for DFID. DFID. 2004. London. Preston C, Valdez ML, Bond K. Strengthening Medical Product Regulation in Low- and Middle-Income Countries. *PLoS Med.* 2012. 9(10): e1001-327.

41. World Health Organization. *How to Develop and Implement a National Drug Policy* (Second Edition). WHO. 2001. Geneva.

42. Musungu, S. The Potential Impact of the Proposed East African Community (EAC) Anti-Counterfeiting Policy and Bill in Access to Essential Medicines. *UNDP BDP HIV Practice*. (March 2010).

Voluntary mechanisms and access to medicines

The UN Special Rapporteur on the Right to Health has noted that, “A company that holds a patent on a lifesaving medicine is to make use of all the arrangements at its disposal to render the medicine accessible to all.”⁴³ Developed countries and multinational companies often highlight the importance of a range of voluntary mechanisms that they claim can also ensure access to medicines. This includes differential pricing (where companies charge higher prices in countries with higher GDPs and lower prices in poorer countries), price discounts and voluntary licences.

However, *Medicins Sans Frontier* in its *Untangling the Web of ARV Price Reductions in 2011* reported that originator pharmaceutical companies have abandoned HIV drug discount programs in middle-income countries, and ARV prices are being negotiated on a case-by-case basis resulting in higher costs of treatment.⁴⁴

In 2010, the Medicines Patent Pool was created, which aims to increase access to affordable ARVs by negotiating voluntary licenses with originator companies that can be used by generic manufacturers. The MPP builds on the preferred pharmaceutical company model of knowledge transfer: voluntary licensing. In voluntary licensing, a patent holder can at discretion license to other producers on an exclusive or non-exclusive basis to manufacture, import, and/or distribute a medicine with whatever negotiated restrictions. The licensee, depending on the terms of agreement, may either effectively be an agent of the patent holder or may be free to set the terms of sale and distribution with a prescribed market based on payment of royalty. This practice is one of outsourcing production through generics. In theory granting licenses to generic manufacturers should allow prices to drop but in reality voluntary licenses awarded to a handful of companies with non-transparent agreements that contain numerous restrictions, such as set price ranges, segment markets, and other terms that can potentially limit access. Rather than increasing competition, in such situations competition is controlled and artificial. Such arrangements have been made for strategic reasons such as market entry. Voluntary licenses are an interesting tactic and a mixed-blessing.⁴⁵

In its attempt to remedy some of these problems with voluntary licences, the Medicines Patent Pool has not made much headway in either the transfer of knowledge from originator to generic companies or a significant reduction in prices, particularly among MICs.⁴⁶ Civil society groups, including key populations, in MICs have reasons to worry about the MPP’s voluntary licence agreements given that they are excluded from receiving the

43. HRC. Expert consultation on access to medicines as a fundamental component of the right to health. A/HRC/17/43. (16 March 2011).

44. Medicins San Frontier. *Untangling the Web of Antiretrovirals*. 14th Edition. July 2011. MSF.

45. Amin, T. Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines? Oxfam. 2007. Available at: <http://apps.who.int/medicinedocs/en/m/abstract/Js19793en/>

46. The Medicines Patent Pool negotiated its first license with Gilead for four drugs, tenofovir, cobicistat, elvitegravir, emtricitibine and a simplified “fixed-dose combination” – or a single pill comprising these four medicines – known as the Quad (brand name: Stribild). To date several Indian generic companies have taken out the sublicense- Aurobindo, Emcure, Hetero, Laurus, and most recently Shahsun. Many of these companies were already producing ARVs, and the added value in increase of coverage or lower prices to these medicines as a result of this agreement are not available on the MPP website. Recently, ViiV put in the license for abacavir but only for pediatric use. Abacavir is also indicated as first-line treatment for adults and is also a prime candidate for co-formulation with lamivudine (3TC) and zidovudine (AZT). All owned by ViiV, but not put into the Medicines Patent Pool. www.medicinespatentpool.org

benefits, and originator companies can select the manufacturing country for sub-licensing production.⁴⁷ The MPP structures and licensing mechanisms comply with the prevailing intellectual property regime framework with originator companies in control and determining the parameters of the agreement, licenses being negotiated in secrecy (though they are revealed once signed), and little evidence of improvement in access (other than in theory).

A broken R&D system

Lastly, another barrier to access to medicines is the lack of investments in science and technology that are needed for production, innovation, and knowledge sharing. Innovation in medicines is a joint public-private venture. Research and development is often initially supported through public funds, either government facilities or universities, and the discovery of a new and promising product is later licensed to private firms for development and exploitation. Correa observes that pharmaceuticals apply for thousands of patents that are unjustified in terms of innovation but get through because of low standards of patentability, resulting in entry barriers for others.⁴⁸ The patent framework in its current form needs to be rethought as it limits innovation, privatizes scientific discoveries with public health benefits, creates monopolies, and serves as a barrier to affordable access for essential life-saving medicines.

The current intellectual property regime is dangerous in its efforts to place restrictions on the flow of knowledge further strengthening monopolies that are bad for health. Because of stricter provisions over knowledge exchange and transfer, countries will face immense difficulty in local manufacturing of life-saving medicines, building effective regulatory systems, and eventually to innovate (as the latter is an incremental process building on what has been learned).⁴⁹

The entire system of research and development has not been able to delink itself from market incentives and patents. At the WHO level, governments are exploring the creation of an R&D treaty to enable such a delinkage. These discussions are based on the report of the Commission on Intellectual Property, Innovation and Public Health that the patent based R&D system was not delivering medicines needed for treating diseases that pre-dominantly affect low and middle income countries.⁵⁰

47. For discussion on issues with the first MPP-Gilead license and exclusion of MICs see documents available at: http://itpc.wikispaces.com/meeting_between_CS_reps_and_MPP_UNITAID

48. Correa C M. Ownership of knowledge – the role of patents in pharmaceutical R&D. *Bulletin of the WHO*. 2004. 82:784-790.

49. World Health Organization. Local Production and Access to Medicines in Low- and Middle-Income Countries. A literature review and critical analysis. WHO. 2011. Geneva.

50. Joint Letter to the 66th World Health Assembly: Follow-up of the report of the CEWG, 17 May 2013, available at www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_Letter_WHAJointLetterCEWG_ENG_2013.pdf

SECTION 3

COSTS AND TREATMENT SCALE UP

In 1998, the AIDS crisis and civil society advocacy challenged the conceptions of trade rules in relation to access to ARVs. Local organizing, global mobilizing, and community pressure coupled with generic production led to significant price drop of ARVs. People living with HIV pressured their governments to provide treatment lead by the example of TAC in South Africa, courageous political leadership issued CLs for ARVs for local use in countries such as Brazil and Thailand and global campaigning resulted in the Doha Declaration which put the rights of governments to protect public health and promote access to medicines on equal footing with trade and intellectual property rights. Community activists had a legal mechanism to challenge the relentless march by wealthy countries of protecting corporate interests and strengthening intellectual property rights without regard for social consequences in MICs. Extensive advocacy by activists also led to the creation of the Global Fund for AIDS, TB and Malaria, a new approach to financing the HIV response.

The past decade has witnessed a treatment scale-up from less than one million persons on treatment in 2003 to nearly 9.7 million on treatment at the end of 2012.

The extent of the challenges in securing access to financially sustainable treatment in MICs is sobering, especially for people living with HIV and key populations in middle-income countries. The WHO preferred option of a single pill, fixed-dose combination of tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV) produced by originator companies is priced at \$613 per person per year for low-income countries and \$1,033 per person per year for lower middle-income countries. But prices for upper middle-income countries are higher, and can vary from country to country. A generic version is available at around \$100 per person per year for countries in which patents do not form a barrier or where originator companies have given voluntary licenses to generic manufacturers. However, better protease inhibitor-based first-line regimens remain unaffordable and require surmounting patent barriers.

Second-line and third-line ARVs are also expensive as a result of patent protections. Those who have been on first-line treatment for a decade or longer require continuous access to newer and more potent ARVs, and unless prices are lowered it will be difficult to scale up treatment programs. Even the most politically committed government will need to weigh providing second-line treatment against providing first-line ARVs. Middle-income countries are already paying exorbitant prices for most ARVs. As noted above, originator companies are no longer offering standardized price discounts including for medicines purchased under programs funded by the Global Fund.⁵¹

The costs of treatment will be an issue for scale up especially given the flat lining and reduction of financial resources. More and more countries will join the fraternity of middle-income nations and face the problems of their long-time donors shifting support as they seek to cut their foreign aid and bilateral ties. These newly emerging MICs may also not be

51. IRIN. "HIV/AIDS: Bad news for drug prices in middle-income countries." (20 July 2011). UNOCHA.

eligible for funding (or entitled to apply for lesser grant amount under more restrictive conditions, i.e. requirement for a counterpart financing) from multilateral institutions, such as the Global Fund. According to the New Funding Model criteria, income status is one of many criteria used to determine resources that will be available. Countries, such as India with public sector spending for HIV control already under strain will need to make tough decisions on who and how many to treat and with which medications. Moreover, expanding access to include treatment for diseases such as HCV will pose a serious challenge. Unless there are overall price reductions on all essential medicines, there will continue to be treatment gaps in access that can potentially widen.

The global commitment is to have 15 million people living with HIV on treatment by 2015⁵², based on WHO's current recommendation that treatment be initiated earlier at 500 CD4 cells/mm³.⁵³ The number of PLHIV eligible for treatment under the new guidelines is 26 million.⁵⁴

Multilateral institutions are already preparing to address how best to scale-up treatment access. UNAIDS and WHO, in addition to their own respective strategies, have developed several strategic frameworks to sustain and catalyze the next phase of HIV treatment. The Strategic Investment Framework⁵⁵ and Treatment 2.0⁵⁶ examine efficiency gains and innovation to help countries reach universal access to treatment. UNAIDS *Getting to Zero Strategy*⁵⁷ – Zero new infections, Zero AIDS-related deaths, and Zero discrimination—underscores the need to sustain and push forward on the progress in treatment access achieved over the last decade. While these strategies speak broadly on the need for increasing access through reducing costs, it is ultimately the responsibility of governments to decide on efficiencies in the system including allocation of resources that must be guided by rights-based principles.

Absent in these strategies is how to confront the challenge of pricing by originator companies for ARVs that are unaffordable and discriminate against people living with HIV, particularly key populations in MICs. Recognising this growing gap in the global response to HIV, in June 2013, UNITAID, WHO, UNAIDS, the MPP, and the Brazilian government convened a meeting on access to HIV medicines in middle-income countries. The meeting sought to examine the access barriers being faced by MICs by examining the role of (1) markets and prices; (2) intellectual property; (3) regulatory concerns; (4) voluntary licencing and (5) R&D and local production. Civil society played a crucial role during the consultation, challenging key policies of their own governments and those of international institutions that create barriers to ensuring universal access.

52. United Nations General Assembly Resolution 65/277. Political Declaration on HIV and AIDS: Intensifying our efforts on eliminating HIV and AIDS. (8 July 2011). United Nations. Paragraph 66 commits governments to have 15 of the 18 million in need of treatment on ARVs by 2015.

53. World Health Organization. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Recommendations for a Public Health Approach. WHO. June 2013. Geneva.

54. World Health Organization. 15 facts on HIV treatment scale-up and new WHO ARV guidelines 2013. WHO. 2013. Geneva.

55. Schwartländer B, Stover J, Hallett T, et al. "Towards an improved investment approach for an effective response to HIV/AIDS." *The Lancet*. (11 June 2011). 337(9782):2031-2041.

56. Hirschall G and Schwartländer B. "Treatment 2.0: Catalyzing the next phase of scale-up." *The Lancet*. (16 July 2011). 378(9787):209-211.

57. UNAIDS. *Getting to Zero. 2011-2015*. UNAIDS. (2011). Geneva. Available at: www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2010/jc2034_unaids_strategy_en.pdf

From this consultation, it is clear the important role civil society in MICs will play in the coming years to gain greater access to affordable HIV and other medicines. As the populations most greatly impacted by the HIV epidemic, key populations and their networks must continue mobilizing and engaging even more on these debates around access issues. HIV treatment advocates through their community therefore have an opportunity to lead the movement on access to essential medicines.

People living with HIV support *Positive, Health, Dignity and Prevention*, a framework that focuses on the holistic health promotion and related needs of people living with HIV, which also emphasizes the need for access to affordable medicines to treat non-HIV related chronic diseases as part of the continuum of care.⁵⁸ This provides an opportunity to integrate HIV access strategies into broader health care demand for affordable medicines. Obstacles to accessing affordable essential medicines are multi-faceted and complex, and first require an agreement that health is a fundamental human right and illness is not an opportunity for profiteering. This basic understanding then allows challenges to the current innovation model that takes from public and private resources, but then through patent protection allows excessive private profits. People living with HIV, key populations and those working on treatment access are going to have to globally mobilize and re-invigorate the solidarity that existed in 2000 to deal with this challenge of debunking this model and ensuring universal access to treatment.

58. GNP+ and UNAIDS. Positive Health, Dignity and Prevention, a policy framework. Available at: www.gnpplus.net/images/stories/PHDP/GNP_PHDP_ENG_V4ia_2.pdf



People who inject drugs and access to hepatitis C treatment

Hepatitis C virus (HCV) affects an estimated 150–185 million persons globally. In communities where sharing of needles is common, it is a significant cause of disease burden. Amongst those who are also living with HIV, HCV co-infection results in more rapid progression of liver disease and mortality. But HCV is a treatable and curable disease. Access to treatment is limited because of the high costs of pegylated interferon, which is patent protected and produced through a biological process. Average treatment costs can run into thousands of dollars ranging from \$15,000 to \$20,000. In Vietnam, a 48-week course of treatment with a combination of ribavirin and pegylated interferon (Peg-IFN) can cost US \$28,000. There is a lack of political commitment to treating the disease. In India, although community groups have been successful in having the patent in pegylated interferon alpha-2a, regulatory concerns with bio-similars appear to be preventing the widespread acceptance of generic versions of this medicine. Ensuring access to affordable PEG-IFN therefore requires work on both the intellectual property and regulatory fronts.

The high price in comparison to the prices of ARVs, makes treatment for HCV unaffordable and those with co-infection are left vulnerable to disease and death. In 2013, civil society mobilized requesting for the inclusion of Peg-IFN on the WHO Essential Medicines List.⁵⁹ Given the gravity of the HCV epidemic, and its substantial overlap with HIV, it is urgent that treatment for HCV is available to all those in need at reasonable prices. Inclusion of PEG-IFN on the WHO Model List of Essential Medicine would allow countries, particularly in low- and middle-income settings, to conduct price negotiations, reduce costs, address intellectual property barriers, ensure technology transfer for generic production, raise awareness, and ultimately increase access to HCV treatment. Eventually, PEG-IFN was added to the complementary list of the 18th Essential Medicines List announced in July 2013, instead of the cost list due to concerns from the Expert Committee about the “high level of expertise and specialized facilities needed for safe and effective use of interferon, as well as its high cost.”

Source: Treatment Action Group, Support inclusion of pegylated interferon on the WHO Essential Medicines List available at: www.treatmentactiongroup.org/hcv/pegifn-who-eml-support-letter

59. The WHO Essential Medicines list is updated every two years. The 17th Edition was released in 2011, and the next edition is aimed for 2013. There is an application process available online for submission of new drugs to be considered by the WHO Expert Committee on the selection and use of medicines. Available at: www.who.int/selection_medicines/committees/expert/18/en/index.html

SECTION 4

POLICY RECOMMENDATIONS

Access to treatment for a whole range of illnesses, infectious and non-communicable diseases, has made survival possible. Wealthy countries with comprehensive health insurance coverage consider expensive medicines as an acceptable part of health care. But for the vast majority PLHIV and members of key populations in the MICs, medicines are unaffordable and economic costs of illness are high for the individual, the family, community, and country. The challenge, for all countries including for MICs, is securing treatment that is financially sustainable particularly in the case of HIV, a chronic disease requiring life-long access to newer and efficacious medicines.



- **Middle-income country governments** must develop/amend national patent laws in order to protect and promote the right to health and guarantee access to affordable essential medicines, by adopting the full range of TRIPS flexibilities including:
 - > high patentability criteria – patents should only be granted for real and meaningful innovation and not for evergreening;
 - > explicit language allowing for the use of compulsory licenses and parallel imports;
 - > the opportunity for the public, generic manufacturers, and civil society to challenge patents through pre- and post-grant patent opposition provisions.
- **Middle-income country governments** will need to effectively regulate all pharmaceutical companies (both originator and generic), which includes a judiciary properly trained on the balance between intellectual property and human rights, better trained and equipped drug regulatory authorities, patent offices trained in the public health oriented examination of patents, and access to information on medicines and producers for civil society.
- **Middle-income country governments** must reject, from the outset, any provisions in all trade-agreements that in anyway impact affordable access to essential medicines, including TRIPS-plus provisions and investment protection provisions.
- **Middle-income country governments** must guarantee access to safe, effective and affordable generic medicines, including developing manufacturing capacity when possible, by broadly and boldly using the TRIPS flexibilities.



- **Pharmaceutical companies** should also be held responsible as part of the human rights framework. They must recognize that the right to health is an ethical imperative and not an economic equation – solely pursuing profits at the expense of those who require access to essential life-saving medicines is morally wrong. Pharmaceutical companies should not undermine government’s attempts at protecting the right to health of their citizens.
- **Pharmaceutical companies** must acknowledge and accept that innovation emerges from the use of public funds and as such long patent terms and extending these protections through minor alterations are unethical. They should be transparent in their research and development costs when it comes to essential life-saving medicines.
- **Pharmaceutical companies** should consider a low, flat rate of return on essential life-saving medicines, agree to shorter patent terms of less than 20 years, and openly transfer knowledge.



- **International agencies and donors** must play an active role in facilitating coordinated action at the global, regional and country level and continue to support governments in implementing strategies that have been developed for increasing access to ART. This includes the establishment of inclusive country coordinating platforms, support to review, strengthening and alignment of legal frameworks particularly as they relate to intellectual property, developing common procurement policies and research agendas, and stimulating economic partnerships for improving local production capacity, among others.
- **International agencies and donors** should support governments in using TRIPS flexibilities, along with community activists advocating for exclusion of TRIPS-plus and investment provisions in free trade agreements.
- **International agencies and donors** must support rights-based claims for treatment by members of key populations particularly those residing in middle-income countries.
- **International agencies and donors** should intensify efforts to protect gains in access to ARVs, encourage and facilitate access to optimized treatment, maintain global commitment and financial resources to reaching universal access goals.



- **High-income governments** should immediately remove TRIPS-plus and investment provisions from FTAs and other trade agreements immediately, and they should desist from retaliating against governments that use TRIPS flexibilities and oppose TRIP-plus measures on treatment access.



- **People living with HIV, key populations and their allies** must continue to lead the fight for the realization of their right to health, including working for broader access to affordable medicines, including ARVs and other co-infections.
- **People living with HIV, key populations and their allies** must hold their governments accountable to recognize their duties to take a human rights approach to all trade-related issues dealing with access to essential medicines.
- **People living with HIV, key populations and their allies** must hold international agencies and donors accountable to guarantee access to affordable essential medicines within a human rights framework.
- **People living with HIV, key populations and their allies** must mobilize and coordinate their advocacy efforts, because only by working in collaboration and as part of a broader coalition can everyone's health and human rights be achieved, including overcoming structural barriers faced by key populations when trying to access health services and access to affordable essential medicines for all.

Acknowledgement and dedication

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Secondary authors are Attapon Ed Ngoksin of GNP+, Noah Metheny of MSMGF, Othoman Mellouk of ITPC and Kajal Bhardwaj, a New Delhi-based independent lawyer working on health and human rights.

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* The views and opinions presented are solely those of the author, and do not necessarily represent those of the organizations. Although all organizations have reviewed and commented on earlier drafts. Any mistakes are solely the responsibility of the author.