

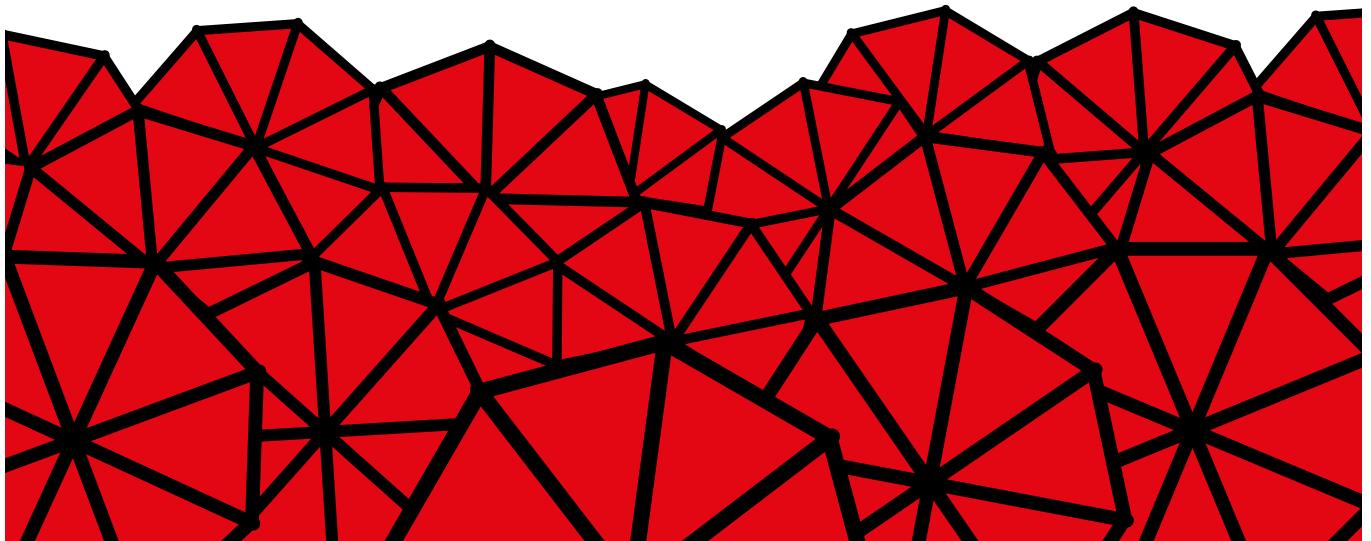


Global Network of Sex Work Projects
Promoting Health and Human Rights

**BRIEFING
PAPER**

**#05 An Overview of
Access to Medicines**

**'DON'T TRADE
OUR LIVES AWAY!'**



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In July 2012, sex workers from all over the world gathered at the 'Sex Worker Freedom Festival: The Alternative IAC2012 Event for Sex Workers and Allies' in Kolkata, India. During the festival, a space was created for and by positive sex workers who came together and discussed the additional needs and demands of being a sex worker living with HIV. These workshops were the beginning of NSWP+, a platform for positive sex workers and others committed to equal rights for sex workers living with HIV¹. One of the initial advocacy priorities identified by NSWP+ was treatment access and joining the campaign against trade-related restrictions and patents used by large pharmaceutical companies to make huge profits from essential medicines. Sex

workers identified the need for accessible information on the trade frameworks that impact upon access to medicines for people living with HIV. This paper provides an overview of those trade frameworks and is designed specifically for sex workers and groups who wish to have a basic background in these issues in order to join the global campaign for access to medicines. These trade frameworks impact significantly on both the availability and affordability of treatment for many long-term, chronic conditions, including cancer and HIV/AIDS. This paper lays out the basics of trade-related matters and outlines how they potentially result in the lack of affordable and accessible medicines² for people living with HIV. The impact of these trade rules has the potential to be devastating, and although sex workers already share a feeling of being 'last in line for treatment' sex workers wish to be included in the fight against trade-related barriers to universal access to health care.

1 <http://www.nswp.org/nswp-plus>

2 For the purpose of this paper, 'access to medicines' and 'access to treatment' include medications, vaccines, diagnostics and other medical products

Sex workers living with HIV

The links between sex work and HIV have been recognised since the earliest days of the epidemic, with recent studies revealing that female sex workers in some countries are 10–18 times more likely to be living with HIV compared to the general population of women of reproductive age³. Male and transgender sex workers are also disproportionately affected by HIV, however, epidemiological data and research are less widely available than those for female sex workers due to the inclusion of male and trans sex workers in other population groups such as men who have sex with men (MSM). Sex workers of all genders experience significant difficulties in accessing HIV prevention and treatment. Factors that limit

access range from everyday realities for sex workers such as human rights violations, police brutality, arrest and detention, and stigma from healthcare professionals, to structural barriers including policy and laws that criminalise sex workers in various ways. All of these factors limit sex workers' access to antiretroviral medicines (ARVs) and other types of care required by HIV+ sex workers, including affordable diagnostics.

The Right to Health and Access to Medicines

In terms of human rights, health and related access to medicines are areas that have been heavily debated and discussed. Fundamentally, the rights to health and access to medicines are realisable rights under the International Covenant on Economic, Social and Cultural Rights (ICESCR), meaning that these rights are not immediate but are to be progressively achieved through allocation of resources and administrative policy planning, rather than by enforcement through the human rights courts. Although access to medical care in section 25 of the Universal

Declaration on Human Rights (UDHR) is often interpreted to position health as a human right, this has been the subject of much discussion and debate.

Outside human rights frameworks, other global commitments have been made and accepted by national governments. For example, published in 1978, the Alma-Ata Declaration on Health for All was the first international declaration that underlined the fundamental importance of primary health care. The declaration expressed the need for

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urgent action by all governments, health and development organisations and workers, and the world community, to protect and promote the right to health for all, and has since been accepted by member countries of the World Health Organization (WHO). In 1977, the WHO launched its first 'Model List of Essential Medicines', which was accepted as one of eight fundamental components of primary health care and set a social goal of the highest possible level of health. 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. Access to essential medicines is also one of the five indicators

³ Baral, S., Beyerer, C., Muessig, K., Poteat, T., Wirtz, AL., Decker MR., 'Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis'. *Lancet Infect Dis* 2012, 12: 538–549

identified by the UN High Commissioner for Human Rights when measuring the progress of realising the right to attaining the highest standard of health. Since 2001 the United Nations General Assembly has demonstrated that they are committed to ensuring access to affordable treatment as part of its political commitment to halting and reversing the HIV epidemic and mitigating its impact. In 2011, all 193 governments of the UN committed to a target of 15 million people living with HIV on ARVs by 2015, and recognised the critical importance of affordable medicines in increasing access. The need to promote and protect access to medicines for the purposes of health care for all has therefore gained global commitment, partly as a result of the HIV epidemic and the global desire to lessen its impact.

However, despite this global commitment, many factors continue to limit treatment access for HIV-positive populations. People living with HIV (PLHIV) in low and middle-income countries experience barriers to accessing treatment and these barriers are known to be heightened amongst key affected populations (KAPs) all over the world, including sex workers (SW), people who use drugs (PUD), and men who have sex with men (MSM). The UN Millennium Project (2005) has identified six categories of barriers to access: inadequate national commitment, inadequate human resources, failure of the international community to keep its promises to developing countries, lack of coordination of international aid, obstacles created by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), and the failure of the current incentive structure for research and development

(R&D) to address priority health needs of developing countries. This paper will now focus on two of the main barriers to accessing medicines for people living with HIV, including the obstacles created by the WTO and the related aspects of Intellectual Property Rights, and the barriers created by the rules on patents which become more harmful when governments lack the political will to protect, respect, and fulfil the human right to health and access to medicines.

The World Trade Organization (WTO) and related aspects of Intellectual Property Rights

Intellectual property describes the protection given to any creation of the mind; for example, a song, a poem, or an invention. When these creations are recognised to have commercial value they can become protected by law for a certain amount of time, which means the creator or the person who holds the 'intellectual property right' can stop others from using or copying it without permission or payment. Intellectual Property Rights (IPR) refers to the rights given to the creators/inventors of a product that is seen to have scientific and/or creative value. There are three categories of intellectual property: copyright, trademarks, and patents. A song or poem would be protected by copyright while the intellectual property rights concerning medicines are patents and trademarks.

The World Trade Organization was set up in 1994 as the international body to regulate trade between countries. Before the WTO was set up, medicines were not widely patented in developing countries, allowing local pharmaceutical manufacturers to develop generic versions of drugs. Generic medicines are identical copies of the original product/medicine but are much less expensive to produce. However with the formation of the WTO, any country that wanted to participate in global trade also had to sign the Agreement on Trade-Related Intellectual

Property Rights (TRIPS). TRIPS requires WTO member countries to give a patent for a minimum of 20 years to all medical produce and products. It also requires the protection of 'originator data' against unfair commercial use, which means that local manufacturers cannot copy the medicines to distribute at a lower price. Countries who are members of the WTO are classified as developed, developing, or least-developed countries (LDCs),

and depending on which category they fall into, a country will have different obligations upon entering the WTO. For example, developing countries were given a period of time to become compliant with TRIPS and all of these countries must now enforce intellectual property standards expected by the rules of the WTO. Countries classified by the UN as Least-Developed Countries (LDCs) and who are WTO members originally had until 2016 to enforce patents on pharmaceutical products, but as a result of civil society and community protest they have secured an extension to comply with TRIPS by 2021.

While those who defend TRIPS argue that this system is set up to encourage scientific innovation, the reality is that this system has led to what is referred to as a 'monopoly of patents' that protects the interests and huge profits of pharmaceutical companies in developed countries at the expense of access to essential medicines by people in developing

countries. While pharmaceutical companies try to defend this monopoly and their resulting profits as necessary for research and development (R&D), studies have shown that actually the biggest expenditure of these companies is on marketing, advertising, and promoting: this does little to encourage innovation and more to encourage profits.

Originator companies (pharmaceutical companies in developed countries) have further abused their power in the patent monopoly by modifying medicines slightly (but with no extra value to health) and then applying for a new patent on the product. This gives the drug an extra 20 years of protection from being copied by generic drug companies and this process is known as

'evergreening'. For example, 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 developed in the 1960s. Overall, these practices have led to less innovation and less health impact and to an increasingly more expensive drug. Consequently, this situation has led to community protests calling for a tighter evaluation system for patents⁴ to prevent evergreening.

⁴ For an example of community protest against evergreening see: <http://www.nswp.org/nswp-plus/topic/tac-msf-memorandum-dti-urgently-fix-the-patent-laws>

The WTO's rules around intellectual property that profits the big pharmaceutical companies advanced at a time when HIV/AIDS was becoming globally recognised as a pandemic. For example, 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 brought the issue of access to affordable ARVs to the international forum. This protest and campaign was highlighted at the 2000 International AIDS Conference in Durban and then through a legal brief filed on behalf of communities in South Africa for treatment access.⁵ 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 with HIV. By 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, allowing India to become known as 'the pharmacy of the world'. This huge coverage for PLHIV on medicines due to the availability of

generics made it clear that the cost of patented medicines was in direct conflict with the universal human right to health.

Before 2005, countries (mainly India) that manufactured and supplied generic drugs were not TRIPS compliant and as a result over 9 million PLHIV now have access to ARVs. However, India is now TRIPS compliant and is required to grant patents on newer medicines, meaning that it is unlikely that Indian companies will be able to manufacture and export new generic ARVs. Global commitments to further scaling-up treatment, and initiating earlier treatment, means that millions more people are eligible to start treatment. Many PLHIV who have been on generic first-line/first-generation ARVs for nearly 10 years, now require access to second-line or third-line ARVs. The price of medicines and associated barriers are only going to increase unless patent monopolies are reformed or governments scale-up their commitment to ensuring access to affordable generic medicines.

TRIPS Flexibilities

When the WTO was formed, the TRIPS Agreement allowed for certain 'flexibilities' that permit developing and least-developed countries to ensure that becoming TRIPS compliant did not negatively impact on access to medicines. Compulsory licensing (CL), parallel importation, and Bolar provisions are forms of flexibilities that were included to protect access to treatment. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. Parallel importation refers to when a government allows a generic version of a drug to be imported into their country without the permission of the patent owner/person who holds the intellectual property right. Bolar provisions allow manufacturers of generic drugs to use the patented invention to get market approval (for example from public health authorities) without the patent owner's

⁵ 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.

permission and before the patent expires. These provisions ensure that once the patent term expires, the generic manufacturer can then quickly market their own cheaper versions and avoid the timely process of awaiting market approval.

The importance of using this approach to ensure access to essential medicines was reaffirmed in November 2001 when all WTO members met in Doha to discuss the potentially dangerous impact of TRIPS. During this meeting, all WTO member countries signed up to what is known as the 'Doha Declaration on the TRIPS Agreement and Public Health', which 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.

This declaration represented an unprecedented political commitment by WTO members and reaffirmed the higher status of the human right to health than that of intellectual property rights.

When used, these TRIPS flexibilities have seen some countries taking measures that significantly protect the right to access medicines for PLHIV. The simplest flexibility is a CL where governments allow the manufacture, use, or sale of a medicine, without the consent of the patent owner, for distribution within that country and sometimes for export to other developing and least-developed countries. Since 1995 there have only been a small number of CLs issued in 17 countries mostly involving medicines for HIV. Examples include Thailand, China, and recently Indonesia who, in an unprecedented move, issued CLs on seven ARVs and one Hepatitis B medicine. The main reason that these flexibilities are often not used is that countries that have issued CLs, especially those that have the capacity to manufacture generic drugs in their own countries, have faced a backlash from wealthy governments. This backlash has included real or threatened trade sanctions, where wealthy countries will refuse to trade with the developing countries. This puts extreme pressure on governments to limit their use of TRIPS flexibilities.

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Communities have played a critical role in ensuring that governments do not dismiss human rights to health in their attempts to become TRIPS compliant, by encouraging either the use of TRIPS flexibilities or campaigning for the protection of public health safeguards in national policy. In India, Thailand, and Brazil for example, civil society groups and networks of PLHIV, including key affected populations, have successfully opposed patents and patent applications on key medicines including ARVs. For example, a crucial health safeguard included in India's patent law that restricts evergreening patents (Section 3d) has been under attack by multinational companies and developed countries, namely the huge Swiss multinational company Novartis. However, following a global campaign mobilised to support Indian groups in maintaining this safeguard, the Indian Supreme Court upheld a strong interpretation of the policy

to prevent patents being granted for 'evergreened' products in April 2013. This was a landmark victory and activists remain hopeful that it will act as an example to other governments because it demonstrated that national policy should be upheld and strengthened to restrict the process of evergreening as a way to ensure governments' commitment to public health.

Free Trade Agreements

Bilateral and regional free trade agreements (FTAs) and economic partnership agreements (EPAs) also present huge threats to access to medicines. These agreements can be negotiated by countries signed up to the WTO and have been used by developed countries to pressure developing countries to better protect intellectual property rights, often at the expense of public health measures. These agreements have become known as 'TRIPS-plus' as they extend trade-related intellectual property measures even further, having an extremely dangerous impact on access to medicines. For example, FTAs and EPAs generally include measures to extend patent terms beyond the twenty-year minimum required by TRIPS. They also often limit the use of CLs, and restrict the use of clinical trial data used to approve original medicines so that this data cannot be applied to generic copies of the medicine (because acquiring clinical data and gaining subsequent

approval takes a long time and is extremely expensive, this process substantially limits the production and distribution of generic drugs). There is significant evidence that essential medicines are much more expensive in countries that have signed TRIPS-plus agreements: the main developed countries that are pushing for these agreements are the USA and the European Union.

The USA is involved in negotiations with multiple developing countries around the development of a large Trans-Pacific Partnership Agreement (TPPA). Although much of these negotiations are taking place in secret, leaked documents have shown that aggressive intellectual property measures are being enforced in the agreement, including preventing countries from restricting evergreening and limiting the use of CLs.

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The EU is also negotiating an EPA with key middle-income countries including India, Thailand, Indonesia, and the Philippines, amongst others. These countries have the capacity to produce generic drugs and the agreement includes damaging measures to limit the production of generics in these countries. Developed countries are in a much more privileged position when negotiating FTAs because countries in the South often comply in order to improve their economy by strengthening good trade relations with developed countries.

Governments that push for stronger IP measures in trade agreements often claim that it is in the interest of patients, as a means to protect them from generic medicines that are below standard and potentially dangerous. Using this argument, a handful of high-income countries, led by the USA, designed the Anti-Counterfeiting Trade Agreement (ACTA), which has led to the seizure of generic medicines at some International borders.

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Although the ACTA does not explicitly allow for the seizure of legitimate generic medicines, ambiguity in the agreement means that this has happened, restricting access of essential medicines to those in need. Eight countries are currently signed up to this agreement including Australia, Canada, Japan, Morocco, New Zealand, Singapore, and the USA. Activists mobilised globally to successfully defeat the ratification of ACTA in the European Parliament in 2012. Advocates for access to medicines have urged governments to resist adopting anti-counterfeit legislation and instead put efforts into

strengthening their drug regulatory authorities (DRA). These authorities can be tasked with ensuring the quality of generics and building trust amongst patients to show that generics are not of a lesser quality than patented original drugs. This is much more effective at a national level than adopting anti-counterfeit legislation that restricts the production and transportation of essential generic medicines.

Where we are now

Local organising, community activism, and global protest have pushed for an unparalleled global commitment to improving access to treatment for all people living with HIV. This commitment, alongside the increased availability of generic drugs, has led to a huge increase in coverage of ARVs for PLHIV, rising from less than one million in 2003 to 9.7 million at the end of 2012. Large-scale community advocacy has challenged the trade rules in the WTO that restrict access to ARVs and local organising

has continued to pressure governments to use TRIPS flexibilities to make sure that rights to health are not compromised by intellectual property rights. However, barriers to accessing medicines remain and high costs still pose huge challenges. The WHO's preferred option of a single pill fixed-dose combination of Tenofovir/

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Emtricitabine/Efavirenz (TDF/FTC/EFV) is extremely expensive when produced by originator companies, priced at \$613 per person per year for low-income countries and \$1,033 per person per year for lower middle-income countries. The generic version is available at a much cheaper price at around \$100 per person per year. 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 will soon need access to newer and more potent ARVs, and unless prices are lowered it will be difficult to scale-up treatment programmes: unless patent barriers can be overcome and generic manufacturers are allowed to continue making and distributing generic medicines, the cost of treatment will remain an issue.

The global commitment is to have 15 million people living with HIV on treatment by 2015⁶, based on WHO's current recommendation that treatment be initiated earlier at 500 CD4 cells/mm³.⁷ Consequently, the number of PLHIV eligible for treatment under the new guidelines is 26 million⁸. However, pricing barriers mean that even where governments are politically committed to achieving access to medicines, these commitments may not be enough to ensure access to treatment for all PLHIV. Political commitments by governments may be reduced if

they are pushed to sign bilateral and multilateral free trade agreements. Even where these measures are resisted, the high prices charged by pharmaceutical companies for patented medicines mean that governments and local health practitioners may ultimately be forced to make decisions on whom to prioritise for treatment.

Sex workers, alongside other key affected populations, must therefore make their voices heard in the campaigns for treatment access and for universal access to medicines, and continue to campaign against being 'last in line for treatment'.

Sex workers, alongside other key affected populations, must therefore make their voices heard in the campaigns for treatment access and for universal access to medicines, and continue to campaign against being 'last in line for treatment'. Mainstream civil society and other community groups must also recognise that stigma towards key affected populations often still occurs in community-led forums and spaces. Wider communities of PLHIV and treatment activists must work to ensure that space is given to the voices, needs, and rights of key affected populations. This includes a sharing of information with sex workers, drug users, and men who have sex with men, and making sure that this information is continually accessible. Furthermore, treatment activist movements can work with networks of key affected populations to ensure a strengthening of all communities of people living with HIV, whilst respecting the additional structural barriers of criminalisation and extreme stigma that KAP's face in their daily lives. Together, treatment activists, SW, PUD, and MSM, must ensure that within the climate of trade-related barriers and high pricing for patented medicines, governments take every possible measure to realise the right of every person to health. We must also work together to continue to challenge the monopoly of patents which makes pharmaceutical companies huge profits while restricting peoples' access to essential medicines. As sex workers at the 'Sex Worker Freedom Festival' articulated, 'we will not stay silent while they trade away our lives!'

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

7 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.

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