



UNAIDS PROGRAMME COORDINATING BOARD

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THIRTY-FIFTH MEETING

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Venue: Executive Board room, WHO, Geneva

Agenda item 1.4

Report by the NGO representative

When 'Rights' cause wrongs: Addressing Intellectual Property barriers to ensure access to treatment for all people living with HIV

Additional documents for this item: none

Action required at this meeting - The Programme Coordinating Board is invited to:

See decisions in paragraphs below:

66. Recall the decisions from previous UNAIDS Programme Coordinating Board meetings¹ and relevant paragraphs from Resolution 65/277 of the UN General Assembly - the Political Declaration on HIV and AIDS: Intensifying our Efforts to Eliminate HIV and AIDS, July 2011 on the importance of supporting low and middle-income countries to scale-up access to essential medicines by implementing the flexibilities contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and consistent with the World Trade Organization Declaration on TRIPS and Public Health (the Doha Declaration).²

67. *Request* UNAIDS to: conduct an analysis of the impact of current Intellectual Property frameworks – including TRIPS plus provisions in Free Trade Agreements - on the availability, affordability and accessibility of treatment and diagnostics for HIV and co-infections in low and middle-income countries; discuss the results of the analysis through a broad consultation process involving people living with HIV and key populations; and present the recommendations from this process at the 37th PCB meeting.

68. *Request* UNAIDS to strengthen existing and develop relevant outcome and output indicators³ in the Unified Budget, Results and Accountability Framework (UBRAF) that measure access to and availability of affordable HIV-related commodities, in order to provide more explicit reporting on progress toward overcoming Intellectual Property-related barriers to treatment access.

69. *Urge* the Joint Programme to intensify technical support to the Governments of low-and middle-income countries aimed to address IP-related barriers to availability, affordability and accessibility of up-to-date treatment and diagnostics of HIV and co-infections through the implementation of TRIPS flexibilities and to review and revise national patent laws and legislation framework in order to address availability and accessibility of up-to-date treatment and diagnostics of HIV and co-infections.

70. *Urge* UNAIDS- consistent with the recommendations of civil society in various global and regional forums and the Global Commission on HIV and The Law (Chapter 6)⁴- to advance dialogue and convene a meeting with the World Trade Organization and relevant actors on developing a more sustainable mechanism to ensure the availability, affordability and accessibility of treatment and diagnostics for HIV and co-infections in low and middle-income countries and the results of such dialogue to be available for consideration and action at the planned 2016 General Assembly High Level Meeting on AIDS.

71. *Request* UNAIDS to report to the PCB meeting no later than July 2016 on the progress of the implementation of these decision points.

¹14th PCB meeting (agenda item 1.4, decision point 12), 15th PCB meeting (agenda item 1.4, decision point 5.3), 18th PCB meeting (agenda item 2, decision point 7.15) and 19th PCB meeting (agenda item 1.3, decision point 3.8); 1.5, decision points 5.4 and 6.1.vii from the 30th PCB meeting which refer to paragraphs 35, 36, 71 (including sub-paragraphs a, b and c) and 72 from Resolution 65/277 of the UN GA

²See Annex 2 for full text of paragraphs.

³ Current indicators are B1.2 and B 1.2.1 and these may serve as a basis for the development of such new indicators

⁴See Annex 3 for full text of recommendations.

EXECUTIVE SUMMARY

1. Today, there are 35 million people living with HIV in low and middle-income countries, of whom 12.9 million are receiving antiretroviral therapy (ART). This is a remarkable scale-up in the provision of life-saving antiretroviral (ARVs) medicines. However, despite rhetoric that no one should be left behind, there remains a major and unacceptable 'treatment gap'. The 2014 NGO Report – based on consultations with communities and a comprehensive desk review - is *When 'Rights' cause wrongs: Addressing Intellectual Property barriers to ensure access to treatment for all people living with HIV*. It focuses on both the *persistent* and *emerging* challenges in this area, showing how the goal of achieving 90% treatment coverage by 2020⁵ is being sacrificed - by governments and pharmaceutical companies – for the sake of patents, profits and trade agreements.
2. **Almost half of eligible people living with HIV still lack access to ART, while demand for second and third-line ARVs and treatment for co-infections is increasing:** In 2013, the World Health Organization (WHO) revised its HIV treatment guidelines. This increased the number of people living with HIV eligible for ART (to 28.6 million); and decreased the already low level of treatment coverage (to 42%). To close the treatment gap – scaling-up to more than *double* the number currently reached - the affordability of ARVs is as crucial as ever. As treatment for people living with HIV is life-long, long-term survival depends on continuous access to newer and quality-assured ARVs, including more robust first-line drug regimens with fewer side effects. As HIV is constantly mutating, resistance develops. As such, access to second and third-line ARVs also needs to be secured and sustained. In addition, people living with HIV not only need access to ART, but treatment for other illnesses, notably HIV co-infections such as Hepatitis C and drug resistant tuberculosis.
3. **Patents continue to have a dramatic, life-threatening impact on access to medicines:** The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) set minimum standards for the protection of Intellectual Property Rights (IPRs), including for medicines. Patents give pharmaceutical companies exclusive rights to market their products and set their price for an (often long) period of time. This permits them to have monopolies and to exclude or delay competition for at least 20 years, including from companies that make lower-cost generic drugs. In 2001, to mitigate the negative impact of IPRs, the WTO adopted the Declaration on TRIPS and Public Health (known as the Doha Declaration). This affirmed that TRIPS "*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*". It reiterated the availability of 'TRIPS flexibilities' – such as parallel importing⁶ and compulsory licenses⁷ - which give low and middle-income countries the option to access cheaper and quality-assured generic medicines. In practice, however, due to pressures and biased technical assistance from developed countries and international organizations, few such countries have incorporated these flexibilities into their national Intellectual Property (IP) laws. Similarly, while

⁵ *90 90 90: An Ambitious Treatment Target To Help End The Aids Epidemic*, UNAIDS, 2014.

⁶ 'Parallel importation' allows countries to import a patented medicine from other countries where it is produced and sold by the patent holder or an authorized party at a lower price than in the domestic market.

⁷ 'Compulsory licensing' allows governments to issue compulsory licenses for the manufacture, sale and import of a patented product without the consent of the patent holder. Countries are free to determine the grounds on which a license should be issued, while the royalty to be paid is negotiated between the country and patent holder.

competition law⁸ is largely used in developed countries to balance monopolies, its use remains either weak or absent from legal structures in most developing countries.

4. **Generic competition is a key driver for ARV price reduction:** The response to HIV has demonstrated that increasing the use of quality-assured generic medicines through competition is a key strategy for reducing prices and therefore improving the affordability and accessibility of medicines. This was made possible because most first-line ARVs were not patented in many developing countries, including India (which has become the leading global producer of generic ARVs). Moreover, some developing countries successfully used TRIPS flexibilities and benefited from lower prices for ARVs. As a result, significant price reductions were achieved. However, such reductions are less likely to happen for newer ARVs, as well as treatment for HIV co-infections - due to the stricter frameworks now in place to protect IPRs.
5. **TRIPS+ provisions worsen access to ART and undermine countries' ability to make full use of TRIPS flexibilities:**⁹Multilateral organizations and civil society advocates have consistently urged governments to make use of TRIPS flexibilities. However, most developing countries, especially those in Africa, have failed to amend their national legislation. This has provoked civil society campaigns for the reform of IP laws and systems in countries such as South Africa and Uganda. The situation is exacerbated by on-going negotiation of stricter IPRs through bilateral and regional agreements, such as those involving the European Union and the United States.¹⁰ Several low- and middle-income countries have signed or are negotiating Free Trade Agreement (FTAs) with developed countries. These include 'TRIPS+' provisions – stricter protections of IPRs that go beyond those required by the WTO. Examples include: the extension of patent terms; the granting of patents on new uses or formulations of existing medicines; and data exclusivity¹¹. These limit developing countries' ability to use TRIPS flexibilities. Numerous studies indicate that TRIPS+ provisions increase the price of medicines or delay price reductions – as they restrict generic competition.
6. **Middle-income countries face a specific set of challenges in access to medicines:** In the post-2015 era, attention should be given to 'pharma-emerging countries' – those with high burdens of disease, and classified as middle-income (and, therefore, not prioritized by development partners). Such countries are paying exorbitant prices for most ARVs and many are not benefitting from HIV drug access programs provided by originator companies. ARV prices are being negotiated on a case-by-case basis, resulting in higher costs.
7. **Industry-driven pricing strategies create a double standard for pricing and do not bring long-lasting price reductions:** Recent initiatives to address the affordability of medicines have mostly centered on industry-driven tiered pricing strategies¹² and voluntary licenses,¹³ rather than proven strategies to promote robust generic competition. In addition,

⁸ 'Competition law' refers to law that promotes or seeks to maintain market competition by regulating anti-competitive conduct by companies.

⁹ *Risks, Rights and Health*. Report of the Global Commission on HIV and the Law, UNDP, New York, 2012.

¹⁰ The potential impact of Free Trade Agreements on public health, UNAIDS, UNDP, Geneva, 2012.

¹¹ 'Data exclusivity' refers to where the original data for a medicine is not allowed to be used and the new entrant has to repeat all of the clinical trials (which takes more time and money).

¹² 'Tiered pricing' refers to where pharmaceutical companies set different prices for different countries, depending on factors such as a country's Gross Domestic Product or World Bank income tier.

¹³ 'Voluntary licensing' refers to a patent holder granting an exclusive or non-exclusive license to other producers to manufacture, import and/or distribute a medicine with whatever negotiated restrictions.

voluntary strategies offered by originator companies to lower prices are insufficient and often limited in scale – often excluding middle-income countries where pharmaceutical companies seek higher profit margins. Voluntary licenses are now more often used by multinational pharmaceutical companies to manage competition or create monopolies. These licenses can also undermine a country's negotiation power and ability to use TRIPS flexibilities to secure treatment for their populations. Analyses of tiered pricing conclude that it does not result in the lowest sustainable prices or price reductions over time. More importantly, it gives too little decision-making power to governments.

8. **Global stakeholders have recognized IP as a barrier to access to medicines, but little political action has been taken:** Public health agencies, academics and civil society have increasingly recognized that there are fundamental flaws in the design and application of the current IP frameworks. Also, analyses have found that there is no evidence that implementing TRIPS in developing countries has increased the research and development of drugs or the transfer of technology - as insufficient market incentives are the decisive factor.¹⁴ The claims that IPRs are essential to foreign direct investment, local innovation and economic development are false.¹⁵ Moreover, TRIPS flexibilities are perceived as repairs to a system that is based on protecting patents, rather than providing structural solutions to meet the needs of the poor¹⁶. Despite the best efforts of civil society, it has been difficult to 'de-technify' and re-politicize the debate around IP – taking it *out* of the hands of international lawyers and pharmaceutical companies and *into* the hands of developing country governments, social movements and affected communities.
9. **Recent years have seen the agreement of non-binding global and regional initiatives to uphold the spirit of the Doha Declaration:** Examples include the extensive IP-related recommendations of the Global Commission on HIV and the Law, such as that the UN Secretary General should convene a neutral, high-level body to review proposals and recommend a new IP regime for pharmaceutical products that is more consistent with human rights obligations¹⁷ (see Annex 3 of this Report). Yet, in practice, such commitments have largely been unfulfilled. There is now an urgent need to both: maximize the use of TRIPS flexibilities within the current IP framework; and identify ways to solve the persistent and emerging challenges within that system. Ideas to explore include: a global moratorium on including IP provisions in any agreement that could limit a country's ability to reduce the cost of HIV-related treatment; and moving away from the current patent-based system to one that, for example, has innovation prize funds and open source drug discovery.
10. **Civil society is a driving force for change:** For civil society, the issues raised in this report are crucial – for the simple reason that they have a life or death impact on community members. As shown by multiple case studies in the report, the sector is at the heart of the drive for access to medicines. This includes by: advocating for the reform of national patent laws and regulatory systems; lobbying governments to make full use of TRIPS flexibilities; monitoring the impact of FTA negotiations; and taking legal action against harmful patents. This is despite significant challenges facing the sector, including limited access to government decision-making platforms on drug pricing and a lack of means to demand

¹⁴ *Commission on Intellectual Property, Innovation and Public Health*, WHO, April 2006

¹⁵ *Debunking IP for Development: Africa Needs IP Space, Not IP Shackle*, B. Baker.

¹⁶ *Lancet Framing Paper*, Lilongwe, UNAIDS, 2013

¹⁷ Recommendations from Chapter 6 of *Intellectual Property Law and the Global Fight for Treatment in Global Commission on HIV and the Law: Risks, Rights and Health*, Global Commission on HIV and the Law, July 2012.

accountability from pharmaceutical companies. Activists, advocates and coalitions have demonstrated how local actions and global solidarity can produce concrete change.

11. **UNAIDS has a critical role and unique mandate to continue to act:** UNAIDS, as the unique public health Joint Programme, is strategically placed to support countries to overcome IP-related barriers and ensure access to ART for all people living with HIV who need it. Relevant decision points from previous Programme Coordinating Board meetings should be recalled and acted upon, while the additional six decision points in this Report should be agreed. Through leadership, UNAIDS can play its full role in ensuring that the world meets its targets for access to treatment and no one is left behind.

INTRODUCTION – FOCUS AND METHODOLOGY OF THE REPORT

12. The **NGO Delegation** brings the unique, first-hand experiences and perspectives of people living with HIV and key populations to the UNAIDS Programme Coordinating Board. Each year, it presents an NGO report - focused on a critical, emerging issue for affected communities and informed by the Delegation's constituencies.
13. The **2014 NGO report** is entitled *When 'Rights' cause wrongs: Addressing Intellectual Property barriers to ensure access to treatment for all people living with HIV*. It articulates the concerns of the people most directly affected by the high cost of HIV-related treatment (namely people living with HIV), as well as of other civil society advocates campaigning on the trade-related barriers to essential medicines. The report aims to raise awareness among the Programme Coordinating Board of the views of affected communities on major –and, at times, controversial- issues related to IP and patent systems/laws and their impact on access to life-saving drugs in both low- and middle-income countries. It also recommends how UNAIDS can strengthen its leadership in this area – ensuring that, as access to treatment continues to be scaled-up, it reaches all people living with HIV who need it.
14. The 2014 NGO report is informed by **consultations** conducted by members of the NGO Delegation in June - September 2014. Organizations and networks of people living with HIV, key populations, AIDS service organizations and human rights advocates were targeted in the elaboration of this report. Virtual interviews and face-to-face meetings, involving a total of 50 stakeholders (39 interviews and 11 consultation participants) from 29 countries were undertaken. Quotations from participants are included in the following pages. The report is also informed by a **literature review** of relevant resources from civil society, Government and United Nations (UN) organizations.
15. Acknowledgements and abbreviations for the 2014 NGO report are provided in Annex 1.

RE-CAP: WHAT IS THE STATUS OF ACCESS TO TREATMENT AND WHERE ARE THE GAPS?

“Access to treatment is still an issue”

16. All people living with HIV have the right to health and the right to life. No one should be left behind in access to treatment.

17. People living with HIV consistently identify access to treatment as the single most **important issue**.¹⁸ Coupled with the public health benefits of reduced transmission, antiretroviral therapy (ART) is, arguably, the single most important tool to end the HIV epidemic.
18. By the end of 2013, there were an estimated 35 million people living with HIV worldwide, with 12.9 million receiving ART¹⁹. This represents a remarkable **scale-up** in access to life-saving treatment. Nearly all of those in developing countries are on generic,²⁰ first-line²¹ ARVs— drugs that are now old and no longer protected by patents.²²
19. However, this overall progress masks **significant variations** between and within regions and populations. In 2013, while ART coverage was 37% in Sub-Saharan Africa, it was just 11% in the Middle East and North Africa. The persistent failure to expand access to treatment has contributed to poor progress in reducing AIDS-related deaths in Central Asia, Eastern Europe, the Middle East and some Asian countries.²³

“Access to treatment among key populations living with HIV is still lagging behind”

20. As highlighted in the 2013 NGO report²⁴ **key populations** living with HIV experience grossly inequitable access to ART. This reflects the social and political marginalization of communities such as men who have sex with men, people who inject drugs, sex workers and transgender people – who lack access to resources, services and involvement in decision-making. Such a scenario not only violates human rights, but undermines national responses to HIV (as, in many contexts, key populations represent a major proportion of new infections).
21. In 2013, the World Health Organization (WHO) revised its treatment guidelines to recommend the earlier initiation of ART when a person’s CD4 cell count is equal or below 500 cell/mm³.²⁵ This increased the number of people living with HIV **eligible for treatment** and widened the existing treatment gap. According to the new guidelines, as of December 2013, only 37% of all people living with HIV were receiving ART.²⁶ To further scale-up – doubling the numbers reached - the affordability of ARVs is a critical concern.

¹⁸ *People living with HIV Call to Action! Global Advocacy Agenda*, GNP+, 2012.

¹⁹ *The Gap Report*, UNAIDS, 2014.

²⁰ ‘Generic’ refers to drugs that are comparable to brand-name drugs in dosage form, strength, quality, performance and intended use. They are manufactured without a license from the innovator company.

²¹ ‘First-line’ refers to the standard treatment that is given to someone for a particular disease or condition.

²² ‘Patent’ refers to the right to prevent people other than the patent holder from making, using, selling, offering to sell or importing an invention for a limited period of time. It can be granted to the creator of a product or a process.

²³ *Ambitious Treatment Targets: Writing The Final Chapter of the AIDS Epidemic*, UNAIDS, 2014

²⁴ *The Equity Deficit: Unequal and Unfair Access to HIV Treatment, Care and Support for Key Affected Communities*, Agenda Item 1.4: Report by the NGO Delegation to the PCB, 33rd PCB Meeting, 2013.

²⁵ *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection*, WHO, 2013.

²⁶ *Ambitious Treatment Targets: Writing the Final Chapter of the AIDS Epidemic*, UNAIDS, 2014.

Box 1: Why addressing trade barriers to treatment matters

“In India, HIV positive people have been successful in fighting against patents. This has been possible because of the joint effort with lawyers and other activists. HIV Positive networks like ours have a great role to play in protecting health in this commercialized health setup. We have to get the government to issue compulsory licenses if the multinational companies (MNCs) get patents for second line and third line regimes. This is not only going to affect positive persons but also other patients groups and that is why we have to oppose and protest against the medicines getting patented by MNCs. Other networks should also educate themselves and oppose patents and other IPR related issues.” - Kousalya, PWN+

“Demands for newer, better first-line, second and third-line ARVs, as well as treatment for co-infections, are rapidly increasing”

22. Each year, some 3% of people living with HIV on first-line ARVs switch to second-line drugs.²⁷ **Resistance** to or failure of an HIV regimen arises due to poor adherence or mutation of the virus. The real figure of regimen failure may be far higher, but without regular viral load testing, which is not available or affordable in most contexts in developing countries, such resistance goes unnoticed. More recent drugs have a better record against resistance, as well as more manageable long-term side effects.
23. Treatment for people living with HIV is a life-long commitment. Their survival depends on continuous access to newer, more effective, less toxic and easier-to-administer ARVs. Access to affordable **second- and third-line** regimens needs to be secured. Such products are generally under patent and cost 2 to 17 times more than generic first-line regimens.²⁸ There is still insufficient evidence to be sure how many will need second and third line regimens in the future, however recent studies suggest that 23% of adults are likely to develop virologic failure after 12 months of ART.²⁹

“Addressing the health needs of people living with HIV requires more than just ARVs”

24. Treatment for people living with HIV goes beyond ART. They also require affordable and high quality treatment for other illnesses, including **co-infections** such as Hepatitis C (HCV) and drug-resistant tuberculosis. In addition, as people living with HIV live longer, they need access to medicines to manage non-HIV related chronic diseases – such as certain cancers and type 2 diabetes³⁰ - which may appear at an earlier age or with higher incidence than in the general public.
25. **HCV** is now a curable infection. Yet it kills over 350,000 people each year. Globally, 5-20% of people living with HIV are co-infected with HCV or the Hepatitis B virus. People who use drugs report that untreated HCV makes living with HIV much harder and taking ART more complicated. Direct-acting agent (DAA) combination therapy³¹ will greatly simplify HCV

²⁷ Report on WHO/UNAIDS Meeting on Forecasting ARV Needs up to 2010: Draft, WHO, 2006.

²⁸ TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, T'Hoën E, 2003.

²⁹ Treatment Outcomes of Patients on Second-Line Antiretroviral Therapy in Resource-Limited Settings: A Systematic Review and Meta-Analysis, Ajose et al, Journal of AIDS, 2012 May 15;26(8):929-38.

³⁰ Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries, MSMGF, ITPC, GNP+, NSWP and INPUD, 2013.

³¹ 'Direct-acting agent' refers to ARVs that selectively target HCV and can, therefore, be highly effective.

treatment and offer unprecedented help to people with co-infection. Being cured of HCV reduces liver cancer, HIV- and all cause-related morbidity and mortality, maximizing the survival benefits from ART.

“Additional challenges are faced by those living with HIV in middle-income countries.”

26. The challenges of access to HIV treatment in low-income countries (LICs) are immense and well documented. However, in the post-2015 era, there is also growing concern for the ‘pharma-emerging countries’³² – those with high burdens of disease with **middle-income status**. These face reduced/removed support from bilateral donors and may not be eligible (or may face *more* restrictions for *smaller* amounts) for multilateral institutions, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). Without *overall* price reductions for essential medicines, such countries – including those with epidemics concentrated among key populations - will experience shortfalls in HIV treatment that could, over time, widen significantly.³³
27. Addressing the **treatment gap** requires all stakeholders in low- and middle-income countries to intensify action on HIV at a time of reduced resources for national responses and competing development priorities. The 2014 NGO Report argues why addressing trade-related barriers (IP frameworks and laws) is critical to such action and how it can contribute to ensuring available, affordable and accessible treatment for all people living with HIV.

EXISTING COMMITMENTS: WHAT DECISION POINTS HAS THE PCB ALREADY MADE?

28. In previous meetings, the Programme Coordinating Board has recommended that Member States and the UNAIDS Secretariat work in partnership with relevant stakeholders to secure access to treatment, including by addressing the trade-related barriers described in this report. Examples of **decision points** include that the Programme Coordinating Board:

“Urges Member States of the World Trade Organization to promote access to treatment in developing countries consistent with the World Trade Organization Declaration on TRIPS and Public Health (Doha Declaration).” (Agenda item 1.4, decision point 12, 14th PCB, 2003),

“Encourages UNAIDS leadership to promote the implementation of the Doha Declaration on TRIPS and Public Health³⁴ as well as supporting countries to utilize the flexibilities permitted by the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in their internal regulations”. (Agenda item 1.4, decision point 5.3, 15th PCB, 2004).

³²Pharma-emerging countries are those with high burdens of disease, and classified as middle-income (and, therefore, not prioritized by development partners). Such countries are paying exorbitant prices for most ARVs and many are not benefitting from HIV drug access programs provided by originator companies. ARV prices are being negotiated on a case-by-case basis, resulting in higher costs.

³³*Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries*, MSMGF, ITPC, GNP+, NSWP and INPUD, 2013.

³⁴ The Doha Declaration was signed at the 4th Ministerial Conference of the WTO in 2001. It reaffirmed members’ commitment that: *“the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health... the (TRIPS) 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.”*

“Include in the framework³⁵..... proposals on how to help enable developing countries to employ the flexibilities outlined in the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights and to strengthen their capacities for this purpose”. (Agenda item 2, decision point 7.15, 18thPCB, 2006).

“Recognizes the high cost of second and third line anti-retroviral drugs as a barrier to treatment access and reaffirms the decision of the 18th Programme Coordinating Board meeting and the Political Declaration of the United Nations High Level Meeting on the use by developing countries of flexibilities outlined in the World Trade Organization’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and strengthen their capacity for this purpose”. (Agenda item 1.3, decision point 3.8, 19thPCB, 2006).

“Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care, including by amending national laws and regulations, as deemed appropriate by respective Governments.” (Agenda item 2, decision point 6.1.vii, 30thPCB, 2012).

*“Improve civil society capacity to advocate for efficient, culturally-sensitive and effective responses to HIV and AIDS in alignment with the 2011 Political Declaration and to build knowledge focused on HIV funding mobilization and mobilizing to address barriers to the AIDS response, especially in the field of prevention, treatment, care and support in particular those addressed in paragraph 71 of the 2011 Political Declaration”.*³⁶ (Agenda item 1.5, decision point 5.4, 30thPCB, 2012).

29. The Programme Coordinating Board’s recommendations reflect those of key UNAIDS initiatives. The **Lancet Commission: Defeating AIDS - Advancing Global Health** highlighted three major concerns on trade, innovation and commodity security³⁷. **Treatment 2015** recommended eligible countries to *“maximize appropriate use of TRIPS flexibilities to lower treatment costs”* and all partners to *“play their part to preserve and expand affordable generic antiretroviral medicine”*³⁸. UNDP’s **Global Commission on HIV and the Law** provided comprehensive recommendations on IP law³⁹ (see Annex 3 for full text).

ON-GOING CHALLENGES: PERSISTENT ISSUES AND BOTTLENECKS IN INTELLECTUAL PROPERTY AND ACCESS TO TREATMENT

The critical role of generic drugs

³⁵ Refers to a 2007-2010 framework for UNAIDS support to countries’ efforts to implement the 2001 Declaration of Commitment on HIV/AIDS and the 2006 Political Declaration on HIV/AIDS.

³⁶ See Annex 2 for full text of paragraph 71.

³⁷i) Inefficiency and capacity prevent the full use of TRIPS flexibilities and result in reliance on one producer country (India) while causing a failure to develop capacity in others; ii) Pharma-emergency countries are not prioritized by development partners, cannot access tiered pricing from industry and are not eligible for TRIPS waivers; and iii) Low standards of patentability have permitted the patenting of too many ‘me-too’ drugs (presenting barriers to drugs entering the market). *UNAIDS and Lancet Commission Address Strategic Challenges for the Future of AIDS and Global Health*, UNAIDS, July 2013.

³⁸ *Treatment 2015*, UNAIDS, 2012.

³⁹ Recommendations from Chapter 6 of *Intellectual Property Law and the Global Fight for Treatment in Global Commission on HIV and the Law: Risks, Rights and Health*, Global Commission on HIV and the Law, July 2012.

“Generic competition is a key driver for sustainable ARV price reduction.”

30. In the past decade, the production of **generic ARVs**– and increased competition in the market - has led to progressive price reductions, contributing to the scale-up of access to treatment. The lowest price for WHO-recommended first-line regimens decreased from over US\$ 10,000 per person per year in 2000 to US\$ 140 in 2014.⁴⁰ This was made possible because most first-line ARVs were not patented in most developing countries, including India (now the leading global producer of generic ARVs). Also, some developing countries exploited patent flexibilities⁴¹ in the international trade rules and the expiry of patents. This is why a large number of first-line ARVs are affordable today.
31. At the same time, activists, concerned about the difference in mortality faced by people living with HIV in developed and developing countries, identified linkages between IPRs, WHO and HIV treatment. WHO developed a Revised Drug Strategy, which built on the concept of **essential drugs** and recommended countries to implement domestic policies to support the use of generic, rather than patented medicines.

The provisions of the Doha Declaration and TRIPS

“The tightened IPR framework reduces affordability of newer ARVs and other essential medicines.”

32. The World Trade Organization (WTO) was established in 1995 and, as of June 2014, has 160 members. Within WTO, the Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) **agreement** sets up a common minimum standard for the protection of IPRs, including the granting of patents on pharmaceutical products. Since then, both access to medicine and the safeguarding of public health have remained issues within WTO negotiations - with NGOs, least developed countries and low- and middle-income countries pressing for IPR exemptions. The Doha Declaration was adopted by WTO member states in 2001. The **declaration** specifies that the TRIPS 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*”.
33. In the **post-TRIPS era**, with the strengthening of IP protection frameworks in most developing countries, the significant price reductions seen for first-line ARVs are unlikely to occur for the newer medicines to treat HIV, co-infections and co-morbidities (which are covered by patents). An example is seen in Morocco – a lower middle-income country with an HIV epidemic concentrated among key populations. Here, first-line ARV regimens mostly comprise of older, unpatented medicines and cost the government around US\$240 per person per year. Yet second-line regimens cost an average of US\$478. Only 20 people are currently on third-line regimens, which cost about US\$20,400. The high price is due to the absence of generic drugs as a result of patent monopolies.⁴²

⁴⁰ *Untangling the Web of Antiretroviral Price Reductions*, 17th Edition, MSF, July 2014.

⁴¹ ‘Patent flexibilities’ refers to patent laws that provide better protection for public health, but are still consistent with WTO and TRIPS.

⁴² *Missing the Target Report 10. Communities and the Treatment 2.0 Initiative: Delivering on the Next Treatment Scale-Up*, ITPC, 2012.

The importance of TRIPS flexibilities

“So far, only a few countries have been able to make the full use of TRIPS flexibilities.”

34. The TRIPS agreement allows for a number of flexibilities to balance the impact of IP rights and public interest. Among these, **compulsory licensing**⁴³ remains critical – and a key tool for reducing the price of medicines. Few developing countries have issued such licenses and lowered the price of ARVs and other drugs. Among examples, in Ecuador, the IP Office granted a compulsory license for the ARV combination lopinavir/ritonavir.⁴⁴ This immediately reduced the cost of a major Government purchase of HIV drugs by 27%, with an over 50% reduction predicted. Such licenses issued by the Government enable the production or import of generic versions of second-line drugs.
35. As a further example, in **Indonesia**, the Government issued a decree in 2012 that overrode the patents on seven HIV and Hepatitis drugs, opening the way for cheaper generic versions.⁴⁵ This renewed a previous compulsory license issued in 2007 on Sustiva (efavirenz) ARV produced by Merck and Company (USA), while adding six more drugs to the list. Also, pre-existing compulsory licenses remained for the ARV Viramune (nevirapine) produced by Boehringer-Ingelheim (Germany) and for the HIV and Hepatitis B treatment lamivudine developed by Shire Pharmaceutical (United Kingdom). These licenses can be granted by the Ministry of Health to pharmaceutical companies to exploit patents on behalf of the Government. They are effective until the end of the term of each patent, with a 0.5% royalty paid to the patent holder.
36. TRIPS also provides for **exceptions to patent rights**.⁴⁶ An example is the Bolar exemption – which allows for the research and experimental use of products that are still under patent (enabling generic versions of drugs to enter the market more quickly after the patents have expired). This has been used in, among other countries, the Philippines -within the Universally Accessible Cheaper and Quality Medicines Act (2008).⁴⁷ The Act also provides for **parallel importation**⁴⁸ - a further TRIPS flexibility which allows a country to import patented products at the lowest price once they have been placed by the patent holder on the market anywhere in the world.
37. **Competition law**⁴⁹ - a further TRIPS flexibility - has also proven an important tool, although it is yet to be systematically used by the majority of developing countries.

⁴³ ‘Compulsory licensing’ allows governments to, in effect, break patents and issue compulsory licenses that allow the manufacture, sale and import of a patented product without the consent of the patent holder. Under TRIPS, countries are free to determine themselves the grounds on which a compulsory license should be issued, while the royalty to be paid is negotiated between the country and the patent holder.

⁴⁴ *By Authorizing Generic Competition, Ecuador Cuts Cost of Key HIV/AIDS Drug*, Press Release, Apr. 22, Public Citizen, 2010.

⁴⁵ Public Citizen. <http://www.citizen.org/PC-statement-on-compulsory-licensing-in-Indonesia>

⁴⁶ TRIPS allows States to establish limited exceptions to the exclusive rights of a patent owner, as long as they do not unreasonably prejudice his or her ownership rights.

⁴⁷ *Summary of Country Mapping Exercise: Expanding Access to ARV Drugs*, UNDP.

⁴⁸ ‘Parallel importation’ allows countries to import a patented medicine from other countries where it is produced and sold by the patent holder or an authorized party at a lower price than in the domestic market. This can happen without the permission of the patent owner.

⁴⁹ ‘Competition law’ refers to law that promotes or seeks to maintain market competition by regulating anti-competitive conduct by companies.

Community action case study 1: Promoting competition law, South Africa⁵⁰

In South Africa, treatment activists successfully used competition law to increase the number of ARV suppliers - resulting in greater competition and reduced prices for essential medicines. In a court case, the Competition Commission of South Africa found two pharmaceutical companies guilty of excessive pricing and referred the matter to the Competition Tribunal. Before a decision was made by the Tribunal, both companies entered into agreements with the Commission and the complainants, allowing for the increased supply of more affordable generic versions of ARVs still under patent within the country.

38. In reality, however - despite the provisions within TRIPS and the consistent calls of civil society and UN agencies – many low- and middle income countries have been **slow and reluctant** to use the flexibilities available to them, in the face of threatened trade retaliations from developed countries and their industries⁵¹. The USA's use of Special 301⁵² is an example where countries deemed to be non-compliant with IPRs are threatened with direct trade sanctions. This creates a scenario whereby countries, for fearing of losing export markets, are unwilling to use measures such as compulsory licenses to enable generic drug manufacturers to meet local needs.⁵³
39. According to a study by the World Intellectual Property Organization (WIPO) on the inclusion of TRIPS flexibilities in **national patent legislation**, over half (56%) of the 95 relevant countries had integrated the Bolar exemption. However, while almost all of the high-income countries had done so, none of the least developed countries had been able to fully incorporate the flexibility. With parallel importation, out of the 112 relevant countries, just 29 allowed international and regional imports, 36 allowed imports only from other countries in the region and 42 totally prohibited imports.⁵⁴

TRIPS+, Free Trade Agreements and the impact on public health

“Bilateral and Free Trade Agreements, negotiated in absolute secrecy, often contain TRIPS+ provisions and undermine countries’ ability to make full use of TRIPS flexibilities.”

40. Many countries have signed, or are currently negotiating, **trade agreements**. Examples include Bilateral Investment Treaties (BITs), Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs). These have extensive implications for the protection of pharmaceutical patents and can directly impact on access to medicines, including for HIV. For example, some developed countries have established FTAs that reflect their standard of (and interests for) IP protection. These are usually negotiated with little transparency or

⁵⁰ See Avafia, T et al (2006), *The Ability of Select Sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries*, Tralac Working Paper No 12; WIPO, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, CDIP/5/4. (2010).

⁵¹ *Cultural, Political, and Social Implications of Intellectual Property Laws in an Informational Economy*, Coombe Rosemary J. and Joseph F. Turcotte in Culture, Civilization and Human Society, 2012.

⁵² ‘Special 301’ refers to an annual process by the Office of the U.S. Trade Representative to assess the adequacy and effectiveness of IP rights protection by USA trading partners.

⁵³ *Cultural, Political, and Social Implications of Intellectual Property Laws in an Informational Economy*, Coombe Rosemary J. and Joseph F. Turcotte in Culture, Civilization and Human Society, 2012.

⁵⁴ *Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels*, WIPO, 2010.

participation from the public and often establish **TRIPS+ provisions**.⁵⁵ The latter undermine the flexibilities and safeguards that developing countries sought to preserve under TRIPS.

41. In recent years, **FTA** negotiations have been used to restrict flexibilities to promote the quality of patents. For example, the USA-Morocco and USA-South Korea FTAs forbid the dispute of patents before they are granted (known as pre-grant opposition).⁵⁶ Negotiations can also limit the grounds on which countries can grant compulsory licenses.

Community action case study 2: Leading pre and post-grant patent opposition for LPV/r, Viet Nam

The Viet Nam Network of People Living with HIV has filed the first ever pre and post-grant oppositions on Lopinavir/ritonavir (LPV/r), a key second-line HIV drug. The post-grant opposition has been filed against the first approved LPV/r application, for which the patent expires in 2014. The pre-grant opposition has been filed against the second LPV/r application, which is currently pending, but, if approved, would be likely to expire in 2026.

Community action case study 3: Preventing patent monopoly for TDF, Brazil⁵⁷

In Brazil, the pharmaceutical company Gilead filed a patent application for the ARV Tenofovir (TDF). In 2003, while the patent was being examined by the Brazilian Patent Office, the lack of competition in the market allowed Gilead to charge US\$ 3,300 per person per year for the drug. In 2006, the Working Group on Intellectual Property from the Brazilian Network for the Integration of Peoples – a coalition of NGOs - used a pre-grant opposition to prevent the patent from being granted and to encourage competition (and a reduced price for the drug). In August 2008, the Patent Office rejected Gilead's application on the grounds that it lacked inventiveness. The Government has since announced the start of local production of TDF through a partnership between public and private manufacturers.

Community action case study 4: Filing pre-grant opposition on Sofosbuvir, India

In India, civil society - using the flexibilities provided in the country's patent law - filed a pre-grant opposition on Sofosbuvir, the first of several direct acting agents (DAAs) against HCV. The aim was to challenge the application before the patent was granted since the drug, which in reality is a modification of an old known substance, doesn't meet the Indian patentability criteria. Networks of people living with HCV, community-based organizations, legal aid groups and treatment providers are campaigning to secure access to Sofosbuvir at an affordable level (US\$ 500 per person per year) that is based on the actual cost of production:⁵⁸ filing multiple oppositions:

On November 25, 2013, the Initiative for Medicines, Access & Knowledge (I-MAK) filed a patent opposition to sofosbuvir (an HCV DAA) with the Kolkata Patent Office in India. The opposition contends that sofosbuvir, despite its real therapeutic value for people with HCV, does not

⁵⁵ 'TRIPS+ provisions' refers to clauses introduced to Free Trade and other bilateral Agreements – for example by originator pharmaceutical companies - that go beyond those required by the WTO. Examples of TRIPS+ include: 'evergreening'; data exclusivity; new enforcement mechanisms for IPRs; and patent linkage.

⁵⁶ FTA between U.S. and Republic of Korea, Article 18.8 § 4, p. 18-17; and FTA between U.S. and Morocco, Article 15.9(5).

⁵⁷ Patent opposition database accessible at: http://patentoppositions.org/case_studies/4f106d0504a7f92f5b000003

⁵⁸ *Minimum Costs to Produce Hepatitis C Direct-Acting Antivirals*, Andrew Hill et al, American Association for the Study of Liver Disease, November 2013.

represent a “novelty” as defined by national patent laws in some countries, including the Indian patent act, and thus should not be granted a patent.

In March 2014, the Delhi Network of Positive People (DNP+) and Initiative for Medicines, Access and Knowledge (I-MAK) targeted Gilead’s patent application 6087/DELNP/2005 (WO2005/003147). This was based on three grounds (novelty, inventive step and efficacy) and urged that the application should be rejected as the standards required for a patent were not met.⁵⁹

In September 2014, the Lawyers Collective - through Sankalp Rehabilitation Trust, the Hepatitis Coalition of Nagaland and Asia Pacific Network of People Living with HIV - filed a pre-grant opposition to sofosbuvir on patent application 3658/kolnp/2009. This is awaiting examination by the Controller of Patents in Kolkata.⁶⁰

“Key global health and developmental institutions (UNAIDS, UNDP, WHO) and funding mechanisms on HIV (UNITAID, the Global Fund), have warned of the devastating impact of TRIPS+ provisions in Free Trade Agreements for all forms on access to medicines”⁶¹

42. Multiple studies demonstrate that TRIPS+ standards contained or proposed in FTAs increase the **price of medicines** – as they delay or restrict generic competition. In his 2009 report to the UN General Assembly,⁶² Anand Grover, then UN Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health highlighted that the purpose of TRIPS+ provisions in FTAs largely relates to harmful steps, such as the introduction of data exclusivity⁶³ and extension of patent terms.⁶⁴
43. A joint policy brief by UNAIDS Secretariat, UNDP and WHO - Using the TRIPS Flexibilities to Improve Access to Treatment – articulated concerns about the **detrimental effects** that TRIPS+ measures in FTAs can have on access to HIV medicines.⁶⁵ It reiterated the call in WHO’s Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,⁶⁶ for countries to *“take into account... the impact on public health when considering adopting or implementing more extensive intellectual property protection than required by the TRIPS Agreement”*.
44. In its 2011 Market Shaping Strategy, the Global Fund expressed concern about the potential impact of the proposed **European Union (EU)-India FTA** on the prices of and access to HIV

⁵⁹ *The Ground for Opposing Patent Applications on Sofosbuvir: Briefing Document*, I-MAK, March 2014.

⁶⁰ *Civil Society Opposes Patent on Sofosbuvir*, Lawyers Collective, 23 September 2014.

⁶¹ Such as... 2006 report of the WHO Commission on Intellectual Property, Innovation and Public Health; the 2008 WHO Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health; the report of the Global Commission on HIV and the Law (HIV and the Law: Risks, Rights and Health

⁶² *Promotion And Protection Of All Human Rights, Civil, Political, Economic, Social And Cultural Rights, Including The Right To Development* Report of the Special Rapporteur on the Right Of Everyone To The Enjoyment Of The Highest Attainable Standard Of Physical And Mental Health, Anand Grover, UN Human Rights Council, March 2009.

⁶³ ‘Data exclusivity’ refers to where the original data for a medicine is not allowed to be used and the new entrant has to repeat all of the clinical trials (which takes more time and money).

⁶⁴ *Using the TRIPS Flexibilities to Improve Access to Treatment*, UNAIDS, UNDP and WHO,

⁶⁵ *Using TRIPS Flexibilities To Improve Access To HIV Treatment – Policy Brief*, WHO, UNAIDS and UNDP, 2011.

⁶⁶ *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, 61st World Health Assembly. 24 May 2008.

treatment.⁶⁷ It emphasized that countries should use TRIPS flexibilities to achieve the lowest possible price for products of assured quality. To retain the benefits of TRIPS flexibilities, countries should, at a minimum, avoid entering into FTAs that contain TRIPS+ obligations that impact on the price or availability of pharmaceuticals. Where countries have undertaken obligations, all efforts should be made to mitigate their negative impact on access to treatment - by using, to the fullest extent possible, remaining public health-related flexibilities.

45. In 2014, UNITAID commissioned a study – based on proposals by the USA - to identify provisions in proposed **Trans-Pacific Partnership Agreement (TPP)** that are likely to have implications for public health and access to pharmaceutical products.⁶⁸ This concluded that TRIPS+ provisions on IP are being negotiated within the TPP and that there are serious concerns that the proposed provisions (related to the financing and/or reimbursement of medicines, as well as to investment) will have adverse effects on access to medicines and the protection of public health. The study also highlighted the secrecy under which TPP negotiations have been conducted.

Community case study 1: Opposing a Free Trade Agreement with the USA, South Africa⁶⁹

In early 2000, the USA engaged in free trade negotiations with various developing countries and regional trading blocs. Among these were South Africa and its Southern African Customs Union partners, commonly referred to as the BNLS countries (Botswana, Namibia, Lesotho and Swaziland). Shortly after the negotiations started, civil society groups began organizing against the potential FTA. The main concern was that elements proposed by the USA would be detrimental to the development aspirations of the countries, while also putting public health, food security and service delivery at risk. For example, the USA sought extensive IPRs, which would constrain the region's ability to provide medical care to its people. Eventually, the negotiators failed to reach consensus on the contested issues and the talks collapsed.

Community case study 2: Campaigning against a Free Trade Agreement with the EU, India⁷⁰

In 2007, the EU began secret talks with India on a potential FTA. When the Delhi Network of People Living with HIV, International Treatment Preparedness Coalition (ITPC) South Asia and others learned of the talks, they began asking questions about the terms of the agreement. They were rebuffed. As a result, they formed a coalition of civil society groups that would be affected by the FTA – including those focused on health, agriculture, environment and trade unions – and began organizing public protests. In March 2009, as a result of their first protest, the coalition was granted a meeting with the Indian government's negotiators. As the talks continued, the coalition maintained public pressure through additional protests (some of which involved police abuse and detention), media actions and letters to Government officials. Activists also publicly presented 5ml of blood to Carla Bruni (the French first lady then and an Ambassador for the Global Fund) to symbolize the deaths that would occur under an FTA that would protect IP over people's health. The protests spread to other parts of Asia, Africa and Latin America – regions that would also be affected if India was no longer able to produce and

⁶⁷ *Report Of The Market Dynamics And Commodities Ad-Hoc Committee*, the Global Fund to Fight AIDS, Tuberculosis and Malaria, May 2011,

⁶⁸ *The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health*, UNITAID, 2014.

⁶⁹ *The Failed SACU-USA Free Trade Agreement in Hindsight: A Lost Opportunity or Disaster Averted?* Palollo Michael Lehloeny, *Journal of International Commercial Law and Technology*, Vol. 4, Issue 2 (2009)

⁷⁰ Don't trade our lives away campaign, DNP+, Source <https://donttradeourlivesaway.wordpress.com/tag/dnp/>

export generic drugs. The Indian government began to make public statements that it would not trade away IPRs.

EMERGING CHALLENGES: EVOLVING TRADE BARRIERS TO ACCESS TO TREATMENT

Specific challenges for second and third-line ARVs

“Needs for second and third-line ARVs are increasing – so are the prices. The battle for accessibility continues across the world.”

46. As a result of patent protections, **second and third-line ARVs** are expensive. People living with HIV who have been on first-line treatment for a decade or longer require continuous access to newer and more effective ARVs. Unless prices are lowered, it will be difficult to scale-up treatment programs. Middle-income countries are often already paying high prices for most ARVs. Meanwhile, originator companies are no longer offering standardized price discounts, including for medicines purchased under programs funded by the Global Fund.⁷¹
47. According to a report by ITPC, in the 15 countries addressed, only 24% of people living with HIV indicate that WHO-recommended **second-line regimens** are available for those in need.⁷² While several developing countries, especially low- and middle-income countries, are able to access a second-line regimen for less than US\$ 500 per patient per year, a range of countries - such as Argentina, Brazil, China, Indonesia, Kazakhstan, Mexico, and Ukraine - continue to pay exorbitant prices for second and third-line ARVs. An example is provided in relation to the cost of sourcing LPV/r (a key component of the WHO-preferred regimen for second line therapy) from the originator companies. In all of the countries, secondary patents on LPV/r have been granted or are pending – which prevent the purchase of generic versions. For LPV/r alone, Argentina and Mexico pay US\$ 2,570 and US\$ 2,511 (respectively) per person per year. This is 12 times the price paid in South Africa (US\$ 204).⁷³
48. Currently, there are no pre-qualified **generic versions** of darunavir (DRV), raltegravir (RAL) or etravirine (ETV). This makes it extremely difficult, if not impossible, even for those countries where patents have not been granted, to procure generic versions of these ARVs. While, in principle, local production would be an option, in practice, the patents granted in China and India on the respective active pharmaceutical ingredients prevent the export of such raw materials in countries with capacity to produce locally.
49. RAL is just one of the drugs needed in a multi-drug **salvage regimen**⁷⁴ (third-line treatment). Yet, for this, Argentina pays US\$8,986 per person per year, Peru US\$5,643, Thailand US\$4,676 and South Africa US\$617.⁷⁵ In India, the main export country of generic ARVs, patents on RAL will not expire before 2022. The lack of generic competition is a barrier to

⁷¹ *Access Challenges for HIV Treatment among People Living With HIV and Key Populations in Middle-Income Countries*, MSMGF, ITPC, GNP+, NSWP and INPUD, 2013.

⁷² *Global Policy, Local Disconnects*, ITPC, 2014

⁷³ *Untangling the Web Of Antiretroviral Price Reduction*, MSF, July 2014.

⁷⁴ ‘Salvage regimen’ refers to drugs provided to a patient who has very few treatment options available, for example because they have become more and more resistant to more common regimens.

⁷⁵ *Untangling the Web of Antiretroviral Price Reduction*, MSF, July 2014.

scaling-up the use of such regimens, despite the fact that the medical need for them is expanding.

Weak content and technical support for national IP laws

“Technical support on IP provided by bilateral and multilateral agencies aren’t addressing public health needs from developing countries”.

50. Consultations for the 2014 NGO report found concern that notions of IPRs are unsuitable for a global agenda. Different nations have different needs and levels of development (such as in terms of their industries). A **‘one size fits all’** approach to IPR is both untenable and unjust.

51. In reality, while TRIPS flexibilities are *available*, very few low or middle-income countries have fully incorporated them into their **national IP laws**. This is particularly the case in Africa – provoking civil society campaigns in countries such as Uganda and South Africa (see case study below) to change legislation. This scenario is, largely, due to trade pressure – such as from the European Union and USA – for bilateral agreements. It is also due to biased technical assistance from developed countries and other international institutions. Similarly, while competition law is largely used in developed countries to balance monopolies, its use remains either weak or absent from legal and institutional structures in the majority of developing and least developed countries.⁷⁶

Community action case study 5: Campaigning for reform of patent law, South Africa

In South Africa, a very large number of patents are granted for pharmaceutical products. For example, 2,442 medicine patents were granted in 2008 alone (compared to in Brazil, 273 for the whole of 2003-2008). One of the reasons for this excess is that such patents are granted without examination to determine if they meet the country’s standard for what it is possible to patent. In response, Treatment Action Group and Médecins Sans Frontières led a Fix the Patent Law campaign. This mobilized a broad range of community groups to demand that the South African Government improve the national patent laws and to call for the reform of the 1978 Patents Act 57.

Strategies that exploit patent rights

“Originator companies exploit patent regimes to make exorbitant profits.”

52. In some countries, national IP laws fail to prevent originator companies from exploiting patent rights by using strategies such as **evergreening**.⁷⁷ Such practices limit the potential for generic companies to gain a significant market share in low and middle-income countries, while originator companies maintain comparable sales numbers and avoid a decline in price. In Thailand, research on the impact of evergreening, carried out by the Health Systems Research Institute, found that over 2,188 requests for patent protection for pharmaceutical products were submitted to the Department of Intellectual Property in 2000 - 2010. Most requests (84%) were to extend the patent term on an existing drug or to provide a new patent for old drugs with only minor changes to the existing formula. The research also

⁷⁶ *World Development Report: Building Institutions For Markets*, World Bank, 2002.

⁷⁷ ‘Evergreening’ refers to patents being extended based on small changes, new applications or longer terms.

showed that this practice cost Thailand Baht 1.1 billion in 1999- 2010 alone, due to the **increased costs of medicines**.⁷⁸

53. Worldwide, up to 108 different patent claims or patent applications have been identified for LPV/r alone. Such multiplication of **non-inventive patents** is issued by originator companies to shut-out competition altogether, increase transaction costs and/or delay the entry of generic drugs.⁷⁹ In many countries where LPV/r is not under patent protection, branded and generic versions are available at prices as low as US\$250 per person per year. However, Abbott prices the drug much higher in middle-income countries– such as China and Ukraine (US\$740), Mexico (US\$2,511) and Argentina (US\$2,570) - where it holds patents. Such exorbitant prices limit the number of PLHIV that, within scarce public health budget, a country can afford to treat.⁸⁰

The limits of voluntary mechanisms

“Not all MICs can enjoy the benefits of the voluntary licensing mechanism.”

54. Developed countries and multinational companies often highlight the importance of a **range of voluntary mechanisms** that, they claim, improve access to medicines. This includes: tiered pricing;⁸¹ price discounts; compassionate use; and voluntary licenses. However, in its report *Untangling the Web of ARV Price Reductions*, Médecins Sans Frontières reported that originator pharmaceutical companies have, in fact, abandoned HIV drug discount programs in middle-income countries, with ARV prices being negotiated on a case-by-case basis (resulting in higher costs for middle-income countries).⁸²
55. 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. 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.⁸³
56. More recently, the Medicines Patent Pool (MPP) made efforts to advance the voluntary licenses agenda. The pool aims to act as a central hub for sub-licensing HIV medicines to generic producers with more transparent licenses and from a public health perspective. However, the licenses agreed on so far have the same limits in term of geographical coverage and other issues. The nature of the voluntary license processes, is such that multinational companies are free to limit the participation of generic producers (exclusive

⁷⁸ *Medicine Patent Laws Drive Up Drug Prices, Says Institute, 'Evergreening' Patents Protect Big Producers*, Bangkok Post, 6 September 2011.

⁷⁹ *Secondary Patenting: Threat to Affordable, Generic ARVs, I-Mak*.

⁸⁰ *Untangling the Web of Antiretroviral Price Reduction*, MSF, July 2014.

⁸¹ 'Tiered pricing' refers to where pharmaceutical companies set different prices for different countries, depending on factors such as their Gross Development Product or World Bank income tier.

⁸² *Untangling the Web of Antiretroviral Price Reduction*, MSF, July 2014.

⁸³ 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/>

licenses) under terms and conditions they specify. To be more useful, it would be important to leverage the public health benefits of license agreements negotiated by the MPP.

57. In conclusion, voluntary licenses could help in reducing prices when there is no alternative. However, they do not create the real competition needed for progressive price reductions: voluntary licenses replace one monopoly with another monopoly. Voluntary licenses do not guarantee the availability of generic versions of medicines on the market either. Several voluntary licenses have not yet led to the production of actual medicines and have remained just public announcements. Some multinational companies use them only to prevent governments from using other TRIPs flexibilities (like compulsory licenses) and retain the monopoly over their products.
58. Civil society groups, including people living with HIV and key populations in middle-income countries, are concerned about the MPP's **license agreements**—as they are excluded from receiving the benefits as the originator companies can select the manufacturing country where the licensed drugs will be produced. The MPP mechanisms comply with the common framework for IP whereby originator companies are in control and determine the parameters of agreements; licenses are negotiated without transparency; and there is little evidence of actual improvement in access to medicines.

Community action case study 6: Advocacy on license negotiations⁸⁴

In 2011, the MPP signed a voluntary license agreement with Gilead Sciences for TDF and three pipeline drugs.^{85,86} While the license claims to improve access to TDF in 116 low and middle-income countries, it excludes over 500,000 people in more than 43 countries. Even more people – in countries such as Botswana and Namibia – are excluded from the pipeline drugs. It is important to note that most of the excluded countries have not granted patents to Gilead on those products, and the company wouldn't be in conditions to claim market monopoly. Civil society organizations expressed concerns that the benefits of the license agreement may have been exaggerated. In reality, it adds just 16 new countries (many of which are small islands) to the previous voluntary agreements confidentially signed between GILEAD and other generic companies.⁸⁷ This represents a less than 1% increase in people coverage. In contrast, adding the middle-income countries that are excluded from the agreement, it would have represented a 12% increase (and significantly expanded the market). The license agreement also limited local generic production - by only licensing India as supplier of the finished product as well as of the active pharmaceutical ingredients. This undermines the use of TRIPS flexibilities, such as parallel importation. Two years after the license agreement was signed, there is still no impact assessment on how it has contributed to improved access to treatment.

Community action case study 7: Advocacy on license negotiations

In September 2014, Gilead Sciences signed another voluntary license agreement with seven Indian-based generic companies.⁸⁸ This allows production and sale of the Hepatitis C drugs

⁸⁴ *Activists' Open Letter to the Medicines Patent Pool Foundation about the Gilead/MPP License; and Statement made by Gilead Sciences Representative at the Hepatitis C World CAB Meeting, Bangkok, February 2014.*

⁸⁵ Pipeline drugs' refers to medications that a company is currently discovering or developing.

⁸⁶ <http://www.medicinespatentpool.org/medicines-patent-pool-announces-first-licensing-agreement-with-a-pharmaceutical-company/>

⁸⁷ <http://www.i-mak.org/i-mak-blog-updates/2011/10/11/implications-of-the-patent-pool-licenses-with-gilead-part-ii.html>

⁸⁸ <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>

sofosbuvir and ledipasvir in 91 countries. Gilead states that the license will improve access to HCV treatment and cure globally. However, 51 middle-income countries with a high burden of HCV are excluded. Activists consider that this initiative has little chance of significantly improving access to treatment – as the highest burden of the disease is located in upper and middle-income countries (where 73% of the world’s 185 million people infected by HCV live). The voluntary license agreement constitutes a backwards step from international consensus on the use of TRIPS flexibilities to protect public health.⁸⁹ Gilead’s license territory includes least developed countries - which have until 2021 to implement the TRIPS agreement and are not obliged to grant patents. The licensing agreements also provide a rationale for market monopolies in excluded countries where Gilead has no patents, nor the right to claim a monopoly. It is also of concern that Gilead’s license agreement excludes the sale of active pharmaceutical ingredients, which are used as raw materials for local production, even in the countries included in the agreement.

Challenges with the application of tiered-pricing

“The industry-driven pricing strategy creates a double standard for prices and does not translate into sustainable price reduction for the MICs.”

59. In some contexts, the application of **tiered pricing** (also called differential pricing) has proven problematic. On 13 May 2014, a coalition of 220 NGOs condemned a proposal from the **Global Fund** that sought to promote this practice.⁹⁰ The concerns centered on the initiative’s primary focus on industry-driven pricing strategies - rather than on proven strategies to promote strong generic competition. Voluntary strategies offered by industry to lower the prices of medicines are insufficient and often limited in scale. They often exclude PLHIV in countries considered to be middle-income where pharmaceutical companies seek future high profits. Analyses of tiered pricing have concluded that the strategy has damaging consequences for access to medicines because it leads to supra-competitive prices (that cannot be sustained) and fosters inequity.⁹¹
60. In 2005 - 2008, the USA’s President’s Emergency Plan for AIDS Relief (**PEPFAR**) saved US\$323 million by buying generic HIV medicines instead of tiered-priced drugs.⁹²

The need for greater dialogue

61. It has become increasingly recognized by public health agencies, academics and communities alike that there are fundamental flaws in the design and application of the current IP frameworks – and little evidence of their concrete benefits to developing countries or their populations. For example, analyses have found that there is no evidence that implementing TRIPS in developing countries has increased research and development of drugs (as insufficient market incentives are the decisive factor);⁹³ the claim that IPRs are essential to foreign direct investment and technology has been shown to be false;⁹⁴ and TRIPS flexibilities are perceived as repairs to a system based on patent protection, rather

⁸⁹ ITPC Press release: « *A step back for millions of people with Hepatitis C* », New York, 2014.

⁹⁰ <http://infojustice.org/wp-content/uploads/2014/05/GF-tier-pricing-letter-Final-May13.pdf>

⁹¹ Civil society letter to Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

⁹² C. B. Holmes et al. in J. Am. Med. Assoc. 304, 313–320, 2010.

⁹³ WHO Commission on Intellectual Property Innovation and Public Health, April 2006

⁹⁴ *Debunking IP for Development: Africa Needs IP Space, Not IP Shackles*, B. Baker.

than solutions to meeting the development and health needs of the poor.⁹⁵ Despite the best efforts of civil society, it has been difficult to ‘de-technify’ and re-politicize the debate around IP and serious measures have not been taken to actually address the identified problems.

62. Recent years have seen a range of non-binding global and regional commitments to uphold the Doha Declaration. Examples include extensive recommendations on IP made by the Global Commission on HIV and the Law⁹⁶ and the recommendations of the WHO Global Strategy and Plan of Action on IP, Innovation and Public Health.⁹⁷ However, these have largely not been acted on by signatories. There is an urgent need to maximize the use of TRIPS flexibilities within the current IP framework and identify ways to solve the persistent and emerging challenges within that system. Ideas that have been put forward include: a global moratorium on including IP provisions in any agreement that could limit a country’s ability to reduce the cost of HIV-related treatment;⁹⁸ and moving away from the current patent-based system to one that, for example, has innovation prize funds and open source drug discovery. Analysis and uptake of these ideas require **honest and open dialogue** among all relevant stakeholders.

Civil society driving action and change

“Local actions and global solidarity create meaningful impact.”

63. The ‘world’ of patents and IP is, undeniably, complex. It is also, often, highly political and controversial. However, for civil society, the issues raised in this report are crucial. This is for a simple reason: they have a **life or death impact** on community members. To benefit from good health and a longer life, people living with HIV need affordable, available and accessible treatment. In practice, however, trade-related barriers pose a significant threat to this.

Why addressing trade barriers to treatment matters

“Is our memory so short that we have forgotten the situation we were in barely 10 years ago? None of us could get effective HIV treatment, because of the stranglehold multinational companies had on medicines. Now the EU wants to shut down generic production and send us back in time – when we watched helplessly as our colleagues, friends and families struggled with ill-health and death, because some big company and its government decided to put profits before people.” - Loon Gangte, president of the Delhi Network of Positive People (DNP+)

“Never ever compromise on access to treatment. It is our first right. We know all this negotiation for medicines is purely political - foreign governments and big pharma lobby with our government. Our voices need to be just as loud if not louder.”—Elango Ramchander, INP+

64. As illustrated by the case studies provided in this report, **civil society - including people living with HIV and key populations**—are playing a key role in mobilizing and advocating against the trade-related barriers to access to medicines. This includes by: advocating for the reform of national patent laws; lobbying Governments to make full use of TRIPS flexibilities; monitoring the impact of trade negotiations; and taking legal action against harmful patents. This is despite significant challenges facing the sector, including limited

⁹⁵ UNAIDS Lancet framing paper, Lilongwe, 2013

⁹⁶ *Risks, Rights and Health*, Report of the Global Commission on HIV and the Law, UNDP, New York, 2012.

⁹⁷ Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHO, Geneva, 2008.

⁹⁸ *Risks, Rights and Health*, Report of the Global Commission on HIV and the Law, UNDP, New York, 2012.

access to Government decision-making platforms on drug pricing and a lack of means to demand accountability from pharmaceutical companies. Activists, advocates and coalitions have demonstrated how local actions and global solidarity can produce concrete change. This is the result of long-term and multi-prong investments in capacity development to build community knowledge (treatment literacy), generate demand and mobilize stakeholders for access to treatment for all people living with HIV— ensuring that no one is left behind.

65. Based on the consultations carried out for the 2014 NGO report, the NGO Delegation has identified priority actions needed to achieve progress in this area. This includes that there is an urgent need for: more extensive and systematic analysis of the impact of current IP frameworks on access to treatment for HIV and co-infections; greater accountability (including among UNAIDS and Co-Sponsors) on what progress is or is not being achieved in this area; more appropriate technical support to low and middle-income countries to implement TRIPS flexibilities and ensure strong national patent and legal frameworks; and open and honest dialogue among the key stakeholders involved in these issues, notably the WTO, people living with HIV and the governments of low and middle-income countries.

RECOMMENDATIONS

Based on the findings of the 2014 NGO report, the Programme Coordinating Board is invited to:

66. *Recall* the decisions from previous Programme Coordinating Board meetings⁹⁹ and relevant paragraphs from Resolution 65/277 of the UN General Assembly - the Political Declaration on HIV and AIDS: Intensifying our Efforts to Eliminate HIV and AIDS, July 2011 on the importance of supporting low and middle-income countries to scale-up access to essential medicines by implementing the flexibilities contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and consistent with the World Trade Organization Declaration on TRIPS and Public Health (the Doha Declaration).¹⁰⁰
67. *Request* UNAIDS to: conduct an analysis of the impact of current Intellectual Property frameworks – including Trade-Related Aspects of Intellectual Property Rights Plus (TRIPS+) provisions in Free Trade Agreements - on the availability, affordability and accessibility of treatment and diagnostics for HIV and co-infections in low and middle-income countries; discuss the results of the analysis through a broad consultation process involving people living with HIV and key populations; and present the recommendations from this process at the 37thPCB meeting.
68. *Request* UNAIDS to strengthen existing and develop relevant outcome and output indicators¹⁰¹ in the Unified Budget, Results and Accountability Framework (UBRAF) that measure access to and availability of affordable HIV-related commodities, in order to provide more explicit reporting on progress toward overcoming Intellectual Property-related barriers to treatment access.
69. *Urge* the Joint Programme to intensify technical support to the Governments of lower and middle-income countries aimed to address IP-related barriers to availability, affordability and accessibility of up-to-date treatment and diagnostics of HIV and co-infections through the implementation of TRIPS flexibilities and to review and revise national patent laws and legislation framework in order to address availability and accessibility of up-to-date treatment and diagnostics of HIV and co-infections.
70. *Urge* UNAIDS- consistent with the recommendations of civil society in various global and regional forums and the Global Commission on HIV and The Law (Chapter 6)¹⁰²- to advance dialogue and convene a meeting with the World Trade Organization and relevant actors on developing a more sustainable mechanism to ensure the availability, affordability and accessibility of treatment and diagnostics for HIV and co-infections in low and middle-income countries and the results of such Dialogue to be available for consideration and action at the 2016 HLM.
71. *Request* UNAIDS to report to the Programme Coordinating Board meeting no later than July 2016 on the progress of the implementation of these decision points.

⁹⁹14thPCB meeting (agenda item 1.4, decision point 12), 15thPCB meeting (agenda item 1.4, decision point 5.3), 18thPCB meeting (agenda item 2, decision point 7.15) and 19th PCB meeting (agenda item 1.3, decision point 3.8); 1.5, decision points 5.4 and 6.1.vii from the 30th PCB meeting which refer to paragraphs 35, 36, 71(including sub-paragraphs a, b and c) and 72 from Resolution 65/277 of the UN GA

¹⁰⁰See Annex 2 for full text of paragraphs.

¹⁰¹ Current indicators are B1.2 and B 1.2.1 and these may serve as a basis for the development of such new indicators

¹⁰²See Annex 3 for full text of recommendations.

[Annexes follow]

ANNEX 1: ACKNOWLEDGEMENTS AND ABBREVIATIONS

Acknowledgements:

The NGO PCB Delegation would like to thank all the individuals and organizations that contributed their time, experience and insights to this report.

Region/Country	Organisation
Asia Pacific	
1. Thailand	Médecins Sans Frontières
2. Thailand	Asia-Pacific Regional Network of People Living with HIV (APN+)
3. Malaysia	Third World Network
4. Malaysia	The Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
5. India	Delhi Network of Positive People (DNP+)
6. India	International Treatment Preparedness Coalition (ITPC) - South Asia
Europe	
7. Ukraine	Independent Expert
8. Ukraine	East Europe & Central Asia Union of PLWH
9. Russia	ITPCru
10. Lithuania	Independent Expert
11. Spain	Independent Expert
12. UK	International Treatment Preparedness Coalition (ITPC)
13. Belgium	Europe AIDS Treatment Group (EATG)
14. France	Coalition PLUS
15. Switzerland	Knowledge Ecology International
16. Portugal	Grupo Português de Activistas sobre Tratamentos de VIH/SIDA (GAT)
Latin America and the Caribbean	
17. Brazil	Brazilian Partnership on TB (Stop TB Brasil)
18. Brazil	Observatório Tuberculose Brasil
19. Brazil	Brazilian Network for the Integration of People's Working Group on Intellectual Property (GTPI)
20. Brazil	Independent Expert
21. Columbia	El Mecanismo social de Apoyo y Control en vih de Colombia – 53 members (MSACV)
22. Bolivia	Institute of Human Development
23. Uruguay	Asociación de Ayuda al Sero Positivo (ASEPO)
24. Argentina	Fundación para Estudio e Investigación de la Mujer (FEIM)
25. Argentina	Independent Expert
26. Guatemala	Asociación Gente Nueva
27. Nicaragua	Latin American and Caribbean Council of AIDS Service Organizations (LACCASO) National Focal Point
Africa	
28. Zimbabwe	The Pan-African Treatment Access Movement (PATAM)
29. Egypt	Egyptian Initiative for Personal Rights

North America		
30.	USA	Treatment Action Group
31.	USA	Independent Expert
32.	USA	Independent Expert
33.	USA	CHANGE
34.	USA	Global Health Justice Partnership Yale Law School-Yale School of Public Health
35.	USA	International HIV/AIDS Alliance
36.	Canada	Canadian HIV/AIDS Legal Network
37.	Canada	Interagency Coalition on AIDS and Development - Coalition interagence sida et developpement (ICAD-CISD)
38.	Canada	LGBTI Aware Carribean
Global		
39.	Scotland	Global Network of Sex Work Projects (NSWP)

In addition to the above stakeholders, a consultation in EECA was held with 11 participants from six countries (including Ukraine).

Abbreviations:

ART: Antiretroviral therapy

ARV: Antiretroviral

BIT: Bilateral Investment Agreement

DAA: Direct-acting agent

DRV: Darunavir

EPAs: Economic Partnership Agreements

ETV: Etravirine

EU: European Union

FTA: Free Trade Agreement

Global Fund: Global Fund to Fight AIDS, Tuberculosis and Malaria

HCV: Hepatitis C virus

IP: Intellectual Property

IPR: Intellectual Property Right

ITPC: International Treatment Preparedness Coalition

LPV/r: Lopinavir/Ritonavir

MPP: Medicines Patent Pool

NGO: Non-governmental organizations

PCB: Programme Coordinating Board

PLHIV: People living with HIV

PEPFAR: President's Emergency Plan for AIDS Relief

RAL: Raltegravir

TPPA: Trans-Pacific Partnership Agreements

TRIPS: Trade-Related Aspects of Intellectual Property Rights

UBRAF: Unified Budget, Results and Accountability Framework

UN: United Nations

UNAIDS: United Nations Joint Program on HIV/AIDS

UNDP: United Nations Development Program

UNGASS: United Nations General Assembly Special Session on HIV/AIDS

USA: United States of America

WHO: World Health Organization

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

ANNEX 2: IP TERMINOLOGY AND EXPLANATIONS

1. **TRIPS**, The **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation, including pharmaceuticals. It requires a patent system to be established.
2. **The Doha Declaration** of 2001 reaffirmed the commitment of its member states to ensure that "*the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health... 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.*"¹⁰³ Specific provisions within this Declaration reaffirm some of the flexibilities contained in the TRIPS Agreement,
 - A 2003 agreement loosened the original domestic market requirement, and allowing developing countries to export to other countries where there is a national health problem.
3. **Transition period:** Least developed countries are not obliged to grant patents on pharmaceutical products until 2021 (initially 2016, extended in 2013) and should take advantage from this transition period.
4. **Strict patentability criteria:** Patents are granted to provide a monopoly right for a period of time in recognition of the cost of development and the reward for innovation. Patents in pharmaceuticals generally cover products and processes. Member states may set high patentability criteria, allowing patents only on those products that are really innovative and new. This means that is harder for a patent to be granted in such countries.
5. **Patent flexibilities:** Patent law that provides better protection for public health and is still consistent with WTO and TRIPS might include:
 - Not allowing small changes that are not innovative such as a minor change in formulation of the drug ("evergreening");
 - Not allowing further patent protection if there is a new application for a drug
 - Patent laws that make it easier for patents to be challenged, such as allowing challenges before a patent is granted (pre-grant opposition);
 - Patent laws that allow a patent to be challenged after it has been granted (post-grant opposition) - patent oppositions ensure higher scrutiny of patent applications before and after they are granted ensuring a novel, inventive step).
6. **Parallel importation** allows countries to import a patented medicine from other countries where it is produced and sold by the patent holder or an authorized party at a lower price than in the domestic market. This can happen without the permission of the patent owner.
7. **Exceptions to patents rights:** TRIPS allows states to establish limited exceptions to the exclusive rights of a patent owner, as long as they do not unreasonably prejudice his or her ownership rights. For example, the Bolar Exception – an 'early working' exception which

¹⁰³ Declaration on the TRIPS Agreement and public health, paragraph 4, adopted on 14 November 2001

allows for research and experimental use of products still under patent. This allows generic versions to promptly enter the market right after the patent expires

Other TRIPS Flexibilities

8. When patents were introduced on pharmaceuticals through the WTO it was recognized that this could mean that developing countries would not get affordable access to essential medicines. An interpretive statement, the Doha Declaration was issued in November 2001, which indicated that TRIPs should not prevent states from dealing with public health crises.
9. **Compulsory licensing (Government use):** The key TRIPS flexibility. This allows governments in effect to break patents and issue Compulsory licenses allowing the manufacture, sale and import of a patented product without the consent of the patent holder. Under the TRIPS Agreement countries are free to determine themselves the grounds on which a compulsory license should be issued, and the royalty that is paid is negotiated between the country and the patent holder. In Africa alone for example, Ghana, Eritrea, Zambia, Mozambique and Zimbabwe have all issued compulsory licenses for generic ARVs. Some more examples are in the picture below.

TRIPS+ Provisions

10. TRIPS sets minimum standards of IP protection. However, net exporters of IP and in particular originator Pharmaceuticals have sought to include so called TRIPS+ clauses in their Free Trade and other bilateral agreements that go way beyond that the WTO requires.

TRIPS+ examples:

- Evergreening: patent extensions for small changes, new applications and longer terms
- Data Exclusivity: Not allowing the use of the original data so that a new entrant must repeat all of the clinical trials taking far more time and at higher cost.
- New enforcement mechanisms for IPRs: expanding the scope of information that can be requested in IP infringement proceedings or criminalizing patent infringement. This resulted in that have in multiple seizures at some ports of shipments of generic medicines heading to developing countries and LDCs.¹⁰⁴
- Patent linkage: The drug regulatory authority must not authorize a product that breaks a patent, so that a technical government body is held responsible to protect a privately held right.

¹⁰⁴ See Statement by Brazil at TRIPS Council: Public Health dimension of TRIPS Agreement, 3 March 2009 and UNITAID, statement on Dutch confiscation of medicines shipment, 4 March 2009.

ANNEX 3: PARAGRAPHS 35, 36, 71 AND 72 OF THE POLITICAL DECLARATION ON HIV AND AIDS (2011)

Paragraph 35: Recognize the critical importance of affordable medicines, including generics, in scaling up access to affordable HIV treatment, and further recognize that protection and enforcement measures for intellectual property rights should be compliant with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) 5 and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all.

Paragraph 36: Note with concern that regulations, policies and practices, including those that limit legitimate trade in generic medicines, may seriously limit access to affordable HIV treatment and other pharmaceutical products in low- and middle-income countries, and recognize that improvements can be made, inter alia through national legislation, regulatory policy and supply chain management, noting that reductions in barriers to affordable products could be explored in order to expand access to affordable and good quality HIV prevention products, diagnostics, medicine and treatment commodities for HIV, including for opportunistic infections and co-infections.

Paragraph 71: Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care, including by amending national laws and regulations, as deemed appropriate by respective Governments, so as to optimize:

- (a) The use, to the full, of existing flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights specifically geared to promoting access to and trade in medicines, and, while recognizing the importance of the intellectual property rights regime in contributing to a more effective AIDS response, ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities, as confirmed in the Doha Declaration on the TRIPS Agreement and Public Health, 8 and call for early acceptance of the amendment to article 31 of the TRIPS Agreement adopted by the General Council of the World Trade Organization in its decision of 6 December 2005.
- (b) Addressing barriers, regulations, policies and practices that prevent access to affordable HIV treatment by promoting generic competition in order to help to reduce costs associated with life-long chronic care and by encouraging all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade in medicines, and to provide for safeguards against the abuse of such measures and procedures.
- (c) Encouraging the voluntary use, where appropriate, of new mechanisms such as partnerships, tiered pricing, open-source sharing of patents and patent pools benefiting all developing countries, including through entities such as the Medicines Patent Pool, to help to reduce treatment costs and encourage development of new HIV treatment formulations, including HIV medicines and point-of-care diagnostics, in particular for children.

Paragraph 72: Urge relevant international organizations, upon request and in accordance with their respective mandates, such as, where appropriate, the World Intellectual Property Organization, the United Nations Industrial Development Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the World Trade Organization and the World Health Organization, to provide national Governments of developing countries with technical and capacity-building assistance for the efforts of those Governments to increase access to HIV medicines and treatment, in accordance with the national strategies of each Government, consistent with, and including through the use of existing flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health.

ANNEX 4: RECOMMENDATIONS OF THE GLOBAL COMMISSION ON HIV AND THE LAW ON IP

- 6.1. The UN Secretary General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. Such a body should include representation from the High Commissioner on Human Rights, WHO, WTO, UNDP, UNAIDS and WIPO, as well as the Special Rapporteur on the Right to Health, key technical agencies and experts, and private sector and civil society representatives, including people living with HIV. This re-evaluation, based on human rights, should take into account and build on efforts underway at WHO, such as its Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property and the work of its Consultative Expert Working Group. Pending this review, the WTO must suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries.
- 6.2. High-income countries, including donors such as the United States, European Union, the European Free Trade Association countries (Iceland, Liechtenstein, Norway and Switzerland) and Japan must immediately stop pressuring low- and middle income-countries to adopt or implement TRIPS-plus measures in trade agreements that impede access to life-saving treatment.
 - 6.2.1. All countries must immediately adopt and observe a global moratorium on the inclusion of any intellectual property provisions in any international treaty that would limit the ability of countries to retain policy options to reduce the cost of HIV-related treatment. Agreements such as the Anti-Counterfeiting Trade Agreement (ACTA) must be reformed; if ACTA is not reformed to exclude such intellectual property provisions, countries should not sign it. All countries must cease unilateral practices to this same, access-limiting end.
 - 6.2.2. High-income countries must stop seeking to impose more stringent, TRIPS-plus intellectual property obligations on developing country governments. High-income countries must also desist from retaliating against countries that resist adopting such TRIPS-plus measures so that they may achieve better access to treatment.
- 6.3. While the Commission recommends that WTO Members must urgently suspend TRIPS as it relates to essential pharmaceutical products for low and middle income countries, we recognise that such change will not happen overnight. In the interim, even though individual countries may find it difficult to act in the face of political pressure, they should, to the extent possible, incorporate and use TRIPS flexibilities, consistent with safeguards in their own national laws.
 - 6.3.1. Low- and middle-income countries must not be subject to political and legal pressure aimed at preventing them from using TRIPS flexibilities to ensure that infants, children and adolescents living with HIV have equal access to HIV diagnosis and age-appropriate treatment as adults.
 - 6.3.2. It is critical that both countries with significant manufacturing capacity and those reliant on the importation of pharmaceutical products retain the policy space to use TRIPS flexibilities as broadly and simply as they can. Low and middle-income countries must facilitate collaboration and sharing of technical expertise in pursuing the full use of TRIPS exceptions

(for instance, by issuing compulsory licenses for ARVs and medicines for co-infections such as hepatitis C). Both importer and exporter countries must adopt straightforward, easy-to-use domestic provisions to facilitate the use of TRIPS flexibilities.

- 6.3.3. Developing countries should desist from adopting TRIPS-plus provisions including anti-counterfeiting legislation that inaccurately conflates the problem of counterfeit or substandard medicines with generics and thus impedes access to affordable HIV-related treatment.
- 6.3.4. Countries must proactively use other areas of law and policy such as competition law, price control policy and procurement law, which can help increase access to pharmaceutical products.
- 6.4. The WTO Members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products. The UN and its member states must mobilize adequate resources to support LDCs to retain this policy latitude.
- 6.5. The August 30, 2003 Decision of the WTO General Council has not proved to be a viable solution for countries with insufficient pharmaceutical manufacturing capacity. It is essential that the system established by that decision be revised or supplemented with a new mechanism, to allow the easier import of pharmaceutical products produced under compulsory license. WTO Members should desist from ratifying the adoption of the August 30, 2003 Decision as a new Article 31 bis of the TRIPS Agreement, and they must pursue efforts to reform or replace the system.
- 6.6. TRIPS failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritising the most promising approaches including a new pharmaceutical R&D treaty and the promotion of open source discovery.

ANNEX 5: ANALYSIS OF THE IMPACT OF TRIPS+ PROVISIONS IN BILATERAL/FREE TRADE AGREEMENTS ON ACCESS TO MEDICINES

1. World Bank research projected that if the US and Thailand had signed the proposed FTA between the two states, the use of compulsory licensing that could have reduced the cost of second-line ARVs by 90% in Thailand would have been severely restricted. The World Bank concludes that issuing compulsory licenses for second-line ARVs would represent a saving of USD\$3.2 billion for the Thai national health budget over 20 years.¹⁰⁵
2. Oxfam found that the US-Jordan FTA increased medicine prices in Jordan by 20 per cent since 2001. The study highlighted that higher medicine prices were threatening the financial sustainability of government public health programmes, and that the TRIPS-plus rules contributed to the increase in medicine prices, as well as will delay or prevent use of public health safeguards to reduce the price of new medicines in the future. In particular, the study found that, data exclusivity had delayed generic competition for 79 per cent of medicines newly launched by 21 multinational pharmaceutical companies between 2002 and mid-2006, that otherwise would have been available in an inexpensive, generic form. As noted by the study, data exclusivity is a TRIPS-plus rule that creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five or more years, even when no patent exists. The study estimated that additional expenditures for medicines with no generic competitor, as a result of enforcement of data exclusivity by multinational drug companies, were between USD 6.3 million and USD 22.04 million.¹⁰⁶
3. The Third World Network reported that when Guatemala introduced data exclusivity due to its US-FTA, instead of paying \$0.01 for the generic version of [a] medicine, the data exclusivity monopoly allowed the IP owner to charge \$84.56 for the same medicine. A similar study carried out by Center for Policy Analysis on Trade and Health articulates the impact of data exclusivity in Guatemala as a result of Central America-US FTA or CAFTA. This study found that in each case, the data-protected drugs are much more expensive than non-protected drugs in the same therapeutic class. For example, the insulin Lantus costs 846 percent more than isophane insulin; the antifungal Vfend costs 810 percent more than the non-data protected amphotericin B; and the intravenous antibiotic Invanz costs 342 percent more than the non-data-protected meropenem (Meronem).¹⁰⁷
4. The study carried out by the Pan American Health Organisation (PAHO) estimated the impact of TRIPS-plus provisions in Costa Rica. The study found that (1) by 2030, the price will increase between 18% and 40% yearly for covered active ingredients; (2) there will be a need for increased public spending from about USD 2.008 million to USD 3.357 million by 2030, depending on the scenario; (3) the strongest impact per measure: patentability criteria (about 55% of the impact), data exclusivity (about 40%), linkage, and patent term restoration (about 5%); (4) if the public budget is not increased, consumption will decrease by 24% in

¹⁰⁵ See Revenga A, et al (2006), *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, World Bank.

¹⁰⁶ Oxfam, *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines*, 2007

¹⁰⁷ *A trade agreement's impact on access to generic drugs: the impact of CAFTA in Guatemala on Access to Medicines*, 2009

the worst case scenario and (5) by 2030, there will be a reduction between 24% to 27% in market share for the local generic industry.¹⁰⁸

5. A study by MisionSalud and IFARMA found that the full impact of the demands on patents i.e. lowering of patent standards and granting of patents on minor modifications of existing medicines, granting of patents on new uses of known medicines and patent term extensions, as proposed by the US-Colombia FTA, could mean an increase in expenditure of US\$ 400 million by 2020 or a decrease of 18% in consumption if the increase in spending is not possible and additionally a loss of up to 28% of market share for the national industry; the requirement for data exclusivity would be responsible for increasing average medicine prices by up to 30% or US\$ 674 million by 2020 or a reduction of 30% in consumption if there is no increase in spending and would cause the national industry to lose up to 47% of its market share; and the implementation of the intellectual property chapter as a whole would result in 63% of the market being under monopoly protection, an increase in the price index of medicines by 40% and increase of US\$ 919 million by 2020¹⁰⁹;
6. Health Action International and IFARMA conducted a study in 2009 to look at the impact of EU-Andean FTA in Peru. The study found that implementing the Supplementary Protection Certificates (i.e. patent term extension) from Article 9.3 of the Intellectual Property Agreement Subgroup (thus extending the effective patent period by 4 years), would lead to a USD 159 million increase in pharmaceutical expenditure in 2025. At the same time, a 10-year test data exclusivity period, as proposed by the EU in Article 10.2 of the aforementioned subgroup, would lead to an increase of more than USD 300 million in medicines' expenditure in 2025 and a cumulative increase in expenditure of USD 899 million for the same year.¹¹⁰
7. The US Trans-Pacific Partnership Agreement, proposed by the US Trade Representatives, pushes countries such as Malaysia into agreeing to patenting provisions. The Third World Network predicts that this will result in the delay in entry of affordable generic medicines into the Malaysian market, wherein pharmacist-recommended generic medicines make up 84.7% of prescriptions requested. If these provisions are agreed to, Malaysians will have to pay higher prices for medicines for a longer time. Some quarters assert that Malaysians could experience price hikes of 60%-80% for certain drugs, while other authorities assert that patented medicines can become 1,044% more expensive than their generic equivalents in Malaysia. The patented version of medicines to treat HIV, for example, cost US\$15,000 per patient per year, while the generic version only costs US\$67 per patient per year.¹¹¹
8. A recent study: "Impact on Access to Medicines from TRIPS-Plus: A Case study of Thai-US FTA)" by Kessomboon N. et al in Thailand projected that the impact of Thai-US FTA was calculated for each TRIPS-plus provision with variations in the period of exclusivity i.e. 2, 5 and 10 years. The impact on pharmaceutical expenditure was calculated for the next 5, 10, 20 and 30 years. In total, 35 different scenarios were examined in the study and all demonstrated a negative impact for the pharmaceutical market. For instance, the study

¹⁰⁸ Greivin Hernandez-Gonzalez, et al. Assessment of the Impact of TRIPS-Plus Provisions on Costa Rica's Institutional Drug Market, 2009

¹⁰⁹ Gamba M. Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia. Mission Salud-Fundacion Ifarma, Bogota, Columbia, 2006, at: http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf

¹¹⁰ Impact of the EU-Andean Trade Agreements on Access to Medicines In Peru, Health Action International and IFARMA, 2009

¹¹¹ <http://www.twinside.org.sg/title2/FTAs/info.service/2013/fta.info.251.htm>

found that (1) 5 years of data exclusivity would result in an increase in pharmaceutical expenditure of USD 2400 million over the next 5 years and (2) 5 year patent term extension would result in an increase in pharmaceutical expenditure of USD 821 million over the next 5 years. The greater negative impact of data exclusivity was attributed to the fact that data exclusivity would apply to patented and non-patented medicines.¹¹²

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¹¹²Kessonbon, et al. Impact on Access to Medicines From TRIPS-Plus: A case study of Thai-US FTA, 2010