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APCASO
ASIA PACIFIC COUNCIL OF AIDS SERVICE ORGANIZATIONS

ITPC
Strengthening Community Responses to HIV Treatment & Prevention

in focus

Civil Society Perspectives on the 2011 HIV/AIDS HLM

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TREATMENT ACCESS & The 2011 Political Declaration on HIV/AIDS

The 2011 Political Declaration on HIV/AIDS adopted by 193 members of the United Nations General Assembly through Resolution 65/277 comes 10 years after the historic 2001 United Nations Special Session on HIV/AIDS. This Political Declaration collectively mobilized member states to commit to a target of working towards having 15 million people living with HIV (PLHIV) on antiretroviral treatment by 2015. This is a firm target on treatment, allowing communities to hold international member states accountable.

Governments are committed to improving HIV treatment access and delivery through provision of good quality, affordable, effective, less toxic and simplified treatment regimens, simple and affordable diagnostics, improved point-of-care health services and patient retention strategy. This includes particular efforts towards populations in rural areas and communities most at risk for HIV.

The scale-up of access is articulated in UNAIDS Treatment 2.0 strategy that is premised on five pillars:

- Pillar 1 – Optimize drug regimens
- Pillar 2 – Provide point of care diagnostics and other simplified tests
- Pillar 3 – Stop cost being an obstacle
- Pillar 4 – Adapt HIV care delivery systems
- Pillar 5 – Strengthen community mobilization

in a nutshell

Of the 105 paragraphs, 13 are dedicated to eliminating AIDS-related illness and death under the heading of Treatment, Care and Support (paragraphs 35, 36, 65 to 76).

- Paragraphs 35 and 36 recognize the critical importance of affordable medicines in scaling up access, and further recognize that governments have an obligation to protect the health of its citizens while balancing intellectual property rights that seriously limit legitimate trade of generic medicines.
- Paragraph 65 pledges to intensify efforts that will help increase life expectancy and quality of life of people living with HIV (PLHIV).
- Paragraph 66 commits to the goal of universal access to antiretroviral treatment based on the World Health Organization (WHO) HIV treatment guidelines [1] with the target of getting 15 million of the 18 million in need of treatment on antiretrovirals by 2015.
- Aiming to get 15 million (83%) on treatment is slightly above the universal target of 80 percent that was meant to be achieved by 2010, and was missed. It is not clear if this newer target will be met given the funding crisis including the recent cancellation of Round 11 of the Global Fund and a significant drop in PEPFAR budget. These two programs together in 2009 supported nearly 4 million people on treatment[2]. Unfortunately, the resource cuts are taking place at a time when scientific evidence shows that a significant investment in treatment could change the course of the epidemic.

unpacking key paragraphs

Commitment to Affordable Medicines (Paras. 35, 36, 71, 72, 74)

Paragraphs 35 and 36 of the Political Declaration recognize the need for affordable medicines and reduction of costs including affordable diagnostics, treatment for opportunistic infections, and health care delivery systems. In the implementation section, governments commit to removing trade barriers in an attempt to make HIV prevention and treatment products, diagnostics, medicines, and other pharmaceutical products more affordable, including through amendments to national laws and regulations and global trade agreements. Paragraphs 71 and its sub-sections, 72, and 74 address the role of the Trade-Related Aspects of Intellectual Property Rights Agreement and the Doha Declaration as well as that of private multilateral actors, national governments, and pharmaceuticals.

The above are an expansion of the 2006 Political Declaration and specifically note that intellectual property rights provisions in trade agreements (referred to as TRIPS-plus) should not undermine the TRIPS flexibilities affirmed by the Doha Declaration that aim to protect public health interests and access to affordable essential medicines.

These paragraphs also request that relevant international organizations such as the World Intellectual Property Organization (WIPO), the United Nations Industrial Development Organization (UNIDO), the United Nations Development Program (UNDP), the United Nations Conference on Trade and Development (UNCTAD), the World Trade Organization (WTO), and the World Health Organization (WHO) to provide technical and capacity-building assistance on intellectual property rights to governments in order to ensure increased access to HIV medicines and treatment.

Pharmaceuticals, in paragraph 74, are called upon to take measures to ensure timely production and delivery of affordable, good quality and effective antiretroviral medicines in order to maintain an efficient national system of distribution. Unfortunately, the language in this section while a vast improvement from the 2006 Political Declaration is still weak given that the largest threat to making medicines and diagnostics more affordable, especially to newer first-line and second-line treatment, is a reduction in prices which are kept high because of trade rights conferred upon name-brand pharmaceuticals.

Commitment to Reducing Co-Infections (Paras. 69, 75, 76)

The focus of three paragraphs (69, 75, and 76) is on improved access to services and treatment for tuberculosis and hepatitis co-infections. Paragraph 69 commits to integrating services for tuberculosis and hepatitis, including access to quality care and affordable primary health care services that are comprehensive and support the physical, spiritual, psychosocial, socio-economic, and legal aspects of living with HIV.

The paragraphs are aimed at addressing treatment needs of key vulnerable groups such as drug users, sex workers, prisoners, and men who have sex with men. Paragraph 75 commits to expanding

efforts to combat tuberculosis as the leading cause of death among PLHIVs and commits to reducing tuberculosis deaths by 50 percent through initiatives such as the Global Plan to Stop TB, 2011-2015.

> ***"We now know that if you treat a person living with HIV effectively, you reduce the risk of transmission to a partner by 96 percent. ….As the world scales up the most effective prevention methods, the number of new infections will go down, and it will be possible to treat more people than are becoming infected each year. And so, instead of falling behind year after year, we will, for the first time, get ahead of the pandemic. We will be on the path to an AIDS-free generation."***
>
> - Hillary Clinton during her *"Creating an AIDS-Free Generation" speech, National Institutes of Health, November 2011*

Paragraph 76 commits to reducing the high rates of HIV and hepatitis B and C co-infections through expanding access to hepatitis B vaccination and improved diagnostics and treatment for hepatitis C. These paragraphs unfortunately fail to acknowledge that diagnostics and treatment for both tuberculosis and hepatitis B and C are expensive and that high prices serve as a major barrier to scaling up access to treatment.

Commitment to Children (Paras. 59 (l), 68)

In paragraph 68, there is a commitment to improve infant diagnostics and access to treatment including access to prophylaxis and treatment for opportunistic infections. The obligation is far-reaching and includes financial, social and moral support to children and adolescents through their families and legal guardians, and aims to promote a smooth transition from pediatric to young adult treatment.

What is conspicuously absent from this text is specific mention of the WHO Guidelines on HIV positive pregnant and lactating women. Paragraph 59(l) under the prevention paragraphs mentions as a sub-point that women of child-bearing age should have access to effective treatment including prophylaxis treatment for their infants.

Commitment to Improving Health Systems & Nutrition (Paras. 70, 73)

There is specific commitment to scale-up treatment and to address factors that limit treatment uptake and contribute to stock-out and delays in production and delivery, including inadequate transportation to clinical sites and inappropriate storage. Paragraph 73 focuses on access to information, addressing treatment-related side effect resulting in poor adherence, and out-of-pocket expenses for non-drug components, the loss of income of PLHIV, and inadequate human resources for health care. While many issues are lumped together in paragraph 73, the commonality is developing appropriate national level AIDS response with strengthened health and social insurance systems. In paragraph 70, there is a specific commitment to integrating food and nutritional support into programs directed at people living with HIV, ensuring access to sufficient, safe and nutritious food as part of a comprehensive health response to HIV.

understanding key concepts[3]

Generics

A generic drug is an identical copy (bioequivalent) of a brand name drug. Generics are exactly the same as branded drugs in terms of dosage, form, safety, strength, quality, performance characteristics, and intended use. The only difference between generic and brand name drugs is the price. Generic companies do not have to spend money on research and trials for drugs. They make drugs out of already known and understood drug compounds (often invented by pharmaceutical companies) so they are able to sell them at lower cost.

Generics are the main reason why HIV medicines are affordable and accessible to more than 6 million people today. A recent study by the International AIDS Society calculates that 90% of donor-funded HIV medicines are generic. Any future scale-up of treatment relies on affordable generic medicines.

Patents and TRIPS

A patent on a drug gives pharmaceutical companies an exclusive right that prevents others from making, using, selling, or importing it. Under TRIPS a patent typically lasts for 20 years.

In 2005, intellectual property legislation (law) was introduced into the international trading systems. The legislation is called Trade Related Aspects of Intellectual Property Rights (TRIPS). It protects the rights of pharmaceutical companies to patent their drugs and prohibits generic drug companies from manufacturing drugs that are under patent. Because the TRIPS agreement was going to have such a major impact on the generic drug industry, developing countries (like India) were given 10 years to comply with the law.

TRIPS+

Any requirements that offer exclusive rights to originator product that go beyond what is agreed upon in the TRIPS Agreement are referred to as TRIPS-plus. The most detrimental TRIPS-plus provision to access is "data exclusivity", which gives an originator company a certain length of time (anywhere between 5 to 10 years) to protect its data so that a generic version cannot be brought to market. As long as the exclusivity lasts, generic producers would have to submit their own safety and efficacy data obliging them to repeat costly clinical trials and delaying the manufacturing of generic products.

Other examples of TRIPS-plus measures include patent-term extensions or evergreening of products by tweaking formulation or process and refiling for a patent to extend beyond the TRIPS 20-year requirement. Other TRIPS-plus measures include limitations on the issuance of a compulsory license for public health reasons violating the provisions of the Doha Declaration; limiting the registration of a generic version if the pharmaceutical product is under patent; and other administrative procedures related to patent applications. These TRIPS-plus measures are being incorporated into bilateral or regional free trade negotiations, and other international agreements. They have serious and possibly catastrophic implications for treatment access and scale-up not only for HIV-related medications, but also other essential medicines.

Notes

1 see back page for guidelines
2 estimates available at http://www.theglobalfund.org/en/mediacenter/pressreleases/PEPFAR_and_The_Global_Fund_collaborate_to_treat_3.7_million_living_with_HIV/AIDS/
3 from ITPC, Factsheet No. 4

Making Use of the Political Declaration

The 2011 Political Declaration has an ambitious agenda. Meeting the targets and commitments set out in its 105 paragraphs will require not only resources but the involvement of key affected populations and civil society as well as development partners in a multi-sectoral approach. As signatories to this document, UN member states therefore have an obligation to be accountable for the commitments they have made.

With respect to treatment access, here are our key messages:

- Keep the promise 15 million on treatment by 2015
- Treat Tuberculosis, Hepatitis C and Hepatitis B
- Adopt and Implement the WHO Treatment Guidelines
- NO FTAs for this region

WHO treatment guidelines

In 2010, the World Health Organization updated its guidelines on Antiretroviral Therapy for treating HIV infection in adults, adolescents, pregnant and lactating women, children, and infants. Main points to note from this revision are as follows:

1. Earlier initiation of treatment for a person living with HIV and with CD4 count of 350 and below. For pregnant women with CD4 count above 350, treatment to start at 14 weeks of pregnancy.
2. Phase out and discontinuation of treatment regimens with the drug d4T (stavudine).
3. Ensure substitution of EFV (efavirenz) with nevirapine or lopinavir. for women trying to get pregnant or already pregnant using EFV in current treatment regimen
4. Proper treatment prophylaxis for infants until 6-weeks.
5. Regular HIV viral load testing for detection of early treat ment failure.

Written by Dr. Sarah Zaidi, Executive Director, ITPC
Copyedited by Moi Lee Liow, APCASO
Design and lay-out by RD Marte, APCASO

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The **International Treatment Preparedness Coalition (ITPC)** is a global network of community organizations, local NGOs, researchers, and activists dedicated to effective, affordable, and quality treatment and health care for people living with HIV. ITPC's mission is to enable communities in need to access treatment.

ITPC is committed to strengthening community knowledge in all aspects of management of HIV and related infections; engaging and supporting communities in advocacy efforts; and developing and strengthening individual, community and network capacity.

International Treatment Preparedness Coalition
Secretariat- Bangkok
51/2 3rd floor Ruam Rudee Building III, Soi Ruam Rudee,
Ploenchit Rd., Lumpini, Pathumwan, Bangkok 10330 THAILAND
Tel :+66 2 2557477-8, Fax:+66 2 2557479, Url://www.itpcglobal.org

The **Asia Pacific Council of AIDS Servce Organizations (APCASO)** is a civil society network of non-governmental (NGOs) and community based organisations (CBOs) that provide HIV and AIDS services within the Asia and Pacific regions.

APCASO supports and promotes the role of CBOs and NGOs in their responses to HIV and AIDS, particularly those representing communities most affected by the pandemic, namely people living with HIV, sex workers, people who use drugs, men who have sex with men, transgender people, migrant and mobile populations, young people and women.

Asia Pacific Council of AIDS Service Organizations (APCASO)
16-3 Jalan 13/48A, Sentul Boulevard, Off Jalan Sentul,
51000 Kuala Lumpur, MALAYSIA
Tel: +603 4044-9666, Fax: +603 4044-9615, Url: www.apcaso.org