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# Fast-tracking HIV treatment: Parliamentary action and policy options

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## Abbreviations

AIDS	acquired immunodeficiency syndrome
HIV	human immunodeficiency virus
IP	intellectual property
IPU	Inter-Parliamentary Union
LDC	least developed country
NGO	non-government organization
TAC	Treatment Action Campaign
TRIPS	Trade-related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization

# Executive summary

HIV treatment is a cornerstone of the AIDS response, helping to prevent AIDS-related deaths and avert new infections. It also helps people living with HIV to live close-to-normal lifespans, thereby reducing HIV-related stigma. Evidence shows that HIV treatment, administered ideally as soon as possible after diagnosis, not only slows disease progression but also prevents onward HIV transmission. Moreover, the right to the highest attainable standard of health necessitates access to treatment and other medicines to ensure that people living with HIV can have long and productive lives.<sup>1</sup>

People are still dying, however, because HIV treatment is not reaching all who need it. Access to HIV treatment is thus a key pillar of a successful AIDS response and is central to the goal of ending AIDS by 2030.

As legislators, overseers of government action and community leaders, members of parliament are well placed to help expand access to HIV treatment. Where parliamentarians are effectively engaged in the HIV response, they can provide critical leadership in realizing a new vision for health that leaves no one behind and makes treatment a reality for all.

What follows is intended as a resource to assist parliamentarians in this endeavour. It is both a call for parliamentary action and leadership and a reference to which parliamentarians and their staffs can turn for information and guidance. It lists actions that parliamentarians can take to increase access to HIV treatment and provides illustrations of good practice by legislatures and individual parliamentarians.

Chapter 1 discusses how parliamentarians can support HIV treatment responses. Chapter 2 recalls the global progress that has been achieved in scaling up treatment access to date and the ambitious “Fast-Track” targets the world must meet to end the AIDS epidemic as a global health threat by 2030.

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<sup>1</sup> UNAIDS (2006). *International guidelines on HIV/AIDS and human rights*. Geneva: UNAIDS, para 145, <http://www.ohchr.org/Documents/Publications/HIVAIDSGuidelinesen.pdf>.

The actions required to meet those targets are detailed in the following three chapters.

Chapter 3 explains the human rights-based response to HIV and legislation that supports enjoyment of the right to health by people living with HIV. Examples are provided of laws relating to essential medicines and constitutional rights to health that can be applied to support access to HIV treatments.

Chapter 4 describes how the patenting of drugs under intellectual property laws affects the cost of HIV treatments. Examples are provided of actions that can be taken under international trade rules to ensure patents do not restrict access to affordable HIV treatments.

Chapter 5 focuses on innovative and sustainable ways to mobilize resources and finance HIV treatment, providing examples of options such as trust funds, special levies, social insurance and universal health coverage schemes.

This paper, intended as a resource for parliamentarians, is the result of long-standing, close collaboration between the Inter-Parliamentary Union (IPU) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). IPU and UNAIDS hope it will inspire and help parliaments and parliamentarians everywhere take strong political leadership and fully exercise their legislative, budgetary and oversight powers to end the AIDS epidemic in their communities and countries.

# Introduction

## The AIDS epidemic is not over

### People living with HIV

Total number of people living with HIV	36.9 million [34.3 million – 41.4 million]
Women aged 15 years and over living with HIV	17.4 million [16.1 million – 20.0 million]
Men aged 15 years and over living with HIV	16.9 million [15.7 million – 19.0 million]
Children under 15 years living with HIV	2.6 million [2.4 million – 2.8 million]

### AIDS deaths

AIDS deaths since the start of the epidemic	34.2 million
AIDS deaths	1.2 million [980,000 – 1.6 million]
Number of deaths averted by treatment, 2000 to 2014	7.8 million

*Source: 2014 UNAIDS estimates.*

By virtue of their constitutional powers, parliamentarians can decisively influence laws and policies to improve the lives of their citizens. This includes addressing the major health challenges that our societies currently face. Globally, AIDS still causes more deaths each year, worldwide, than any other infectious disease.

An ambitious set of Fast-Track targets has been adopted by UNAIDS for 2020: these targets cover prevention, non-discrimination and treatment. The treatment targets focus on the following: 90% of people living with HIV tested, 90% of those tested receiving treatment and 90% of those receiving treatment achieving viral suppression.<sup>2</sup> These global targets cannot be reached without strong political leadership.

This document focuses specifically on the issue of access to treatment. Ending the AIDS epidemic is possible within our lifetime, but only if the AIDS response is put on a fast track, with intensified efforts to scale up HIV prevention and treatment and end discrimination. Central to ending AIDS is an unprecedented focus on rapidly scaling up national HIV treatment programmes, which requires urgent action to address related legal, policy and financial obstacles.

<sup>2</sup> Chapter 2 provides an explanation of these targets. See UNAIDS (2014). *90-90-90: an ambitious treatment target to help end the AIDS epidemic*. Geneva: UNAIDS.

# The role of parliamentarians in ending the global AIDS epidemic

## As legislators

As lawmakers, parliamentarians can develop, review and enact legislation to expand access to treatment. Such an agenda should include legislation to:

- guarantee a right of access to essential HIV treatment through government programmes;
- introduce public health-sensitive intellectual property right legislations to enhance availability of more affordable generic drugs;
- enhance procurement supply capacities;
- provide a framework for sustainable financing of HIV treatments, through social insurance, trust funds, levies or other innovative mechanisms; and
- guarantee good-quality treatment and care services that protect people living with HIV from stigma and discrimination when accessing health services.

## In overseeing budgets and programmes

In their budget oversight role, parliamentarians can:

- ensure that gaps in the funding for treatment costs are identified and addressed;
- advocate for innovative financing of treatment programmes from domestic sources, regardless of the fact that external aid is being reduced, as part of their own contribution to the local responses;
- influence the funding levels provided for treatment programmes and ensure that funds are invested strategically and efficiently; and
- prioritize resources to maximize impact and ensure that resources are directed towards populations whose unmet needs are the greatest.

In overseeing programmes, parliamentarians can:

- monitor the work of national AIDS authorities and other government agencies in the planning and implementation of comprehensive national treatment programmes;
- track whether health services are reaching all populations in need, including women, children and marginalized populations; and
- investigate whether and ensure governments are respecting their international commitments to scale up HIV treatment.



## As representatives and opinion leaders

Parliamentarians can:

- ensure that access to HIV treatment remains a national political priority, working with colleagues and stakeholders to build a broad-based movement in support of expanded access;
- raise awareness about the urgency of treatment needs and the gaps in funding to meet them, working through the media, including social media, as part of a broader campaign to Fast-Track treatment programmes;
- conduct public consultations and constituency visits to ensure that laws and policies are informed by the concerns of those at the frontline, including representatives of the medical professions, people living with HIV and marginalized groups, so that national policymakers fully understand the local challenges to scaling up treatment; and
- exchange expertise and advice on effective approaches to leadership on AIDS with parliamentarians in other countries. IPU and UNAIDS convene global and regional meetings that bring parliamentarians together to build capacity and strengthen leadership.<sup>3</sup>

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<sup>3</sup> IPU and UNAIDS convene meetings for MPs to coincide with regional and international events, e.g. International AIDS Conference, Washington, 2012: <http://www.ipu.org/splz-e/aids12.htm>; opportunities are also provided for discussion of AIDS at parliamentary assemblies, e.g. Joint Parliamentary Assembly of the African, Caribbean and Pacific States and the European Union, 2014; Francophone Parliamentary Assembly, 2013.



Mobile clinics are often frontline sources of information about HIV prevention, testing and treatment. © The Global Fund / Efrem Lukatsky

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At the **First Global Parliamentary Meeting on HIV/AIDS** (Manila, 2007), parliamentarians agreed to the following:<sup>4</sup>

- We should take advantage of our position as leaders in society to do everything possible to break the silence about HIV/AIDS and encourage openness when discussing the epidemic. We are in a unique position to speak out against stigma, discrimination, gender inequality and other drivers of the epidemic, and to demand that governments take action.
- We are concerned that access to treatments for people living with HIV/AIDS is restricted by the fact that the necessary drugs are not affordable in many countries.
- While endorsing strong action to reduce vulnerability to HIV of women, children and young people, we are concerned that others are neglected in the response to HIV/AIDS. They include gay men and other men who have sex with men, people who use drugs, sex workers, people in prison, refugees and internally displaced persons, and people with disabilities.
- Only when we acknowledge that all people, including the most ostracized, need access to prevention, treatment, care and support will we be able to develop national strategic plans that bring evidence-informed HIV prevention and treatment to scale and act on the drivers of the epidemic.

In the **Political Declaration on HIV and AIDS** (2011), governments at the United Nations General Assembly committed to:<sup>5</sup>

- overcoming legal, regulatory or other barriers that block access to treatment, care and support, medicines, commodities and services; and
- making improvements to legislation, regulatory policy, procurement and supply chain management in order to accelerate and intensify access to affordable and good-quality medicines and treatment commodities.

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4 IPU (2007). *Final conclusions: first global parliamentary meeting on HIV/AIDS – parliaments and leadership in combating HIV/AIDS*. Manila, Philippines, 28–30 November 2007.

5 United Nations (2011). *Political declaration on HIV and AIDS: intensifying our efforts to eliminate HIV and AIDS*. New York: United Nations, paras 24 and 42.



HIV treatment consists of antiretroviral drugs that have to be taken every day of a person's life.  
© UNAIDS/J. Ose

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Key recommendations to governments in the **International Guidelines on HIV/AIDS and Human Rights** (2006) include the following:<sup>6</sup>

- Enact legislation to provide for the regulation of HIV-related goods, services and information, to ensure safe and effective medication at an affordable price.
- Take measures necessary to ensure for all people, on a sustained and equal basis, the availability and accessibility of safe and effective medicines.
- Pay particular attention to vulnerable individuals and populations.

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<sup>6</sup> Office of the High Commission on Human Rights (OHCHR) and UNAIDS (2006). *International guidelines on HIV/AIDS and human rights*. Geneva: OHCHR and UNAIDS.

# Accelerating progress: the Fast-Track approach ending the AIDS epidemic by 2030

## 90-90-90: treatment targets to end the global AIDS epidemic

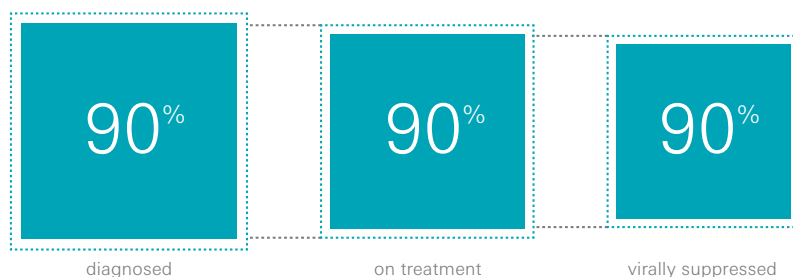
The Fast-Track approach is aimed at both scaling up HIV prevention and treatment services and ending related discrimination. In an effort to galvanize national scale-up efforts, UNAIDS has set the following global targets for 2020:<sup>7</sup>

- **90% of people living with HIV will know their HIV status.**
- **90% of people with diagnosed HIV infections will receive sustained antiretroviral therapy.**
- **90% of people receiving antiretroviral therapy will have viral suppression.**

For the 2030 horizon, each of these targets rises to 95%.

By achieving these ambitious targets and scaling up prevention activities, the world can end the AIDS epidemic as a major global health threat by 2030, which will generate profound health and economic benefits. But action is required now – particularly in the period 2015 to 2020 – to lay the foundations for success. The chapters that follow describe the actions required to make this ambition a reality.

**Figure 1. The 90-90-90 targets**



<sup>7</sup> UNAIDS (2014). Fast-track: ending the AIDS epidemic by 2030. Geneva: UNAIDS; UNAIDS (2014). *90-90-90: an ambitious treatment target to help end the AIDS epidemic*. Geneva: UNAIDS.

## The global epidemic

HIV has spread to every region in the world. It can affect people from all parts of society, whether they live in cities or rural areas, regardless of their age, gender, wealth or sexual orientation.

In parts of sub-Saharan Africa and the Caribbean, HIV prevalence is high throughout the general population. But women and girls are disproportionately affected: gender inequality and violence against women and girls increase their risk of acquiring HIV. In sub-Saharan Africa, women comprise 58% of people living with HIV. Studies have shown that intimate partner violence increases women's vulnerability to in high-prevalence settings.<sup>8</sup>

HIV also has a severe impact on children and young people. AIDS claims the lives of adults in the prime of their lives, many of whom are parents. Adolescents living with HIV are the only age group where AIDS-related deaths are not declining; in fact, AIDS is the leading cause of death among adolescents in Africa.<sup>9</sup>

In some countries, the epidemic mainly affects people in situations of heightened vulnerability, such as sex workers, gay men and other men who have sex with men, transgender people and people who inject drugs. Women whose husbands or partners engage in such high-risk behaviours often account for a significant proportion of the infections, a pattern typical in Asia, Eastern Europe, Latin America and North America.

## Saving lives

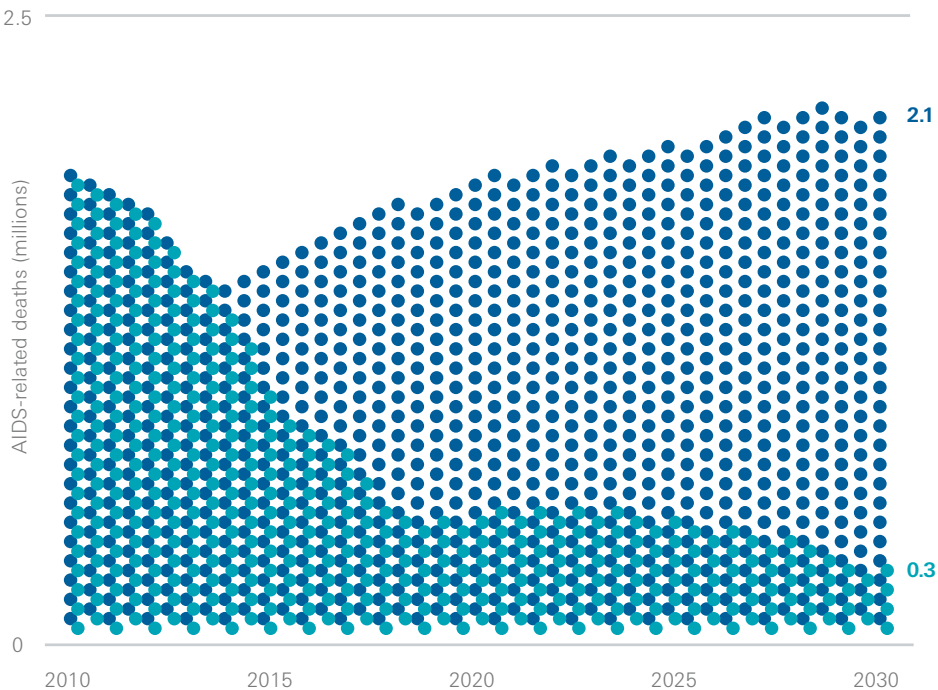
Achieving the 90-90-90 treatment targets and rolling out prevention tools, according to the modelling on which they were based, would end the AIDS epidemic as a major global health threat by 2030. Combined with scale-up of other prevention tools, it would reduce the annual number of new infections after 2030 by 90% and the number of AIDS deaths by 80%, saving 21 million lives (Figure 2).

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8 Jewkes RK, Dunkle K, Nduna M, Shai N (2010). Intimate partner violence, relationship power inequity and incidence of HIV infection in young women in South Africa: a cohort study. *Lancet*. 376(9734):41–48. See also Maharaj P, Munthree C (2007). Coerced first sexual intercourse and selected reproductive health outcomes among young women in KwaZulu-Natal, South Africa. *J Biosoc Sci*. 39(2):231–244.

9 World Health Organization (WHO) (2014). *Health for the world's adolescents: a second chance in the second decade*. Geneva: WHO, <http://apps.who.int/adolescent/second-decade/>.

**Figure 2. AIDS-related deaths in low- and middle-income countries, 2010–2030: status quo (2013 treatment coverage levels) versus the Fast-Track scenario**



**21 million**

Total AIDS-related deaths averted,  
2015–2030

- Ambitious targets
- Constant coverage

Source: UNAIDS.

The targets relate to all phases of care, from testing to treatment. HIV testing, an entry point to both treatment and prevention, should comply with the “5 Cs”:

1. Consent.
2. Confidentiality.
3. Counselling.
4. Correct test results.
5. Connection to prevention, care and treatment.

For all individuals who are diagnosed with HIV, it is recommended they should be offered HIV treatment, along with the relevant information to make an informed decision about treatment initiation. New evidence demonstrates the benefit of starting people early on treatment – data from the START trial indicate that the risk of progression to AIDS diagnosis, other serious illnesses or death was reduced by 53% among people who initiated early treatment.<sup>10</sup>



© Victor Suarez Diaz

“Ending AIDS will require uninterrupted access to lifelong treatment for tens of millions of people. Although we do not yet have a cure for AIDS, in most cases treatments can stop the progression of HIV disease, especially if people commence treatment before their immune system is seriously damaged. Treatment also plays a critical role in HIV prevention and has dramatically reduced cases of mother-to-child transmission in my country and many others across the world.”

**Víctor Suárez Díaz**, MP, Dominican Republic

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10 National Institutes of Health (NIH) (2015). *Starting antiretroviral treatment early improves outcomes for HIV-infected individuals*. Bethesda, MD: NIH, 27 May, <http://www.niaid.nih.gov/newsreleases/2015/Pages/START.aspx>.



### Treatment for prevention

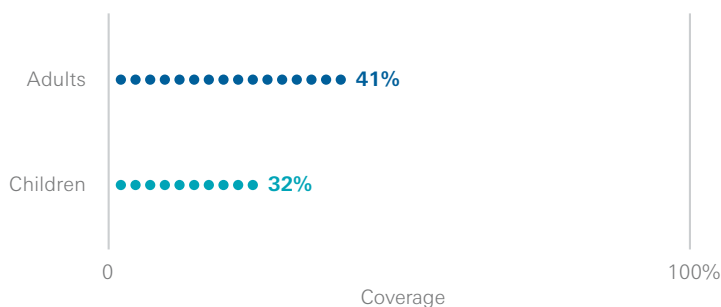
The 90-90-90 targets are based on the assumption that HIV treatment not only keeps people alive but also prevents further HIV transmission. By suppressing the amount of virus in a person's body ("viral suppression"), HIV treatment reduces a person's risk of HIV transmission to almost zero. Once a person starts treatment, support is needed to ensure adherence to daily treatment regimens to achieve viral suppression.

Treatment is recommended for pregnant women living with HIV to prevent mother-to-child transmission. Antiretrovirals may also benefit people who engage in behaviours that put them at higher risk of acquiring or transmitting HIV. Recent studies are showing that the use of antiretroviral medicines by people at major risk of contracting HIV can prevent transmission when in combination with other prevention methods, such as condoms.<sup>11</sup>

### The need for increased coverage of services

Among the 36.9 million [34.3 million – 41.4 million] people living with HIV globally, only 41% [38%–46%] of the adults and 32% [30%–34%] of the children have access to treatment (Figure 3).<sup>12</sup>

**Figure 3. HIV treatment coverage for adults and children, 2014**



Source: UNAIDS 2014 estimates.

11 See UNAIDS (2014). *Fast track: ending the AIDS epidemic by 2030*. Geneva: UNAIDS; and World Health Organization (WHO) (2013). *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach*. Geneva: WHO, para 5.2.4.

12 There are many reasons why children lack access to treatment. These include missed opportunities for HIV testing, out-of-stock key HIV drugs, lack of family resources for travel to clinics, clinics located far from the community, fear of stigma and lack of health-care worker training. Often children require complex and expensive treatment formulations. See UNAIDS (2014). *The gap report*. Geneva: UNAIDS.

Some countries are making strong progress in scaling up access to treatment. Globally, the number of people receiving HIV treatment has increased from 2.2 million in 2005 to over 15 million in 2015, but treatment coverage varies from region to region. The progress has been significant in Latin America and the Caribbean but much slower in the Middle East and North Africa, Eastern Europe and Central Asia (Table 1). The reasons for different levels of coverage relate, among others, to health-care system capacity, HIV-related stigma and discrimination, access to funding and the cost of treatment. More information about the situation in specific countries can be obtained from country progress reports submitted to UNAIDS.<sup>13</sup>

**Table 1. HIV treatment coverage by region, 2014<sup>14</sup>**

Region	Percentage of adults aged 15 years and older living with HIV receiving treatment
Sub-Saharan Africa	43 [39–47]
Middle East and North Africa	14 [9–19]
Asia and the Pacific	36 [32–41]
Latin America	47 [40–56]
Caribbean	44 [33–54]
Eastern Europe and Central Asia	18 [16–21]

13 Country data are published in the annual UNAIDS gap report, and progress is summarized in global AIDS response reports available at <http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports>.

14 UNAIDS (2014). *The gap report*. Geneva: UNAIDS. UNAIDS estimates the proportion of people receiving HIV treatment, as opposed to those eligible to receive it according to national or international guidelines, for which the criteria vary over time and by country.



Information and counselling on HIV testing are critical to the AIDS response in the Russian Federation, as elsewhere. © WHO /Sergey Volkov

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### **Making treatment affordable**

The cost of HIV treatment can be a significant obstacle to access. The cost of a standard combination of first-line treatment, which exceeded US\$ 10,000 per person per year in 2000, had fallen to around US\$ 150 by 2014<sup>15</sup> because of the increased availability of HIV medicines from generic pharmaceutical companies. Cost remains a key concern, however, particularly for newer treatments (i.e. second- and third-line treatments) still under patent.

### **Expanding epidemics**

Particularly troubling is the low coverage of HIV treatment in regions and countries that are still seeing rapid growth of new infections and a rise in AIDS-related deaths, such as the Middle East and North Africa, Eastern Europe, Central Asia and some countries in Asia (e.g. Bangladesh, Indonesia and the Philippines). Even countries that have a low HIV prevalence at the

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15 Médecins Sans Frontières (MSF) (2014). *Untangling the web of antiretroviral price reductions*. Geneva: MSF.

national level can have high HIV prevalence among key groups, such as young gay men and other men who have sex with men in Western Europe, North America and Latin America.<sup>16</sup>

Prevalence rates are higher in many countries among gay men and other men who have sex with men, transgender people, people who use drugs, sex workers, and people in prisons, than among the general population. Stigma and discrimination faced by these populations are barriers to accessing HIV services.

### **Key populations have higher HIV prevalence**

Socially marginalized people are more affected by HIV than the general population. Compared with other adults of reproductive age, HIV prevalence is:<sup>17</sup>

- 12 times higher among sex workers;
- 19 times higher among gay men and other men who have sex with men;
- 28 times higher among people who inject drugs; and
- 49 times higher among transgender women than among the general population in Gap and MDG report.

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<sup>16</sup> UNAIDS (2014). *The gap report*. Geneva: UNAIDS.

<sup>17</sup> Data reported in UNAIDS (2014). *The gap report*. Geneva: UNAIDS, p. 127.

# Access to HIV treatment: a human right

## Introduction

A human rights-based response to HIV is effective, because it ensures that services reach the most vulnerable in society – and because people are more likely to come forward for testing and treatment if they are confident their rights will be respected. A human rights-based approach addresses the social drivers of HIV, such as gender inequalities, social marginalization, stigma and discrimination. Such an approach requires that treatment services respect the dignity of all people living with HIV.

The internationally recognized human rights that are relevant to HIV treatment include:

- the right to health;
- the right to life;
- the right to non-discrimination; and
- the right to enjoy the benefits of scientific progress.

This chapter describes the practical actions parliamentarians can take to ensure that HIV responses are human rights-based, with an emphasis on the right to health and the right to non-discrimination.

The right to health is enshrined in the Universal Declaration of Human Rights and recognized in key international treaties, including the International Covenant on Economic, Social and Cultural Rights,<sup>18</sup> the Convention on Elimination of All Forms of Discrimination Against Women<sup>19</sup> and the Convention on the Rights of the Child.<sup>20</sup> The core obligations of governments in relation to the right to health include the provision of access to health facilities and essential medicines.<sup>21</sup>

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18 United Nations (1966). *International Covenant on Economic, Social and Cultural Rights*. 169 countries have signed or ratified this convention. Countries that have neither signed nor ratified are Andorra, Antigua and Barbuda, Botswana, Bhutan, Brunei Darussalam, Myanmar, Fiji, Haiti, Kiribati, Malaysia, Marshall Islands, Micronesia (Federated States of), Mozambique, Nauru, Oman, Qatar, Saint Kitts and Nevis, Saint Lucia, Samoa, Saudi Arabia, Singapore, South Sudan, Tonga, Tuvalu, United Arab Emirates and Vanuatu.

19 United Nations (1979). *Convention on Elimination of All Forms of Discrimination Against Women*. 189 countries have ratified this convention. Countries that have not ratified or acceded are Iran (Islamic Republic of), Palau, Somalia, Sudan, Tonga and the United States of America.

20 United Nations (1989). *Convention on the Rights of the Child*. All countries are party to this convention, except the United States.

21 In 2001, the United Nations Commission on Human Rights confirmed that the right to the highest attainable standard of health includes access to antiretroviral therapy for HIV.

# What parliamentarians can do

## Parliamentarians as legislators

In their role as legislators, parliamentarians can ensure that people living with HIV enjoy a legal right to access HIV treatments. Table 2 sets out mechanisms that can be used to guarantee such access in law and policy. These mechanisms include national legislation and constitutional recognition of the right to health.

**Table 2. Legal and policy mechanisms for promoting access to HIV medicines**

Legal mechanism	Explanation	Country examples
<b>Constitutional recognition of the right to health and the right to life</b>	<p>Inclusion of the right to health in the national constitution signals the highest level of government commitment. National constitutions can be revised to specifically include the right to health, including the right to essential medicines for HIV treatment.</p> <p>Constitutional guarantees of the right to life have been interpreted to include a right of access to essential medicines in some countries.</p>	<p>Most national constitutions include the right to health. Courts in some countries have interpreted this right specifically to include access to HIV treatments. For example:</p> <ul style="list-style-type: none"><li>• The Constitutional Court in Colombia invoked the constitutional right to health to require the Government to provide HIV treatments.<sup>22</sup></li><li>• Brazil's constitutional right to health has been interpreted by the courts to include access to HIV treatment.<sup>23</sup></li><li>• The Supreme Court of India has ordered the Government to make HIV treatments available based on the right to life.<sup>24</sup></li></ul>

22 Case T-271/95 of 23 June 1995; see World Health Organization (WHO) (2004). *Ruling for access: leading court cases in developing countries on access to essential medicines as part of the fulfilment of the right to health*. Geneva: WHO, p. 24.

23 Nunn A, Massard da Fonseca E, Bastos FI, Gruskin S (2009). AIDS treatment in Brazil: impacts and challenges. *Health Affairs*. 28(4):1103–1113.

24 *Sankalp Rehabilitation Trust v. Union of India* W.P. (C) 512/1999, orders made in 2010 and 2013. See <http://www.lawyerscollective.org/hiv-and-law/current-cases.html>.

Legal mechanism	Explanation	Country examples
<b>Recognition of the right to health under international law as an integral part of domestic law</b>	The constitutions of some countries provide that international human rights laws are automatically integrated into domestic law.	This approach has been adopted to introduce a right to health in the domestic laws of several countries, including a landmark case in Argentina establishing a right to HIV treatment. <sup>25</sup> The Government in that case was found responsible for ensuring such access because it had ratified treaties providing for the right to health.
<b>Laws and policies that guarantee a right of access to all essential medicines</b>	Legislation can provide rights to access drugs listed on an essential medicines list at no charge or at a subsidized price. Most countries maintain an essential medicines list. Adding an HIV drug to such lists may not require legislation but only an updating of regulations or policies. Laws and policies relating to universal health coverage, market competition and pricing can also support access to HIV treatment.	The World Health Organization maintains a Model Essential Medicines List that includes 18 HIV drugs, but the number actually included on national lists varies between countries: <sup>26</sup> <ul style="list-style-type: none"> <li>• Brazil: 22</li> <li>• China: 3</li> <li>• Indonesia: 5</li> <li>• Kenya: 12</li> <li>• Malawi: 10</li> <li>• Philippines: 11</li> <li>• South Africa: 37</li> </ul>
<b>Laws and policies that provide a specific right of access to HIV treatment</b>	Some countries have passed HIV-specific laws on access to treatment. HIV-specific laws can highlight the priority and urgency of the national HIV response.	<ul style="list-style-type: none"> <li>• Legislation in Cambodia establishes a right to primary health care for people with HIV.<sup>27</sup></li> <li>• HIV legislation in Kenya requires the Government, to the maximum extent permitted by available resources, to ensure access to essential health services and medicines at affordable prices by people with HIV and those exposed to risk of HIV.<sup>28</sup></li> <li>• The Philippine HIV law includes a right for all people living with HIV to basic health services in public hospitals.<sup>29</sup></li> <li>• The United Republic of Tanzania's HIV law includes a right to HIV treatment.<sup>30</sup></li> <li>• Viet Nam's HIV law includes a legal right to access HIV treatment.<sup>31</sup></li> </ul>

25 *Asociación Benghalensis et al. v. Ministerio de Salud y Acción Social*, Constitutional Court, File No. A.186.XXXIV, 1 June 2000 (2000-323-1339); see World Health Organization (WHO) (2004). *Ruling for access: leading court cases in developing countries on access to essential medicines as part of the fulfilment of the right to health*. Geneva: WHO, p. 24.

26 IMS Institute for Health Informatics (IHI) (2015). *Understanding the role and use of essential medicines lists*. Parsippany, NJ: IHI.

27 Law on the Prevention and Control of HIV/AIDS of 2002, Article 26, (Cambodia).

28 HIV and AIDS Prevention and Control Act 2006, Section 19(2) (Kenya).

29 Philippine AIDS Prevention and Control Act of 1998, Section 22 (Philippines).

30 HIV and AIDS (Prevention and Control) Act, Section 24 (United Republic of Tanzania).

31 Law on HIV/AIDS Prevention and Control of 2006, Article 39 (Viet Nam).



Face-to-face contact is often the only way to share information about HIV, especially among key populations. © The Global Fund / Miguel Samper

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### **Action to address stigma and discrimination**

Discrimination can be a major barrier to HIV testing and treatment. Surveys through the People Living with HIV Stigma Index<sup>32</sup> reveal that substantial percentages of people living with HIV in countries around the world have experienced violence, loss of employment or housing, or denial of essential health or social services as a result of their HIV status. Especially concerning is the high frequency of stigma in health-care facilities.<sup>33</sup>

There is mounting evidence that stigma and discrimination are barriers to HIV testing and treatment. The attitudes of some health-care workers are judgemental and can result in discriminatory acts. Such acts include minimizing contact with people living with HIV, denying assistance to pregnant women, delaying treatment and demanding additional payment for services.

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32 The People Living with HIV Stigma Index is a stigma measurement tool that operationalizes the principle of greater involvement of people living with HIV (GIPA). More information can be found at <http://www.stigmaindex.org/about-index>.

33 UNAIDS (2012). Treatment 2015. Geneva: UNAIDS, p. 20.



For example:

- A survey of health-care workers in India found that 20% of doctors sometimes refused to treat people living with HIV.<sup>34</sup>
- A study in Bangladesh found that 80% of nurses and 90% of doctors exhibited discriminatory behaviour and that health-care workers were pressured by their spouses to stop providing care to people living with HIV.<sup>35</sup>
- A study of health-care workers in Nigeria found that 9% of professionals reported denying care to people living with HIV.<sup>36</sup>
- A review of studies in the eastern Mediterranean region revealed health-care discrimination against people living with HIV, including neglect, differential treatment, denial of care, verbal abuse, avoidance and isolation of patients, the incineration of bedding upon discharge, patient charges for the cost of infection control supplies, and overuse of protection, regardless of physical contact.<sup>37</sup>

Parliamentarians can support legal and policy initiatives to eradicate stigma and discrimination in the delivery of health care. Legislation can protect people from discrimination through penalties or liability for compensation. Table 3 describes legal mechanisms to protect against discrimination, in addition to ethical guidelines on duty of care, confidentiality and consent. It should be noted, however, that the implementation of a law is as important as the law itself and parliamentarians can also help ensure that protective laws are well implemented.

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34 Kurien M, Thomas K, Ahuja R, Patel A, Shyla PR, Wig N, Mangalani M (2007). Screening for HIV infection by health professionals in India. *Natl Med J India*. 20(2):59–66; see also Bharat S (2011). A systematic review of HIV/AIDS-related stigma and discrimination in India: current understanding and future needs. *Sahara J*. 8(3):138–149.

35 Ullah AKM (2011). HIV/AIDS-related stigma and discrimination: a study of health care providers in Bangladesh. *J Int Assoc Provid AIDS Care*. 10(2):97–104.

36 Reis C, Heisler M, Amowitz LL, Moreland RS, Mafeni JO, Anyamele C, Iacopino V (2005). Discriminatory attitudes and practices by health workers toward patients with HIV/AIDS in Nigeria. *PLoS Med*. 2(8):e246.

37 Bernard D and Hermez J (2011). *HIV stigma and discrimination in health care settings in the Eastern Mediterranean Region*. Presented at the conference Family, the Millennium Development Goals and AIDS in the Middle East and North Africa region: linkages, challenges and opportunities, Doha.



© Petra Bayr

“As legislators, we can strengthen the AIDS response by ensuring that the laws affecting people living with HIV are protective and empowering, rather than stigmatizing. Punitive laws that criminalize people living with HIV and key populations can drive the very people we need to reach away from the treatment services they so urgently need. Instead, we need laws that protect against stigma and discrimination so that people don’t hesitate in seeking out testing, care and treatment. On treatment, people living with HIV can have normal and productive lives. Also, the more people we treat, the more we can prevent HIV transmission in the community. Protecting the rights of the vulnerable also protects public health; it’s in everyone’s interests.”

**Petra Bayr, MP, Austria**

Laws that penalize and act as barriers to services for key populations, such as laws that criminalize same-sex sexual relations and mandatory testing laws, should be replaced with laws that protect against discrimination and support access to voluntary HIV testing, counselling and treatment. IPU and the United Nations Development Programme (UNDP) have published separate guidance for parliamentarians on non-discriminatory legal frameworks for HIV responses.<sup>38</sup> The guide aims to encourage and assist parliamentary scrutiny of legislation that impedes effective HIV interventions. It highlights the processes applied in selected parliaments that led to the adoption of laws with a positive impact on the AIDS response. Moreover, the IPU and UNAIDS have identified other key human rights programmes that parliamentarians can encourage, including trainings for police and law enforcement and mainstreaming human rights into national strategic plans.<sup>39</sup>

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38 See IPU (2013). *Effective laws to end HIV and AIDS: next steps for parliaments*. Geneva: IPU and United Nations Development Programme, [http://www.ipu.org/PDF/publications/law\\_hiv\\_en.pdf](http://www.ipu.org/PDF/publications/law_hiv_en.pdf).

39 IPU, United Nations Development Programme (UNDP) and UNAIDS (2007). *Taking action against HIV and AIDS: a handbook for parliamentarians*. Geneva: IPU, UNDP and UNAIDS, <http://www.ipu.org/pdf/publications/aids07-e.pdf>.

**Table 3. Legal mechanisms to protect against discrimination**

Legal mechanism	Explanation	Country examples
<b>Constitutional protections</b>	The constitutions of some countries provide protection from discrimination on the grounds of health, disability, HIV status or other status.	The Constitution of Ecuador (2008) provides that no one shall be discriminated against by reason of the person's HIV status. <sup>40</sup>  The Constitution of Fiji (2013) states that a person must not be unfairly discriminated against, directly or indirectly, on the grounds of his or her health status. <sup>41</sup>
<b>General human rights laws</b>	Some governments have updated human rights laws or anti-discrimination laws to include HIV. While HIV is not mentioned specifically in some cases, legal protection is provided based on "health status," "disability" or "other status." Courts or bodies administering these laws may interpret these terms to include HIV and AIDS.	South Africa's Equality Act (2000) addresses discrimination against people living with HIV, including in the delivery of health and other services. <sup>42</sup>  Courts have defined HIV as a disability under federal anti-discrimination law in the USA. <sup>43</sup>
<b>HIV-specific laws</b>	Some countries prohibit discrimination through HIV-specific legislation. Provisions can protect people living with or assumed to have HIV, as well as their associates, caregivers and family members.	Countries with HIV-specific laws prohibiting discrimination based on HIV status include Cambodia, Kenya, Mongolia, Nigeria, the Philippines, the United Republic of Tanzania and Viet Nam. For example, the Philippine AIDS Prevention and Control Act of 1998 provides that no person shall be denied a health-care service or be charged with a higher fee on account of actual, perceived or suspected HIV status. <sup>44</sup>

40 Constitution of Ecuador (2008), Article 11(2).

41 Constitution of Fiji (2013), Article 26(3).

42 Promotion of Equality and Prevention of Unfair Discrimination Act (2000), s.34.

43 *Bragdon v. Abbott*, 524 U.S. 624 (1998).

44 Philippine AIDS Prevention and Control Act of 1998, s.40.



© Faustine Ndagulile

“The Tanzania Parliamentarians AIDS Coalition (TAPAC) has championed the rights-based approach to testing and treatment. The Coalition pushed for the introduction of East Africa’s first human rights-based AIDS law, Tanzania’s HIV and AIDS Prevention and Control Act. This was a proud achievement. The law provides rights to voluntary testing and treatment, confidentiality, consent and protection from discrimination.

TAPAC has also advocated for an act establishing Tanzania’s HIV/AIDS Trust Fund. The act will enable the country to mobilize the much-needed domestic and external resources to bridge the existing gap in the fight against AIDS.

There’s much more work to do, for example to ensure people know about their legal rights and to educate health-care workers. Other laws need updating so they don’t undermine rights of sex workers, people in prison, people who use drugs, men who have sex with men and transgender people to access HIV/AIDS prevention and care interventions. Despite the many challenges, Tanzania is making steady progress to ensure its people are accessing prevention packages as well as care and treatment interventions, in the process saving many lives.”

**Dr. Faustine Ndagulile**, MP, United Republic of Tanzania

### **Parliamentarians as overseers of budgets and programmes**

The right to health can be supported through budget and programme oversight to ensure that a comprehensive national HIV treatment response is in place. Parliamentarians can:

- Monitor whether policies and practices on procurement and distribution ensure a reliable and sustainable supply chain of medicines. It is critically important to avoid stockouts or shortages of HIV medicines: HIV treatment must be taken daily, and interruptions can place patient health and lives at risk.
- Monitor whether HIV testing and counselling services are reaching vulnerable populations and whether consideration has been given to the potential benefits and risks of innovative approaches, such as home-based testing and self-testing.

- Monitor government action to expand community-level access to testing and treatment, for example by adopting policies to:
  - encourage physicians to delegate HIV treatment to primary care nurses or other health staff where appropriate;
  - ensure that HIV treatments are made available at local outlets such as pharmacies and community health posts; and
  - involve civil society organizations in the delivery of services and/or establish community-based service delivery, ensuring integration with the health system, where appropriate.

Programmes should aim to stop people dropping out of care. This means addressing obstacles to access such as:

- high out-of-pocket costs for medicines, examinations and transport to clinics;
  - lack of accessible testing and treatment sites located in the community;
  - stigma and discrimination, including fear of judgmental health care providers; and
  - lack of services accessible to migrants, displaced people, women and other marginalized populations.
- Hold governments accountable for implementing programmes that are non-discriminatory and reach all populations in need. Programmes should ensure that key populations such as sex workers, people who inject drugs, prisoners, gay men and other men who have sex with men and transgender people enjoy access to HIV testing and treatment without discrimination, and that health services are able to respond to the specific needs of women and girls living with HIV.
  - Encourage integration of HIV services with other clinical services, such as maternal and child health, tuberculosis and reproductive health services, to ensure patient-centred care. Service integration can help to break down stigma and provide better-coordinated care that takes into account the health and well-being of the whole person. Family-centred service integration can help to ensure that women and children receive the care they need when they need it.

### Checklist: Oversight of national HIV treatment programmes

- ✓ Have measures been taken to cap the price of HIV treatments charged to patients?
- ✓ Are HIV treatments included in the country's essential medicines list?
- ✓ Have steps been taken to ensure that supplies of HIV medicines are well-stocked (i.e. that they do not run out, are not overstocked and are not expired)?
- ✓ Are paediatric treatments available?
- ✓ Are HIV medicines available for the prevention of mother-to-child transmission, post-exposure prophylaxis for health professionals, rape survivors and HIV-negative sexual partners in serodiscordant couples, and for other prevention approaches)?
- ✓ Does the government support the active participation of people living with HIV in the design, development and implementation of national treatment programmes?
- ✓ Do health-care services provide accurate information on HIV treatment options, including where and how to access treatment, care and support?
- ✓ Are health-care workers trained in and aware of their responsibilities to provide treatment and care without discrimination?
- ✓ Are treatment education programmes provided to people living with HIV and their caregivers?
- ✓ Have measures been taken to integrate HIV treatment services with maternal and child, reproductive and other health services?

### Zimbabwe: Public Accounts Committee working with communities<sup>45</sup>

In 2006, the Parliament of Zimbabwe's Public Accounts Committee conducted a project in partnership with a local non-government organization (NGO), the Women and AIDS Support Network, to assess the national HIV treatment programme. The project analysed whether HIV services were reaching the most vulnerable people, especially women and children, in a high-priority district.

To identify treatment obstacles, a group of people living with HIV conducted a survey of community needs. The survey found that families often give higher priority to paying for food, housing and school fees

45 Adapted from African Parliamentary Poverty Reduction Network (2007). *APRN Newsletter*. 3(2):13.

than for medicines. The costs of treatments and medical consultations were often considered too high. The cost of transportation to clinics and stigma in the community and health facilities were also deterrents.

After the survey, the Public Accounts Committee met with health service providers and the community to discuss measures to increase treatment access. Its recommendations included providing access to treatment at primary health centres to reduce transport costs, establishing a monitoring framework involving parliamentarians and the community, and periodic reporting on the use of public funds for HIV services.

### **Parliamentarians as representatives and opinion leaders**

As representatives and opinion leaders, parliamentarians can:

- visit the clinics that provide HIV testing and treatment in their constituencies and meet with local organizations representing people living with HIV to gather first-hand knowledge of the challenges faced in accessing treatment; seek suggestions on how treatment services can be strengthened and reach all who need them, including marginalized populations; find out about the difficulties families face in getting children tested and treated;
- engage with key stakeholders, such as professional associations of health care workers, media organizations, religious leaders and organizations of people living with HIV, in calling for expanded access to treatment;
- raise awareness among parliamentary peers and constituents about the rights-based approach to health and how it applies to essential medicines, including HIV treatments; publicly champion access to treatment as a human right; and
- publicly challenge the fears, myths and misconceptions about HIV and AIDS and insist that responses be based on medical science and evidence, rather than ill-informed prejudices; speak out against stigma and discrimination.<sup>46</sup>

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46 IPU (2014). *HIV and AIDS in Viet Nam: facing the challenges*. Geneva: IPU. <http://www.ipu.org/pdf/publications/hiv-vietnam-en.pdf>.

# Case study

## HIV treatment and the right to health in South Africa



© MB Goqwana

“South Africa has made tremendous progress in addressing HIV and AIDS in recent years. Since 2010 more than 20 million South Africans have tested for HIV and treatment services are currently reaching more than 2.8 million people. Yet we cannot become complacent; AIDS remains an unprecedented health crisis for South Africa and we have witnessed more AIDS-related deaths than any other country in the world. As parliamentarians, it is vitally important that we take a public stance against HIV. As community leaders, we are well placed to alert the public to the importance of early testing and treatment to save lives, to mobilize support and to challenge the stigma that deters people from seeking care. We must focus our efforts on the ground and ensure we reach those populations and locations that risk being left behind.”

**Dr MB Goqwana, MP, South Africa**

Over 6 million South Africans were living with HIV in 2014. As of 2014, an estimated 18.9% [17.9%–19.9%] of adults aged 15–19 were living with HIV. Young women are the worst affected. Women’s poverty, lowly status and subjection to gender-based violence make them more vulnerable to HIV. Other vulnerable populations include sex workers and their clients, poor people living in informal settlements, people who use drugs and gay men and other men who have sex with men.

### **Emergence of a national campaign for HIV treatment**

A lack of leadership fuelled the rapid growth of South Africa’s HIV epidemic in the 1990s and early 2000s. The need for action was highlighted by the Parliament’s Joint Monitoring Committee on the Improvement of the Quality of Life and Status of Women. The Committee conducted extensive public hearings to examine the impact of AIDS on women and girls in 2001 and considered the rights of women under the Constitution of South Africa,



which states that everyone has the right to access health-care services.<sup>47</sup> The Committee concluded that women have a right to HIV medicines to reduce the risk of mother-to-child HIV transmission and to prevent HIV infection after rape.

When the Government failed to act on the Committee's recommendations, a group of community activists known as the Treatment Action Campaign (TAC) won a decision from South Africa's Constitutional Court ordering the Government to provide HIV medicines to prevent transmission from mothers to their babies. The decision was based on the rights to life and health contained in the Constitution. The Government was held responsible for expanding access to HIV medicines in all public health centres to prevent mother-to-child transmission.<sup>48</sup>

TAC has successfully litigated the right to health on several other occasions, winning access to HIV treatment for people in prison and challenging the multinational pharmaceutical companies to make HIV treatments affordable.<sup>49</sup> In each of these cases, litigation was backed by campaigning strategies such as protest marches, media and social mobilization to build political support for expanded access.

Eventually responding to community pressure, the Government established the world's largest national HIV treatment programme. Key to this success was legal and political recognition of the right to health in response to a vibrant activist movement.

Parliamentarians are playing a leadership role in championing the importance of HIV testing and treatment among their constituents. As part of the national testing campaign launched in 2010, the Parliament offers HIV counselling and testing services to its own members. In 2013 parliamentarians volunteered for HIV testing as part of a two-day campaign to dispel the stigma of testing and lead by example.

### **Joint Committee on HIV and AIDS**

A regional seminar on AIDS hosted by the Parliament and IPU in 2009 recommended the establishment of multi-party parliamentary committees on AIDS, a recommendation subsequently supported by a National

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47 Constitution of South Africa (1996), Article 27.

48 *Minister of Health and Others v. Treatment Action Campaign and Others* (No. 1) (CCT9/02) [2002] ZACC 16; 2002 (5) SA 703; 2002 (10) BCLR 1075 (5 July 2002).

49 See Heywood M (2009). South Africa's Treatment Action Campaign: combining law and social mobilization to realize the right to health. *J Human Rights Practice*. 1(1):14–36.

Assembly resolution. A Joint Committee on HIV and AIDS was thus established with cross-party representation to monitor implementation of the Government's HIV programmes and evaluate related legislation, policies and budgetary allocations. In 2013, the Committee held civil society consultations and meetings on such high-priority issues as access to HIV services in prisons and the health rights of sex workers.

### **Lessons from South Africa**

A cross-party committee on HIV and AIDS is a useful model for parliaments to consider. Such parliamentary committees can act as a link between advocacy organizations and parliament; bring attention to neglected aspects of the national AIDS response, such as the treatment rights of women and key populations (sex workers, people in prison); hold governments accountable for implementing human rights-based approaches to treatment and care; monitor and evaluate progress in treatment scale-up; recommend legislative provisions; and gain priority for prevention and treatment in the national agenda and budget.

IPU produced a guide in 2012 on how to set up a cross-party committee or informal parliamentary group on HIV and AIDS. See: *Raising the Profile of HIV and AIDS in Your Parliament*, <http://www.ipu.org/PDF/publications/hiv-aids-guide-e.pdf>.

# Intellectual property rights and access to affordable medicines

## Introduction

### The TRIPS Agreement

Patents over pharmaceutical products can increase drug prices and constitute a major obstacle to treatment. Intellectual property (IP) protection implies a monopoly over pharmaceutical products for a minimum period of 20 years, preventing competitors from manufacturing and selling lower-cost generic versions.

A country's IP laws are influenced by its trade agreements with other countries. Countries that are members of the World Trade Organization (WTO) are required to comply with the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement stipulates the minimum standards of patent protection that member states are required to have in place, including a minimum 20-year patent period. TRIPS also provides flexibilities that can ensure the local capacities in importing or, when applicable, in producing generic and/or cheaper versions of patented products.

The WTO Doha Declaration on the TRIPS Agreement and Public Health of 2001<sup>50</sup> highlighted how flexibilities in the TRIPS Agreement can be invoked to support access to medicines. The Declaration affirms that the Agreement does not and should not prevent members from taking measures to protect public health and that TRIPS flexibilities can be used to that effect. There are key public health-related TRIPS flexibilities that affect the availability and pricing of antiretroviral medications and other essential medicines; they include, but are not limited to:<sup>51</sup>

- parallel importation;
- strict criteria for patentability;
- “early working” exceptions to facilitate registration of generic medicines;
- compulsory licensing;

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50 Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001.

51 See the basic definitions of these key TRIPS flexibilities in [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260\\_DOHA+10TRIPS\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf).

- scope of pharmaceutical test data protection;
- competition law; and
- transition periods (which includes exemption periods for least developed countries (LDCs)).

Approaches to promoting treatment access are explained in more detail in the sample memo below. The memo is based on a fictional situation in which a “Parliamentary Group on Health” seeks to ensure that its country’s IP laws include TRIPS flexibilities and other measures to support access to treatments.

## Memo

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**To: National AIDS Authority and Ministry of Law and Justice**  
**From: Parliamentary Group on Health**  
**Re: Review of intellectual property laws: actions to support access to HIV treatment and other essential medicines**

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Members of the Parliamentary Group on Health are highly concerned that our country is failing to scale up access to HIV treatment for all in need.

We urge immediate action to ensure that our intellectual property laws support access to affordable medicines. We are concerned that the Government is imposing strict patenting requirements on HIV drugs without consideration of the full range of measures permitted under international trade rules to support treatment access.

We respectfully request your consideration of the following measures:

### **Compulsory licencing**

The Patents Law should be amended to include compulsory licencing and government use. Compulsory licencing occurs when a government allows a company to produce a patented product without the consent of the patent owner. It can also be used to authorize importation of generic drugs. Please consider the experience of other countries that have made effective use of compulsory licencing to expand access to HIV treatments, including Brazil, Ecuador, Thailand, Indonesia, Kenya, Malaysia, Peru, Zambia and Zimbabwe.

### **Parallel importation**

The Patents Law should be amended to permit parallel importation of medicines (imports of a patented medicine from a country where it is already marketed at a lower price). This will enable people requiring HIV drugs in our country to access the drugs at lower cost.

### **Strict criteria of patentability**

The Patents Law should strictly define the criteria for patentability and should exclude patents on new medical uses of known substances. This can prevent “evergreening” of drug patents – the practice of making minor modifications to an existing patented drug as the basis for a patent extension or new patents over existing molecules/products.

### **“Early working” exception**

HIV medicines must be registered with our national Medicines Regulatory Authority before they are placed on the market. We are concerned that this registration process can result in significant delays in generic medicines becoming available. Including an “early working” exception in our Patents Law will allow generic companies to begin developing production of patented medicines to accelerate regulatory approval once the patent expires. Access to generic HIV medicines can also be supported by allowing the Medicines Regulatory Authority to rely on test data from the original patent holder when assessing the safety and efficacy of generic medicines.

### **Voluntary licensing**

We urge the Government to approach the major global pharmaceutical companies to confirm whether they can provide voluntary licences allowing generic HIV drugs to be produced for our country. Some of the global companies may be willing to provide voluntary licences to local generic companies. Some participate in the Medicines Patent Pool, a non-profit patent sharing mechanism used to make cheaper drugs available to developing countries through voluntary licensing.

### **Trade agreements**

Please ensure that our government does not enter into free trade agreements that include more extensive patent protections than those required by the WTO TRIPS Agreement. Please be vigilant to ensure the Government does not enter into trade agreements that restrict the right to health by limiting its ability to take advantage of TRIPS flexibilities in protecting public health.

Thank you for considering these measures. We look forward to your updates on progress.

### **Chair, Parliamentary Group on Health**

## Other considerations for parliamentarians

### Export of generic medicines produced under a compulsory licence<sup>52</sup>

In 2003, WTO introduced a new procedure authorizing members to grant compulsory licences for the manufacture of generic drugs for export to countries with insufficient or no pharmaceutical manufacturing capacity. The Canadian Government, which issued a compulsory licence to authorize the export of HIV treatments to Rwanda,<sup>53</sup> found the procedure cumbersome, and its practicability is the subject of ongoing debate. Parliamentarians should advocate simplified procedures for authorizing exports and imports of generic medicines under compulsory licences.

### Anti-counterfeiting laws that restrict access to medicines

Laws against counterfeiting medicines sometimes overreach, defining “counterfeit” so widely as to include generic drugs. Such laws need to be scrutinized carefully to ensure that enforcement practices do not restrict access to generic medicines. For example, the High Court of Kenya found an anti-counterfeiting law unconstitutional because by denying access to generic HIV medicines it violated the right to health of people living with HIV.<sup>54</sup>

### Extended transition periods for TRIPS enforcement in least developed countries

The TRIPS Agreement includes transitional periods for countries defined as LDCs.<sup>55</sup> LDCs are not obliged to enforce patents on pharmaceutical drugs until 1 January 2016. In 2015 Bangladesh, on behalf of the LCD group, submitted a request to the WTO TRIPS Council for a further extension.<sup>56</sup> LDCs are allowed to defer the application of all TRIPS provisions for a transition period ending in 2021. LDCs that have postponed

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52 See UNAIDS, World Health Organization (WHO) and United Nations Development Programme (UNDP) (2011). *Using TRIPS flexibilities to improve access to HIV treatment*. Geneva: UNAIDS, WHO and UNDP.

53 Government of Canada (2004). *Canada’s Access to Medicines Regime, Act to Amend the Patent Act and the Food and Drugs Act*.

54 *P.A.O. and two others v. Attorney General* [2012] eKLR.

55 The UN categorized the following as least developed countries as at 2014: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Lao People’s Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sudan, Timor-Leste, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen and Zambia.

56 Bangladesh made a request on behalf of the LDC Group at the TRIPS Council, February 2015.

patent requirements relating to pharmaceuticals until 2016 or later include Bangladesh, Cambodia, Rwanda and Uganda.<sup>57</sup>

### Kenya: Good practice in parallel importing

Kenya's Industrial Property Act 2001 includes a very broad rule permitting parallel importation of medicines sold abroad either as patented medicines or as generic products. Most medicines used in Kenya are generic versions imported under this parallel importation framework. Since 2002, the leading organizations that provide HIV treatment services in Kenya have relied on these provisions to import generic HIV treatments.<sup>58</sup>

### What parliamentarians can do

- In their capacity as **legislators**, parliamentarians can ensure that TRIPS flexibilities are incorporated into national laws. A useful resource in that regard is the Report of the Global Commission on HIV and the Law, which made a series of recommendations about IP rights and TRIPS flexibilities.<sup>59</sup>
- In their **budget oversight** role, parliamentarians can ensure that governments consider the significant health budget savings that can be achieved by expanding access to generic medicines. Parliamentarians can lobby their governments to apply TRIPS flexibilities such as compulsory licensing and parallel importation to permit access to cheaper HIV medicines.
- In their capacity as **representatives and opinion leaders**, parliamentarians can raise awareness in the government and broader community about the importance of challenging patent protections that undermine public health goals by making essential medicines unaffordable.

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57 See e.g. Industrial Property Act 2014 (Uganda) Section 8(3)(f); Law on Patents, Utility Model Certificates and Industrial Designs, Article 136 (Cambodia). Similarly the Zanzibar Industrial Property Act 2008 excludes pharmaceutical products from patent protection until 1 January 2016 or the expiry of such later period of extension agreed upon by the TRIPS Council.

58 See Maleche A, May E (2014). Right to health encompasses right to access essential generic medicines: challenging the 2008 Anti-Counterfeit Act in Kenya. *Health and Human Rights*. 16(2).

59 Global Commission on HIV and the Law (2012). *Risks, rights and health*. New York: United Nations Development Programme, p. 87.

## Checklist on IP rights

- ✓ Does your country's IP law include provisions for:
  - compulsory licensing, including for government use?
  - parallel importation?
  - early working exception, to facilitate registration of generic medicines?
  - strict criteria for patentability?
  - competition law?
- ✓ Has your government explored options to reduce the cost of HIV treatments through voluntary licensing?
- ✓ Does anti-counterfeiting legislation avoid conflating the problem of counterfeit medicines with generic medicines?
- ✓ Does the law exclude pharmaceutical products from patent protection during the extended transition periods allowed for LDCs?



Treatment can reduce the risk of HIV transmission from a mother to her baby from up to 45 per cent to less than 5 per cent. © The Global Fund / John Rae



# Case study

## Brazil: flexible approach to IP rights supports rapid scale-up of treatment

The prevalence of HIV in Brazil, confined largely to key populations, has been stable at the national level. The prevalence rate among adults aged 15–49 was less than 1% in 2014, compared with 10.5% among gay men and other men who have sex with men. HIV prevalence is also high among transgender people, people who use drugs and sex workers.<sup>60</sup>

### Universal access and Fast-Track targets

Brazil has created one of the world's most comprehensive national HIV treatment programmes. Factors critical to success have been strong political leadership, supportive national legislation, domestic production of HIV drugs, engagement of civil society and willingness to take a strong position in international negotiations on IP rights.

The Ministry of Health established the goal of universal access to HIV treatment in 1996. By 2014, over 350,000 people were receiving treatment. In 2014 a new policy offered early treatment to all adults living with HIV, and the Government formally adopted the UNAIDS 90-90-90 targets to end AIDS by 2030.

### IP rights and local production

HIV treatments are distributed through the public health system. Brazil has a large pharmaceutical industry and around 40% of HIV treatments purchased by the Government are manufactured domestically.

In price negotiations with pharmaceutical companies, the Government used the threat of compulsory licences, and issuing them when the negotiations stalled, to gain significant price reductions for HIV medicines.

In 2005, the Government threatened to revoke the patent for an antiretroviral drug (Kaletra), because of concerns about excessive pricing. The Government threatened to produce the drug locally if the price was not reduced. After negotiations, an agreement was reached and the price of the drug was reduced by almost 50%.

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60 Ministry of Health, Brazil (2014). *Global AIDS response progress report*. Brasilia: Ministry of Health, Brazil.

In 2007, negotiations between the Government and a pharmaceutical company for purchase of another antiretroviral drug (efavirenz) were unsuccessful until the Government issued a compulsory licence for the importation of generic versions. The price of the drug then dropped by more than 50%, saving the Government over US\$ 103 million for the period 2007–2011.<sup>61</sup>

The Brazilian Chamber of Deputies led a consultation process to inform a new national patent policy in 2012–2013. Representatives of research institutions, Brazilian and multinational companies, NGOs, Government officials, the judiciary and the congress took part in the discussions. The resulting recommendations, published in a Chamber of Deputies report, included reforms to strengthen public health safeguards in the patents law, enable generic competition and bring drug prices down. The proposed reforms included stricter rules for patenting, a more robust patent opposition system to curb frivolous patenting practices by drug companies, and strengthening of the right to issue compulsory licences.

### **Lessons from Brazil's approach to IP rights<sup>62</sup>**

The experience of Brazil illustrates how a compulsory licensing provision in IP law can strengthen a country's negotiating position with patent holders, prevent abuses of monopoly power by pharmaceutical companies and help develop local industry and expertise.

Brazil's experience also highlights some of the political difficulties that developing countries face in implementing the TRIPS Agreement. Brazil came under tremendous pressure from pharmaceutical companies and developed countries. As a large middle-income country, Brazil was able to resist this pressure. Smaller countries with less bargaining power may find that more difficult, given the risk of damaging trade relationships.

Drawing from Brazil's experience, parliamentarians can:

- encourage their government to use its compulsory licensing powers in negotiations to secure access to cheaper HIV treatments;
- partner with local industry, academics and NGOs to review whether national patent laws include sufficient flexibilities allowing generic competition to drive medicine prices down; and
- consider whether options such as developing local manufacturing capacity to produce HIV treatments, including TRIPS flexibilities in national patent law or voluntary licencing will improve access to cheaper HIV treatments.

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61 Da Silva FVN, Hallal R, Guimaraes A (2012). *Compulsory license and access to medicines: economics savings of efavirenz in Brazil*. Presented at the 19th International AIDS Conference, Washington, Dc, July 2012.

62 See Avafia T, Narasimhan S (2006). *The TRIPS agreement and access to ARVs*. New York: United Nations Development Programme, p. 21.

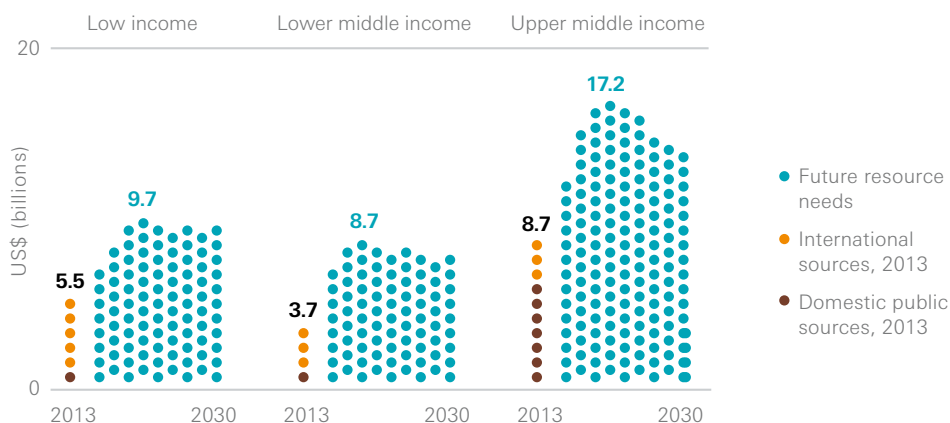
# Increasing sustainable financing for treatment

## Introduction

HIV has long-term implications for health budgets because it is a chronic condition that requires treatment for life. Financing of national HIV programmes has often been characterized by high levels of donor dependency, with many countries relying on donors to fund the bulk of treatment costs. However, this situation is changing and there is increasing uncertainty regarding future levels of international assistance for HIV. Development policies of major donors increasingly emphasize country ownership and shared responsibility, with domestic budgets expected to bear a greater burden of treatment costs.

A substantial gap exists between available resources and the amounts needed to scale up national HIV treatment programmes to meet Fast-Track targets (Figure 4).

**Figure 4. Resources available in 2013 and resources required in the period 2015–2030, by level of national income**



Source: UNAIDS.

### IPU Advisory Group warns against high levels of donor dependency

The IPU Advisory Group on HIV/AIDS and Maternal, Newborn and Child Health conducts field visits to countries to document good practice, provide advice and exchange views with parliamentarians on HIV policies and programme implementation. This is an example of how parliamentary exchanges can strengthen the HIV response. The Advisory Group has identified high levels of dependence on external funding as a major concern in several countries visited recently. For example:

- The Advisory Group's mission to Burundi in 2013 found that donors provided 96% of the funding for HIV response. The IPU mission recommended that Burundi's parliamentarians study examples of countries that fund the HIV response domestically.<sup>63</sup>
- The Advisory Group's mission to Viet Nam in 2014 noted that donors have begun to withdraw their HIV funding and are increasingly focusing on ensuring country ownership of programmes. The Advisory Group recommended that the National Assembly of Viet Nam advocate clear roadmaps for the transition to domestic budgets.<sup>64</sup>

There are many ways countries can increase the funding of access to treatment, as well as the overall HIV response, from domestic sources. Some countries are investing more domestically to ensure sustainable funding for the long term. For example:

- **Belarus:** with international HIV funding likely to be withdrawn or severely reduced in future years, Belarus plans to assume 100% of the costs associated with HIV treatment by the end of 2015, compared with only 40% in 2013.
- **Jamaica:** the Global Fund to Fight AIDS, Tuberculosis and Malaria is requiring Jamaica to assume at least half of all HIV-related costs. The government has concluded that such costs are manageable and fiscally sustainable and is developing a long-term sustainability plan that will include financing options and strategies to increase programmatic efficiency. The country has established a private foundation to mobilize domestic resources for the response.<sup>65</sup>

63 IPU (2014). *HIV and AIDS in Burundi: facing the challenges*. Geneva: IPU. [http://www.ipu.org/pdf/publications/burundi\\_en.pdf](http://www.ipu.org/pdf/publications/burundi_en.pdf).

64 IPU (2015). *HIV and AIDS in Viet Nam: facing the challenges*. Geneva: IPU. <http://www.ipu.org/pdf/publications/hiv-vietnam-en.pdf>.

65 UNAIDS (2013). *Smart investments*. Geneva: UNAIDS.

## Sustainable financing and universal health coverage

Many countries are seeking to lay the foundation for long-term financial sustainability by integrating HIV funding into universal health coverage schemes that rely primarily or exclusively on domestic financing. These countries are seeking to transition from HIV-specific funding sources to models that integrate the funding of HIV treatment costs into general health financing mechanisms.

Low- and middle-income countries for which universal health coverage is a national priority include Bangladesh, Brazil, Cambodia, China, Gabon, Ghana, Indonesia, Rwanda, Senegal, Thailand, Turkey and Viet Nam.<sup>66</sup> Many high-income countries have already achieved universal health coverage supported by national health insurance schemes.<sup>67</sup> To implement such coverage governments need to take responsibility for establishing equitable mechanisms for pooling funds through taxation and insurance. Under typical national health insurance arrangements, some costs may be borne by patients when they access treatment but most are covered by compulsory insurance and tax revenues.

## Local production

Some governments are investing in local production of HIV treatments as part of a broader strategy to reduce dependence on international aid. Investing in the domestic pharmaceutical industry can improve reliability of supply. While the local manufacturing of HIV treatments may provide a solution for some countries, many low-income countries lack the infrastructure or market size to make production viable. It may be cheaper to import HIV treatments from countries with established pharmaceutical industries, such as India. Careful assessment is required to determine whether local production is technically and economically feasible. Key challenges include financing costs, access to skilled workers, quality assurance, IP rights and the cost of raw materials.

## International mechanisms for financing HIV treatments

### *The Global Fund to Fight AIDS, Tuberculosis and Malaria*

The Global Fund to Fight AIDS, Tuberculosis and Malaria (often called “the Global Fund”) is an international financing organization that aims to attract and disburse resources to prevent and treat HIV, tuberculosis and malaria. Founded in 2002, the Global Fund is a partnership between

66 World Health Organization (WHO) (2014). *HIV, universal health coverage and the post-2015 development agenda: discussion paper*. Geneva: WHO, p. 56.

67 e.g. Australia, Canada, New Zealand and most European countries.

governments, civil society, the private sector and people affected by the diseases. The Global Fund raises nearly US\$ 4 billion a year, which is disbursed to national and multi-country programmes based on approval of proposals submitted by governments or civil society.

### UNITAID

UNITAID was established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom as an international drug purchasing facility for HIV, tuberculosis and malaria. It is supported by a membership of high- and low-income countries, including Cyprus, the Republic of Korea, Luxembourg, Spain alongside Cameroon, Congo, Guinea, Madagascar, Mali, Mauritius and Niger. Civil society groups also participate in the governance of UNITAID, giving a voice to NGOs and communities living with HIV, malaria and tuberculosis. UNITAID uses innovative financing to increase funding for greater access to treatments and diagnostics in low-income countries. Approximately half of UNITAID's finances come from a levy on air tickets.

### HIV-specific financing mechanisms

Increasingly, countries are looking to new approaches to mobilize resources, beyond the traditional forms of assistance from international donors. Table 4 describes innovative approaches to financing HIV treatments that countries have used around the world.

**Table 4. Innovative financing mechanisms**

Financing mechanism	Explanation	Country examples
<b>AIDS trust funds</b>	AIDS trust funds can consolidate funds raised from different sources to ensure they are spent in an effective and targeted way on HIV and related programmes.	<p>Zimbabwe has had a national AIDS trust fund since 1999. The National AIDS Council administers the fund.</p> <p>Kenya has proposed an AIDS trust fund with coverage possibly extending to non-communicable diseases.<sup>68</sup></p> <p>The United Republic of Tanzania's National AIDS Strategy lists the establishment of an AIDS trust fund as a priority.<sup>69</sup> Legislation to establish such a fund was tabled in 2015.</p> <p>Uganda plans to establish an AIDS trust fund and is considering the use of levies on bank transactions, air tickets and products such as cigarettes and alcohol to fund HIV services.<sup>70</sup></p>

Financing mechanism	Explanation	Country examples
<b>Levies on goods and services</b>	<p>Levies can be imposed on air tickets, financial transactions, mobile phones, tobacco, alcohol and other products.</p> <p>The levy can be enacted in legislation, passed as an executive order or included as a provision in the budgetary framework.</p> <p>The burden of taxes on financial transactions and airline tickets falls on high-income taxpayers rather than poor people.</p> <p>A financial transactions tax has been proposed as an additional way to generate revenue for the Global Fund.</p>	<p>Countries that have implemented an airline ticket levy include Cameroon, Chile, Congo, France, Madagascar, Mali, Mauritius, Niger and the Republic of Korea. The levy is added to the price of airline tickets, and the funds raised are provided to UNITAID to pay for bulk purchases of medicines. Developing countries can consider whether to contribute to UNITAID by imposing a levy on air tickets.</p> <p>Rwanda and Uganda imposed levies on mobile phone use to fund HIV programmes.</p> <p>Cape Verde and Comoros have earmarked funds from alcohol excise taxes for HIV programmes.</p> <p>National health insurance in Gabon provides coverage for the poorest members of society. It is funded by a 10% levy on mobile phone company turnover and a 1.5% charge on international money transfers.<sup>71</sup></p>
<b>Levies on employment</b>	<p>Levies on employees and employers may be an option for countries with large epidemics affecting the general population. The revenue generated varies according to unemployment rates and the number of people in formal employment.</p>	<p>Zimbabwe introduced an AIDS levy in 2000.<sup>72</sup> Employees are taxed 3% of their salary and companies are taxed 3% of their profits. Funds are channelled to the National AIDS Trust Fund. Around 50% of the funds are used for treatment costs. The levy is collected by the Ministry of Finance and managed by the independent National AIDS Council.</p>
<b>Debt swaps</b>	<p>Debt-2-Health is a partnership between two countries facilitated by the Global Fund. The creditor country cancels a debt in exchange for the debtor country agreeing to reinvest funds in health projects through the Global Fund.</p>	<p>Germany has entered agreements with Côte d'Ivoire, Indonesia and Pakistan to cancel debt in exchange for national HIV investments from these countries to the Global Fund.<sup>73</sup></p>

68 Katz I, Routh S, Bitran R, Hulme A, Avila C (2014). Where will the money come from? Alternative mechanisms to HIV donor funding. *BMC Public Health*. 14:956.

69 Government of the United Republic of Tanzania. *Third national multi-sectoral strategic framework for HIV and AIDS, 2013/14–2017/18*.

70 Kinyanjuni K (2013). African countries adopt innovative financing to bridge gaps in AIDS funding. *AIDSpan*. Issue 209, 12 February 2013.

71 Oxford Business Group (2014). Expanding coverage: universal health insurance is being rolled out. *The report: Gabon 2014*. London: Oxford Business Group, <http://www.oxfordbusinessgroup.com>.

72 Katz I, Routh S, Bitran R, Hulme A, Avila C (2014). Where will the money come from? Alternative mechanisms to HIV donor funding. *BMC Public Health*. 14:956.

73 Katz I, Routh S, Bitran R, Hulme A, Avila C (2014). Where will the money come from? Alternative mechanisms to HIV donor funding. *BMC Public Health*. 14:956.

# What parliamentarians can do

## Legislators and opinion leaders

Parliamentarians can:

- bring to the attention of governments the range of different financing mechanisms that can be used to mobilize resources;
- propose legislative and policy solutions to the funding of HIV treatment programmes, including levies and special purpose taxes, as well as sustainable universal health coverage schemes;
- encourage governments to consider how to link HIV with other high-priority health areas (e.g. malaria, tuberculosis and non-communicable diseases) to facilitate joint resource mobilization. Innovative financing mechanisms, such as taxes on products like tobacco and alcohol that cause severe harm to health, can raise revenue for a range of health needs and have been used to fund both HIV and non-communicable disease programmes; and
- lead an informed debate about the benefits and risks of investing in domestic manufacturing of HIV treatments in the national context, taking into account local technological and regulatory capacities, opportunities to reduce costs and projections of future demand for treatments.

## Budget oversight

Parliamentarians can:

- influence allocation of funds to HIV treatment programmes through the budget review and approval process;
- advocate the systematic analysis of future HIV treatment costs and funding gaps, to make the “investment case” for national HIV programmes. An investment case identifies the funding required to meet future treatment costs and demonstrates the return on investing in HIV treatment, taking into account the medical cost savings and broader social and productivity gains to be derived from early and effective treatment. The investment case should take a long-term perspective (over 10 years) and include a plan for sustainable financing of the HIV response. The investment case can be used to influence finance ministries and donors to plan for sustainable financing. UNAIDS has issued guidance on the development of HIV investment cases;<sup>74</sup>
- propose solutions to budget challenges through committee processes. For example, Zambia’s Portfolio Committee on Health, Community Development and Social Welfare undertook an analysis of the national HIV

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<sup>74</sup> UNAIDS (2012). *Investing for results: results for people – a people-centred investment tool towards ending AIDS*. Geneva: UNAIDS.



- situation in response to a rapid rise in new HIV cases. The Committee's report highlighted concerns about the budget impact of increasing treatment costs and recommended, as a matter of urgency, that the Government approach international drug companies and funding agencies to negotiate significant reductions in the cost of HIV treatments;<sup>75</sup> and
- propose innovative financing mechanisms and suggest ways to transition from HIV-specific funding sources to general health financing mechanisms, as many countries move towards universal health coverage.

### **Checklist: Budget oversight**

#### *How are funds raised?*

- What are your government's main sources of funding for HIV treatment?
- How much funding is from international donors and how much from the domestic budget?
- When are donor funds due to expire or be reduced from current levels?
- What are the implications of future reductions in donor funding for the sustainability of HIV treatment programmes?

#### *How are funds spent?*

- Are there ways of accessing cheaper drugs to reduce treatment costs? Can costs be cut by negotiating with drug companies for voluntary licences, purchasing drugs through pooled procurement, issuing compulsory licences or investing in local production of drugs?
- Are there differences in levels of spending on HIV treatment for each province?
- Does the per capita spending in each province correspond with the number of people living with HIV who require treatment in each province?
- Are resources strategically focused on the key settings and populations where HIV prevalence is highest and unmet treatment needs are greatest? Are resources focused on addressing the particular needs of women and girls?
- Are essential services (i.e. basic services for HIV prevention, treatment and care) covered by domestic funds?

75 Commission on Social Determinants of Health (2008). *Closing the gap in a generation: health equity through action on the social determinants of health – final report of the Commission on Social Determinants of Health*. Geneva: World Health Organization, p. 112.

## Case study

### HIV treatment and universal health coverage in Thailand<sup>76</sup>



© Jon Ungphakorn

“Since 2006, Thailand has relied on its own domestic budget to pay for AIDS treatments. HIV has long-term implications for health budgets because it requires treatment for life. Funding treatment is a necessary public health investment, firstly to reduce AIDS deaths and secondly to prevent HIV transmission. We now know that when people receive treatment the virus is suppressed, reducing infectiousness so it is much more difficult to pass it on to others. It is imperative to invest in treatment today, because bringing the epidemic under control will dramatically reduce the pressure on national health budgets in years to come.”

**Jon Ungphakorn**, Former Senator, Thailand

There were 450,000 [400,000–490,000] people living with HIV in Thailand in 2014. That number and the numbers of new HIV infections and AIDS-related deaths in Thailand have declined steadily over time. High HIV prevalence is still reported, however, among gay men and other men who have sex with men and people who inject drugs.

Thailand has committed to ending AIDS by 2030 and scaling up HIV treatment to ensure that universal access is a national priority. In 2014, the country became the first in Asia to offer life-saving treatment to everyone living with HIV, regardless of their immune system status (CD4 count).<sup>77</sup>

76 Bhakeecheep S (2014). *ASEAN plus Three UHC Network and HIV/AIDS services under UHC: Thailand experience*. Presented at the National Health Security Office, Chiang Mai, Thailand, 23 June 2014. PHAMIT (Prevention of HIV/AIDS migrant workers in Thailand): <http://www.phamit.org/?lang=en>.

77 Thai National AIDS Committee (2014). *Thailand AIDS response progress report 2014*. Thai National AIDS Committee.



The production of generic antiretroviral medicines in developing countries has helped to reduce treatment costs and increase access.  
© UNAIDS/T.Znidarcic

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### **Funding HIV treatment through national health insurance**

Thailand is a middle-income country that provides access to free HIV treatments through national health insurance schemes. The National Health Security Act of 2002 is the legislative basis for Thailand's Universal Coverage Scheme, which provides equitable access to health services through health insurance.

HIV treatments were excluded from the Universal Coverage Scheme when it was established. Due to pressure from civil society groups, HIV treatments were included from 2003 and initially financed by contributions from domestic budgets and the Global Fund. Patients were initially required to make co-payments of baht 30 (less than US\$ 1), but that requirement was abolished in 2006. Health services are now free to patients under the insurance scheme.

The Universal Coverage Scheme is the largest of three public health insurance schemes in Thailand, covering most of the population. It largely targets poor people in the informal agricultural sector who lack regular income to pay insurance premiums. The other two schemes are the Compulsory Social Security Scheme, financed by contributions from employees, employers and central government, and the Civil Servant Medical Benefits Scheme. Both the Civil Servant Medical Benefits Scheme and the Universal Coverage Scheme are financed from general tax revenues.

### **Migrant workers**

The treatment needs of migrant workers are also covered. Migrants receive a health insurance card for an annual fee (2,200 baht / US\$ 65) allowing them to receive basic health services with co-payments of only 30 baht. Since 2013, that has included access to antiretroviral therapy, HIV tests and treatments for co-infections such as tuberculosis. NGOs report that coverage of migrant populations remains patchy, however, so more resources are required to fully implement this policy.<sup>78</sup>

### **Compulsory licensing and local production**

Thailand has issued compulsory licences for two kinds of HIV medicines and has centralized procurement and supply chain management of all HIV medicines to keep costs down. Six HIV drugs are manufactured in Thailand. Compulsory licensing is used to authorize imports of some other medicines from India.<sup>79</sup>

### **Levy on tobacco and alcohol**

Another method of financing used by Thailand is a 2% additional excise levy on tobacco and alcohol. The proceeds are allocated to the Thai Health Promotion Foundation, an institution established by the Health Promotion Foundation Act that funds campaigns against a range of public health problems, including HIV and non-communicable diseases.<sup>80</sup>

### **Lessons from Thailand**

The success of Thailand's national HIV treatment programme was made possible through political leadership to mobilize domestic resources. Factors critical to success included:

- a clear government commitment to include HIV treatment under the country's universal health coverage scheme;
- an effective price regulation mechanism for medicines to ensure programme sustainability, with centralized procurement and management; and
- domestic manufacturing of the most commonly used HIV medicines, combined with compulsory licensing for imports of affordable generic medicines; and
- a public health oriented management of intellectual property rights.

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78 Tang A (2015). *HIV-positive migrants denied care at Thai public hospitals*. Reuters, 8 February 2015.

79 Efavirenz and lopinavir/ritonavir.

80 Srithamrongsawat S et al. (2010). *Funding health promotion and prevention: the Thai experience – World Health Report (2010) background paper 45*. Geneva: World Health Organization.

# Conclusion

The information and case studies provided above indicate the range of practical measures that can be taken to accelerate greater access to HIV treatment. To recap the main points:

- Countries can help to end AIDS as a public health threat by 2030 by rapidly scaling up HIV testing and treatment and meeting the **90-90-90 targets of the Fast-Track** approach. Achieving the targets requires a series of detailed actions, and parliamentarians can play a central role.
- As **legislators**, parliamentarians can take action to ensure laws are in place that guarantee access to essential medicines and good-quality treatment and care services, and that protect people living with HIV from discrimination. Issues connected with intellectual property rights have been highlighted as an area requiring particular consideration, given the impact pharmaceutical patents can have on the affordability of HIV treatments. Parliamentarians are urged to familiarize themselves with TRIPS flexibilities, such as compulsory licensing and parallel importing, and to review intellectual property laws to ensure those flexibilities are used. Parliamentarians can also support laws that provide a framework for sustainable financing, for example through trust funds, levies and the inclusion of HIV treatments under universal health coverage schemes.
- In **overseeing national programmes**, parliamentarians can ensure that treatment programmes are comprehensive, addressing the needs of women, children and all key populations. The complex care needs of children, often overlooked, require particular attention. Parliamentarians should actively reach out to people living with HIV to help inform the response, eliciting their views on ways to expand treatment access. These could include new, more accessible approaches to HIV testing and treatment at the community level, greater involvement of nurses and pharmacies, and integration of HIV services with other health services.
- In their **budget oversight** role, parliamentarians can advocate sustainable mechanisms for funding HIV treatment. Governments should avoid excessive dependence on international donors, identifying instead where domestic sources can be developed to sustain HIV programmes. Parliamentarians can urge governments to systematically analyse future HIV treatment costs, to plan for sustainability and to consider options for

innovative domestic financing and for social health insurance coverage of HIV costs. To help sustain health budgets, parliamentarians can highlight the significant savings that can be achieved by expanding access to generic medicines.

- As **representatives and opinion leaders**, parliamentarians need to gather first-hand knowledge from people living with HIV and health-care workers about the challenges faced in implementing treatment programmes. Informed by these perspectives, they can publicly champion improved access. They can highlight the particular challenges faced by women, children and key populations and challenge fears, myths and misconceptions about AIDS. They can insist that responses be based on medical science and evidence, rather than ill-informed prejudices. And they can raise government and community awareness about the impact of intellectual property rights on the cost of treatments and ways to make treatments more affordable.

HIV remains one of the most profound health and development challenges of our time. Thankfully, we now have the tools to bring this global epidemic to an end. Recent advances in the efficacy of HIV treatments and a better understanding of how treatment also contributes to prevention can bring an AIDS-free generation finally within reach. Critical to success, however, will be an acceleration in the expansion of treatment access to all in need – ensuring no one is left behind. Parliamentarians can help make that a reality.





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