

# **GLOBAL POLICY BRIEFING**

# FINANCING THE GLOBAL HIV RESPONSE TO SECURE AN AIDS-FREE FUTURE

#### Summary

HIV is both preventable and treatable, yet getting the global HIV response back-on-track requires international solidarity to improve public health outcomes, particularly through targeted government investment in HIV diagnostics, prevention, treatment and people-centred care. The world needs go further and faster to deliver sustainable investment in R&D, to strengthen health system resilence, to promote evidence-based policy, programming and service delivery as well as improve monitoring and evaluation needed to end AIDS as a public health threat by 2030.

Resourcing the community-led HIV response is a critical pillar to make AIDS history. For ViiV Healthcare, political leadership and health partnerships which seek to improve <a href="health-related quality of life">health-related quality of life</a> for people living with HIV (PLHIV) and improve public health outcomes for society-at-large are particularly important. Investing to accelerate the global HIV response also supports wider health security and has the potential to strengthen health system resilience against chronic and infectious disease at both regional and national levels.

The importance of a well-resourced global HIV response is underlined in the new <u>UN Global AIDS Strategy</u> (2021-2026), the updated <u>2025 HIV Targets</u>, and the <u>2021 Political Declaration</u>. Together, the new strategy and targets place PLHIV and vulnerable communities at the heart of the global response. The targets are ambitious but achievable and seek to promote social, legal and institutional environments which are free from stigma and discrimination, as well as uphold universal human rights (social enablers). Delivering the strategy and achieving the targets requires annual global HIV investments to increase to US\$29 billion by 2025. Uppermiddle-income countries represent 51% of the resource needs, required to deliver this strategy. For every additional US\$1 invested in implementing the global AIDS strategy across low- and middle-income countries, a return of more than US\$7 is generated in health benefits.

No infectious disease can be successfully fought at the expense of another;<sup>5</sup> and mobilising dedicated finance to tackle HIV has the potential to address factors which create and compound vulnerability to other communicable diseases. This includes addressing racism, structural poverty, <u>LGBTQIA+</u><sup>c</sup> discrimination as well as gender-based inequalities and violence - all of which impact access to comprehensive and integrated healthcare and HIV services.<sup>6</sup>

ViiV Healthcare works with diverse stakeholders across the public, private and not-for-profit sectors, particularly PLHIV and communities all united to end AIDS. Together, we advocate to adequately finance the global HIV response through committed national, regional and global investments. **To this end, ViiV Healthcare advocates for and is committed to the following policy principles:** 



A well-resourced HIV response which includes sustained R&D investment in HIV. This creates an enabling environment to deliver innovative health products critical to meet ambitious and achievable HIV targets by 2025. ViiV Healthcare is researching and delivering innovative options to treat and prevent HIV, which contributes to ending AIDS and averting HIV transmission. Our ambition is to make HIV a smaller part of people's lives.



**Strategic and long-term investment in civil society and the community-led** HIV response is critical to create an AIDS-free future. ViiV Healthcare has a long-established track record of investing in and enabling the capacity and capabilities of diverse community-driven initiatives to leave no person living with or affected by HIV behind.



National public investment in and replenishment of key global health agencies and institutions. ViiV Healthcare is an active supporter of global and bilateral agencies which are critical to enabling

<sup>&</sup>lt;sup>a</sup> health-related quality of life includes long-term physical, psychological and social health needs. HRQoL represents an important public health priority which supports health promotion and resilience.

<sup>&</sup>lt;sup>b</sup> Upper-middle-income economies are those in which 2020 GNI per capita was between \$4,096 and \$12,695

clesbian, gay, bisexual, transgender, queer, intersex and asexual people



community, national, regional and global policies and programmes key to progressing the HIV response.



**Adopting diverse approaches to enable access to our medicines.** ViiV Healthcare takes a proactive approach to enable access to antiretroviral regimens. We continue to explore new models that are firmly based on medical and public health needs to address the HIV epidemic.



**Supporting development of local manufacturing capacity.** ViiV Healthcare has established a strategic alliance to enable local manufacturing of antiretrovirals in Russia.



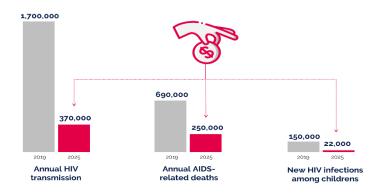
**Resourcing a multi-sector HIV response to address HIV in urban areas.** ViiV Healthcare has supported the <u>Fast-Track Cities</u> (FTCs) initiative, a global network of 350+ cities and municipalities working to accelerate their local HIV, tuberculosis, and viral hepatitis response. Cities represent a significant and increasing driver of national HIV epidemics.<sup>7</sup>

#### The Challenge

# Securing a well-resourced HIV response

According to the new Global AIDS Strategy, fully resourcing the 2025 HIV targets has the potential to reduce annual HIV transmission from 1.7 million (2019) to 370,000 by 2025; decrease AIDS-related deaths each from 690,000 (2019) to 250,000 in 2025<sup>d</sup>; and, reduce vertical transmission of HIV from 150,000 (2019) to less than 22,000 in 2025.<sup>8</sup> Government investment plays a critical role in achieving these important health outcomes to improve lives, livelihoods and living standards.

Successfully implementing the Global AIDS Strategy also requires investments in primary prevention<sup>e</sup> services to annually increase from an estimated US\$ 5.3 billion (2019) to US\$ 9.5 billion by 2025. This includes increasing the number of Pre-Exposure Prophylaxis (PrEP)<sup>f</sup> users from 845,000 people at the end of 2020 to 10.6 million in 2025. 47% of the investments will need to be dedicated to key populations<sup>g 9</sup> - this does not include the specific investments in PrEP required for this population group.<sup>10</sup>





Investments in primary prevention services to annually increase from:



#### The need for investment, including in HIV Research and Development (R&D)

# A regional focus on HIV investment required to progress the HIV response

All governments regardless of their gross national income (GNI) status are required to increase investments in their local HIV response across a range of issues. Without adequately addressing this critical investment gap, unsatisfactory HIV health outcomes may undermine national health security to end chronic infectious diseases.

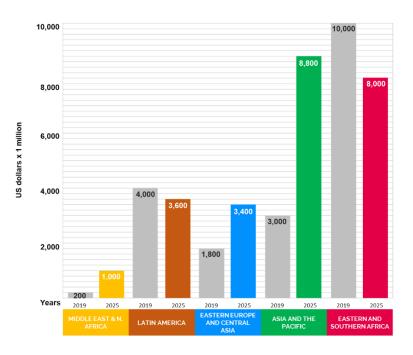
 $<sup>^{\</sup>rm d}$  includes tuberculosis deaths in PLHIV

e HIV prevention can be considered in three phases: (i) **primary prevention**, mainly directed towards persons hitherto uninfected by HIV, (ii) **secondary prevention**, which includes early detection of HIV infection in those who have been newly infected by HIV with a goal to initiate appropriate prevention strategies (reducing transmission to others, termed prevention in positives, or "positive prevention") (including PrEP) and to reduce complications in the infected person, and (iii) **tertiary prevention** targeting persons with chronic HIV infection.

FPEP: Pre-Exposure Prophylaxis - an HIV prevention drug taken daily by HIV-negative people to prevent acquiring HIV from HIV+ sexual partners given populations include gay men and other men who have sex with men (MSM), people who inject drugs, sex workers, transgender people and those detained or incarcerated



UNAIDS has produced a range of regional estimates which indicate the annual investment required to meet the new 2025 global HIV targets for each year from 2022 to 2025. Across Asia and the Pacific, domestic financing will need to increase annually, climbing to over USD 7 billion and eventually exceed USD 8 billion by 2025.11 In the case of Latin America, annual estimates suggest that resources will need to exceed USD 3.5 billion by 2025.12 For the Middle East and North Africa, it is estimated that resources need to exceed USD 800 million each year and to eventually exceed USD 1 billion by 2025.13 In the case of Eastern Europe and Central Asia, it is estimated that resources need to increase to USD 3 billion each year from 2022 climbing to USD 3.5 billion by 2025.14 In the case of Western and Central Africa, resource needs from 2022 to 2025 are estimated to range from USD 2.3 billion to over USD 2.5 billion between 2022 and 2025. 15 Finally, in the case of Eastern and Southern Africa, resource needs are estimated to range from just under USD 8 billion each year until 2025.16



# Investing in key treatment and prevention priorities to accelerate securing the 2025 HIV targets

The annual regional investments needed to finance the new 2025 HIV global targets<sup>17</sup> are required to focus on multiple priorities to accelerate the regional HIV response. These priorities include access to and the availability of innovative options to prevent and treat HIV. Key treatment and prevention priorities include expanding access to high quality and high impact combination HIV prevention and treatment. Services need to target key and priority populations which includes adolescent girls & young women, young people and other underserved groups. Investment in treatment and prevention also needs to focus on updating differentiated service delivery, including scaling-up access and availability to PrEP, harm reduction services, multi-month dispensing (consolidating medication refills) and in some regions, transitioning to dolutegravir-based first-line regimens. Additional priorities also includes addressing gaps in service availability and uptake of paediatric HIV treatment and preventing vertical transmission (from mothers-to-children) as well as securing reliable access to comprehensive HIV services for migrants and asylum seekers.<sup>18</sup>

#### **Investment in HIV R&D**

Increasing investments in HIV R&D with a particular focus on long-acting antiretrovirals, HIV vaccines and a HIV cure are also important priority actions to end AIDS; particularly for Western & Central Europe and North America.19

According to <u>AVAC</u>h, investments in HIV cure research, including <u>therapeutic HIV vaccines</u> (for treatment), increased by approximately one percent, from US\$323.9 million invested in 2018 to US\$328.2 million in 2019. This represents a significantly smaller annual increase compared to levels previously observed. Yet the HIV epidemic is in its fourth decade having missed key global targets for testing, access to treatment, viral suppression and preventing HIV transmission. The public sector continues to represent a majority R&D funder contributing US\$306.7 million in 2019. Without dedicated and sustainable public investment, transforming the impact of HIV across health systems will be undermined.<sup>20</sup>

ViiV Healthcare's commitment to researching and delivering innovative HIV treatment and prevention options, supports many of the Global AIDS Strategy's regional priorities needed to accelerate progress to secure the new HIV global targets.

<sup>&</sup>lt;sup>h</sup> AVAC was formerly known as the 'AIDS Vaccine Advocacy Coalition'



# Researching and delivering innovative HIV treatment and prevention options

Our R&D investments include a range of innovative ART options for those who are treatment-naïve; heavily treatment experienced; as well as age-appropriate formulations for paediatric populations which seek to:

- i) minimise the risk of certain drug toxicities for PLHIV and other comorbidities
- ii) offer a more convenient and in some cases a discreet treatment option
- iii) may reduce the number of drugs needed in an ART regimen.

In addition, we are investing in R&D to deliver innovative HIV prevention options, which includes researching the potential to extend choice in HIV prevention through providing alternatives to existing PrEP medication. This includes the possibility of long-acting injectables; slow-release and self-administered options, as well as investigational medicines with new mechanisms of action.

#### The importance of civil society and the community-led response

# Our longstanding support for community engagement including ViiV Healthcare's investment to mitigate the COVID-19 impact on HIV

ViiV Healthcare supports the new global AIDS strategy requirements which stipulate specific targets for the proportion of services to be delivered through community-led organisations. Overall, the strategy recommends that 30% of testing and treatment services, 80% of HIV prevention programmes and 60% of programmes to address social enablers to end HIV-related marginalisation, stigma, discrimination, criminalisation and violence should be delivered through community-led organisations. This requires that communities must be adequately resourced to deliver impact and transformation for PLHIV and vulnerable communities.

The impact of the COVID-19 pandemic on the HIV responses reinforces the importance of civil society to address global health crises ranging from their instrumental role to contain disease outbreaks through disseminating trusted information and education to the innovative use of technology and social media to support service delivery.<sup>22</sup> Recent studies from England and South Africa indicate that the mortality risk associated with COVID-19 among PLHIV doubled compared to the general population.<sup>23</sup> <sup>24</sup> The elevated risk of COVID-related illness and death for PLHIV underlines the importance of community and research alliances - supported by ViiV Healthcare - which seek to find solutions to address the impact of COVID-19 on HIV. Building on our longstanding strategic commitment to the community-led HIV response though our Positive Action programme; we created a £3 million COVID-19 Emergency Response Fund investing in research and community-led initiatives.<sup>25</sup> The fund resourced innovation and adaptation to ensure access to HIV services and community-led health service delivery during the crisis. This response fund reinforces our longstanding commitment to community-led organisations which remain a critical component for strong and resilient health systems including during epidemics and pandemics.<sup>26</sup>

#### ViiV Healthcare's global HIV investment in the community-led response

ViiV Healthcare has a long-established track record of investing in locally-led and community-driven initiatives to end AIDS. In 2019, Funders Concerned About AIDS (FCAA) ranked us as<sup>27</sup>

- the largest HIV-specific philanthropic funder;
- both the second largest corporate philanthropic HIV & AIDS funder and global philanthropic donor in several regions including the US, West and Central Africa, South Asia and the Pacific;
- both the third largest corporate donor in West and Central Europe and HIV-related philanthropic supporter for black, indigenous, and other people of colour (BIPOC) Communities in the US.<sup>28</sup>

Our focus on PLHIV and communities has also been recognised by patient groups, organisations and networks across the world, and resulted in ViiV Healthcare ranking number one in the annual global <u>PatientView</u> survey, over several consecutive years. This survey evaluates the corporate reputation of pharmaceutical companies among the population groups they serve.<sup>29</sup>

In the case of HIV prevention, mechanism of action describes the process by which a drug averts HIV transmission. Includes those led by key populations and women



# Supporting and replenishing global health institutions

## Advocating for investment in and the replenishment of global health organisations.

In order to secure the sustainable funding needed to drive the global HIV response, the power of partnerships remains key - galvanised by decisive and committed political leadership and meaningful civil society engagement. Together, global health agencies create an evidence-informed and enabling environment for effective policy as well as programme development and execution – essential to progress the 2025 HIV targets and UN Sustainable Development Goals associated with HIV.<sup>30</sup> Our support to this important body of agencies includes advocating for the continued replenishment and political support for the Global Fund, PEPFAR, UNAIDS, the WHO, Unitaid, UNFPA, and Unicef, including organisations across academia and the civil society sector. We recognise the need for decisive political solidarity to ensure these and other organisations are effectively resourced to fulfil their critical public health mandates which progress the HIV response for everyone, everywhere.

# Multilateral and bilateral investment supporting the local HIV response

In 2020, bilateral and multilateral funding to address HIV in low-and middle-income countries reached US\$8.2 billion. This represented an increase of US\$377 million compared to US\$7.8 billion in 2019. The increase is explained by the timing of the US's contribution to Global Fund to Fight AIDS, Tuberculosis and Malaria; without which, total funding would have decreased, given only Germany and Japan increased their 2020 contributions. <sup>31</sup> Investment from donor governments in 2019 equated to the same level of funding as 2010, yet there has been a 25% increase in the number of PLHIV in low- and-middle-income countries. <sup>32</sup> It is also important to note that implementing governments have invested significantly in their own HIV response through mobilising domestic resources. In 2019 this exceeded funds provided by international donors; accounting for 61% of the total global funding in 2019. <sup>33</sup> <sup>34</sup> Yet, too few countries met the 2020 UN 90-90.90 targets and overall investment in the global HIV response remains increasingly uncertain. <sup>35</sup> <sup>36</sup> The 2022 replenishment of the Global Fund will be critical, given the ongoing economic and social impacts of COVID-19 which have ushered in acute budget constraints globally and particularly in regions where gross national income is low. <sup>37</sup>

## Adopting diverse approaches to enable access to our medicines

# HIV remains everyone's business

Upper Middle-Income Countries (UMICs) are predominantly responsible for financing their own HIV response and account for 53% of the annual \$29 billion required to achieve the new 2025 global HIV targets.<sup>38</sup> Therefore, it is critical that UMIC governments prioritise increases in their HIV investments to improve health outcomes and strengthen public health to tackle chronic infectious diseases.

At ViiV Healthcare, we take a proactive approach to enable access to medicines by utilising and exploring a range of models that are firmly based on medical and public health needs to address the HIV epidemic. Existing access models will continue to play a key role in enabling access to our high volume, low-cost, oral, solid dose, generic antiretroviral tablet formulations in all low- and middle- income, least-developed and sub-Saharan African countries. As our pipeline progresses however, we continue to explore new models to enable access to our latest approved medicines. Production of these innovative medicines require different, more specialist manufacturing equipment and capabilities. In addition, for some innovations, service delivery may also differ. Finally, the role these emerging options may play in public health programmes remains to be established. The importance of partnerships across the public, private and not-for-profit sectors and public investment to transform the access landscape remains critical.



## Our access to medicine solutions include voluntary licensing for specific antiretrovirals

Together with the Medicines Patent Pool(MPP), other global health agencies and generics manufacturers, we collaborate to accelerate the development, registration and supply of access to DTG-based antiretroviral therapies across all low-income countries (LICs), least-developed countries (LDCs), all lower-middle-income countries (LMICs), and countries in sub-Saharan Africa.<sup>39 40</sup> These commitments have enabled:

- 17 non-exclusive voluntary licenses for adults (16 with the MPP);<sup>41</sup>
- 13 non-exclusive and royalty-free paediatric voluntary licenses (12 with the MPP) covering 123 countries<sup>42</sup>
- 94% of adults and 99% of children living with HIV in low and middle income countries are covered by our DTG voluntary licences;<sup>43</sup>
- 82% of PLHIV to access DTG-based antiretroviral therapies (ART) across low- and middle-income countries.<sup>44</sup>

PTG voluntary licences
executed across developing countries in 2014

94%
of PLHIV covered

95%
of children living with HIV covered

As of 2020, our voluntary licences have enabled

16.3m PLHIV
to access generic DTG-based medicines

82%
of PLHIV on DTG-based ART across LMICs,

In 2020, we announced a new voluntary license agreement with the Medicines

Patent Pool MPP. This partnership enables greater access to DTG-based regimens<sup>k</sup> for PLHIV, in four UMICs <u>Azerbaijan, Belarus, Kazakhstan and Malaysia</u>. This novel voluntary licensing agreement for DTG-based regimens aims to increase medicine affordability by allowing generics manufacturers to supply generic DTG-based medicines at a significantly reduced price; compared to the prevailing local prices at the time of agreement execution.

ViiV Healthcare's approach to access has been recognised in the biennial <u>Access to Medicines Index (ATMI)</u> report which contributed to GSK, ViiV Healthcare's majority shareholder, retaining the top rank among 20 of the world's largest pharmaceutical companies.<sup>45</sup>

# Supporting locally-led manufacturing to improve ART access in certain countries

ViiV Healthcare works with GSK to support local pharmaceutical manufacturing to address clinical needs and make DTG-based antiretroviral regimens more widely available to PLHIV by supporting local production where established capacities exist. Locally-led manufacturing has the potential to support epidemic preparedness and strengthen healthcare systems to address the needs of populations living with HIV. We have established a local manufacturing partnership with Servier Russia. Russia, has the largest number of PLHIV in its region.<sup>46</sup>

## Supporting a multi-sector HIV response to address the critical urban HIV epidemic

The global HIV response also requires an approach which focuses on indicator conditions and gateway services critical to progress the HIV response. For example, according to the WHO, HIV, viral hepatitis and sexually transmitted infections collectively account for over 2.3 million deaths annually. These communicable diseases result in more than one million new daily transmissions and contribute to 1.2 million people developing cancer annually. ViiV Healthcare supports leveraging multi-sector partnerships to provide an integrated approach across sexual health and reproductive rights, child, adolescent, women and maternal health as well as mental health.

The potential to improve public health outcomes by adopting an integrated approach also supports the impact of investments to address the complex inequalities driving the HIV epidemic. This includes targeted sexual health promotion education, social protection as well as structural responses to address poverty, vulnerability, all forms of stigma, discrimination<sup>48</sup> and inequality including across urban areas. Given, currently 200 cities represent more than 25% of PLHIV globally, the urban response is critical.<sup>49</sup>

 $<sup>^{\</sup>rm k}$  DTG-based regimens, as recommended by the WHO and the US Department of Health and Human Services



At ViiV Healthcare, we have supported Fast-Track Cities, in collaboration with the International Association of Providers of AIDS Care (IAPAC), UNAIDS, UN-Habitat and Mairie de Paris. The initiative mobilises youth movements, leverages digital technology and promotes a human rights approach to generate data and reports on HIV status, access to treatment, and viral suppression to end the HIV epidemic by 2030. The network publishes HIV data dashboards at <a href="www.fast-trackcities.org">www.fast-trackcities.org</a> to support communities map access to local comprehensive HIV services and also encourage key decision-makers, to remain accountable to affected communities by tracking progress. This enables policymakers to prioritise and resource high-impact HIV interventions and to integrate evidence-based interventions to end HIV-related stigma and discrimination.

Securing ambitious and achievable targets by 2025 fundamentally requires sustainable and predictable public investment supported by robust political and policy prioritisation secured through responsible, accountable leadership. Civil society engagement represents a critical pillar to accelerate actions and impact. Investing for success requires that PLHIV and vulnerable communities are at the heart of each response, at every level.

#### ViiV Healthcare global policy briefings series:

# Making HIV a smaller part of people's lives

ViiV Healthcare has developed a series of global policy briefings which outline our commitments through diverse partnerships to tackle key global public health priorities affecting the global, regional, national and community HIV response. We aim to inform public policy and healthcare delivery to ensure no person living with HIV is left behind, by supporting communities affected by HIV.

#### **About ViiV Healthcare**

Established in November 2009, we are the only pharmaceutical company solely focused on combating, preventing, and ultimately curing HIV & AIDS. ViiV Healthcare is dedicated to researching and delivering innovative HIV medicines and solutions which make HIV a smaller part of people's lives.

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