

# GLOBAL POLICY BRIEFINGS

## IMPROVING ACCESS AND AVAILABILITY TO MEDICINES

### ViiV Healthcare's policy principles and priorities for action

Our access to medicines strategy recognises there is no one-size-fits-all approach to enable access to medicines globally. ViiV Healthcare adopts a tailored approach which is country-specific and informed by local epidemics and national economic status (as defined by the [World Bank](#)). Geographically, we focus on [low- and middle- income countries \(LMICs\)](#)<sup>1</sup> and [Sub-Saharan Africa \(SSA\)](#) countries where there is ongoing unmet need for HIV prevention and treatment options. We also recognise that enabling universal access to HIV testing, prevention, treatment, and care needs to be underpinned by the power of partnership across diverse national, regional and global health decision makers and key stakeholders across the public, private, and not-for-profit sectors. This is essential to drive progress to achieve the [Sustainable Development Goals \(SDGs\)](#), revised [UNAIDS 95-95-95 targets](#) and national HIV goals, targets and ambitions.<sup>2</sup> Our commitments and contributions to expanding access and availability to medicines include:

#### ViiV Healthcare's Access to Medicines Principles Overview



[Investment in clinical needs-driven research and development \(R&D\) accompanied by product registration strategies](#)



[Innovative partnerships and solutions to share intellectual property \(IP\) and develop voluntary licensing agreements – where the epidemic is most acute](#)



[Tailored business models to promote access including flexible pricing and local manufacturing partnerships, where appropriate](#)



[Investment to strengthening healthcare systems including recognising and resourcing community-led expertise, interventions and services](#)

In a world that continues to grapple with the effects of preventable and manageable infectious disease, it is imperative to deliver access and availability of [health technologies](#) (including medicines and prevention options) to end epidemics as public health threats. Yet, improving public health also requires enabling political, legal, and regulatory environments that appropriately resource health systems - including community-led services – and prioritises health equity for all to shape the access to medicines landscape. HIV continues to disproportionately affect LMICs, comprising 69% of all new HIV transmissions and 78% of all AIDS-related deaths in 2022.<sup>1</sup> As the only biopharmaceutical company 100% focused on developing and delivering innovation to prevent and treat HIV, our access to medicines approach aims to make our health technologies available to people and communities regardless of who they are or where they live. This is underpinned by our mission to ensure no person living with HIV is left behind and our vision to end the AIDS epidemic.

#### Call to action

ViiV Healthcare advocates for more ambitious investments to expand access to available health technologies from governments including multilateral and bilateral agencies, [development finance institutions \(DFIs\)](#), and other public agencies focused on health. These agencies and institutions have resource endowments with the

<sup>1</sup> The World Bank's 2024 definitions of country income group classifications are based on; per capita gross national income (GNI) levels. GNI per capita of \$1,135 or less is low-income status. Between US\$1,135 and US\$4,465 represents lower middle-income status.; Between US\$4,466 and US\$13,845 denotes upper middle-income status, and US\$13,846 or higher indicates high-income status. Collectively, the low, lower-middle, and upper-middle income economies are known as low- and middle- income countries (LMICs).

<sup>2</sup> UN HIV 2025 targets includes 95-95-95 targets which stipulate that 95% of people living with HIV know their HIV status, 95% of people who know their status are on treatment and 95% of people on treatment achieve viral suppression. Launched as the 90-90-90 targets in 2014, they were revised to 95-95-95 in 2021 to accelerate achieving the 2030 UN SDG goals and associated targets.

potential to increase innovative financing to improve infectious disease health outcomes and public health, particularly in LMICs.

## The Challenge

### Scaling-up access to medicines to secure HIV targets

Improving access to HIV testing, prevention, and treatment has driven much of the reduction in HIV transmission and AIDS-related deaths globally. However, of the 39 million people living with HIV who require anti-retroviral therapy (ART) under the 'Treat All' approach<sup>3</sup> endorsed by the World Health Organization (WHO), only 29.8 million (76.4%) were on treatment as of 2022, compared to global targets of 95%.<sup>iiii</sup> By 2022, only 2.5 million people had accessed [Pre-exposure prophylaxis \(PrEP\)](#) to avert HIV transmission, off track to achieve the UN target of making PrEP available to 10 million people by 2025<sup>iv</sup>

### Access to medicines, a complex public health priority

Access to HIV prevention and treatment options is complicated by barriers and enablers ranging from people and communities to health systems and public policy environments. While the price of medicines remains important, issues such as inadequate investment in healthcare resources, shortages in trained healthcare providers, insufficient health infrastructure, fragile health logistics and distribution networks, low levels of health literacy, inadequate public health promotion, and unsatisfactory public policy responses to address stigma and discrimination, can all impact access and health outcomes. These challenges are compounded by a lack of political priority, responsibility, and accountability, resulting in an inadequate focus on national HIV responses across government agendas and budget allocations.

Effectively addressing these challenges requires collaboration and coordination across diverse sectors including government agencies, international non-governmental organisations (iNGOs), local civil society, academia, regulators, and the private sector. ViiV Healthcare recognises the importance of and is committed to multisector partnerships to support country-led HIV responses.

### ViiV Healthcare's access to medicines approach

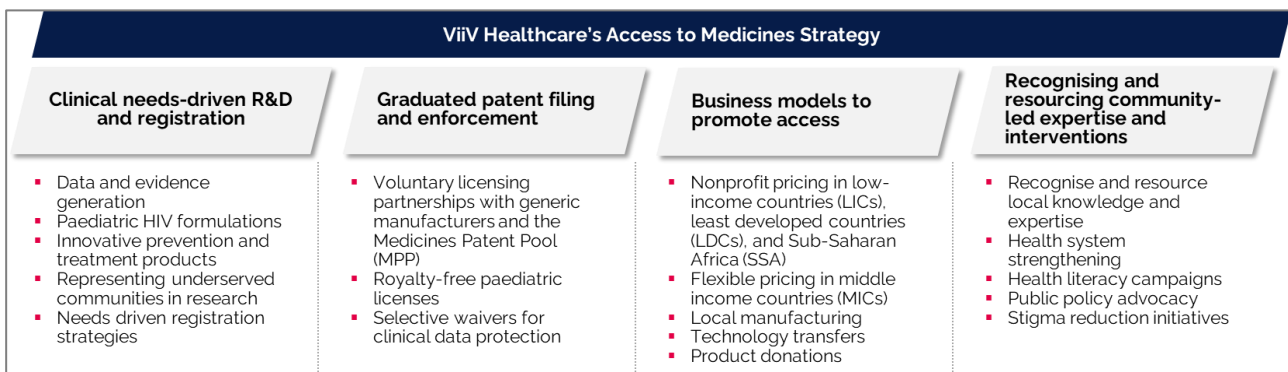


Figure 1: Our access to medicines strategy

Recognising the biopharmaceutical industry's contribution to improving access to HIV products and services, we are fully committed to collaborate with global stakeholders to address challenges impacting the global HIV response. Our approach recognises the need to improve long-term access to innovation in ways which are responsible, sustainable, and inclusive. Our strategy is informed by consultation with people and communities affected by HIV and driven by public health priorities established by [WHO](#) working groups.

Our access considerations begin in early product development, typically from phase II, when we start to evaluate key challenges and opportunities for a health technology's emerging clinical profile. More detailed access plans are developed once sufficient information on the manufacturing process and clinical profile of a product is available during Phase III development. Our approach helps to evaluate the potential impact of new treatment and/or prevention options in LMICs, by tailoring our access strategies accordingly.

<sup>3</sup> Under the 'Treat All' approach, WHO recommends ART is initiated in all people living with HIV, regardless of the disease's clinical stage and at any CD4 cell count. WHO also recommends the use of preferred first-line dolutegravir (DTG) based-regimens, and the use of pre-exposure prophylaxis (PrEP) as an additional prevention option to avert HIV transmission.

## 1. Investment in clinical needs-driven research and development (R&D) accompanied by product registration strategies

### Inclusive research and development

ViiV Healthcare invests in R&D through a clinical needs-driven approach that aims to address the key challenges associated with the epidemic, experienced by people living with and affected by HIV globally. We seek to support health systems to address key questions about the use and effectiveness of our medicines to improve public health outcomes in a variety of settings. Underpinning this investment approach is an emphasis on partnerships, exemplified through our collaborations with research networks, academia, global health organisations, community-led organisations, and healthcare professionals, among others.

ViiV Healthcare invests in and is committed to collaborate to:

- ✓ **Build reliable data and evidence** that demonstrate safety and effectiveness. We also undertake research studies to bridge the implementation divide, helping to better understand which implementation strategies work best and why for different population groups in specific LMIC settings. This data informs health programmes to improve access, availability, and adoption of health technologies. For healthcare systems and community-led responses, this evidence also contributes to improved understanding about what matters most to people and communities being left behind. This enables us to collaborate to improve [health-related quality of life](#) and public health outcomes.
- ✓ **Develop drug formulations** for prevention and treatment including those which are suitable for paediatric populations where health outcomes continue to lag adults. In the case of children, we focus on global health priorities championed by the WHO's [Paediatric ARV Drug Optimisation \(PADO\) Working Group](#) which works to identify key priority health products through addressing research gaps to impact the availability of suitable therapeutics for children.<sup>4v</sup>
- ✓ **Proactively set ambitious targets to recruit diverse communities from under-represented and under-served populations (disproportionately impacted by the epidemic) into clinical trials** including children, women, LGBTQIA+<sup>5</sup> communities, those living with unsuppressed HIV viral loads, and those experiencing multi-drug resistance. We invest in research to understand drug interactions and support optimal ART in resource-limited settings, where unique challenges such as high rates of tuberculosis (TB) co-infection remain public health threats.
- ✓ **Invest in strengthening clinical and implementation research** which seeks to translate evidence into practice. This supports progress in delivery approaches enabling broader access for people living with HIV and those who could benefit from greater choices for HIV prevention across all resource settings. We support local civil society, iNGOs, and academic institutions to address key implementation research gaps while recognising and resourcing the implementation research and clinical expertise of healthcare providers in LMICs.

### Implementation Science to support access to HIV prevention in LMICs

ViiV Healthcare's implementation science research collaborates with diverse partners working to bridge the gap between clinical research and healthcare practice. These implementation studies aim to identify best practices and novel delivery methods, training modalities, and awareness campaigns to support demand generation and improve access to PrEP. In LMICs, we partner to support studies which focus on prioritising access to innovation for young women and girls, a priority population disproportionately impacted by HIV.<sup>vi</sup>

### Clinical needs-driven product registration strategies

Our product registration strategies are informed by a clinical needs-driven approach which considers the clinical profiles of medicines, country-specific healthcare system structures and national epidemics. Furthermore we collaborate with regulators and public agencies to accelerate product registration through

<sup>4</sup> The WHO Paediatric Drug Optimization for HIV (PADO-HIV) group brings together stakeholders and experts every 2-3 years to identify priority products and define research gaps in the development of new HIV drugs and formulations for children in low-income and middle-income countries.

<sup>5</sup> The term LGBTQIA+ collectively refers to people who identify as lesbian, gay, bisexual, transgender, queer (or those questioning their gender identity or sexual orientation), intersex, and asexual (or their allies).

[Collaborative Registration Procedures \(CRPs\)](#), or other facilitated pathways specifically designed for faster approvals and minimising regulatory duplication, where appropriate.<sup>vii</sup>

## 2. Innovative partnerships and solutions to share intellectual property (IP) and develop voluntary licensing agreements – where the epidemic is most acute

### **Our graduated approach to IP enables access while safeguarding and incentivising R&D**

[IP](#) plays an essential role in incentivising biopharmaceutical R&D. This underpins a global system that has led to breakthroughs in drug discovery and development in HIV and other disease areas. IP protections can work to support mechanisms which improve access to medicines. In part, this system operates through support from countries with higher purchasing power and more established, well-resourced health systems. The IP framework recognises the value of innovative medicines and prioritises introduction and uptake, while multilateral and bilateral agencies as well as other donors and national governments collaborate to deliver access in countries with lower incomes.

Our graduated approach to filing patents in LMICs is tailored to a nation's economic maturity, prioritising sustainable access to health technologies. Notably, ViiV Healthcare does not apply for patents in [least developed countries \(LDCs\)](#) or [low-income countries \(LICs\)](#), allowing generic manufacturers to supply versions of our medicines across these regions. For [lower middle-income countries](#), we may continue to seek patent protection for our medicines but will provide voluntary licences, where appropriate.

### **Voluntary licences (VLs); increasing access to WHO-recommended antiretrovirals (ARVs)**

Through VLs, patent holders can share IP with generic manufacturers to enable the development, manufacture, and supply of health technologies in greater volumes and at lowered costs. While VLs have proven to be very successful for specific products in the global HIV response, they may not always be a viable option enabling access in all circumstances and for all health technologies. More complex innovations may require significant investment including specialist manufacturing capabilities, equipment, and facilities. In some cases, certain health technologies may not be considered a priority product recommended by global health organisations.

Our tailored approach to VLs includes, working with the UN-backed [Medicines Patent Pool \(MPP\)](#), along with collaborating directly with generic manufacturers. In some cases, for medicines that are particularly complex to manufacture or due to other critical factors, we also provide technical support to generic manufacturers. This includes the provision of technology packages and support to further expedite development and enable access to high-volume, low-cost formulations of our health technologies for HIV prevention and treatment.

### **Voluntary licensing agreements for HIV treatment - [dolutegravir \(DTG\)](#)**

In 2014, ViiV Healthcare established VL agreements with the [MPP](#) and generic manufacturers to scale-up access to WHO-recommended DTG-based medicines. These agreements enable generic manufacturers to develop, manufacture and supply adult and paediatric formulations of DTG for all [LICs](#), [lower-middle income countries](#), all [LDCs](#), all countries in [SSA](#), and certain upper-middle income countries ([UMICs](#)) for paediatric licences. As a result of these agreements, by the end of 2023, more than 90% of people living with HIV on ARVs in DTG generic-accessible LMICs were estimated to be on generic DTG-based regimens.

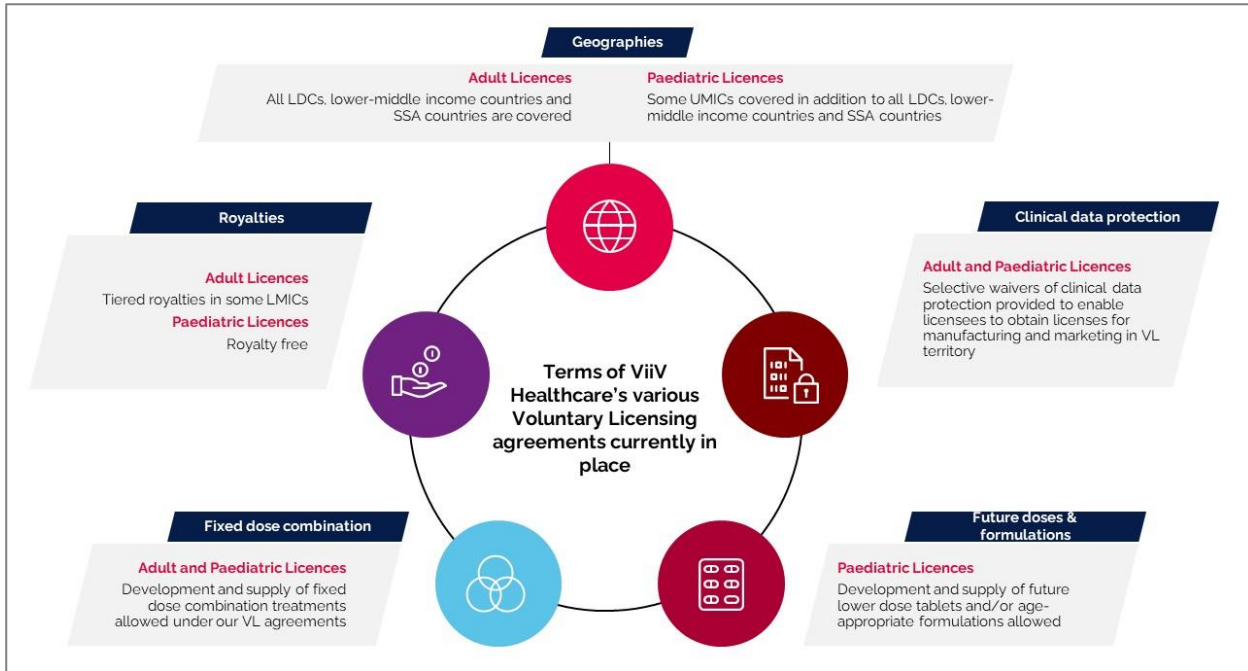


Figure 2: Key terms for our current voluntary licensing agreements

### 3. Tailored business models to promote access including flexible pricing and local manufacturing partnerships, where appropriate

#### Flexible pricing to promote access, while supporting long-term growth and investment in R&D

We also employ flexible pricing strategies that consider manufacturing complexity and cost relative to country-specific factors including product demand and market size. We seek to strike a balance between broadening access to our health technologies and maintaining commercial sustainability to support long term investment in next generation options to prevent and treat HIV and deliver for shareholders.

**Non-profit pricing in LICs, LDCs, and SSA:** ViiV Healthcare actively supports public health and donor-funded programmes in [LICs](#), [LDCs](#), and [SSA](#). Our commitment is to supply health technologies to public programmes supporting these countries, without seeking profits from sales.

**Flexible pricing in middle income countries (MICs):** In [MICs](#), characterised by higher gross national incomes and more robust health systems, ViiV Healthcare collaborates with governments to implement flexible pricing models that consider national income and the nature of local HIV epidemics. We negotiate prices based on local affordability, domestic healthcare system funding, and purchasing patterns and volumes which promote access.

#### Local manufacturing partnerships

To advance our commitment to increasing access, we actively engage in local manufacturing partnerships on a case-by-case basis.

Recognising that manufacturing health technologies involves complex processes which can often offer economies of scale at high volumes, our approach to local manufacturing partnerships - in the currently limited context in which this is feasible - is tailored based on local needs and available infrastructure. This approach seeks to reduce costs and accelerate access, while promoting local investment, and generate benefits which further develop domestic manufacturing knowledge and expertise.

#### Targeted product donations during crises to ensure continuity of care

ViiV Healthcare is committed to providing targeted product donations to meet humanitarian needs during emergency situations, such as conflict and natural disasters. These ad-hoc, time-limited donations are critical to ensure that people living with HIV can continue to access treatment, particularly in scenarios where regular

supply is temporarily compromised at a programmatic level. When deploying product donations in response to requests from partners, ViiV Healthcare operates in line with all applicable laws, regulations and codes of practice, including the latest [WHO Guidelines for Medicine Donations](#). We work closely with Ministries of Health, UN agencies and experienced NGOs to ensure our donations are directed and monitored appropriately. However, we recognise that product donations are exceptions and therefore cannot offer a long-term and sustainable response to address structural healthcare challenges and advance health system resilience during emergencies or humanitarian crises. In such cases, we recognise the importance of a multilateral response to protect and promote public health.

## 4. Investment to strengthening healthcare systems including recognising and resourcing community-led expertise, interventions and services

### Enabling access through strengthening health systems

The complex nature of access challenges in countries with limited incomes means that research, pricing and manufacturing strategies alone are not sufficient to ensure reliable access to prevention and treatment options. Often national public policies, service delivery and implementation challenges required at very local levels impede access to life-saving interventions. To address this public health gap, ViiV Healthcare prioritises investment and partnerships to strengthen health systems and resource community-led expertise and advocacy to develop, support and deliver people-centred services.

### Positive Action Programmes support access by promoting community-led HIV responses

ViiV Healthcare's [Positive Action](#) programme invests in innovative community-led initiatives seeking to transform the lives of people living with and communities affected by HIV. To progress ending AIDS in children and support our access agenda, we established the [Paediatric Breakthrough Partnership in 2020](#).<sup>viii</sup> This £10 million multi-year programme aims to improve engagement in HIV treatment, prevention and care for mothers and children living with or affected by HIV. We collaborate with global paediatric stakeholders and programme implementers including the [Elizabeth Glaser Paediatric AIDS Foundation \(EGPAF\)](#), [Aidsfonds](#), [United Nations Children's Fund \(UNICEF\)](#), and [Paediatric and Adolescent Treatment Africa \(PATA\)](#). Together, we work in Mozambique, Nigeria, and Uganda and have reached over 300,000 women and children.

### In conclusion

At ViiV Healthcare, we recognise the importance of partnership across the public, private and not-for profit sectors, needed to create equitable and sustainable access to life-saving testing, prevention, treatment, and care. We play our part through delivering a novel approach to R&D and collaborate to improve access to health technologies which is crucial to transform health outcomes for people living with HIV or those who could benefit from an expansion in HIV prevention options. While we are dedicated to scale-up access to ensure we focus on what matters most to people and communities, we acknowledge this cannot be achieved alone. ViiV Healthcare recognises each health technology access model is not universally applicable but is determined by country context, our diverse partnerships for action and targeted access tools and strategies to improve health outcomes and public health.

**This brief is part of a six-part policy briefing series. Other titles will be available to read shortly**

1. Financing the HIV Response and Investing in Innovation
2. Testing & Prevention
3. Scaling up Access Through Community-led Services
4. Mobilising People, Communities, and Others to Advocate for Access to Next Generation Health Technologies
5. Ending Paediatric AIDS

### About ViiV Healthcare

Established in November 2009, we are the only biopharmaceutical company solely focused on combating, preventing, and ultimately curing HIV & ending AIDS. ViiV Healthcare is dedicated to researching and delivering innovative HIV prevention and treatment options. We also support public policy, advocacy and programmatic solutions which contribute to end the epidemic as a public health threat, leave no one living with or affected by HIV behind and makes HIV a smaller part of people's lives.

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## References

- <sup>i</sup> UNAIDS. (2023). *HIV estimates with uncertainty bounds 1990-Present*. [https://www.unaids.org/en/resources/documents/2023/HIV\\_estimates\\_with\\_uncertainty\\_bounds\\_1990-present](https://www.unaids.org/en/resources/documents/2023/HIV_estimates_with_uncertainty_bounds_1990-present)
- <sup>ii</sup> CHAI. (2023). *Global HIV Markets Report*. <https://www.clintonhealthaccess.org/report/2023-hiv-market-report-the-state-of-hiv-market-in-low-and-middle-income-countries/>
- <sup>iii</sup> UNAIDS. (2023). *2023 UNAIDS GLOBAL AIDS UPDATE*. [https://thepath.unaids.org/wp-content/themes/unaids2023/assets/files/2023\\_report.pdf](https://thepath.unaids.org/wp-content/themes/unaids2023/assets/files/2023_report.pdf)
- <sup>iv</sup> UNAIDS. (2023). *2023 UNAIDS GLOBAL AIDS UPDATE*. [https://thepath.unaids.org/wp-content/themes/unaids2023/assets/files/2023\\_report.pdf](https://thepath.unaids.org/wp-content/themes/unaids2023/assets/files/2023_report.pdf)
- <sup>v</sup> WHO. (2022). *Priorities for antiretroviral drug optimization in adults and children report of a CADO, PADO and HIVResNet joint meeting*. [https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/pado4.pdf?sfvrsn=26d4169c\\_5](https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/pado4.pdf?sfvrsn=26d4169c_5)
- <sup>vi</sup> AVAC. (2023). *Integrated Study Dashboard*. <https://www.prepwatch.org/resources/implementation-study-tracker/>
- <sup>vii</sup> Access to Medicine Index. (2022). *Company profiles & report cards*. <https://accesstomedicinefoundation.org/sectors-and-research/index-ranking>
- <sup>viii</sup> ViiV Healthcare. (2023). *Paediatric Breakthrough Partnership Report 2020-23*. [https://viivhealthcare.com/content/dam/cf-viiv/viivhealthcare/en\\_GB/files/viiv-positive-action-pbppr-v31.pdf](https://viivhealthcare.com/content/dam/cf-viiv/viivhealthcare/en_GB/files/viiv-positive-action-pbppr-v31.pdf)