



ViiV
Healthcare
Access to Medicines Policy

Executive Summary

ViiV Healthcare's access to medicines strategy considers the specific challenges faced in terms of epidemic burden and economic status, and includes all low-income, least-developed, middle income and Sub-Saharan African countries (developing countries) where the unmet need for anti-retroviral therapy (ART) is greatest. ViiV Healthcare recognises that no one category of stakeholder can successfully achieve universal access to HIV treatment alone and that stakeholders from all elements of society – government, Non-Governmental Organisations (NGOs) and the private sector - must work together to ensure that UNAIDS 90-90-90* targets are met, the Sustainable Development Goals (SDGs) are achieved and consequently that no people living with HIV (PLHIV) are left behind.

Our access to medicine commitments include

- Investment in developing country clinical need-driven **research and development and product registration** strategies
- Innovative partnerships and solutions around **patents and voluntary licensing**
- New business models including **flexible pricing** models and **local manufacturing** partnerships
- Investment in **healthcare and community capacity building** activities which foster more effective healthcare service provision

The Issue

36.7 million people are eligible ART under the 'Treat All' approach advocated by the World Health Organization (WHO) 2016 guidelines¹. As of 2017 however, only around 57% of all PLHIV are accessing treatment². Scaling up access to treatment and ensuring that all PLHIV have access to HIV medicines is a crucial part of the global response to the epidemic. Not only does sustained access to ART lead to better medical and psycho-social outcomes for PLHIV, there is now a growing body of evidence that shows that effective ART can act as a robust prevention (Treatment as Prevention [TasP]) method and may help halt the progression of the HIV epidemic³.

Access to medicine is complex and multifaceted. Pricing of medicines is important, but there are many other more significant barriers including healthcare resources, lack of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, high levels of patient illiteracy, significant stigma and discrimination, and a lack of political will and inadequate prioritisation of HIV care in Government budgets. Improving treatment and care for PLHIV presents a complex challenge to the global HIV community. It can only be addressed if the significant barriers are tackled as a shared responsibility by all sectors of global society - governments, international agencies, civil society, academic institutions, the pharmaceutical industry and others.

ViiV Healthcare Access to Medicine Policy

As a company 100% focused on the needs of PLHIV, making our medicines as widely available to patients regardless of income or where they live is central to both ViiV Healthcare's access to medicines strategy and a core element of our corporate strategy. ViiV Healthcare is committed to playing a full part in addressing the healthcare challenges surrounding HIV of the developing world by taking an innovative, responsible and, above all, sustainable approach. Our strategy to support the global response is informed by consultation with the global HIV community, in line with identified global health strategies, and supports the global HIV agenda and targets set by UNAIDS* as well as contributing to the achievement of the SDGs⁴.

Research & Development

We invest in clinical need-driven research and development that supports registration and addresses key clinical questions about the use of our medicines in developing countries and/or addresses specific challenges for the developing world through a variety of partnerships and collaborations with a range of stakeholders including healthcare professionals, research networks (such as US National Institutes of Health (NIH) Division of AIDS, International Maternal Paediatric Adolescent AIDS Clinical Trials Group (IMPAACT), AIDS Clinical Trials Group (ACTG), HIV Prevention Trials Network (HPTN), Medicines Research Council (MRC), Paediatric European Network for Treatment of AIDS (PENTA), ANRS and the HIV-Netherlands-Australia-Thailand (NAT) Collaboration, academic institutions and community based organisations. Our mission – to leave no person living with HIV behind – is embodied by our focus on numerous areas that are key to tackling HIV/AIDS:

- ViiV Healthcare invests in building data packages for our medicines that demonstrate value via Real World Evidence. We are collaborating with payers to improve our understanding of real world HIV practice patterns, the role of adherence and the contribution that simplified dosing regimens offer patients and payers. We are studying the effectiveness of our medicines in active healthcare systems and institutions to complement our head-to-head studies.
- ViiV Healthcare is fully committed to the development of optimal paediatric formulations of our medicines in accordance with Global Health priorities which are shared by the Paediatric ARV Drug Optimisation (PADO) Working Group led by the WHO⁵.
- ViiV Healthcare recognises that prevention methodologies, including TasP, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and other behavioural strategies are a core element of HIV care. Through extensive collaborations with global trial networks and government and philanthropic agencies, we explore the potential of some of our marketed and pipeline assets for PrEP to potentially provide more options both in resource-poor settings and for hard to reach populations. We are also researching new technologies such as nanotechnology and different types of medical interventions that can prevent HIV infections, such as gels, intravaginal rings and implantable devices.
- ViiV Healthcare also collaborates actively with researchers to understand how our medicines work in the context of under-represented and under-served populations including women, patients over 50 years old, people with high viral loads and heavily treatment experienced patients with multi-class resistance. We also invest in research that will help enable optimal use in resource-limited settings where other challenges like high rates of tuberculosis co-infection exist.

**UNAIDS 90-90-90* targets: By 2020, 90% of all PLHIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained ART and 90% of all people receiving ART will have viral suppression.*

Product Registration

We adopt clinical need-driven product registration strategies to help accelerate access to our medicines and support introduction of generic versions of our medicines in the countries covered by our voluntary licensing policies. Our clinical need-driven approach considers the clinical profile of each medicine, country-specific challenges, the epidemic burden and the country's economic status. This approach means we will sometimes register our products in countries where ViiV Healthcare does not intend to supply directly to help facilitate generics manufacturer's registration of their generic formulations of our medicines.

We commit to work on the access to medicine strategy for products in clinical development from when the phase 3 clinical studies start. By this time in a product's development we believe we have sufficient information on the manufacturing process and clinical profile of the product to help us to evaluate the potential position in treatment and/or prevention the product may fulfil in developing countries, pending phase 3 clinical study results and registration with stringent regulatory authorities.

Patents & Licensing

We believe that intellectual property (IP) stimulates and underpins continued investment in research and development for new and better medicines, and that improving access to ART for PLHIV in developing countries requires a flexible and multi-faceted approach to intellectual property (IP) protection. In March 2016, alongside our majority shareholder GSK, we evolved our graduated approach to filing and enforcing patents so that IP protection reflects a country's economic maturity.

Under this graduated approach, moving forwards, ViiV Healthcare will not apply for patents on medicines in Least Developed Countries and Low Income Countries, as defined by World Bank Country Classifications. For Lower Middle Income Countries, ViiV Healthcare will continue to apply for patent protection for its medicines, where it considers appropriate. However, ViiV Healthcare will offer voluntary licences (VL) to these patents, to allow generic manufactures to supply medicines for PLHIV in these countries, that they otherwise could not (inc. generic versions of ViiV Healthcare medicines).

Although not a universal solution, VLs have clearly demonstrated a significant and sustainable impact in tackling the global HIV/AIDS epidemic by helping to increase the availability of medicines and contribute to better security of supply. ViiV Healthcare is committed to providing VLs across our product portfolio as well as for products in clinical development when they receive stringent regulatory authority (SRA) approval. ViiV Healthcare utilises direct VL approaches with generic manufacturers as well as partnering with the United Nations-backed Medicines Patent Pool (MPP).

Key terms of ViiV Healthcare voluntary licence agreements:

	ADULT LICENCES	PAEDIATRIC LICENCES
GEOGRAPHIES	All low-income, all least developed, all lower-middle income and all Sub-Saharan African (SSA) countries as defined by World Bank Country Classifications at the date of signature of the licence agreement.	All low-income, all least developed, all lower-middle income, all Sub-Saharan African (SSA) and some upper middle income countries as defined by World Bank Classifications at the date of signature of the licence agreement.
	When a country has been included in the territory of a voluntary licensing agreement it will not be removed for the effective period of the agreement even if it graduates to a higher World Bank Country Classification than is usually eligible. Licencees are not prevented from supplying generic medicines in countries outside of the licensing territory where there are no relevant patents in force.	
ROYALTIES	Tiered royalties in some lower middle income countries.	Royalty-free
FIXED DOSE COMBINATIONS	Voluntary licence agreements allow the development and supply of fixed dose combination treatments of our patented innovations that are constructed from regimens recommended by the World Health Organization (WHO) HIV Treatment Guidelines and/or the U.S. Department of Health and Human Services (DHHS) Guidelines.	
FUTURE DOSES & FORMULATIONS	Paediatric licences include a commitment to allow the development and supply of future lower dose tablets and/or age appropriate formulations to meet the needs of younger children with HIV, including those developed by ViiV Healthcare, when and if approved by a major regulatory authority.	
DATA EXCLUSIVITY WAIVERS	Some countries provide manufacturers with a period of data exclusivity (regulatory data protection) following regulatory approval. For countries included in the voluntary licensing territory, ViiV Healthcare provides selective waivers of its data exclusivity rights to the extent necessary to enable voluntary licencees to obtain the licences required to manufacture and/or sell relevant ARVs in the licensing territory.	

Flexible Pricing

Our flexible pricing approach forms an integral part of our broader access strategy for our medicines and reflects our objective of ensuring no PLHIV are left behind. This includes considerations towards finding the right balance between ensuring access to our ARVs for PLHIV wherever they live, the need to invest in the research and development of future innovative treatments and delivering value to our shareholders.

- **At-Cost Pricing:** ViiV Healthcare provides at-cost prices (covering manufacturing plus distribution costs) for its marketed product portfolio to all public markets and international donor agency programmes in all least developed countries (LDCs), low-income countries (LICs) and all Sub-Saharan African (SSA) countries until generic formulations of the products are available in these countries. This ensures that the countries with the greatest barriers to affordability are supplied at the lowest possible prices.

- **Flexible Pricing:** In middle income countries, where incomes are higher and infrastructure is more developed, ViiV Healthcare works directly with governments using a flexible pricing approach that factors in the gross national income (GNI) and the public health need in terms of the epidemic burden. Middle income prices are then refined considering local affordability, healthcare system funding, purchasing patterns and volumes and accessibility for PLHIV.

Local Manufacturing

We proactively consider establishing local manufacturing partnerships on a case-by-case basis, taking into account local needs. This approach can bring the cost of the medicines down and provides an opportunity to invest locally and share our expertise to build skills in the local economy at the same time.

Capacity Building

We are committed to investing in healthcare and community capacity building activities which foster better access to services and more effective healthcare service provision. Examples of our capacity building efforts include:

- **Research and Clinical Capacity Building:** We continually look to invest in strengthening research and clinical capability and capacity, with the ultimate aim of developing new therapeutic options and/or approaches for PLHIV in different populations and resource settings. We work with non-governmental organisations and international academic institutions, such as the International AIDS Society (IAS) and the London School of Hygiene and Tropical Medicine (LSHTM), to fill key research gaps whilst building research and clinical capacity of healthcare providers in LMICs.
- **Manufacturing Capacity Building:** We build innovative partnerships with generic manufacturers and other stakeholders, including Unitaid and the Clinton Health Access Initiative (CHAI), to provide technology transfer and support, when appropriate, to enable and expedite development and introduction of more affordable generic versions of our medicines across our voluntary licensing territory.
- **Healthcare System Strengthening:** Our Fast-Track Cities programme⁶ is a global partnership between the City of Paris, International Association of Providers of AIDS care (IAPAC), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the United Nations Human Settlements Programme (UN-Habitat), in collaboration with local, national, regional, and international partners and stakeholders. Fast Track Cities aims to accelerate the top 200 highest burden cities of HIV in the world in achieving UNAIDS 90-90-90 targets.⁷
- **Community Capacity Building:** Our Positive Action programmes have been supporting communities affected by HIV and AIDS since 1992. The programmes work with both global and local organizations on innovative and sustainable projects that scale up access to therapy and care for key affected populations living with HIV; tackle stigma and discrimination; strengthen education; build the capacity of communities; enable greater and meaningful involvement of people living with HIV; and deliver tangible results for communities affected by HIV. ViiV Healthcare supports more than 300 programmes globally that address the needs of people living with or affected by HIV with a particular focus on key populations.

Conclusion

Achieving universal access to HIV medicine is a journey that countries will travel at their own pace given their own needs, capacities and burden of the epidemic. In order to be successful, all countries must be at the centre of the process, taking the lead in setting direction, developing and executing strategies as well as monitoring progress and adjusting, if necessary.

ViiV Healthcare's access to medicine approach aims to support and enable scale up of access to medicine and care for PLHIV with a focus on the most deprived and most at need areas of the world. ViiV Healthcare recognises that no one category of stakeholder can successfully achieve universal access to HIV treatment alone and that stakeholders from all elements of society – government, NGOs and the private sector - must work together to ensure that UNAIDS 90-90-90 targets are met, the SDGs are achieved and consequently that no PLHIV are left behind.

References:

1. WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection – Recommendations for a Public Health Approach (2016): http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf?ua=1 . Last accessed Feb '18
2. UNAIDS Fact Sheet 2017: http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf . Last accessed Feb '18
3. WHO Prevent HIV, Test and Treat All 2016: <http://apps.who.int/iris/bitstream/10665/251713/1/WHO-HIV-2016.24-eng.pdf?ua=1> . Last accessed Feb '18
4. United Nations Sustainable Development Goals: <http://www.un.org/sustainabledevelopment/sustainable-development-goals/> . Last accessed Feb '18
5. Paediatric ARV Drug Optimisation (PADO) Working Group: <http://www.who.int/hiv/pub/meetingreports/paediatric-arv-optimization-pado3/en/>
6. UNAIDS Fast Track Cities: www.fast-trackcities.org . Last accessed Feb '18
7. UNAIDS 90-90-90 targets: <http://www.unaids.org/en/resources/909090> . Last accessed Feb '18