GLOBAL POLICY BRIEFING

ACCESS TO MEDICINES

Summary

ViiV Healthcare's access to medicines strategy considers the specific challenges faced by countries in terms of local HIV epidemic burden and economic status. This applies to all LDCs[a] (least developed countries), LICs (low-income countries), MICs (middle income countries) and SSA (Sub-Saharan African) countries ; where the unmet need for anti-retroviral therapy (ART) is greatest and where people are most at risk to being affected by HIV.[1] ViiV Healthcare recognises that successfully achieving universal access to HIV treatment requires collaboration across all parts of society – public, private and not-for-profit sectors – working collaboratively to ensure that UNAIDS 90-90-90 targets[b] (progressing to 95-95-95 targets by 2030) are met as well as, achieving the UN Sustainable Development Goals (SDGs)[c] to ensure no person living with, or at risk of HIV infection is left behind.

Our commitments to expanding access to medicines include:

- Investment in clinical need-driven **research and development** and **product registration strategies**
- **Formation of innovative partnerships** and solutions around **patents and licensing**
- Development of novel business models that reflect domestic needs and challenges, including **flexible pricing** and **local manufacturing** partnerships and collaborations
- Investment in **healthcare and community capacity building** activities that foster more effective healthcare service provision

The challenge

37.9 million people are eligible for ART under the 'Treat All' approach advocated by the World Health Organization's (WHO) 2016 guidelines.[2] However, as of June 2019, only 62% of all PLHIV were accessing treatment.[3] Ensuring that all PLHIV have access to HIV medicines is a crucial part of the global response to address the epidemic. Sustained access to ART not only leads to better medical and psycho-social outcomes for PLHIV, but Treatment as Prevention [TasP[d]] can also act as a robust prevention method and may help halt the progression of the HIV epidemic.[4] The 2016 UN General Assembly's Political Declaration on ending AIDS, supported by the 2020 Global Prevention commitments and targets, aim to reduce the number of people newly infected by HIV to fewer than 500,000 globally. This includes a target of ensuring that three million of the most vulnerable people and those at greatest risk have access to Pre-Exposure Prophylaxis[e] (PrEP).[5,6,7]

Access to medicine is complex and multifaceted. As innovative medical options for treatment and prevention are brought to market, a deeper understanding of both the supply factors (including manufacturing processes, costs and investments) and demand factors (including service delivery models, novel implementation approaches) by all stakeholders will increase the acceptability and global impact of promising new interventions. The pricing of medicines is important, but there are many other significant barriers including availability of healthcare resources, lack of medical facilities, fragile distribution networks, limited numbers of trained healthcare providers, low levels of health literacy, significant stigma and

a The UN Committee for Development Policy defined Least Developed Countries as low-income developing countries suffering from severe structural impediments to sustainable development. Indicators of such impediments are a high vulnerability to economic and environmental shocks and low levels of human assets.
b The UN's 90-90-90 Targets seek to achieve (by 2020): 90% of all people living with HIV will know their HIV status.,90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral suppression.
c A universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity by 2030
d Treatment as Prevention (TasP) refers to the use of antiretroviral (ARV) medication to prevent HIV transmission.
e PrEP is a pill that can be taken to protect an individual who considers themselves at risk of HIV. It is extremely effective when taken properly.

discrimination, a lack of political will and inadequate prioritisation of HIV prevention and care in government budgets. Improving treatment and care for PLHIV as well as populations at risk of HIV infection presents a complex challenge. This can only be effectively addressed if all sectors of society - governments, international agencies, civil society, academic institutions, the pharmaceutical industry, regulators and the wider private sector among others - work collaboratively to tackle them.

ViiV Healthcare's Access to Medicine Policy

ViiV Healthcare is 100% focused on the needs of people living with and affected by HIV, and we make our medicines widely available to those in need - regardless of income or where they live - through innovative access mechanisms and partnerships. ViiV Healthcare is fully committed to playing its part in addressing the HIV-related healthcare challenges encountered in developing countries. We do this by taking an innovative, responsible, and above all, sustainable approach. Our strategy is informed by consultation with the global HIV community, aligned to universal global health strategies, and supports the global HIV agenda and targets set by UNAIDS and integrated into the SDGs.[8]

Research & Development and Product Registration

Research & Development

We invest in clinical need-driven research and development that supports registration, addresses key clinical questions about the use of our medicines, and tackles specific HIV challenges affecting the developing world. These investments support a variety of partnerships and collaborations with a range of stakeholders including healthcare professionals, research networks[f], academic institutions, global health organisations (such as the Bill & Melinda Gates Foundation), and community-based organisations. Our mission – to leave no person living with HIV behind – is embodied by our R&D focus on numerous areas that are key to ending AIDS as a public health threat by 2030.

ViiV Healthcare:

- **Invests in building data packages** for our medicines that demonstrate value by using evidence which reflects real-world experiences. We collaborate with payers to improve our understanding of real-world HIV care management, the role of adherence and the contribution that simplified dosing regimens offer PLHIV and payers. We also study the implementation and effectiveness of our medicines in healthcare systems and institutions to complement our clinical studies.

- **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 World Health Organisation (WHO).

- **Is committed to researching, developing and enabling diverse HIV prevention options** including TasP, PrEP, post-exposure prophylaxis (PEP)[g] and other behavioural strategies as core elements of HIV prevention and care. Through extensive collaborations with global trial networks and government and philanthropic agencies, we are committed to evaluating the potential of relevant pipeline assets for PrEP. We are also investigating new technologies including nanotechnology and implantable devices to prevent HIV infections globally, as well as multi-purpose prevention technologies to simultaneously prevent unintended pregnancy and protect against HIV.

- **Actively collaborates with researchers to understand how our medicines work in the context of under-represented and under-served populations** including children, women, PLHIV who are over 50 years old, people with high viral loads and those who are heavily treatment experienced with multi-drug resistance. We also invest in research that seeks to enable optimal anti-retroviral (ARV) use in resource-limited settings where challenges such as high rates of tuberculosis co-infection exist.

Product Registration

We adopt clinical need-driven product registration strategies to help accelerate access to our medicines and support the introduction of generic versions of our medicines in the countries covered by our voluntary licensing policies (outlined below). Our clinical need-driven approach considers the clinical profile of each medicine, country-specific challenges, the HIV 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 in order to facilitate generic manufacturers' registration of generic versions of our medicines.

[f] Networks include: The US National Institutes of Health (NIH); Division of AIDS (DAIDS); International Maternal Paediatric Adolescent AIDS Clinical Trials (IMPAACT) Group; AIDS Clinical Trials Group (ACTG); HIV Prevention Trials Network (HPTN); Medicines Research Council (MRC); Paediatric European Network for Treatment of AIDS (PENTA); The French National Agency for AIDS Research (ANRS) and the HIV-Netherlands-Australia-Thailand (NAT) Collaboration

g Post-exposure prophylaxis (PEP) means taking HIV medicines within 72 hours after a possible exposure to HIV to prevent HIV infection.

We commit to work on the access to medicine strategy for products in clinical development as soon as phase III clinical studies (to demonstrate drug safety and efficiency) commence. By this stage in a product's development, we believe that we have adequate information on the manufacturing process and clinical profile of the product. This helps us evaluate its potential role in HIV treatment and/or prevention programmes in developing countries. This process is subject to phase III clinical study results and registration with stringent regulatory authorities. Our strategies for low- and middle-income countries are guided by global health priorities, published by the WHO-led Combined Antiretroviral (ARV) Drug Optimization (CADO) and Paediatric ARV Drug Optimization (PADO) working groups.

Patents & Licensing

We believe that intellectual property (IP) stimulates and underpins continued investment in research and development for new and better medicines. Therefore, improving access to ARVs 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, ViiV Healthcare will not apply for patents on medicines in Least Developed Countries (LDCs) and Low-Income Countries (LICs), as defined by World Bank Country Classifications. For Lower Middle-Income Countries (LMICs), ViiV Healthcare will continue to apply for patent protection for its medicines, where it considers appropriate. However, where the execution of voluntary licences (VL) will deliver on the goals of reducing prices and increasing supply capacity for developing countries, ViiV Healthcare will offer VLs to these patents. This allows generic manufacturers to supply generic versions of these ViiV Healthcare medicines in the regions specified.

While VLs may not enable broader access in all circumstances, they have clearly demonstrated a significant and sustainable impact in tackling the global AIDS epidemic in appropriate settings. For many years, VLs have driven increased access and availability of some ARVs and have contributed to improved security of supply. Notably, VLs have successfully enabled broader access to high volume, low-cost, oral, solid dose, generic ARV tablet formulations in developing countries. These VLs have enabled price reductions, improved supply availability and expanded manufacturing capacity. Nonetheless, some innovative medicines require specialist manufacturing equipment, facilities and capabilities, and others have not yet been prioritised by global health organisations to have a clear role in the global HIV response; which means that VLs are not always a viable option.

ViiV Healthcare is committed to providing VLs for ARVs where it can be established that they will improve affordability and supply of our medicines in LICs, LDCs, LMICs and SSA countries. ViiV Healthcare utilises direct VL approaches with generic manufacturers as well as partnering with the United Nations-backed Medicines Patent Pool (MPP). In situations where VLs are not viable, we are committed to exploring alternative mechanisms and working through partnerships to enable clinical-need driven access determined by global public health priorities.

Key terms of ViiV Healthcare voluntary licensing agreements[h]

	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. Licensees 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 Organisation (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 licensees to obtain the licences required to manufacture and/or sell relevant ARVs in the licensing territory.	

Flexible pricing and local manufacturing

Flexible pricing

Our flexible pricing approach forms an integral part of our broader access strategy for our medicines and reflects our objective to ensure no person living with HIV is 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.

- **Non-Profit Pricing in LICs, LDCs and SSA:** ViiV Healthcare does not expect to profit from sales of its marketed products to public HIV programmes and international donor agency programmes in all LICs, LDCs, and SSA countries. This ensures that the countries with the greatest barriers to affordability can be sustainably supplied at the lowest possible prices.
- **Flexible Pricing in middle income countries (MICs):** In MICs, where incomes are higher and infrastructure is more developed, ViiV Healthcare works directly with governments using a flexible pricing approach that factors in gross national income (GNI) and public health need defined in terms of the epidemic burden. Prices in MICs are then refined based on local affordability, domestic healthcare system funding, purchasing patterns and volumes as well as accessibility for PLHIV.

Local manufacturing

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

h Based on existing executed VLs

Healthcare and community capacity building

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

- **Research and Clinical Capacity Building:** We continually invest in strengthening implementation research and clinical capability and capacity, with the aim of developing new prevention and treatment options and/or approaches for PLHIV and at-risk populations across different 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 address key implementation research gaps whilst building the implementation research and clinical capacity of healthcare providers in LMICs.

- **Manufacturing Capacity Building:** We build innovative partnerships with generic manufacturers and other global health stakeholders such as Unitaid and the Clinton Health Access Initiative (CHAI), to provide technology transfer[i] and other support, when appropriate. For some of our medicines, this enables and expedites the development and introduction of more affordable generic medicines across our VL territories.

- **Healthcare System Strengthening:** The Fast-Track Cities (FTC) programme is a global partnership which aims to accelerate achieving the UNAIDS 90-90-90 targets for more than 300 cities and municipalities with the highest HIV burden globally.[9]

- **Community Capacity Building:** Our Positive Action programmes has been supporting PLHIV, communities affected by HIV & AIDS, and those most at risk of HIV infection, to improve their quality of life since 1992. The 2020 – 2030 Positive Action strategy builds on our previous successes and learnings, with a mission to achieve healthy communities in a world free of AIDS. We create strategic partnerships and offer community grants to enable organisations to secure sustainable change for communities affected by HIV. Programmes include: designing and testing innovative approaches or scaling up proven interventions that support service provision for key affected populations living with HIV, tackling stigma and discrimination, promoting education and improving community understanding of HIV and enabling greater and more meaningful involvement of PLHIV in HIV care and service provision.

Conclusion

Achieving universal access to HIV medicine and prevention interventions is an evolution in which countries will progress at their own pace given domestic needs, capacities and specific epidemic burden. To succeed, countries must be at the centre of the process, taking the lead in setting the direction needed to develop and execute strategies as well as monitor progress and adapt each national response, where necessary.

ViiV Healthcare's approach aims to support and enable scale-up of access to medicines and care for PLHIV and affected populations; with a focus on those most in need and at greatest risk across resource limited settings. ViiV Healthcare recognises that successfully achieving universal access to HIV treatment requires collaboration across all parts of society – public, private and not-for-profit sectors - working together to ensure that UNAIDS 90-90-90 targets are met, the SDGs are achieved, and to ensure that no person living with, or at risk of HIV, is left behind.

i Technology transfer refers to the process by which a developer of a healthcare technology makes its technology available to a manufacturing partner to enable them to use it to develop their own product.

ViiV Healthcare Global Policy Briefing 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.

UK Address: GSK House, 980 Great West Road, Brentford, TW8 9GS

Website: www.viivhealthcare.com

Twitter: @ViiVHC

Facebook: @ViiVHealthcare

References

1 UNAIDS Committee for Development Policy. (2018). CDP Policy Review Series Comparison of Indicators for Identification of Least Developed Countries and for Measuring Progress Towards the Sustainable Development Goals. Retrieved from: https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/CDP-review-2018-1.pdf
2 WHO Global Health Observatory (GHO) Data. Retrieved from: https://www.who.int/gho/hiv/epidemic_response/ART_text/en/
3 UNAIDS Fact Sheet World AIDS Day 2019. Retrieved from:https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf
4 United Nations General Assembly Political Declaration on Ending AIDS. Retrieved from: https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/june/20160608_PS_HLM_PoliticalDeclaration.
5 United Nations Sustainable Development Goals. Retrieved from: http://www.un.org/sustainabledevelopment/sustainable-development-goals/
6 United Nations General Assembly Political Declaration on Ending AIDS. Retrieved from: https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/june/20160608_PS_HLM_PoliticalDeclaration
7 Iwantprepnow.org. (2020). All about PrEP. Retrieved from: https://www.iwantprepnow.co.uk/about/
8 United Nations Sustainable Development Goals. Retrieved from: http://www.un.org/sustainabledevelopment/sustainable-development-goals/.
9 UNAIDS Fast Track Cities. (2020). Retrieved from: www.fast-trackcities.org .