



CABOTEGRAVIR: WHAT ARE WE WAITING FOR?

Why the most effective form of HIV prevention is out of reach for people at highest risk of HIV



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MSF community health worker Rozi (not her real name) interacting with a sex worker in Mwanza town in Malawi. Sex workers are one of the groups disproportionately affected by and at greater risk of HIV infection.

INTRODUCTION

In 2020, around 1.5 million people were newly infected with HIV.¹ Women and girls account for half of all new infections, while key populations (men who have sex with men, sex workers, people who inject drugs, people in prisons and closed settings, and transgender people) represent two-thirds. Although the majority of new infections continue to occur in sub-Saharan Africa, rates of infection in the region have declined. This is in stark contrast to the 43% increase in infection rate in Eastern Europe and Central Asia.

Global targets endorsed at the World Health Assembly 2022 aim to reduce new HIV infections from 1.5 million to under 370,000 by 2025 and under 335,000 by 2030.² To achieve this, a goal has been set for 95% of people at risk of HIV infection to have access to and be able to use person-centred and effective combination prevention options, and for the 10 million people at substantial risk of HIV to have access to pre-exposure prophylaxis (PrEP) by 2025. The targets also specifically call for availability of effective combination prevention options for 95% of people within humanitarian settings at risk of HIV.³

PrEP refers to medicine taken to prevent HIV infection. It is one element of an effective combination prevention strategy, alongside condom promotion and distribution, post-exposure prophylaxis (PEP), and screening and treatment of sexually transmitted infections. In 2020 approximately 845,000 people in 54 countries received PrEP. Just 28% of the target for PrEP use for low- and middle-income countries (LMICs) was achieved, and geographical and social inequities resulted in even poorer access to PrEP for key populations within these countries.⁴

Three types of PrEP have been approved for use by people at risk of HIV infection: oral PrEP, dapivirine (DPV) vaginal ring and long-acting injectable cabotegravir (CAB-LA).

Currently oral PrEP containing tenofovir (TDF) is the method routinely offered. It involves taking a once-daily pill. Oral PrEP has been implemented in some MSF programmes with integrated, comprehensive key population services and for those assessed as high risk in the general population.

While oral PrEP is highly effective, taking a daily pill can be challenging for some people. Long-acting forms of PrEP such as DPV vaginal ring and CAB-LA offer a more discreet option that can facilitate adherence for people at risk of HIV infection.

In January 2021, WHO recommended use of the long-acting DPV vaginal ring and it was added to its list of prequalified medicines based on having received a positive scientific opinion from the European Medicines Agency (EMA) via its EU Medicines 4 All programme in July 2020. The ring delivers an antiretroviral medicine (ARV) called dapivirine over the course of one month directly to vaginal tissue to help protect against HIV at the site of potential infection.

In December 2021, the United States Food and Drug Administration (FDA) approved CAB-LA as a third option for prevention of HIV infection.⁵ CAB-LA is from the class of antiretrovirals called HIV-1 integrase strand transfer inhibitors that block the replication of the virus. It is also approved for treatment of HIV if used in combination with the long-acting injectable rilpivirine. CAB-LA is supplied as 600mg/3ml vial, and delivered as an injection every two months. It is approved for use in at-risk adolescents and adults weighing at least 35kg. WHO is expected to release recommendations for the use of CAB-LA in July 2022.

CAB-LA is the most effective means to prevent HIV infection and can help turn the tide against new HIV infections globally. However, a number of factors currently constrain access to this drug in places where it is needed most, threatening progress towards global targets for HIV prevention.

This Issue Brief outlines the evidence for the efficacy of CAB-LA, and its current implementation and access challenges. In particular, the brief focuses on the lack of transparency around pricing and registration of the medicine, licensing and supply arrangements, and the harmful effects of the restrictive access conditions imposed by ViiV Healthcare, the originator of CAB-LA.

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HOW EFFECTIVE IS CAB-LA AT PREVENTING HIV TRANSMISSION?

Two landmark trials, HPTN 083 and HPTN 084, have demonstrated that the efficacy of CAB-LA is superior to that of oral PrEP; it is therefore the most effective form of PrEP currently available.⁶

HPTN 083 was the first study to compare the efficacy of bi-monthly injectable CAB-LA to daily oral PrEP for HIV prevention. HPTN 083 enrolled 4,570 cisgender men who have sex with men (MSM) and transgender women who have sex with men at 43 sites in Argentina, Brazil, Peru, the United States, South Africa, Thailand and Vietnam.⁷ HPTN 084 compared a bi-monthly injection of CAB-LA to oral PrEP in women aged 18 to 45 years at risk of acquiring HIV. 3,223 cisgender women were enrolled from Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda and Zimbabwe.⁸

While a very small number of participants tested positive for HIV in the CAB-LA arm of the trials, a more detailed analysis found that some of these infections were acquired prior to initiation of CAB-LA. Overall, CAB-LA was found to be 68% and 92% more effective than oral PrEP in HPTN 083 and HPTN 084, respectively.

Ongoing studies are investigating CAB-LA's use in women under the age of 18 (when many infections occur) and its safety in pregnant and breast-feeding women.

A modelling study considering CAB-LA's use in South Africa has estimated that providing CAB-LA to 10% of the adult population could avert more than 15% of new infections between 2023 to 2050, whilst uptake by those most at risk of infection, particularly young women, could improve the efficiency of any intervention.¹⁰

ACCESS TO CAB-LA: CURRENT SITUATION AND CHALLENGES

PRICING TRANSPARENCY

CAB-LA is patented and produced by ViiV Healthcare, an offshoot of pharmaceutical corporations Pfizer, GlaxoSmithKline and Shionogi. It was first approved by the FDA in January 2021 for treatment of HIV (used in combination with long-acting rilpivirine from pharmaceutical corporation Janssen), and then for use alone for prevention of HIV in December 2021. In the US market, CAB-LA is priced at US\$3,700 per vial, or \$22,200 per person per year.¹¹

The Clinton Health Access Initiative (CHAI) has conservatively estimated that CAB-LA can be produced by generic manufacturers for approximately \$2.60 per vial, or \$15.64 per person per year (including active pharmaceutical ingredients, formulation, sterilisation, development and capital expenditure) – less than the price of oral PrEP options (\$41-49 per person per year).^{12,13}

While ViiV's stated policy is to provide their medicines "at cost" for low-income, least developed and sub-Saharan African countries, they have yet to publicly announce what that price is.¹⁴ The price has been shared with a number of actors but under a signed confidentiality agreement (CDA). On May 4, 2022, the civil society organisation Health GAP (who did not sign a CDA) published the price, indicating it will be available for \$240-270 per person per year, or \$40-45 per vial.¹⁵ However, ViiV informed MSF in July 2022 that the non-profit price is \$210-240 per person per year (six vials) and is "subject to change at any time".

REGISTRATION

As of March 2022, ViiV has registered CAB-LA in the US and filed to register in only eight other countries: Australia, Botswana, Brazil, Kenya, Malawi, South Africa, Uganda and Zimbabwe.¹⁶ These countries were selected based on ViiV's focus on prevention of HIV in girls and young women in the sub-Saharan Africa region. While registration in these countries is a start, not all countries that hosted clinical trials for CAB-LA are included. The list also notably excludes



Brang Seng, a person living with HIV, outside MSF's Myitkyina clinic in Kachin state, Myanmar. As of July 2022, ViiV has failed to file for registration of CAB-LA in countries in Asia and Eastern Europe.

high-burden countries such as Mozambique, as well as other contexts and regions with highly vulnerable key populations such as Asia and Eastern Europe.

ViiV has not made its plans for future registration filings public and has said that in countries where the drug is not registered, it can only be considered for supply in the context of being an investigational product. **Lack of transparency around future registration plans and availability limits the countries where introduction pilots and studies can be planned.**

“Being able to offer oral PrEP over the last few years has been an extremely important part of our MSF HIV programmes as it helps prevent those who are most vulnerable to HIV infection from becoming HIV positive. Although many have benefitted from oral PrEP, for some the stigma of taking oral pills home has been a real challenge. We also see a lot of people stop oral PrEP after just two to three months despite their ongoing risk.

Having access to CAB-LA could be a potential game-changer for our HIV programmes as it would empower people to take the prevention method of their choice. We need to include CAB-LA in our PrEP offer but that will only be possible if it is available at a price similar to our current methods. As implementers of PrEP we are ready to deliver this new method. Every day we wait will result in more infections that could have been prevented.”

– Dr Helen Bygrave, Chronic Diseases Advisor, MSF Access Campaign

VOLUNTARY LICENSING

ViiV holds patents on CAB-LA in multiple MICs, including Brazil, India, Nigeria and South Africa. The patent monopolies of the pharmaceutical company will block access to affordable generic formulations and allow them to sell CAB-LA at high prices, keeping the medicine out of reach for many who need it. The patents on CAB-LA parenteral composition have been opposed in India and Brazil, and if they are revoked by the patent offices, it would be a step towards allowing access to generic formulations.^a

Despite voluntary licensing being a part of ViiV’s Access to Medicines Strategy, in March 2022 it announced that it would not consider a voluntary license for CAB-LA “due to the complexities of manufacturing, regulatory requirements, capital investment needs and unpredictable demand”.^{17,18}

After considerable backlash from various civil society organisations, ViiV did a U-turn and announced that it was open to the possibility of a voluntary license.¹⁹ In May 2022, ViiV and the Medicines Patent Pool (MPP) announced that they were engaged in negotiations for a voluntary license on CAB-LA.²⁰

While this is a step in the right direction, a voluntary license for CAB-LA should improve upon the most recent ViiV/MPP license, which was for dolutegravir. Under its terms, generic dolutegravir is available only in the public market and to NGOs; the more

lucrative private market is excluded. It will be essential for ViiV to include all LMICs in the territory of the license for CAB-LA, and to cover both public and private markets in a country to broaden access to the medicine.

MSF urges ViiV to register CAB-LA broadly, including in countries where registration of the originator product is a requirement for registration of generics. ViiV should also allow for technology transfer to the generic manufacturers who request it, without additional strings attached, to expedite development of their products.

Unfortunately, with negotiations having been left so late, even if a voluntary license is signed tomorrow, it could take up to 4-5 years for generic manufacturers to develop CAB-LA, scale up manufacturing, complete bioequivalence testing and submit registration. This unnecessary delay by ViiV will likely result in many governments being unable to provide CAB-LA in the interim, and may lead to potentially millions of additional HIV infections if left unaddressed.

SOLE SUPPLIER

Given the delay in voluntary licensing and potential generic entry into the market, ViiV will likely be the sole supplier of CAB-LA in the short term. While ViiV has stated publicly that half of their supply will be allocated to high-income countries (HICs), and half for LMICs, the actual production capacity and timeline for potential expansion of this capacity is unknown. Furthermore, having only one supplier for a medicine comes with inherent risks for supplying the market.

BIOEQUIVALENCE REQUIREMENTS

In April 2022, WHO added CAB-LA to its priority list of medicines eligible for assessment of quality by its Pre-Qualification Programme (PQP).²¹ Ideally, WHO PQP will issue guidance for bioequivalence requirements—testing to show that the generic formulation is essentially the same as the originator. Bioequivalence testing for a long-acting injectable medicine that stays in the body for many months may be more complicated and take longer compared to the usual oral tablet formulations, thereby increasing the time it will take to develop a generic formulation.

“PrEP is for people at risk of HIV to prevent them from transitioning to being HIV positive. By taking PrEP, patients are taking control of their own health, practising a health seeking behaviour which we promote as health care workers.”

– Rejoice Ncube, MSF nurse in Eswatini

^a MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in LMICs. For status of patents on CAB-LA in Brazil and India, see: <https://www.medsPAL.org/?product%5B%5D=Cabotegravir+200+mg%2Fml&countries%5B%5D=Brazil&countries%5B%5D=India&page=1>

The need for independent implementation science for CAB-LA

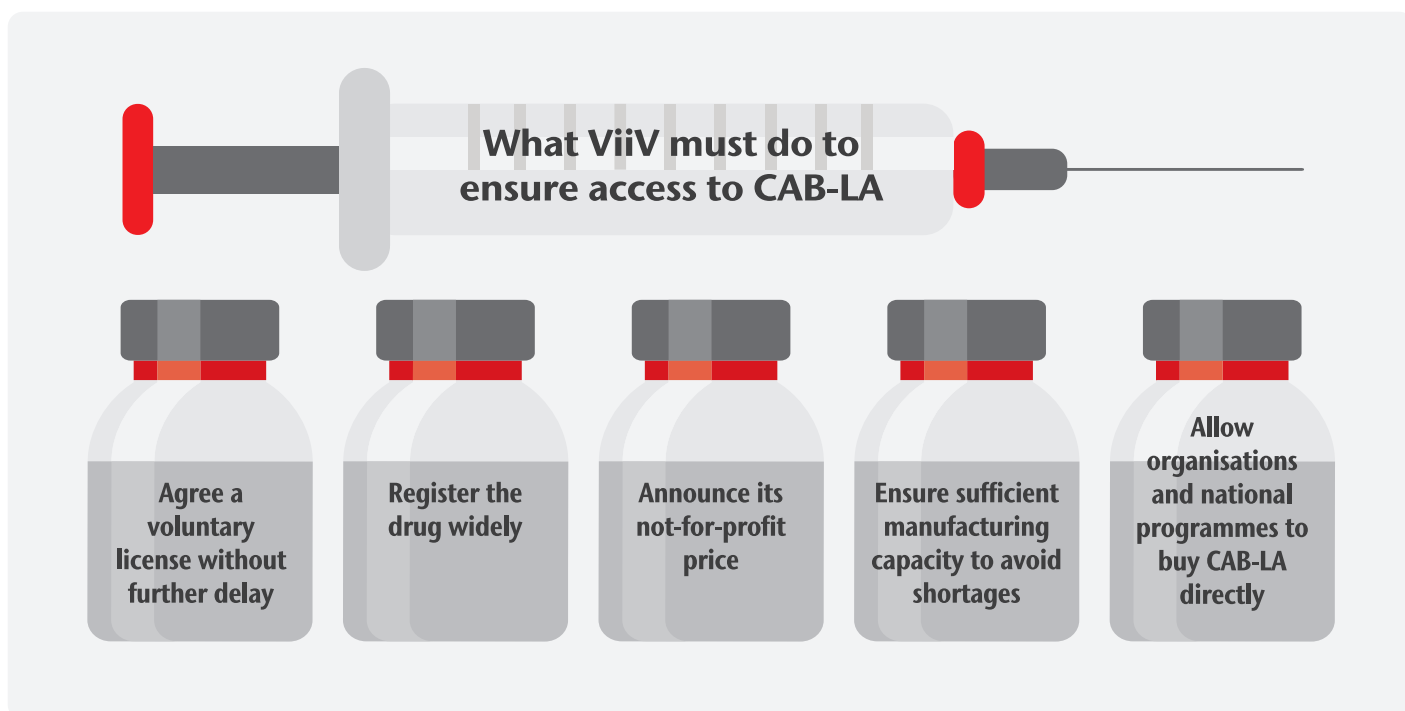
Access to CAB-LA for LMICs is currently limited mainly to use within ViiV's implementation science programme.²² Under this programme, partners submit research proposals and protocols to study the use of CAB-LA for PrEP to ViiV for approval. If approved, the company will consider a donation of the drug.

Although implementation science is essential to better understand how to scale up CAB-LA use, ViiV's conditions pose several problems. First, implementation science for all available PrEP products should be carried out independently of any manufacturer in order to ensure there is no bias or conflict of interest. Funding for such research therefore must include procurement of PrEP, whether oral TDF-based tablets, the DPV vaginal ring or injectable CAB-LA. **ViiV has no legitimate role in approving and overseeing research proposals of other organisations. Its implementation science**

requirements are an affront to good research practice and will hamper HIV prevention efforts.

Second, granting access exclusively within such a research framework may deny the most vulnerable populations, particularly within humanitarian settings, access to the most effective HIV prevention method currently available. CAB-LA is an FDA-approved medicine and soon to be WHO-recommended, and in such settings, implementation protocols can be agreed in collaboration with ministries of health. Also, in countries where medicines are not yet registered, they may be imported using a humanitarian waiver. **Tying access to CAB-LA to implementation science protocols approved by ViiV will block the goal of reaching 95% of people at risk of HIV with effective combination prevention tools.**

Finally, this approach could artificially stifle demand as countries, fearing shortages and stockouts, may be unable to or deterred from rolling out this game-changer in the HIV pandemic.



THE WAY FORWARD

To achieve the global PrEP coverage targets, **it will be important to establish models of care that fit the needs and lives of the people who want to use it.** Models of care will need to decentralise and simplify PrEP delivery, including for CAB-LA, as part of comprehensive sexual and reproductive health services, taking it beyond health facilities and empowering people to self-manage their medication. Several implementation challenges remain for CAB-LA, including determining which type of HIV testing will be acceptable, minimising the risks of development of integrase inhibitor resistance, and assessing how a drug requiring an intramuscular injection might be delivered outside a health facility setting. These challenges are not insurmountable.

The FDA approved CAB-LA with a requirement that people test negative using a nucleic acid test (NAT) for HIV before every injection, to reduce the risk of developing drug resistance if they were to become positive. Although NAT testing is available through multi-disease molecular diagnostic platforms in many settings, requiring its use would pose a considerable operational and cost barrier to rolling out CAB-LA.

NAT HIV testing in the context of CAB-LA use is under review by WHO. Whether or not a NAT test remains a requirement in the upcoming recommendations, more research and evidence will be needed to determine the ideal HIV testing protocol for CAB-LA, balancing the needs for access at scale with concerns about drug resistance.

Healthcare providers need to work with communities to design and deliver effective differentiated service delivery models for PrEP including CAB-LA, in a range of populations and geographies, including humanitarian settings. In addition to the service delivery

model, developing tools that empower healthcare workers and people receiving PrEP, to offer and select from a menu of PrEP options, will be a significant implementation challenge to overcome.



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Mr. and Mrs. Kimboi visit MSF's clinic in Chakpikarong in Manipur, India, to collect their HIV medication. In order to achieve global PrEP coverage targets, models of care will need to simplify PrEP delivery, including for CAB-LA.

RECOMMENDATIONS

CAB-LA is a game-changer in HIV prevention and the most effective form of PrEP currently available to people at high risk of HIV. However, the lack of transparency around the pricing (including requirement to sign CDAs) and registration of the drug, unnecessary delays over agreeing a voluntary license, and arbitrary implementation science conditions, have acted as barriers to access to this injectable, particularly in LMICs. If allowed to continue, this could result in potentially millions of additional HIV infections. To address this dangerous trend, and to make CAB-LA available and affordable to people who need it the most, we recommend the following actions:

- ViiV must publicly announce their non-profit price of CAB-LA for low-income, least-developed and sub-Saharan African countries, as well as the price for countries that are not eligible for the non-profit price. Prices must be made available transparently and not be contingent on signing confidentiality agreements
- ViiV must finalise the voluntary license with the MPP, covering all LMICs and providing technology transfer to the generic manufacturers that request it
- Until generics are registered and available in LMICs, ViiV must ensure sufficient supply without constraining countries and organisations with implementation science requirements
- ViiV must cease the requirement to approve any implementer or academic organisation's research plans, and allow normal procurement, importation and use
- National HIV programmes should include CAB-LA in their PrEP guidance in line with 2022 WHO recommendations
- WHO should support countries in the implementation and roll-out of CAB-LA in line with its 2022 recommendations
- PEPFAR, Global Fund and other donors must include CAB-LA in their medicines lists for procurement and encourage countries to include CAB-LA in their PrEP programmes

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