



Q&A on long-acting cabotegravir (CAB-LA) for pre-exposure prophylaxis (PrEP)

Last updated: 30 March 2023

1. What is the state of the HIV epidemic globally?

According to [UNAIDS global HIV and AIDS statistics](#), 38.4 million people globally were living with HIV in 2021, and around 1.5 million people were newly infected with HIV in 2021.

[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. In order to meet these targets, it will be essential to urgently and broadly expand access to combination HIV prevention options including medicines known as pre-exposure prophylaxis (PrEP).

2. What is long-acting cabotegravir (CAB-LA)?

CAB-LA is a long-acting antiretroviral (ARV) medicine patented and produced by ViiV Healthcare, an offshoot of pharmaceutical corporations Pfizer, GlaxoSmithKline and Shionogi.

Delivered as an injection every two months, clinical trials have shown CAB-LA to currently be the most effective form of PrEP. As CAB-LA is more long-lasting and discreet than oral PrEP, and so may facilitate better adherence, it can help turn the tide against new HIV infections globally.

CAB-LA was [approved](#) by the US Food and Drug Administration (FDA) in December 2021 and [recommended](#) for HIV prevention by the World Health Organization (WHO) in July 2022. It was also approved by the FDA for treatment of HIV in combination with the long-acting injectable rilpivirine. However, due to the need for cold chain storage for rilpivirine and concerns around drug resistance, this combination (marketed as CABENUVA) is not a viable treatment option for low- and middle-income countries (LMICs).

3. Why is access to CAB-LA important?

Adherence to existing PrEP options such as the once-daily oral PrEP pill is frequently influenced and undermined by social factors, [including](#) stigmatising associations with pill-taking and HIV prevention within relationships, or moralising attitudes within families. Access to the more discreet injectable CAB-LA, which is also the most effective form of PrEP, could allow people at risk of HIV infection to access PrEP without anyone in their family or community knowing and so may enable greater adherence.

4. What is the history of MSF's negotiations to procure CAB-LA from ViiV, and where do these negotiations stand now?

As ViiV is the only supplier of CAB-LA, MSF has been in contract negotiations with ViiV to procure CAB-LA since August 2022. Initially ViiV insisted on restricting supply to research settings. As a result, MSF's team developed a research concept, also shared with ViiV, for two settings – Mozambique and Eswatini. Discussions and protocol development have advanced, in part based on the verbal commitment from ViiV to sell MSF the CAB-LA required for these studies by the end of Q2 2023. MSF focused on its key population programmes in Mozambique, which include both female sex workers and men who have sex with men (MSM), for implementation research.

Additionally, during the contract negotiations between ViiV and MSF, the MSF team was encouraged by ViiV to seek out further demand. MSF made efforts to include several other countries where we are operational and

there is clear demand for the use of CAB-LA for PrEP, and in settings where other partners are not planning implementation studies.

After eight months of efforts and time invested by MSF's teams to advance these implementation research plans, including in discussion with ministries of health, the corporation is still unable to confirm if MSF's order can be fulfilled in 2023 due to limited supply capacity allowing for only enough CAB-LA to meet the needs of people during and after clinical trials, for implementation studies agreed through ViiV's research panel, and for those on CAB-LA as part of a treatment regimen already commenced.

MSF programmes in Eswatini and Mozambique are ready to start offering CAB-LA to people for the prevention of HIV in 2023. However, it is extremely difficult to move forward, as ViiV cannot assure MSF of the availability of CAB-LA.

5. Why is MSF calling for ViiV to provide transparency on the current available volume and planned global distribution of CAB-LA?

As highlighted earlier, CAB-LA is approved for use in both treatment (in combination with rilpivirine) and prevention (on its own) of HIV. While cabotegravir/rilpivirine is not more effective than existing ARV combinations for *treatment*, CAB-LA is the most effective agent for *prevention*.

However, there is lack of transparency on the currently available volumes and distribution of CAB-LA across these two indications. MSF has called for such transparency and for distribution to be guided by data demonstrating where available supplies will have the most impact on addressing the HIV epidemic.

6. What are the current barriers to accessing CAB-LA?

Monopoly: ViiV applied for the compound patent on CAB-LA in 2006 and this was granted widely, including in key manufacturing countries such as India. As a result, the corporation currently has a monopoly on the supply of the drug. The lack of additional sources of supply carries the risk of shortages.

The issue of increasing supply capacity, including through licensing to open up generic competition, has been repeatedly raised by the HIV community during the development of the drug. ViiV has maintained, against all logic, that there would not be significant demand, and they would take responsibility of being the sole supplier globally. ViiV waited 16 years after filing for patents to license this lifesaving medicine. Its current global supply monopoly cannot meet demand, and efforts from the corporation to increase supply will likely not have effect until sometime in 2024. In addition, it will take time for generic companies to develop, register, and make generic CAB-LA commercially available.

Pricing: ViiV have not been transparent about the "access price" for low-income, least developed, and sub-Saharan African countries, and have not published it themselves. However, according to [publicly available information](#), ViiV's "access price" will be between US\$240-276 per person per year which is 12 times higher than what the Clinton Health Access Initiative (CHAI) [estimates](#) a generic price could be, namely less than \$20 per person per year. Today's oral HIV PrEP pills are priced at \$40 for one year. ViiV should publicly announce its "access price" and ensure that it is comparable to the current price of oral PrEP in LMICs so that governments and treatment providers can accelerate rollout of this lifesaving intervention at the scale needed.

Registration: ViiV has [registered](#) CAB-LA in only five countries, the US, Australia, Zimbabwe, South Africa, and Malawi, and filed to register in others. Many countries with a high burden of existing and new HIV infections are not included in this list.

7. How and when will the voluntary license announced by the Medicines Patent Pool (MPP) and ViiV result in an increased global supply of CAB-LA?

In July 2022, ViiV and the Medicines Patent Pool (MPP) [announced](#) a voluntary license on CAB-LA. It will allow generic companies that sign the license to supply the generic version of CAB-LA in 90 countries. On 30 March 2023, ViiV and MPP [announced](#) the three generic drug manufacturers selected to produce CAB-LA under the voluntary license agreement: Aurobindo, Cipla, and Viatrix. However, due to the added complexity of manufacturing a long-acting agent and the uncertainty of ViiV's willingness to assist in technology transfer, it may take them as long as four to five years to do so.

MSF has concerns about the effectiveness of the voluntary license due to several issues with the terms and conditions offered by ViiV to MPP:

- The geographical scope of the license is limited and does not even match that of the licenses for dolutegravir (2014 and 2020), the other HIV medicine licensed by ViiV to MPP. Further, it excludes 47 out of 54 upper middle-income countries (UMICs).
- Though sublicenses can normally be issued to any qualified manufacturer, in the ViiV/MPP license the number of sublicensees is unreasonably restricted to a maximum of [three](#).
- The license agreement imposes 'public market only' restrictions in 10 of the included LMICs. As a result, if the drug is not available in the public market, i.e. with the government, NGOs recognised by the government, UN organisations and other agencies and in the HIV programme in these 10 countries, people will not be able to access more affordable generic versions of CAB-LA on prescription from private medical care providers. This would prevent generic manufacturers from supplying to people who may want to access CAB-LA from private health care providers if it is unavailable in the public market.
- The license contains a clause for "assistance with product development and regulatory approvals", which might help generic sublicensees receive data and sample products needed to conduct bioequivalence studies for developing generic CAB-LA and seeking regulatory approval. However, this assistance would be at the "sole discretion" of ViiV, and be negotiated individually and confidentially with the sublicensees, outside the purview of the ViiV/MPP license.
- Moreover, while ViiV may waive its exclusive rights on regulatory data for a sublicensee, the corporation can revoke its waiver. This clause therefore introduces uncertainty into the development of a generic product.

For more information, please see MSF's reports on CAB-LA:

- [Agents of change: Long-acting formulations for prevention and treatment of HIV](#) (2 February 2023)
- [Cabotegravir: What are we waiting for?](#) (25 July 2022)