# CAB-LA Community Forum Statement

**Kampala, 21-23 June 2022**

Continued high rates of new HIV infections in our communities are unacceptable. In 2020 alone, there were over 1 million new HIV infections in low- and middle-income countries (LMICs).[1] Thousands of our children, sisters, brothers, friends, and neighbors become newly infected with HIV every week. We have waited for highly effective, acceptable prevention tools for decades while our communities were transformed forever. Prevention programs have not yet met our needs at scale.

The development of Cabotegravir Long-Acting injectable (CAB-LA) for HIV prevention comes at a crucial time. With its high efficacy, strong tolerability and bimonthly dosing, CAB-LA offers a vital tool for our communities and represents an essential addition to our prevention programs. The arrival of CAB-LA has the potential to mark a turning point in the HIV response. We have waited long enough, and we need CAB-LA to reach the millions at risk of HIV, as quickly as possible.

On 21-23 June, Afrocab and its partners, CHAI and Unitaid, hosted a forum for nearly 60 community and civil society organization (CSO) representatives from 18 countries in Eastern and Southern Africa, West and Central Africa, Brazil, UK, and the US. The group charted a way forward for access to long-acting technologies, with an immediate focus on CAB-LA.

> ***"CAB-LA will give me the power to have the freedom of choice. We are raising our voices for access. The community must be included at every step." –Forum Participant***

Forum consensus was clear: **urgent action is needed to accelerate access to CAB-LA at scale in our communities.** This forum will hold key stakeholders, including ViiV Healthcare, donors (CIFF, the Gates Foundation, the Global Fund, MedAccess, PEPFAR, Unitaid and others), governments, WHO, MPP, and other partners accountable against the access needs outlined below:

## Call to Action

**To drive rapid CAB-LA access, communities call on key stakeholders to initiate the following actions immediately:**

1. By AIDS 2022, ViiV must issue a broad **voluntary license** for CAB-LA and commit to supporting effective **technology transfer** to accelerate generic development.
2. Donors, including CIFF, the Gates Foundation, the Global Fund, MedAccess, PEPFAR, and Unitaid, must **advance required investments to accelerate generic development**.
3. Donors and ViiV must work together to reach an **affordable price point for CAB-LA** that will enable LMIC access while ViiV is the sole supplier. ViiV's previously shared "non-profit" price of $250+ per person per year will severely restrict access.
4. ViiV must **submit for registration in additional countries** immediately to enable evidence generation and experience with CAB-LA ahead of generic availability. To this end, ViiV must also commit to ensuring **sufficient availability** of their product in all LMICs that wish to procure CAB-LA or include the product in implementation projects.
5. Country regulators must commit to carrying out **accelerated reviews** of ViiV's CAB-LA registration submissions since the product is already US FDA-approved.
6. Regulatory authorities and normative bodies (including WHO PQ, the US FDA and national regulatory authorities) must commit to **increased transparency on review timelines**.

[1] UNAIDS, 2021.

**In the medium-term, communities call on stakeholders to address the following demands by World AIDS Day (December 2022):**

1. PEPFAR must commit to **including PrEP products in the US FDA tentative approval process** to ensure accelerated regulatory review of generic CAB-LA.
2. MPP must ensure generic CAB-LA is produced in a country that PEPFAR can procure from to ensure there are **no patent barriers.**
3. Ministries of Health must initiate **readiness assessments to understand how to deliver CAB-LA** effectively and capacitate providers.
4. Donors must support **implementation studies that include all populations** at risk to help us address key delivery questions like integration, testing, and provider support needs. Narrowly-focused studies that exclude any groups seeking PrEP are unacceptable.

## CAB-LA Access Priorities

The above demands represent crucial first steps to pave the way for an accelerated pathway for widescale access to CAB-LA in LMICs. Forum presentations and deliberations also identified a wider set of access priorities needed to ensure CAB-LA reaches those who need it most.

### Generic Development

Impactful CAB-LA delivery at scale will not be possible without an affordable, quality-assured generic product. ViiV Healthcare's negotiations with MPP to license CAB-LA are a critical first step, but will not be enough to drive accelerated access. Additional donor investment is urgently needed to ensure generic development progresses rapidly and effectively. Ongoing collaboration from ViiV to support an effective technology transfer process is also crucial.

### Price

There is an urgent need to address CAB-LA pricing. The group agreed that impactful CAB-LA access will not be possible until there is an affordable price, comparable to oral PrEP. On the advocacy front, there is a need for like-minded organizations and individuals to increase pressure to ensure an affordable access price for CAB-LA. There was consensus to continue to exert community pressure "… until we get what we want" – this means coordination between ViiV, donors, and other partners to reach an acceptable price for CAB-LA that supports LMIC access, both while ViiV is the sole supplier and once generic CAB-LA comes into the market. Alongside pricing, the meeting agreed that patent barriers must be addressed in tandem in order to ensure access to CAB-LA in upper middle-income countries. In the long-term, building production capacity in the African region can serve as a potential pathway to lower price.

### Regulatory

To ensure access to affordable, quality-assured generic CAB-LA, regulatory and normative bodies must commit to accelerated, transparent timelines, pathways, and requirements. To ensure a viable regulatory pathway for US FDA approval, which will facilitate rapid registration across LMICs, PEPFAR must include PrEP products in the tentative approval process with the US FDA. In addition, WHO has the capacity to help fast track access through the Pre-Qualification (PQ) process. To drive rapid country registration, transparency on timelines and strong communication with generic suppliers from WHO PQ is essential. In the nearer, term, to enable access to ViiV's product while generic CAB-

LA is being developed, it will be critical for ViiV to rapidly expand its country registration efforts beyond the countries where CAB-LA trials took place.

### Communications and Partner Engagement

The group also agreed on the need to come together to ensure advocacy efforts target donors and other funding mechanisms to support CAB-LA access and introduction. As introduction activities continue, it will be critical for countries to work with the community groups to develop an investment case for CAB-LA, including mechanisms for local funding. Strong support from the media in our fight for CAB-LA access will be essential for ensuring information about CAB-LA reaches national and sub-national communities.

### Implementation Research and Evidence Generation

PrEP Implementation projects, such as those supported by USAID and Unitaid, are integrating CAB-LA and other new products to address pending research questions. Key areas for evidence generation include identifying effective testing algorithms, delivery models, and demand generation strategies. However, more work is needed to ensure these projects cover all populations at risk of HIV across a wider range of geographies. In the long-term to inform supply planning, we also need more research to understand unmet need of every prevention option.

The forum highlighted that importance of engaging health care workers early, to ensure CAB-LA delivery is 'person-centered,' effectively addressing the priorities and needs of those at risk of HIV. Many groups eligible for PrEP already experience significant stigma. Moreover, proving "eligibility" for PrEP may create an access barrier. Without supportive health care workers, those at risk of HIV will not be reached by new services, even preferred product forms like long-acting injectables. Advocacy is needed to ensure critical training needs are assessed as we move towards a multi-product menu with choice-driven programming.

### Country and Local-level Needs

Community advocacy is needed at country-level, and must start before CAB-LA is included in guidelines. There is need to advocate at country-level for CAB-LA to be quickly adopted and rolled out at scale. While guidelines are being developed, there will be a need to build capacity in the community using different platforms to mobilize advocacy and generate demand. There will also be need for communities to engage in PEPFAR Country Operational Plans (COPs), as well as during Global Fund discussions and other national prevention processes. As a meeting participant noted:

> ***"We need to raise Community voices. They need to be raised at every opportunity to drive demand for CAB-LA."***

A regional approach that addresses different stages of engagement will also be essential to raise community voices, such as with the African Union. The group highlighted the need to ensure information is spread at the grassroots-level, including peri-urban and rural settings. To achieve this, part of the engagement with MoHs must include prioritizing community preparedness. Resources must be developed for community engagement including key population groups. The group also reaffirmed the need to focus on PrEP more broadly, and ensure resources support choice in a multi-product menu.

# Forum Participants

Abdulwahid Abdulrazak
Abraham Johnson
Alice Kayongo
Amina Hassan
Antonia Caroline Mubaira
Bahati Haule
Carolyne Njoroge
César Mufanequico
Charles Brown
Chilufya Kasanda
Cindy Amaiza
Daisy Ouya
Duncan Kwaitana
Gabriela Chaves
Geoffrey Mwesigye
Grace Kamau
Henry Kabwe
Ibrahim Lwingi
Imelda Mahaka
Iriebi Gboh
Jacque Wambui
Janet Bhila
Kenly Sikwese
Kunyima Banda
Lilian Mwakyosi
Lloyd Mulenga
Loyiso Saliso
Matias Langa
Memory Sachikonye
Msizi Mkhabela
Nomawethu Ngcukana
Ntombifuthi Shongwe
Olubukola Ayinde
Peter Njoroge
Raymond Kwesiga
Rosemary Tshuma
Ruvimbo Tumbu
Sage Semafara
Samuel Githaiga
Shakirah Namwanje
Sharifah Nalugo
Sia Ngowo
Star Rugori
Sylvia Nakasi
Thabiso Sibinda
Thatayotlhe Molefe
Victoria Quaynor
Zahara Mahamood
Chantal Kamanli
Arafah Kabugo
Caroline Akello
Tutegyereizi Lilian
Njambi Njuwuna
Leah Alupo
Ruth Ninsiima
Bridget Ndagaano Juuko