Issue 2

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CAB-LA in the News

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PATHWAY TO CAB-LA ACCESS: What's Next after ViiV Healthcare's Voluntary License?

Progress reducing new HIV infections has stalled. Between 2020 and 2021, we saw the smallest annual decline in new HIV infections since 2016.[1] Communities urgently need access to effective, acceptable HIV prevention interventions. In 2020, two large-scale clinical trials with nearly 8,000 participants demonstrated that long-acting injectable cabotegravir (CAB-LA) is highly effective at preventing HIV.[2,3] However, while CAB-LA received regulatory approval in December 2021, there were no plans to ensure access in low and middle-income countries where it is needed most. After significant pressure from community and advocacy groups, **ViiV Healthcare announced a voluntary license for CAB-LA on July 28th**. This is a crucial step for ensuring access in our communities. While ViiV Healthcare's announcement marks an important step in the journey to increase access to CAB-LA, **more work is needed to ensure this product is available in our communities as quickly as possible**. Now it is time for donors to step up to the plate to drive accelerated generic development and support efficient evidence generation.

"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"

-CAB-LA Forum Statement

Key Next Steps for Generic Development

1. Based on the terms agreed between ViiV and the Medicines Patent Pool, **three generic manufacturers** will be awarded licenses based on their existing capacity to manufacture CAB-LA. The licensing agreement also specifies which countries will be able to access the generic product. The CAB-LA license covers 90 countries, 9 less than the 99 countries in the dolutegravir license as demanded by activists in the March 1st Afrocab Statement.
2. **Donor investment will be needed to support accelerated generic development** and ensure the product is available at an affordable cost. Key needs for donor support include capital investment to purchase manufacturing equipment, support for development and bioequivalence study costs (see Glossary) as well as a potential volume guarantee to secure the ready market for long-acting technologies. While new infections continue at unacceptable rates in our communities, it is **critical to minimize the time between licensing and product registration**. An accelerated pathway **will not be possible without rapid, sufficient donor support**, leveraging the models and approaches that worked well for previous life-saving products.
3. **Technical support**, as well as **clear guidance** from **regulatory authorities and normative bodies** (such as WHO PQ) is required to enable and motivate generic companies to design bioequivalence studies and gather the evidence needed to secure regulatory approval of generic CAB-LA efficiently. PEPFAR and the US FDA still do not include PrEP products in their "tentative approval process" – this must be changed to ensure rapid approval of CAB-LA.

[1] UNAIDS, 2022.
[2] Landovitz et al. (2021). Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. *New England Journal of Medicine*; 385:595-608.
[3] Delany-Moretlwe et al. (2022) Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomized clinical trial. *The Lancet*, 399 (10337): 1779-1789.

Immediate Priorities for CAB-LA Access:

Urgent Donor Action

Now that a voluntary license has been granted, we **cannot afford to lose any time**. A Community Activist present in the Global Village at the recent International AIDS Society Conference in Montreal noted that "a license alone **does not translate into making CAB-LA widely accessible** because generic companies still need support to develop and register CAB-LA"**.** Donors, including CIFF, the Gates Foundation, the Global Fund, MedAccess, PEPFAR, and Unitaid, must **advance required investments to accelerate generic development.** Failure to take immediate action and capitalize on the progress achieved through the MPP/ViiV licensing agreement is unacceptable.

Evidence Generation and Affordability of ViiV's Product

While generic CAB-LA is being developed we must gain **as much experience as possible with ViiV's product** in order to prepare for successful implementation at scale. We must identify the **best delivery models**, **demand generation strategies** and **testing approaches** as soon as possible. **Without sufficient real-world experience and evidence generation** to draw from, it will **not be feasible to rapidly scale-up generic CAB-LA once it is available**. This means that the **price of ViiV Healthcare's product is a critical issue**. Whilst we know that ViiV-manufactured product will not be as cheap as a generic version, it still remains vital that we ensure it is **affordable enough to support evidence generation efforts**. As such, donor support may be needed to **achieve an acceptable price point** and **sufficient volumes** for programs.

Key Glossary

- **Medicines Patent Pool** is an organization which supports low- and middle-income countries to license medicines and to pool intellectual property to encourage generic manufacture and the development of new formulations.
- **A bioequivalence (BE) study** proves that two drugs share the same active ingredients and desired outcomes. In order to for generic CAB-LA to achieve regulatory approval, companies that have been granted a license must conduct BE studies to prove that the product they have developed is the same as ViiV's product. Because CAB-LA is long-acting, the BE studies are longer and, therefore, more costly than those needed for a daily oral formulation.
- **PEPFAR:** The U.S. President's Emergency Plan for AIDS Relief is a United States governmental initiative to address the global HIV/AIDS epidemic. PEPFAR is a major purchaser of HIV treatment and prevention commodities, so their buy-in for CAB-LA is essential. PEPFAR also works with the US FDA to support the "tentative approval process," which enables rapid regulatory review of generic HIV treatment commodities and is a key mechanism for accelerating access in low- and middle-income countries. PrEP commodities are not currently included in this process, but if PEPFAR decide to include PrEP products, it could help to accelerate access to CAB-LA.
- **The United States' Food and Drug Administration (US FDA)** is the division of the United States' Department of Health and Human Services. It is considered a "Stringent Regulatory Authority" so achieving US FDA approval can pave the way for rapid registration in other countries.
- **The WHO Prequalification (PQ) Programme** is a part of the WHO which helps ensure medicines meet acceptable standards of quality, safety, and efficacy. Once a company has developed CAB-LA and gathered the needed evidence to prove it is the same as ViiV's product (bioequivalence), it can be submitted for WHO PQ review. Achieving WHO PQ review will help support rapid review and registration by national regulatory authorities.

"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" – CAB-LA Community Forum Participant

Next CAB-LA Forum meeting:
16th August
3-4pm CAT/4-5pm EAT