**Focus Group 3 – Global access to generic formulations: progress and pitfalls.**
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Proposed discussion questions.

- What are the biggest risks today to accelerating development of LA products for HIV?
- Beyond injectables, what are the other LA products on the horizon with significant potential?
- As a public health community, how to ensure that the pipeline developments do not delay access?
- Given the broad range of potential LA-ER product formulations and delivery systems and uncertain global markets for these products, how can generic manufacturers be incentivized to make these major investments?

# Overview to frame the discussion.

## HIV Prevention.

LA CAB.

- December 2021 – US FDA Approval.
- July 2022 – ViiV/MPP voluntary licensing agreements executed with three generic manufacturers.
- PEPFAR announced procurement of CAB-LA in 5 LMICs.
- November 2023 – ViiV announced non-profit price of $30 per vial.
- February 2024 – First African country (Zambia) launched CAB-LA programs using PEPFAR-donated vials.
- CAB-LA is now approved in 11 LMICs.
- There is strong demand from the community, notably AFROCAB.
- Since US FDA approval, there have been over 2 million new infections in LMICs.

LEN (Q6M SC injection).

- PURPOSE 1 and 2 programs are in P3 with primary completion expected in Sept 2024 and January 2025, respectively.
- No commitments for generic licensing or access pricing.
- Unknown production capacity.
- No donor commitments to support market shaping.
- Strong demand from the community.
- Can we learn from CAB?

## HIV Treatment.

- LA CAB +RPV does not meet TPP for some LMICs (cold chain and one injection every two months).
    - SC injections and longer intervals between injections, would be preferable.
- LEN not currently for ART-naïve populations, and need companion drugs.
- Much discussion about usefulness of trials of CAB+LEN.
- LMIC HIV treatment programs have been designed around QD oral pills.
    - Oral programs are well-designed: Many are nurse and community driven; Dispense a 6-month supply; Incorporates a lot of service delivery in the community; does not require sophisticated HCWs for most people starting ART.
    - LAIs would need sophisticated trainings for HCWs.
- Implementation of treatment is less well understood than prevention – a lot more needs to be done before we can talk about normalization of LA treatment in LMICs.

# Important discussion themes.

## De-risking.

- The fickleness of drug development can make generic manufacturers cautious – it is not easy to pivot to a new formulation (i.e., the shiny new thing in P2 trials).

        - Example: Imagine a 3-year investment in CAB-LA for PrEP, then LEN is found to be as effective, but with a longer Q6M dosing interval.
        - Injectables are far more complicated than pills – the technology is very different across different formulations and could require an entirely new facility.
        - The pipeline is not guaranteed – nothing is guaranteed until people receive the agent.
    - Market signals can play a massive role in levels of investment.
- Are there incentives that are not financial? Are there other things that would reduce the perceived risk.
  ***No one had an answer to this question.***
    - Voluntary licenses that include the process (i.e. technology transfer), not just the molecule.
        - From the originator company's point of view, this would be important to have in the future.
        - ***The group considered this to be a significant barrier contributing to the delays*** – with some of the new delivery systems, the process is perhaps as important as the molecule.

## Better coordination between prevention and treatment.

- LA drugs are currently not available for treatment studies – it is difficult to obtain CAB for implementation research for treatment studies.
- If prevention becomes focused on LEN, then could we lose CAB, which could be an important treatment option.

## Can we be more ambitious: global framework for rapid access?

- By focusing on single formulations, are we missing opportunities to develop a global framework for rapid access to novel drugs and formulations and the potential for substantial public health impact.
- The issue extends beyond HIV.
    - COVID has been one example; imagine a worse pandemic and prevention and treatment were not available in LMICs.
- Could the World Health Organization (WHO) take the lead (In the same way that the WHO hosts the essential medicines list)