

**Statement by Southern African Women Advocates in Advance of ViiV Convening**  
**9 March 2022**

***Background:***

We, a group of Southern African women advocates, came together on Monday, 7 March and Tuesday, 8 March in advance of a meeting convened by ViiV on Wednesday, 9 March 2022. The purpose of these advocate pre-meetings was to debrief on recent discussions convened by ViiV and other key stakeholders around CAB for PrEP, review outstanding concerns and questions, and plan a way forward that would be respectful on both sides, productive and specific. Based on these discussions, we developed the following statement outlining expectations, demands, and outstanding questions and presented these messages to ViiV:

**Expectations around process, and of civil society and advocacy engagement:**

1. ***We expect transparency and respect.*** These are the rules of engagement with civil society and, we hope, with all stakeholders. Recent discussions have been very troubling and do not reflect a commitment to partnership with advocates and civil society. Advocates bring much to the table (e.g. advising on program design, gaining input from community, putting pressure on funders and governments, etc.), and we would like to reset the tone. We would like to move forward, but it must be with these values as a foundation.
2. ***This cannot be a one-off, tokenistic conversation.*** We expect a clear plan for ongoing engagement that builds on models that exist (e.g. Good Participatory Practice Guidelines). Those who were part of the previous ViiV AdBoard discussions are working on a Terms of Reference to formalize the group and further outline how to operationalize robust engagement. However, this should be only one element of a comprehensive plan by ViiV to engage with advocates and civil society across all populations and geographies.
3. ***Per our questions below, we would like to move beyond generalities.*** As advocates, we will hold ViiV to account regarding the specifics of their responsibilities and actions (past and future) around CAB introduction and access. We ask ViiV to engage us in detailed, specific, actionable discussions moving forward.

**We stand in solidarity with, and are building from, AfroCAB's recently released [statement](#). To make good on the promise of this product:**

1. ***We demand transparency on price.*** Citing that the price is in the 'tens of dollars' will be insufficient when engaging with governments, funders and policymakers to advocate for the introduction of CAB for PrEP. ViiV needs to get the price to be comparable/as low as generic oral PrEP to get government, funder and policymaker support and buy-in.
2. ***We expect licensing through the MPP and engagement with generics, especially Africa-based manufacturers, to make injectable CAB for PrEP.*** Generic manufacturers in Africa should be engaged in discussions around identifying a manufacturer, and for consideration for capital expenditures, to demonstrate commitment to build local capacity. This will also serve as a gateway for local manufacturers to be able to produce other nano-formulated injectables, antibodies and vaccines.

3. ***We want to see programs that are not redundant (e.g. answering the same questions), involve diverse population groups, and can be taken to scale (e.g. are not too small).*** Advocates are already engaging in implementation studies to support introduction efforts, and are in communication with communities, governments and policymakers to prepare for and build support in CAB introduction. Advocates can only successfully do this with clear and consistent information from ViiV on the product plans.
4. ***Testing cannot be a barrier to entry for CAB for PrEP.*** Advocates are engaging in this space to ensure messages focus on the importance of prevention, and the need to carefully examine any issues around resistance and testing.
5. ***Civil society representation must be a requirement in all introduction studies,*** including Community Advisory Boards at site level. Groups who would like to introduce CAB should have plans for advisory boards that include at least three members of civil society. While we understand that ViiV may not fund or control these projects, they do control the product supply and should make these requirements as part of the supply of any product.
6. ***We would like more specific details around the conclusions noted in ViiV's updated statement regarding voluntary licensing.*** We would like to understand what evidence has been collected to reach conclusions around manufacturing, cost, etc. We expect ViiV to answer key outstanding questions with specificity:
  - a. If ViiV is the sole supplier of CAB for the first year or two of product introduction, what is its actual manufacturing capacity in the short and long-term? E.g. How much can ViiV supply and at what price? How much of this supply will be allocated to sub-Saharan Africa/low- and middle- income country vs High-income country markets?
  - b. Who are the manufacturers that ViiV spoke with, how long ago was this mapping done, and what was the nature of the discussions? Which conversations have ended and which, if any, are ongoing? Has ViiV explored any manufacturers in Africa (e.g. Aspen)? Can ViiV provide documentation or summaries of these discussions to the public? Please provide specific detail around the identified “complexities of manufacturing, regulatory requirements, capital investment needs and unpredictable demand”.
  - c. Provide further details about ViiV's registration plans for LMICs, including timelines for filing in countries where applications for CAB for PrEP have not yet been filed. Will ViiV supply product in countries prior to registration (i.e., will ViiV accept import waivers for importation by MOHs/GF/PEPFAR/etc)?
  - d. What type of investment is still needed in generics to get to the place where they can manufacture CAB? Has ViiV discussed with donors making strategic investments to ensure commodity security in the event that demand and use increase as we all hope? If so, which donors have been engaged? Which conversations have ended and which are ongoing?
  - e. Please clarify ViiV's intention as sole supplier of the product, and the desire to donate under implementation research (that would have to be approved by ViiV) vs. selling CAB at ViiV's “at-cost” price. Can ViiV sell CAB “at-cost price” to those that want to implement CAB outside MOSAIC and Unitaid projects?

- f. What is the status of negotiations with the Medicines Patent Pool (MPP), and why hasn't ViiV licensed injectable CAB for PrEP to the MPP?
  - g. What is meant when ViiV says 'we will go as low as we can' in price? What is the lowest possible price? Tell us the price per person, per annum.
  - h. ViiV has said it wants to produce CAB in a 'responsible way' -- what does this mean? How will ViiV ensure sustainable supply as a sole manufacturer? Are there multiple manufacturing sites in case there is a production issue at one of them? Where are the manufacturing sites? Are there manufacturing sites in Africa?
7. **We would like more specific details around introduction study plans.** We expect ViiV to answer key outstanding questions with specificity:
- a. How will operational research and implementation science be made available to the public and what type of information will be collected by ViiV on CAB?
  - b. What are ViiV's interests and priorities in the implementation studies? What is the process for determining the merit, size, etc. of an introduction study? What kind of data is being collected to get CAB widely rolled out by governments -- e.g. the vision beyond pilots?
  - c. How is ViiV going to work with governments and policymakers to ensure introduction studies are conducted with buy-in from local governments, studies are conducted in parallel with roll-out to accelerate access, and that sufficient resources are available to support introduction? Or does everything depend on introduction studies? What is ViiV's plan for engaging with governments in priority and non-priority countries? What is the current status?
  - d. How is ViiV thinking about access for youth? This is a priority for advocates. How are we building on lessons from youth engagement in oral PrEP?

Injectable CAB for PrEP gives us an important opportunity to advance HIV prevention for populations most at risk. We are committed to ensuring we get rollout right so that a broad range of options are available to people who want and need them, especially young women. We must learn from the lessons of oral PrEP introduction and will work with all stakeholders, including ViiV, to make a real impact in HIV prevention.

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