**Coalition to Accelerate Access to Long-Acting PrEP**

**TERMS OF REFERENCE**

February 2024

1. **Rationale**

More than 10 years ago, research showed oral PrEP was safe and effective in preventing HIV. In 2012, it was approved for use by the US Food and Drug Administration and subsequently recommended for all people at substantial risk of HIV by the World Health Organization (WHO). But the global health community moved too slowly and a decade later, only some 3.8 million people have initiated oral PrEP use, a tiny fraction of the estimated number of people who need it and could benefit from it.

With new, longer-acting PrEP options reaching the market, the global health field needs to bring bold actions, global urgency, and coordinated partnerships to meet the challenges of product access, roll-out, and use. Product developers, policy makers, normative agencies, donors, program implementers, researchers, manufacturers, civil society, advocates, and communities all have critical roles to play. Concerted, strategic action is needed to ensure that science is translated into public health impact without unnecessary delay. The **Coalition to Accelerate Access to Long-Acting PrEP (the Coalition)** was formed to drive and coordinate this process, focused especially on low- and middle-income countries (LMICs).

1. **Purpose**

The Coalitionbuilds on several past and ongoing activities and seeks to bring together donors, civil society, ministries of health, implementation science think tanks and partner organizations to ensure an accelerated, sustainable, and collaborative approach to ensure equitable access to long-acting PrEP options as quickly as possible. The Coalition is convened by the Global Fund, PEPFAR, UNAIDS, Unitaid, and WHO, with AVAC as the Secretariat.

The Coalition’s objective is practical: to coordinate key stakeholder activities on long-acting PrEP access, including jointly developing strategies to identify and overcome access challenges for new PrEP options in the near term (especially related to injectable cabotegravir (CAB), including ViiV and future generics’ product, and the dapivirine vaginal ring (DVR)) and in the medium term (especially injectable lenacapavir (LEN), the dual prevention pill (DPP) and other future PrEP products).

The Coalition is committed to the following guiding principles in driving engagement with all stakeholders:

* **Lead with Equity:** Products don’t end pandemics if they aren’t delivered with equity and urgency; oral PrEP and COVID vaccine delivery are the most recent reminders.
* **Center the Community and User:** It is critical to center communities in design and implementation of programs and center users in actual product delivery.
* **Accelerate Scale and Speed:** We need to break the sequential nature of traditional approaches to scale and speed up introduction. Part of accelerating speed is moving toward a parallel approach where research, implementation science, and scale programs are designed, funded and implemented in parallel.
* **Deliver Impact:** Priorities and targets for the next 12 months must focus on building a pathway to public health impact. Assess and set a deadline for analyzing current operational studies and another deadline for when a coverage target towards impact could be in place.
* **Work with what we know, while continually adding to the evidence-base.** There is still much we don’t know about the newest products reaching the market, but there is also a lot we do know. We must not let the perfect be the enemy of the good and learn from past experiences. The introduction of new prevention products is a chance to reorient, reimagine and re-energize HIV prevention programs.
* **Strategically link with long-acting treatment efforts.** While the Coalition is focused on long-acting prevention options, many of the products also have possible treatment indications. The Coalition will coordinate with long-acting treatment groups and ensure that bidirectional communications and information-sharing between the Coalition and these groups are collaborative and consistent and maximize efficient and effective coordination to ensure access for both prevention and treatment, when feasible, and open communication between prevention and treatment stakeholders
1. **Structure**

The Coalition will work through structures and systems designed to facilitate critical work in specific technical areas while ensuring that these work streams are coordinated, linked to other key efforts driving access to long-acting PrEP, and capitalize on opportunities to advocate for and strengthen delivery of these new PrEP products. Membership in the Coalition’s different structures will balance representation of expertise and perspectives with the need for each effort to be productive, responsive, and nimble.

**Coalition**: The full group of Coalition stakeholders includes the Convenors, Donor Caucus, Civil Society Organization Caucus, MoH representatives (focused especially on countries with implementation science and programmatic activities), MPP and BioPIC stakeholders*.*

* + - The function of Coalition meetings is for each stakeholder group to provide updates and discuss identified Coalition plans and priorities. This will be an opportunity to identify cross-cutting issues and cross-pollination and discussion between stakeholder groups around priority issues. The Coalition meeting will also serve as a reminder to all stakeholders of their responsibility to influence key opinion leaders on a global scale to recognize, participate and implement the outputs of the Coalition. The Coalition will meet quarterly.
		- All members of each stakeholder group are to be invited to all Coalition meetings and encouraged to attend. In addition, each stakeholder group may choose to elect representatives to serve as the key representatives for their caucus, or stakeholder group, meaning they would join all Coalition meetings on their stakeholder group's behalf. These representatives would take on the responsibility to garner input from and report back to their broader stakeholder group on Coalition-wide meetings.
	1. **Co-Convenors**: The Coalition is co-convened by the Global Fund, PEPFAR, UNAIDS, Unitaid, and WHO. The convenors are responsible for driving and championing the Coalition’s overall effort to ensure its internal cohesion and external visibility. The Convenors and Secretariat (as described in 3.3) will meet monthly to ensure priorities are identified and addressed across the Coalition and clear communication is being developed and disseminated to Coalition stakeholders.
	2. **Secretariat/Communications:** AVAC serves as Secretariat and Communications lead, coordinating the Coalition and communications, internally among entities in the Coalition and externally to key constituencies. As Secretariat, AVAC staff and consultants will support the Coalition including all Coalition stakeholders and any ad-hoc working groups (WGs) by synthesizing and centralizing evidence required for decision making; drafting documents; scheduling calls; producing and distributing call notes and action items; ensuring coordination among any ad-hoc WGs and other tasks as needed. AVAC staff and consultants will be assigned to support any ad-hoc WGs and the Coalition overall. AVAC will establish and maintain an online platform for sharing documents and will regularly update this platform. To ensure transparency, AVAC will also be responsible for developing a communications strategy and consolidating and disseminating quarterly updates on key developments related to long-acting PrEP delivery.
	3. **Ad-hoc Working Groups:** Sometimes, the Coalition may identify topics that would benefit from specific, focused work. Once identified, the Coalition, Conveners and Secretariat will identify and articulate the specific issue(s) to be addressed, the relevant expertise that is needed, and the timeframe for engagement (whether a one-off convening or an ongoing engagement).
	4. **Related efforts:** The global effort to ensure swift rollout of long-acting PrEP, including CAB, DVR LEN, and DPP, extends beyond the Coalition. To ensure the greatest reach and impact of the Coalition’s work, it will strategically link to and to collaborate with the following stakeholders or ongoing pieces of work:
		1. **Donor Caucus** that was established in 2019 is coordinated by USAID and the Bill & Melinda Gates Foundation. This donor-only forum is a platform for confidential conversations among donors to ensure alignment on long-acting PrEP investments. The Donor Caucus will have a standing agenda item at Coalition quarterly meetings.
		2. **Civil Society Organization (CSO) Caucus** was established in 2022 to ensure civil society expertise influences the rollout of long-acting HIV PrEP options. This Caucus includes representation from the African Women Community Prevention Accountability Board; AfroCAB; APCOM; AVAC; the Coalition to Accelerate and Support Prevention Research (CASPR); Global Black Gay Men Connect (GBGMC); the Global Key Population Advisory Group; and other civil society groups working on long-acting PrEP introduction. The group meets bi-monthly for updates on long-acting PrEP activities, direct engagement with key stakeholders (including donors and product developers), and shared strategy development. Caucus members are also expected to provide updates to the groups and coalitions they represent. The CSO Caucus will have a standing agenda item at Coalition quarterly meetings.
		3. The Coalition will collaborate with **MPP on generic licensing efforts**, including with

originator companies.

* + 1. The Coalition will collaborate with **ongoing and planned implementation science projects** through participation in the Biomedical Prevention Implementation Collaborative (BioPIC) and the bi-monthly think tanks that link projects on key issues that are coordinated by WHO and AVAC.
		2. Members of the **HIV Modeling Consortium** met in March 2023 and identified a need to link more directly with implementation science projects that are gathering actual data that can be fed into models that might be used to guide decision-making. The Coalition Conveners and BioPIC are working with the Modeling Consortium to ensure these links are embedded in planning activities.
		3. **Additional Caucuses**: The Coalition currently includes links to two caucuses, one for CSOs and the other for donors. Other caucuses may represent interest groups and perspectives critical to shaping the Coalition and its work and will be designed to ensure that these views infuse the Coalition’s efforts at all levels. The Coalition may convene specific groups as needed.
		4. **The Global HIV Prevention Coalition:** Established in 2017 and housed at UNAIDS,

GPC includes United Nations Member States, UNAIDS Cosponsors, donors, CSOs and implementers to support global efforts to GPC is to strengthen and sustain political commitment for primary prevention by setting a common agenda among key policymakers, funders, and program implementers. The Coalition will coordinate with GPC and ensure that bidirectional communications and information-sharing between the coalitions are collaborative and consistent and allow for efficient and effective coordination.

1. **Communication**

The Coalition is committed to transparency, and its internal and external communications will include, but not be limited to the following approaches:

Internal:

* Overarching communications strategy about the Coalition, membership, activities, and messages.
* Monthly Convener calls.
* Quarterly Coalition-wide calls.
* Organize in-person meetings of Coalition stakeholders (independently and/or alongside scheduled HIV-related conferences usually attended in-person), frequency to be determined and adjusted as needed.
* Online platform for sharing documents. AVAC Secretariat will maintain and update this platform.

External:

* Updated fact sheet about the Coalition.
* Quarterly update to chart progress overall with periodic updates to the [*Plan for Accelerating Access and Introduction of Injectable CAB for PrEP*](https://www.avac.org/press-release/plan-cabotegravir) *as well as progress with LEN, DPP,* and other future PrEP products, including timelines and milestones.
* Regular (at least bi-annual) Coalition-sponsored webinars to provide public updates.
* Materials cataloged and available on dedicated [PrEPWatch](https://www.prepwatch.org/) page for the Coalition.