Translating Scientific Advance into Public Health Impact:

A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP

July 2022

AVAC

In June, AVAC published *Translating Scientific Advance into Public Health Impact: A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP* to provide a **comprehensive view of all the moving parts and identify specific priority actions and actors** responsible for ensuring time is not wasted and opportunity not squandered in introducing injectable cabotegravir for PrEP. ViiV, policy makers, normative agencies, donors, program implementers, researchers, generic manufacturers, civil society, advocates and communities each have critical roles to play in the coming months, at this summary provides an overview of the plan.

Top-line Summary

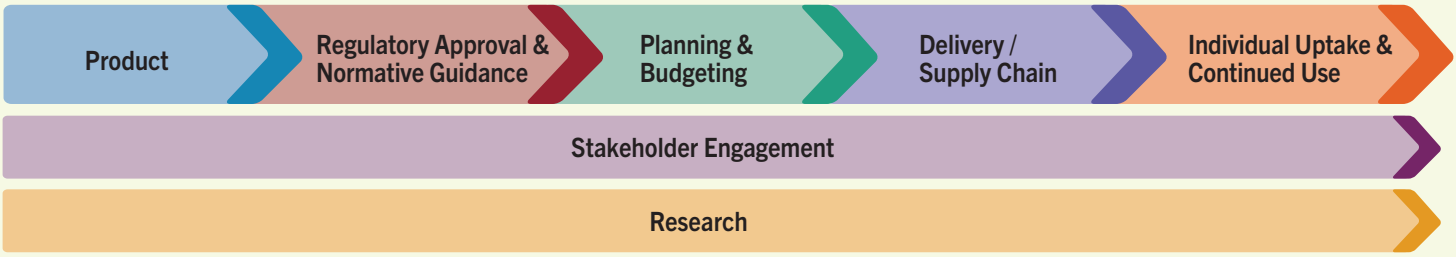
- ViiV Healthcare, the developer of injectable CAB for PrEP, will be the sole supplier in this initial period. Current capacity and price are uncertain, and ViiV and donors must urgently identify an appropriate price-volume commitment during this initial 4-5 year period to answer critical questions and build the market.
- Despite progress, HIV infection rates remain high.
- PrEP options have an important role to play in ending the epidemic, and no one option will address the needs of all.
- Injectable cabotegravir offers an additional option with high efficacy.
- It has been approved by the US FDA, submitted to other regulators, and WHO guidelines are expected in mid-2022.
- Answering operational questions around distribution, HIV testing, delivery and demand is critical.
- So, too, is securing an affordable, cost-effective price for injectable CAB.
- Voluntary licensing to generic manufacturers, along with capital investments, will be necessary to secure a low-cost, sustainable and diversify product supply—and this process will likely take at least 4-5 years.

Guiding Principles

The overarching goal and focus must be to move faster, **more strategically, more coordinated and with an acceleration towards impact** with injectable CAB for PrEP than the field did with oral PrEP in the first decade. To do so, the following principles must drive all parties:

- **Lead with Equity:** Products don't end pandemics if they aren't delivered with equity and urgency; COVID vaccine delivery is yet another harsh reminder.
- **Center the Community and User:** It is critical to center the community in design and implementation of programs and center users in actual product delivery. We have learned from the Good Participatory Practice Guidelines that effective community engagement builds mutually beneficial, sustainable relationships and strengthens programs.
- **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. Wildly ambitious coverage targets on the one hand, and small-scale thinking related to initial projects on the other, provide the extremes, as seen in the oral PrEP experience. Coverage-based targets can add to confusion when there's so much that needs to be understood about delivery for impact. Instead, it makes sense to 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 injectable cabotegravir, but there is also a lot we do know. We have consistently failed at prevention and let the perfect be the enemy of the good. But we can learn from past mistakes and missteps, and CAB for PrEP is a chance to reorient, reimagine and re-energize HIV prevention programs.

The Pathway to Access and Impact



Pathway	Immediate Priorities
Product	▸ **ViiV** to license injectable CAB to the Medicines Patent Pool (MPP). ▸ **The MPP and ViiV** to work with generic manufacturers and donors, including Africa-based manufacturers, to expedite technology transfer and ensure sustainable supplies of the product. ▸ **Generic manufactures, with MPP**, to identify capital expenditure needs and timeframe to be able to develop capacity. ▸ **Innovative donor(s)** to fund capital investments needed for generic manufacturing to reach scale. ▸ **ViiV** to confirm publicly, maximum quantity and minimum price for 2022-2025. ▸ **Donors** to negotiate this price/volume guarantee to ensure sustainable supply for initial introduction period, given the timeline for generic licensing agreements and manufacturing upgrades (likely 4-5 years).
Regulatory Approval & Normative Guidance	▸ **Eight regulators** currently reviewing injectable CAB for PrEP to ensure priority review. ▸ **ViiV** to pursue widespread registration of CAB in high-burden countries. ▸ **ViiV** to register with WHO Pre-Qualification (PQ) to allow expedited registration in countries participating in WHO's Collaborative Procedure for Accelerated Registration process.
Planning & Budgeting	▸ **Governments and donors** to set targets for supply and programs at scale – what is needed and possible in 2022-2023 in implementation science projects, and what is needed from 2024 to begin programs at scale.
Delivery / Supply Chain Individual Uptake & Continued Use	▸ **Large, resourced and coordinated implementation studies** to begin immediately to answer critical questions about how CAB performs outside the clinic setting and across populations. ▸ **Provider training** materials and tools updated to incorporate CAB administration and implementation studies that assess the feasibility of task-shifting to expand the cadres of providers that are authorized and trained to administer injections and that offer choice (explaining efficacy, clinic visits, side effects, etc. of all methods available) and assist in shared decision-making. ▸ **Innovative demand creation** strategies (for injectable PrEP and for "choice" among options) developed with process to test and iterate, and share across projects.
Delivery / Supply Chain	▸ **Testing requirements** should not become a barrier to CAB introduction. Testing strategies should be both robust and feasible and work with locally available tests and assays to, maximize the benefits of access to CAB while minimizing the risk of undetected cases.
Research	▸ **Data to be collected on the benefit of injectable CAB as PrEP for populations that were not part of efficacy trial**s, especially adolescents, pregnant and breast-feeding people, and transmasculine and gender non-conforming individuals. ▸ **Study alternate injection sites and frequency of injections**, recognizing that the impact of injectable CAB holds the potential to expand, if the injection schedule could align with injectable contraception.
Stakeholder Engagement	▸ **Integrate and engage civil society** in all decision-making relevant to planning and preparation for access to CAB, including designing, conducting and monitoring implementation studies and delivery programs.

Full Report *Translating Scientific Advance into Public Health Impact: A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP* —available at **www.avac.org/blog/accelerating-access-and-introduction-injectable-cab-prep**.