### The Pathway to Accelerating Access and Introduction of Injectable CAB for PrEP

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| **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 manufacturers, 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** | - 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. |
| **Individual Uptake & Continued Use** | - **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 trials, 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. |