EXECUTIVE SUMMARY

Tracking Progress to Market of New Long-Acting HIV PrEP Products:

A quarterly update from Coalition for Access to Long-Acting PrEP

QUARTER 1 2024

Coalition to Accelerate Access to Long-Acting PrEP

Document Structure

- Executive Summary
- Long-Acting HIV PrEP Coalition Purpose, Rationale and Structure
- Long-Acting HIV PrEP Coalition Priorities 2024
- Long-Acting HIV PrEP Pipeline update
- Tracking progress to market of new Long-Acting (LA) PrEP products

Cabotegravir (CAB)

Dapivirine Vaginal Ring (DVR)

Executive Summary

Coalition Convenors and Secretariat

COALITION CO-CONVENORS

THE GLOBAL FUND

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

UNAIDS

World Health Organization

Unitaid

COALITION SECRETARIAT

AVAC
Advocacy. Access. Equity.

More information here; contact the Coalition at: *LAPrEPcoalition@avac.org*

Coalition Structure

COALITION TO ACCELERATE ACCESS TO LONG-ACTING PREP

Conveners
The Global Fund, PEPFAR, Unitaid, UNAIDS, WHO

Secretariat
AVAC

Civil Society Caucus

Donor Caucus

Ministries of Health

Implementation Science Think Tanks

IP management (e.g. voluntary licensing)

Ad-hoc Working Groups

The Coalition aims to:

- Build on lessons learned from oral PrEP and coordinate stakeholders activities
- Jointly develop strategies to identify and overcome access challenges for new PrEP options in near-term (injectable CAB and DVR, including generics) and medium- to long-term (injectable LEN and future products)
- Ensure new, longer-acting PrEP options reaching the market will be available and equitably accessible to all who need them more quickly than ever before

Coalition Convenors and Secretariat

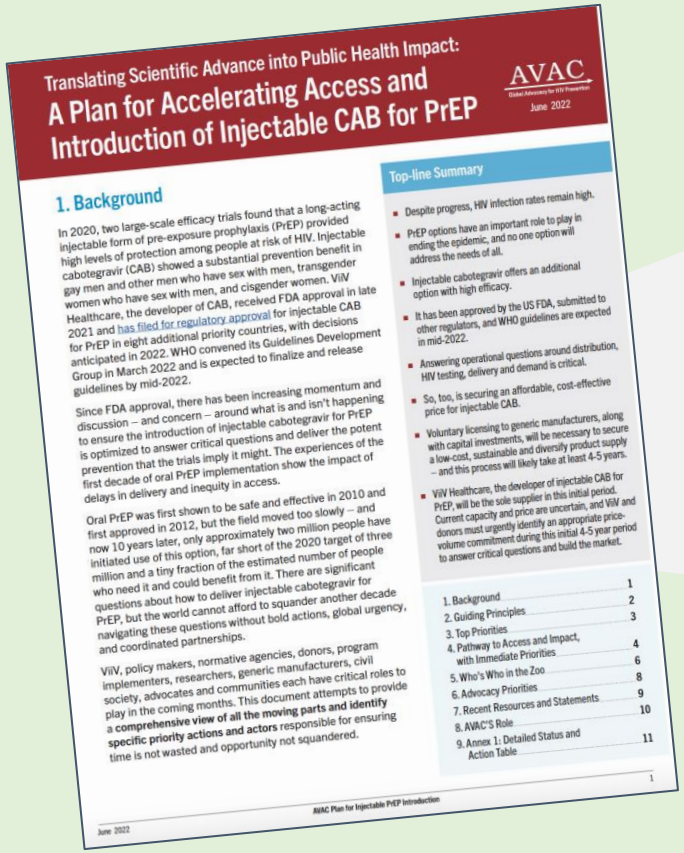
Priorities for 2024

- Focus on **priority actions (per product and product-agnostic)**
- Establish and **maintain a fully operational and agile Coalition that connects essential stakeholders for collaborative decision-making**
- Enhance and **optimize coordination efficiency and effectiveness among donors, normative agencies, national governments, implementers, civil society, and product developers** to achieve more streamlined and impactful collaboration
- Establish a **structured and strategic approach to effectively convey information, messages, and ideas about the Coalition** to the various stakeholders and audiences
- **Implement a system to track, report and disseminate quarterly progress on LA PrEP** to ensure accountability, transparency and foster trust among stakeholders

In June 2022, the ‘Plan for CAB’ document was published

It is a comprehensive view of the pathway to market for CAB and identified specific priority actions along the product pathway to ensure that opportunity was not squandered in introducing injectable CAB for PrEP.

A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP — June 2022



Translating Scientific Advance into Public Health Impact:
A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP

AVAC
Global Advocacy for HIV Prevention
June 2022

1. Background

In 2020, two large-scale efficacy trials found that a long-acting injectable form of pre-exposure prophylaxis (PrEP) provided high levels of protection among people at risk of HIV. Injectable cabotegravir (CAB) showed a substantial prevention benefit in gay men and other men who have sex with men, transgender women who have sex with men, and cisgender women. ViiV Healthcare, the developer of CAB, received FDA approval in late 2021 and has filed for regulatory approval for injectable CAB for PrEP in eight additional priority countries, with decisions anticipated in 2022. WHO convened its Guidelines Development Group in March 2022 and is expected to finalize and release guidelines by mid-2022.

Since FDA approval, there has been increasing momentum and discussion – and concern – around what is and isn't happening to ensure the introduction of injectable cabotegravir for PrEP is optimized to answer critical questions and deliver the potent prevention that the trials imply it might. The experiences of the first decade of oral PrEP implementation show the impact of delays in delivery and inequity in access.

Oral PrEP was first shown to be safe and effective in 2010 and first approved in 2012, but the field moved too slowly – and now 10 years later, only approximately two million people have initiated use of this option, far short of the 2020 target of three million and a tiny fraction of the estimated number of people who need it and could benefit from it. There are significant questions about how to deliver injectable cabotegravir for PrEP, but the world cannot afford to squander another decade navigating these questions without bold actions, global urgency, and coordinated partnerships.

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. This document attempts 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.

Top-line Summary

- 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 diversity product supply – and this process will likely take at least 4-5 years.
- 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.

4. Pathway to Access and Impact, with Immediate Priorities

This table outlines the immediate priorities across the pathway to access and impact and includes key actors responsible for them, while ***Annex 1: Detailed Status and Action Table*** provides a more detailed description of Status and Key Questions/Priorities/Next Steps for each issue area.

The Pathway to Access and Impact

Priority actions identified along each part of the pathway to access and impact (outlined on next slide).

Document link: https://avac.org/resource/report/translating-scientific-advance-into-public-health-impact-a-plan-for-accelerating-access-and-introduction-of-injectable-cab-for-prep/

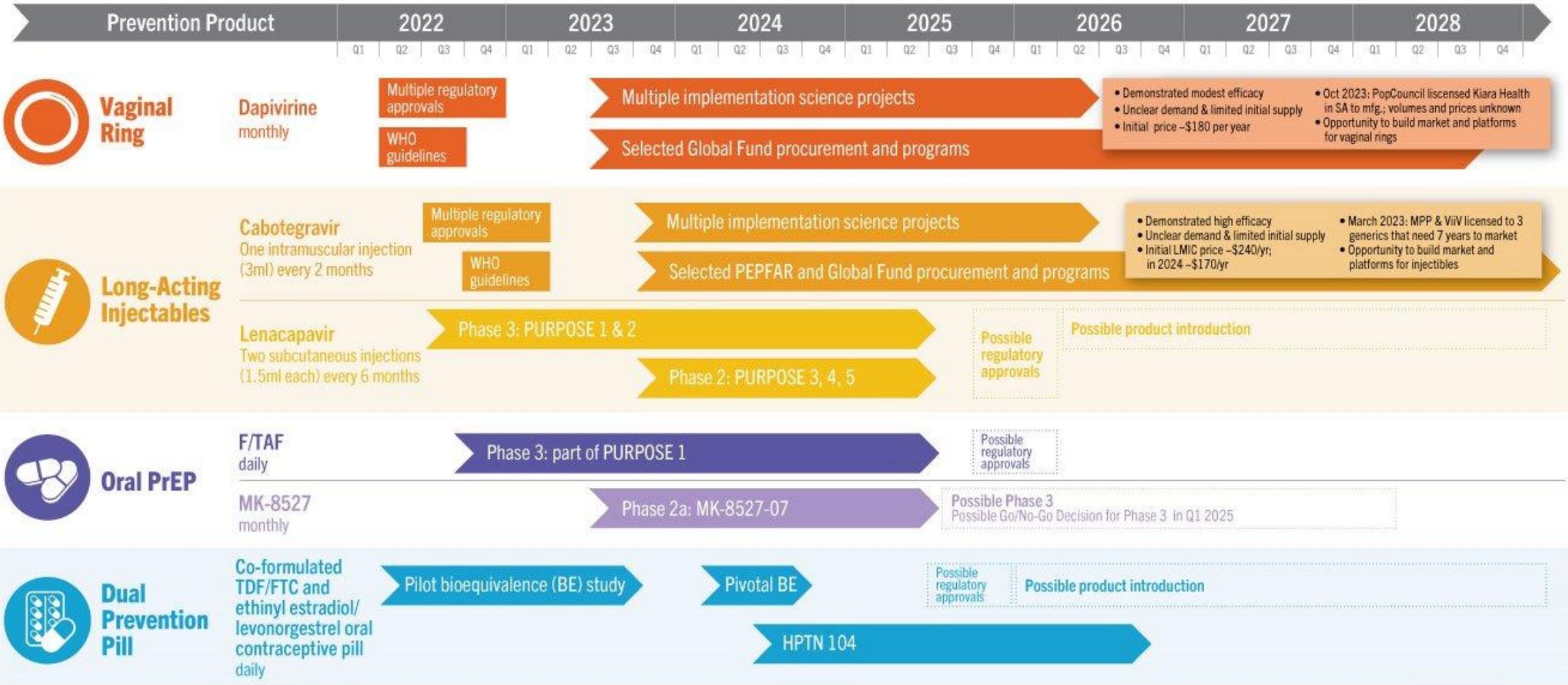
Progress on Pathway to Access & Impact for LA PrEP

The next slides will review each product along the pathway to access

Cabotegravir (CAB)

Dapivirine Vaginal Ring (DVR)

Updated Product Pipeline



Product Overview (include prices, timeline, etc.)

	Product		Brand Name	Developer	First Regulatory Approval	Number of other approvals	LMIC price	
							Originator	Generic / local manufacturing
Vaginal Ring	Dapivirine		DapiRing	PopCouncil	2021 (Medicines Control Agency of Zimbabwe)	11 countries	$156 / year ($13/ring x 12 rings)	Possible local manufacturing in South Africa (Kiara Health), pending license and funding
Long-Acting Injectables	Cabotegravir		Apretude* (injection for HIV PrEP)	ViiV	2021 (US FDA)	46 countries (including EMA)	Approx. $180/year (£23.50/vial x 6 inj. = £141/year)	Voluntary licenses to 3 generic manufacturers Q1 2023; tech transfer ongoing
	Lenacapavir		*Product in phase 3 clinical trial; results anticipated be end of 2024*					
Oral PrEP	F/TAF	Cis men/trans women	Descovy	Gilead	2019	96 countries	N/A	N/A
		Cis women			*Product in phase 3 clinical trial; results anticipated be end of 2024*			
	MK-8527		TBD	Merck	*Products in Phase 2 clinical trial; Phase 3 could begin in 2025*			
Dual Prevention Pill	Co-formulated TDF/FTC and ethinyl estradiol/ levonorgestrel oral contraceptive pill		*Products in pivotal bioequivalence study; could reach market in 2025*					

*Brand name Vocabria for HIV treatment

Moving A Product to the “Real World”

	TDF/FTC (Truvada)	DVR	CAB
Efficacy results	2010	2016	2020
THEN NUMBER OF YEARS FROM EFFICACY RESULTS TO…			
1st Regulatory Approval	2 years	5 years	1 years
1st African Regulatory Approval	5 years	5 years	2 years
WHO Recommendation	5 years	5 years	2 years
Product in LMIC Projects	6 years	6 years	3 years
Programmatic Scale	10 years	?	?
Generic (gx) Availability in LMICs	6 years until gx manufacturing (since generic TDF/FTC was already available for tx)	License for gx manufacturing in ~8 years; >12 years to reach market	License for gx manufacturing in ~2 years; >6 years to reach market

Long-Acting PrEP—Current Status as of March 2024

	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Current price from ViiV made public: approx. $180/year. Voluntary license granted from MPP to 3 generics	MOU signed with Kiara Health to manufacture DVR in South Africa	Both PURPOSE 1 & 2 clinical efficacy trials fully enrolled; results anticipated by end of 2024.
Regulatory Approval & Normative Guidance	Approved in 46 countries; WHO pre-qualification in 2023	Approved in 11 countries, 2 pending review/appeal, 3 submissions in preparation. WHO PQ in 2021	
Planning & Budgeting	Total 2023-2025 volume: 1.2M doses for non-commercial supply (955k for programs; remainder for studies)	400k rings available currently, 500k additional projected for 2024-25; initial procurement in several countries for supplies via Global Fund GC7	
Delivery & Supply Chain	PEPFAR procured in 4 countries (Ukraine, Zambia, Zimbabwe & Malawi) with programmatic roll-out launched Q1 2024	Currently, 1,052 product initiations on DVR since Q4 2023	
Stakeholder Engagement	Establishment of the Coalition's Civil Society (CS) Caucus; facilitating reoccurring meetings with stakeholders.		
Research	Implementation studies ongoing or planned in 22 countries	Implementation studies ongoing in 7 countries	
Monitoring & Evaluation	Continued monitoring and assessment of initiations via trackers and think tanks. Understand country-specific product introduction issues to inform programmatic rollout		

Long-Acting PrEP—Priorities for 2024

	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Collaborate with ViiV to understand procurement plans, build demand and accelerate generics progress	Collaborate with PopCouncil on price/volume for 2024/25 & plans for local mfg with Kiara; track development of 3-monthly & dual-purpose rings	Engage with Gilead now to influence access and pricing and encourage transparency
Regulatory Approval & Normative Guidance	Advocate for more regulatory submissions, in-country adoption of CAB for PrEP guidelines and monitor removal of oral CAB from generic sub-licenses	Advocate for additional submission in high-burden countries and understand what data PEPFAR may need to consider programmatic procurement	Follow-up with Gilead on their stated plans to work with national and regional African regulatory mechanisms
Planning & Budgeting	Build demand in country and develop long-term demand forecast	Build demand in country and develop long-term demand forecast	Request Gilead to articulate plan for oral F/TAF once the PURPOSE 1 trial results are available
Delivery & Supply Chain	Track current implementation studies and share early insights; continue to identify and address evidence gaps	Track current implementation studies and share early insights; continue to identify and address evidence gaps	TBD later in 2024
Stakeholder Engagement	Create collective advocacy strategies and continue to integrate civil society thinking	Create collective advocacy strategies and support implementation of HIV Prevention Choice Manifesto	TBD later in 2024
Research	Ensure further studies are planned to research long-term effects, and continue to identify gaps in product introduction by country	Advocate for further research on long-term effects and use in conjunction with other prevention methods	Start discussing plan for IS studies with Gilead
Monitoring & Evaluation	Continue to coordinate modeling exercises; assess gaps in in product introduction by country. Push to advance a learning agenda for programmatic rollout	Continue to assess gaps in in product introduction by country. Push to advance a learning agenda for programmatic rollout	TBD later in 2024