

Long-Acting PrEP Status as of April 2024

Tracking Progress towards Access for New Long-Acting HIV PrEP Products

SUMMARY REPORT

A quarterly update from the Secretariat of the Coalition to Accelerate
Access to Long-Acting PrEP

SECRETARIAT:





Important Note

This report is developed by AVAC, Secretariat to the Coalition to Accelerate Access to Long-Acting PrEP, to synthesize the current status of long-acting PrEP. This is done in service to the wider ecosystem - the report is not a deliverable of the Coalition or representative of the views of the individual institutions that make up the Coalition.

Document Structure

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



**Cabotegravir
(CAB)**



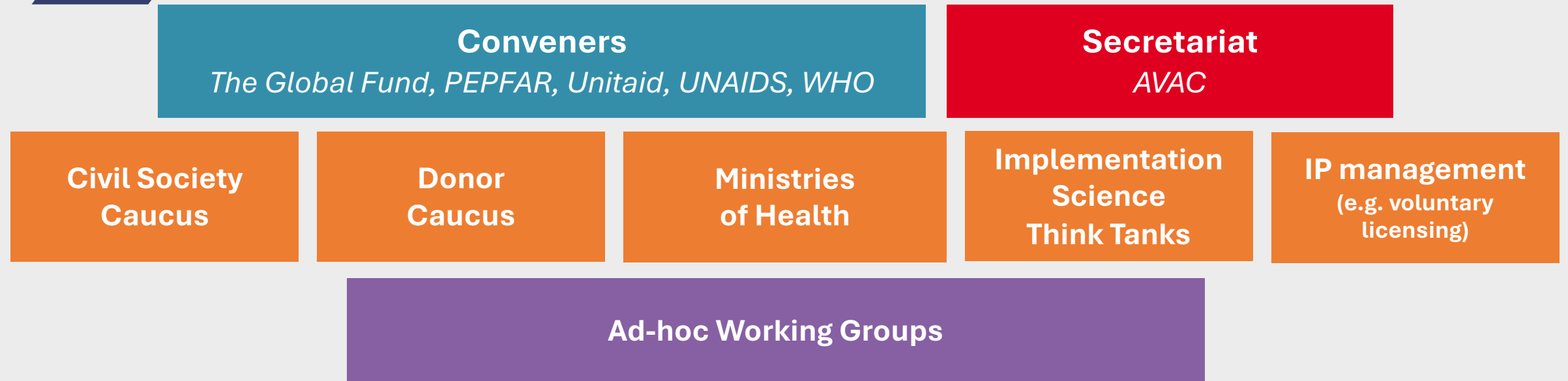
**Dapivirine Vaginal Ring
(DVR)**



Executive Summary

Coalition Structure

COALITION TO ACCELERATE ACCESS TO LONG-ACTING PREP



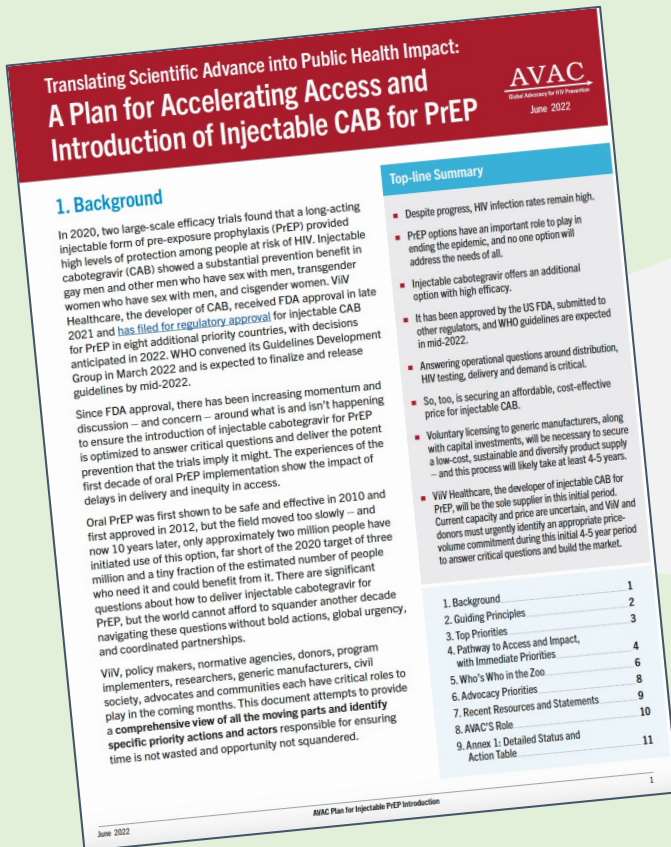
The Coalition aims to:

- 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

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



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

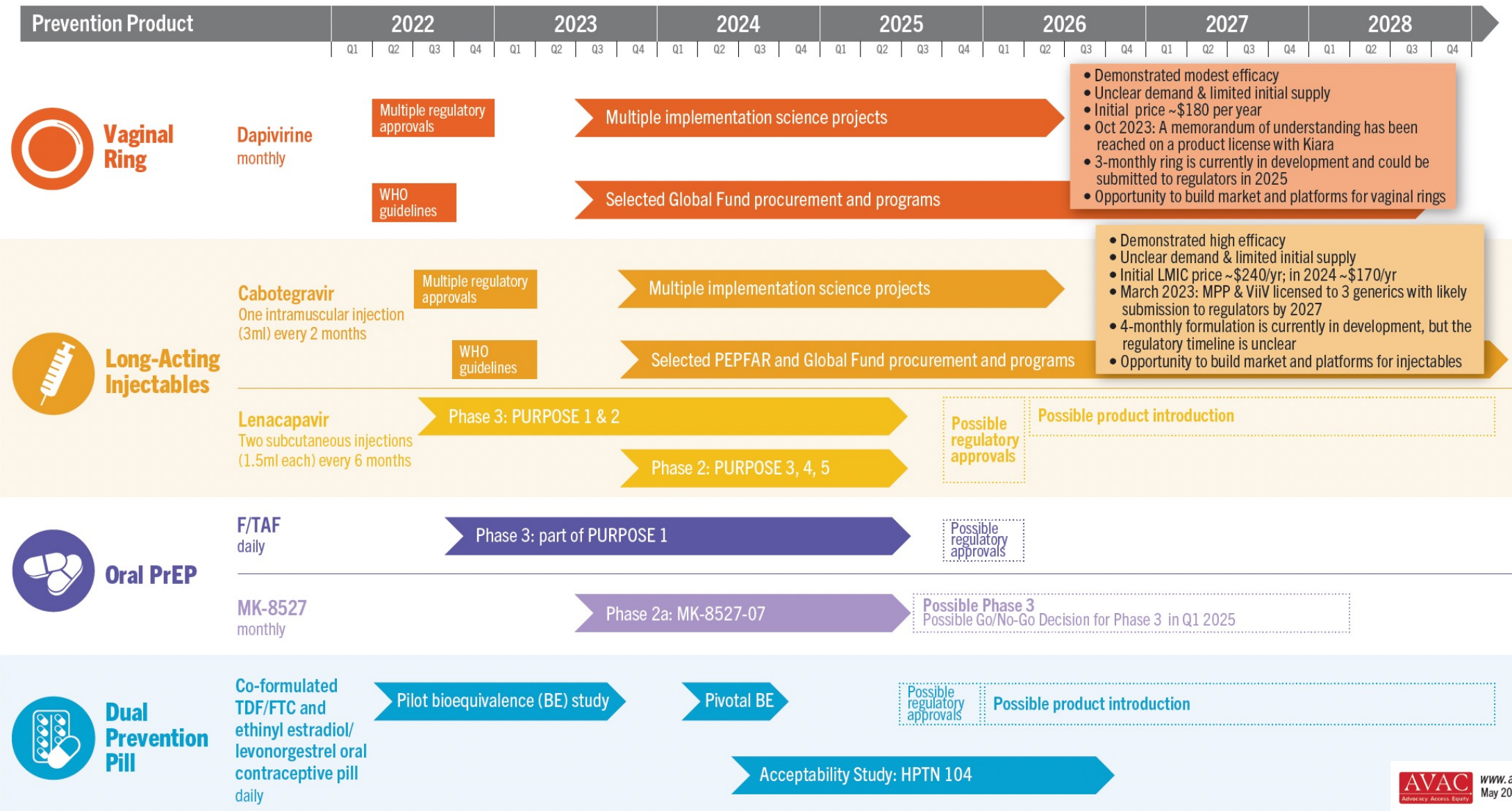


Cabotegravir (CAB)



Dapivirine Vaginal Ring (DVR)





Updated Product Pipeline



- Demonstrated modest efficacy
- Unclear demand & limited initial supply
- Initial price ~\$180 per year
- Oct 2023: A memorandum of understanding has been reached on a product license with Kiara
- 3-monthly ring is currently in development and could be submitted to regulators in 2025
- Opportunity to build market and platforms for vaginal rings

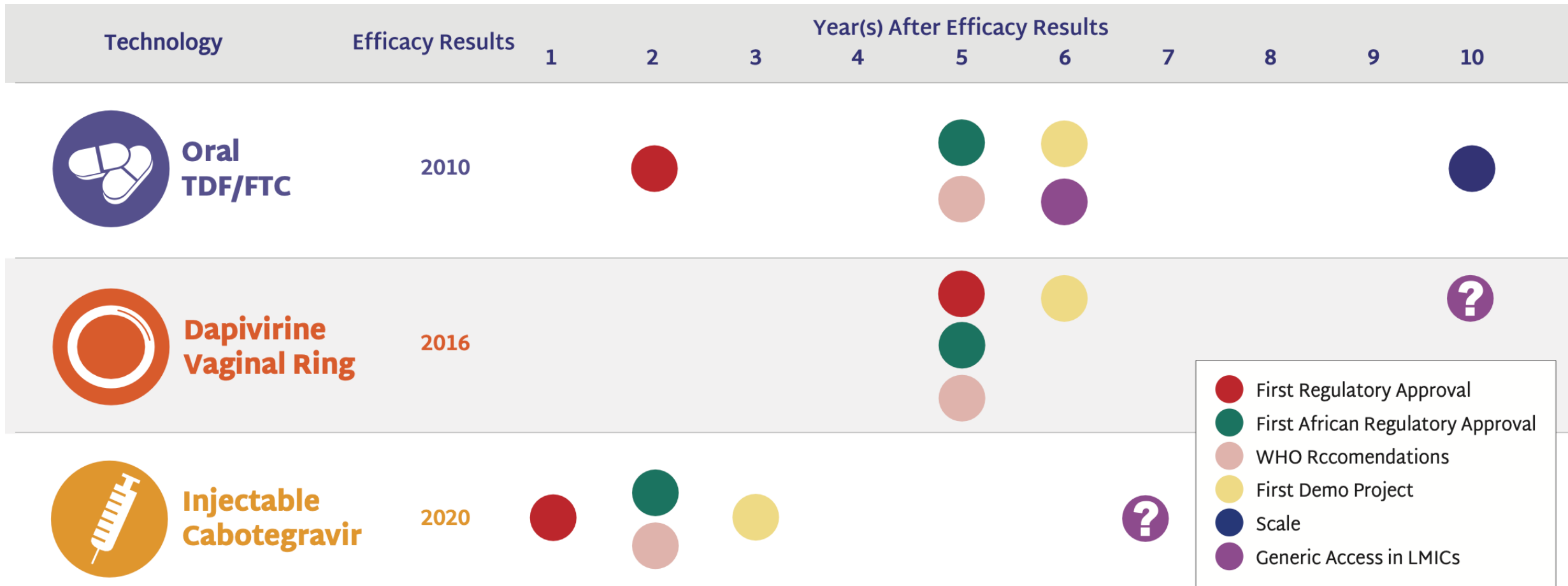
- Demonstrated high efficacy
- Unclear demand & limited initial supply
- Initial LMIC price ~\$240/yr; in 2024 ~\$170/yr
- March 2023: MPP & ViiV licensed to 3 generics with likely submission to regulators by 2027
- 4-monthly formulation is currently in development, but the regulatory timeline is unclear
- Opportunity to build market and platforms for injectables

Product Overview

	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)	48 countries (including EMA)	Approx. \$180/year (£23.50/vial x 6 inj. = £141/year)	3 generic manufacturers signed voluntary license in March 2023; tech transfer ongoing	
	Lenacapavir	<i>Product in phase 3 clinical trial; results anticipated be end of 2024</i>						
 Oral PrEP	F/TAF	Cis men/trans women	Descovy	Gilead	2019	96 countries	Price unknown	2 generic manufacturers with tentative FDA approval; price unknown
		Cis women						
	MK-8527	TBD	Merck	<i>Products in Phase 2 clinical trial; Phase 3 could begin in 2025</i>				
 Dual Prevention Pill	Co-formulated TDF/FTC and ethinyl estradiol/levonorgestrel oral contraceptive pill	<i>Products in pivotal bioequivalence study; could reach market in 2025</i>						

*Brand name Vocabria for HIV treatment

Moving A Product to the “Real World”



Long-Acting PrEP—Current Status as of March 2024

As of March 2024	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Current price from ViiV made public: £23.50/vial (approx. \$180/year). Voluntary license granted from MPP to 3 generics	MOU signed with Kiara Health to manufacture DVR in South Africa	
Regulatory Approval & Normative Guidance	Approved in 48 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 have delivered programmatic supply in 4 countries (Ukraine, Zambia, Zimbabwe & Malawi) since Q1 2024	Currently, 1,052 product initiations on DVR since Q4 2023	Both PURPOSE 1 & 2 clinical efficacy trials fully enrolled; results anticipated by end of 2024.
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— Proposed Priorities for 2024

As of March 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	Monitor progress on the need to remove oral CAB development and registration from sublicense agreements	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