

PrEP Pipeline and Promising Prevention Tools

SCOPE Community e-Meeting

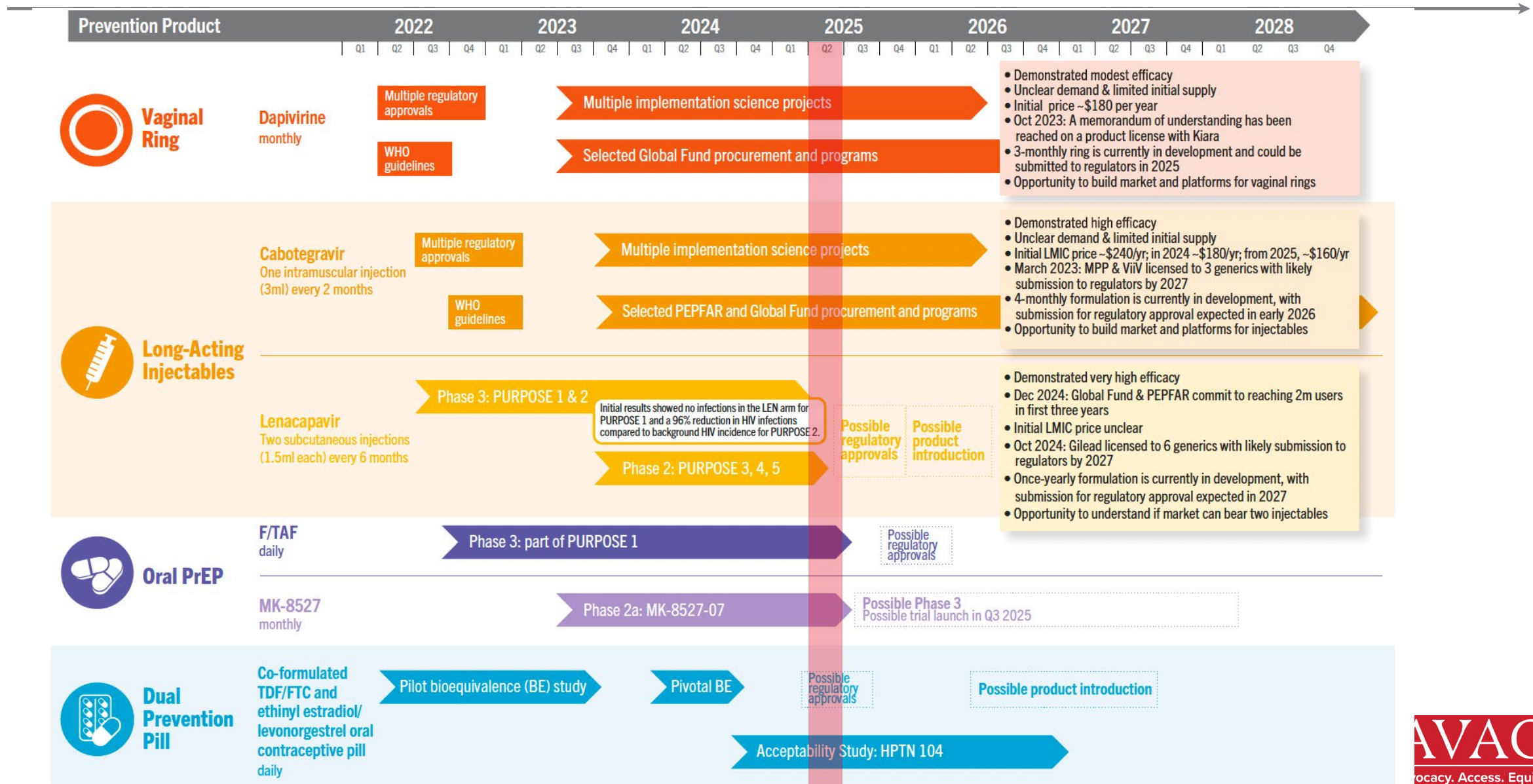
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14 May 2025

Overview

- Pipeline Overview
- Product spotlights
 - Oral PrEP
 - Injectable cabotegravir for PrEP
 - Dapivirine vaginal ring
 - Injectable lenacapavir for PrEP
 - Dual Prevention Pill
 - MK-8527
- Advocacy for Prevention Research and Implementation

PrEP Pipeline



New Innovations in Oral PrEP

New options for cisgender women could soon be available

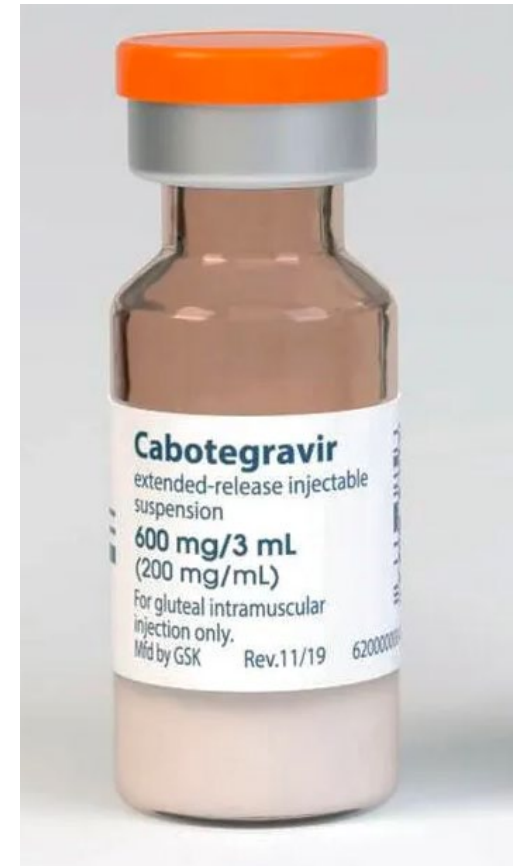
- **TDF/FTC**- the most commonly available form of oral PrEP (Truvada)
 - **What's new?**
 - Currently, “on demand” dosing regimens (2-1-1) are only indicated for AMAB individuals (cisgender men / transgender women)
 - New data shows PrEP can be **highly effective in cisgender women** using modified “on demand” regimes- 2-1-1-1 or 2-2-2-2
- **F/TAF**- another form of oral PrEP, less widely available (Descovy)
 - **What's new?**
 - Currently, F/TAF is only indicated for AMAB individuals
 - New data from the PURPOSE 1 trial shows that **F/TAF should be considered for cisgender women**
 - Like TDF/FTC, adherence is important and protection increases with the frequency of pills



Injectable Cabotegravir (CAB) for PrEP

The first commercially available injectable PrEP

- An **intramuscular injection** given in the **buttocks** every **two months**, developed by ViiV Healthcare
- Approved in 50+ countries, including by **the EMA, UK, and Ukraine**
- **Not currently widely available** in Europe- small scale PEPFAR funded programme in **Ukraine**- currently under threat due to US government funding cuts
- Concerns about **cost** have made some European government bodies **hesitant to recommend it** for use
- **Generics** are expected by **2027**, but the voluntary license only covers **Georgia, Kosovo, Kyrgyzstan, Tajikistan, Ukraine, and Uzbekistan** (in Europe/Central Asia)
- Show to be **superior to oral PrEP** in trials- but this may be primarily because it helps **facilitate adherence**
- A **four-month version** is under investigation and could be available in **2027**



The Dapivirine Vaginal Ring (DVR)

User-controlled, locally acting prevention

- A flexible **silicone ring** inserted into the **vagina** by **the user** which releases **dapivirine** over the course of **one month**, developed by International Partnership for Microbicides (now Pop Council)
- **Locally-acting**, meaning fewer side effects
- Reduces risk of acquiring HIV by **35%- 50%**
- Approved in 12 African countries, though **not currently widely available** outside of [implementation studies](#)
- **No plans to submit in Europe** at this time, though was given a **positive opinion by the EMA** (not the same as approval)
- A **three-month** version is currently **under investigation**



Injectable Lenacapavir (LEN) for PrEP

A new type of injectable PrEP in the pipeline

- **Two subcutaneous injections** given in the **abdomen** every **six months**, developed by Gilead (developers of oral PrEP)
- Show to be **safe and highly effective** in two large Phase III trials
- Currently approved in limited settings for use as **treatment**- first approval for **use as PrEP** expected from US FDA in **June 2025** with other countries to follow- also **submitted to EMA in February 2025** with expected decision by end of 2025
- **Generics** are planned via six direct licenses, expected by **2027**- licenses cover **Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan** (in Europe/Central Asia region)
- Early data shows a **yearly formulation** of LEN to be **safe and effective**- if further trials are positive, yearly LEN could be available **as early as 2027**



Dual Prevention Pill (DPP)

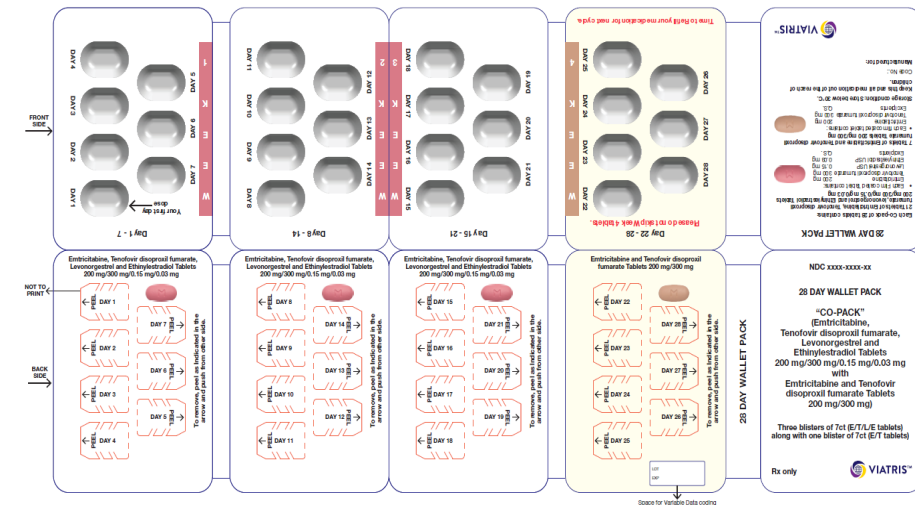
A daily oral pill that prevents HIV and pregnancy

- Co-formulated tablet that **combines oral PrEP + combined oral contraception** in a single pill, developed by **Viatriis**
- **28-day regimen** of 21 PrEP/COC pills (pink) and 7 days PrEP-only pills (peach)
- Successfully demonstrated **bioequivalence**- showing the drugs are absorbed into the body at the same rate as when the oral PrEP and OC are taking separately at the same time
- **Could receive regulatory approval in 2025**- initial target market will be **African countries**
- Will be the first commercially available **Multipurpose Prevention Technology** since condoms- and pave the pathway for other MPTs

Figure 1: Viatriis DPP tablet colors



Figure 2: Illustrative mock-up of DPP packaging by Viatriis

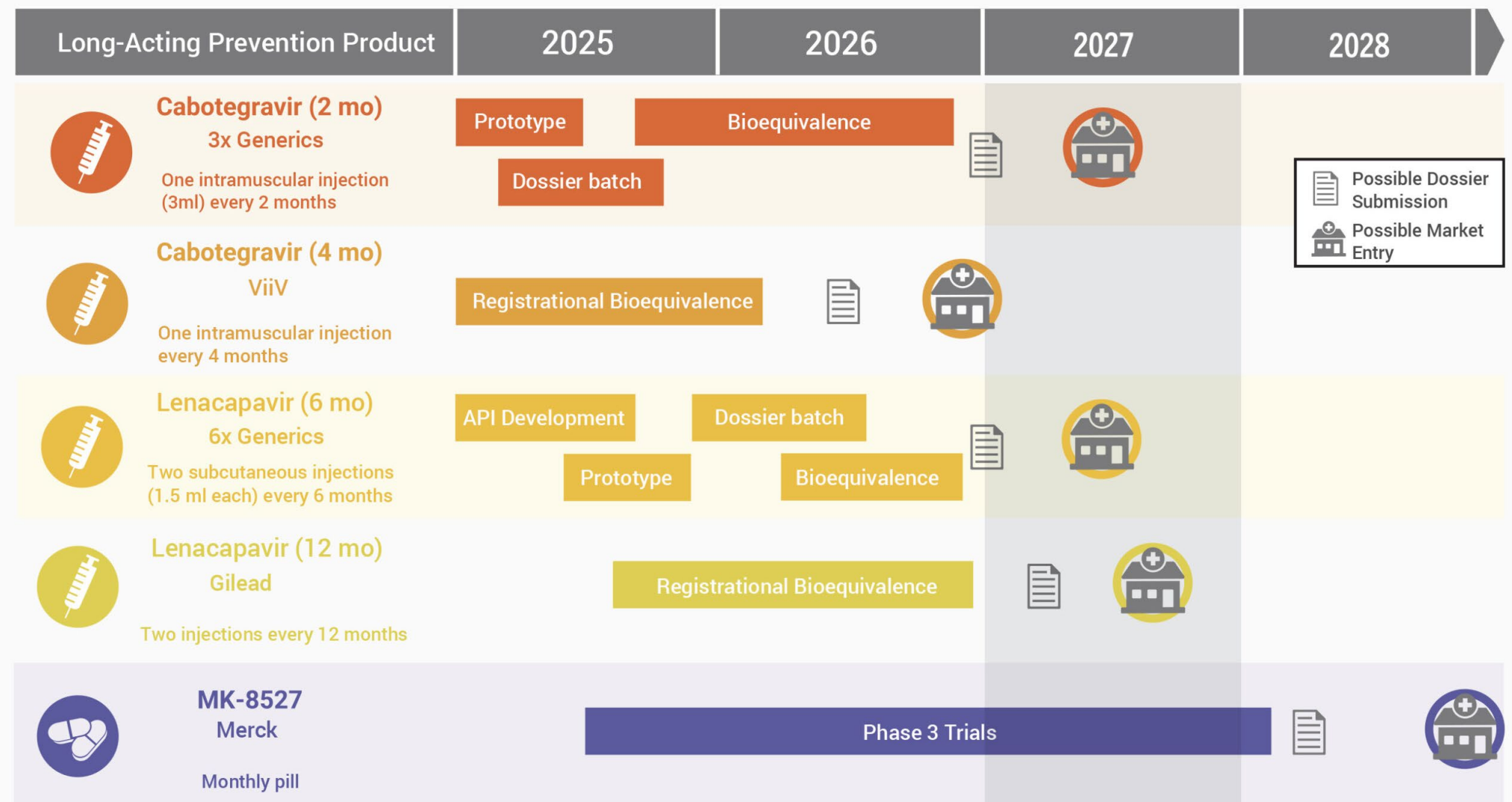


MK-8527

The next long-acting PrEP option?

- A **monthly oral pill** developed by Merck under investigation for use as HIV prevention
- Also under investigation as a weekly treatment
- Recently completed a **Phase II trial**, which looked at safety, tolerability, and pharmacokinetics (how the drug is absorbed/works in the body)
- A larger **Phase III trial** expected to begin in **mid-2025**
- Would be first long-acting PrEP in pill form- **easier to deliver** than an injection

When will these options be available?



Advocacy for HIV Prevention Research

Research in Europe

Non-ARV-based Efficacy Trials in Europe, completed

- Vaccine: Mosaico, Argentina, Brazil, Italy, Mexico, Peru, **Poland, Spain** and the U.S (discontinued, 2023)
- Antibody-related research: AMP Study, Brazil, Peru, **Switzerland**, US (completed 2020; established Proof of Concept)

ARV-based Efficacy Trials in Europe, ongoing

- Injectable PrEP (LEN): PURPOSE 5, **France, UK**

Research Advocacy

You have a say—beyond oral PrEP

- Which products should be developed?

The People's Research Agenda

“The products that have shown efficacy have different delivery mechanisms, levels of effectiveness, and durations of protection. There are more options than ever—with more to come. . . With less or limited resources, the stakes for decisions about which products to develop and eventually deliver become even higher for funders, communities, policy makers and governments.”

- How to ensure community ownership in research?

Good Participatory Practice Guidelines

UNAIDS' Ethical considerations in HIV prevention trials

Advocacy for PrEP Implementation

Advocacy for PrEP (ARV-based Prevention)

The Goal

- PrEP options that are
 - Easy to use, effective, low cost, covered by insurance—including migrants—and prescribed in community settings
- Caution: inequalities in oral PrEP will be replicated by only offering more products. Robust PrEP programs will take concerted advocacy and a call to action.



For EECA countries not implementing oral PrEP

Engage

- Build community networks of advocates to
 - Engage national level decision-makers on the health and cost benefits of PrEP. (Ukraine and Georgia models of success)
 - Refer decision-makers to UNAIDS and WHO priorities
 - Engage with WHO Europe and country offices to encourage govts
- Global Fund recipients
 - Include PrEP program in grants: join and/or influence CCM writing teams

For all EECA countries: planning for Long-acting PrEP

Advocacy for CAB-LA and LEN

- Community-led education, demand creation, access campaigns
- National level regulatory approval (~2026) and guidance for equitable access; follow WHO lead and recommendations
- National level financial commitments
 - Generic CAB-LA and LEN (~2027)
- Third-party procurement mechanisms such as Global Fund, UNICEF, etc., where needed and applicable
 - PEPFAR supplying CAB in Ukraine ????
- Collaboration with UNAIDS, Gilead and donors to strengthen regional coordination mechanisms that bring advocates, healthcare providers, and policymakers to the table, particularly in Eastern Europe and Central Asia (EECA)

Countries outside of ViiV CAB LA MPP license

Advocacy for generic CAB-LA

- Currently, \$**180/year (\$160 starting 2025)** for LMICS; one price throughout Europe is ideal
- What about HIC countries? UK, France, Spain, Australia rejecting CAB LA for its price
- ViiV must expand its voluntary license territory for purchase of generic CAB LA
 - Currently, direct license coverage includes
 - Ukraine, Kyrgyzstan, Tajikistan, Uzbekistan, Mongolia
 - No patents, indirect license coverage includes
 - Kosovo, Georgia

Countries outside of Gilead's license territory

Advocacy for generic LEN

- Gilead must expand the voluntary license territories to include all of EECA
 - 120 country territory for generic LEN leaves out most of EECA
 - Voluntary license covers only 67% of new HIV acquisitions and excludes countries with fast-growing epidemics (e.g., Latin America, MENA, Eastern Europe).
- Gilead must drop its diversion requirements: generic manufacturers cannot sell to countries beyond Gilead's allotted territory
- Companies capable of producing LEN to scale (e.g., Cipla, Aurobindo, Macleods) should be licensed to manufacture, compete and lower high prices
- EECA countries could implement compulsory licenses

DIY PrEP in Europe

In the meantime, if you want something done . . .

- Oral PrEP
 - **Dynamix International**
 - <https://www.purchase-prep.com/>
 - **PrEPster's Little Black Pocket Guides for PrEP and DoxyPEP**
 - <https://www.queerhealth.info/lbgt/prep>
 - <https://www.queerhealth.info/lbgt/doxy pep>

Pipeline Resources

Where to find more information

- [Pipeline Overview Graphic](#)
- [PrEPWatch.org](#)- the latest PrEP information and data
- [Product Pages](#)- info on all PrEP products currently available and in the pipeline
- [Global PrEP Tracker](#)- tracking PrEP initiations by country over time

Contact catherine@avac.org with any questions!

Advocacy Resources

- **The Peoples' Research Agenda**
- <https://avac.org/blog/introducing-peoples-research-agenda/>
- **Good Participatory Practice Guidelines**
- <https://avac.org/project/good-participatory-practice/>
- **UNAIDS ethical considerations in HIV prevention trials**
- <https://www.unaids.org/en/resources/documents/2021/ethical-considerations-in-hiv-prevention-trials>
- **Gears Framework for Lenacapavir for PrEP Rollout**
- <https://avac.org/resource/gears-framework-lenacapavir/>
- **Health Gap Activist Plan**
- <https://healthgap.org/wp-content/uploads/2024/12/WAD-Toolkit-8.pdf>
- **Medicines Patent Pool**
- <https://medicinespatentpool.org/>
- **PrEPster**
- <https://prepster.info/>