PrEP : SHOW US THE DATA!

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TUPE127

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Free online portals of curated data, news, infographics, guidelines, clinical trials, regulatory approvals, tracking tools and other resources to help the global community speed the delivery of accessible PrEP methods to everyone who needs them.

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FOR

- Communities
- Researchers
- Manufacturers
- Health professionals
- Advocates
- Implementers
- Policy makers
- Funders
- Procurers

ABOUT

- Access
- Advocacy
- Accountability
- Equity
- Innovation

PrEPWatch

The PrePWatch resource library contains over 900 PrEP-related resources and is growing every day. It includes tools for advocates, demand generation resources, costing guides, M&E tools, WHO guidelines, national HIV strategies, published research and service delivery best practice. These continually updated tools and information are instrumental to delivering the growing range of HIV prevention options. The Global PrEP Tracker, providing quarterly updates on global trends in PrEP initiation, along with other indicators, has become an indispensable resource for following the state of the field in delivering PrEP.

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LAPaL

THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

LAPaL is a new collaborative platform supporting access to innovation in the long-acting space. It contains expertly curated information on long-acting therapeutics and technology platforms, including their global clinical development and regulatory approval status. It aims to facilitate collaborations and advocate for access, in particular for for users in low- and middle-income countries. It offers a compilation of technical and intellectual property information on long-acting technologies and their potential applications.

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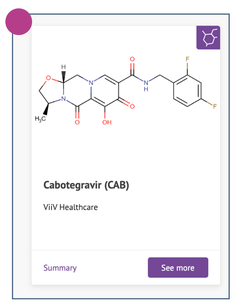
Case study: Cabotegravir long-acting for PrEP

Know the product



https://lapal.medicinespatentpool.org/compounds/cabotegravir-cab

Injectable Cabotegravir (CAB) for PrEP is highly effective at protecting people from HIV. Below are details on its distinct characteristics, approval history, availability, safety and effectiveness. Evidence and resources to learn more are also provided.

The Basics

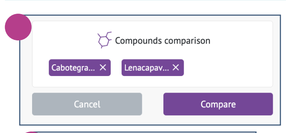
- An injection with the antiretroviral (ARV) cabotegravir (CAB) given every two months.
- Intramuscular injection in the buttocks.
- Developed by ViiV Healthcare.
- First approved in 2021 by the US Food and Drug Administration.
- Approved in 50+ countries, but not yet widely available outside of implementation studies.
- Can be used by adults and adolescents who weigh at least 35 kg (77 lb) and are at risk of getting HIV through sex.
- Brand name Apretude.
- Generics currently in development but won't be available until at least 2027.
- ViiV has granted a voluntary license to the Medicines Patent Pool.
- An oral version is also available though it is not widely used.

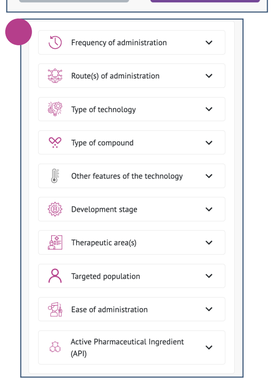
Effectiveness

- Highly effective if injections taken on time.
- The second injection must be taken one month after the first; after that, must be taken every two months to confer protection.
- Protection begins approximately one week after the first injection.
- May help improve adherence because it is longer-acting and may be more discreet than daily pills.

https://www.prepwatch.org/products/injectable-cab-for-prep/

Compare products





https://lapal.medicinespatentpool.org/

Injectable Cabotegravir vs Injectable Lenacapavir: Key Differences

	Cabotegravir (CAB)	Lenacapavir (LEN)
ARV drug class	Integrase Strand Transfer Inhibitor	Capsid Inhibitor
Injection type	Intramuscular	Subcutaneous
Injection site	Gluteal muscle (buttocks)	Abdomen
Injection volume	One 3 ml injections	Two 1.5 ml injections
Frequency/interval	First injection followed by a second one month later, then every 2 months	First injection along with two oral tablets, followed by two more tablets on day 2 and then injections every 6 months
Efficacy	Very high efficacy in all populations	Very high efficacy among cisgender women; data in other populations pending
Regulatory approvals and guidelines	19 regulatory approvals as of June 2024; WHO recommendation as additional prevention option in July 2022	Regulatory submissions and potential normative guidance anticipated in 2025
Price in LMICs	±$180/year	TBD
Developer/Manufacturer	ViiV Healthcare	Gilead Sciences
Generic Manufacturers	Three licenses through MPP to Aurobindo, Cipla and Viatris – all Indian-based manufacturers, with expected earliest market access in 2027	Gilead announced its intention to sign direct voluntary licenses with generic drug makers in several regions

https://www.prepwatch.org/products/injectable-cab-for-prep/

Get a sense of manufacturing

Scale-up and manufacturing prospects

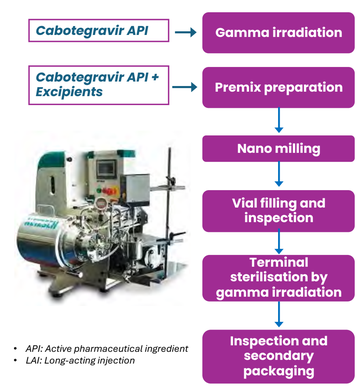
Scale-up prospects
Compound is commercially manufactured by the innovator and three generic manufacturers have received a licence through the medicines patent pool to manufacture generic versions by 2026/2027.

Tentative equipment list for manufacturing
Conventional wet-bead milling (ball mill), depyrogenated glass vials.

Manufacturing
Cabotegravir is subject to a gamma-irradiation pre-sterilization step prior to a conventional wet-bead milling manufacturing procedure. The Cabotegravir milling process is initiated alongside pharmaceutical excipients (polyethylene glycol 3350, water for injection, polysorbate 20 and mannitol) for an overall 200nm drug particle size. Sterilized de-pyrogenated glass vials are used to store the finished drug nanosuspension, before an additional gamma irradiation (25kGy) step to ensure aseptic packaging conditions.

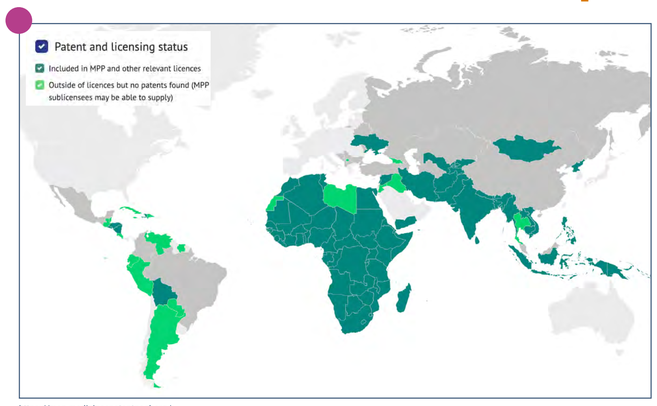
Specific analytical instrument required for characterization of formulation
PANalytical X'Pert PRO diffractometer equipped with a theta/theta coupled goniometer (or equivalent x-ray powder diffractor) to determine drug particle size, Mettler TGA/DSC 1 instrument for thermal analysis, HPLC to evaluate drug content, impurities and dissolution, HPLC UV-Vis Detector for drug identification.

https://lapal.medicinespatentpool.org/compounds/cabotegravir-cab



- *API: Active pharmaceutical ingredient*
- *LAI: Long-acting injection*

Visualise intellectual property landscape



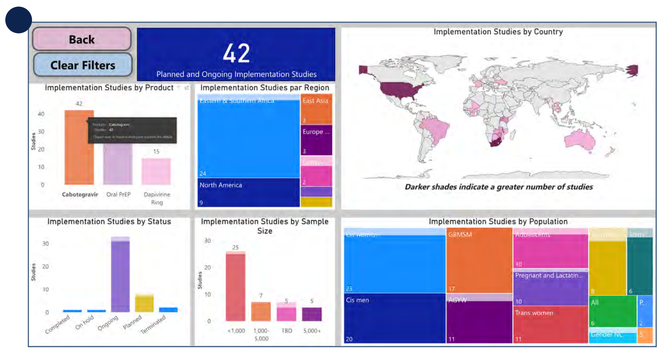
https://map.medicinespatentpool.org/

Compound patent families

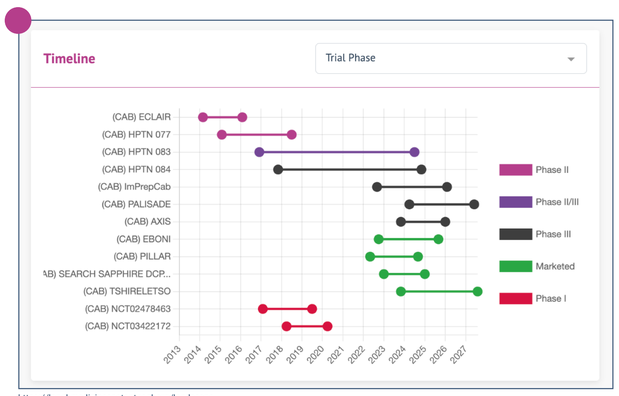
Patent description	Representative patent
Cabotegravir crystalline forms **Expiry date:** 25 Jan 2038	WO2018149608
Cabotegravir long-acting parenteral compositions **Expiry date:** 15 Sep 2031	WO2012037320
Cabotegravir processes and intermediates **Expiry date:** 22 Mar 2031	WO2011119566
Dolutegravir and Cabotegravir compounds **Expiry date:** 28 Apr 2026	WO2006116764

https://lapal.medicinespatentpool.org/compounds/cabotegravir-cab#patent

Visualise clinical trials data and timelines

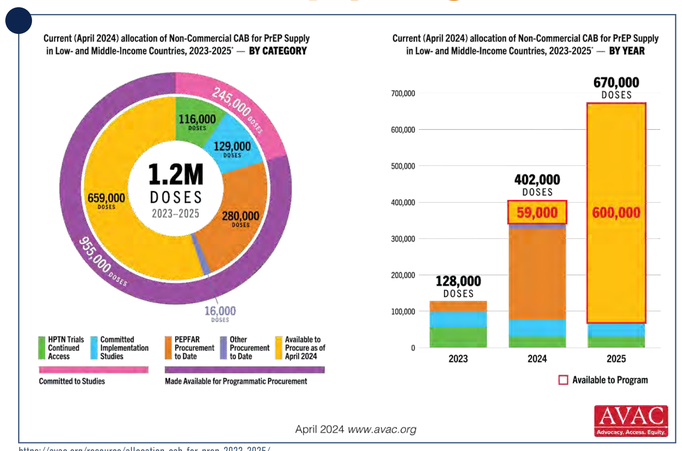


https://tinyurl.com/2p9wn2xm



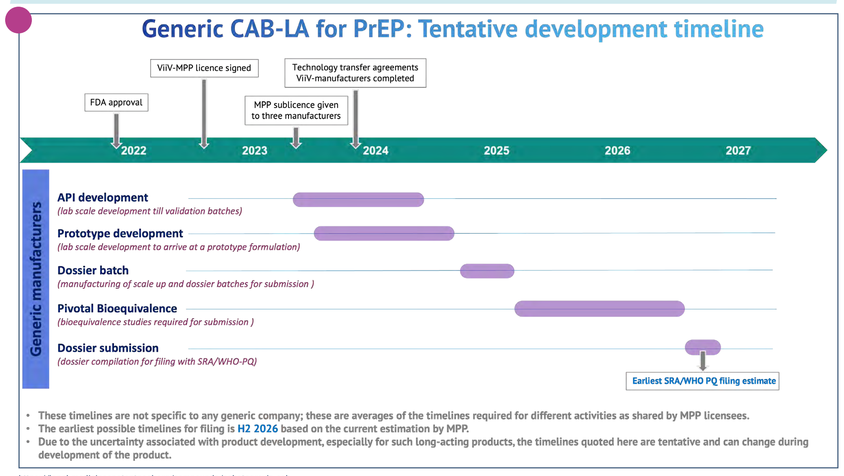
https://lapal.medicinespatentpool.org/landscape

Quantify progress



https://avac.org/resource/allocation-cab-for-prep-2023-2025/

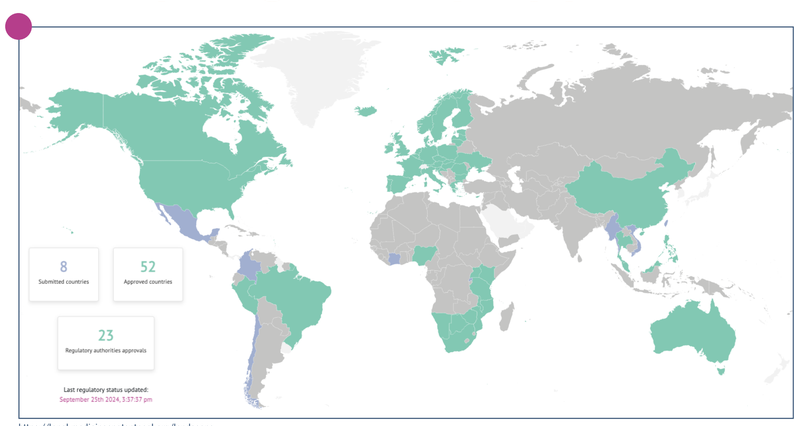
Understand timelines



- These timelines are not specific to any generic company; these are averages of the timelines required for different activities as shared by MPP licensees.
- The earliest possible timelines for filing is H2 2026 based on the current estimation by MPP.
- Due to the uncertainty associated with product development, especially for such long-acting products, the timelines quoted here are tentative and can change during development of the product.

https://lapal.medicinespatentpool.org/compounds/cabotegravir-cab

Map regulatory approvals



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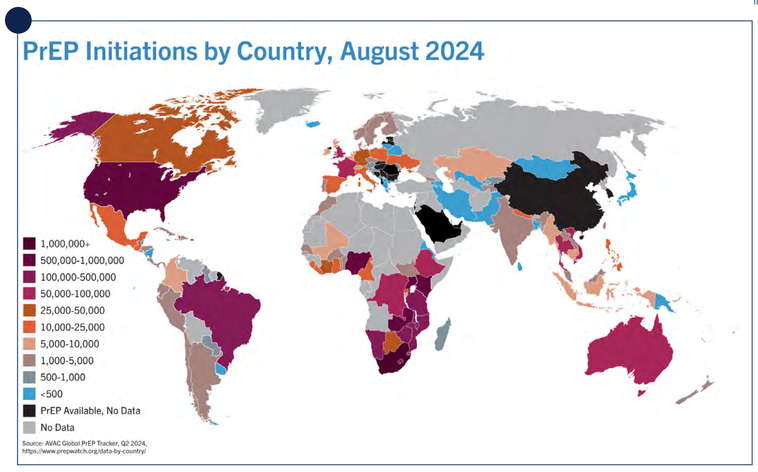
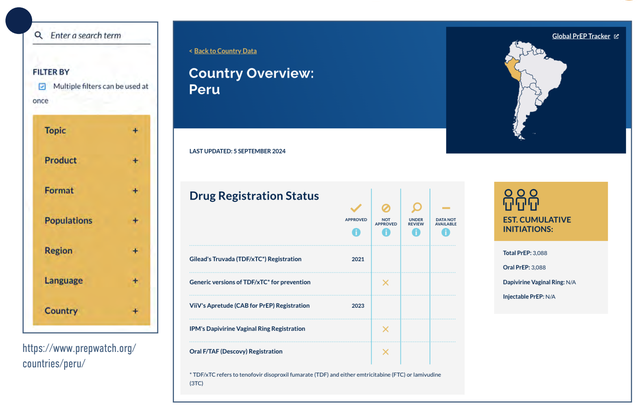
Track country planning

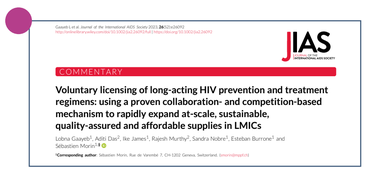


https://avac.org/resource/infographic/prep-initiations-by-country-worldwide/ https://data.prepwatch.org/



https://www.prepwatch.org/countries/peru/

Learn from toolkits, publications, webinars, infographics & briefings



Injectable Cabotegravir Evidence Gap Tracker

https://www.prepwatch.org/gap-tracker/

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HIVR4P 2024 6-10 October Lima, Peru, and virtual

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