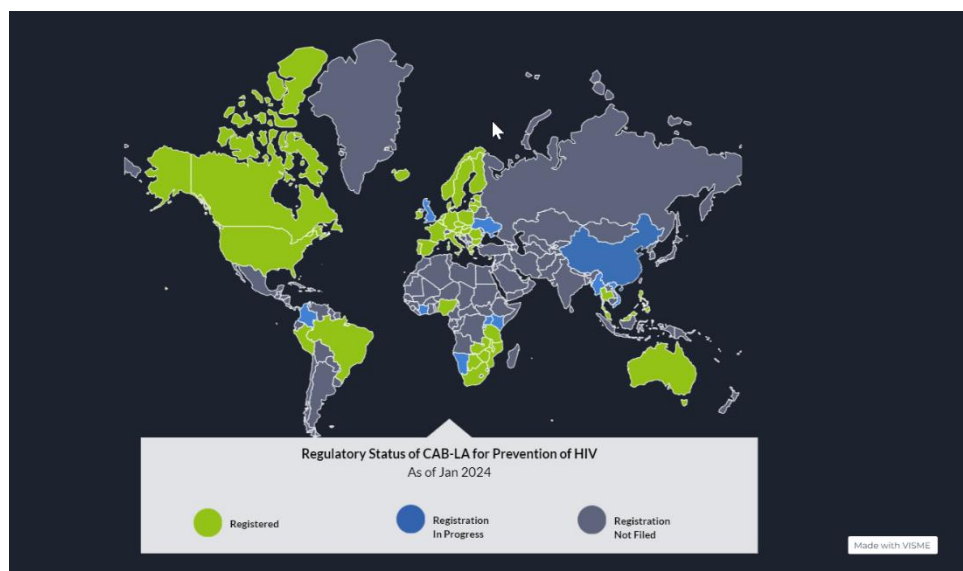




Long-acting cabotegravir (CAB-LA) for HIV prevention

Background note on distribution of the drug in 2023

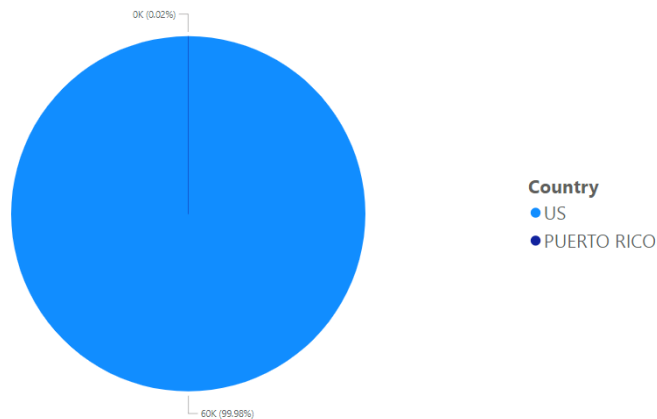
- CAB-LA is a highly effective long-acting injectable medicine used for HIV pre-exposure prophylaxis (PrEP), with the first 2 injections administered 4 weeks apart and an injection every 8 weeks thereafter. Thus, in their first year of initiation, people need 7 injections of CAB-LA.
- CAB-LA was approved by the [US Food and Drug Administration in 2021](#) and recommended by the [World Health Organization in July 2022](#). As of [January 2024](#), it had received regulatory approval in 43 countries, and ViiV had applied for approval in 14 other countries. Only 5 middle-income countries (Malaysia, Peru, Brazil, Philippines, Thailand) feature in the list of countries where the drug is approved.



- An estimated 1.3 million people were newly infected with HIV in 2023. In order to meet the global [targets for reduction of new HIV infections](#) (370,000 by 2025), greater access to PrEP and other prevention options is essential.
- According to MSF's analysis of annual 2023 sales data licensed by MSF from IQVIA¹, approximately 60,000 vials of CAB-LA for prevention were sold commercially in 2023. These sales were almost exclusively in the US.

¹ Note - IQVIA traditionally audits sales volume through wholesalers; pharmacies and specialist distribution channels may not be audited. Some markets have both a retail and hospital capture, whilst others (Greece, Estonia, Luxembourg, Venezuela, Central America, Colombia, Morocco, Pakistan, Bangladesh, Sri Lanka, Algeria, Jordan, West Africa) only currently have a retail view of the market available on IQVIA MIDAS. Brazil, Mexico and Ecuador non retail channels, although available on IQVIA MIDAS, have restrictions around data access and

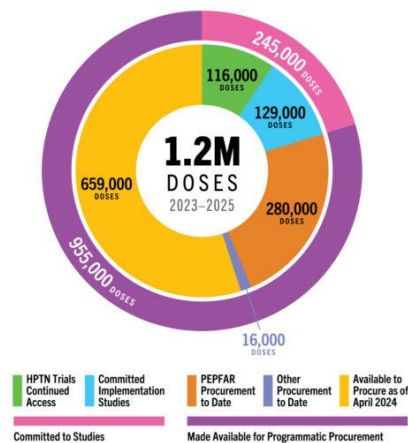
Total Vials Sold for PrEP (Apretude) by Country, 2023



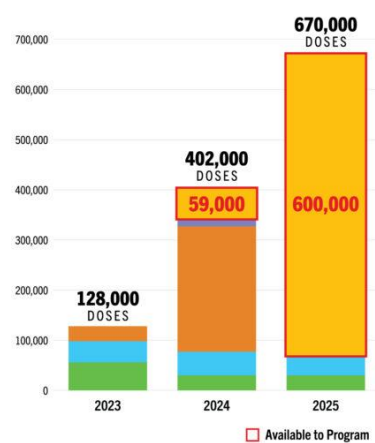
Source: Based on IQVIA MIDAS® annual sales data for 2023 in US and Puerto Rico, reflecting estimates of real world activity. Copyright IQVIA. All rights reserved.

- According to [data from “access markets” compiled by AVAC](#), an international NGO dedicated to accelerating ethical development and equitable delivery of effective HIV prevention options, only **128,000 vials of CAB-LA were available outside of ViiV’s commercial territory in 2023**. Of these, approx. **100,000 vials were reserved for continued access to the drug by clinical trial participants and for studies ViiV had committed to**, and approx. **28,000 vials were procured by PEPFAR**.

Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 — BY CATEGORY



Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 — BY YEAR



April 2024 www.avac.org



- Therefore, in 2023, only **88,000 vials were made available commercially and non-commercially for prevention of HIV by ViiV for use outside of studies**. 88,000 vials translates to access to one year of CAB-LA for prevention for less than 13,000 people, a

were therefore not included in the data licensed from IQVIA. The statements, findings, conclusions, views, and opinions contained and expressed herein are not those of IQVIA Ltd. or any of its affiliated or subsidiary entities.

miniscule fraction of the global need for the drug to prevent the 1.3 million new HIV infections annually.

Beyond the US market and supply to PEPFAR, there were no sales of CAB-LA in other countries where it was registered for prevention of HIV (i.e., Zimbabwe, South Africa, Malawi, Botswana, Brazil, Philippines, Zambia, Malaysia, Peru, Nigeria and Thailand).
