Where We Are Now with LEN for PrEP

THE GLOBAL FUND
PEPFAR
Global Fund & PEPFAR announce coordination to reach 2 million people with LEN for PrEP

World Health Organization
WHO guidelines development group to review evidence **and formulate clinical guidance**

FDA
FDA grants Gilead Priority Review status of LEN for PrEP

FDA
FDA grants approval of LEN for PrEP

World Health Organization
WHO guidelines and recommendations announced at IAS in Kigali

Funding freezes, litigation, widespread closures, and confusion jeopardize scaled LEN procurement

Dec 17 2024 — **Dec 19 2024** — **Jan 28-30 2025** — **Feb 3 2025** — **Feb 18 2025** — **Feb 24 2025** — **Jun 18 2025** — **July 9 2025** — **July 14 2025** — **Sept 2025**

GO?

FDA **PEPFAR** **THE GLOBAL FUND**

FDA
Gilead submits new drug application to U.S. Food and Drug Administration for twice-yearly lenacapavir for HIV prevention

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
Gilead submits marketing authorization application to the European Medicines Agency

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
European Medicines Agency agrees to accelerated review of LEN for PrEP

GILEAD
THE GLOBAL FUND
**Gilead and Global Fund announce access agreement and finalize initial supply

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
EMA approval is expected

PEPFAR and Global Fund can procure after regulatory approvals and WHO recommendation

AVAC Advocacy. Access. Equity.

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July 2025