Sign-on letter to Gilead CEO: Expand regulatory plans, transparency for long-acting lenacapavir

Dear CEO Daniel O'Day,

We are writing as HIV, access-to-medicines and human rights advocates to call on Gilead to announce and expand its commitment to register long-acting lenacapavir (LEN-LA) for broad use in low- and middle-income countries (LMICs). Delays in registration are delays in access, with potentially deadly consequences.

This is especially so since Gilead will be the sole supplier of LEN-LA until 2027, when generic product and export/import will start. Long-acting PrEP is poised to make a transformative difference in the fight against HIV, but only if access is massively accelerated and scaled-up.

Gilead has not disclosed under its agreement with the Global Fund its price or plans for seeking regulatory approval (registration or marketing authorization), which is ordinarily a prerequisite for marketing and use of a medicine.

Gilead has been relatively non-transparent about its regulatory intentions:

In its initial Access Strategy, Gilead identified 18 focus low- and middle-income countries for registration. However, according to more recent announcements, it has only filed for regulatory approval in the US, EU, Australia, Canada, Switzerland, South Africa (March), and Brazil (April).

Gilead has not disclosed what low- and middle-income countries are listed as targets for registration in its EU-Medicines-for-all application but the EMA recommendation for marketing approval lists only Uganda, Zambia, Kenya, Nigeria, Zimbabwe, South Africa, Thailand and Vietnam as "target countries".

Gilead has not yet applied for WHO prequalification, which it could have done even while US FDA and EMA applications were pending.

Regrettably, Gilead has not publicized any intent to use WHO Collaborative Registration Procedures, which would accelerate regulatory decisions by national regulatory authorities within 90 days, though it has said it would do so verbally.

Rapid regulatory approval of Gilead's LEN-LA in the vast majority of LMICs is uncertain at best. Although some of those countries supported by LEN-LA procurement by entities like the Global Fund can benefit from import waivers, that will not be a long-term solution for countries procuring LEN-LA directly.

We call on Gilead to urgently address this inadequate regulatory agenda that will harm access during its two-year period as a sole supplier and further hobble efforts to register generic equivalents in the future.

We call on Gilead to:

Commit to accelerating applications for regulatory approval of LEN-LA in all LMICs;

Disclose the non-EU countries it has identified for registration in its EU-M4all application and amend its application to include all LMICs, if they are not already included;
When its M4all approval is finalized, promptly file for registration in all countries that can rely on EU approval;
Expedite its application for WHO prequalification; and
File its required expressions of interest and consent to the WHO Collaborative Registration system for all LMICs, not just the 66 participating countries.
We request your response by [ten days after letter is sent], 2025.
Sincerely,