GILEAD
Creating Possible

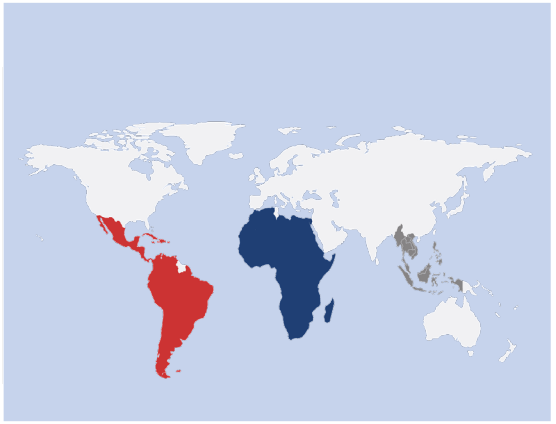
Lenacapavir for PrEP

Case Study

Kat Green
Senior Director, GPS Regulatory Affairs

Context

Unmet Need



African Continent

1.3M new infections annually;
~3,600 new HIV infections daily;
50% in Sub-Saharan Africa

544 AGYW (age 15-24) contract HIV EVERY DAY

Southeast Asia

In Thailand, after 6 months of PrEP initiation, only 30% of users still use PrEP with sufficient adherence to prevent HIV infection

Latin America

HIV incidence of new cases has only declined 1% since 2010

External Environment

World Health Organization
ZAMBIA MEDICINES REGULATORY AUTHORITY
THE GLOBAL FUND
PEPFAR
MCAZ
BILL & MELINDA GATES foundation
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
PAHO
Pan American Health Organization
PMRA Quality Medicines for Malawi
NAFDAC
AVAC Global Advocacy for HIV Prevention
USAID FROM THE AMERICAN PEOPLE
SAHPRA South African Health Products Regulatory Authority
BOMRA
EFDA
RWANDA FDA
สำนักงานคณะกรรมการอาหารและยา Food and Drug Administration
REPUBLIC OF KENYA MINISTRY OF HEALTH PHARMACY AND POISONS BOARD
anarme Autoridade Nacional Reguladora de Medicamento. IP
DRUG ADMINISTRATION OF VIETNAM
FDA Food and Drug Administration PHILIPPINES
Safe Drugs Save Lives
TMDA Tanzania Medicines & Medical Devices Authority

Sources: UNAIDS AIDSInfo Database, AVAC PrEPWatch Q4 2023 data. Murphy, L, The Adv Infect Dis (2023); Zhang J., et al. Lancet HIV (2022); https://www.unaids.org/sites/default/files/media_asset/2021-political-declaration_summary-10-targets_en.pdf | AGYW = Adolescent Girls and Young Women

Rationale

Lenacapavir for PrEP (L4P)

Simultaneous global filings of major markets at same time as low and lower middle-income countries (LLMICs) to enable fastest access to PrEP in those markets with the biggest HIV burden

The Context	The Approach
Gilead Ambition	EU Medicines for All
+	▼
Regulatory Objectives	WHO PQ
+	▼
Geographic Scope	WHO SRA CRP

WHO PQ = World Health Organisation Prequalification
WHO SRA CRP = World Health Organisation Stringent Regulatory Authority Collaborative Registration Procedure

Collaboration

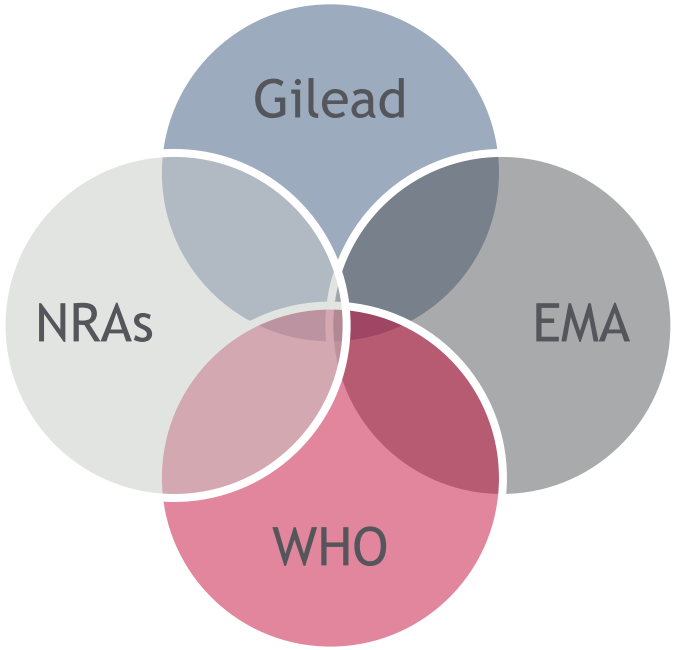
The LEN4PrEP regulatory strategy is underpinned by the principle of partnership

WHO SRA CRP

Gilead/NRAs
Definition of Reliance
WHO SRA CRP acceptability

Gilead/WHO/NRAs
WHO SRA CRP
NRA experience

WHO/NRAs
NFPs in NRAs



Gilead/EMA
Accelerated review

Gilead/EMA/WHO
Scientific Expert Selection

EMA/WHO
Eligibility

EU Medicines for All

Gilead/WHO
- PQ application
- Authority insights

NRAs/EMA
- Collaborative review

WHO PQ = World Health Organisation Prequalification
WHO SRA CRP = World Health Organisation Stringent Regulatory Authority Collaborative Registration Procedure
EMA = European Medicines Agency
NRA = National Regulatory Authority
NFP = National Focal Point

Summary of Successes and Challenges

Challenges

- EUM4all pre-submission steps were not clear
- National government alignment requires a x-functional engagement plan
- Lack of detailed guidance can prolong execution activities
- Post-opinion collaboration with EMA to navigate the end of the EUM4all process
- Significant upfront investment for planning
- Appropriately setting Internal and External expectations

Successes

- Parallel EUM4all Submission & timeline to EU centralised procedure
- Questions from Scientific Expert countries
- Experts from the WHO and 8 national regulatory authorities contributed to scientific discussions
- Parallel submission requested by SAHPRA
- Abridged PQ application
- Expedited review timelines

Key Considerations for Success

Environmental

External regulatory environment – emerging reliance pathways

External political will – PrEP has a significant role to play to support global goals

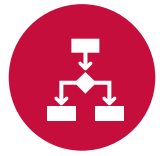
Strong clinical evidence

Aligned ambition with external partners

Scientific Innovation: unmet medical need for prevention options to reduce new infections

Internal

Early Strategic discussions with key regulators



Socialisation of proposed procedural route

Gain external regulatory guidance

Create a global dossier and meet the sameness requirements of reliance

Commitment to a global access strategy for LEN

Thank you