

# THEMATIC SEGMENT CASE STUDIES

## **Beyond 2025 – Long acting antiretrovirals: potential to close HIV prevention and treatment gaps**

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## Introduction

The Thematic Segment of the 57th UNAIDS Programme Coordinating Board (PCB) meeting will be held on 18 December 2025 and will focus on “Long acting antiretrovirals: potential to close HIV prevention and treatment gaps”.

In preparation for the Thematic Segment, UNAIDS issued a call for submission of examples of best practices and country case studies. The case studies inform the development of the background note to the thematic segment as well as the discussions during the day.

A total of 18 case submissions were received. The submissions reflect the work of governments, civil society, and other stakeholders, as well as collaborative efforts. The case studies highlight the importance of working towards having a sustainable response to the HIV epidemic.

## Africa

### Ghana

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**Submitted by:** Civil society

April 2025 – September 2025 (6 months)

**5. Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy
- ☒ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☒ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☐ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

**6. Case study demonstrates** (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☒ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☒ Community engagement, improved community literacy, and knowledge translation
- ☒ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☒ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☐ Data collection, monitoring, accountability, including community-led monitoring

- **Background and Objectives:**

As part of efforts to scale up quality HIV care and address human rights barriers within the Global Fund/WAPCAS GC7 Project, the West Africa AIDS Foundation (WAAF) implemented key interventions across three districts in the Ashanti Region. The Kumasi Metropolitan Assembly (KMA), Atwima Kwanwoma, and Atwima Nwabiagya. The initiative sought to strengthen HIV prevention, treatment and human rights protection for vulnerable men and transgender women.

The goal was to increase access to quality HIV prevention and treatment services, reduce stigma, and enhance community participation through peer-led outreach and referrals. The project also aimed to prepare communities for the integration of new HIV technologies, such as long-acting antiretrovirals, by improving treatment literacy and adherence support.

Activities were implemented over a six month period, focusing on education, linkage to care, psychosocial support, and community monitoring.

- **Description:**

The project utilized a community-led approach involving 16 Outreach Volunteers, 2 Transgender Women Liaisons, 8 Community Paralegals, 3 Community Case Managers, 2 Support Nurses and 1 Project Officer. These actors worked collaboratively across three districts to provide comprehensive HIV prevention education, testing, PrEP screening, STI management, and referral to ART services.

Through one-on-one sessions, small group discussions and social media outreach, vulnerable men and transgender women received education on HIV, PrEP, PEP, STI, TB, Hepatitis B, condom use, and gender-based violence. Peer educators referred participants to three partner health facilities for ARV initiation, PrEP services, and STI management.

Case managers and paralegals supported clients by addressing human rights concerns, providing psychosocial and adherence counselling, and linking abused individuals to redress mechanisms. This ensured that no one was left behind due to stigma, discrimination, or fear of arrest.

By emphasizing peer involvement, human rights awareness, and service linkage, the project bridged gaps between communities and healthcare providers. It also enhanced community readiness for future long-acting ARV adoption through treatment education and literacy.

- **Results, outcomes and impact:**

Over the 6 months implementation period, the project achieved the following:

1. 950 vulnerable men and transgender women reached with HIV prevention education and testing
2. 210 clients linked to ARV and PrEP services
3. 60% improvement in treatment literacy and adherence among participants receiving peer support
4. Increased trust in health services, with 85% of participants reporting reduced fear of stigma during service access

## 5. 1 human rights related case identified and referred for redress

The program strengthened collaboration between communities and health facilities, resulting in improved service delivery, retention in care, and awareness of future treatment options, including long-acting ARVs.

- **Gaps, lessons learnt and recommendations:**

Despite significant achievements, the project faced challenges including limited access to ARV commodities, transportation barriers to referral centers and fear of discrimination at some health facilities. Additionally, Ghana is yet to introduce long-acting injectable ARVs, limiting options for clients seeking flexible treatment alternatives.

Key lessons learned include the effectiveness of peer-led interventions in improving access and adherence and the importance of integrating human rights education into HIV programs. Community paralegals proved essential in bridging gaps between legal awareness and healthcare access.

It is recommended that Ghana's national HIV response:

1. Strengthen supply chain and health worker sensitivity training
2. Pilot long-acting ARV models within existing PrEP and ART programs
3. Sustain investment in peer-led HIV and human rights initiatives to ensure equitable access for LGBTQIA+ individuals

- **Annexes:**

<https://drive.google.com/drive/folders/16ZWYQ9Fao092zePED4WdkT0L42fpUPja>

**Malawi**

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2024-2025

**Submitted by:** Government

**5. Area of intervention of case study** (tick all that apply) \*

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• **Background**

Case Study: Introducing Long-Acting Injectable CAB-LA PrEP in Malawi (2024–2025)

Malawi introduced its national PrEP program in 2022, offering oral PrEP in roughly 600 health facilities nationwide. The program expanded rapidly and improved access to HIV prevention services, particularly for adolescent girls, young women, and key populations at higher risk of infection.

Building on this foundation, the Ministry of Health (MoH) approved long-acting cabotegravir (CAB-LA) for PrEP in 2023 and revised national HIV prevention guidelines in 2024 to include both oral and injectable options. CAB-LA implementation began in March 2024 in selected facilities in Blantyre and Lilongwe cities, serving as pilot sites to generate operational evidence and inform national scale-up.

In early 2025, a temporary USAID/PEPFAR stop-work order (SWO) paused new enrollments from February to July. Despite the disruption, the program-maintained continuity through oral-PrEP bridging and resumed full CAB-LA services immediately after the suspension was lifted.

This case study documents Malawi's experience in introducing CAB-LA PrEP, its



contribution to the HIV response, early results, and lessons for sustaining and expanding long-acting HIV prevention options within the health system.

- **Description**

#### Description / Contribution to Access and Use of Long-Acting ARVs

**Policy and guidance:** In 2024, the Ministry of Health finalized updated service-delivery guidelines that established client choice between oral and injectable PrEP. The guidelines specify eligibility criteria, HIV testing to exclude acute infection, dosing intervals, and protocols for tail-phase management and stock limitations.

**Service delivery model:** CAB-LA was offered through 38 public health facilities and key-population–friendly drop-in centers supported by PEPFAR. Services were integrated within existing oral-PrEP and sexual and reproductive health (SRH) platforms, improving convenience, reducing stigma, and leveraging existing clinical workflows.

**Path to Scale initiative:** Under the Path to Scale consortium—led by the MoH and National AIDS Commission with partners including PSI, FHS, UCSF-HealthQual, Cooper/Smith, and academic institutions—CAB-LA was implemented at 46 sites by 2025. The model emphasized real-world learning and systems strengthening, supported by ScanForm AI, which digitizes paper records to produce near-real-time data for program monitoring and supply-chain management.

**Health-systems approach:** The introduction of CAB-LA was guided by a comprehensive health-systems framework, drawing on existing governance, human resources, and supply-chain structures. Community insight (stakeholder engagement), labs and quality-improvement cycles helped tailor services to local needs and sustain demand.

**Resilience amid funding shocks:** During the SWO period, public facilities continued service provision using national commodities, while private and KP sites quickly resumed operations once restrictions were lifted. This demonstrated the program’s growing institutional resilience.

- **Results, outcomes, and impact**

Across the 46 Path to Scale Sites in Blantyre and Lilongwe, 2,843 clients had initiated PrEP (oral and CAB-LA combined) by October 2025, with 1,734 (≈60.8%) continuing at last contact. The cohort comprised 2,413 (85%) first-time assessments, 389 (14%) re-assessments, and 41 (1%) transfers-in. Among initiations, xx% were first-time users and xx% had switched from oral PrEP to CAB-LA.

The program’s target of 9,900 PrEP clients by September 2025 was not fully met. However, based on 2025 UNAIDS estimates, approximately 9,500 new HIV infections occurred among adults aged 15 years and above in 2024 (6,149 females and 3,344 males). Using the 3% annual-incidence threshold that defines individuals at substantial risk and eligible for PrEP, an estimated 289 adults would have been expected to benefit from CAB-LA. The 1,734 clients continuing on CAB-LA by September 2025 far exceed this benchmark, underscoring effective identification and retention of high-risk populations.

Despite temporary suspensions during the SWO, the program maintained service continuity through oral-PrEP bridging, active client follow-up, and close supervision. The Path to Scale sites are now transitioning to full Ministry of Health support, positioning Malawi for sustainable national integration of long-acting PrEP.

- **Gaps, lessons learnt and recommendations**

Key gaps and bottlenecks:

CAB-LA delivery through 38 public facilities and dedicated drop-in centers revealed two major challenges: (1) limited numbers of trained and mentored health workers, and (2) heavy dependence on donor funding, which poses risks to long-term sustainability.

Data management:

The program employed ScanForm, a digital data-capture platform providing near-real-time information for program monitoring and supply-chain management. A two-way feedback mechanism enabled generation of data-quality reports shared with providers for rapid correction. Continuous supervision by implementing partners and MoH staff improved data quality, identified implementation gaps early, and strengthened accountability. Future systems should prioritize simple, scalable data tools that can be adopted even in sites with minimal external support.

Lessons learnt:

Malawi's experience shows that introducing CAB-LA within an existing PrEP framework is feasible when guided by a health-systems approach—anchored in national leadership, provider training, supply-chain integration, and meaningful community engagement.

Recommendations:

Expand and mentor provider capacity.

Diversify financing and strengthen domestic resource mobilization.

Reinforce supply-chain forecasting and buffer stocks.

Scale and sustain digital tools such as ScanForm.

Institutionalize community participation to sustain demand and accountability.

## Morocco

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2022-2025

**Soumise par :** Gouvernement: ONU ou autre OI

### 5. Domaines d'intervention (cliquez tous ceux qui s'appliquent) \*

- ☒ Leadership national dans l'élimination des obstacles politiques et juridiques à l'accès (par ex. licences et approbations réglementaires)
- ☒ Génération de la demande menée par les communautés, soutien par les pairs, redevabilité et plaidoyer
- ☐ Expériences vécues liées à la réception de médicaments antirétroviraux à action prolongée (par ex. perspectives des patient·e·s)
- ☐ Surmonter les obstacles à la prestation et à la rétention des services pour les populations cibles et/ou dans les zones géographiques mal desservies
- ☒ Mécanismes ou partenariats de financement innovants

### 6. L'étude de cas démontre (cliquez tous ceux qui s'appliquent) \*

- ☒ Partenariats entre parties prenantes et coordination mondiale (par ex. bailleurs de fonds, entreprises pharmaceutiques, gouvernements, communautés, cliniciens)
- ☒ Planification stratégique nationale pour l'accès aux médicaments antirétroviraux à action prolongée (par ex. inclusion des antirétroviraux à action prolongée dans les plans et lignes directrices nationaux de traitement et de prévention, liste des médicaments essentiels, paniers de prestations, plans d'approvisionnement, etc.)
- ☒ Rapport coût-efficacité et/ou accessibilité financière (par ex. plans pour des génériques à bas prix, amélioration des chaînes d'approvisionnement, procédures réglementaires accélérées, production locale, etc.)
- ☒ Financement des médicaments antirétroviraux à action prolongée
- ☐ Acceptation et demande des médicaments antirétroviraux à action prolongée de la part des communautés et des personnes vivant avec ou à risque pour le VIH
- ☒ Engagement communautaire, amélioration de la littératie communautaire et traduction des connaissances
- ☒ Amélioration de l'équité dans l'accès à la prévention et au traitement grâce aux médicaments antirétroviraux à action prolongée
- ☐ Intégration des services pour faciliter l'accès et l'utilisation des médicaments antirétroviraux à action prolongée
- ☒ Collecte de données, suivi, redevabilité, y compris le suivi mené par les communautés

#### • Contexte et objectifs

Le Maroc est le premier pays de la région de l'Afrique du Nord et du Moyen-Orient à avoir mis en place un programme d'accès à la PrEP. Initialement, un projet pilote a été lancé de 2017 à 2019 à la suite d'une étude d'acceptabilité qui a montré une forte demande de PrEP

parmi les hommes ayant des relations sexuelles avec des hommes (HSH). Ce projet pilote a débuté dans trois Cliniques de la Santé Sexuelle et Reproductive (CSSR) de l'Association de Lutte Contre le Sida (ALCS) à Casablanca et Marrakech pour les HSH, et à Agadir pour les HSH et les professionnelles du sexe (PS).

L'expérience pilote a été consolidée par un projet d'extension progressive de la PrEP sur une période de trois ans, conformément au Plan Stratégique National de Lutte contre le Sida (PSN) 2020-2023. Actuellement, la PrEP est dispensée dans 8 cliniques de santé sexuelle et reproductive de l'ALCS. En 2022, ce service a été étendu aux CSSR de Nador, Safi, et Tanger, avec un objectif de dispenser la PrEP à 800 nouveaux HSH et 400 nouvelles TS. Une évaluation menée en 2022 a conclu qu'il était nécessaire d'étendre la PrEP à d'autres ONG. Le PSN prévoit d'augmenter la couverture à 1350 bénéficiaires HSH et PS en 2022, en particulier dans les sites à prévalence élevée. Actuellement, environ 1200 HSH et TS suivent une PrEP orale, dont les deux tiers sont des HSH.

Un protocole d'extension de la PrEP au niveau communautaire et dans les Etablissements de Soins de Santé Primaires (ESSP) a été élaboré et l'extension est en cours. Par ailleurs, un projet d'introduction de la PrEP injectable à longue durée d'action est en préparation en collaboration avec l'ALCS, avec un projet pilote prévu pour les professionnelles de sexe au Maroc.

- **Description**

Le Maroc a franchi une étape décisive dans la prévention du VIH avec la mise en œuvre du plan national d'extension de la Prophylaxie Pré-Exposition (PrEP), inscrit dans la stratégie nationale de prévention combinée. Ce dispositif, lancé par le Ministère de la Santé et de la Protection Sociale (MSPS) avec l'appui de ses partenaires, vise à réduire le risque d'infection parmi les populations les plus exposées, notamment les professionnelles du sexe (PS) et les hommes ayant des rapports sexuels avec des hommes (HSH).

Ce déploiement s'appuie sur les résultats positifs d'une phase pilote, qui a permis d'en valider la faisabilité et de préciser les conditions nécessaires à une extension réussie. Cinq nouvelles cliniques de l'Association de Lutte Contre le Sida (ALCS) ont depuis intégré la PrEP à leurs services, selon des modalités flexibles : soit via des consultations dédiées, soit intégrée aux services existants, garantissant une adaptation aux réalités locales.

L'extension de la PrEP s'inscrit dans une approche de prévention combinée, articulant dépistage, préservatifs, réduction des risques, soutien psychosocial et prophylaxie.

L'évaluation nationale conduite en 2022 a permis d'identifier les leviers essentiels pour sa réussite : renforcement des capacités humaines, intégration dans les soins primaires, mobilisation communautaire et amélioration du suivi-évaluation.

Un atelier national organisé en octobre 2024 a rassemblé les professionnels de santé et les ONG partenaires (ALCS, AMPF, OPALS) autour d'une formation sur la PrEP, la prévention combinée et l'utilisation du système DHIS2 pour le suivi des données VIH.

Cette initiative, portée conjointement par les acteurs institutionnels et communautaires, traduit un engagement fort du Maroc à rendre les outils de prévention plus accessibles, efficaces et durables. Elle s'inscrit pleinement dans le Plan Stratégique National Intégré VIH-

IST-Hépatites 2024-2030, confirmant la position du Maroc comme modèle régional en innovation et santé publique. Le Maroc est en cours de préparation d'un plan d'introduction de PrEP Injectable avec l'appui du Fonds mondial, OMS et l'ONUSIDA.

- **Résultats, effets et impact**

Les premiers résultats de la mise en œuvre de la PrEP au Maroc sont prometteurs et confirment son potentiel à renforcer la prévention combinée du VIH. L'introduction progressive de la PrEP dans plusieurs sites pilotes a permis d'accroître l'accès des populations clés — notamment les professionnelles du sexe et les hommes ayant des rapports sexuels avec des hommes — à un outil de prévention hautement efficace et scientifiquement validé.

Cependant, les questions d'adhérence et de suivi demeurent des éléments déterminants pour garantir l'impact de la PrEP. Le maintien d'une observance régulière au traitement, associé à un suivi clinique et biologique rigoureux, est essentiel pour assurer une protection optimale et éviter les risques de résistance.

Les données collectées à travers le système national DHIS2 montrent une appropriation progressive du service, une meilleure intégration dans les soins de santé primaires et une mobilisation accrue des acteurs communautaires. Ces avancées témoignent d'un impact positif sur la prévention du VIH, avec une amélioration de la couverture des populations à haut risque et un renforcement de la coordination entre les acteurs institutionnels et communautaires. L'expérience marocaine illustre ainsi une étape majeure vers une prévention plus accessible, durable et centrée sur les besoins des usagers.

- **Lacunes, enseignements tirés et recommandations**

La mise à l'échelle de la PrEP au Maroc a révélé plusieurs lacunes et défis structurels. Parmi les principaux goulets d'étranglement figurent la faible connaissance de la PrEP parmi certaines populations cibles, la stigmatisation persistante dans les services de santé, et le manque de ressources humaines formées à son suivi clinique et communautaire. L'adhérence au traitement reste également un enjeu majeur : certains bénéficiaires interrompent la PrEP en raison de contraintes sociales, de mobilité ou de méconnaissance du schéma de prise.

Sur le plan du système, l'intégration complète de la PrEP dans les soins primaires et le suivi-évaluation régulier à travers le DHIS2 nécessitent encore un renforcement, notamment en matière de collecte et d'analyse des données.

Les enseignements tirés soulignent l'importance de l'accompagnement communautaire, de la sensibilisation continue et du renforcement des capacités des prestataires pour garantir la qualité et la durabilité du programme.

Il est recommandé de consolider les partenariats régionaux, de renforcer la formation continue, d'améliorer le suivi de l'observance et de la rétention, et de développer des campagnes ciblées de communication afin d'élargir l'accès et de favoriser une appropriation durable de la PrEP par les populations les plus exposées.

- **Annexes** : Rapport National sida 2025

## Nigeria

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2016-2025

**Submitted by:** Government, civil society, UN or other IO, Other (did not specify)

### 5. **Area of intervention of case study** (tick all that apply) \*

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- ☐ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
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- ☐ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☒ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☐ Data collection, monitoring, accountability, including community-led monitoring

### • Background

Nigeria continues to face a significant HIV burden with an estimated 1.8 million people living with HIV in 2023, an overall prevalence of 1.3% among adults aged 15–49 years<sup>1</sup>. This burden is disproportionately higher among women (1.8%) compared to men (1.0%), HIV prevalence among females aged 20–24 years is 1.3%, compared to 0.3% among males of the same age group. Similarly, among those aged 15–19 years, prevalence is 0.3% in females versus 0.1% in males. These disparities highlight the urgent need for targeted and effective HIV prevention strategies for Adolescent and young people.

There is also significant heterogeneity in HIV prevalence across states and among key populations (KPs), where the epidemic is most concentrated. Prevalence rates are high among the key population with 16.7% among brothel-based female sex workers (BBFSW), 15% among non-brothel-based female sex workers (NBBFSW), 25% among men who have sex with men (MSM), 10.9% among people who inject drugs (PWID), and 28.8% among transgender persons (TG). This underscores the need for tailored interventions that address the unique vulnerabilities of these groups.

In response, Nigeria has adopted a comprehensive and evolving HIV prevention strategy that aligns with global best practices and World Health Organization (WHO) recommendations

### • Description

#### Implementation Milestones and Achievements

##### 1) Policy and Programmatic Framework



Nigeria's HIV prevention landscape has evolved from oral-based PrEP (tenofovir disoproxil fumarate, introduced in 2016) to long-acting options—cabotegravir (CAB-LA) adopted in 2024 and lenacapavir (LEN) in 2025, making Nigeria one of nine early adopter countries.

Over the years, policy and programmatic framework developed to facilitate implementation include:

- incorporation of PrEP into the National Strategic Framework on HIV and AIDS (2019-2021)
- launch of the National HIV Self-Testing and PrEP Communication Strategy (2022), supported by UNAIDS, PEPFAR, and the Global Fund, emphasizing community engagement, social media mobilization, and integration within HIV and SRH platforms.
- updates of the 2020 and 2024 National Guidelines for HIV Prevention, Treatment, and Care to reflect PrEP choice and new PrEP options such as Long acting injectable Cabotegravir and Lenacapavir
- development of a two-year implementation plan and roadmap for PrEP scale-up (2022-2024)
- Update of the national PrEP training curriculum for healthcare providers to reflect safe delivery, pharmacovigilance, and counselling for long-acting injectable PrEP (CAB-LA)

## 2) Service Delivery

Between 2018 and 2024, PrEP service delivery expanded from 15 pilot facilities to more than 400 sites across 31 states, supported by PEPFAR, the Global Fund, implementing partners and local CSOs. By late 2024, approximately 43,000 individuals were receiving oral PrEP, according to national program data.

To facilitate uptake, PrEP choice is fully integrated into routine counselling, adherence support, and follow-up services while delivering unbiased, client-centered services through trained service providers to ensure continuity of PrEP use. By strengthening the range of available options and aligning services with client preferences, Nigeria can accelerate progress toward reducing new HIV infections and meeting national and global prevention targets.

Key achievements include:

- Decentralization of PrEP services to one-stop shops (OSS), youth-friendly centers, and community pharmacies.
- Task-shifting to nurses and community health officers, increasing service accessibility for key populations.
- Use of HIV self-testing (HIVST) for oral PrEP initiation and integration into gender-based violence response services, improving uptake, linkage and retention.
- Introduction of oral PrEP for pregnant and breastfeeding women in high-burden antenatal settings in Lagos, Cross River, and Benue States.
- Inclusion of AYP into population targeted for PrEP uptakes

### • **Results, outcomes and impact**

#### Emerging Innovation: Long-Acting Injectable PrEP

Recognizing adherence and stigma challenges associated with daily oral PrEP, Nigeria commenced the rollout of CAB-LA in 2024 through a pilot in 2 states (Lagos-supported by PEPFAR and Gombe-supported by GF).

However, following the executive order by the US government, the pilot was halted in Lagos. Consequently, to mitigate the impact of the stop-work order, the Federal Ministry of Health conducted a gap analysis and issued a Rapid Advice for continuity of PrEP services to ensure uninterrupted provision of PrEP across all service delivery points in Nigeria.

Additionally, 3 other GF-funded states were included in the CAB-LA pilot to offset the disruptions resulting from the stop-work order.

Subsequently, with support from WHO, between July-September 2025, the Federal Ministry of Health conducted a national PrEP landscape and site-readiness assessment across 10 states to support the preparatory phase of the national LEN rollout and strengthen integration of PrEP into STI, GBV, Family Planning and other reproductive health services.

Key outcomes from this preparatory phase:

- Update of National PrEP implementation plan (2025-2028) to reflect CAB-LA and LEN.
- Development of the national rollout plan for LEN PrEP and identification of more than 70 high-volume facilities equipped for cold-chain storage and injection administration.
- Ongoing update of the national PrEP training curriculum to reflect Lenacapavir as an additional PrEP option.
- Engagement with the National Agency for Food and Drug Administration and Control (NAFDAC) for fast-track national regulatory approval for the use of LEN and pharmacovigilance monitoring.

- **Gaps, lessons learnt, and recommendations**

Best Practices, Descriptions, and Key Outcomes

1) Integration into existing health platforms

Description: Embedding PrEP in HIV testing, FP, ANC, SRH, and adolescent health clinics

Key Outcomes: Increased reach among women and youth; cost efficiency

2) Policy updates and agility

Description: Timely revision of guidelines (2020, 2024) and rollout plans to include CAB-LA and LEN PrEP

Key Outcomes: Rapid adoption of innovations and strengthened preparedness for emerging technologies

3) Community-led service delivery

Description: PrEP dispensed through community pharmacies and OSS

Key Outcomes: Improved uptake and adherence; reduced stigma

4) Digital demand creation

Description: Social media influencers and mobile apps promoting PrEP literacy

Key Outcomes: Awareness among young people improved from 18% (2018) → 48% (2024)

5) Task-shifting and mentoring

Description: Nurses and CHEWs empowered to initiate and monitor PrEP

Key Outcomes: Service expansion to rural and underserved areas; human resource optimization

6) Country leadership and coordination

Description: Strong national stewardship by FMOH and NACA enabled rapid response and resource mobilization to close gaps. The halt of the CAB-LA pilot in Lagos due to the PEPFAR funding pause underscored the need for stronger multi-stakeholder coordination.

Key Outcomes: Faster mitigation of service disruptions and renewed focus on coordinated PrEP implementation across government, donors, and civil society.

7) Resilience planning

Description: Multi-sector financing task force activated during funding pause

Key Outcomes: Continuity of services and prevention of total program collapse

#### Challenges

- 1) Persistent stigma and criminalization of key populations limit access to PrEP services.
- 2) Supply chain and data integration gaps across implementing partners.
- 3) Heavy dependence on donor funding threatens sustainability.
- 4) Inadequate domestic financing for PrEP commodities and laboratory monitoring.
- 5) Limited awareness among adolescents and rural women.

#### Next Steps and Policy Directions

1) Domestic Financing: Promote a Total Market Approach (TMA) for sustainable HIV prevention financing. The TMA will diversify funding, engage the private sector, and mobilize domestic resources for PrEP and other prevention services..

2) Introduction of Long-Acting PrEP: Complete NAFDAC registration and phased rollout in 2025–26, beginning with high-burden states.

3) Demand Generation and Community Engagement: Strengthen community ownership and demand for PrEP through engagement of CSOs and community stakeholders at national and state levels. With AVAC support, a national CSO coalition on PrEP was formed to coordinate PrEP and LEN advocacy, aligning interests and amplifying community voices.

Demand generation will raise awareness among target groups, providers, policymakers, and the public to ensure equitable access, stigma-free services, and better adherence.

Key strategies (aligned with the National HIV Self-Testing and PrEP Communication Strategy) include:

- Targeted IEC materials
- Community mobilization
- Digital and social media engagement
- Strategic events and launches
- Policy and stakeholder advocacy

4) Digital Health Solutions: Expand use of mobile Health for PrEP adherence reminders and virtual counselling.

5) Research and Learning: Conduct implementation science and operational research evaluating rollout strategies, service delivery models, cost-effectiveness and user preferences for CAB-LA and Lenacapavir.

Equity Lens: Strengthen enabling environment for key populations through stigma reduction, legal reform advocacy, and community empowerment.

#### • Annexes:

- <https://docs.google.com/presentation/d/1X3QLW-P81GKgjDEoHGjUDH-jivODzI7F/edit?usp=sharing&ouid=105892539621983257191&rtpof=true&sd=true>
- <https://www.youtube.com/watch?v=aNcFk0wpulA>

## Senegal

Ndeye Fatou Ngom, Directrice Executive du reseau EVA (Enfants et VIH en Afrique)

Debut : Septembre 2023, fin :30 juin 2026

**Soumise par :** Institution academique: ONU ou autre OI

### 5. Domaines d'intervention (cliquez tous ceux qui s'appliquent) \*

- ☒ Leadership national dans l'élimination des obstacles politiques et juridiques à l'accès (par ex. licences et approbations réglementaires)
- ☒ Génération de la demande menée par les communautés, soutien par les pairs, redevabilité et plaidoyer
- ☒ Expériences vécues liées à la réception de médicaments antirétroviraux à action prolongée (par ex. perspectives des patient·e·s)
- ☐ Surmonter les obstacles à la prestation et à la rétention des services pour les populations cibles et/ou dans les zones géographiques mal desservies
- ☐ Mécanismes ou partenariats de financement innovants
- ☒ Recherche, collecte de données, suivi et évaluation, y compris le développement et le suivi des schémas thérapeutiques
- ☒ Intégration dans les systèmes de prévention et de soins du VIH et/ou dans d'autres secteurs du système de santé (par ex. soins prénatals et postnatals, services de santé sexuelle)

## 6. L'étude de cas démontre (cliquez tous ceux qui s'appliquent) \*

- ☒ Partenariats entre parties prenantes et coordination mondiale (par ex. bailleurs de fonds, entreprises pharmaceutiques, gouvernements, communautés, cliniciens)
- ☒ Planification stratégique nationale pour l'accès aux médicaments antirétroviraux à action prolongée (par ex. inclusion des antirétroviraux à action prolongée dans les plans et lignes directrices nationaux de traitement et de prévention, liste des médicaments essentiels, paniers de prestations, plans d'approvisionnement, etc.)
- ☒ Rapport coût-efficacité et/ou accessibilité financière (par ex. plans pour des génériques à bas prix, amélioration des chaînes d'approvisionnement, procédures réglementaires accélérées, production locale, etc.)
- ☒ Financement des médicaments antirétroviraux à action prolongée
- ☒ Acceptation et demande des médicaments antirétroviraux à action prolongée de la part des communautés et des personnes vivant avec ou à risque pour le VIH
- ☒ Engagement communautaire, amélioration de la littératie communautaire et traduction des connaissances
- ☒ Amélioration de l'équité dans l'accès à la prévention et au traitement grâce aux médicaments antirétroviraux à action prolongée
- ☒ Intégration des services pour faciliter l'accès et l'utilisation des médicaments antirétroviraux à action prolongée
- ☐ Collecte de données, suivi, redevabilité, y compris le suivi mené par les communautés

### • Contexte et objectifs

CABRILADO: étude de la faisabilité d'un traitement injectable à longue durée d'action par CABotégravir – RILpivirine chez les ADOlescents vivant avec le VIH en Afrique de l'Ouest et du Centre (Bénin, Cameroun, Côte d'Ivoire et Sénégal).

Objectif principal : décrire et analyser les conditions d'acceptabilité et de faisabilité de l'implémentation en Afrique de l'Ouest et du Centre d'un traitement antirétroviral injectable à longue durée d'action (LDA), associant Cabotégravir (CAB) et Rilpivirine (RPV), chez des adolescents (âgés de 12 à 17 ans), infectés par le VIH-1

Il s'agira ainsi de préparer l'introduction de ces nouvelles formes galéniques dans 4 pays où est implanté le réseau EVA (Enfants – VIH – Afrique) et un passage à l'échelle futur.

Objectifs secondaires :

- Déterminer la proportion d'adolescents de 12 à 17 ans éligibles cliniquement (c'est à dire sans contre-indication médicale) à une bithérapie CAB/RPV à LDA parmi les patients actuellement suivis.
- Déterminer la proportion d'adolescents ayant une contre-indication virologique à une bithérapie par CAB/RPV à LDA
- Identifier les enjeux, contraintes et conditions de mise en œuvre pratique des injectables par les systèmes de soins
- Evaluer le niveau et les conditions d'acceptabilité des adolescents, parents/tuteurs et soignants du traitement ARV injectable à longue durée d'action.

Pour autant, leur implémentation pose différents défis, qui seront évalués dans chacun des 4 work-packages (WP):

- WP clinique : identification de la proportion d'AdVIH présentant une contre-indication médicale à un tel traitement. Il s'agira de Recueil d'informations cliniques et thérapeutiques
- WP virologique : identification de la proportion d'AdVIH présentant une contre-indication virologique à la bithérapie CAB/RPV.
- WP « Organisation des services » : Identification des enjeux, contraintes et conditions de mise en œuvre pratique
- WP « Acceptabilité » : exploration du niveau et des conditions d'acceptabilité des AdVIH, des parents/tuteurs et des soignants du traitement injectable à LDA, ainsi que des facteurs associés à ce niveau d'acceptabilité.

Résultats : 642 enfants inclus, 630 CV réalisées, 600 Ag HBs, 598 Anticorps anti-HBs et 595 Anticorps anti-HBc. L'étude est toujours en cours

- **Description**

L'étude est toujours en cours, ce que nous pouvons retenir des résultats préliminaires, la demande est forte auprès des prestataires et des bénéficiaires mais il y a lieu de renforcer les capacités de tous les acteurs avec un plaidoyer auprès des autorités et des PTF.

- **Résultats, effets et impact**

le projet est toujours en cours

**Sans lacunes et sans annexes.**

## **Tanzania**

Richard Muko, Senior Regional Manager for Implementation Advocacy-AVAC,  
richomuko@gmail.com or [rmuko@avac.org](mailto:rmuko@avac.org)

Start Date: January 2018 End Date: December 2025

**Submitted by:** Civil society

**5. Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☒ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy
- ☐ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☒ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☒ Innovative funding/financing mechanisms or partnerships
- ☒ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

**6. Case study demonstrates** (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☒ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☒ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☒ Financing of long-acting antiretroviral medicines
- ☒ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☒ Community engagement, improved community literacy, and knowledge translation
- ☒ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☒ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

- **Background and objectives**

Since 2018, the Coalition to build Momentum, Power, Activism, Strategy & Solidarity (COMPASS) in Tanzania has evolved into a national platform aligning government, civil society, and communities toward equitable HIV service delivery. Under the leadership of the Benjamin Mkapa Foundation (BMF), NACOPHA, Sikika, the KVP Forum, TaNPUD, GABINET-RIO, Focus for the Future Generation (2FG), and the National Network of Women Living with HIV (NNW+), COMPASS has catalyzed systemic reforms that now position Tanzania to scale long-acting antiretrovirals (LA-ARVs) efficiently and equitably. Over eight years, COMPASS partners have supported national leadership to remove policy and legal barriers, institutionalize community systems, and strengthen human resources for health (HRH). They have worked closely with the Ministry of Health, the National AIDS Control Programme (NACP), and regulatory bodies engaged in approving biomedical innovations such as PrEP and six-month ART dispensing; establishing policy-regulatory alignment crucial for LA-ARV rollout. Simultaneously, COMPASS partners advanced community-led monitoring, stigma-reduction and gender-responsive training for health workers, harm-reduction frameworks, and the first Social Contracting Guideline for sustainable community financing. Collectively, these achievements created an enabling environment for equitable, affordable, and integrated LA-ARV access—advancing Tanzania’s vision to end AIDS as a public-health threat by 2030.

- **Description**

Over eight years, COMPASS Tanzania has laid a strong foundation for equitable access and sustainable use of long-acting antiretrovirals (LA-ARVs) through policy reform, systems strengthening, and community leadership. The coalition has translated advocacy into structural change across the HIV continuum.

At policy level, COMPASS partners worked with the Ministry of Health (MoH) and National AIDS Control Programme (NACP) to institutionalize differentiated service delivery (DSD), multi-month dispensing (6MMD), and PrEP scale-up. A major milestone was the 2019 reform lowering the age of consent for HIV testing from 18 to 15 years, enabling adolescents to independently access testing, prevention, and treatment—an essential precursor for LA-ARV uptake among young people. BMF’s advocacy on the National Health Workforce Volunteerism Guideline and HRH Sustainability Plan ensured that community and primary-care facilities are staffed and ready to deliver new ARV formulations.

Financially, Sikika’s domestic-resource-mobilization advocacy expanded the AIDS Trust Fund (ATF) and diversified national revenue streams, while NACOPHA’s development of the Social Contracting Guideline created a pathway for direct government financing of community-led HIV services, including future LA-ARV literacy and adherence initiatives.

At community level, 2FG and NNW+ championed gender-responsive and adolescent-centered engagement, improving literacy, demand, and peer-support networks for women and girls. The KVP Forum, TaNPUD, and GABINET-RIO advanced biomedical literacy, stigma reduction, and violence-response mechanisms, making facilities safer and more inclusive.

Collectively, COMPASS Tanzania has built the policy, financing, workforce, and community systems that now position the country to integrate long-acting ARVs into routine HIV prevention and treatment—ensuring no one is left behind beyond 2025.

- **Gaps, lessons learnt and recommendations**

While Tanzania has made major progress toward readiness for long-acting antiretrovirals (LA-ARVs), several gaps and bottlenecks remain. Regulatory and procurement pathways for new formulations such as Cabotegravir (CAB) still require faster post-approval processes



and clearer pricing mechanisms to enable national rollout. Human-resources shortages—particularly in rural and hard-to-reach areas—continue to strain service delivery despite recent gains through volunteerism initiatives. Community-led financing remains fragile; the Social Contracting Guideline needs full operationalization and sustained government budget lines to secure long-term civil-society participation. Persistent stigma, gender inequality, and violence against key populations and women still limit uptake of innovative prevention options.

Lessons learnt include the value of linking community evidence with policy dialogue; aligning donor and domestic financing to sustain reforms; and embedding gender and human-rights principles in service delivery to build trust and demand.

Recommendations:

Expedite regulatory and supply-chain integration for LA-ARVs under TMDA and MoH oversight.

Institutionalize financing for community-led literacy, monitoring, and demand-creation within ATF and council budgets.

Strengthen HRH recruitment and retention strategies to ensure equitable access nationwide.

Sustain cross-sector partnerships between government, civil society, and donors to accelerate equitable LA-ARV access and uphold rights beyond 2025.

## • Annexes

Key Supporting Documents and Links Guidance for COMPASS Tanzania Partners: Key Outcomes Since Inception (2018–2025) – Internal consortium report documenting policy reforms, outcomes, and lessons (AVAC/COMPASS Secretariat, 2025). Ministry of Health (Tanzania). PrEP Implementation Framework (September 2021) – National guideline introducing PrEP and enabling future long-acting ARV integration. National AIDS Control Programme (NACP). Essential Medicines List (2024) – Inclusion of Cabotegravir (CAB) as a preferred biomedical prevention option. Government of Tanzania. National Health Workforce Volunteerism Guideline (NHWVG), 2021 and Health Sector Strategic Policy Priorities 2024/25. Sikika (2025). Domestic Resource Mobilization for Health: Budget Analysis Report (2024/25–2025/26). NACOPHA and TACAIDS (2025). Draft Social Contracting Guideline and HIV Sustainability Framework. GABINET-RIO and KVP Forum (2023–2024).

Documentation on abolition of forced anal examinations and establishment of Violence Prevention and Response (VPR) Mechanism. Media: The Citizen Tanzania (2021):

“Government Lowers Age of Consent for HIV Testing to 15.” The Guardian (2024):

“Cabotegravir Added to Tanzania’s Essential Medicines List.” Photo & Evidence Repository:

[www.avac.org/compass-tanzania](http://www.avac.org/compass-tanzania) LinkedIn: <https://www.linkedin.com/company/compass-africa> Facebook: <https://www.facebook.com/share/1B3jad7sZp/?mibextid=wwXlfr>

Instagram: [https://www.instagram.com/compass\\_africa](https://www.instagram.com/compass_africa) Youtube:

[www.youtube.com/@COMPASSAfrica](https://www.youtube.com/@COMPASSAfrica) X/Twitter: [https://x.com/compass\\_africa](https://x.com/compass_africa).

The COMPASS Tanzania 8 Years Impact Document is also being Completed and will be ready for sharing soon

**Multi-Country Case: Botswana, Eswatini, Kenya, Namibia, Nigeria, Lesotho, South Africa, Uganda, Zambia, and Zimbabwe**

Helen Anyasi, Project Director, FHI 360, [hanyasi@fhi360.org](mailto:hanyasi@fhi360.org)

October 2021- March 2025

**Submitted by:** UN or other IO

**5. Area of intervention of case study** (tick all that apply) \*

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- ☒ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
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- ☐ Innovative funding/financing mechanisms or partnerships
- ☒ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

## 6. Case study demonstrates (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
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- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
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- ☒ Community engagement, improved community literacy, and knowledge translation
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- ☒ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

### • Background

MOSAIC (Maximizing Options to Advance Informed Choice for HIV Prevention) was a five-year global initiative funded by PEPFAR through USAID, designed to accelerate access to new biomedical HIV prevention products. Operating in 10 countries across sub-Saharan Africa, MOSAIC supported the introduction and scale-up of long-acting ARVs, including long-acting injectable Cabotegravir (CAB-LA), the Dapivirine vaginal ring, and pipeline products like Lenacapavir. The project centered the needs and preferences of adolescent girls and young women (AGYW), key populations, and other underserved groups. This case study highlights MOSAIC's global coordination, country-level technical assistance, and community engagement efforts that have enabled policy reform, service integration, and demand generation for long-acting ARVs. It draws on examples from the countries where MOSAIC was implemented: Lesotho, South Africa, Uganda, Zimbabwe, Namibia, Kenya, Zambia, Nigeria, Eswatini and Botswana

### • Description:

MOSAIC supported countries to introduce long-acting ARVs using a strategic framework that spans the full life cycle of product introduction across the value chain. In Nigeria and Namibia, MOSAIC co-developed CAB-LA pilot protocols and supported regulatory approvals while in South Africa, Uganda, and Zimbabwe, the project facilitated provider training and integration of CAB-LA into national guidelines. The CATALYST study, implemented in five countries, provided real-world evidence on product choice, acceptability, and continuation, informing WHO guidance and national rollout strategies. MOSAIC developed and disseminated tools including the PrEP Implementation Plan Template, CAB-LA Site Readiness Assessment Tool, and updated M&E indicators. The project supported national PrEP communication strategies in Kenya and Uganda and launched the "PrEPisChoice"

campaign in Zimbabwe, South Africa, and Eswatini. MOSAIC's youth-led NextGen Squad (NGS) moderated webinars, contributed to guideline development, and advocated for inclusion of youth in national technical working groups. Across all settings, MOSAIC's technical assistance enabled countries to align policies, train providers, and engage communities—laying the foundation for equitable access to CAB-LA and other long-acting ARVs.

- **Results, outcomes and impact**

By the end of 2024, MOSAIC-supported countries to update national guidelines to include CAB-LA, train over 200 providers, and launch pilot or programmatic rollout in Nigeria, Zambia, Zimbabwe, and South Africa. CATALYST Stage II provided access to all three PrEP methods in Lesotho, South Africa, Uganda, and Zimbabwe, with early data showing high acceptability and continuation. The 'PrEPisChoice' campaign reached thousands of youth and key populations, increasing awareness and demand. MOSAIC's technical tools were adopted by Ministries of Health and Implementing Partners, streamlining planning, training, and monitoring. The project's youth engagement model was replicated across countries, elevating youth voices in policy and programming. PrEPWatch, supported by MOSAIC, saw a 13% increase in users and has now become a global hub for PrEP resources. These outcomes demonstrate MOSAIC's impact in accelerating access to long-acting ARVs and strengthening national HIV prevention platforms.

- **Gaps, lessons learnt and recommendations**

The project encountered challenges such as delays in protocol approvals, limited provider familiarity with injectable ARVs, and gaps in community awareness. However, these were addressed through phased rollout, targeted training, and youth-led demand generation. Lessons include the importance of co-developing tools with ministries of health, integrating new products into existing systems, and centering user experience. Future introductions of long-acting ARVs should prioritize multi-method choice, community engagement, and real-time monitoring. MOSAIC's consortium model—combining global coordination with country-led implementation—proved effective in navigating diverse contexts. Continued investment in research utilization, local partner capacity, and digital platforms will be key to sustaining momentum and expanding access to long-acting ARVs.

- **Annexes:**

- <https://www.prepwatch.org/wp-content/uploads/2022/10/MOSAIC-Across-the-Product-Introduction-Framework-1.pdf>;
- <https://www.prepwatch.org/resources/mosaic-annual-report-2024/>;
- <https://www.prepwatch.org/resources/catalyst-study-overview/>;
- <https://www.prepwatch.org/resources/prepchoice-campaign-toolkit/>;
- <https://www.prepwatch.org/resources/cab-la-site-readiness-assessment-tool/>;
- <https://www.prepwatch.org/prep-communications-companion/>;
- <https://www.prepwatch.org/vibe-with-the-nextgen-squad/>;
- <https://www.who.int/news/item/28-07-2022-who-recommends-long-acting-cabotegravir-for-hiv-prevention>;

## Senegal

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CABRILADO: étude de la faisabilité d'un traitement injectable à longue durée d'action par CABotégravir – RILpivirine chez les ADOlescents vivant avec le VIH en Afrique de l'Ouest et du Centre (Bénin, Cameroun, Côte d'Ivoire et Sénégal).

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- Evaluer le niveau et les conditions d'acceptabilité des adolescents, parents/tuteurs et soignants du traitement ARV injectable à longue durée d'action.

Pour autant, leur implémentation pose différents défis, qui seront évalués dans chacun des 4 work-packages (WP):

- WP clinique : identification de la proportion d'AdVIH présentant une contre-indication médicale à un tel traitement. Il s'agira de Recueil d'informations cliniques et thérapeutiques
- WP virologique : identification de la proportion d'AdVIH présentant une contre-indication virologique à la bithérapie CAB/RPV.
- WP « Organisation des services » : Identification des enjeux, contraintes et conditions de mise en œuvre pratique
- WP « Acceptabilité » : exploration du niveau et des conditions d'acceptabilité des AdVIH, des parents/tuteurs et des soignants du traitement injectable à LDA, ainsi que des facteurs associés à ce niveau d'acceptabilité.

Résultats : 642 enfants inclus, 630 CV réalisées, 600 Ag HBs, 598 Anticorps anti-HBs et 595 Anticorps anti-HBc. L'étude est toujours en cours

- **Description**

L'étude est toujours en cours, ce que nous pouvons retenir des résultats préliminaires, la demande est forte auprès des prestataires et des bénéficiaires mais il y a lieu de renforcer les capacités de tous les acteurs avec un plaidoyer auprès des autorités et des PTF.

- **Résultats, effets et impact**

le projet est toujours en cours

**Sans lacunes et sans annexes.**

## Asia Pacific

### Cambodia

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January-October 2025

**Submitted by:** Government

**5. Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy

**6. Case study demonstrates** (tick all that apply) \*

- ☐ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☒ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☒ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☐ Community engagement, improved community literacy, and knowledge translation
- ☒ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☒ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☐ Data collection, monitoring, accountability, including community-led monitoring

- **Background**



This case study highlights Cambodia's early adoption of long-acting PrEP, including CAB-LA and DVR, as part of a comprehensive HIV prevention strategy for key populations. The initiative aims to expand prevention options that better meet the diverse needs of these communities. The National Centre for HIV/AIDS, Dermatology and STD (NCHADS) of the Ministry of Health, with technical support from UNAIDS and FHI360-EpiC, led the process from conceptualization to the rollout of long-acting PrEP in Cambodia. In 2023, NCHADS conducted acceptability and feasibility studies on CAB-LA and DVR. The findings informed the development of SOPs and Concept Notes for the phased implementation of both products. The SOP for CAB-LA was adopted in May 2025, followed by the adoption of the Concept Note for DVR in August 2025 by the Minister of Health, marking their formal introduction as HIV prevention tools. Training materials, implementation tools, and demand creation resources were developed to support the phased rollout, which began at four sites in Phnom Penh. Community-based organizations have played a central role in ongoing demand creation efforts through physical and virtual-based outreach interventions to reach their peers. Early indications suggest promising uptake of CAB-LA among key populations. Building on lessons learned from the initial phase, further rollout of long-acting PrEP is planned for the remainder of 2025 and 2026.

- **Description**

Cambodia has made significant strides in its HIV response, evolving from one of Asia's most affected countries in the 1990s to a regional leader in treatment coverage and viral suppression. By the end of 2024, 92% of people living with HIV (PLHIV) knew their status, 100% of those diagnosed were on antiretroviral therapy (ART), and 98% of those on ART achieved viral suppression. New HIV infections declined by 45% since 2010, yet an estimated 1,200 new cases occurred in 2024—three per day—highlighting persistent prevention challenges.

Key populations and youth remain disproportionately affected, accounting for 88% of new infections, with 44% among those aged 15–24. HIV prevalence among men who have sex with men (MSM) rose from 4% in 2019 to 5.5% in 2023, and among transgender women (TGW) from 9.6% to 13.5%. Expanding access to pre-exposure prophylaxis (PrEP) is a national priority under the Health Sector Strategic Plan 2021–2025.

Community-based PrEP delivery, combined with community-led demand creation, has improved service accessibility and responsiveness to key populations' needs. Long-acting PrEP options—such as CAB-LA and the Dapivirine Vaginal Ring (DVR)—are being recently introduced to address barriers to daily oral PrEP, including stigma, privacy concerns, and inconsistent clinic access. These innovations offer discreet, less frequent dosing and are especially relevant for MSM, TGW, female entertainment workers, and serodiscordant couples.

By diversifying PrEP options and strengthening community engagement, Cambodia enhances its client-centered, differentiated HIV services. Long-acting PrEP is a game-changer in reducing new infections, improving adherence, and empowering individuals at risk—bringing the country closer to its 95-95-95 targets and ending AIDS as a public health threat.

- **Results, outcomes and impact**

Cambodia is the first country in Asia and the Pacific region to introduce CAB-LA and DVR as part of its national HIV prevention strategy. Following the adoption of SOP for CAB-LA and Concept note for DVR by the Minister of Health, CAB-LA was officially launched in June 2025 and DVR in October 2025 for phased implementation, with services currently available

at four PrEP sites in Phnom Penh. These include two national clinics under NCHADS, one public health center (Tuol Kork), and one community-based clinic (Chhouk Sar). As of 7 October 2025, 325 individuals have initiated CAB-LA—66% of whom are MSM—while DVR uptake remains low at 2 users. Community-based organizations have played a key role in demand creation through both physical outreach and virtual platforms. Healthcare providers have been trained to administer both products, and integration into existing PrEP services has facilitated access. Early results show strong interest in CAB-LA, indicating its potential to meet prevention needs among key populations. However, additional efforts are needed to increase awareness and uptake of DVR. These innovations are critical to addressing Cambodia's HIV epidemic, where 88% of new infections occur among key populations and their partners, and 44% among youth.

- **Gaps, lessons learnt and recommendations**

Cambodia's rollout of long-acting PrEP—CAB-LA and DVR—faces challenges in reaching individuals who avoid clinics due to stigma and logistical barriers, and in generating sufficient demand, particularly for DVR. Tailored outreach and community-led services are being considered to address these gaps. Currently, procurement of PrEP products is funded by the Global Fund, with activity support from UNAIDS/DFAT and technical assistance from FHI360, raising concerns about long-term sustainability.

To scale up effectively, Cambodia is strengthening digital data systems to monitor uptake and outcomes, enhancing community engagement to build trust, and integrating CAB-LA and DVR into existing HIV prevention databases. Key priorities include expanding geographic coverage beyond Phnom Penh, diversifying delivery models through community-based organizations, and improving data systems to identify and address service delivery barriers. Ensuring affordability and sustainable supply is critical, as is engaging key populations in program design and demand generation. Integration of PrEP into broader STI and sexual and reproductive health services is also underway.

Cambodia's leadership in introducing long-acting PrEP offers a regional model. Continued investment, innovation, and community partnerships are essential to closing the HIV prevention gap, especially among key populations and youth, who account for the majority of new infections.

- **Annexes**

- 1. Standard Operating Procedures for CAB-LA implementation:  
[https://www.nchads.gov.kh/wp-content/uploads/2025/05/2\\_CAB\\_PrEP\\_SOP\\_final\\_en.pdf](https://www.nchads.gov.kh/wp-content/uploads/2025/05/2_CAB_PrEP_SOP_final_en.pdf)

Concept Notes for DVR Phased Implementation: [https://www.nchads.gov.kh/wp-content/uploads/2025/08/2-EN-DVR-PrEP\\_final.pdf](https://www.nchads.gov.kh/wp-content/uploads/2025/08/2-EN-DVR-PrEP_final.pdf)

## India

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2022-2025

**Submitted by:** Civil society

### 5. **Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy
- ☐ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☒ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☒ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

## 6. Case study demonstrates (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☐ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☒ Community engagement, improved community literacy, and knowledge translation
- ☐ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☐ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

### • Background and objectives

Advancing HIV Care in India: Contributing to the Upcoming Rollout of Long Acting ARVs through Community-Centric Strategies and Policy Innovation:

Background and Objectives:

India is among the countries with the highest burden of the three of the world's most fatal communicable diseases – HIV, Malaria and Tuberculosis. These disproportionately affect the country's poorest and most marginalized populations.

Long-acting antiretroviral (ARV) medicines represent a transformative advancement in HIV treatment, promising improved adherence, reduced pill burden, and enhanced quality of life for people living with HIV (PLHIV). However, access and uptake remain limited in many settings due to barriers such as stigma, healthcare infrastructure challenges, and lack of community engagement.

Alliance India's extensive community-based programs, including the Vihaan Care & Support Centres (supported by the Global Fund), SAHAS transgender welfare centers (supported by Ajim Premji Foundation), and the project Spectrum's integrated HIV services (supported by Elton John AIDS Foundation), Prevention Coalition Project (supported by the Frontline AIDS) provide a strategic foundation to facilitate the introduction and scale-up of long-acting ARVs. The primary objective is to leverage these platforms to improve awareness, acceptance, and accessibility of long-acting injectable ARVs among diverse populations, thereby strengthening the continuum of HIV care and achieving better health outcomes.

### • Description

Alliance India's comprehensive approach significantly enhances access to and effective use of long-acting antiretroviral (ARV) medicines. Central to this effort are the Vihaan program's Care & Support Centres, which function as vital community hubs. These centres identify eligible people living with HIV (PLHIV), facilitate linkage to antiretroviral therapy (ART), and provide adherence support—an essential component for the successful implementation of injectable ARVs. The centres also play a crucial role in educating communities about the benefits of long-acting ARVs, helping to dispel myths, reduce stigma, and promote acceptance of these innovative treatments.

In addition to community outreach, Alliance India leverages the integration of services through projects like Spectrum and SAHAS. These initiatives focus on capacity-building among healthcare providers, ensuring they are well-prepared to administer injectable ARVs and manage potential side effects effectively. This comprehensive training and readiness are vital for maintaining the quality of care and fostering trust among patients.

Alliance India's commitment extends to research efforts that explore stigma, retention in ART, and community perceptions. These insights enable the development of tailored strategies to address barriers and improve uptake. Advocacy forms another cornerstone of their work, ensuring sustainability and scale-up HIV testing, treatment, and care and support facilities.

Furthermore, the organization employs digital tools for tracking adherence and collecting community feedback, facilitating ongoing monitoring and continuous improvement of programs. Alliance India also contributes to the global HIV response through partnerships like Frontline AIDS engaging key population networks across India to strengthen the country's HIV prevention mechanism. Overall, Alliance India's multifaceted approach is instrumental in contributing and roll out of access, acceptance, and optimal use of long-acting ARV medicines, ultimately advancing India's fight against HIV/AIDS.

- **Results, outcomes and impact**

Alliance India has made significant strides in fostering an enabling environment for the access and adoption of long-acting antiretroviral (ARV) treatments. Their community-centric approach emphasizes engaging key populations, to raise awareness, reduce stigma, and promote acceptance of innovative HIV therapies. Till date, Vihaan project has successfully re-engaged over 816,000 PLHIV back into ART treatment and linked 442,000+ to welfare schemes. Vihaan Community Service Centers (CSCs), Spectrum hubs and SAHAS centers have demonstrated the feasibility and community receptivity, serving as models for larger scale implementation. These programs focus on improving adherence support, integrated healthcare services, easing treatment burdens, and addressing societal stigma, which collectively enhance retention in care and viral suppression among people living with HIV (PLHIV).

By integrating community-led interventions, Alliance India aims to contribute and expand the coverage of long-acting ARVs, ultimately improving health outcomes and quality of life for PLHIV. Their work aligns with the national HIV response, contributing to the achievement of broader public health goals. Additionally, these efforts are supported by partnerships with government and civil society to ensure sustainability and scale-up of effective strategies. Through these comprehensive interventions, Alliance India is advancing towards a future where HIV treatment is more accessible, acceptable, and effective for all populations, driving progress toward ending the epidemic.

- **Gaps, lessons learnt and recommendations**

While significant progress has been made in the adoption of long-acting ARVs, several gaps remain. Policy deficiencies, supply chain limitations, and ongoing stigma continue to impede

widespread implementation.

Lessons learned emphasize the critical role of community engagement, capacity-building, and integrating new treatments into existing health systems.

To address these challenges, strengthening advocacy efforts to influence policy reforms and ensuring sustainable procurement mechanisms are essential. Additionally, expanding digital tracking systems can improve supply management and patient adherence. Future strategies should focus on large-scale pilot programs, community-led education initiatives, and ongoing monitoring of treatment acceptability and side effects. Building on the foundation of community platforms, Alliance India recommends fostering partnerships with government agencies, private healthcare providers, and community organizations to promote equitable and stigma-free access to long-acting ARVs. These steps are vital to overcoming barriers and advancing toward universal, patient-centered HIV care. A comprehensive approach that combines policy reform, community involvement, and technological innovations will be crucial for scaling up access and ensuring sustainable, stigma-free treatment for all.

- **Annexes:** <https://allianceindia.org/publications/>

**Multi-Country Office: UNAIDS Asia and Pacific**

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July-October 2025

**Submitted by:** UN or other IO

**5. Area of intervention of case study** (tick all that apply) \*

- ☐ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☐ Community-led demand generation, peer support, accountability, and advocacy
- ☐ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☐ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☒ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☐ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

## 6. Case study demonstrates (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
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- ☐ Community engagement, improved community literacy, and knowledge translation
- ☐ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☐ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

### • Background

UNAIDS/RST commissioned a regional PrEP scoping study to investigate the potential integration of Long-Acting (LA) PrEP, particularly Lenacapavir (LEN), into the national HIV prevention strategies of eight focus Asia-Pacific countries: Cambodia, Indonesia, Fiji, Malaysia, Papua New Guinea (PNG), the Philippines, Thailand, and Vietnam. This initiative is critically important given an emerging HIV prevention crisis in the region, which hosts the world's second-largest HIV epidemic, accounting for 23% of annual new global infections. Rapidly accelerating epidemics in Fiji, Papua New Guinea and the Philippines pose a significant threat to meeting the 2030 goal of ending AIDS.

The primary objective was to conduct a rapid assessment of current PrEP implementation, policies, strategies and practices, identifying key enabling factors for and structural barriers to the successful introduction, implementation and long-term sustainability of PrEP, with a focus on future LEN introduction. Currently, overall oral PrEP implementation coverage is below 10% of the target, underscoring the urgency for improved strategies.

In addition to desk research, more than 60 stakeholder representatives were interviewed. The data obtained inform a regional PrEP landscape analysis and reviews of current PrEP implementation in the 8 focus countries.

### • Description

This study provides a comprehensive regional landscape analysis, outlining the stages of PrEP programme implementation across the region. While oral PrEP uptake is very low regionally, the 8 focus countries have each demonstrated innovative advances in service rollout, creating valuable opportunities for cross-learning. The strategic approach to delivery



emphasizes a multi-faceted set of interventions focusing on client-centered care, user choice, and flexibility. Key delivery models contributing to access include:

- Differentiated Service Delivery (DSD): Tailoring services to key populations' preferences.
- Key Population-Led Health Service (KPLHS) Model: Utilizing trusted community organizations to deliver stigma-free, culturally competent services.
- Decentralization via nurse-led/lay provider models, pharmacy-delivered PrEP, and the use of telehealth/digital platforms.

However, the analysis highlights that successful roll out and implementation of LA PrEP might be deterred by pervasive challenges: affordability, reliance on donor funding, social and political resistance that marginalizes key populations, critical gaps in capacity and infrastructure, e.g., cold-chain supply for LEN, HIV testing and). By providing a clear analysis of these operational, financial, structural, and systems issues, the case study informs policymakers on how to strategically develop PrEP programme planning to facilitate the successful phased introduction and scale up of LEN.

Consultations with over 60 stakeholders revealed considerable optimism for the introduction of LEN due to its potential to significantly impact the HIV epidemic. However, this optimism is hedged with caution. Though oral PrEP experience is valuable, many unknowns remain about injectable PrEP and LEN currently lacks regulatory approval in the region.

LA PrEP scale-up faces significant obstacles, including precarious funding relying on uncertain donor support, and social and political resistance. Critical gaps in implementation capacity (e.g., HIV testing) and the need for community-led demand generation must be systematically addressed in policy and planning.

### • **Results, outcomes and impact**

The key outcome of this study is the development of a structured pathway for the phased introduction and scaling up of all new PrEP products, including LEN. This strategic framework is built on lessons learned from the enabling and hindering factors of oral PrEP programming across the region.

This pathway provides the essential context for policy and programme development by establishing a three-phase model for implementation:

1. Preparation: Focusing on establishing robust policy and programmatic foundations necessary for launch;
2. Evidence-based service delivery: Centered on testing diverse service delivery models tailored to local contexts and client needs; and
3. Scaling up: Aiming for full national integration, long-term sustainability, and independence from external donor funding.

The study's analysis of the eight countries, spanning from oral PrEP introduction to early scaling of multiple options, provides crucial evidence for policymakers and programme implementers. This comparative spectrum of country experiences, particularly in sustainable financing (Thailand, Cambodia) and service delivery innovation (Philippines, Vietnam), serves as a resource for significantly increasing the likelihood of successful, system-wide integration of LA PrEP to meet diverse prevention needs.

### • **Gaps, lessons learnt and recommendations**

Political will and innovation

LA PrEP introduction is supported by robust political will with widespread enthusiasm for LEN across the eight focus countries. Sustainable financing models are taking shape: Thailand and Cambodia demonstrate successful national integration, while Vietnam and Malaysia employ public-private or subsidy schemes. Access is maximized through effective delivery models, including phased implementation, KPLHS, and DSD – notably in the Philippines and Vietnam – supported by community-led demand generation activities.

Critical barriers to LA PrEP scale-Up

Significant barriers remain. Funding is precarious, with high reliance on external donors and

expansion slowed by cuts to technical assistance (e.g., USAID). The LA PrEP injection requirement re-medicalizes care, introducing logistical complexities such as the need for new cold-chain infrastructure. Pervasive stigma, driven by conservative policies and cultures together with the criminalization of key populations significantly hinders access to PrEP services.

#### Recommendations

1. Price and procurement: Achieve an affordable generic cost of \$40 USD to ensure accessibility;
2. Regulatory approval and guidelines: Secure national regulatory approval and develop National PrEP guidelines integrating LEN; and
3. Strategic planning: Build on existing political will to develop a costed national implementation plan with a robust monitoring framework, ensuring resources are strategically allocated to sustain LA PrEP delivery.

## Nepal

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October 2022 to August 2023

**Submitted by:** UN or other IO

### 5. **Area of intervention of case study** (tick all that apply) \*

- ☐ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
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- ☒ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☒ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☐ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

## 6. Case study demonstrates (tick all that apply) \*

- ☐ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
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- ☐ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☒ Community engagement, improved community literacy, and knowledge translation
- ☐ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☐ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

### • Background and objectives

Since 2017, rapid antiretroviral therapy (ART) initiation has been offered to all people living with HIV (PLHIV) in Nepal. Early initiation is linked to better health outcomes, lower mortality, and reduced HIV transmission. However, even with once-daily oral ART available, many PLHIV delay starting treatment due to behavioral, social, or structural challenges.

From October 2022-August 2023, we (EpiC Nepal, FHI 360) collected reasons from individuals and reported by case-mangers, who delayed or refused (once-daily) ART and were not on treatment after HIV diagnosis. A total of 372 individuals were followed over time via visits/phone/text. Data collected included population type, gender, and reasons for not being on treatment. Since it was possible for one person to have multiple reasons over time, total reasons summed to 504. Listed reasons were coded, and qualitative content analysis conducted to identify emerging themes. Eight themes were identified.

The objective was to assess client/provider-reported reasons for not being on ART, and to identify barriers. This is a pre-implementation evidence case study that highlights why long-acting ARVs (LA-ARVs) are needed, for whom, and how they can close existing gaps. Findings support the benefits of LA-ARVs, which could reduce pill burden, improve adherence, and promote rapid ART initiation.

### • Description

This case study contributes to HIV response by identifying behavioral, medical, and structural barriers that delay ART initiation and highlights opportunities where LA-ARVs could have the most impact. Findings show recurring challenges related to treatment

readiness, medical co-morbidities, mobility, stigma, and personal or work priorities. For many clients, the decision to start ART is influenced by barriers such as travel for employment, fear of disclosure, and difficulties managing daily pill routine. LA-ARVs can help address these barriers. Clients newly diagnosed and still adjusting to their status could receive LA-ARVs early, avoiding the challenge of starting daily pills immediately. Similarly, people who are mobile, working long hours, or frequently away from home could maintain treatment coverage even when out of contact. By reducing daily pill burden, LA-ARVs can also lessen stigma and improve privacy. For those with lifestyle factors or medical conditions that make adherence difficult, LA-ARVs could ensure continuous protection and reduce mortality.

This evaluation uses systematic data collection, follow-up, and thematic analysis to provide evidence-based insights into the barriers that prevent ART initiation, identifies specific populations and contexts that would benefit most from LA-ARVs, and offers practical recommendations for integrating such regimens into national HIV programs.

- **Results, outcomes and impact**

A total of 372 newly diagnosed PLHIV who had not yet started ART were followed from diagnosis until they either began treatment, were lost to follow-up, or had died. Case-managers regularly contacted them by visits/phone/text and recorded reasons for delaying ART. Since some gave different reasons at different times, 504 unique responses were analyzed. Eight main themes emerged.

The first was being newly diagnosed and still processing or preparing for treatment; many wanted time to disclose their status, change their treatment site, or had to wait for pending baseline test results. Second was underlying medical conditions, including hospitalization or infections that required delaying ART. The third and fourth were being out of contact, migration for work, relocation, or changed contact details. The fifth was denial/treatment refusal, with some opting for alternative therapies or re-testing elsewhere. Other reasons included death before starting ART, social or work priorities, and substance use, which delayed treatment readiness.

By the end of the study, 292 (78%) had started ART, 55 remained out of contact, and 24 had died. The findings show that behavioral and structural barriers, especially mobility, stigma, and fear of disclosure delay ART initiation. LA-ARVs could help overcome many of these challenges.

- **Gaps, lessons learned, and recommendations**

This study shows that many clients need time, proper counseling, and consistent follow-up after diagnosis to start ART. Acceptance of one's HIV status, personal readiness, lifestyle adjustments, and trust in the service provider all influence ART initiation. Consistent engagement from case managers and peer networks helps clients feel supported, especially during the first few weeks after diagnosis. While some barriers such as denial, medical co-morbidities, or emotional readiness may not be addressed by LA-ARVs, other barriers like stigma, fear of disclosure, frequent travel, migration and unstable living conditions could be reduced. LA-ARVs would make treatment initiation easier and simpler by removing the need for daily pills and reducing the visibility of medication use. Based on the lessons learned, it is recommended that programs focus on client-centered approaches to promote early ART initiation, such as community-based ART delivery, multi-month dispensing, and effective tracking and contact system to maintain contact with PLHIV who move frequently. Offering LA-ARVs to those with challenges, along with continued follow-up and community-based support can help improve early initiation and reduce loss to follow-up and make treatment more sustainable for people with limited stability or high mobility.

- **Annexes: Dataset: Dataset-NotOnART Reason-EpiC Nepal-Prasana.xlsx**

## Latin America and the Caribbean

### Brazil

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2024-2025

**Submitted by:** Other (did not specify)

#### 5. Area of intervention of case study (tick all that apply) \*

- ☐ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
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- ☐ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☐ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

#### 6. Case study demonstrates (tick all that apply) \*

- ☐ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
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- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☒ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV

#### • Background

Composed by 594 parliamentarians, the Brazilian National Congress controls a great part of the federal budget, besides create and sustain public policies. This programmatic and budgetary prerogative is strategic for the response to HIV/AIDS, an area where the parliament has historically been a decisive actor, both in allocating funds and in ensuring the participation of the most affected populations.

The main agent of this influence is the Mixed Parliamentary Front for the STIs/HIV/Aids Response. Since 2000, the Front can be defined as a multi-party association that requires at least 198 members for its creation. It unites parliamentarians, experts, civil society, and health entities to strengthen prevention, surveillance, and comprehensive care related to HIV/AIDS in Brazil. The front has the reach to apply political pressure through public mobilization and advocacy on a specific issues. It promotes debates under the public policy monitoring structure of Congress while also propose new legislation to foster a better response to HIV.

In this regard, in partnership with UNAIDS Brazil and civil society, the Front has been implementing various strategies focused on incorporating new medications into the Unified Health System (SUS). Using its legislative and budgetary influence, the group actively works to strengthen prevention and comprehensive care.

- **Description**

Parliamentary advocacy for access to long-acting injectable HIV medications has centered on two complementary pillars: institutional and communicational. This effort originated from a civil society demand, supported by UNAIDS Brazil, to reduce inequalities by implementing new long-acting medicines. Notably, parliamentarians began discussing public implementation even before price negotiations with pharmaceutical companies.

Institutionally, Representatives Erika Kokay, Ana Pimentel, and Daiana Santos initiated a joint public hearing across the Health, Science/Technology, and Human Rights parliamentary commissions. This strategy aimed to decentralize the HIV response from a purely biomedical view, treating it as a human rights issue. They argued that access to new long-acting medications and PrEP for vulnerable populations remains urgent, despite Brazil's pioneering role in free HIV treatment.

Representative Erika Kokay also requested a meeting with the Minister of Health to discuss the implementation of new HIV medications in the public health system (SUS). Meanwhile, Representative Duda Salabert also held meetings with representatives from Gilead to understand how lenacapavir could be implemented in the country. Her office advocated for the voluntary licensing of the medication.

Duda also submitted a formal request to the President of Brazil asking for the suspension of patents for HIV/AIDS medications and other serious diseases. The proposal was based on the new Law of Economic Reciprocity, which allows for such a measure in the event of 'commercial or financial threats' to national sovereignty.

In the communicational field, Representative Duda Salabert's office utilized traditional and digital media to boost the discourse and knowledge about the medications. In this regard, the representative wrote articles and posts aiming to portray the high prices at which lenacapavir is being commercialized in other countries, and [to argue] that without pressure for fair prices, Brazil runs the risk of seeing a medical revolution transform into a privilege for the few.

- **Results, outcomes and impact**



A public hearing brought together civil society, government representatives, UNAIDS, the national health surveillance agency, and Gilead. Nearly 5,000 people have viewed the session online, which received strong media coverage highlighting how high drug prices imposed by pharmaceutical companies hinder equitable HIV treatment. Participants proposed measures such as patent breaking and public drug production.

Following the event, Representative Erika's office committed to further discussions with the government on generic patents, while Representative Jorge Solla requested a follow-up hearing focused on the high cost of essential public health medicines. Representative Duda Salabert's related media posts also gained wide support.

The parliamentarians demonstrated rare alignment in acknowledging the need to reduce medication prices and to pursue dialogue on incorporating new HIV treatments into Brazil's public health system (SUS). This unified stance strengthened institutional and public communication efforts, complementing the advocacy of civil society, the federal government, and international organizations. In the broader global context, this parliamentary mobilization for equitable access to long-acting injectables as a human right stands out as an innovative and strategic form of political action.

- **Gaps, lessons learnt and recommendations**

Throughout the implementation, the legislative strategy had to undergo some changes in view of the landscape for these medications. In the beginning, the discussion was much more governmental; however, over time, it was understood that it was necessary to also be in dialogue with pharmaceutical companies and involve them in these discussions.

Furthermore, even without a definition on price, fostering debates about Brazil's best practices in the case of patent breaks was essential to understand how it could be done with the new long-acting medications.

Even without all the answers from the pharmaceutical companies, pushing the public debate about incorporation allows for a real understanding of the current HIV response and how we could improve it. Moreover, the entire strategy occurred in parallel with other debates, webinars, meetings, and discussions that took place on the topic.

Here, the role of the legislature is much broader than just creating laws; it involves taking pertinent issues and highlighting them at an institutional as well as a communicational level.

- **Annexes:**

- [https://www.unaids.org/en/resources/presscentre/featurestories/2025/september/20250909\\_brazil](https://www.unaids.org/en/resources/presscentre/featurestories/2025/september/20250909_brazil)
- <https://www.congressoemfoco.com.br/artigo/109081/brasil-nao-pode-ficar-para-tras-na-corrida-pelo-combate-a-aids>
- <https://adiadorim.org/noticias/2025/07/duda-pede-que-lula-suspenda-patentes-de-remedios-para-hiv-apos-tarifaco/>
- [https://www.tiktok.com/@duda\\_salabert/video/7510976925033041208](https://www.tiktok.com/@duda_salabert/video/7510976925033041208)

## Ecuador

De enero 2023 a agosto 2025

**Submitted by:** Government

### 5. **Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☐ Community-led demand generation, peer support, accountability, and advocacy
- ☐ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☐ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☐ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)

**6. Case study demonstrates** (tick all that apply) \*

- ☐ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☐ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☐ Community engagement, improved community literacy, and knowledge translation
- ☐ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☐ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☒ Data collection, monitoring, accountability, including community-led monitoring

- **Background**

The Elimination of Mother-to-Child Transmission (EMT) of HIV and syphilis is a regional strategy promoted by PAHO/WHO to ensure that no mother transmits these infections to her child during pregnancy, childbirth, or breastfeeding. In Ecuador, the initiative is framed within national sexual and reproductive health policies and international commitments aimed at eliminating vertical transmission. The country has progressively strengthened early detection, access to antiretroviral treatment for pregnant women with HIV, and the administration of benzathine penicillin for the timely treatment of syphilis during pregnancy. Technical guidelines have also been developed, health personnel have been trained, prenatal screening has been strengthened, and follow-up of mother-child dyads has been improved.

Despite these advances, challenges remain related to gaps in timely screening coverage, continuity of treatment, equitable access to services in rural areas, and ensuring the supply of necessary resources.

The main objective of the ETMI strategy in Ecuador is to achieve and maintain mother-to-child transmission rates of HIV and syphilis below the thresholds established by PAHO/WHO, guaranteeing comprehensive and continuous care for pregnant women and newborns, with a focus on rights, equity and quality.

- **Description**

The Elimination of Mother-to-Child Transmission (EMT) strategy has been a fundamental component in strengthening Ecuador's national response to AIDS. By prioritizing prevention, early diagnosis, and timely treatment of HIV in pregnant women and their children, the EMT

strategy has consolidated comprehensive actions that extend beyond the maternal and child health sphere and strengthen the health system.

- **Results, outcomes and impact**

Thanks to the implementation of the ETMI-Plus strategy, Ecuador has made significant progress in reducing mother-to-child transmission of HIV and syphilis. For example, the regional target stipulates an HIV transmission rate of 2% or less and a congenital syphilis incidence of 0.5 cases or less per 1,000 live births.

In Ecuador, for the evaluation period, estimated data showed a mother-to-child HIV transmission rate of 3.13%, according to the 2018 regional report, and in recent years it has fallen below 2%, reaching 1.18% in 2024.

At the same time, the country consolidated integrated prenatal screening systems for HIV and syphilis, facilitated access to antiretroviral treatment for pregnant women, and improved epidemiological surveillance processes.

These advances have allowed Ecuador, with the motto: "Towards a generation without HIV or syphilis", the actors of the Comprehensive Public Health Network (RPIS) and the Complementary Network (RC), which make up the National Health System (SNS), to commit to implementing the Initiative for the Elimination of Mother-to-Child Transmission of HIV and Syphilis in Ecuador; which represents a milestone in public health as it reflects less exposure of newborns to these infections, less associated child morbidity and strengthening of the maternal-child system as a whole.

- **Gaps, lessons learnt, and recommendations**

Despite the progress made in eliminating mother-to-child transmission (MTCT) of HIV and syphilis in Ecuador, challenges remain that limit sustainability and full compliance with international standards. Among the main shortcomings are gaps in timely prenatal screening coverage in rural areas and vulnerable populations, and inconsistent treatment continuity due to geographic and social barriers.

Lessons learned demonstrate that multisectoral coordination, ongoing training of health personnel, strengthening information systems, and community participation are essential to sustaining these achievements and moving toward certification.

It is recommended to prioritize investments to ensure the continuous availability of supplies and outreach strategies for hard-to-reach areas, optimize digital surveillance systems with alerts for case follow-up, and expand social communication efforts to reduce stigma and promote early access to prenatal services. Consolidating these actions will ensure sustainable elimination and progress toward certification.

**Annexes:** <https://www.salud.gob.ec/boletines-epidemiologicos-prevencion-atencion-y-seguimiento-en-vih-sida-its-y-hepatitis-virales-b-y-c/>

## Haiti

Soeurette Policar , Coordonatrice du CLM pour le Forum de la Societe Civile  
2021- 2025

**Soumise par :** Société civile

### 5. Domaines d'intervention (cliquez tous ceux qui s'appliquent) \*

- ☐ Leadership national dans l'élimination des obstacles politiques et juridiques à l'accès (par ex. licences et approbations réglementaires)
- ☒ Génération de la demande menée par les communautés, soutien par les pairs, redevabilité et plaidoyer
- ☒ Expériences vécues liées à la réception de médicaments antirétroviraux à action prolongée (par ex. perspectives des patient-e-s)
- ☒ Surmonter les obstacles à la prestation et à la rétention des services pour les populations cibles et/ou dans les zones géographiques mal desservies
- ☐ Mécanismes ou partenariats de financement innovants
- ☐ Recherche, collecte de données, suivi et évaluation, y compris le développement et le suivi des schémas thérapeutiques
- ☒ Intégration dans les systèmes de prévention et de soins du VIH et/ou dans d'autres secteurs du système de santé (par ex. soins prénatals et postnatals, services de santé sexuelle)

## 6. L'étude de cas démontre (cliquez tous ceux qui s'appliquent) \*

- ☐ Partenariats entre parties prenantes et coordination mondiale (par ex. bailleurs de fonds, entreprises pharmaceutiques, gouvernements, communautés, cliniciens)
- ☐ Planification stratégique nationale pour l'accès aux médicaments antirétroviraux à action prolongée (par ex. inclusion des antirétroviraux à action prolongée dans les plans et lignes directrices nationaux de traitement et de prévention, liste des médicaments essentiels, paniers de prestations, plans d'approvisionnement, etc.)
- ☒ Rapport coût-efficacité et/ou accessibilité financière (par ex. plans pour des génériques à bas prix, amélioration des chaînes d'approvisionnement, procédures réglementaires accélérées, production locale, etc.)
- ☒ Financement des médicaments antirétroviraux à action prolongée
- ☒ Acceptation et demande des médicaments antirétroviraux à action prolongée de la part des communautés et des personnes vivant avec ou à risque pour le VIH
- ☐ Engagement communautaire, amélioration de la littératie communautaire et traduction des connaissances
- ☒ Amélioration de l'équité dans l'accès à la prévention et au traitement grâce aux médicaments antirétroviraux à action prolongée
- ☒ Intégration des services pour faciliter l'accès et l'utilisation des médicaments antirétroviraux à action prolongée
- ☒ Collecte de données, suivi, redevabilité, y compris le suivi mené par les communautés

### • Contexte et objectifs

La situation des personnes vivant avec le VIH (PVVIH) en Haïti demeure critique, aggravée par l'insécurité, la pauvreté, les déplacements forcés, la stigmatisation et la pénurie de médicaments. Ces conditions impactent la continuité du traitement et menacent la vie de milliers de patients, tandis que la coupure de certains financements fragilise la riposte nationale au VIH.

Face à cette crise, les organisations communautaires et les membres du Forum de la Société Civile, en collaboration avec le Gouvernement, intensifient leurs efforts pour assurer la continuité des soins et renforcer la génération de la demande, le soutien par les pairs, la collecte de données et le suivi communautaire. Ces actions visent à garantir la redevabilité des acteurs institutionnels et à maintenir la confiance des communautés dans le système de santé.

Dans ce cadre, le Forum de la Société Civile, en partenariat avec le Gouvernement, soumet cette étude de cas au 57e Segment thématique du Conseil de coordination du programme de l'ONUSIDA (CCP). Elle met en lumière les efforts communautaires en matière de plaidoyer, de redevabilité et d'équité dans l'accès à la prévention et au traitement, notamment à travers la demande croissante d'antirétroviraux à action prolongée .

### • Résultats, effets et impact

L'introduction des médicaments antirétroviraux à action prolongée (ARV-AP) représente une avancée majeure pour le maintien d'une charge virale indétectable et la préservation du système immunitaire des personnes vivant avec le VIH (PVVIH).

Les principaux effets et impacts identifiés sont les suivants :

- Suppression virale durable : les médicaments antirétroviraux à action prolongée réduisent efficacement la quantité de VIH dans le sang, permettant à la majorité des patients d'atteindre et de maintenir une charge virale indétectable.
- Renforcement du système immunitaire : la reconstitution des cellules CD4 améliore la fonction immunitaire et réduit les risques d'infections opportunistes.
- Prévention de la transmission : la suppression virale renforce le principe de ce qu'on appelle I=I, Indétectable = Intransmissible, contribuant ainsi à la réduction des nouvelles infections.
- Amélioration de la qualité de vie : la réduction de la fréquence de prise et des visites médicales diminue la stigmatisation, allège les contraintes logistiques et renforce l'adhérence au traitement.
- Impact communautaire positif : une meilleure adhérence au traitement et un accès plus équitable aux soins renforcent la confiance des communautés et soutiennent la durabilité de la riposte nationale puisqu'une population en santé contribue grandement au développement de l'économie du pays.

- **Lacunes, enseignements tirés et recommandations**

Les lacunes et les goulots d'étranglement sont :

Manque d'information et vulgarisation sur l'importance d'avoir au pays des médicaments antirétroviraux à action prolongée.

Manque de financement pour les pays pauvres comme Haïti

Manque de financement pour une campagne d'information et de sensibilisation

Les renseignements que nous pouvons tirer c'est que les médicaments antirétroviraux à action prolongée offrent une option de traitement efficace pour les personnes vivant avec le VIH, avec des résultats positifs sur le contrôle du virus et le renforcement du système immunitaire. En termes de recommandation, il sera très important de mettre en place une bonne stratégie de suivi médical régulier et important afin de bien gérer les effets secondaires potentiels, y compris les risques systémiques à long terme, et pour assurer une bonne qualité de vie.

**Sans annexes.**

## Western Europe

### Italy

Tufo Ciro Representative of Caritas Italiana, Member of the Technical Scientific Committee – Italian Ministry of Health, mail cirotufo@ Yahoo. It

January 2023 – ongoing

**Submitted by:** Civil society

**5. Area of intervention of case study** (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☐ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy
- ☐ Lived experiences of receiving long-acting antiretroviral medicines (e.g. patient perspectives)
- ☐ Overcoming service provision and retention barriers for target populations and/or to geographically underserved locations
- ☐ Innovative funding/financing mechanisms or partnerships
- ☐ Research, data collection, and monitoring and evaluation, including regimen development/monitoring for treatment
- ☒ Integration into HIV prevention and care systems and/or other sections of the healthcare system (e.g. antenatal and post-natal care, sexual health services)



## 6. Case study demonstrates (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☐ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☐ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☐ Financing of long-acting antiretroviral medicines
- ☐ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV
- ☒ Community engagement, improved community literacy, and knowledge translation
- ☒ Improved equity in prevention/treatment access via long-acting antiretroviral medicines
- ☐ Service integration to facilitate access and use of long-acting antiretroviral medicines
- ☐ Data collection, monitoring, accountability, including community-led monitoring

### • Background and objectives

Caritas Italiana, the national branch of Caritas within the Catholic Church, has a long-standing commitment to social inclusion and health promotion. In collaboration with the Italian Ministry of Health and local healthcare services, Caritas supports people living with HIV and populations at higher risk through psychological assistance, awareness activities, and community engagement. The main objective is to strengthen prevention and early testing, reduce stigma and discrimination, and ensure that people affected by HIV can access care and social support in a welcoming, non-judgmental environment. This initiative also aims to build stronger cooperation between civil society and institutional actors in the national AIDS response.

### • Description

Caritas Italiana operates through a network of local centers that provide counseling, referral, and psychological support to people living with HIV and vulnerable populations, including migrants, women, and transgender people. In collaboration with healthcare professionals and public institutions, Caritas promotes educational workshops on treatment adherence and new therapeutic options, including long-acting antiretroviral medicines. The approach combines medical information with psychosocial support, fostering trust and empowerment among beneficiaries. Caritas also contributes to data collection on barriers to treatment access, identifying issues such as social stigma, economic vulnerability, and lack of health literacy. By bridging communities and the healthcare system, the project enhances access to care and improves retention in treatment programs, complementing the public health strategy with a strong community dimension.

### • Results, lessons learned and recommendations

Key challenges include limited funding for community-based services and the need for continuous training for volunteers and professionals in the field of HIV prevention and counseling. Lessons learnt highlight the importance of integrating psychosocial and spiritual dimensions into HIV care, especially to reach individuals who face social isolation or cultural barriers. It is recommended to enhance collaboration between faith-based organizations, NGOs, and public institutions to ensure equitable access to innovative treatments, including long-acting ARVs. Strengthening communication between healthcare providers and communities remains crucial to achieving the UNAIDS 95-95-95 goals.

**Monaco**

Julie MALHERBE - Direction de l'Action Sanitaire - dass@gouv.mc

2 journées par an

**Soumise par:** Gouvernement

**5. Domaines d'intervention** (cliquez tous ceux qui s'appliquent) \*

- ☐ Leadership national dans l'élimination des obstacles politiques et juridiques à l'accès (par ex. licences et approbations réglementaires)
- ☒ Génération de la demande menée par les communautés, soutien par les pairs, redevabilité et plaidoyer

**6. L'étude de cas démontre** (cliquez tous ceux qui s'appliquent) \*

- ☐ Partenariats entre parties prenantes et coordination mondiale (par ex. bailleurs de fonds, entreprises pharmaceutiques, gouvernements, communautés, cliniciens)
- ☐ Planification stratégique nationale pour l'accès aux médicaments antirétroviraux à action prolongée (par ex. inclusion des antirétroviraux à action prolongée dans les plans et lignes directrices nationaux de traitement et de prévention, liste des médicaments essentiels, paniers de prestations, plans d'approvisionnement, etc.)
- ☐ Rapport coût-efficacité et/ou accessibilité financière (par ex. plans pour des génériques à bas prix, amélioration des chaînes d'approvisionnement, procédures réglementaires accélérées, production locale, etc.)
- ☐ Financement des médicaments antirétroviraux à action prolongée
- ☐ Acceptation et demande des médicaments antirétroviraux à action prolongée de la part des communautés et des personnes vivant avec ou à risque pour le VIH
- ☒ Engagement communautaire, amélioration de la littératie communautaire et traduction des connaissances

- **Contexte et objectifs**

L'association Fight Aids Monaco, présidée par S.A.S. la Princesse Stéphanie œuvre depuis 2004 à l'accompagnement des personnes touchées par le VIH et à la prévention et au dépistage de cette maladie. Conformément à une convention de partenariat entre la Direction de l'Action Sanitaire et l'association Fight Aids Monaco, cette dernière est habilitée à réaliser des campagnes de dépistage, dont la plus emblématique est la journée « Test in the city ».

- **Description**

Lors de ces journées réalisées plusieurs fois par an, les bénévoles de l'association, sous supervision médicale, réalisent sur la voie publique (au sein d'installation garantissant l'hygiène et la confidentialité) plus d'une centaine de tests rapides d'orientation diagnostique (TROD) auprès de la population monégasque et des travailleurs pendulaires de la

Principauté. En plus de dépister le VIH (1 et 2), ces TROD dépistent également d'autres infections sexuellement transmissibles, dont les hépatites (VHB et VHC) et la syphilis. En outre, ces tests, qui permettent un résultat quasi immédiat, sont anonymes et entièrement gratuits.

- **Résultats, effets et impact**

Cet évènement, bien connu du public sur un territoire aussi restreint qu'est Monaco, contribue à participer de manière active et concrète à la lutte contre cette maladie. Ce dépistage a pour intérêt de toucher un plus large public, dont certains n'auraient peut-être pas fait le pas de se rendre dans un laboratoire ou dans un centre de dépistage. Les bénévoles réalisant ces tests sont spécialement formés à leur réalisation et un protocole est mis en place en cas de résultat positif, prévoyant l'annonce du résultat par un médecin. Enfin, afin de garantir une totale sécurité, un protocole strict d'élimination des déchets doit être respecté.

**Sans lacunes et sans annexes**

## Multi-Country Case Study: Belgium and Italy

Filippo von Schlösser, Nadir, EATG, [filippo.vonschloesser@gmail.com](mailto:filippo.vonschloesser@gmail.com)

August, September and October 2025

**Submitted by:** Civil society

### 5. Area of intervention of case study (tick all that apply) \*

- ☒ HIV Prevention, testing and treatment programmes for key populations, especially transgender people
- ☒ Country leadership in removing policy, and legal barriers to access (e.g. licensing, and regulatory approvals)
- ☒ Community-led demand generation, peer support, accountability, and advocacy

### 6. Case study demonstrates (tick all that apply) \*

- ☒ Partnerships between stakeholders and global coordination (e.g. funders, pharmaceutical companies, governments, communities, clinicians)
- ☒ National strategic planning for access to long-acting antiretroviral medicines (e.g. inclusion of long-acting antiretrovirals in national-level treatment and prevention plans and guidelines, essential medicines list, benefits packages, procurement plans, etc.)
- ☒ Cost-efficacy and/or affordability (e.g. plans for low-priced generics, improved supply chains, expedited regulatory processes, local manufacturing, etc.)
- ☒ Financing of long-acting antiretroviral medicines
- ☒ Acceptance and demand for long-acting antiretroviral medicines from communities and people living with or at risk of HIV

#### • Background and Objectives

EMA has approved injectable LA for prevention approximately 2 years ago. Recently Germany, Scotland and UK have approved the reimbursability of CAB for PrEP. Spain is going to approve it in these days. The majority of European countries still did not authorize reimbursed LA PrEP. The Italian agency AIFA approved LA only for treatment. The regions did not adapt human resources and structures in Italy to face the request. 12 dedicated HIV NGOs decided to write a letter to the President of AIFA with the request to meet him and discuss the approval of LA PrEP for people intolerant to oral PrEP and its cost effectiveness. Since September 17 we sent the request, nobody has received an answer. We have copied also other health authorities and the Italian Society for Infectious diseases (SIMIT) but nobody has been able to receive a position from AIFA.

#### • Description

The epidemiology data the National Institute of Health (ISS) show for 2024 the same number of newly diagnosed people. The percentage of late presenters is steady at the same levels of over 15 years: 59,7%. Of these, the majority passes 60 YO and go to the emergency due to pneumonia or cancer and learn of their HIV in that event. The letter to AIFA was the first move we did for the approval of LA PrEP. In 2019 to 2023 some of us, me included, helped

Honorable D'Attis, member of the Chamber of Deputies, to write the draft of the new law on HIV and STDs. The project of law, though it was approved by the internal Commissions, has not been voted and it never came to light. Though we did a lot of pressure to have it signed by the Parliament, we know that there are interests not to have it voted. In the law, we wrote down the concept that all measures for prevention and treatment of STDs and HIV have to be implemented. The injectable PrEP is only a new way to have the right of health implemented. We wanted to contribute to the AIDS response, so far unsuccessfully.

- **Results, Outcomes and Impact**

So far no region in Italy has adapted its structure to the requirements neither of LA treatment nor to LA prevention. By consequence, the only evidences are the lack of a LA legislation and the lack of community leadership. The support of pharma companies is almost over or shaved to the lowest levels of the HIV history.

- **Gaps, lessons learned and recommendations**

So far in Italy no region has adapted its structure to the request of the LA and doctors have to slow down the offer due to the increasing need. The gap at this point is the overwhelming ignorance of the Italian politicians about HIV and STDs. The bottleneck is the budgets of the regions that cannot change much as funds have not been budgeted for the Healthcare system. There are 2 ways of debottlenecking: 1) is to give some influential politicians the task of educating other members of the Parliament, 2) is to show politicians a way to capture votes but in their fantasy we (community) are unaccountable because of the stigma (if you have it, you did something you should not do).

- **Annexes:**

<https://docs.google.com/document/d/18693Xj64IxAWgw6JRwnU7acOjW70bbIApiGtCz7ee-E/edit?tab=t.0>

*[End of document]*