



# IMPLEMENTATION PLAN FOR THE INTRODUCTION OF THE PREP RING AND LONG-ACTING INJECTABLE CABOTEGRAVIR FOR HIV PREVENTION

Aug 2024



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## Abbreviations

|          |  |
|----------|--|
| 3TC      | lamivudine   |
| AFAB     | assigned female at birth   |
| AGYW     | adolescent girls and young women                                 |
| ARV      | antiretroviral   |
| ASPIRE   | A Study to Prevent Infection with a Ring for Extended Use study  |
| CAB PrEP | cabotegravir long-acting injectable pre-exposure prophylaxis     |
| DREAM    | Dapivirine Ring Extended Access and Monitoring study             |
| FTC      | emtricitabine  |
| GBV      | gender-based violence  |
| HOPE     | HIV Open-Label Prevention Extension                              |
| HPTN     | HIV Prevention Trials Network                                    |
| HTS      | HIV testing services   |
| IPM      | International Partnership for Microbicides                       |
| LMIS     | logistics management information system                          |
| M&E      | Monitoring and evaluation  |
| MOSAIC   | Maximizing Options to Advance Informed Choice for HIV Prevention |
| MTN      | Microbicide Trials Network                                       |
| PEPFAR   | U.S. President's Emergency Plan for AIDS Relief                  |
| PrEP     | pre-exposure prophylaxis   |
| SOP      | standard operating procedures                                    |
| STI      | sexually transmitted infections                                  |
| TDF      | tenofovir disoproxil fumarate                                    |
| USAID    | U.S. Agency for International Development                        |
| WHO      | World Health Organization  |

## BACKGROUND

### The HIV epidemic in Eswatini.

While Eswatini nears epidemic control and has surpassed the UNAIDS targets for treatment and viral suppression in advance of the 2025 date, new infections remain high. Adolescent girls and young women (AGYW) 15-24 years comprise 38% of the total new infections in Eswatini. The Eswatini Government has remained committed to increasing access to appropriate HIV prevention interventions such as the introduction of new biomedical HIV prevention products to meet different needs of the groups most affected.

### HIV prevention in Eswatini.

Oral PrEP was introduced in 2017 in Eswatini and following successful demonstration studies scaled up in 2019. By the end of 2023, more than 200 public and private facilities as well as key population (KP) and AGYW specific outreaches are offering oral PrEP as part of a comprehensive HIV prevention package. Although the MoH has identified specific population to be prioritized for PrEP based on their vulnerability to acquire HIV and high incidence, PrEP is available for all HIV negative individuals that feel they can benefit from it.

### Global prevention guidance

Randomized controlled trials and subsequent open label extension studies and demonstration projects showed oral PrEP containing tenofovir, the dapivirine ring (PrEP ring) and cabotegravir long-acting injectable for PrEP (CAB PrEP) to be protective against HIV infection across populations. As a result, the World Health (WHO) recommended these products as additional prevention options for people at substantial risk of HIV infection in 2015, 2021, and 2022, respectively. Providing additional choices for PrEP and supporting clients to select their preferred methods offers the potential to increase uptake and effective use of PrEP. In addition, new biomedical HIV prevention technologies are currently in development or undergoing safety and efficacy trials. These prevention methods include various administration modalities, such as injectables, implants, vaginal and rectal gels and inserts, and intrauterine devices—among others. Multipurpose prevention technologies, which provide both HIV prevention and contraceptive benefits, are also being developed.<sup>1</sup>

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<sup>1</sup> AVAC. Research pipeline. PrEPWatch, October 2022 [cited 2023 Oct 26]. Available from: <https://www.prepwatch.org/research-pipeline/>.

### CAB PrEP overview

CAB PrEP is a long-acting PrEP method containing 600 mg of cabotegravir extended-release injectable suspension. It is an intramuscular injection administered into the gluteal muscle. CAB PrEP should be injected only into the gluteal muscle; the pharmacokinetics and efficacy of CAB PrEP when injected in other sites has not been studied. The first two injections are four weeks apart, followed by injections every eight weeks. Cabotegravir belongs to a class of antiretroviral (ARV) drugs called integrase strand transfer inhibitors that reduce the ability of HIV to replicate itself inside a healthy cell. CAB PrEP delivers cabotegravir systemically, so the drug is absorbed throughout the body.

Evidence from two randomized controlled trials shows CAB PrEP is highly effective at preventing sexual HIV acquisition and may be offered as an additional prevention choice as part of combination prevention approaches. It has not yet been studied for HIV prevention for parenteral exposure or for those who may be exposed during vertical transmission during pregnancy, childbirth, or breastfeeding. CAB PrEP may be suitable for clients seeking less frequent dosing or increased privacy around PrEP use.

In clinical trials, CAB PrEP has been shown to be highly effective in cisgender and transgender women and cisgender men. Although data on CAB PrEP use among transgender men and nonbinary people is limited, it is likely that CAB PrEP has a similar safety and effectiveness profile in these populations as well. In recent randomized controlled trials, CAB PrEP was shown to be more effective than oral PrEP, though that is likely due largely to better adherence to CAB PrEP. If a client is using CAB PrEP for HIV prevention, it is important they keep up with regular appointments for injections to make sure that there is enough cabotegravir in their body to continue to prevent HIV. When a client misses a scheduled injection or discontinues CAB PrEP, concentrations of the medication in the body slowly decline. During this pharmacokinetic “tail,” CAB PrEP becomes gradually less protective against HIV acquisition, and seroconversion may occur if the client continues to be exposed to HIV.

### CAB PrEP summary of key evidence

**Efficacy:** CAB PrEP was shown to be statistically superior to daily oral tenofovir/emtricitabine (TDF/FTC) in preventing HIV acquisition when administered every eight weeks among cisgender men, transgender women, and people assigned female at birth (AFAB) who were mostly cisgender women, in two large clinical trials. HPTN 083, a Phase 2B/3 double-blind study among cisgender men and transgender women, found a 66% reduction in risk of HIV acquisition

compared to oral PrEP.<sup>2</sup> In HPTN 084, a Phase 3 double-blind study among people AFAB, participants in the CAB PrEP arm were found to have an 89% reduction in risk of HIV acquisition compared to the oral PrEP arm.<sup>3</sup>

Safety profile: Two Phase 3 clinical trials (HPTN 083, 084) established that CAB PrEP administered every eight weeks for HIV prevention was well-tolerated among cisgender men, transgender women, and people AFAB in eastern and southern Africa.<sup>4</sup> Injection site reactions were usually mild, associated with pain, and typically occurred after the first injection. HPTN 077 evaluated injectable cabotegravir safety, tolerability and pharmacokinetics among HIV-uninfected males and females in sequentially enrolled cohorts of two dosing strategies; preferences for injectable versus other PrEP methods were found to be higher among U.S. males than females, but higher among males and females in non-U.S. settings.<sup>5</sup>

Acceptability: Ongoing research regarding the acceptability of CAB PrEP across Africa includes three studies, HPTN 083, HPTN 084, and HPTN 084-01, a sub-study of HPTN 084 that has enrolled participants younger than 18.

CAB PrEP research to date has included more than 7,920 participants, including cisgender and transgender women and men.<sup>2,3,4,5</sup>

### PrEP ring overview

The PrEP ring is a long-acting HIV prevention method that has been studied for HIV prevention among people AFAB and is recommended by WHO for use by cisgender women. Currently, the ring is recommended for prevention of HIV acquisition only through receptive vaginal sex. It is inserted into the vagina and should remain in place for 28 days. The ring is made of a flexible silicone material containing 25 mg of dapivirine, an ARV drug. Dapivirine belongs to a class of ARVs called non-nucleoside reverse transcriptase inhibitors that reduce the ability of HIV to replicate itself inside a healthy cell. The ring delivers the drug directly to the site of potential

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<sup>2</sup> Landovitz, RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med*, 2021 Aug 12;385(7):595–608.

<sup>3</sup> Delaney-Moretlwe S, Hughes JP, Bock P, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomized clinical trial. *Lancet*. 2022 April 1;399(10337):1779-1789.

<sup>4</sup> Landovitz, RJ, Li S, Grinsztejn B, Dawood H, et al. Safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in low-risk HIV-uninfected individuals: HPTN 077, a phase 2a randomized controlled trial. *PLoS Med*, 2018 Nov 8;15(11):e1002690.

<sup>5</sup> Tolley, EE, Zangeneh SZ, Chau G, et al. Acceptability of long-acting injectable cabotegravir (CAB LA) in HIV-uninfected individuals: HPTN 077. 2020 Sep;24(9):2520–2531.



infection over the course of one month, with low absorption elsewhere in the body, lowering the likelihood of systemic side effects. Each month, clients can insert, remove, and replace the ring themselves or with the assistance of a health care provider if desired.

### PrEP ring summary of key evidence

**Efficacy:** The ring was clinically shown to reduce the likelihood of HIV-1 acquisition through vaginal sex in two randomized controlled trials: by 35% in IPM-027/The Ring Study and 27% in MTN-020/ASPIRE<sup>6,7</sup>. Two subsequent open-label extension studies— DREAM and HOPE—found increased ring adherence compared to adherence in the clinical trials. In DREAM, 95% of returned rings showed some use compared to 83% in The Ring Study, while in HOPE, 90% of returned rings showed use compared to 77% in ASPIRE.<sup>8</sup> Multiple efficacy analyses among participants who used the ring consistently suggest that the PrEP ring can reduce the likelihood of HIV acquisition during receptive vaginal intercourse by 50% or more with consistent use throughout the month.<sup>9,10</sup> A recent secondary analysis suggests a 63% risk reduction per-sex-act when ring is used consistently.<sup>11</sup>

**Safety profile:** The number of pregnancies among participants actively using the ring during the clinical trials was small; however, the data collected to date shows the ring is safe during pregnancy and breastfeeding, with adverse pregnancy outcomes and complications proving uncommon and dapivirine concentrations detected at extremely low levels in infant plasma

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<sup>6</sup> Nel A, van Niekerk N, Kapiga S, et al. Safety and Efficacy of a Dapivirine Vaginal Ring for HIV Prevention in Women. *N Engl J Med*. 2016 Dec 1;375(22):2133-2143. doi: 10.1056/NEJMoa1602046. PMID: 27959766.

<sup>7</sup> Baeten JM, Palanee-Phillips T, Brown ER, et al. Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. *N Engl J Med*. 2016 Dec 1;375(22):2121-2132. doi: 10.1056/NEJMoa1506110. Epub 2016 Feb 22. PMID: 26900902; PMCID: PMC4993693.

<sup>8</sup> Baeten JM, Palanee-Phillips T, Mgodini NM, et al. MTN-025/HOPE Study Team. Safety, uptake, and use of a dapivirine vaginal ring for HIV-1 prevention in African women (HOPE): an open-label, extension study. *Lancet HIV*. 2021 Feb;8(2): e87–e95.

<sup>9</sup> Peebles K, Brown ER, Hendrix CW, et al. Dapivirine ring HIV-1 prevention effectiveness for women engaged in vaginal and anal intercourse: insights from mathematical modeling. *J Acquir Immune Defic Syndr*. 2022 Oct 3. doi: 10.1097/QQAI.0000000000003110.

<sup>10</sup> Brown ER, Hendrix CW, van der Straten A, et al. Greater dapivirine release from the dapivirine vaginal ring is correlated with lower risk of HIV-1 acquisition: a secondary analysis from a randomized, placebo-controlled trial. *J Int AIDS Soc*. 2020 Nov;23(11): e25634.

<sup>11</sup> Stalter RM, Dong TQ, Hendrix CW, Palanee-Phillips T, van der Straten A, Hillier SL, et al. Assessing per-sex-act HIV-1 risk reduction among women using the dapivirine vaginal ring. *J Infect Dis*. 2023 Dec 14;jiad550. doi: 10.1093/infdis/jiad550.

samples.<sup>12,13, 14</sup> In a small study of PrEP ring use among lactating people, ring use was associated with low concentrations of detectable dapivirine in breastmilk and plasma and was shown to have a favorable safety profile.<sup>15</sup> Results from a clinical trial of ring use while breastfeeding demonstrated a favorable safety profile of the PrEP ring in both breastfeeding people and infants.<sup>16</sup> Additional results expected in 2024.

**Acceptability:** Studies exploring the safety and acceptability of the ring among adolescents and young people AFAB ages 15–21 have demonstrated that the ring is acceptable to younger individuals, has a similar favorable safety profile among younger and older individuals, and can be used effectively by younger individuals with proper adherence support.<sup>17,18</sup> Research to date on the ring has included over 8,700 participants in East and Southern Africa – including women of reproductive age, pregnant and breastfeeding women, adolescent girls and young women, male partners, and other key stakeholders. 12·13·14·15·16·17·18·19,20

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<sup>12</sup> Bunge K, Balkus JE, Fairlie L, et al. DELIVER: A safety study of a dapivirine vaginal ring and oral PrEP for the prevention of HIV during pregnancy. *J Acquir Immune Defic Syndr*. 2023 Sep 27. doi: 10.1097/QAI.0000000000003312.

<sup>13</sup> Makanani B, Balkus JE, Jiao Y, et al. Pregnancy and infant outcomes among women using the dapivirine vaginal ring in early pregnancy. *J Acquir Immune Defic Syndr*. 2018 Dec 15;79(5):566–72.

<sup>14</sup> Owor M, Noguchi L, Horne E, et al. Dapivirine ring safety and drug detection in breastfeeding mother-infant pairs. [abstract]. 30<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI). 2023 February 19–22; Virtual. Available from: <https://www.croiconference.org/abstract/dapivirine-ring-safety-and-drug-detection-in-breastfeeding-mother-infant-pairs/>.

<sup>15</sup> Noguchi LM, Hoesley C, Kelly C, et al. Pharmacokinetics of dapivirine transfer into blood plasma, breast milk, and cervicovaginal fluid of lactating women using the dapivirine vaginal ring. *Antimicrob Agents Chemother*. 2019 Feb 26;63(3):e01930–18.

<sup>16</sup> Noguchi L, Owor M, Mirembe B, et al. Phase 3B, randomized, open-label, safety study of dapivirine vaginal ring and oral emtricitabine 200mg/tenofovir disoproxil fumarate 300mg tablet in breastfeeding mother-infant pairs. [poster] 24<sup>th</sup> International AIDS Conference; 2022 Jul 29 – Aug 2; Montreal, Canada. Available from: <https://programme.aids2022.org/Abstract/Abstract/?abstractid=12893>.

<sup>17</sup> Bunge KE, Levy L, Szydlo DW, et al. Phase IIa safety study of a vaginal ring containing dapivirine in adolescent young women. *J Acquir Immune Defic Syndr*. 2020 Feb 1;83(2):135–39.

<sup>18</sup> Nair G, Celum C, Szydlo D, et al. Adherence, safety and choice of the dapivirine vaginal ring and oral emtricitabine-tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis among African adolescent girls and young women: A randomized crossover trial. *Lancet*. Forthcoming 2023.

<sup>19</sup> Baeten JM, Palanee-Phillips T, Brown ER, et al; Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. *N Engl J Med*. 2016 Dec 1;375(22):2121-2132. doi: 10.1056/NEJMoa1506110. Epub 2016 Feb 22. PMID: 26900902; PMCID: PMC4993693.

<sup>20</sup> Nel A, van Niekerk N, Kapiga S, et al; Safety and Efficacy of a Dapivirine Vaginal Ring for HIV Prevention in Women. *N Engl J Med*. 2016 Dec 1;375(22):2133-2143. doi: 10.1056/NEJMoa1602046. PMID: 27959766.

## SITUATION ANALYSIS

A value chain situational analysis (VCSA) for the PrEP ring introduction was done in 2021 and in 2023 for CAB-LA. Inputs to this analysis included a desk review, secondary research, and interviews with a variety of stakeholders in Eswatini. The following strengths and barriers were identified across the value chain (Table 1).

**Table 1. Strengths and barriers across the value chain**

| Category                             | Strengths  | Barriers and Gaps  |
|--------------------------------------|--|--|
| Planning and budgeting               | <ul style="list-style-type: none"> <li>PrEP core team recommends the introduction of the PrEP ring and CAB-LA.</li> </ul>  | <ul style="list-style-type: none"> <li>PrEP ring and CAB-LA have not yet been registered in Eswatini.</li> </ul>   |
| Supply chain management              | <ul style="list-style-type: none"> <li>Procurement of PrEP ring and limited amounts of CAB-LA included in Global Fund application.</li> <li>Quantification for CAB-LA submitted to PEPFAR.</li> <li>PrEP it tool used for national target setting.</li> </ul>                    | <ul style="list-style-type: none"> <li>Recurrent stock outs of HIV testing kits and oral PrEP.</li> <li>Poor quality of national PrEP data reduces accuracy and confidence in PrEP-it tool target estimates.</li> </ul>  |
| Delivery platforms                   | <ul style="list-style-type: none"> <li>New products can be integrated in existing oral PrEP delivery models.</li> <li>Oral PrEP has been integrated in all service delivery points.</li> <li>Availability of implementing partners to support PrEP service provision.</li> </ul> | <ul style="list-style-type: none"> <li>Gaps in offering PrEP in private sector outside of private clinics.</li> <li>Need for strong social and behavior change programs to support demand creation for PrEP.</li> </ul>  |
| Uptake and effective use             | <ul style="list-style-type: none"> <li>Availability of testing and counseling services in majority of public and private facilities.</li> <li>High number of providers trained in PrEP provision.</li> </ul>   | <ul style="list-style-type: none"> <li>National training materials need to be updated with more comprehensive information on new PrEP products and for use in additional populations as new evidence emerges.</li> </ul> |
| Monitoring, evaluation, and learning | <ul style="list-style-type: none"> <li>Majority of PrEP (72%) sites are using electronic client management information system.</li> </ul>  | <ul style="list-style-type: none"> <li>National M&amp;E tools do not include new PrEP methods.</li> <li>Unavailability of reliable national PrEP continuation data.</li> </ul>   |

# IMPLEMENTATION FRAMEWORK

## **Vision:**

Eswatini at increased likelihood of HIV exposure to have choices to prevent HIV infection.

## **Goal:**

Eswatini has set a national goal to end HIV as a public health threat by 2028. The goal of this framework is to provide guidance and strategic direction to achieve these results and accelerate the impact of combination HIV prevention strategy.

## **Implementation objectives:**

- To increase awareness of new PrEP products among HIV negative individuals in need of HIV prevention services, with a focus on key and priority populations.
- To expand access to the PrEP ring and CAB-LA among priority populations at increased likelihood of exposure to HIV in Eswatini by 95% by 2028.
- To increase uptake of the PrEP ring among eligible women with increased likelihood of HIV exposure to 20% of the eligible target population by 2028.
- To increase uptake of CAB-LA among individuals with increased likelihood of HIV exposure to 40% of the eligible female population and 10% of the eligible male population by 2028.
- To expand the number of facilities that can offer more than one PrEP method to 204 by 2028.
- To ensure 204 PrEP facilities have at least 60% of providers trained to offer and support the use of all available PrEP products.

## **Policy Environment**

### **Clinical guideline development**

The PrEP implementation guidelines for healthcare providers have been developed with extensive input from a variety of stakeholders including MoH, PEPFAR, Implementing partners, community partners and representatives of key populations and young people. The guidelines give comprehensive information on the process of identifying individuals who could benefit from PrEP, screening for PrEP eligibility and initiation of PrEP as well as providing ongoing support and conducting follow up visits for oral PrEP, the PrEP ring and CAB-LA. As new evidence emerges and new WHO recommendations might be released, these guidelines will be updated, or addendums will be developed and circulated. Additional clinical details are outlined in the different training packages.

## Human Resources

### Cadres

PrEP initiation and refills for any method can be done by trained medical doctors and registered nurses. Nurses should have completed IMAI training and training in PrEP. There is no requirement to have completed the NARTIS training curriculum. HTS counsellors and other cadres will support PrEP choice counselling as well as other supportive counselling related to PrEP method use. The MoH, with the support of stakeholders, will continue to build the capacity of health care providers in new PrEP products.

### Provider training

An initial trainer of trainers will be conducted by the Ministry of Health for a selected group of providers, technical advisors and nurse mentors from implementing partners. Following the TOT, a mixture of off-site and on-site trainings will be conducted with providers from facilities that will receive the PrEP ring and/or CAB-LA. These trainings will be led by implementing partners and training reports should be submitted to the MoH on a monthly basis. (See template, Annex 2). A summarized training module will be integrated within national trainings, included IMAI and NARTIS trainings.

| Type of training                                    | Content   | Target audience   |
|---|---|---|
| Training of trainers                                | Detailed information on new PrEP products.  | Technical advisors<br>Nurse mentors<br>Selected trainers                    |
| Integrated PrEP training                            | Comprehensive training material that includes choice counselling and information on all available and soon to be available PrEP methods.                | New PrEP providers  |
| IMAI  | HIV prevention module with summarized information on choice counselling providing different PrEP products.  | New nurse graduates   |
| NARTIS  |   | New nurses not previously trained in NARTIS                                 |
| Product specific training                           | Detailed information on the new product   | Nurses and counsellors  |
| Training for community partners and peer navigators | Basic information on product choice and the available PrEP methods.<br>Messages to be provided in the community.<br>Frequently asked questions on PrEP. | Staff from community-based organizations, Peer navigators, outreach workers |

## Mentorship/Supervision

Onsite mentorship and supervision will be done by the MoH and clinical implementing partners, integrating in existing systems. Mentorship will be expected to bridge the gap between initial training and implementation to ensure high quality services are provided offering PrEP choice. Once a PrEP delivery site has been trained in providing a new product, a minimal of two mentoring visits per months should be conducted for the first three months. Challenges and success should be documented, and a summary of challenges will be provided during monthly PrEP core team meetings. Once a facility is comfortable to provide a new product, mentoring reports do not highlight any major challenges, visits will continue as per implementing partners standard of care.

## Service Delivery

### Service delivery model

The PrEP ring and CAB-LA will be introduced in Eswatini in a phased approach. Products will be introduced across different facility and community-based delivery models upon satisfactory site assessments conducted by MoH or implementing partners and pending product availability.

### PrEP ring

|                | Phase description  | Criteria to start phase   | Expected start |
|----------------|--|---|----------------|
| <b>Phase 1</b> | Introduction in eight PrEP service delivery sites as part of a demonstration study supported by FHI 360        | Phase 1 started in May 2023, following approval from the Eswatini Health and Human Research Review Board. | May 2023       |
| <b>Phase 2</b> | Introduction of the PrEP ring in all PEPFAR supported Facilities and outreaches.                               | Training of healthcare providers completed  | September 2024 |
| <b>Phase 3</b> | Scale up of the PrEP ring in all non-PEPFAR supported facilities and outreach models, including private sites. | Training of providers completed. Reporting system to MoH in place.  | February 2025  |

### CAB-LA

|                | Phase description  | Criteria to start phase   | Expected start |
|----------------|--|---|----------------|
| <b>Phase 1</b> | A total of 32 PEPFAR supported sites have been prioritized for CAB-LA Phase 1 (See annex 4). Selection criteria included volume of PrEP clients, geographic location or the priority population they are | <ul style="list-style-type: none"><li>Completed provider training.</li><li>Completion of site-readiness assessment and addressing any potential site barriers.</li><li>Arrival of CAB-LA tranche 1 and subsequent tranches.</li></ul> | June 2024      |

|                |  |  |                  |
|----------------|--|--|------------------|
|                | <p>serving. Initially, only a subset of 6 facilities will start offering CAB-LA. Based on availability of CAB-LA and timeline of subsequent tranches, additional sites among the Phase 1 priority sites will be added.</p> | <p>Availability of HIV testing kits.</p>   |                  |
| <b>Phase 2</b> | <ul style="list-style-type: none"> <li>- Remaining PEPFAR supported sites</li> <li>- Selected DREAMS outreaches with fixed monthly schedules</li> </ul>  | <p>Adequate availability of HIV RDT and CAB-LA.</p>  | <p>June 2025</p> |
| <b>Phase 3</b> | <ul style="list-style-type: none"> <li>- Non PEPFAR supported sites and private facilities.</li> <li>- Remaining outreaches</li> </ul>   | <p>Training of providers is completed.<br/>Reporting system to MoH is in place.<br/>Adequate availability of HIV RDT and CAB-LA.</p> | <p>2025</p>      |

**Site readiness**

A site readiness tool will be used to establish site readiness and identify any barriers for site implementation. The site assessment will look at the minimal needs for infrastructure, HR, laboratory systems and training in order to provide new products. No site can start offering new PrEP products until potential barriers identified with the assessment have been addressed. See annex 3 for a draft Site assessment tool.

**Counseling components**

Counseling will be provided by HTS providers and nurses. The following job aid and IEC material will be available to support choice counselling and enable clients to make a fully informed choice.

| <b>Job aids for providers</b>   | <b>IEC material for clients</b>  |
|---|--|
| <ul style="list-style-type: none"> <li>- Assessing PrEP eligibility (all products)</li> <li>- Product choice counselling</li> <li>- CAB-LA initiation and continuation injections</li> <li>- Management of side effects</li> <li>- Restarting vs resuming CAB</li> <li>- Switching between different methods</li> </ul> | <ul style="list-style-type: none"> <li>- Journey tool (electronic/ paper based)</li> <li>- Product specific factsheets               <ul style="list-style-type: none"> <li>o Oral PrEP</li> <li>o PrEP ring</li> <li>o CAB-LA</li> </ul> </li> <li>- Comparison of different products</li> <li>- PrEP use in pregnancy</li> </ul> |

### Package of services offered with PrEP

PrEP is offered as a comprehensive package of services. This include:

|   |  |
|---|--|
| Minimal package   | <ul style="list-style-type: none"> <li>▪ Counselling and information</li> <li>▪ HIV testing</li> <li>▪ Discussion on potential exposure to HIV</li> <li>▪ PrEP eligibility assessment including assessing the need for PEP and ruling out AHI.</li> <li>▪ Pregnancy testing and provision of contraceptives.</li> </ul>  |
| Additional services (if not available should not be a barrier to PrEP initiation) | <ul style="list-style-type: none"> <li>▪ Hepatitis B and C testing</li> <li>▪ Kidney function test for some clients.</li> <li>▪ Screening and treatment for STIs</li> <li>▪ Provision of gender-based violence services, including intimate partner violence services.</li> <li>▪ Assessment for mental health and substance abuse.</li> <li>▪ Provision of or referral to voluntary male medical circumcision.</li> <li>▪ Screening for and treatment of NCDs.</li> </ul> |

For more information, see PrEP implementation guidelines page 30, section 3.2.

### Integration with other services

PrEP should be provided at any service delivery point as specified in the 2024 national PrEP implementation guidelines. This includes but is not limited to Antenatal and post-natal department, Family planning department and Out-patient department.

### Key and priority populations

While oral PrEP is widely available for any individual eligible for PrEP, and the PrEP ring can be provided to any individual assigned female at birth not able or willing to use oral PrEP, CAB-LA introduction will target the following population groups:

| Population                       | Oral PrEP | PrEP ring | CAB-LA |
|----------------------------------|-----------|-----------|--------|
| AGYW                             | X         | X         | X      |
| Females 25-34 years              | X         | X         | X      |
| Pregnant and breastfeeding women | X         |           |        |
| Female Sex workers               | X         | x         | X      |
| MSM                              | X         |           | X      |
| TG                               | X         |           | X      |
| PWID                             | X         |           | X      |
| Other high-risk males            | x         |           | X*     |



\*For the first subset of CAB-LA phase 1 sites, AGYW, females 25-34 and KPs will be prioritized and high-risk males will not be eligible for CAB-LA

## Supply Chain Management

### Product profile

Oral PrEP is available at the Central Medical Store (CMS) procured through government funding. The PrEP ring will be procured by Global Fund and is expected to be introduced in 2024. CAB-LA will be procured by PEPFAR and Global Fund and is expected to be introduced in 2024. All import licenses will be obtained through CMS under the Ministry of Health. Products will be stored at CMS and distributed to PrEP sites through the national distribution system.

**Table 3. PrEP product profiles.**

| PrEP Product                               | Dosage and Administration (Adults)   | Shelf life | Storage   | Packaging   |
|--|--|------------|---|---|
| <b>Oral PrEP</b>                           | Orally: fixed-dose tablet taken daily; tenofovir (TDF) 300 mg/lamivudine (3TC) 300 mg  | 2–4 years  | 20°–25°C (68°–77°F); excursions permitted 15°–30°C (59°–86°F)               | Bottles of 30 tablets   |
| <b>Dapivirine ring</b>                     | Monthly ring removal/insertion (self-administered but can be supported by a health provider); 25 mg of dapivirine  | 5 years    | 15°–30° (59°–86°F); exposure up to 40°C (120°F) permitted for up to 56 days | Rings are individually packaged in one month or three-month packaging           |
| <b>Long-acting injectable cabotegravir</b> | Gluteal injection: the first two injections are four weeks apart, followed by injections every eight weeks; cabotegravir extended-release injectable suspension (3 mL) at a dose of 600 mg | 2 years    | 2°–25°C (36°–77°F); exposure up to 30°C (86°F) permitted (length unknown)   | Single-use vials with 3ml (600mg) of CAB PrEP are packaged in boxes of 25 vials |

### Commodities associated with PrEP implementation

Additional commodities are needed for CAB-LA and the PrEP ring. One syringe and 2 needles are needed for every CAB-LA injections. For women not on effective family planning and where

pregnancy cannot be excluded through standard screening questions as per National PrEP guidelines, a pregnancy test should be done to exclude pregnancy.

|                 | CAB-LA  | PrEP ring | Oral PrEP |
|-----------------|---|-----------|-----------|
| Syringes (1)    | At every injection visit  | None      | None      |
| Needles (2)     |   |           |           |
| Pregnancy tests | For female clients not on effective family planning at every visit. |           |           |

### Product registration

|           | Registration status  | Included in guidelines   | Included in essential medicine list   |
|-----------|--|--|---|
| Oral PrEP | Registered   | All PrEP products (Oral PrEP, PrEP ring and CAB-LA) are included in the Integrated HIV management guidelines and in the 2024 PrEP implementation guidelines. | Yes   |
| PrEP ring | Conditional approval excluding women <18 years and those known to be pregnant or breastfeeding. Import waiver will be obtained by the MoH. |  | Submissions for including the PrEP ring and CAB-LA in the essential medicine list have been made in January 2024. |
| CAB-LA    | Registered for use in clinical trial. Import waiver will be obtained by MoH.   |  |   |

### Commodity forecasting and procurement processes and systems

#### Oral PrEP

- Forecasting of Oral PrEP is done annually by a national quantification team. Procurement is done by the MoH with funding from MoH and PEPFAR.

#### PrEP ring

- An initial quantification was done as part of the Global fund GC7 application process and has been submitted.
  - o Procurement of 78,555 rings have been approved and the order has been placed in March 2024 with an expected arrival in August 2024.
- In 2025, it is expected that ring forecasting will be included in the annual national forecasting.

#### CAB-LA

- Initial forecasting of CAB-LA has been done by the Global Fund and PEPFAR.

- An initial order of 53,673 vials was approved by PEPFAR and the first tranche of 4,750 vials is expected to arrive in May 2024.
- In 2026, it is expected that CAB-LA forecasting will be included in the annual national forecasting under the MOH.

### Inventory management and distribution processes and systems

- All new products arriving in country will be received by CMS and entered in the national inventory management system.
- Distribution to facilities will be done as per existing national system where facilities order either through a mother facility or directly from CMS. Orders are distributed by CMS directly to the ordering facility.
- New products need to be included in the paper-based ordering form.
  - In the interim, order quantities for the PrEP ring and CAB-LA can be indicated on an empty line on the ARV ordering form (See example Annex xxx)
- All products received at the facility is entered on a stock card which is used to track consumption.

### Monitoring and Evaluation

Routine monitoring and evaluation (M&E) of PrEP program implementation should provide PrEP providers, program implementers, policymakers, and donors with data on the scale of the PrEP program, whether the program is expanding and reaching new clients, the extent to which the program is reaching priority populations, and whether adverse events are occurring. These data should allow stakeholders to:

- 1) assess progress toward targets,
- 2) monitor PrEP method choice,
- 3) assess resources used against program outputs,
- 4) project resource needs,
- 5) estimate the coverage of the PrEP program, and
- 6) estimate the epidemiological impact of the PrEP program.

In order to enable to routinely monitor and evaluate new PrEP products, a submission has been made to CMIS to include the PrEP ring and CAB-LA within the CMIS PrEP module.

### National core indicators for PrEP

The following national indicators will be used to monitor the progress and success with new product introduction.

| Indicator  | Numerator   | Denominator                             | Disaggregation  |
|--|---|---|-----------------|
| No. of trainings conducted   |   |   | Region          |
| No. of healthcare providers trained in new PrEP products                       |   |   | Region<br>Cadre |
| % of PrEP facilities offering choice in more than one PrEP method              | No. PrEP facilities offering PrEP choice in more than one PrEP method | No. of PrEP facilities                  | PrEP methods    |
| % of eligible clients accepting PrEP offer who are newly initiated on PrEP     | No. of clients newly initiated on PrEP                                | No. of clients that accepted PrEP offer |                 |
| % of clients due for 1 month follow-up that received a PrEP refill at 1 month* | No. of clients that came for 1-month visit and received a PrEP refill | No. of clients due for 1-month visit    |                 |
| Volume of PrEP prescribed/dispensed  | Number of units of each PrEP product dispensed                        | Not applicable                          |                 |
| No. of client visits in which a PrEP product was provided                      | Number of client visits during which a PrEP product was provided      |   |                 |
| No. of Tinkhundla with sensitizations conducted on new PrEP methods.           |   |   |                 |

### M&E training

- An M&E specific training package will be developed.
- Training of M&E officers and data collectors will be conducted on PrEP tools, revised HTS and PrEP CMIS modules and new PrEP method indicators.
- An initial TOT will be done for M&E staff of Implementing partners and regional teams.
- Trainers will be responsible to ensure M&E staff and data collectors in each region are trained and provide ongoing support and supervision as needed.

### Pharmacovigilance

For all new PrEP methods, safety monitoring will be done as per Eswatini's 2022 National Pharmacovigilance Guideline. Refresher training on monitoring and reporting of Adverse drug reactions and serious adverse events will be included in all providers trainings for new PrEP products. All ADRs will be reported back to the national pharmacovigilance team and summaries

shared with the PrEP core team. The availability of the national Pharmacovigilance monitoring tool will be a criteria for a successful site readiness assessment prior to introducing the new product.

### Resistance Monitoring

Monitoring of HIV drug resistance (HIVDR) will be done for all PrEP seroconverters regardless of the method used through the MOSAIC supported PrEP HIVDR study until January 2026, after which it will be transitioned to the Ministry of Health as part of routine surveillance. Criteria for the collection of a blood sample for genotyping will differ by PrEP method used:

- Exposure to oral PrEP and/or PrEP ring in the last three months
- Received CAB-LA injection in last 12 months.

Samples for HIVDR testing should be collected at the time of the first HIV positive test. All clients seroconverting will be initiated on the first line recommended ART regimen as per Eswatini 2022 National Guidelines for HIV prevention, care and treatment. Results of HIVDR testing will be returned to the facility as per routine procedures and entered in the national HIVDR data base. Reporting of PrEP seroconverters and HIVDR results will be done quarterly in the PrEP Core Team meeting. HIV positive test results after PrEP exposure will be documented in the HYS CMIS module with an option to indicate if a sample for genotyping has been collected.

### Demand Generation

Demand creation will be done following the guiding principles of the 2022 Eswatini National PrEP Communication, Advocacy and Behavior Change Strategy.

### Budgeting and Financing

| PrEP product/ Commodity  | Funder   |
|--|--|
| PrEP ring  | <ul style="list-style-type: none"> <li>▪ Ring procured through Global Fund GC6 Y3 and GC7 Y1.</li> <li>▪ Subsequent orders to be made by Government</li> </ul>                                 |
| CAB-LA   | <ul style="list-style-type: none"> <li>▪ Phase 1 and 2 CAB-LA to be procured by PEPFAR and Global Fund.</li> <li>▪ For COP 2024, CAB-LA procurement will be included in COP budget.</li> </ul> |
| HIVST for PrEP ring  | <ul style="list-style-type: none"> <li>▪ Procured by Global Fund</li> </ul>  |
| Additional HIV RDTs for CAB-LA users and CAB-LA discontinuers (tail) |  |
| Syringes and needles for CAB-LA                                      | <ul style="list-style-type: none"> <li>▪ Procurement through Government</li> </ul>   |
| Pregnancy tests for CAB-LA and ring users                            |  |

# APPENDICES

## Appendix 1. Implementation Plan Timeline 2024

|  | 2024 |     |     |     |     |     |     |     |      |     |     |     | 2025 |     |     |     |     |     |
|--|------|-----|-----|-----|-----|-----|-----|-----|------|-----|-----|-----|------|-----|-----|-----|-----|-----|
|  | Jan  | Feb | Mar | Apr | May | Jun | Jul | Aug | Sept | Oct | Nov | Dec | Jan  | Feb | Mar | Apr | May | Jun |
| <b>Policy environment</b>                                  |      |     |     |     |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Completion of new product introduction implementation plan | x    | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Completion of revised PrEP implementation guidelines       | x    | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Registration of PrEP ring                                  |      |     | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Registration of CAB-LA                                     |      |     | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| <b>Service delivery</b>                                    |      |     |     |     |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Updating of training packages                              |      | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Revision of data collection tools                          | x    | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Development of Job aids, SOPs and IEC material             |      | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Development of site-readiness assessment                   |      | x   | x   | x   |     |     |     |     |      |     |     |     |      |     |     |     |     |     |
| Conducting site assessments                                |      |     |     |     | x   | x   | x   | x   | x    | x   | x   | x   | x    | x   | x   | x   | x   | x   |
| Ongoing site-mentoring by IPs                              |      |     |     |     | x   | x   | x   | x   | x    | x   | x   | x   | x    | x   | x   | x   | x   | x   |
| Documentation of challenges and best practices             |      |     |     |     | x   | x   | x   | x   | x    | x   | x   | x   | x    | x   | x   | x   | x   | x   |

| <b>Human Resources for Health</b>                                   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Trainer of trainers CAB-LA  |  |   |   |   | x |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trainer of trainers Ring  |  |   |   |   |   |   |   |   | x |   |   |   |   |   |   |   |   |   |
| Training of healthcare providers (nurses, counsellors, pharmacists) |  |   |   |   | x | x | x | x | x | x | x | x | x | x | x | x | x | X |
| Training of community-based organisations and peer-educators.       |  |   |   |   | x | x | x | x | x | x | x | x | x | x | x | x | x | X |
| <b>Supply Chain Management</b>                                      |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inclusion of new product in paper-based facility ordering forms.    |  |   |   |   | x | x | x |   |   |   |   |   |   |   |   |   |   |   |
| Discussion of ring fencing for HTS test kits and CAB                |  |   |   |   | x | x |   |   |   |   |   |   |   |   |   |   |   |   |
| Monthly monitoring of stock levels                                  |  |   |   |   | x | x | x | x | x | x | x | x | x | x | x | x | x | X |
| <b>Monitoring and Evaluation</b>                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Revision of data collection tools                                   |  | x | x | x |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pre-testing of new data collection tools                            |  |   |   |   | x |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Monthly reporting   |  |   |   |   | X | x | x | x | x | x | x | x | x | x | x | x | x | X |
| Phase one evaluation and reflection                                 |  |   |   |   |   |   |   |   |   |   |   | x |   |   |   |   |   |   |
| <b>Pharmacovigilance and Resistance Monitoring</b>                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |



|                                       |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|--|--|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Reviewing reported side-effects/ SAEs |  |  |  |  | x | x | x | x | x | x | x | x | x | x | x | x | x | X |
| Reviewing seroconverters              |  |  |  |  | x | x | x | x | x | x | x | x | x | x | x | x | x | X |
| <b>Demand Creation</b>                |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Developing messages for new products  |  |  |  |  | x | x | x | x | x |   |   |   |   |   |   |   |   |   |
| Training of community partners        |  |  |  |  | x | x | x | x | x |   |   |   |   |   |   |   |   |   |

## Appendix 2. Training report template

|                                      |   |   |
|--------------------------------------|---|---|
| <b>Training dates:</b>               |   |   |
| <b>Training duration (HRS):</b>      |   |   |
| <b>Training name:</b>                |   |   |
| <b>Purpose of the training:</b>      |   |   |
| <b>Training coverage:</b>            | <input type="checkbox"/> National<br><input type="checkbox"/> Regional: _____<br><input type="checkbox"/> Facility: _____ |   |
| <b>Training venue:</b>               |   |   |
| <b>Training format:</b>              |   |   |
| <b>Name of lead trainer:</b>         |   |   |
| <b>List of other facilitators:</b>   |   |   |
| <b>Supporting partner:</b>           |   |   |
| <b>Total nr of people trained:</b>   | _____ Medical doctors<br>_____ Nurses<br>_____ HTS counsellors<br>_____ Lab personnel                                     | _____ Pharmacy personnel<br>_____ Data collectors/ M&E<br>_____ Expert clients/ M2Ms<br>_____ Other |
| <b>Attendance register attached:</b> | <input type="checkbox"/> Yes <input type="checkbox"/> No  |   |
| <b>Agenda/ timetable attached:</b>   | <input type="checkbox"/> Yes <input type="checkbox"/> No  |   |

**Expectations from Participants:**

**Issues raised during the training:**

| <b>Challenges:</b> | <b>Way forward/ recommendations:</b> |
|--------------------|--------------------------------------|
|                    |                                      |
|                    |                                      |
|                    |                                      |
|                    |                                      |
|                    |                                      |

**Parking lot questions not addressed at the end of the training:**

### Appendix 3. Site readiness assessment template for new product introduction

|   |   |
|---|---|
| <b>Date:</b>  |   |
| <b>Facility name:</b>   |   |
| <b>Region:</b>  |   |
| <b>Name, designation, contact of facility representative:</b> |   |
| <b>Name(s) and title (s) of assessment team:</b>              |   |
| <b>New PrEP product(s) to be introduced:</b>                  | <input type="checkbox"/> CAB-LA<br><input type="checkbox"/> PrEP ring |

| Site Operations   |   | Comments |
|---|---|----------|
| Implementing partner support:   | <input type="checkbox"/> ASPIRE/EGPAF<br><input type="checkbox"/> GU<br><input type="checkbox"/> URC<br><input type="checkbox"/> FHI 360<br><input type="checkbox"/> Other: _____ |          |
| Does the site have a copy available of the 2024 PrEP implementation guidelines: | <input type="checkbox"/> Yes, electronic copy<br><input type="checkbox"/> Yes, hard copy<br><input type="checkbox"/> No   |          |
| Does the site use CMIS? If not, indicate reporting channels to MoH.             | <input type="checkbox"/> Yes<br><input type="checkbox"/> No   |          |

| Commodity Management   |   |  |
|--|---|--|
| How is the site ordering/ receiving HIV testing and PrEP commodities | <input type="checkbox"/> Direct ordering from CMS<br><input type="checkbox"/> Receiving through mother facility.<br><input type="checkbox"/> Other: |  |
| Does the site have sufficient storage space for new products (ring): | <input type="checkbox"/> Yes<br><input type="checkbox"/> No   |  |
| Is the storage space dry, cool and clean?                            | <input type="checkbox"/> Yes<br><input type="checkbox"/> No   |  |

|   |  |  |
|---|--|--|
| Is there a storage place for new products with temperatures between 2° to 30°C?       | <input type="checkbox"/> Yes, describe.<br><input type="checkbox"/> No |  |
| Is there a temperature monitoring device available in the main storage area?          | <input type="checkbox"/> Yes, describe.<br><input type="checkbox"/> No |  |
| Are there stock cards available to monitor product dispensing?                        | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |  |
| How will the facility ensure that they have enough RDTs to test for CAB-LA? Describe. |  |  |

| Human Resources  |              |                 |                    |                     |
|--|--------------|-----------------|--------------------|---------------------|
| Indicate the nr of staff on site and how many have been trained in providing CAB-LA and the PrEP ring. | <b>Staff</b> | <b>Total nr</b> | <b>CAB trained</b> | <b>Ring trained</b> |
|  | Doctor       |                 |                    |                     |
|  | Nurse        |                 |                    |                     |
|  | HTS/ Phleb   |                 |                    |                     |
|  | EC/ M2M      |                 |                    |                     |
|  | Other        |                 |                    |                     |

| Tools and job aids   |  |        |
|--|--|--------|
| Which of the following job aids and counselling tools are available? (tick all that apply) | <input type="checkbox"/> PrEP method comparison/ choice counselling<br><input type="checkbox"/> PrEP visit check list<br><input type="checkbox"/> Missed CAB-LA visit<br><input type="checkbox"/> Rule out pregnancy checklist<br><input type="checkbox"/> Screening for PEP and ruling out AHI<br><input type="checkbox"/> PrEP journey tool<br><input type="checkbox"/> Other: _____ |        |
| Is there an anatomical model for ring insertion demonstration?                             | <input type="checkbox"/> Yes<br><input type="checkbox"/> No  | Notes: |
| Is there a demo ring available?  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No  | Notes: |

| Infrastructure   |   |        |
|--|---|--------|
| Is there a private room for HIV testing and counselling? | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | Notes: |

|  |   |        |
|--|---|--------|
| Is there a private room with a handwashing station for demonstration of PrEP ring insertion and for clients to practice ring insertion?  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | Notes: |
| Does the site have a system in place to follow up PrEP clients that miss their appointment? Describe e.g. appt reminders/register, CMIS, cellphone? Who is responsible for this? | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | Notes: |
| Is there a facility SOP available for PrEP?  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | Notes: |
| Is the facility providing FP commodities?  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | Notes: |

|  |   |                          |
|--|---|--------------------------|
| <b>Demand creation</b>                                   |   |                          |
| Does the site have IEC material available for PrEP ring? | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | List available material: |
| Does the site have IEC material available for CAB-LA?    | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | List available material: |

|  |   |
|--|---|
| <b>Overall comments</b>  |   |
| <b>Site ready to introduce:</b>  |   |
| <b>CAB-LA:</b><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No    | <b>If site is not ready for new product introduction, document barriers and action points to resolve barriers.</b><br><b>Barriers:</b><br><hr/> <hr/> <hr/><br><b>Action points to resolve barriers:</b><br><hr/> <hr/> <hr/> |
| <b>PrEP ring:</b><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No |   |

## Appendix 4. Priority PEPFAR-Supported sites for CAB-LA introduction Phase 1

The following facilities have been selected to be prioritized for the introduction of CAB-LA. Criteria for the selection included: PrEP volumes, geographic location and access to specific priority populations.

|  |  |
|--|--|
| <p><b>HHOHHO REGION</b></p> <ul style="list-style-type: none"> <li>▪ <b>Mbabane KP DIC</b></li> <li>▪ <b>Ezulwini Satellite Clinic</b></li> <li>▪ Mangweni Clinic</li> <li>▪ Horo Clinic</li> <li>▪ Bulandzeni Clinic</li> <li>▪ Dvokolwako Health Centre</li> <li>▪ Motshane Clinic</li> <li>▪ Msunduzu Salvation Army</li> </ul> | <p><b>MANZINI REGION</b></p> <ul style="list-style-type: none"> <li>▪ <b>Manzini KP DIC</b></li> <li>▪ <b>Mathangeni Clinic</b></li> <li>▪ AHF Matsapha</li> <li>▪ Phocweni USDF Clinic</li> <li>▪ TLC Miracle Campus</li> <li>▪ Luyengo Clinic</li> <li>▪ Mliba Nazarene</li> <li>▪ Mafutseni Clinic</li> <li>▪ Mbikwakhe Clinic</li> <li>▪ Mankanyane Hospital</li> <li>▪ Cana Clinic</li> </ul> |
| <p><b>LUBOMBO REGION</b></p> <ul style="list-style-type: none"> <li>▪ <b>Bholi Clinic</b></li> <li>▪ Siteki Nazarene Clinic</li> <li>▪ Lomahasha Clinic</li> <li>▪ Vuvulane Clinic</li> <li>▪ Mpolomjeni Clinic</li> <li>▪ Siphofaneni Clinic</li> <li>▪ Saint Phillips</li> </ul>   | <p><b>SHISELWENI REGION</b></p> <ul style="list-style-type: none"> <li>▪ <b>FTM 2 Clinic</b></li> <li>▪ Silele Red Cross Clinic</li> <li>▪ Nkwene Clinic</li> <li>▪ Gege Clinic</li> <li>▪ Nhlangano HC</li> <li>▪ New Haven Clinic</li> <li>▪ Lavumisa Clinic</li> </ul>  |

\*Facilities in bold are among the first priority sites for CAB-LA introduction within Phase 1.