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## The PrEP Ring Quarterly—Edition 1, October 2024

IPM South Africa

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Welcome to the first edition of The PrEP Ring Quarterly newsletter, which will bring you information, updates, and resources dedicated to the dapivirine vaginal ring (DVR) also known as PrEP ring.

## RECENT PrEP HIGHLIGHTS

### 3-MONTH PrEP RING RESULTS

- Recent results from a phase 1 bioavailability crossover trial (IPM 054) found that a 3-month PrEP ring is pharmacokinetically superior to the 1-month PrEP ring. ([link to press release](#))
- The results of the study, conducted among 124 women, suggest the efficacy of a longer-acting 3-month PrEP ring will be at least equal to that of the 1-month PrEP ring and support the use of the 3-month PrEP ring as an alternative to the 1-month PrEP ring.
- The Population Council plans to submit this data to the European Medicines Agency (EMA) for approval of the 3-month PrEP ring as a line extension of the 1-month PrEP ring in early 2025.

### ESWATINI PUBLIC HEALTH ROLL-OUT OF THE PrEP RING

- IPPF's Member Association in Eswatini, the Family Life Association of Eswatini (FLAS), is soon to roll-out the PrEP ring. FLAS will be among the first organisations globally to offer the PrEP ring outside implementation or pilot studies. ([link to press release](#))
- Preparing for public health roll-out: The Ministry of Health (MOH) plans to introduce the PrEP ring in all PEPFAR (~140) supported facilities and scale up the PrEP ring in all non-PEPFAR supported facilities and outreach models (including private sites). This roll-out is supported by Eswatini's Global Fund grant.

### BREASTFEEDING AND THE PrEP RING

- The PrEP ring has been shown to be safe for use during breastfeeding in the B-Protected/MTN-043, a phase 3B open-label study. Based on data from this trial, the European Medicines Agency (EMA) approved the addition of breastfeeding women as a special population in the positive opinion. ([link to article](#))

### GLOBAL FUND/CIFF FUNDING ANNOUNCEMENT

- The Children's Investment Fund Foundation (CIFF), in partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund), announced at the 25th International AIDS Conference an initiative of up to US\$2 million over the 2024-2025 period for the purchase of approximately 150,000 PrEP rings in countries that implement Global Fund grants to fight HIV and AIDS. ([link to press release](#))
- Requests are accepted at [emav@ciff.org](mailto:emav@ciff.org) on a rolling basis after launch in October 2024.

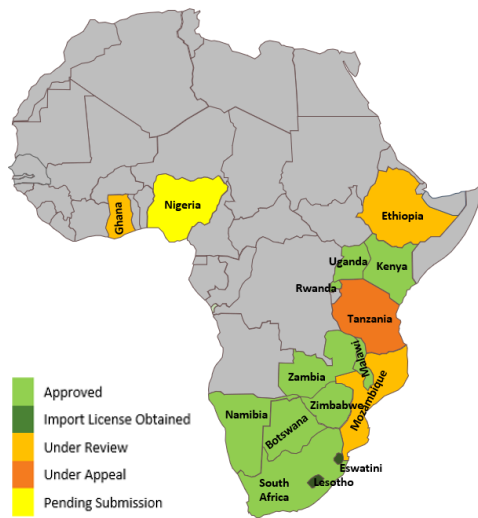
### DISSEMINATION OF FINDINGS FROM ACCEPTABILITY AND FEASIBILITY STUDY FOR THE PrEP RING IN THE THREE CITIES OF INDONESIA (BALI, MAKASSAR, AND TEGAL)

- A qualitative study was conducted to assess acceptability of the PrEP ring among Indonesian cisgender women.
- Initial exposure to the PrEP ring showed strong interest from healthcare providers and female sex workers, despite low product awareness.
- The PrEP ring is likely to be acceptable as an additional preventive measure for women who consider themselves to be at substantial risk of contracting HIV.
- Regarding service delivery, there is a preference towards delivery through non-governmental organisations (NGOs) or community-based organisations (CBOs).
- [Report link.](#)



# REGULATORY UPDATES

Currently, the PrEP Ring is approved in 11 countries. To expand further access in Africa, additional submissions to regulatory authorities in Mozambique, Ghana and Ethiopia are under review.



Country	Submission Date	Status
South Africa	26 Mar 2021	Product Registration 08 Mar 2022
Zimbabwe	03 Feb 2021	Product Registration 06 Jul 2021
Rwanda	11 Feb 2021	Approved by RFDA 10 Feb 2023
Uganda	17 Feb 2021	Product Registration 05 Oct 2021
Malawi	22 Feb 2021	Product Registration 10 May 2021
Tanzania	11 Mar 2021	On 12 Apr 2022 TMDA rejected the registration of DapiRing. An appeal was submitted.
Zambia	05 Mar 2021	Product Registration 10 May 2021
Kenya	23 Mar 2021	Product Registration 16 Jul 2021
Namibia	01 Sep 2021	Product Registration 27 Jul 2023
Botswana	08 Sep 2021	Product Registration 21 Dec 2022
Mozambique	28 Jun 2024	Under Review
Ghana	08 Aug 2024	Under Review
Ethiopia	06 Sep 2024	Under Review
Nigeria	On hold	Requirement for clinical data in West African populations in discussion with Nigerian FDA
Eswatini and Lesotho	Import licenses have been issued	

# SPECIAL POPULATIONS STUDY UPDATES

Additional safety and acceptability studies have been conducted in adolescent girls and young women (REACH) and pregnant (DELIVER). These studies showed high ring acceptability and a favourable safety profile. This data will support future regulatory applications for approval of ring use in women under 18 and in pregnant people.

## **DELIVER STUDY/MTN-042: PREGNANT WOMEN**

- Interim findings suggest no safety concerns were found in all cohorts (3-9 months pregnant)
- Follow up for cohort 3 concluded in mid 2023, and babies followed up for an additional year after birth
- Final results anticipated late 2024 or early 2025



## **REACH STUDY/MTN-034: ADOLESCENT GIRLS AND YOUNG WOMEN**

- Choice: twice as many adolescents chose the PrEP ring over oral PrEP (67% vs 31%)
- Safety: no safety concerns noted
- Acceptability: higher for the PrEP ring than oral PrEP (88.5% vs 64%)
- Adherence: high adherence - drug release  $\geq 4.0\text{mg}$  consistent with continuous 28 days of PrEP ring use per month



# LOCAL MANUFACTURING AND LICENSING

The Population Council has signed a memorandum of understanding with Kiara Health, a 100% Black-owned African-based company, for commercial distribution and manufacturing of the 3-month PrEP ring to help shift leadership of PrEP rings to sub-Saharan Africa.

Moving into the future with a long-term goal of commercial sustainability and local leadership, The Population Council is working toward granting an exclusive license for the PrEP ring in the current territories to Kiara Health.

Kiara Health plans to set up local manufacturing capabilities over the next several years with the goal of substantially lowering the cost of the product. PrEP rings are currently available for procurement through Population Council's current distribution partnership with Imres BV.



# IMPLEMENTATION STUDIES

PrEP Ring access continues to expand through a number of implementation studies currently underway in Africa. There are currently 21 planned or ongoing implementation studies supported by a number of donors including the USAID, UNITAID, Global Fund and CIFF.

## PROJECTS INCLUDING THE PrEP RING COUNTRIES IMPLEMENTED

CATALYST

Kenya, Lesotho, South Africa, Uganda and Zimbabwe

Project PrEP

South Africa

DREAMS PrEP Choice

South Africa

Let's Talk and LAPIS

South Africa

FastPrEP and PrEPared

South Africa

DO PrEP

South Africa

My Journey

South Africa

National SWP

South Africa

Imagine

South Africa

MSF PrEP Ring Study

Eswatini

MOSAIC/GOKE PrEP Ring Study

Eswatini

CeSHHAR PrEP Study

Zimbabwe

Going the Last Mile

Zimbabwe



# COMMUNITY ENGAGEMENT, ADVOCACY AND PARTNERSHIPS

**IPM South Africa NPC presented at the Third Health Research and Policy Conference** in Rwanda in May 2024 on a panel discussion with the Ministry of Health, World Health Organization (WHO), and civil society organizations on plans for access and implementation of the PrEP ring in Rwanda.



In collaboration with Rinda Ubuzima, IPM South

Africa NPC met with the WHO Local Mission to discuss initiating implementation projects in Rwanda.



**Zambia Ministry of Health and TALC hosted IPM South Africa NPC**, in June 2024 to discuss the integration of the PrEP ring into Zambia's HIV Prevention Choice Implementation Plans.

# THE 3-MONTH PrEP RING

The Population Council has developed a 3-month PrEP ring as a line-extension of the 1-month PrEP ring, with plans to submit for European Medicines Agency (EMA) review in Q1 2025. The 3-month PrEP ring is the same size and shape as the monthly PrEP ring and has several key advantages over the 1-month PrEP ring:



## COST

The 1-month PrEP ring currently costs US\$12.80 per month of use. The 3-month PrEP ring will cost less than US\$16, excluding distribution, representing a nearly 60% cost reduction. The Population Council is engaged in scaling and optimizing the 3-month PrEP ring manufacturing process to further reduce the cost of goods and production costs.



## CONVENIENCE

By increasing convenience to women and reducing replacement frequency, the 3-month PrEP ring may increase acceptability and adherence and may lead to fewer gaps in between PrEP ring usage.



## WASTE

The 3-month PrEP ring will reduce waste, as only 4 PrEP rings and packaging will be needed for a full year of protection (versus 12 needed for the 1-month PrEP ring).



## CHOICE

The 3-month PrEP ring will expand options and choice for women to protect their health and accelerate global efforts to end the HIV epidemic.

## OTHER PIPELINE PRODUCTS



### **CONTRACEPTIVE DAPIVIRINE VAGINAL RING (OR DAPIVIRINE-LEVONORGESTREL RING/DPV-LNG RING)**

A dual purpose vaginal ring with dapivirine and levonorgestrel for HIV and contraceptive protection. This DPV/LNG ring is an ethylene vinyl acetate core-sheath vaginal ring that can be used for 3-months.

**Status of the DPV/LNG ring:** Two Phase 1 trials demonstrated no safety concerns and above-target plasma levels with the dapivirine-levonorgestrel combination. Together with the NICHD, a Phase 1b trial will be completed in October 2024. The DPV/LNG ring is a natural extension of the PrEP ring with a relatively short pathway to regulatory approval. We can't speak to a submission target yet, as it is too early in development to tell.

## WHERE TO FIND RESOURCES

- **Global PrEP Ring Training Manual** ([link](#))
- **Video on How to Insert and Remove the PrEP Ring** ([link](#))
- **Demonstration Vaginal Ring Kits** ([hcpsupport@popcouncil.org](mailto:hcpsupport@popcouncil.org))

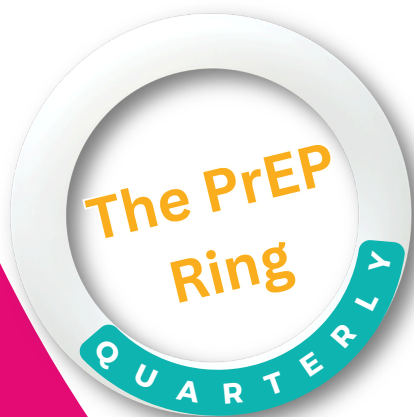


# CONFERENCE PROCEEDINGS

## HIV R4P 2024

### Orals and Posters:

- Pharmacokinetic superiority of a 3-month dapivirine vaginal ring (100 mg) compared to the 1-month dapivirine vaginal ring (25 mg)
- End user market segmentation, messaging and positioning for the dapivirine vaginal ring: A Lesotho case study
- Acceptability of the 3-month dapivirine ring versus the 1-month dapivirine vaginal ring: Qualitative findings from a crossover bioavailability trial among 18- to 45-year-old women in Bloemfontein, South Africa
- Characterizing behavioral exposure and predictors in PrEP users
- Early user experiences with the dapivirine ring (“PrEP ring”) among women in Eswatini
- Provider perceptions of offering PrEP choice: A quantitative assessment of early experiences in Eswatini
- Feasibility of assessing prevention effective use (PEU) utilizing a phone-based self-reporting system: Early CATALYST study findings
- Novel considerations for inventory management of long-acting PrEP in a supply-constrained environment
- Optimizing the delivery of PrEP choice through a multi-country quality improvement collaborative approach
- Patterns of PrEP use among women in the context of choice: Early results from CATALYST, an implementation study offering oral PrEP and the PrEP ring across five African countries
- PrEP choice for women in Africa: Uptake of oral PrEP and the PrEP ring
- PrEP choice implementation in Africa: Early experiences of health facilities delivering informed choice of daily oral PrEP and the PrEP ring through the CATALYST study
- PrEP method choice in the context of gender-based violence: Early observations from the CATALYST study in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe
- Client perceptions of PrEP choices and service delivery in health facilities in Africa: Interim results from the CATALYST study
- Provider and client perspectives on PrEP choice: Quality of PrEP choice and factors influencing its provision in the CATALYST implementation study
- Provider attitudes, perceptions, and the acceptability of offering PrEP choice in CATALYST study implementation sites in sub-Saharan Africa



*'We need to prioritize HIV prevention as much as we prioritize treatment from a political perspective. There is no magic wand that is going to help and we need to change the mentality that there is a one-size-fits-all all solution for women. We need to have options that meet the needs of all women so they can make decisions to prevent themselves from getting HIV.'*

*- Yvette Raphael*

If you have any questions, please contact [prepringinfo@popcouncil.org](mailto:prepringinfo@popcouncil.org).