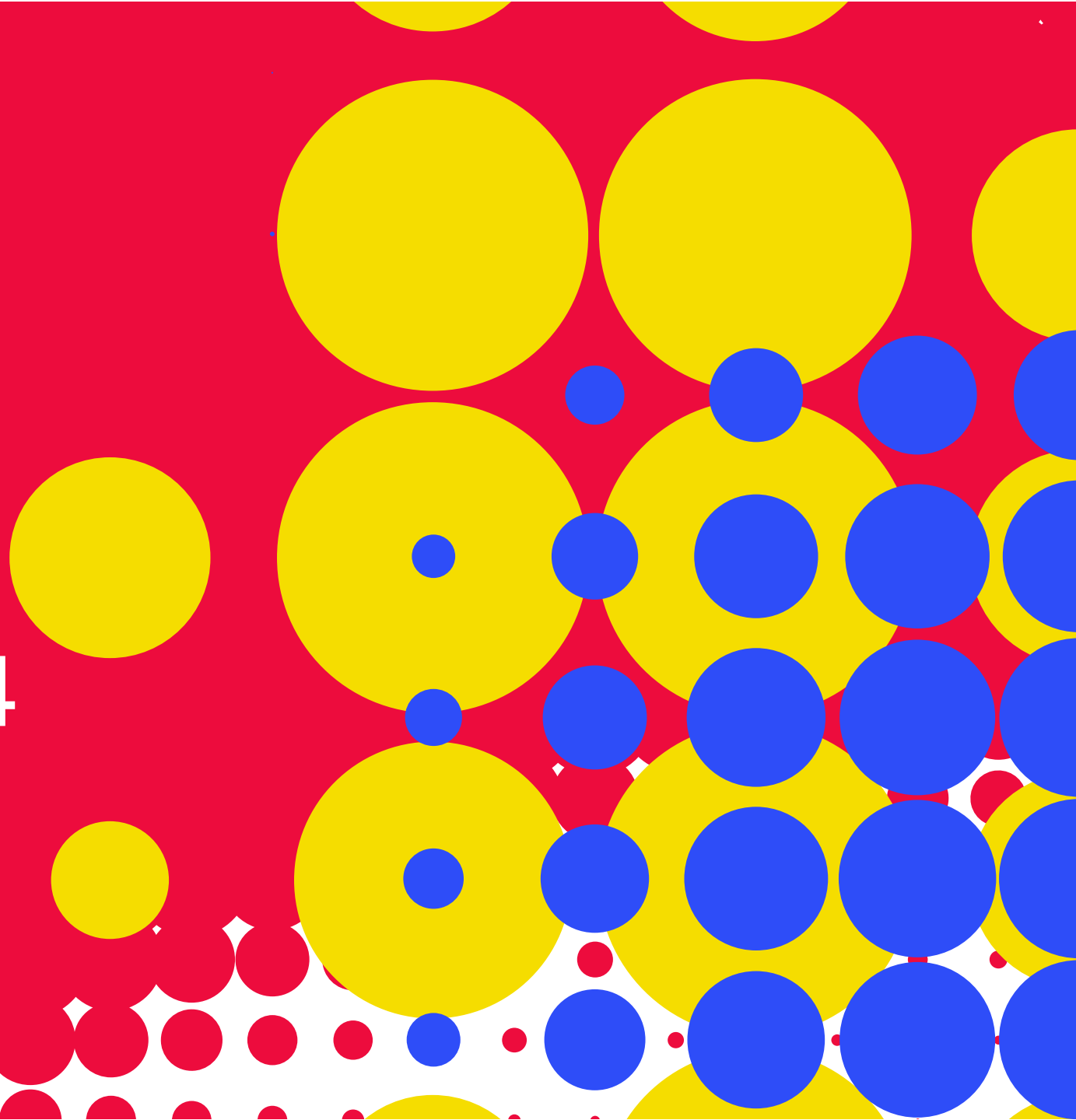




PrEP Ring Early Market Access Vehicle

30 September 2024



VOLUNTARY MEDICAL MALE
CIRCUMCISION (VMMC)



PRE-EXPOSURE PROPHYLAXIS (PREP)



OPIOID SUBSTITUTION THERAPY

PRE-EXPOSURE PROPHYLAXIS +
ORAL CONTRACEPTIVE (DUAL PREVENTION PILL)



HIV SELF-TEST (HIVST)



STERILE INJECTION
EQUIPMENT



CONDOMS AND
LUBRICANTS



HIV PREVENTION
TOOLKIT



POST-EXPOSURE
PROPHYLAXIS (PEP)

Considerations for People Needing HIV Prevention

PERCEIVED BENEFITS

PERCEIVED LIMITATIONS

	Condoms	Oral PrEP (TDF/FTC or TDF/3TC)	Dapivirine vaginal ring (PrEP ring)	Cabotegravir long-acting injectable (CAB-LA)
PERCEIVED BENEFITS	<ul style="list-style-type: none"> • Triple prevention - HIV, other STIs, unintended pregnancy • User controlled (insertive partner) • Familiar • Easy to use (esp. with lubricants) • Available beyond clinics in pharmacies/shops/kiosks • Strong efficacy if used consistently • Effective for both vaginal and anal sex; inexpensive • No side effects. 	<ul style="list-style-type: none"> • Familiar for most potential users • Ease of use • User-controlled • Easy to cycle on and off • Available now • Can be used to prevent HIV during all modes of exposure • Strong efficacy with effective use • Opportunities to align visits with quarterly visits for family planning 	<ul style="list-style-type: none"> • Familiar for some potential users • User-controlled • User action required only once per month • Easy to cycle on and off • Can be discreet for some users • Can be used to prevent HIV during receptive vaginal sex • Opportunities to align visits with quarterly visits for family planning 	<ul style="list-style-type: none"> • Familiar for some potential users • Injection once every two months • Can be discreet for some users • Familiar modality for many who use injectable contraception or have received other injections • Can be used to prevent HIV during vaginal or anal sex • Strong efficacy with effective use
PERCEIVED LIMITATIONS	<ul style="list-style-type: none"> • Effects on sexual pleasure/performance • Limited control/agency for receptive partners • Requires negotiation/use each time • Requires lubricants for maximum effectiveness/pleasure • Can be used as evidence of illegal and/or stigmatized behaviors- sex with more than one partner, sex work, sex between men or trans and gender diverse people 	<ul style="list-style-type: none"> • Pill burden • Pill size • Requires daily use for many potential users • Stigma; pill bottles and regular use are not discreet enough for all users • Side effect profile • Pre- and post-sex dosing needed for highest effectiveness • Quarterly healthcare visits are standard 	<ul style="list-style-type: none"> • Low familiarity or discomfort with vaginally inserted products • Side effect profile • Must be used before, during, and after sex for highest effectiveness • Cannot be used to prevent HIV during anal sex or injection related exposures • Concerns with efficacy • Quarterly healthcare visits or dispensation is likely to be standard 	<ul style="list-style-type: none"> • Delays in HIV detection with available tests • Long PK “tail”; potential for resistance • Not reversible • Gluteal injection requires privacy • Side effect profile • Not known to prevent HIV during injection related exposures • Healthcare visits every two months in a clinic are likely to be standard • Few opportunities to align visits with quarterly visits for family planning

Note: Not exhaustive of all HIV prevention options

Adapted from MOSAIC, 2022, Overview of PrEP Product Pipeline

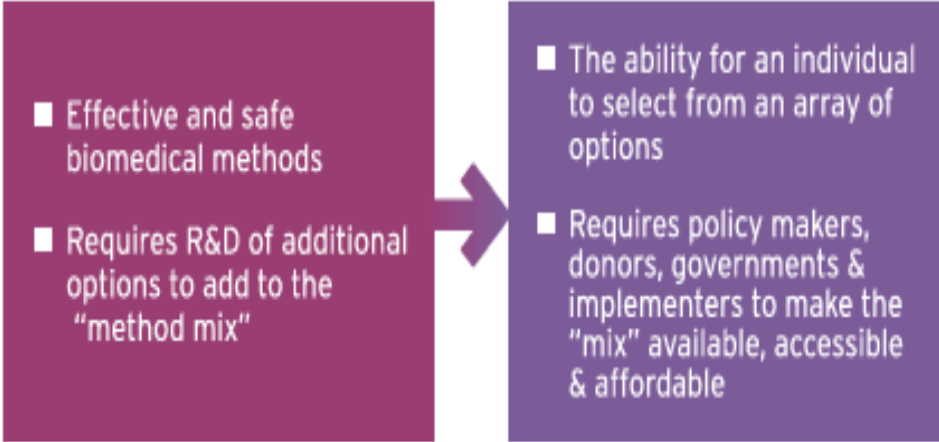
Choice Manifesto for Women and Girls in Africa

Call to Action:

Choice Is Key

1. Ensure available HIV prevention options are in the hands of women and girls.
2. Ensure massive scale-up and increased access to all safe and effective HIV prevention methods. A choice-centered approach for programming and procurement of new biomedical strategies must be adopted. No strategy should be presented as “preferred” or “better”.
3. Ensure women and girls have control over their health and their bodies and access to the full range of safe and effective options so that they can choose what works best for them at different times of their lives.

Options vs. Choice



PrEP ring regulatory approvals and access are expanding

Reg. Status/Region	Countries
Submitted (Pending Approval)	Ethiopia, Ghana, Mozambique, Nigeria (Pending), and Tanzania,
Approved	Botswana, Eswatini*, Kenya*, Lesotho*, Malawi, Namibia, Rwanda, South Africa*, Uganda*, Zambia, and Zimbabwe*
Planned Implementation	Burundi, Cambodia, Indonesia, Tunisia, and Sierra Leone


Population Council is willing to consider additional regulatory submissions and support import waivers

*Countries with current implementation

Countries which have already placed orders with GF support

Countries with planned orders 2024-2026 with GF support

The cost of the PrEP ring is expected to plummet in the years ahead

Ring Type	Cost/month	Availability	Manufacturing Location
1-month ring	\$12.78/month	Currently in use	Sweden
3-month ring	<\$5.33/month	Within ~1.5 years	Sweden
3-month ring	~\$?/month	Within ~2-3 years	South Africa* 

Pricing of the 1-month and 3-month rings manufactured in Sweden may be further reduced by other mid- and long-term options supporting cost reductions for rings eventually manufactured in South Africa.

PrEP Ring Access Initiative

The Global Fund, ClFF, and Unitaid

Key Points

1. Expanding ring access is a responsibility of the global community required by the [Choice Manifesto for Women and Girls in Africa](#). With limited quantities of CAB-LA in the near future, the ring is the only other long-acting option that could be available to users immediately – **if we do nothing, near-term PrEP choice will be highly limited**
2. Current pricing is a barrier to widescale uptake, hampering development of an attractive market for future products – **if we do nothing, current product will not be accessed at-scale, and future products may not come to market**

The Way Forward: As the largest funder of the PrEP ring, the Global Fund alongside Children Investment Fund Foundation (ClFF) are implementing the PrEP Early Market Access Vehicle (EMAV) aimed at achieving sustained impact faster and creating a bridge to lower cost products.

PrEP Ring EMAV announcement at AIDS 2024

CIFF To Propel PrEP Revolution with up to US\$2 Million for Immediate Access to PrEP Rings

21 July 2024

MUNICH – The Children’s Investment Fund Foundation (CIFF), in partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), announced on 21 July 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 dapivirine vaginal rings in countries that implement Global Fund grants to fight HIV and AIDS. The PrEP ring is a long-acting HIV pre-exposure prophylaxis (PrEP) option for women.

[Bis zu 2 Millionen US-Dollar der CIFF für sofortigen Zugang zu PrEP-Ringen revolutionieren Präexpositionsprophylaxe](#)

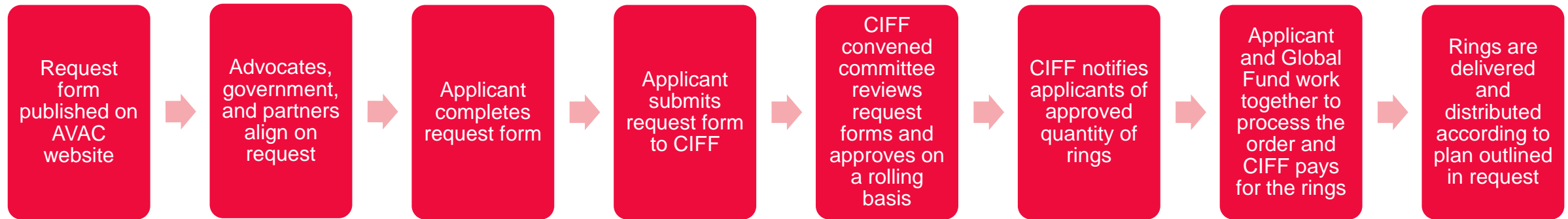
[[download in Deutsch](#)]



PrEP Ring EMAV Summary

Objective: Facilitate immediate access to one-month ring to accelerate availability for users, expand PrEP choice, and catalyze impact while less expensive rings come to market with an approximate 60% drop in price/month

Mechanism Summary:



Eligible Applicants: Country entities with HIV product procurement and supply chain responsibilities who may or may not be GF PRs or SRs in countries which received an HIV allocation for GC7. Endorsement by National Ministry of Health or other government agency responsible for the HIV response is required. Product registration is not required if import waiver can be obtained.

Available Volumes: 2,400 (min.) and 24,000 (max.) one-month rings, per country, for use across 2025 and 2026. Available rings will be allocated on a first-come first-served basis to requests which meet the criteria below. CIFF will fund up to 150k rings in total. The AVAC website will be updated as volumes are allocated.

Deadline: Requests are accepted at emav@ciff.org on a rolling basis after launch in October

M&E: Quarterly reporting to CIFF and leveraging reporting of GF and PEPFAR, when applicable.

Potential Technical Support for Request Development and Implementation

Organization	Offer	How to Access
PEPFAR	Possibly support planning and programmatic implementation for rings procured with support from the Global Fund in PEPFAR-supported countries	Contact PEPFAR country office with HQ backup as needed: Emily Dorward, USAID (edorward@usaid.gov), Ramona Bhatia, CDC (nxa9@cdc.gov), and Trista Bingham, GHSD (tub9@cdc.gov)
MOSAIC	Provision of tools and templates to support policy development and implementation planning, virtual TA potentially available to support programmatic implementation for rings procured with support from the Global Fund in African PEPFAR countries.	Contact Katie Schwartz (kschwartz@fhi360.org)
World Health Organization	Provide technical assistance	Contact WHO country offices and Michelle Rodolph (rodolphm@who.int) and Heather Ingold (ingoldh@who.int)
Population Services International and Clinton Health Access Initiative	Possible support for Kenya, Mozambique, Nigeria, South Africa, Uganda, and Zambia as part of SHARP technical assistance mechanism for PrEP Matching Fund Countries	Contact Karin Hatzold (Khatzold@psi.org) and Sarah Jenkins (sjenkins@clintonhealthaccess.org)

Ring EMAV Request Form

Dapivirine Vaginal Ring (DVR Ring) Early Market Access Vehicle (EMAV) Request Form

Instructions: Complete the portions of the form which are green. Do not make changes to any other part of the request form.

Section 1. By submitting this request, the applicant acknowledges they have read and understood the parameters outlined above.

Section 2. Which organizations were involved in the development of the Request Form? Add rows as needed to show full breadth of organizations included in developing the request, including that from community organizations.



	Organization Name	Primary point of contact name	Primary point of contact email
Lead organization			

Section 3. Which organizations are supportive of this request? Attach documentation of support (email, letter, etc.) with submission of the Request Form. Add rows as needed to show full breadth of support, including that from community organizations.

Organization*	Yes/No/Unsure	Is documentation of support provided?
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Evaluation Criteria

Criteria	Response
1 Does the request have endorsement from the National Ministry of Health or other government agency responsible for the HIV response? (Section 3)	Yes/No
3 Does the request outline a strategy to have national guidelines or operational procedures that are aligned with WHO guidance in place before rings are delivered? (Section 5)	Yes/No
4 Does the request outline a plan to provide rings to populations and geographies where they have high potential for impact? (Sections 6 & 7)	Yes/No
5 Does the request thoroughly describe how and who will be responsible for product customs clearance, storage, distribution to sites, pharmacovigilance, provider training, client awareness, and engagement of focus populations? (Section 8)	Yes/No
6 Does the request describe how all results will be reported and if not leveraging reporting mechanisms for Global Fund and PEPFAR, commit to reporting quarterly results directly to CIFF? (Section 9)	Yes/No
7 Does the request outline an intended plan to ensure ongoing access to rings for those who want them after the EMAV has ended? (Section 10)	Yes/No

Questions