**Dapivirine Vaginal Ring (DVR Ring) Early Market Access Vehicle (EMAV)**

(*revised 9 April 2025)*

The DVR ring (also known as PrEP ring or simply the ring) is an intravaginal ring which releases the antiretroviral drug dapivirine into the vagina to prevent HIV acquisition. The ring reduces HIV acquisition by over 50%, with some analyses finding even higher effectiveness. Once inserted, the ring is kept in place for a month before being changed. A ring which is changed every three months will soon be under regulatory review. The World Health Organization (WHO) has recommended the ring since 2021 and the ring has received a positive scientific opinion from the European Medicines Agency (EMA). It is approved by national regulatory bodies in Botswana, Eswatini, Kenya, Lesotho, Malawi, Namibia, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe.

The Ring EMAV is a partnership between the Children’s Investment Fund Foundation (CIFF) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund). Through the PrEP Ring EMAV, the costs of the product and shipment to in-country delivery point of up to 150k rings to countries will be covered by CIFF when ordered through wambo.org.

**Objective:** Facilitate immediate access to one-month ring to accelerate availability for users, expand PrEP choice, and catalyze impact while three-month rings come to market with an [approximate 60% drop in price/month](https://www.theglobalfund.org/en/news/2024/2024-07-21-ciff-propel-prep-revolution-usd2-million-immediate-access-prep-rings/).

**Eligible Applicants:** Requests can be submitted to CIFF by country entities with HIV product procurement and supply chain responsibilities who may or may not be Global Fund Principal Recipients (PRs) or Sub-recipients (SRs) in countries which received an HIV allocation from the Global Fund for Grant Cycle 7 (hereafter referred to as applicants) and for populations which meet the criteria outlined the table below.

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| Population | Criteria |
| Female Sex Workers | National adult (15–49 years) HIV prevalence > 3% |
| Other women | Combination of national or subnational incidence in women 15–24 years AND reported behavior from DHS or other ≥2 partners; or reported STIs in previous 12 months which indicate > 3% incidence OR 1-3% incidence AND high-risk reported behavior |

Only one request can be submitted per country and coordination must be managed in coordination with and endorsement by the National Ministry of Health or other government agency responsible for the HIV response.

**Available Volumes:** Applicants can request for total of between 2,400 (minimum) and 24,000 (maximum) one-month rings, per country, for use across 2025 and 2026. Additional rings beyond 24,000 can be requested in Section 12 should more rings be available for allocation to the applicant. Available rings will be allocated on a first-come first-served basis to requests which meet the criteria below.

**Evaluation Criteria:** Requests will be reviewed based on the following criteria. If the CIFF-convened evaluation committee answers “yes” for each item, rings will be allocated in alignment with other conditions outlined in this document.

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| 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 |

**Deadline:** Requests will be evaluated on a rolling basis and should be submitted to emav@ciff.org. Submission of a request does not guarantee provision.

**Process:** Time between Request Form submission and delivery in country will vary by country due to regulatory requirements and other factors. Generally, once Request Forms are submitted and approved, it should take between 3-4 months for product to arrive in country.

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| Action | Responsible | Timeline |
| Complete and submit Request Form | Applicant | Requests are accepted on a rolling basis until all rings are allocated. |
| Evaluate Request Form | CIFF-convened evaluation committee | Within two weeks of submissions |
| Notify applicants of decision | CIFF | Within one week of decision |
| Wambo onboarding and order placement on wambo.org | Global Fund (Supply Operations (SO)) / Applicant | Within four weeks of decision notification |
| Process order (including payment, delivery, and obtaining needed document for regulatory waivers, where applicable) | Global Fund (SO)/ Procurement Services Agent / CIFF / Applicant | 6-12\* weeks |
| Customs clearance, storage, distribution, pharmacovigilance, and implement programming | To be identified in Section 8 | To be identified in Section 8 |
| Report results | To be identified in Section 9 | To be identified in Section 9 |

\*without the requirement of an importation waiver and tax exemption

**Potential Technical Support for Request Development and Implementation:**

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| **Organization** | **Offer** | **How to Access** |
| **World Health Organization** | Provide technical assistance | Contact WHO country offices and Michelle Rodolph ([rodolphm@who.int](mailto:rodolphm@who.int)) and Heather Ingold ([ingoldh@who.int](mailto: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](mailto:Khatzold@psi.org)) and Sarah Jenkins ([sjenkins@clintonhealthaccess.org](mailto:sjenkins@clintonhealthaccess.org)) |

**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.*

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| --- | --- | --- | --- |
|  | Organization Name | Primary point of contact name | Primary point of contact email |
| Lead organization |  |  |  |
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**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.*

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| --- | --- | --- |
| **Organization\*** | **Yes/No/Unsure** | **Is documentation of support provided?** |
| National Ministry of Health or other government agency responsible for the HIV response (Yes required) |  |  |
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**Section 4.** If the ring is not approved by your national drug authority, does your national drug authority have a process to provide a registration import permit. If so, please describe what documentation will be required to obtain such a registration import permit.

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**Section 5.** What is the status of current national guidelines for the ring? If guidelines are not in place, what is the strategy to support WHO-aligned guideline finalization or operational procedures prior to ring arrival?

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**Section 6.** How many rings are planned for each year for each population in each geographic area?

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Population** | **Population 1\*** | | **Population 2\*** | | **Population 3\*** | | **Population 4\*** | |
| **Prevalence\*\*** |  | |  | |  | |  | |
| **Incidence\*\*** |  | |  | |  | |  | |
| **Year** | **2025** | **2026** | **2025** | **2026** | **2025** | **2026** | **2025** | **2026** |
| **Geography 1\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 2\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 3\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 4\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |

\*replace populations/geography names and add additional columns or rows as needed.

\*\*provide data where available

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| --- | --- |
| Total # of rings requested |  |

**Section 7.** Provide a rationale for how the populations, geographies, and volumes were arrived at in Section 6.

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**Section 8.** How will implementation take place?

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| **Question** | **Response** | |
| What is the strategy for engaging focus populations throughout planning, implementation and monitoring? Who will be responsible for doing this, paying for this, and when will it take place? |  | |
| What is the strategy for supporting awareness and driving demand for the PrEP ring? Who will be responsible for doing this, paying for this, and when will it take place? |  | |
| What is the strategy for ensuring informed choice and developing IEC materials for clients? Who will be responsible for doing this, paying for this, and when will it take place? |  | |
| What is the strategy for developing and delivering provider trainings and creating and disseminating job aids? Who will be responsible for doing this, paying for this, and when will it take place? |  | |
| Who will be responsible for customs clearance, storage, distribution, and pharmacovigilance? Who will be responsible for paying for this, and how long will it take to distribute once product arrives at the in-country delivery point? |  | |
| Where will the ring be made available (types of healthcare facilities, mobile sites, pharmacies, online, etc.) for clients? How will this expand on existing services for health, including those for HIV? |  | |
| Which organizations will be involved in providing the ring to people and what is their role? *Add rows as needed.* | Organization | Role |
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**Section 9.** How will results be reported?

Applicants are expected to report quarterly results to [emav@ciff.org](mailto:emav@ciff.org) using the template found on page six.

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| **Select all that apply below:** | **YES/NO** |
| PrEP rings will leverage reporting mechanisms for PEPFAR and reported through [PEPFAR indicators](https://help.datim.org/hc/en-us/articles/360000084446-MER-Indicator-Reference-Guides) PrEP\_NEW and PrEP\_CT and disaggregated under “other”. |  |
| PrEP rings will leverage reporting mechanisms for the Global Fund and reported through the Global Fund indicators KP-6 (abcd) and/or YP4 and disaggregated by product type. |  |
| PrEP rings will be delivered by non-PEPFAR and non-Global Fund partners and reporting for this will be included in quarterly reporting to emav@ciff.org |  |

**Section 10.** How will rings continue to be made available after support through the EMAV has ended? How will the costs of ring procurement be covered?

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**Section 11.** Optional: What additional information would you like to share about your plans that isn’t covered above?

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**Section 12 (Optional):** If you would like additional rings beyond the 24,000 maximum for use in 2025/2026, outline your plans below showing additional ring requests beyond those outlined in Section 6 above.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Population** | **Population 1\*** | | **Population 2\*** | | **Population 3\*** | | **Population 4\*** | |
| **Prevalence\*\*** |  | |  | |  | |  | |
| **Incidence\*\*** |  | |  | |  | |  | |
| **Year** | **2025** | **2026** | **2025** | **2026** | **2025** | **2026** | **2025** | **2026** |
| **Geography 1\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 2\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 3\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |
| **Geography 4\*** | ring # | ring # | ring # | ring # | ring # | ring # | ring # | ring # |

\*replace populations/geography names and add additional columns or rows as needed.

\*\*provide data where available

|  |  |
| --- | --- |
| Total # of Additional PrEP Rings Requested |  |

**Section 13 (Optional):** Provide a rationale for how the populations, geographies, and volumes were arrived at in Section 12.

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**Frequently Asked Questions**

1. Will this initiative apply to past orders of the ring?
   1. No, it only applies to orders which have not been placed yet.
2. If a country already has orders of the ring planned through an existing Global Fund grant, can the EMAV fund those quantities?
   1. No, the procurements planned under the existing Global Fund grant will be funded with grant funds. Orders planned with grant funds that are placed and have a purchase order with the supplier by 30 June 2025, can benefit from lower negotiated pricing.
3. Can rings accessed through the EMAV be used for formal studies?
   1. No, countries are encouraged to consider how to address implementation questions through routine programmatic monitoring rather than formal studies which may delay introduction and impact.
4. Does the EMAV fund in-country distribution, training, demand creation, or any other aspects of implementation?
   1. No, the EMAV only covers product costs and delivery to in-country delivery point.
5. What happens if rings are all allocated before a request is received?
   1. CIFF and the Global Fund will explore additional interventions to make rings available to countries.

**Reporting Template to be Filled and Submitted to** [**emav@ciff.org**](mailto:emav@ciff.org)

|  |  |
| --- | --- |
| **Organization Name:** | |
| **Quarter** | **Number of rings dispensed** |
| Q1 2025 |  |
| Q1 2025 |  |
| Q3 2025 |  |
| Q4 2025 |  |
| Q1 2026 |  |
| Q2 2026 |  |
| Q3 2026 |  |
| Q4 2026 |  |