

The Dapivirine Ring Global Action Plan

MAY 2021



Context for the Global Action Plan

- In July 2020, the European Medicines Agency (EMA) issued a [positive scientific opinion](#) for the dapivirine ring's (the ring) use by cisgender women ages 18 and older in developing countries to reduce their HIV risk.
- In November 2020, the dapivirine ring received WHO prequalification, a designation that confirms the ring meets global standards for quality, safety and efficacy and that will help guide global and national procurement decisions. In January 2021, the ring was [recommended for use](#) by the WHO as an additional prevention choice for women at substantial risk of HIV infection who cannot or choose not to use oral PrEP. In March 2021, WHO updated its [clinical guidelines](#) on antiretroviral (ARV) drugs for HIV prevention to include the ring.
- As a long-acting, self-initiated HIV prevention method designed specifically for women, the dapivirine ring could help address a widely recognized need for more HIV prevention options across countries.
- Pending country approvals, the introduction of the ring will require a collective effort by a range of stakeholders, including the International Partnership for Microbicides (IPM), national governments, donors, implementing partners, civil society organizations, and researchers. Coordination among these stakeholders along with strong political will and funding will be essential for the ring to be available, accessible and affordable to women who urgently need HIV prevention options.
- This Global Action Plan is a living document that will serve as a consolidated map that describes current and planned activities at the global level to support ring introduction. Its primary objective is to support coordination across partners for the planning, funding and introduction of the dapivirine ring in Africa in the context of combination prevention, including oral pre-exposure prophylaxis (oral PrEP) and integrated service delivery.

Need for the Dapivirine Ring

In consultations across countries, stakeholders raise several reasons why the ring is critical for HIV prevention

- » Addressing HIV incidence among **women** is a priority for many sub-Saharan African countries
- » Expanding the portfolio of HIV prevention options could increase overall **HIV prevention use** and the monthly dapivirine ring will complement existing options, including oral PrEP
- » The ring offers an opportunity to further explore de-medicalization to **expand access** to HIV prevention for new users that cannot or choose not to use oral PrEP
- » The ring offers an opportunity to prepare policies and systems to deliver a **broader portfolio** of HIV prevention options, including future multi-purpose technologies

“HIV is a highly feminized epidemic, so we’ve always wanted a female-initiated method to empower women. One thing we see with oral PrEP is that some people need a product that does not require daily use. We need to give people options. We look forward to the ring – we needed it yesterday!”
- Policymaker, Zimbabwe

Five Action Areas to Support Ring Introduction



Regulatory Process and Global Policy

- **WHO prequalification and normative guidance**
- Global **Essential Medicines List (EML)**
- Global **pharmacovigilance plan**
- National **regulatory approvals**



Product and Supply Chain

- **Manufacturing**, packaging, and branding of the ring
- **Quantification, forecasting and procurement** planning for the ring
- **Distribution and logistics** planning for the ring



Demand and Market Considerations

- **Market research** to identify ring users and understand their needs and preferences
- Development of **demand creation** strategies and materials that align with combination prevention



National Policy and Program Support

- Development of national **policies, implementation plans, financing and M&E frameworks**
- Development of **healthcare provider** clinical guidelines, training and supervision materials
- Initiatives for early **ring introduction** (e.g., demo projects)



Donor Support and Advocacy

- Allocation of **resources** to support ring rollout and scale-up
- Engagement with **civil society** to bolster advocacy and engagement on the ring

Summary | Regulatory Process and Global Policy



Regulatory Process and Global Policy

Current Status

- EMA issued a [positive scientific opinion](#) for the ring in July 2020
- The WHO issued [a recommendation](#) for the ring in January 2021 and added the ring to the prequalified list of medicines in November 2020; updated [WHO guidelines](#) including the ring were released in March 2021 with further updates anticipated in July 2021
- The ring is currently under review at the US FDA, with a decision anticipated by Q4 2021
- The ring is currently under review by National Medical Regulatory Authorities in Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe with decisions anticipated in Q2 and Q3 2021, although COVID-19 may cause delays

Next Steps

- Support dapivirine ring inclusion on the Global Essential Medicines List (EML)
- Establish a pharmacovigilance system to ensure compliance with global and national regulatory requirements and reporting obligations, and Good Pharmacovigilance Practices (GVP)
- In consultation with the EMA and other stakeholders, design and raise funds to carry out further research to better understand ring use among younger women

Summary | Product and Supply Chain



Product and Supply Chain

Current Status

- Supply chain mapping completed across seven countries
- Development of detailed strategy for ring quantification, forecasting to support procurement planning underway
- Engagement with Global Health Supply Chain (GHSC) on PEPFAR procurement initiated; GHSC QA approval received for product
- Initial discussions held with procurement agencies such as Global Fund, the National Department of Health in South Africa, and UNFPA
- Work underway to ensure stable and sufficient ring supply for launch at QPharma in Sweden
- Provisional brand name and brand imagery for packaging of the ring developed
- Instructions for use completed
- Commercial manufacturing of initial rings for launch initiated

Next Steps

- Explore distribution partnership models
- Package, label and make available initial ring supplies in 2021 following NMRA approvals

Summary | Demand and Market Considerations



Demand and Market Considerations

Current Status

- [Dapivirine Ring Design Guide](#) developed, using a human-centered design (HCD) approach, offering design concepts and tools to increase the adoption and sustained use of the ring
- End-user market research completed in five countries (South Africa, Zimbabwe, Malawi, Uganda and Kenya) using HCD that identified target end-user segments and co-created segment-specific positioning and messaging; planning underway to hold workshops to support integration of key findings into national demand creation strategies
- Work underway in four countries (Kenya, South Africa, Zambia, Zimbabwe) to landscape HIV prevention and family planning demand creation priorities and activities and to develop a framework and set of tools to support integration of the ring

Next Steps

- Extend end-user segmentation, positioning, and messaging work to additional countries
- Launch the brand name and create brand guidelines for the ring
- Support national efforts to apply evidence and integrate ring promotion into relevant demand creation strategies and develop a package of field-tested resources
- Adapt existing PrEP demand creation resources to include ring, such as the OPTIONS [HIV Prevention Ambassador Training Package](#), the POWER [PrEP and FP Decision Tool](#), and the South Africa [MyPrEP website](#)

Summary | National Policy and Program Support



National Policy and Program Support

Current Status

- Evidence shared with countries (e.g., Kenya, South Africa, Zimbabwe, Zambia) reviewing national guidelines for inclusion of ring
- Development of planning tools for the ring is underway to support national policy and implementation planning; the *Plan 4 Ring Toolkit* will include several resources including adaptable templates for the development of national guidelines for the ring
- Healthcare providers (HCP) knowledge, attitudes and practices (KAP) research conducted in seven countries
- Development of HCP resources for the ring are underway including sensitization information, a training resource package, and a technical assistance program
- Revision of [*PrEP-it*](#) underway to include ring (*PrEP-it* helps countries assess service delivery capacity, set targets, track initiation/continuation, forecast supply, and estimate program costs and impact)
- The Ring Learning Collaborative has been launched to support cross-country information sharing, learning, and planning for ring integration into national HIV prevention programming and other services

Next Steps

- Provide country-specific technical assistance for national ring introduction including guideline development, implementation planning, technical working group support, stakeholder engagement and implementation projects (e.g., demonstration projects)

Summary | Donor Support and Advocacy



Donor Support and Advocacy

Current Status

- Information dissemination via media and virtual platforms underway to share information about the ring, the EMA positive opinion, WHO recommendation and PQ and next steps for ring introduction with global, regional and national stakeholders
- [PrEPWatch.org](https://www.prepwatch.org) revision underway to support and expand ring knowledge sharing
- Global network of current and potential future donors briefed on the EMA positive scientific opinion, including: PEPFAR in partnership with USAID, Danish Ministry of Foreign Affairs, the German Federal Ministry of Education and Research through the KfW Development Bank, Irish Aid, the Ministry of Foreign Affairs of the Netherlands, UK Aid from the UK Government's Foreign, Commonwealth & Development Office, and the Bill & Melinda Gates Foundation
- Ring included in the PEPFAR Country Operating Plan (COP) [guidance for 2021](#)
- Meetings with advocates held in early 2021 to provide updates on regulatory status and planning for rollout; messaging framework and tools to support advocacy on the ring are being co-created with advocates in Kenya, Zambia and Zimbabwe

Next Steps

- Conduct key stakeholder outreach and consultations to increase public awareness about the ring, and to identify policy and advocacy needs to foster an enabling environment for dapivirine ring introduction
- Increase advocacy and community engagement activities in donor countries and African countries to position the ring within combination HIV prevention and sexual and reproductive health rights (SRHR) policies and programs
- Scale resource mobilization efforts to secure the financing needed for ring introduction