

24 May 2022

Statement on the Dapivirine Ring for Women: Call for Accelerated Global Access

- African feminists and advocates are united in calling for continued political and financial support to introduce and roll out the monthly Dapivirine vaginal ring in sub-Saharan Africa, where the need for new women-centered HIV prevention options remains public health, reproductive justice, and human rights imperative.
- A WHO meeting on 24 May 24, 2022, to disseminate findings from consultations with national ministries of health (MOHs), civil society, ring users, donors, implementing partners, and other key stakeholders in sub-Saharan Africa on moving forward with DVR registration and rollout in the country found that there was resounding support for ensuring the choice of HIV prevention options and the governments were supportive but concerned about financial backing.
- However, recent news indicates that PEPFAR and USAID are backing away from their support of the dapivirine ring for rollout beyond in planned implementation. It is the responsibility of the donors who brought the ring this far to ensure it is included in the range of HIV options women can choose from in protecting their health and lives.
- In addition, USAID has indicated they will no longer support research and development of the three-month ring, which could be a significant additional option to increase acceptance and ease of use and to reduce the cost for a year of protection by two-thirds.
- We acknowledge the decision taken by the International Partnership for Microbicides, which developed the Dapivirine ring, to withdraw its application for the ring approval from the US Food and Drug Administration in December 2021 after feedback from the FDA that they are unlikely to support US approval at this time because of the perceived lack of relevance to the US epidemic.
- The FDA decision primarily affects Black and brown women in the US as one of the communities who already have limited access to oral PrEP compared to other vulnerable groups. Women need more products than only limiting their choices to daily oral PrEP. Hence, we are concerned about the exclusion of the Dapivirine ring as an additional option for women in the US. We will continue to push that all women globally have access to the Dapivirine ring.
- However, this decision is now being seemingly applied to decisions to support African countries, several of which have already approved the use of the ring as an additional HIV option (namely South Africa and Zimbabwe) with many others on the cusp of approving the ring.
- The decision to withdraw the Ring for review by the FDA, cannot and should not affect plans to support its ring introduction and rollout in Africa by African Ministries of Health and funders. The severity of the HIV epidemic among women in our countries demands action and makes it critical that this product becomes available in our countries and region.
- For too long, we have seen very high rates of HIV among women here. This is driven by many factors, including high rates of gender-based violence, intergenerational and transactional sex driven by poverty and inequality, and inadequate access to quality, comprehensive sexuality education.

- We need to give women more control over their health and bodies and access to a range of safe and effective options, including the Dapivirine ring, to choose from so they can decide to use what works best for them at different times of their lives.
- The recent results from the REACH study which studied informed choice including both ring and oral PrEP made this point unmistakable. Almost all of the 247 adolescent girls and young women in this study chose to use either the ring or oral PrEP when given a choice, with two-thirds of them choosing the ring. REACH shows the potential impact of what simply by allowing young women and girls the ability to choose.
- At the same time, we applaud WHO in their statement of continued support of their 2021 recommendation for the ring as an additional prevention option for women at substantial risk of HIV; and the Global Fund for their inclusion of the dapivirine ring in their procurement catalog.
- And we applaud the African governments who have approved the ring thus far and see the importance of listening to the communities who have said that choice matters in HIV prevention. We call on other African governments to approve the ring and ensure that young women in particular have options to choose from that can work in their lives.
- As the FDA recently approved an injectable PrEP as a new prevention option, we watch with caution. While this is a welcome addition to the prevention toolkit, this does not replace the need for the Ring and other options in the future for women.
- The Ring could be another choice that puts more control in their hands when other more efficacious options are not feasible for them. The ring is discreet, long-acting, and localized — and those features could be important for some women and fill a gap for a long-acting method when women who are at the highest risk of HIV won't use oral PrEP or use condoms consistently.
- Many communities and thousands of women have invested in research and development that brought us here – with their bodies and their time as trial participants, community advisors, advocates, and peer educators. It is an ethical imperative that their expectations and invested investments be respected!
- We have watched as women continue to be left behind by progress against the epidemic. Women must be at the center of our HIV responses moving forward. It's a matter of health, rights, of equality. Let us act without delay and get the monthly Dapivirine ring into the hands of women who want and need this product. We need the Dapivirine ring in sub-Saharan Africa without delay.
- We urgently request a meeting with leadership from USAID and PEPFAR, as well as UNAIDS and other donors, to meet with us to explain their positions on the dapivirine vaginal ring, on programming for choice generally, and on the overall biomedical prevention options. We fully recognize the limitation of resources available but demand an opportunity to engage in the conversations and decision-making and not be told by donor agencies what options are possible. We urgently want to collaborate with all stakeholders to ensure that we learn the lessons of 40 years of HIV and three years of COVID: center communities; lead with equity; translate R&D options into viable choices for impact.
- Today, we call on all funders, country governments, and community leaders to continue the sustained support for the Dapivirine Ring's introduction and rollout in sub-Saharan Africa and for prompt regulatory reviews where it is under consideration.

- And, we call on all HIV programs, especially those already delivering oral PrEP in our countries and communities, to develop strategic introduction plans to integrate the ring. We stand committed to partnering with those programs to ensure they are co-designed in collaboration with communities.

Authors

Yvette Raphael, Advocates for the Prevention of HIV in Africa, South Africa

Nomfundo Eland, Emthojeni, South Africa

Lillian Mworeko, ICW East Africa, Uganda

Vuyiseka Dubula, AEDC, South Africa

Chilufya K Hampongo, Treatment Advocacy and Literacy Campaign, Zambia

Maureen Luba, AVAC, Malawi

Rosemary Mburu, WACI Health, Kenya

Definate Nhamo, PZAT, Zimbabwe

Manju Chatani-Gada, AVAC, USA

Georgina Caswell, GNP+, South Africa

Dr. Lilian Benjamin Mwakyosi, DARE, Tanzania