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IPM Welcomes WHO's Recommendation for Dapivirine Vaginal Ring as New Women's HIV Prevention Option

WHO recommends the monthly ring be offered as part of a combination prevention approach for women at substantial HIV risk

SILVER SPRING, Md. (January 27, 2021)—The nonprofit International Partnership for Microbicides (IPM) welcomes today's recommendation by the World Health Organization (WHO) that the monthly dapivirine ring may be offered as an additional prevention choice for women at substantial risk of HIV infection. The WHO's recommendation supports expanding the prevention portfolio with the first long-acting option that a woman could control herself and use discreetly to reduce her HIV risk during vaginal sex, pending regulatory approvals for the product.

Made of flexible silicone, the ring slowly releases the antiretroviral (ARV) drug dapivirine in the vagina, with minimal absorption elsewhere in the body. Women insert the product and replace it every month.

The [WHO's recommendation](#) was based on a systematic review and meta-analysis of available scientific evidence on the ring, including results of two large Phase III studies supported by data from two subsequent open-label extension studies. The agency recommended the ring as a complementary prevention method in addition to other safer sex practices, and which could be offered alongside daily oral PrEP as a choice for women who do not want to or are unable to take a daily oral ARV pill. The WHO is expected to include its recommendation for the ring in updated ARV treatment and prevention guidelines, which many countries use to develop their own policy and programmatic guidelines.

Today's news follows a [positive scientific opinion](#) from the European Medicines Agency under [Article 58](#) for the ring's use among cisgender women ages 18 and older in July 2020, and the addition of the ring to WHO's list of [prequalified](#) medicines in November 2020.

"The WHO's recommendation for the dapivirine ring is a critical step toward introducing this woman-controlled option as part of a comprehensive HIV prevention strategy, pending country approvals," said Dr. Zeda F. Rosenberg, founder and chief executive officer of IPM, which developed the dapivirine ring and is the product's regulatory sponsor. "IPM is committed to working with the WHO and other partners to ensure that women have the information and support they need to make informed choices about their sexual and reproductive health."

IPM is pursuing regulatory approvals for the ring's use in eastern and southern Africa, where the need is particularly urgent. Given current timelines, IPM hopes to receive first African country approvals as soon as mid-2021 and to begin making the ring available in some countries later this year. IPM is also applying for regulatory approval from the US Food and Drug Administration.

IPM is also working with a global network of partners across sectors to plan for the ring's potential rollout, including efforts to address additional research and implementation considerations outlined by the WHO Guideline Development Group. These include:

- The REACH study underway among adolescent girls and young women to collect additional safety data on the ring and PrEP, and to gain insights into product preferences and adherence support strategies, led by the US National Institutes of Health-funded Microbicide Trials Network (MTN)
- Studies underway to assess the safety of the ring and PrEP among pregnant women (DELIVER) and breastfeeding women and their infants (B-PROTECTED), both led by MTN
- Planning for a study to collect additional data on the ring's efficacy and use among young women
- Market introduction planning, including end-user and healthcare provider research development of demand creation and provider training materials, procurement and supply chain readiness, and additional cost-effectiveness research

Women bear a disproportionate burden of the global HIV/AIDS epidemic, with nearly 60% of new adult infections in sub-Saharan Africa occurring among women. Expanding women's options so that they can choose the method that best meets their individual needs—whether systemic or non-systemic, long-acting, daily or on-demand—is essential to controlling the HIV/AIDS epidemic. IPM is also developing a three-month dapivirine ring as well as a three-month multipurpose dapivirine-contraceptive ring to further expand women's choices.

IPM received the rights to develop dapivirine as a vaginal microbicide from Johnson & Johnson, which is also partnering closely with IPM to plan for the ring's introduction. IPM is also grateful for the generous support of our donors: the Danish Ministry of Foreign Affairs, the German Federal Ministry of Education and Research (BMBF) 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, the American people through the US President's Emergency Plan for AIDS Relief (PEPFAR) in partnership with the United States Agency for International Development (USAID), and the Bill & Melinda Gates Foundation.

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About IPM: IPM is a nonprofit organization dedicated to developing new HIV prevention tools like the [dapivirine ring](#) and other sexual and reproductive health technologies for women, and making them available in developing countries. IPM has offices in the United States, South Africa and Belgium. Please visit www.IPMglobal.org.

About dapivirine: Dapivirine is a non-nucleoside reverse transcriptase inhibitor that blocks HIV's ability to replicate itself inside a healthy cell. IPM holds an exclusive worldwide license for dapivirine from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. The license is designed to ensure that women in low-resource settings have affordable access to any dapivirine-based vaginal HIV prevention method.