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IPM's Dapivirine Ring for Women's HIV Prevention Receives WHO Prequalification

- ***WHO prequalification brings the dapivirine vaginal ring another step closer to introduction, pending country approvals***
- ***Confirms that this new HIV prevention method meets global standards for quality, safety and efficacy***

SILVER SPRING, Md. (November 30, 2020)—The nonprofit International Partnership for Microbicides (IPM) is pleased to announce the World Health Organization's (WHO) prequalification of the dapivirine ring, a monthly vaginal ring to reduce women's HIV risk.

This designation from the WHO confirms that the ring meets global standards for quality, safety and efficacy. The product's addition to the WHO's list of prequalified medicines will help guide national and global procurement decisions, pending country regulatory approvals for its use. The ring's prequalification follows a [positive scientific opinion](#) for the product in July 2020 from the European Medicines Agency (EMA) under [Article 58](#).

"WHO prequalification brings the dapivirine ring an important step closer to being made available to women, who want and deserve new choices in HIV prevention," said Dr. Zeda F. Rosenberg, founder and chief executive officer of IPM, which developed the dapivirine ring and is the product's regulatory sponsor. "Our aim is to make the ring available first in sub-Saharan Africa, where women face persistently high HIV risk."

The [WHO prequalification](#) program facilitates access to quality-assured medicines that respond to urgent public health priorities. Many countries consider prequalification in their regulatory reviews.

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. The monthly dapivirine ring could help fill an important gap with a long-acting product that a woman controls and could use discreetly to reduce her HIV risk during vaginal sex. Women insert the product and replace it every month. Made of flexible silicone, the ring slowly releases the antiretroviral (ARV) drug dapivirine in the vagina, with minimal absorption elsewhere in the body.

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 will initially seek approvals for the ring's use in eastern and southern Africa where the need is urgent. First regulatory submissions will begin this year through a [collaborative procedure](#) led by the WHO that accelerates country regulatory reviews for products that have received a positive opinion from the EMA or other stringent regulatory authority. IPM will also submit an application to the US Food and Drug Administration in 2020.

IPM received the rights to develop dapivirine as a vaginal microbicide from Johnson & Johnson, who 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.