

IPM: Pioneering HIV Prevention Options for Women



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

Nineteen years ago, the International Partnership for Microbicides (IPM) entered the HIV prevention field with a promise and a clear vision to create products that women in developing countries could use discreetly to prevent HIV and protect their sexual and reproductive health. Every step we have taken since then has brought that vision into sharper focus. Today, IPM is poised to introduce the first monthly HIV prevention product choice, specifically designed for women.

The HIV/AIDS epidemic continues to disproportionately affect women, especially in developing countries. Currently available prevention options are often not practical for many women, who urgently need new tools they can control and that make sense for their lives. IPM's monthly dapivirine ring and other technologies in development could help empower women with discreet and long-acting tools they can use to protect their health, on their own terms.

Our Progress

Since IPM was founded as a nonprofit organization in 2002, we have leveraged public, philanthropic and private sector resources to accelerate the development of potentially lifesaving technologies for women.

IPM builds on partnerships—with governments, foundations, researchers, pharmaceutical companies, policymakers, advocates and communities—to bring scientific ingenuity, political will and financial resources to bear on all phases of product development. Key achievements include:

- **Developing the first long-acting HIV prevention product specifically for women**

IPM led the development and testing of the monthly dapivirine vaginal ring, designed to deliver the antiretroviral (ARV) drug dapivirine over the course of one month. Women can insert and remove the ring themselves.

By marshalling scientific know-how and resources through partnerships, we took a novel approach to developing woman-controlled HIV prevention technologies that have significant public health potential but lack a traditional market incentive.

Two Phase III trials found that the dapivirine ring reduced women's HIV risk with no safety concerns, and subsequent open-label extension studies saw increased product use and suggested greater risk reduction. In 2020, the dapivirine ring received a positive regulatory opinion by the European Medicines Agency for use by cisgender women in



IPM's monthly dapivirine ring is currently under regulatory review.

developing countries. In 2021, the World Health Organization recommended the product in its updated clinical guidelines, an important step that will inform country-level policymaking, if the ring is approved.

IPM is seeking country regulatory approvals for the ring's use in sub-Saharan Africa, where women have an urgent unmet need for new prevention choices. The ring is also under review by the US Food and Drug Administration.

- **Negotiating innovative licenses for potent ARVs**

Since our inception, IPM has negotiated royalty-free licenses and an exclusive worldwide rights agreement from five leading pharmaceutical companies to develop nine promising ARVs as microbicides. These licenses ensure future IPM products will be affordable where the need is most urgent.



■ Conducting rigorous research studies

IPM has worked in 11 countries in Africa, Europe and North America to conduct more than 35 clinical trials to date on a variety of products as well as 13 incidence studies and two acceptability studies, all of which continue to inform our work and the field.

■ Strengthening medical research capacity

IPM has collaborated with in-country partners and research staff to build and strengthen capacity at more than 15 research centers in sub-Saharan Africa. We trained more than 600 research center clinical staff, including community engagement teams, on microbicide trial implementation and HIV and health literacy. These staff are equipped to conduct rigorous HIV prevention and other clinical trials that contribute to the health of their communities.

■ Streamlining manufacturing processes

IPM led a state-of-the-art manufacturing facility to produce vaginal gel and ring prototypes for early trials, resolving a manufacturing bottleneck and saving costs for more than 10 clinical studies. Because no manufacturers had previously produced vaginal rings for HIV prevention, IPM engineered the technology and manufacturing processes.

We later transferred ring production to a commercial partner, QPharma, beginning with our Phase III studies to ensure cost-efficiencies for large-scale production. IPM has continued to work with QPharma to upgrade its manufacturing capacity in preparation for the dapivirine ring's potential introduction, to keep production costs as low as possible.

What May the Future Hold?

■ Expanded HIV prevention choices for women

IPM is collaborating with global, regional and national partners to determine how the dapivirine ring could fit into combination prevention strategies, and to plan for its potential rollout, including supporting women to make informed choices.

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■ Building on dapivirine ring research

In addition, IPM is leveraging its ring technology to develop follow-on products that advance the science of HIV prevention, including a three-month dapivirine-only ring. The first Phase I trial of the three-month dapivirine ring reported encouraging results in 2021, with plans for an additional study.



A research staff member demonstrates how to insert a vaginal ring at a journalist training on women's HIV prevention and microbicides.

■ Advancing multipurpose tools to meet women's overlapping sexual and reproductive health needs

Because HIV and unintended pregnancy are major causes of serious health complications and death for women worldwide, IPM is developing a multipurpose technology: a three-month dapivirine-contraceptive ring designed to offer both HIV prevention and contraception. Encouraging results from two Phase I trials supported the product's continued development, with the next Phase I trial planned for 2021.

From Promise to Product

As women have remained the face of HIV, IPM is dedicated to its vision by pioneering critically needed microbicide research and development to help fill a gap for woman-controlled HIV prevention options.

IPM extends its deepest thanks to our partners around the world and to our generous donors, all of whom amplify our efforts to improve women's health. Realizing the lifesaving potential of new products for women may be within our reach. But only by continuing to unite scientific discovery with political will and financial commitment, can we meet women's urgent sexual and reproductive health needs globally.