



INTERNATIONAL PARTNERSHIP *for* MICROBICIDES

Investing in Research and Development for Women's HIV Prevention

Written Submission for the Pre-Budget Consultations in Advance of the 2020 Budget

By: The International Partnership for Microbicides (IPM)

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RECOMMENDATION: That the Government reinstate funding to the International Partnership for Microbicides (IPM) in the amount of CAD 5 million/year for 5 years, as part of Canada’s investment in sexual and reproductive health rights

INTRODUCTION

The International Partnership for Microbicides (IPM) is a non-profit product development partnership which pioneers the development of female-initiated HIV and multipurpose prevention technologies by marshalling scientific knowledge and resources through partnerships with public sector donors, philanthropic foundations, research institutions and civil society organizations. Canada was previously one of these public sector donors, contributing CA\$30 million from CIDA from 2005-2010. This funding supported the pre-clinical development and early stage clinical trials of the dapivirine ring and, as such, was instrumental in the ring's recent success.

OVERVIEW

Women in sub-Saharan Africa remain at an alarming risk of HIV infection due to biology and gender inequities. The number of new HIV/AIDS cases continues to challenge the world's ability to contain the epidemic. Treatment has been revolutionary, but treatment alone is not the solution. According to UNAIDS, although overall new infections have declined since 2010, the rate of decline is too slow to reduce annual new infections to 500,000 by 2020, and women continue to be at high risk for HIV. HIV/AIDS remains the leading cause of death for women ages 15-44 worldwide.

Women need HIV prevention products that fit into their lives and meet their individual needs, which change over time. While some women are able to negotiate condom use or use the daily antiretroviral (ARV) pill/pre-exposure prophylaxis (PrEP), others are not. Because no one product will suit everyone, women need a range of options they can choose from to help reduce their HIV risk.

For the first time, a discreet woman-centered method that requires only monthly action could empower women with a new HIV prevention option. In 2016, IPM's monthly vaginal ring containing the ARV drug dapivirine was found to reduce women's HIV risk in two Phase III clinical trials and to be well-tolerated (one study was led by IPM and the other by the US National Institutes of Health-funded Microbicide Trials Network, or MTN). The ring helps protect women against HIV transmission through vaginal sex. Women insert the flexible ring themselves into the vagina, where it slowly releases dapivirine, and replace it every month.

In 2019, final results from two subsequent open-label studies of the ring showed increases in ring use and modeling data suggest greater risk reduction—by over 50% across both studies—compared to the Phase IIIs. Although these modeling results are limited due to the lack of a placebo comparison group, they indicate an encouraging trend. This data highlights that when women know that the product was shown to reduce HIV risk, they are more likely to use it consistently and may see higher levels of risk reduction. IPM is also preparing for potential roll out the product in countries where women face high HIV risk. Modeling data suggest that the ring would both increase the number of women using any HIV prevention method and prevent infections that would otherwise not be averted by any other method. Multiple modeling studies also show that a combination prevention approach is needed to achieve epidemic control—and that microbicides like the ring could have a meaningful impact as part of that approach.

IPM is now leading efforts to obtain approvals for the ring, which is currently under regulatory review by the European Medicines Agency (EMA). A positive opinion from the EMA would facilitate a decision by the WHO on the ring's prequalification, a designation that many national regulatory authorities in Africa use to determine their own product approvals.

IPM's next regulatory steps include plans to submit applications to the US Food and Drug Administration in late 2019 followed by the South African Health Products Regulatory Authority in 2020, with other African regulators to follow, pending WHO prequalification. IPM hopes to receive first approvals in target African countries sometime in 2021.

If the monthly dapivirine ring is approved, its successful introduction will be crucial to launching next-generation products like IPM's three-month dapivirine-contraceptive ring. That "multipurpose" product is designed to offer long-acting protection against HIV and unintended pregnancy – overlapping threats to women's sexual and reproductive health in developing countries. Pending further study results and regulatory approval, potential roll-out for that product could take place in 2025.

CONCLUDING STATEMENT

Canada has shown its commitment to improving the health, well-being and empowerment of women around the world through its Feminist International Assistance Policy (FIAP) and through its recent bold commitment to increased funding to women's health. The FIAP's [Action Area Policies](#) highlight Canada's commitment to HIV prevention and gender empowerment, as well as to innovative approaches and improved solutions, including new technologies. In the Public Health Agency of Canada's recently released [Accelerating Our Response: Government Of Canada Five-Year Action Plan On Sexually Transmitted and Blood-Borne Infections \(STBBI\)](#), Canada commits to continue to invest in the development of innovative biomedical prevention strategies and vaccines for HIV, hepatitis C and other STBBI.

IPM maintains strong and ongoing support from Canadian civil society, in part through a long standing partnership with the Interagency Coalition on AIDS and Development (ICAD), a Canadian organization. We have also been encouraged by ongoing support in recent years from the all-party Global Health Caucus on HIV, TB and Malaria and by our discussions in a recent meeting with the Parliamentary Secretary to the Minister for International Development, and the Official Opposition Critic for International Development.

We are now at a critical moment in the dapivirine ring's lifecycle where Canada has the opportunity to make a vital contribution to women's health and empowerment through investment in the ring's development, licensure and roll out. Preventing HIV among women and girls is transformative and promises to yield significant development benefits—empowered, healthy women are more likely to have healthy families, educate their children, and make positive social and economic contributions to society.

Renewed support from Canada, at approximately CAD \$5 million/year over five years, would represent a significant and important investment that would help IPM advance the dapivirine ring through: the regulatory process and preparations for market introduction to ensure that the ring, pending regulatory approvals, is accessible to and affordable for the women who need it the most. Such funding would also build on the success of the dapivirine ring as a platform for the continued development of next-generation products such as the longer-acting 90-day HIV and multipurpose prevention rings (that contain both ARV and contraceptive), and adapt the ring technology to deliver multiple ARVs that target HIV at different points in its life cycle, which could potentially provide greater protection than a single drug alone.

We urge Canada to reinstate funding to IPM as part of Canada's commitment to addressing HIV and empowering women across the globe. Investing in microbicide research, development and introduction offers Canada a specific opportunity to achieve significant progress towards women's empowerment and gender equality by improving the sexual and reproductive health and rights of women and girls. Scientific innovations, such as microbicides alone and in combinations, are key to delivering solutions that will transform women's health and support Canada's commitment to eliminating HIV as a global public health threat by 2030.

We thank the Standing Committee on Finance for reviewing this submission and request your consideration in inviting IPM to provide a verbal submission.

Respectfully submitted,



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