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In Milestone for Women's HIV Prevention, European Medicines Agency Adopts Positive Opinion on Monthly Vaginal Ring to Reduce HIV Risk

IPM's Dapivirine Ring Could Give Women in Sub-Saharan Africa First Long-Acting HIV Prevention W(M)-5.4HO tial [(R)1.7egula (t)0.6oharRV

IPM submitted to the EMA for its assessment data from a package of studies, including two Phase III studies—The Ring Study led by IPM, and ASPIRE, conducted by IPM’s clinical trial partner the National Institutes of Health-funded Microbicide Trials Network (MTN)—two subsequent OLE studies, and a number of smaller safety studies.

In addition to working closely with the WHO during its review, the EMA’s evaluation also included the testimony of two women living in countries in Africa where there is a high burden of HIV.

As the EMA requested, IPM will also conduct additional research among cisgender women ages 18-25 to better understand the ring’s efficacy and to collect additional data on safety and potential ARV resistance. Results from the study could also inform strategies to support young women to use the ring consistently.

A potential new option to meet women’s needs

As the EMA indicated, the monthly ring could be an important option for women who choose not to or are unable to use the daily oral antiretroviral (ARV) pill known as PrEP (Truvada).

Next steps for potential country approvals and introduction

Given the urgency for women, IPM has been working with partners to shorten the time to potential introduction as much as possible, but rolling out the ring will require a collective effort by a range of global stakeholders, particularly as responding to COVID-19 alongside other priorities continues to challenge health systems. With strong political will and funding, it may be possible to begin making the dapivirine ring available sometime in 2021 in some communities in Africa where the need is urgent, pending several next steps, including:

- **WHO guidelines and prequalification:** WHO will review evidence on the ring as part of its guideline process and consider using an abbreviated review of the product for prequalification, a quality assurance designation for medicines that facilitates access to medicines that meet global standards for quality, safety and efficacy.
- **Regulatory reviews in Africa:** In parallel, the ring will be reviewed by regulators in each country where it would be used and, if approved, adopted into national HIV prevention policies. Because the EMA's Article 58 opinion is recognized by many countries in Africa and IPM is submitting to those countries through a process coordinated by the WHO, it may help accelerate national reviews. IPM plans to submit the first applications this year to countries in eastern and southern Africa where the need remains high, studies of the ring took place and where IPM can build on oral PrEP implementation .

