

The Monthly

What is the Article 58/EU-M4all procedure?

Through Article 58/EU-M4all, the EMA, in cooperation with the World Health Organization (WHO), provides a scientific opinion on a product intended for use outside of the European Union—specifically to address a disease of major public health interest in developing countries. This procedure uses the same rigorous standards as for medicines intended for use in the EU. It involves experts from WHO and observers from national regulatory authorities in representative countries where a product may be used. A positive opinion from the EMA through Article 58/EU-M4all is recognized by many countries in Africa, which can facilitate regulatory reviews there, and it can shorten the timeline to WHO prequalification.

What is WHO prequalification? What does it mean for the ring?

In November 2020, the dapivirine ring received WHO prequalification, a designation that confirms the product meets global standards for quality, safety and efficacy and an important step toward making the ring available in Africa. 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.

What does the WHO recommendation mean for the ring?

In January 2021, the WHO recommended the ring as a new HIV prevention choice for women at substantial risk as part of a comprehensive HIV prevention strategy—which means the ring may be offered to women as part of a menu of product options and with the complete information they need to make an informed choice about the potential benefits and risks of all those options. The WHO also incorporated the ring into its consolidated HIV guidelines in July 2021. Many countries use the WHO's recommendations and guidelines to inform their own policies.

Where could the ring be available first? Why did you select those countries?

We are prioritizing initial introduction of the ring in sub-Saharan Africa, where HIV incidence rates among women are high and they have an urgent unmet need for new prevention choices. The countries selected for the first phase of introduction are Botswana, Eswatini, Kenya, Lesotho, Malawi, Namibia, Rwanda, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. Given women's high risk, making the ring available across Africa is vital, and regulatory submissions to additional countries will follow as soon as possible.

What are the next steps for the ring's review in African countries?

IPM is submitting applications for the ring's use in eastern and southern Africa

woman-controlled tools like rings as well as future injectables and methods in development like rectal microbicides, implants and vaccines. No product is perfect, so offering all products is important to ensure every woman has a way to protect herself.

What is IPM doing to ensure women can access the ring when approvals are received?

IPM is working with a global network of partners across sectors to support the ring's introduction. This includes engaging with partners in manufacturing, procurement and supply chain management; conducting research to inform education and demand creation among women, communities and healthcare providers; and working with policymakers and implementers to learn from the rollout efforts of other biomedical products.

Would women have to pay for the ring?

As a nonprofit, our goal is for the ring to be publicly funded and provided to women at no cost in public healthcare facilities.

Where would women get the ring—pharmacies, hospitals, clinics?

The ring's distribution would vary by country. Because the dapivirine ring contains an ARV drug and will require periodic HIV testing, a physician or nurse would prescribe the ring, and some countries may also allow other health workers such as pharmacists to dispense the product in the future. IPM is working with regulatory agencies, policymakers, health worker associations, implementing organizations, advocates and others to identify distribution channels.

Because IPM's license for dapivirine is through the Janssen Pharmaceutical Companies of Johnson & Johnson, do they get royalties? Does IPM?

No, neither Janssen nor IPM will receive royalties on the ring. In fact, our licensing agreement with Janssen ensures that dapivirine-based products are made available at affordable cost in any low-resource setting where they are approved for use.