

PrEP Ring Consultations South Africa Detailed Summary

WHO-led consultation: February 4, 2022

IPM-led consultation: December 3, 2021

MOSAIC-led consultations: January 13-14, 2022



SOUTH AFRICA WHO-LED CONSULTATION SUMMARY (MOH)

NMRA UPDATE

As of Friday, March 11, 2022, SAHPRA has approved the ring. This consultation was conducted prior to approval.

OVERALL REACTIONS

- All plans for the ring will depend on SAHPRA's approval of the product.
- Further studies are needed so we can understand the ring's acceptability and effectiveness in the real world compared to CAB PrEP and oral PrEP.

GUIDING QUESTION	SUMMARY
IMPRESSIONS AND UNDERSTANDING OF THE RING	<ul style="list-style-type: none"> • The benefits of the ring — safety, lack of systemic side effects, and no HIV testing issues or drug resistance concerns — are balanced with its lower efficacy compared to oral PrEP, especially since oral PrEP is not always used effectively by AGYW. • An accurate understanding of PrEP method preferences will become clearer when AGYW can be offered multiple products.
RING PLANS AND CONSIDERATIONS	<ul style="list-style-type: none"> • Because the ring is self-administered, has a high safety profile, and does not require any clinical monitoring other than HIV testing, wider distribution may be possible (e.g., in family planning clinics and in certain pharmacies). • In the short/medium-term, the NDOH will be supportive of implementation science projects that will determine acceptability, interest, and potential demand.
WITHDRAWAL EFFECT	<ul style="list-style-type: none"> • The withdrawal of the NDA is not considered relevant for South Africa because the stakeholders recognize it was made on the view that the ring was a product that would not benefit women in the USA and not because of new information/data.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none"> • The price of ring compared to oral PrEP is of interest.
PROCUREMENT/FUNDING	<ul style="list-style-type: none"> • MOH is seeking a combination of national funding, funding through the Global Fund, and potentially through PEPFAR-funded programs.

SOUTH AFRICA IPM-LED CONSULTATION SUMMARY (IPM, NDOH)

GUIDING QUESTION	SUMMARY
OVERALL REACTIONS	<ul style="list-style-type: none"> • SAHPRA is most important to the NDOH for ring rollout.
RING PLANS & CONSIDERATIONS	<ul style="list-style-type: none"> • Once WHO has completed review of the ring, there is the potential to move forward with introduction. • No more clinical trials are needed. Any implementation will be real world, with demonstration sites to develop a model where the ring can be introduced where it is most needed.
WITHDRAWAL EFFECT	<ul style="list-style-type: none"> • South Africa has not traditionally relied on the US FDA in decision-making for health products. • Researchers are disappointed and feel the lack of submission might impact other products in the pipeline (i.e., multipurpose technologies focused on pregnancy prevention and STIs).
PROCUREMENT	<ul style="list-style-type: none"> • Costing analysis from HE2RO implementation approach will be through private models. Donor funding is going to be critical for this approach. • Government is reliant on donor funds — PEPFAR and Global Fund, among others — for new product rollout before government funds can be used. However, there are examples of products being paid for under waivers.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none"> • The needs of pregnant and breastfeeding people must be considered. • Questions remain about PEPFAR funding and IPM engagement of the Global Fund.

SOUTH AFRICA MOSAIC-LED CONSULTATION SUMMARY (AGYW, HCPs, CBO REPRESENTATIVES, RESEARCHERS)

OVERALL REACTIONS

- Women who struggle with pill taking want a discreet product to prevent HIV, and those who might not want injections need a product that works for them.
- The foundation for next-generation HIV prevention products will be based on ring acceptability.
- The ethical implications of ensuring access to a product for the women who participated in its clinical trials must be considered.
- Former trial participants' access to the product will affect future trial enrollment and research overall.
- Not all CBOs and HCPs are aware that IPM withdrew the ring's application from US FDA. The immediate reaction was disappointment; however, WHO's recommendation is most important.

GUIDING QUESTION	SUMMARY
RING PLANS & CONSIDERATIONS	<ul style="list-style-type: none"> • Women must understand what the ring is, how it works, and its efficacy so they can make an informed choice. • If clients seroconvert while using the ring, there might be backlash over South Africa's regulatory approval.
PERCEPTIONS OF THE RING	<ul style="list-style-type: none"> • HCPs believe the uptake of the ring would be high, and many clients ask them when it will become available. • The ring would be a good fit for South African AGYW and would play a role in South Africa's journey to an HIV-free generation. • The ring would increase choice in HIV prevention, especially by providing another option for women who have tried oral PrEP but would prefer a different product.
WITHDRAWAL EFFECT	<ul style="list-style-type: none"> • Researchers are disappointed and feel the lack of IPM's NDA submission might impact the future of other products in the pipeline (i.e., multipurpose technologies focused on pregnancy prevention and STIs). • There is discomfort among civil society over IPM's decision to withdraw the NDA, with the understanding that South Africa will need to evaluate the ring itself and make its own decision. • There is speculation that the ring's lack of US FDA approval could mean that it is not as effective as the studies suggest.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none"> • No additional information needs were discussed.
CIVIL SOCIETY ROLE & REACTION	<ul style="list-style-type: none"> • Civil society has played an active role in advocating for the ring. • Education on HIV prevention (including PrEP) is crucial. • If the ring gets approved in South Africa, it will be up to civil society to educate women about the product so they can make their own decisions.

Verbatims from South Africa



“Some clients at clinics have already heard about the ring, and they often ask when we will get the ring. Many of them struggle to remember to take a pill every day and also struggle with side effects. The ring will eliminate the problem of forgetting pills. I believe the uptake rate will actually be high and it will lead us to the goal of [an] HIV-free generation. It is very excited to have the first inter-vagina product.” – Health care provider



“I understand why they withdrew the application based on the fact that perhaps women in the USA are not at as high risk as in South Africa, so I have no problem with it. We need to try and save lives, and if it will save lives in South Africa, then we should go for it.” – Civil society representative