

PrEP Ring Consultations Zimbabwe Detailed Summary

WHO-led consultation: March 8, 2022

IPM-led consultation: December 2, 2021

MOSAIC-led consultations: January 4-10, 2022



ZIMBABWE WHO-LED CONSULTATION SUMMARY (MOH)**OVERALL REACTIONS**

- Continuing with ring rollout is about choice and understanding which PrEP methods AGYW prefer.
- A pilot study to better understand ring acceptability and real-world effectiveness and implementation is the necessary next step for Zimbabwe.

GUIDING QUESTION	SUMMARY
IMPRESSIONS AND UNDERSTANDING OF THE RING	<ul style="list-style-type: none"> • Zimbabwe needs to conduct a small pilot to make sure they understand the dynamics and logistics of the ring and to understand if AGYW want the product. • The country's experience with PrePex for VMMC was referenced during the consultation and not wanting a similar situation with the ring.
RING PLANS AND CONSIDERATIONS	<ul style="list-style-type: none"> • The next step is a pilot study to contribute to the evidence on the ring. Based on the results of the study, Zimbabwe would either continue promoting the ring or make an informed decision that the product is not working for Zimbabweans.
WITHDRAWAL EFFECT	<ul style="list-style-type: none"> • IPM's withdrawal of its NDA from the US FDA raised concerns, and new leadership within the MOHCC will need reassurance that the withdrawal does not mean the ring is a substandard product.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none"> • Results from a pilot study in Zimbabwe will address the remaining questions about the ring.
PROCUREMENT/FUNDING	<ul style="list-style-type: none"> • Procurement and funding were not discussed.

ZIMBABWE IPM-LED CONSULTATION SUMMARY (IPM, MOH)

GUIDING QUESTION	SUMMARY
OVERALL REACTIONS	<ul style="list-style-type: none">• The MOH has embraced the ring, saying it can help women who cannot access/use oral PrEP.• The MOH needs a clear understanding of the reasons behind the NDA withdrawal.
RING PLANS & CONSIDERATIONS	<ul style="list-style-type: none">• Zimbabwe is waiting for the WHO guideline adaptation process before making a decision.• The MOH was very keen to move ahead with demonstration projects and was waiting for the release of the guidelines in January.
WITHDRAWAL EFFECT	<ul style="list-style-type: none">• The question arose of why countries such as Zimbabwe are dependent on US FDA approvals to introduce any product.• There were calls for independent assessments of products in sub-Saharan Africa.
PROCUREMENT	<ul style="list-style-type: none">• The MOH brought up the example of PEPFAR not wanting to pay for HIV self-testing that was not US FDA approved and the resulting procurement challenges.• The MOH hopes that PEPFAR will pay for rings.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none">• Additional information needs were not discussed.

ZIMBABWE MOSAIC-LED CONSULTATION SUMMARY (AGYW, KOLs, RESEARCHERS, COMMUNITY LEADERS, CBOs, ETHICIST, FORMER RING TRIAL PARTICIPANTS)

OVERALL REACTIONS

- Researchers and former ring trial participants were frustrated about the NDA withdrawal.
- Concerns were voiced on the future of research if the country does not introduce the ring.
- Potential end users will do their own research about the ring. Many are presumed by CS leaders to still want the ring if it is offered at their local clinic/pharmacy, especially if oral PrEP is not suitable for them.
- Former ring trial participants expressed that the ring worked well for them during the trial, so they were surprised that a regulatory body such as the US FDA would reject a product that has been proven to work.
- AGYW encouraged that trust be maintained between AGYW in the communities and organizations that work in the communities because that trust is the foundation for how these new prevention technologies will be perceived.
- Key opinion leaders and the ethicist consulted stressed that no woman should be unprotected against HIV when it is known that there are methods that can protect them. The ring works, and the major issue to be addressed is how to make it available as soon as possible.

GUIDING QUESTION	SUMMARY
RING PLANS & CONSIDERATIONS	<ul style="list-style-type: none"> • Civil society representatives perceived as expected the absence of US FDA approval because more effective products such as CAB PrEP are on the horizon, but said the ring is still worth pursuing in Zimbabwe's context given that other prevention products are a long way from being introduced. • The ring is likely to be accepted by young women because of its discreetness, regardless of the withdrawal of the NDA, especially for AGYW who cannot easily negotiate safer sex. • Former ring trial participants are waiting for the ring because oral PrEP does not work for their lifestyles and needs.
PERCEPTIONS OF THE RING	<ul style="list-style-type: none"> • Participants expressed excitement about the opportunity for women to have additional HIV prevention options besides oral PrEP. • AGYW appreciated that the ring was developed as an alternative option for women who have challenges with using oral PrEP as a result of circumstances that do not allow them to protect themselves without experiencing stigma and IPV.
WITHDRAWAL EFFECT	<ul style="list-style-type: none"> • The question arose of why countries such as Zimbabwe are dependent on US FDA approvals to introduce any product. Participants called for independent assessments of products in sub-Saharan Africa. • A key opinion leader who had not been familiar with the ring expressed confusion over why the US FDA would not approve a product recommended by WHO. • The NDA withdrawal presents the opportunity for misconceptions about the ring to become widespread. Messaging to mitigate this will be needed if the ring is rolled out in Zimbabwe.
ADDITIONAL INFORMATION NEEDED	<ul style="list-style-type: none"> • A formal statement from IPM, talking points, and FAQs on the rationale for the withdrawal of the NDA, including information about the ring's efficacy, are needed.
CIVIL SOCIETY ROLE & REACTION	<ul style="list-style-type: none"> • Community leaders need to provide consistent messaging on the ring, its effectiveness, and benefits.

Verbatims from Zimbabwe



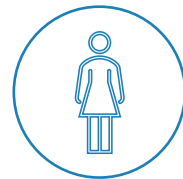
"Considering how adolescent and young girls are quite inquisitive about whatever it is they use, most of them will not go forward to use it and a lot of myths will be created around the ring, hence making it unpopular. " – AGYW representative



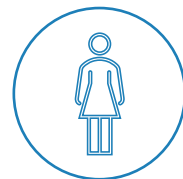
"The USA is a great power politically and it has its allies. These allies are likely to avoid using the ring because the US FDA has not approved it. So, this issue might become politicized. Countries that will need aid from the USA might also end up not using the ring." – AGYW representative



"Maybe the ring will actually improve things by reducing the number of HIV infections among women. Even though the US believes that the ring is the least [effective] HIV prevention product that they need, in our case it might be the best product that we need." – AGYW representative



"If the ring is said to be available at the nearest clinic, I possibly won't go and take it because I would rather prefer to wait for someone to use it and recommend it to other people. Then I'll definitely go and collect the ring." – AGYW representative



"People will always talk and have varied opinions. I have used the ring and it personally worked for me. So, I am concerned about my health, and I will use the ring regardless of other people's opinion." – Former ring trial participant