

# PrEP Ring Consultations Eswatini Detailed Summary

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WHO-led consultation: March 7, 2022

IPM-led consultation: December 7, 2021

MOSAIC-led consultations: February 2, 2022



## ESWATINI WHO-LED CONSULTATION SUMMARY (MOH)

### OVERALL REACTIONS

Eswatini's MOH confirmed their commitment to introducing the ring as an additional method for "female users" during a conversation with WHO.

The MOH held consultations with civil society and potential end users and decided not to hold a formal consultation with WHO due to the decision already under way in country to put in place an import waiver for the ring.

### GUIDING QUESTION

### SUMMARY

#### MOH ACTIONS

- Following IPM's voluntary withdrawal of the NDA for the ring, the MoH led consultations with civil society and potential end users.
- No major concerns for ring introduction emerged from the consultations.
- The MOH decided to introduce the ring and put in place an import waiver for the product as of February 28.

#### RING PLANS & CONSIDERATIONS

- National registration for the ring and inclusion on the essential medicines list is under way.
- The process for local registration has started. and documents have been submitted to the Central Medical Stores (CMS) focal person.
- The approval process is not dependent on SAHPRA.

#### INTRODUCTION STUDY

- Selected facilities in Eswatini will be part of the MOSAIC-led, USAID-supported CATALYST study.
- MOH confirmed that 2,000 rings will be provided by MOSAIC, with an additional 3,000 rings procured through PEPFAR COP22.
- The introduction study will further inform forecasting for rollout and for inclusion in the national quantification process.

#### ADDITIONAL INFORMATION

- Updates on new product introduction will continue to be provided during the PrEP core team and task team meetings.

## ESWATINI IPM-LED CONSULTATION SUMMARY (IPM, MOH, Eswatini National AIDS Programme)

GUIDING QUESTION	SUMMARY
<b>OVERALL REACTIONS</b>	<ul style="list-style-type: none"><li>• MOH very keen to introduce the ring in country.</li></ul>
<b>RING PLANS &amp; CONSIDERATIONS</b>	<ul style="list-style-type: none"><li>• Once the ring has been approved in South Africa, the process will be very quick in Eswatini.</li><li>• Pilot project work would be important to scale up ring rollout and product orders.</li><li>• End-user research should continue.</li></ul>
<b>WITHDRAWAL EFFECT</b>	<ul style="list-style-type: none"><li>• IPM withdrawal of the NDA from the US FDA is not very important. Eswatini will follow WHO recommendations.</li><li>• The EMA opinion is important.</li></ul>
<b>PROCUREMENT</b>	<ul style="list-style-type: none"><li>• The remaining question is the procurement process for the ring.</li><li>• PEPFAR support is needed for ring purchases; MOH will wait for independent review.</li></ul>
<b>ADDITIONAL INFORMATION NEEDED</b>	<ul style="list-style-type: none"><li>• Will IPM be assisting with the import license?</li></ul>

### UPDATE

As of the week of February 28, Eswatini's MOH is moving forward to put in place an import waiver for the ring and is not waiting for SAHPRA.

## ESWATINI MOSAIC-LED CONSULTATION SUMMARY (AGYW, FSWs, CBOs)

### OVERALL REACTIONS

- The PrEP ring will help prevent HIV for AGYW and FSWs who find it difficult to take daily pills.
- AGYW had mixed feelings about the withdrawal of PrEP ring's NDA from the US FDA. This is a delicate issue, but WHO's guidance is most important.
- Several civil society representatives mentioned that not introducing the ring could create distrust toward the government in Eswatini.
- Many AGYW and CBOs did not know about the ring until these consultations. Now that they have been made aware, they are excited about the possibility of the ring's introduction in Eswatini. Many young people have been waiting for a product like the ring.

GUIDING QUESTION	SUMMARY
<b>RING PLANS &amp; CONSIDERATIONS</b>	<ul style="list-style-type: none"><li>• Most AGYW were willing to take up the ring despite it not yet having regulatory approval.</li><li>• AGYW referred to the COVID-19 vaccines that are not approved in the US but are distributed in other countries.</li><li>• Ring introduction will require PEPFAR support, as well as recommendations from the EMA and WHO.</li><li>• Some hesitation was expressed about a product that is inserted in the vagina.</li></ul>
<b>PERCEPTIONS OF THE RING</b>	<ul style="list-style-type: none"><li>• Most women want the ring to be introduced and feel it will broaden the options for HIV prevention.</li><li>• The ring would be especially beneficial for young people who have trouble with daily pill taking.</li></ul>
<b>WITHDRAWAL AFFECT</b>	<ul style="list-style-type: none"><li>• AGYW had mixed views on whether Eswatini should move ahead with the ring after its NDA was withdrawn from the US FDA. One women commented, "It doesn't matter, so long as WHO has approved it."</li><li>• CS representatives expressed disappointment at the possibility of the ring not being introduced.</li></ul>
<b>ADDITIONAL INFORMATION NEEDED</b>	<ul style="list-style-type: none"><li>• CBOs requested more information on the ring.</li><li>• Some participants feared a rise in STIs and unwanted pregnancies resulting from the ring's introduction. Messaging on the ring's purpose is needed.</li></ul>
<b>CIVIL SOCIETY ROLE &amp; REACTION</b>	<ul style="list-style-type: none"><li>• CBOs requested more information on the ring.</li><li>• Some participants feared a rise in STIs and unwanted pregnancies resulting from the ring's introduction. Messaging on the ring's purpose is needed.</li></ul>

## VERBATIMS FROM ESWATINI



“Yes, we totally agree to the vaginal ring being introduced to our country... This will help us deal with tough situations when dealing with clients.” – Female sex worker



“[If ring is not introduced,] I think people might feel that the government is not serious with the fight against HIV.”  
– Civil society representative



“It would be great to be the first country to try this and become an ambassador for the ring, given our high HIV incidence rate. This would also position our MOH well in terms of having the ability to diversify and provide maximum alternative for people to stay safe.” – Civil society representative