All correspondence should be addressed to the Director General

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

LET_LSE_PMS_0011/03/26

PUBLIC NOTICE

Date: 24th March 2026

To: National malaria, HIV, and sexually transmitted infection (STI) control programme managers, their implementing partners, procurement agencies, healthcare professionals, pharmaceutical outlets and public

URGENT PUBLIC ALERT:

WHO INFORMATION NOTICE ON IN VITRO DIAGNOSTIC MEDICAL DEVICES MANUFACTURED BY MERIL DIAGNOSTICS PTY. LTD. AT THE MANUFACTURING SITES LISTED IN ANNEX 1

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to ensure the quality, safety and efficacy (performance) of medicines and allied substances, including medical devices for human and animal health protection.

Alert Purpose: To alert users and programme managers of malaria, HIV, and HIV/syphilis rapid diagnostic tests (RDTs) of concerns for products manufactured by Meril Diagnostics Pvt. Ltd. At specified Manufacturing Sites located at: D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191 India (site 1) and Meril Academy, Block No – MD1, Survey No. – 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India (site 2) (collectively , the "Manufacturing Sites").

Description of the situation: WHO's Prequalification Unit conducted a special (for-cause) inspection of the quality management system (QMS) at the above-stated manufacturing sites following specific concerns or evidence of potential non-compliance or product quality issues.

The inspection found critical nonconformities across the QMS at the Manufacturing Sites which may pose a risk to patient safety for the product. Find more information here: https://www.who.int/news/item/16-03-2026-medical-product-alert-n-1-2026--who-information-notice-for-in-vitro-diagnostic-medical-devices

Possible actions that could be taken by users:

1. Following consideration of the risks and benefits of continued use or not:
   - for Products in health facilities, if suitable alternative is available in-country inside the supply chain, strongly consider switching to alternative products.
   - for Products in country but not yet deployed, if suitable alternative is available in-country inside the supply chain, strongly consider switching to alternative products.

Head Office
Plot No: 2350/M
Off Kenneth Kaunda International Airport Road.
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351
E-mail: pharmacy@zamra.co.zm

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail: npvu@zamra.co.zm
Website: www.zamra.co.zm

- review all orders of Products, including in process, in production, pending shipment, in transit, in country but not yet accepted, if suitable alternative is available, strongly consider switching to the alternative products.

2. Review the WHO list of prequalified in vitro diagnostic products, and WHO programmatic guidance and technical resources such as the WHO Toolkit to optimise HIV testing algorithms for HIV RDTs.

3. Report if any product problem and/or adverse event is detected with respect to the Products.

Special consideration for malaria Products:

4. If malaria RDTs are already in a country where there are no suitable alternatives, strongly consider requesting WHO lot testing prior pre or post deployment.

5. Consider the risk-benefit profile of continuing to use malaria RDTs that are currently deployed, on order or in stores.

In the case that the risk-benefit profile favours continued use until product replacement is achieved: if the RDT results are negative and no alternative diagnosis is available, advise patients to return for re-evaluation or re-testing if their symptoms worsen or their condition does not improve. All cases of suspected severe malaria should be treated empirically, and health workers should be reminded to treat all faint/weak test lines as positive results.

Products registered in Zambia

Users in Zambia are hereby informed that the products below are registered by ZAMRA. Therefore, where these products are available at facility level, ZAMRA strongly advises that you switch to alternative products. Products that are in the country and have not yet been deployed should not be distributed.

Apply the risk-benefit profile of continuing to use malaria RDTs that are currently deployed, on order or in stores. In the case that the risk-benefit profile favours continued use until product replacement is achieved: if the RDT results are negative and no alternative diagnosis is available, advise patients to return for re-evaluation or re-testing if their symptoms worsen or their condition does not improve. All cases of suspected severe malaria should be treated empirically, and health workers should be reminded to treat all faint/weak test lines as positive results.

Brand Name	MA Number
Meriscreen Malaria Pf HRP-II Ag	ZAMRA-MDR-24-02
MERISCREEN Malaria Pf Pv Ag	ZAMRA-MDR-24-01
MERISCREEN Malaria Pf Pan Ag	ZAMRA-MDR-24-44
Meriscreen HIV 1-2 WB	ZAMRA-MDR-24-45

Annex 1. Implicated Product names

The following Products manufactured by Meril Diagnostics Ltd. at the Manufacturing Sites that are listed in the WHO Information Notice, located at: D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191 India (site 1) and Meril Academy, Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India (site 2):

Product names
One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag
One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag
One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag
MERISCREEN HIV 1-2 WB
Meriscreen HIV+ Syphilis Antibody Test
HIVFIND Whole Blood HIV 1/2 Antibody Detection Self-Test
Meriscreen Malaria Pf HRP-ll/pLDH Ag

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL