QA Information Notice for Health Products

IN N° 2025-05 **Version 1- 2025-10-16**	**Precautionary measures: Suspension of WHO Prequalification status of Alpa-cypermethrin & Piperonyl Butoxide Insecticide Treated Net -Yahe 4.0 Insecticide-Treated Nets supplied by Fujian Yamei Industry & Trade Co. Ltd**

Addressees

- Through Health Product Management (HPM) Specialists, all Principal Recipients (PR)
- All procurers, buyers reporting procurement of the impacted product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to draw attention to the suspension by WHO of the WHO Prequalification status of Alpa-cypermethrin & Piperonyl Butoxide Insecticide Treated Net -Yahe 4.0 commercialized by Fujian Yamei Industry & Trade Co. Ltd (P-04983).

This QA Information Notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name & Address of the Manufacturer	Fujian Yamei Industry & Trade Co. Ltd Room 2001, Building C2, Fuli Centre, Qinghua Street, Taijiang District, Fuzhou City, Fujian Province
Commercial / Brand Name(s)	Yahe 4.0
Formulation	Alpa-cypermethrin & Piperonyl Butoxide (PBO) ITN

Background

On 12th September 2025, WHO Prequalification Unit published a decision to suspend the prequalification status of the ITN-Yahe 4.0 (P-04983) following uncertainty regarding the quality of the product. According to the communication, it cannot be determined if the data submitted to WHO to support the prequalification decision as published in their WHO Public Assessment Report (WHOPAR) is still applicable to the product as formulated and manufactured. Based on the information obtained by WHO, there is insufficient evidence to ensure that if the ITNs were to be produced at the declared manufacturing site, that the resulting product could be considered the same as what was declared and assessed through its prequalification procedures. As a result, the Yahe 4.0 prequalification has been suspended. To date, according to the supplier, no batch of the Yahe 4.0 product was sold or distributed.

Nature of defect(s)

Details of the defect or problem	There is uncertainty regarding the quality of Yahe 4.0 (P-04983), and it cannot be determined that the data submitted to WHO to support the prequalification decision as published in WHOPAR is still applicable to the current product as formulated and manufactured. Thence the suspension of the WHO prequalification status of Yahe 4.0
Is there any evidence or suspicion of a risk to users/others	Not applicable. No batch of the product has been produced, sold or distributed according to the manufacturer.
Extent of the problem (e.g. No. of batches)	No batch of the product has been produced, sold or distributed according to the manufacturer
Extent of distribution of the product / batch(es)	No batch of the product has been sold or distributed according to the manufacturer.
Number of users/others potentially impacted	None. No batch of the product has been produced, sold or distributed according to the manufacturer.

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance & Compliance team

- **New orders**

1. Halt any new orders or procurements of the Yahe 4.0 ITNs product until further notice.

2. Consider alternative procurement of:

   a) Similar product from a different supplier.

   b) Different ITN product as per the National Malaria program guidelines.

In case of programmatic concerns, requests for case-by-case assessment can be addressed to the respective country Team / HPM specialist for discussion with the Quality Assurance and Compliance team.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization.

Please maintain awareness of this QA Information Notice and resulting actions for an appropriate period to ensure effectiveness of the actions.

Validity

The QA Information Notice will be valid from date of publication on the Global Fund Information Notice webpage https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/ until it is either removed or superseded by a new notice.

Contacts

This QA Information Notice does not require specific written response from PR and procurers to the Global Fund.

PRs and procurers should copy the Global Fund's Country Team/HPM Specialist on correspondences regarding the matter for follow-up.

Please direct any questions about this matter to the technical contact listed below.

Organisation	Name / Function	E-mail address
Global Fund	Respective Country Team/HPM Specialist for the portfolio	
Global Fund	Anne-Sophie Briand, Senior Specialist, Vector Control Products, Direct Sourcing	Anne-Sophie.Briand@theglobalfund.org
Global Fund	Stephen Kimatu, Specialist-Vector Control Quality Assurance, Quality Assurance & Compliance	Stephen.Kimatu@theglobalfund.org

Annex 1: WHO Prequalification Unit: Letter of Suspension

20250912 Suspension (Yahe 4.0, P-04983).pdf



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