

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2023-08 Version 1- 04/12/2023	Risk mitigations measures for procuring of Insecticide Treated Net (ITN) product, Yahe LN manufactured by Fujian Yamei Industry & Trade Co. Ltd
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Addressees

- Procurement Agents
- All PRs

Purpose

The Global Fund QA is issuing this notice to support implementation of risk mitigations measures on the procurement of Insecticide Treated Net product, Yahe LN manufactured by Fujian Yamei Industry & Trade Co. Ltd

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders including the national regulatory authority in charge of vector control products regulation, as appropriate.

Identification of the product(s) and manufacturer

Name of Supplier	Fujian Yamei Industry & Trade Co. Ltd
Commercial Name(s)	Yahe LN
Packaging & Pack size & Type	All (Size, Colour)
Batch(es)	All
Manufacturing Date	All

Background

In November 2023, Global Fund QA was notified of an out of specifications (OOS) result by one of the Principal Recipients, upon testing the product in a reference laboratories. One of batches tested by the Principal Recipient failed to comply with the requirements of the WHO specification 333/LN/5 (January 2019), and more particularly for the deltamethrin wash resistance index before and after accelerated storage. The supplier has been notified of the OOS and requested to carry out a root cause analysis and submit corrective and preventive actions (CAPA).

While waiting for the outcome of the investigations and the related corrective actions to be implemented, Global Fund QA is issuing this notice to recommend risk mitigation measures when procuring the product.

Nature of defect(s)

Details of defect or problem.	Active Content: Deltamethrin Wash resistance index before and after accelerated storage below the specification
Is there any evidence or suspicion of a risk to public health?	No concrete evidence of risk to public health but lack of efficacy could be a risk
Extent of the problem (eg. No. of batches).	One batch impacted so far
Extent of distribution of the product / batch (es).	Eritrea. One batch impacted at pre-shipment stage has been rejected
Number of end-users potentially impacted	No directly impacted end-users known/reported

Next steps

Based on the information available to date and until further notice, the following actions are recommended by Global Fund QA:

- For nets distributed in country: Not to recall the nets already distributed in countries.
- For nets pending distribution or in transit, batches that have already been inspected and passed QC testing: Not to suspend the delivery of the placed orders for batches that have already been inspected and passed QC testing, to avoid disruptions in supply chain and access.
- For orders already sampled and awaiting testing at QC labs or due for inspection, sampling and testing: To proceed with the inspection, sampling and testing and release the product upon receipt of complying results. PRs are reminded to forward any non-compliant results to Global Fund QA Team via their respective CT/HPM Specialist.
- For any new procurements or nets due for inspection and sampling: To inspect ALL batches, and to increase the sample size by doubling the quantity of nets to be inspected and tested. All samples to be tested as per full WHO specifications.

Contacts

This Notice does not require specific written responses from PRs.

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

Organisation	Name / Function	E-mail address
Global Fund	Stephen Kimatu, Specialist-Vector Control Products, Quality Assurance team	Stephen.Kimatu@theglobalfund.org
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