

## Quality Assurance (QA) for Health Products

### QA Information Notice

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| <b>IN N° 2019-01</b><br><br><b>Version 2 - 22/03/2019</b> | <b>Quality issues with DawaPlus 2.0 commercialized by Tana Nettings Co Ltd manufactured by H. Sheikh Noor-ud-Din &amp; Sons (HSNDS)</b> |
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#### Addressees

- Any person having products in stock, in transit
- Any procurers, buyers

#### Purpose

The GF QA is issuing this information notice to provide recommendations and advises on the basis of information that was transmitted by the manufacturer H. Sheikh Noor-ud-Din & Sons (HSNDS) regarding the Quality issues of DawaPlus 2.0 commercialized by Tana Nettings.

This 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 of Manufacturer         | <b>Tana Nettings Co Ltd,</b> |
| Commercial Name(s)           | <b>DawaPlus 2.0</b>          |
| Packaging & Pack size & Type | <b>All (Size, Color)</b>     |
| Batch(es)                    | <b>All</b>                   |
| Manufacturing Date           | <b>All</b>                   |

#### Background

GF Sourcing and Supply Chain (SSC) Department received the information from the manufacturer **H. Sheikh Noor-ud-Din & Sons** (HSNDS) in Pakistan of quality issues with LLINs products of the brand DawaPlus 2.0 commercialized by Tana Nettings Co Ltd.

Consequently, and as precautionary measures, SSC has suspended the procurement of beds nets via the PPM mechanism until further investigations are concluded.

Information have been forwarded to WHO Prequalification for further investigations and advice. In a letter addressed to procurement agencies dated 8<sup>th</sup> February 2019, WHO PQ Control recognized the uncertainty regarding the quality of products produced between January 2017 and April 2018. As a preliminary results of their investigations WHO PQ advise not to recall these nets and to continue with established testing procedures.

At the date of publication of this notice, WHO PQ currently maintains DawaPlus 2.0 on the list of prequalified LLINs.

## Nature of defect(s)

|  |   |
|--|---|
| Details of defect or problem.                                  | <b>Initially, 21 batches were found to have a content of deltamethrin of less than 1.5 g/Kg which is the formal minimum threshold. Based on review of QC data, the manufacturer concluded that a majority of nets manufactured between January 2017 and April 2018 were not manufactured according to formulation. The products were therefore not fully in conformity with approved specifications. No non-compliance reported for products manufactured after April 2018.</b> |
| Is there any evidence or suspicion of a risk to public health? | <b>The failure may decrease the efficacy of the nets to kill mosquitos. However, the physical barrier of the nets remains.</b>  |
| Extent of the problem (eg. nb batches).                        | <b>The batches manufactured during the period of January 2017 to April 2018. Pending the outcome of the investigations, specific risk mitigations measures will be put in place for products manufactured before and after April 2018.</b>  |
| Extent of distribution of the product / batch (es).            | <b>Afghanistan, Angola, Benin, Cameroun, DRC, Ghana, Guinea, Kenya, Madagascar, Malawi, Mali, Mozambique, Myanmar, Niger, Nigeria, Pakistan, Philippines, Rwanda, Somalia, South Sudan, Sudan, Togo, Zambia</b><br><br><b>(This list of countries is based on current data available and should not be considered as fully exhaustive. (See Annex 1 for an indicative list of quantity in quarantine by countries)</b>  |
| Number of patients potentially impacted                        | <b>No directly impacted patients known/reported</b>   |

## Action/Investigations taken

- To temporarily suspend dispatching of on-going order produced for PPM procurement.
- To suspend current production for PPM procurement
- No new order for PPM procurement

## Next Steps

Based on the information available to date and until further notice, the following actions are recommended by GF QA as risk mitigations measures. As we understand that the nets could be at different stages in the delivery process, the information below attempts to provide guidance for each possible setting. The below recommendations will bear additional cost. The costs for testing and quarantine will be supported by Sourcing and Supply chain through relevant arrangement for both PPM and non-PPM countries unless countries prefer to make their own arrangements.

### PR

- For non-PPM PRs to consider suspending current orders
- For non-PPM PRs: Not to place new orders

### Nets at manufacturing site

- Implement sampling and quality control testing of quarantined products as per the requirements set in Annex 2. GF Sourcing and Supply Chain can manage these steps unless countries prefer to make their own arrangements. If results show compliance, the quarantine can be lifted.
- If the results show non-compliance, this should be reported to country / PR to assess the risk together with Malaria program, Procurement Agent, Country Team, and supporting partners (if necessary) **to balance the risk related to the potential quality issue versus the public health risk related to not having the products**
- **The nets can be shipped after sampling occurred in parallel of the testing, but an agreement between the manufacturer and PR needs to be formalized on liability, prior to shipment.**

### Nets in Transit and/or Central & Regional warehouse Level

- Implement sampling and quality control testing of quarantined products as per the requirements set in Annex 2. GF Sourcing and Supply Chain can organize these steps unless countries prefer to make their own arrangements. If results show compliance, the quarantine can be lifted.
- If the results show non-compliance, (i.e. failed), this should be reported to country / PR to assess the risk together with Malaria program, Procurement Agent, Country Team, and supporting partners (if necessary) **to balance the risk related to the potential quality issue versus the public health risk related to not having the products.**
- **The nets can be shipped from central to regional warehouses after sampling occurred in parallel of the testing, but an agreement between the manufacturer and PR needs to be formalized on liability, prior to transport.**

### Nets at lower level or already distributed

- Do not recall the nets. As the original quality of the net cannot be verified at this level and appropriately traced back to improper manufacturing, these nets should not be tested and should continue to be used, as they will at least continue to provide a physical barrier.

## Contacts

This IN does require specific written response from PR. PRs should copy GF QA Team of any correspondence regarding the matter for follow-up. **All sampling reports and certificate of analysis should be forwarded without delay to GF Quality Assurance team.**

Please direct the respective answers and any questions about this matter to the technical contact listed below

| <b>Organisation</b> | <b>Name / Function</b>                                     | <b>E-mail address</b>  |
|---------------------|--|--|
| Global Fund         | Alain Prat, Quality Assurance Team Lead                    | <a href="mailto:Alain.Prat@theglobalfund.org">Alain.Prat@theglobalfund.org</a>             |
| Global Fund         | Aziz Jafarov, Manager, Global Sourcing Health Technologies | <a href="mailto:Azizkhon.Jafarov@theglobalfund.org">Azizkhon.Jafarov@theglobalfund.org</a> |
| Global Fund         | Sussann Nasr, Senior Disease Advisor, Malaria              | <a href="mailto:Sussann.Nasr@theglobalfund.org">Sussann.Nasr@theglobalfund.org</a>         |

**Annex 1: List of Impacted countries**

| <b>Country</b>     | <b>Quantities in Quarantine at manufacturing site / Nbr batches</b> | <b>Quantities In transit / Nbr batches</b> | <b>Quantities in quarantine at Central &amp; Regional Store / Nbr batches</b> |
|--------------------|---|--|---|
| <b>Cameroon</b>    | 1,340,404 / 6   |  |   |
| <b>DRC</b>         | 2,843,758 / 12  |  | 843,141 / 4   |
| <b>Laos</b>        | 515,650 / 3   |  |   |
| <b>Pakistan</b>    |   |  | 600.000 (Est.)  |
| <b>South-Sudan</b> | 2,072,800 / 9   | 690,900 / 3                                | 1,487,100 / 8   |

## Annex 2: Sampling & Testing requirements

### *Sampling requirements*

- To perform sampling by independent sampling agent
- Not to conduct physical inspection
- To perform sampling for each manufacturing batch (e.g. xxxx, xxxA, xxxxB, xxxxC)
- To sample two sets of 10 nets per batch (e.g. Tana batch is of 250.000)
- To distribute the sampling among the number of bales produced, as much as possible
- To identify samples such as GF QC TANA OP/Country Name/Batch Number/Bale Number
- To send the first set of 10 samples to the requested laboratory via DHL Rapid Courier
- To retain the second set of 10 samples at Central or Regional Medical stores keeping records of storage conditions for further investigations

### *Testing requirements*

- To perform testing in the following designated 3rd party independent laboratory  
Dr. Olivier PIGEON, Head of Research Unit, Test Facility Manager  
Walloon Agricultural Research Centre (CRA-W)  
Agriculture and Natural Environment Department (D3) Plant Protection Products and Biocides  
Physico-chemistry and Residues Unit (U10) Carson Building Rue du Bordia, 11  
B-5030 GEMBLOUX, BELGIUM  
Phone ++32 (0)81 62 52 62 - Fax ++32 (0)81 62 52 72  
[E-mail o.pigeon@cra.wallonie.be](mailto:o.pigeon@cra.wallonie.be)
- To test as per CIPAC / approved method
- To test **only** specific parameters of the WHOPES approved specifications 333/LN/2 July 2019 for
  - Active Content – Section 2.2 of the WHOPES Specifications
  - Wash Resistance Index – Section 2.3 of the WHOPES Specifications, and
  - Storage Stability – Section 4.1 of the WHOPES Specifications

NOTE: Bioassay testing can be organized upon request in case of failure of chemical test