

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2019-11 Version 2 - 06/01/2021	Re-instatement of the WHO Prequalification status of Tsara Soft commercialized by NRS Moon Netting
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Addressees

- Any person or entity having affected products in stock or in transit
- all procuring entities or authorities, purchasers, buyers

Purpose

The GF QA is issuing this information notice (IN) to provide recommendations and advice on the basis of information that was released by the WHO Prequalification Team regarding the re-instatement of the WHO Prequalification Status for the Tsara Soft Long Lasting Insecticidal Net (LLIN), also known as DawaPlus 2.0, commercialized by NRS Moon Netting.

This notice is for internal and external dissemination and country teams are requested to communicate this information to their relevant stakeholders. This information notice will also be published on the Global Fund's website.

Identification of the product(s) and Supplier

Name of Supplier	NRS Moon Netting
Commercial Name(s)	Tsara Soft, historically known as DawaPlus 2.0
Packaging & Pack size & Type	All (Size, Color)
Batch(es)	All
Manufacturing Date	All

Background

GF Supply Operations received information from the WHO Prequalification Team of uncertainty regarding the quality and efficacy of the product Tsara Soft (PQ Ref # 028-003), historically known as DawaPlus 2.0 commercialized by NRS Moon Netting, Dubai, UAE.

This decision is based on a series of complaints and information by Tana Netting management received by WHO PQ regarding product failures and mis-production of DawaPlus 2.0 nets manufactured by Tana Netting at the contracted manufacturing site in Lahore, Pakistan. Although the information received cannot be directly attributed to the Tsara Soft nets, the WHO Prequalification raised uncertainty regarding the quality and efficacy of the Tsara Soft products.

On the 9th October 2020, the WHO Prequalification issued a letter demonstrating that the product submission of the above mentioned has been completed and it has been found to meet the norms and standards recommended by the World Health Organization (WHO) for long lasting insecticide treated net

products and is acceptable, in principle, for procurement by the United Nations (UN) and other international agencies and countries.

On the basis of the evidence provided by the supplier, the Global Fund QA Team publishes this revised notice.

Nature of defect(s)

Details of defect or problem.	N/A
Is there any evidence or suspicion of a risk to public health?	N/A
Extent of the problem (eg. nb batches).	N/A
Extent of distribution of the product / batch (es).	N/A
Number of patients potentially impacted	N/A

Action/Investigations taken

- No Specific actions are required at this stage,

Next Steps

- No Specific actions are required at this stage,

Contacts

This IN does require specific written response from PR.

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

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