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In reply please refer
to : V2-447-3/ML/DS/1

Your reference: 018-001

Mainpol GmbH
Mr Rafael Pérez del Castillo
Daimlerstrasse 10
73095 Albershausen
Allemagne

19 April 2023

Dear Mr Perez,

**WHO Prequalification Unit
Vector Control Product Assessment: Letter of Concern**

According to the established procedures for the prequalification of vector control products, the World Health Organization (WHO) reserves the right to notify stakeholders about the outcome of investigations relating to post-prequalification activities, including handling of complaints, for any prequalified vector control product. Additionally, failure of manufacturers to maintain compliance with the relevant WHO specifications may lead to the requirement for corrective and preventative actions to be established by the manufacturer in cooperation with WHO prequalification assessment and inspection teams to ensure compliance or the manufacturer must submit the necessary application/information to establish new/revised specifications.

Several complaints, submitted by the Pan American Health Organization (PAHO) and the United Nations Development Programme (UNDP), have been received regarding Out of Specification (OOS) findings for certain batches of the Insecticide Treated Net (ITN) product SafeNet manufactured by Mainpol GmbH. In general, the OOS findings were submitted to share results pertaining to the active ingredient (AI) alpha-cypermethrin content being above or below the specified tolerance.

In accordance with the established procedures, WHO PQT/VCP opened investigations for each submitted complaint through which the available information was reviewed to consider the identified issue and determine the potential root cause. In one case, the Active Ingredient (AI) content was found to be above the established tolerance during the post-shipment testing, while in another report, the AI content was found to have decreased significantly during 2 years of storage under conditions declared to be in line with manufacturer recommendations.

To date, the investigations have not led to the identification of a specific root cause of the problems due to limitations in the availability of information, specifically, the consistency and completeness of information received. The contributing factors include:

- No clear data submitted or in some cases no data submitted at all
- Summary reports submitted without raw data
- Testing protocols used by independent laboratories not submitted
- Lack of reviewable information regarding ITN transport and storage conditions
- Inconsistent access to testing results pre- and post-shipment and post storage
- Incomplete information shared with the manufacturer by complainants

However, due to the number of complaints received and unexplained reasons for the inconsistency in product characteristics/OOS findings, WHO is issuing this letter of concern to alert stakeholders of complaints received and potential issues related to the product.

WHO continues to collaborate with all parties involved to obtain concrete data and information to determine the root cause of the OOS findings. Among specific actions to be taken, WHO will be conducting an on-site inspection of the new manufacturing site on 15-17 May 2023, observe pre-shipment testing, and review documentation. WHO will request the manufacturer to submit updated batch data on the physical/chemical characteristics of the product as currently formulated at the declared manufacturing site(s) in order to characterize the potential inter/intra-batch variability in the manufacturing process.

In the meantime, WHO is advising that Member States, procurement agencies and other stakeholders who are planning the procurement of this product, or have recently purchased the product, consider the advice below:

- Expand the number of samples for pre-/post-shipment testing, focused on AI content and Wash Resistance Index (clauses 2.2 and 2.3) of the WHO specification 454/LN/1.
 - o <https://extranet.who.int/pqweb/vector-control-product/document/alpha-cypermethrin-coated-ln-2015>
- Responsible parties should monitor the conditions under which the ITNs are transported and stored, for example, temperature and humidity

Yours sincerely,



Deus Mubangizi

Unit Head

WHO Prequalification Unit