World Health Organization

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

Your reference: 018-001

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

23 February 2024

Dear Mr Perez,

WHO Prequalification Unit – Vector Control Product Assessment (PQT/VCP)
Product assessment in relation to complaints received and issuance of a Letter of Concern

Background:

Several complaints were 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 for the prequalification of vector control products, the World Health Organization (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.

WHO PQT/VCP requested Mainpol GmbH to provide supporting information as part of these investigations.

Assessment:

In response to the requests by WHO PQT/VCP to provide supporting information on the current formula, manufacturing process, and physical/chemical characteristics of the product, Mainpol GmbH submitted the following information:

- Current Declaration of Product Formulation
- Description of Manufacturing Process
- Declaration of Manufacturing Sites
- Statement supporting the plan of action regarding the intermediate suspension concentrate (SC) formulation produced by Jiangsu Bio-tech
- Complete physical/chemical characterization GLP study on a minimum of 3 recently produced batches of the product following the formulation and process declared

The submitted information was assessed. The declarations of product formulation, manufacturing process and manufacturing sites met the requirements for WHO PQT/VCP by providing complete and clear information on the production process of the product. Additionally, Mainpol GmbH provided the appropriate documentation to clarify its ownership/responsibility for the production of the SC intermediate used in the formulation of the product as well as the physical/chemical characteristics used for quality assurance in acceptance of starting materials.

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The physical/chemical characteristics of recent batches (three batch GLP study and 10 batches of QC data) were provided. These data confirmed the compliance of the product with the established specifications and continuity of the production to comply with the related tolerances.

In order to characterize the release properties of active ingredient from the product, the resistance of the product to 20 standard laboratory washes, and to investigate the duration and continuity of bioavailability of the active ingredient, a wash resistance study with chemical and bioassay analysis was requested for a minimum of two of the three batches included in the physical/chemical characterization GLP study. This study was not submitted by the manufacturer.

Inspection:

An on-site inspection of the facility China Jiujiang Health Tex Industries Co Ltd was conducted from 15 to 17 May 2023. Following two rounds of CAPAs, the actions taken, or proposed to be taken to correct the deficiencies have been reviewed and the site is deemed compliant with the requirements of ISO 9001:2015 standard. The site is accepted as the sole manufacturing site of the finished product with activities declared as formulation, cutting, sewing, packaging, release testing, and storage for the VCP product: SafeNet, 018-001.

Conclusions:

Based on the information provided on the current formulation and manufacturing process, supporting studies confirming compliance of the product with established specifications over 11 batches, and the outcome of the on-site inspection, WHO has determined that the Letter of Concern dated 19 April 2023 can be rescinded and will therefore be removed from the website.

In light of the publication of the updated WHO Guideline for the prequalification assessment of insecticide-treated nets and its implementation plan, it was determined that the wash resistance study requested should be submitted as part of the implementation plan as published here.

Considering that the product is an equivalent product for which a complete product dossier is required to be submitted, in this case, PQT/VCP will require that the Module 3 dossier be submitted by **31 December 2024** to ensure continuity of the product characteristics and ensure that proposals for semi-field testing be developed in an appropriate manner based on the supporting quality data.

For further information regarding the submitted dossier of this product and in the case of questions arising in relation to the application process, please use the email address - **pqvectorcontrol@who.int** - ensuring that any such email mentions the corresponding product name and reference number.

Your cooperation is appreciated.

Yours sincerely,

Mr Rogerio Paulo Pinto de SÁ Gaspar
Acting Unit Head
WHO Prequalification Unit
Regulation and Prequalification Department