World Health Organization

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In reply please refer to: MI/no

Your reference:

Tagros Chemicals India Pvt. Ltd
Attention: Mr Rajesh Mathew
General Manager-Regulatory Affairs
Department: Registration
Jhaver Centre, Raja Annamalai Building
IV Floor, 72, Marshalls Road
Egmore-Chennai, 600008
Inde

7 December 2017

Dear Mr Mathew,

WHO Prequalification Team – Vector Control
VCP Prequalification – Letter of Prequalification

Product number: 004-011

Thank you for submitting the information requested and for your voluntary participation in this procedure for conversion. The review of your company's application for conversion on:

- **004-011 – LIMITOR 5 GR**

has been completed and it has been found to meet the criteria for conversion to Prequalification and is acceptable, in principle, for procurement by UN and other international agencies and countries.

This conclusion is based on information available to WHO at the current time, i.e. the information in the application for conversion and previous evaluations/reports. Please note, however, that this decision may change based on new information that may become available. Therefore, the product will now be included on the list of vector control products, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at http://www.who.int/pq-vector-control/prequalified-lists/en/.

Please note that inclusion on the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

ENCLS: (1)

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO could, at regular intervals, arrange for the products included on the list to be re-evaluated.

Yours sincerely,

Marion Law
Group Lead, Vector Control Products
Prequalification Team
Regulation of Medicines and other Health Technologies

Statement of Conversion to Prequalification

Criteria for Conversion

For those manufacturers of vector control products who wish to have their product(s) considered for prequalification based on a previous recommendation by WHO, an application for conversion is required to be submitted.

All applications for conversion are screened for completeness and the products are reviewed to ensure supporting WHO safety and efficacy evaluations and specifications are available.

In cases of country-level major regulatory actions (for example, cancellation of registrations/uses) in regards to an active ingredient, WHO may require additional analysis prior to conversion of any associated products.

Description of Product

PQT-VC Product Reference Number	004-011
Product Name	LIMITOR 5 GR
Product Type	Larvicide
Applicant	Tagros Chemicals India Pvt Ltd
Active Ingredient	Pyriproxyfen
AI Concentration	0.5%
Formulation Type	GR
Equivalent Reference Product	Sumilarv 0.5G; PQT-VC Ref 001-002

Statement of Review

An application for conversion of the product **LIMITOR 5 GR** was submitted by **Tagros Chemicals India Pvt Ltd** on **27/11/17**. The application was deemed to be complete for the purposes of conversion.

Upon review of the product it was determined that the submitted product is supported by WHO evaluations for safety and efficacy. The WHO specification identified by the applicant was verified and found to be applicable to the product submitted for conversion.