Appendix 3

Expression of interest to national regulatory authority (NRA) in the assessment and accelerated national registration, acceptance by NRA and notification of Procedure outcomes

Appendix 3, Part A

Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified Vector Control Product

In line with the " *Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified Vector Control Product*" (hereafter referred to as "the Procedure"), the undersigned Applicant[1] expresses its interest in the application of the Procedure by the NRA of ……. [country] ("the NRA") in respect of the following submission for national registration:

☐ Vector Control Product

Application details:

Name of entity:

Street:

City and country:

Email:

[1] If the applicant for national registration is not the same as the WHO prequalification (PQ) holder, the WHO PQ holder must confirm to the NRA and to WHO/Prequalification Team (PQT) by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned

Telephone:

Date of application (dd/mm/yyyy):

Product name in national system (if known):

National reference number (if known):

Product details for Vector Control Product

Product name:

Product code(s):

Regulatory version:

Manufacturer:

Manufacturing site(s):

Packaging:

WHO prequalification details:

WHO PQ reference number:

Date of prequalification (dd/mm/yyyy):

WHO PQ holder:

The Applicant confirms that the information and documentation provided in support of the above-mentioned submission for national registration is true and correct, that the product submitted for national registration is the same[2] as the WHO-prequalified product and that the technical information in the registration dossier is the same[3] as that approved by WHO-PQT during the initial prequalification procedure,

[2] Within the context of this Procedure, the same Vector Control Products is characterized by the same name, including proprietary name, the same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of the manufacturer and quality management system, the same data on quality, the same intended use, same labelling and packaging, and the same instructions for use.

[3] Only the technical data included in the dossier must be the same. There may be country-specific differences in administrative data, or if required by NRAs under exceptional circumstances, additional technical data can be provided.

and consecutive variation/change procedures. Minor differences[4] from the information submitted to WHO-PQT are the following:

Subject to the NRA agreeing to conduct the assessment and consider the accelerated registration of the Product under the Procedure, the Applicant:

1. undertakes to adhere to, and collaborate with the NRA and WHO-PQT in accordance with the terms of the Procedure; and
2. will authorize WHO-PQT[5] to provide the NRA confidential access to the following information and documentation and to freely discuss the same with the aforesaid NRA for the above-mentioned Purpose:
   - the full WHO-PQT assessment and inspection outcomes (reports), results of laboratory testing and if relevant, also assessment and inspections reports of other regulatory bodies, provided that these bodies gave their written consent to the use of such reports for the purpose of the Procedure,
   - information and documentation on subsequent variations (as defined in WHO guidelines[6]), as well as information and documentation on any actions taken by WHO-PQT post- prequalification of the Product.

   As regards sharing the outcomes of assessments, inspections and laboratory testing, only data owned by the WHO PQ holder and

[4] As defined in section 3.2. of the Procedure, examples of minor differences which are not considered essential may include differences in administrative information, name of applicant (provided that the applicant is acting for, and has the authority to represent the WHO PQ holder), and language of product information.

[5] If the applicant for national registration is not the same as the WHO PQ holder, then the authorization to WHO/PQT must be provided by the WHO PQ holder or their legal representative.

WHO are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

3. authorizes the NRA to freely share and discuss with WHO-PQT all registration-related and Product-related information provided by the Applicant to the NRA, subject to the obligations of confidentiality and restrictions on use as contained in the NRA's participation agreement and focal points' undertakings.

☐The application for national registration was submitted before the Applicant decided to apply the Procedure to the Product and therefore at the time of submission the registration dossier did not respect conditions of the Procedure. Steps taken to update the submission to the NRA to make the dossier "the same" as required by the Procedure are listed and referenced in the attached letter.

☐The Applicant is not the WHO PQ holder. An authorization letter from the WHO PQ holder is attached.

For the Applicant

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):