Appendix 2

Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure

Reference is made to the attached expression of interest in the assessment and accelerated national registration under 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 Products*" (hereafter referred to as "the Procedure") of the following WHO-prequalified Vector Control Products (hereafter referred to as "the Product") in _____[country] (the "Country").[1]

☐ Vector Control Product

WHO prequalification details:

WHO prequalification (PQ) reference number:

Date of prequalification (dd/mm/yyyy):

Date of requalification (if applicable):

Name of WHO PQ holder:[2]

Application details:

Name of entity:

Street:

City and country:

Email:

---

[1] Please complete a separate copy of this Appendix for each country.

[2] If the applicant for national registration is not the same as the holder of WHO prequalification ("WHO PQ holder"), the WHO PQ holder must confirm to the NRA and to WHO-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

Telephone:

The WHO PQ holder hereby consents to the WHO Prequalification Team (WHO-PQT) providing the following information and documentation to the national regulatory authority (NRA) of [country] ("the NRA") for the assessment and accelerated registration of the Product in the country under the Procedure and to freely discuss the same with the aforesaid NRA for this 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), as well as information and documentation on any actions taken by WHO-PQT post-prequalification of the Product;
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

As regards sharing the outcomes of assessments, inspections and Laboratory testing, only data owned by the WHO PQ holder and WHO-PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.[3]

Such consent is subject to the NRA having entered into an agreement with WHO-PQT as per Part A of Appendix 1 to the Procedure and having agreed to conduct the assessment and consider the accelerated registration of the Product under the Procedure, by having submitted the form reproduced in Part B of Appendix 3 to the Procedure to WHO-PQT.

The WHO PQ holder/Applicant commits to submit post-prequalification variations to WHO-PQT and any relevant participating authorities respecting national regulatory requirements. Variations should be submitted to participating authorities at the latest 30 calendar days after acceptance of the variation by WHO-PQT. Participating authorities should be informed about the fact that the same application for a variation

[3] In the case that certain data submitted to WHO-PQT by the WHO PQ holder in relation to the prequalification of the Product are not in his/her ownership, the WHO PQ holder specifies such data in an annex to this declaration of consent.

is being processed by WHO-PQT. If a national variation procedure the same[4] as the WHO-prequalified product, or if a variation of the WHO-prequalified product is not followed by a variation of the nationally registered product and, as a consequence, the nationally-registered product is no longer the same, the WHO PQ holder/Applicant will inform WHO-PQT of the differences and their reasons.

For the WHO PQ holder

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

[4] Within the context of this Procedure, the same Vector Control Product 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.