Appendix 2

Consent of WHO prequalification holder for WHO to confidentially share information with the NRA under the Procedure

Reference is made to the attached expression of interest in the assessment and accelerated national registration under the WHO Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics (hereafter referred to as "the Procedure") of the following WHO-prequalified IVD (hereafter referred to as "the Product") in:

Country: ("the Country").[19]

IVD

WHO prequalification details

WHO prequalification (PQ) reference number:

Date of prequalification (dd/mm/yyyy):

Name of WHO PQ holder:[20]

Application details

Name of entity: ("the Applicant")

Street:

City and country:

Telephone number: (please include codes)

Email:

The WHO PQ holder hereby consents to WHO 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 assessment and inspection outcomes (reports), results of performance evaluation and, if relevant, dossier assessment and inspection 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;

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

[20] If the applicant for national registration is not the same as the holder of the WHO prequalification ("WHO PQ holder") then the WHO PQ holder must confirm to the NRA and to WHO via 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 WHO PQ holder agrees with the application of the Procedure in the country concerned.

- information and documentation on subsequent changes (as defined in WHO guidance),[21] as well as information and documentation on any actions taken by WHO post-prequalification of the Product; and
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

As regards sharing the outcomes of dossier assessment, inspections and performance evaluations, only data owned by the WHO PQ holder and WHO are shared. Sharing of any other data is subject to the additional agreement of the data owners concerned.[22] Such consent is subject to the NRA having entered into an agreement with WHO as per Appendix 1: Part A 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 Appendix 3: Part B to the Procedure to WHO.

The WHO PQ holder/Applicant commits to submit post-prequalification changes to WHO and any relevant participating authorities, respecting national regulatory requirements. Changes should be submitted to participating authorities at the latest 30 calendar days after acceptance of the changes by WHO. Participating authorities should be informed of the fact that the same application for a change is being processed by WHO. If a national change procedure results in the nationally registered product being no longer the same[23] as the WHO-prequalified product, or if a change to the WHO-prequalified product is not followed by a change to 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 of the differences and the reasons for them.

For the WHO PQ holder

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

[21] Reportable changes to a WHO prequalified in vitro diagnostic medical device. Geneva: World Health Organization; 2016 (Document WHO/EMP/RHT/PQT/2016.01; https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf, accessed 14 December 2020).

[22] In the case that certain data submitted to WHO by the WHO PQ holder in relation to the prequalification of the Product are not in their ownership, the WHO PQ holder specifies such data in an annex to this declaration of consent.

[23] Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name (including proprietary name), same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of manufacturer and quality management system, same data on quality and performance, same intended use, same labelling and packaging, and same instructions for use.