Appendix 1: Part B

Undertaking for national regulatory authority (NRA) focal point(s)

The undersigned:

- Mr/Ms/Dr

First name (and initials):

Surname/family name:

Title in NRA:

Name of NRA: ("the NRA")

Country: ("the Country")

Telephone number: (please include codes)

Email:

Applicants for the national registration of WHO-prequalified in vitro diagnostics (hereafter referred to as "Applicants") may express to the NRA their interest in the assessment and accelerated national registration of such products 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").[17] Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA – and the NRA will communicate the outcomes of the national registration procedure and post-registration actions in respect of such products to WHO – through a restricted-access website which can be accessed only by the focal points designated by the NRA. For the purpose of accessing the restricted-access website and downloading the Information, and uploading reports in accordance with and subject to the terms of the Procedure, WHO will provide the undersigned with a secret access code. The undersigned undertakes to treat this access code as strictly confidential and not to disclose it to any other person whatsoever. The undersigned furthermore undertakes to take all precautionary measures that may be needed to prevent any other person whatsoever from obtaining the aforesaid secret access code and from accessing the restricted-access website (that is, except for other designated NRA focal points who have signed this Undertaking).

The aforesaid "Information" comprises any information and documentation relating to a WHO-prequalified product to be provided by WHO to the NRA under the Procedure, including but not necessarily limited to:

- the full WHO assessment and inspection outcomes (reports) and the results of performance evaluation;
- information and documentation on subsequent changes (as defined in WHO guidance),[18] as well as information and documentation on any actions taken by WHO or NRAs post-prequalification of the Product.

As regards sharing the outcomes of dossier assessment, inspections and performance evaluation, 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.

The undersigned confirms that:

1. the NRA has bound them to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1: Part A to the Procedure; and
2. the aforesaid obligations of confidentiality and restrictions on use shall not cease on completion of the assessment and accelerated registration of any Product in the Country, or on completion of any post-registration processes that may be required, or on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease to have the right to access the restricted-access website when the NRA designates a new focal point to replace the undersigned or when the undersigned ceases to be an employee of the NRA.

This Undertaking shall not be modified except with the mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes to promptly inform WHO of any circumstances or changes in circumstances that may affect the implementation of this Undertaking.

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Undertaking. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the UNCITRAL Arbitration Rules in effect on the date of this Undertaking. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in or relating to the Procedure or this Undertaking shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted by the undersigned:

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

[17] 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.

[18] 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 202