Appendix 1, Part B

Undertaking for 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")

Email: _____

Telephone: _____

Applicants for national registration of WHO-prequalified pharmaceutical products or vaccines (hereafter referred to as "Applicants") may express their interest to the national regulatory authority (NRA) in the assessment and accelerated national registration of such products 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 pharmaceutical products and vaccines" (hereafter referred to as "the Procedure").[6]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO/PQT will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA, and the NRA will communicate outcomes of the national registration procedure and post-registration actions in respect of such products to WHO/PQT, through a restricted-access website, which can be accessed only by the focal points designated by the NRA, including the undersigned. For the purpose of accessing the restricted-access website and downloading Information and uploading reports in accordance with and subject to the terms of the Procedure, WHO/PQT 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

[6] If the applicant for national registration is not the same as the 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 holder, and that the PQ holder agrees with the application of the Procedure in the country concerned.

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 (i.e. except for the other designated focal points who have signed this Undertaking).

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

- the full WHO/PQT assessment and inspection outcomes (reports) and if relevant, also results of laboratory testing;
- information and documentation on subsequent variations (as defined in WHO guidelines[7]), as well as information and documentation on any actions taken by WHO/PQT or NRAs post-prequalification of the Product.

As regards sharing the outcomes of assessments, inspections and results of 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.

The undersigned confirms that:

1. the NRA has bound him or her to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1, Part A to the Procedure; and that
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, nor on completion of any post-registration processes that may be required, nor on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease having 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 by mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes

[7] *For pharmaceutical products*: WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto).
For vaccines: http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

to promptly inform WHO/PQT of any circumstances or change 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 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 in NRA: _____

Place and date: _____