Appendix 1

NRA participation agreement and undertaking for NRA focal point(s)

Appendix 1: Part A

Agreement to participate in 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

1. Details of the NRA

Name of NRA: ("the NRA")

Postal address:

Country: _____ ("the Country")

Telephone number: ___ (please include codes)

Email:

2. Scope of agreement

Applicants for national registration of a particular WHO-prequalified in vitro diagnostic product (hereafter referred to as "Applicants") may express their interest to the participating NRA in the assessment and accelerated registration of this in vitro diagnostic product ("the Product") in the Country under the 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").[55]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of the Product under the Procedure (by submitting

[55] 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.

the form provided in Appendix 3: Part B of the Procedure to WHO through the restricted-access website), the NRA hereby confirms that for each such Product it will adhere to the terms of the Procedure, and will collaborate with WHO and the Applicant in the registration of the Product.

3. Confidentiality of information

Information and documentation relating to the Product and provided by WHO to the NRA under the Procedure may include but shall not necessarily be limited to:

- the full WHO assessment, performance evaluation and inspection outcomes (reports); and
- information and documentation on changes (as defined in WHO guidance),[56] as well as information and documentation on any actions taken by WHO or participating NRAs or the manufacturer 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 assessments, inspections and performance evaluation, only data owned by the manufacturer and WHO are shared. Sharing of any other data is subject to the additional agreement of the data owners concerned.

WHO agrees to make such information available to the NRA through a restricted-access website exclusively for the purpose of the assessment and accelerated registration of the Product in the Country, and any post-registration processes that may be required, in accordance with and subject to the terms of the Procedure ("the Purpose"). The NRA agrees to treat the aforesaid Information provided by WHO as strictly confidential and proprietary to WHO, the WHO PQ holder/Applicant and/or third parties collaborating with WHO and/or the WHO PQ holder/Applicant, as applicable. In this regard, the NRA agrees to use such Information only for the Purpose and to make no other use thereof. Thus, the NRA undertakes to maintain the Information received from WHO in strict confidence and to take all reasonable measures to ensure that:

- the Information received from WHO shall not be used for any purpose other than the Purpose; and

[56] 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).

- the Information shall be disclosed only to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation which are no less stringent than those contained herein.

The NRA warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.

The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.

The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the NRA is clearly able to demonstrate:

- was in the public domain or the subject of public knowledge at the time of disclosure by WHO to the NRA under the Procedure; or
- becomes part of the public domain or the subject of public knowledge through no fault of the NRA; or
- is required to be disclosed by law, provided that the NRA shall in such event immediately notify WHO and the Applicant in writing of such obligation and shall provide adequate opportunity to WHO and/or the Applicant to object to such disclosure or request confidential treatment thereof (provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction).

Upon completion of the Purpose, the NRA shall cease all use and make no further use of the Information disclosed to it under the Procedure, and shall promptly destroy all of the Information received from WHO which is in tangible or other form, except that the NRA may retain copies of the Information in accordance with its established archival procedures, subject always, however, to the above-mentioned obligations of confidentiality and restrictions on use. The Purpose for each product shall be deemed completed as soon as:

- the WHO PQ holder/Applicant discontinues participation in the Procedure for the particular product; or
- the Product is deregistered by the NRA and/or delisted by WHO.

The access right of the NRA focal point(s) to the restricted-access website will cease automatically upon the NRA ceasing to participate in the Procedure. If and as soon as an NRA focal point is replaced by a new focal point or ceases to be an employee of the NRA, such a focal point's access to the restricted-access website shall automatically terminate.

The NRA agrees that it has no right in or to the Information and that nothing contained herein shall be construed, by implication or otherwise, as the grant of a licence to the NRA to use the Information other than for the Purpose.

4. Timelines

In respect of each Product that the NRA agrees to assess and consider for accelerated registration under the Procedure, the NRA undertakes to abide by the terms of the Procedure, including but not limited to the following timelines for processing each application:

- the NRA undertakes to take a decision on the national registration of the Product within 90 calendar days of regulatory time[57] after obtaining access (through the WHO restricted-access website) to:
  - the data submitted to WHO for prequalification of the Product and owned by the WHO PQ holder; and
  - the full WHO dossier assessment, performance evaluation, and inspection outcomes (reports);
- within 30 working days of the NRA's decision on national registration of the Product, the NRA undertakes to inform WHO of this decision and of any deviations from WHO conclusions during prequalification (with an indication of the reasons for such deviations) by completing and submitting the form attached to the Procedure as Appendix 3: Part C to WHO through the restricted-access website;
- if a national change procedure results in the nationally registered product being no longer the same[58] as the WHO-prequalified product, or if and to the extent change to a 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 as the WHO-prequalified product, the NRA undertakes to inform WHO thereof (together with an indication of the reasons for such deviations) within 30 days of the conclusion of the national

[57] Regulatory time starts after a valid application for the registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time granted to the applicant to complete missing parts of the documentation, provide additional data or respond to queries raised by NRAs.

[58] 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.

change procedure or within 30 days of having received access to the information and documentation provided by WHO, as the case may be (that is, by completing and submitting the form attached to the Procedure as Appendix 4 to WHO through the restricted-access website);[59]

- the NRA undertakes to inform WHO in the case that the NRA deregisters or suspends the registration of the Product in the Country by completing and submitting the form attached to the Procedure as Appendix 4 to WHO through the restricted-access website, and to do so promptly if this decision is based on quality, safety or efficacy concerns, and within 30 days if this decision is based on other reasons.

5. Focal points for access to the WHO restricted-access website

The NRA has designated the person(s) listed below to act as focal point(s) for access to the WHO restricted-access website. The undertaking(s) completed and signed by the focal point(s) is (are) attached hereto as an Appendix to this agreement.

Any change in designated focal points must be communicated to WHO in writing without delay and will be subject to the new focal point having signed and submitted to WHO the undertaking ("the Undertaking") provided in Appendix 1: Part B to the Procedure. The NRA also undertakes to inform WHO if and as soon as a designated focal point ceases to be an employee of the NRA.

6. Focal point for inspections

If applicable, this should be the same focal point as for the WHO Collaborative procedure between the World Health Organization (WHO) and selected national medicines regulatory authorities (NMRAs) in inspection activities.[60] This same person should be designated for IVD-related inspections.

- Mr/Ms/Dr

First name (and initials): Sunday Kisoma

Surname/family name:

Title in NRA:

Telephone number: (please include codes)

Email:

☐ A signed Undertaking (see Appendix 1: Part B below) is attached

[59] If the fact that a WHO-prequalified product has been registered in a country pursuant to this Procedure has been made public, any subsequent deviations should also be made public.

[60] See: https://extranet.who.int/pqweb/inspection-services

7. Focal point(s) for dossier assessment

Different persons can be nominated for dossier assessment and performance evaluation. The same person may be nominated to be the focal point for inspections, performance evaluation and dossier assessment. If additional person(s) are nominated for dossier assessment, please complete the details below.

- Mr/Ms/Dr as a focal point for

Dossier assessment only ☐

Dossier assessment and performance evaluation ☐

First name (and initials): Sunday Kisoma
Surname/family name:
Title in NRA:
Telephone number: (please include codes)
Email:

☐ A signed Undertaking is attached

- Mr/Ms/Dr as a focal point for performance evaluation

First name (and initials): Sunday Kisoma
Surname/family name:
Title in NRA:
Telephone number: (please include codes)
Email:

☐ A signed Undertaking is attached

8. Miscellaneous

The NRA agrees that WHO may list its name on the WHO website as a participant in the Procedure. Except as provided hereinbefore, neither party shall, without the prior written consent of the other party, refer to the relationship of the parties under this agreement ("the Agreement") and/or to the relationship of the other party to the Product, the Information and/or the Purpose in any statement or material of an advertising or promotional nature.

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

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Agreement. 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 Agreement. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in or relating to the Procedure or this Agreement 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 for IVDs.

For the NRA

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

Attachments:

- Signed Undertaking(s) of NRA focal point(s) (see Appendix 1: Part B below)