Appendix 3

Expression of interest to NRA in the assessment and accelerated national registration, acceptance by NRA and notification of Procedure outcomes

Appendix 3: Part A

Expression of interest to NRA in the assessment and accelerated national registration of a WHO-prequalified in vitro diagnostic

In line with 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") the undersigned Applicant[68] expresses its interest in the application of the Procedure by the NRA of Click or tap here to enter text [country] ("the NRA") in respect of the following submission for national registration:

☐ IVD

Application details:

Name of entity: Click or tap here to enter text ("the Applicant")
Street: Click or tap here to enter text
City and country: Click or tap here to enter text
Telephone number: Click or tap here to enter text (please include codes)
Email: Click or tap here to enter text
Date of application (dd/mm/yyyy): Click or tap here to enter text
Product name in national system (if known): Click or tap here to enter text
National reference number (if known): Click or tap here to enter text

[68] 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.

Product details for IVD

Product name: Click or tap here to enter text
Product code(s): Click or tap here to enter text
Regulatory version: Click or tap here to enter text
Manufacturer: Click or tap here to enter text
Manufacturing site(s): Click or tap here to enter text
Packaging: Click or tap here to enter text

WHO prequalification details

WHO PQ reference number: Click or tap here to enter text
Date of prequalification (dd/mm/yyyy): Click or tap here to enter text
Name of WHO PQ holder: Click or tap here to enter text

The Applicant confirms that the information and documentation provided in support of the above-mentioned submission for national registration is true and correct, that the product submitted for national registration is the same[69] as the WHO-prequalified product and that the technical information in the registration dossier is the same[70] as that approved by WHO during the initial prequalification procedure, and any subsequent change procedures. Minor differences[71] from the information submitted to WHO are as follows:

Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text

Subject to the NRA agreeing to conduct the assessment and consider the accelerated registration of the Product under the Procedure, the Applicant:

1. undertakes to adhere to, and collaborate with the NRA and WHO in accordance with, the terms of the Procedure; and

[69] 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.

[70] Only the technical data included in the dossier must be the same. There may be country-specific differences in administrative data or, if required by NRAs under exceptional circumstances, additional technical data can be provided.

[71] As defined in section 4.2 of the Procedure, examples of minor differences which are not considered essential may include differences in administrative information, name of applicant (provided that the applicant is acting for, and has the authority to represent, the WHO PQ holder) and the language of product information.

2. will authorize WHO[72] to provide the NRA with confidential access to the following information and documentation and to freely discuss the same with the aforesaid NRA for the above-mentioned Purpose:
   - the full WHO dossier assessment and inspection outcomes (reports), results of performance evaluation and, if relevant, the 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; and
   - information and documentation on subsequent changes (as defined in WHO guidance),[73] as well as information and documentation on any actions taken by WHO post-prequalification of the Product.

   As regards sharing the outcomes of dossier assessments, 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.

3. authorizes the NRA to freely share and discuss with WHO all registration-related and Product-related information provided by the Applicant to the NRA, subject to the obligations of confidentiality and restrictions on use as contained in the NRA's participation agreement and focal point undertakings.

☐ The application for national registration was submitted before the Applicant decided to apply the Procedure to the Product and therefore at the time of submission the registration dossier did not respect the conditions of the Procedure. Steps taken to update the submission to the NRA to make the dossier "the same" as required by the Procedure are listed and referenced in the attached letter.

☐ The Applicant is not the WHO PQ holder. An authorization letter from the WHO PQ holder is attached.

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[72] If the applicant for national registration is not the same as the WHO PQ holder then the authorization to WHO must be provided by the WHO PQ holder or their legal representative.

[73] 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).

For the Applicant

Signature: Click or tap here to enter text
Name: Click or tap here to enter text
Title: Click or tap here to enter text
Place: Click or tap here to enter text
Date (dd/mm/yyyy): Click or tap here to enter text

Template for authorization letter

[To be provided if the applicant is not the WHO PQ holder. Please provide a separate letter for each NRA concerned, with a copy to WHO]

This is to confirm that Click or tap here to enter text (name of applicant) seeking registration for the WHO-prequalified in vitro diagnostic product number Click or tap here to enter text (WHO prequalification number) in Click or tap here to enter text (name of 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 ("the Procedure") is acting for, or pursuant to rights derived from, Click or tap here to enter text (name of WHO PQ holder) and that Click or tap here to enter text (name of WHO PQ holder) agrees with the application of the Procedure in the country concerned.

For Click or tap here to enter text (name of WHO PQ holder)

Signature: Click or tap here to enter text
Name: Click or tap here to enter text
Title: Click or tap here to enter text
Place: Click or tap here to enter text
Date (dd/mm/yyyy): Click or tap here to enter text

Appendix 3: Part B

Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified in vitro diagnostic product and request for access to product-specific information and documentation

Please complete all fields marked with an *. For other fields, if there have been changes to the details provided in Part A above please also complete the relevant fields below. Where fields below are left blank, the data in Part A are considered to be valid.

Application details

Name of entity: Click or tap here to enter text ("the Applicant")
Street: Click or tap here to enter text
City and country: Click or tap here to enter text
Telephone number: Click or tap here to enter text (please include codes)
Email: Click or tap here to enter text
*Date of receipt of submission (dd/mm/yyyy): Click or tap here to enter text
Product name in national system (if known): Click or tap here to enter text
*National reference number (if known): Click or tap here to enter text

Product details for IVD

Product name: Click or tap here to enter text
Product code(s): Click or tap here to enter text
Regulatory version: Click or tap here to enter text
Manufacturer: Click or tap here to enter text
Manufacturing site(s): Click or tap here to enter text
Packaging: Click or tap here to enter text

WHO prequalification details

*WHO PQ reference number: Click or tap here to enter text
Date of prequalification (dd/mm/yyyy): Click or tap here to enter text
Name of WHO PQ holder: Click or tap here to enter text

Please complete either section A or section B below.

☐ **Section A**

The NRA agrees to conduct the assessment for accelerated registration of the above-mentioned product ("the Product") under the Procedure and requests access to product-specific information, in accordance with and subject to the terms of the Procedure and the Agreement between WHO and the NRA dated Click or tap here to enter text (dd/mm/yyyy).

☐ **Section B**

The NRA has decided not to apply the Procedure to the above-mentioned Product for the following reasons:

Click or tap here to enter text

Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text

***For the NRA of** Click or tap here to enter text **(indicate country)**

Signature:	Click or tap here to enter text
Name:	Click or tap here to enter text
Title:	Click or tap here to enter text
Place:	Click or tap here to enter text
*Date (dd/mm/yyyy):	Click or tap here to enter text

Appendix 3: Part C

Notification of outcomes of national registration procedure by the NRA

Product and application details as completed in Parts A and B above apply unless otherwise indicated below.

Please complete either section A or section B below.

☐ **Section A**

Registration has been granted under the terms of the Procedure, and the above-mentioned product ("the Product") is identified as follows in the national medicines register:

Name of the Product:	Click or tap here to enter text
National registration number:	Click or tap here to enter text
Date of registration (dd/mm/yyyy):	Click or tap here to enter text
Non-regulatory time (days):	Click or tap here to enter text

Product details (if different from those specified in Parts A and B)

Product name:	Click or tap here to enter text
Product code(s):	Click or tap here to enter text
Regulatory version:	Click or tap here to enter text
Manufacturer:	Click or tap here to enter text
Manufacturing site(s):	Click or tap here to enter text
Packaging:	Click or tap here to enter text

Registration holder (if different from the Applicant as specified in Parts A and B)

Name of entity: Click or tap here to enter text
Street: Click or tap here to enter text
City and country: Click or tap here to enter text
Telephone number: Click or tap here to enter text (please include codes)
Email: Click or tap here to enter text

Are the national registration conclusions different from the prequalification outcomes?[74]

☐ Yes ☐ No

If you answered yes to the above question, please specify:

Deviation	Reason
Click or tap here to enter text	Click or tap here to enter text
Click or tap here to enter text	Click or tap here to enter text

Please specify whether registration is subject to specific commitments, the registration is provisional or conditional, use of the Product is limited by specific restrictions, or additional trials or additional data are required:

Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text

☐ **Section B**

Please complete as appropriate.

The application for registration of the Product was rejected for the following reasons:

Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text

[74] This refers to deviations in indications, contraindications, intended use, special warnings and precautions for use, storage conditions and shelf-life.

☐ The Procedure was discontinued for this application for the following reasons:

Click or tap here to enter text
Click or tap here to enter text
Click or tap here to enter text

For the NRA

Signature:	Click or tap here to enter text
Name:	Click or tap here to enter text
Title:	Click or tap here to enter text
Place:	Click or tap here to enter text
Date (dd/mm/yyyy):	Click or tap here to enter text