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[24] expresses its interest in the application of the Procedure by the NRA of [country] ("the NRA") in respect of the following submission for national registration:

IVD

Application details:

Name of entity: ("the Applicant")

Street:

City and country:

Telephone number: (please include codes)

Email:

Date of application (dd/mm/yyyy):

Product name in national system (if known):

National reference number (if known):

Product details for IVD

Product name:

Product code(s):

Regulatory version:

Manufacturer:

Manufacturing site(s):

Packaging:

[24] 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.

WHO prequalification details

WHO PQ reference number:

Date of prequalification (dd/mm/yyyy):

Name of WHO PQ holder:

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[25] as the WHO-prequalified product and that the technical information in the registration dossier is the same[26] as that approved by WHO during the initial prequalification procedure, and any subsequent change procedures. Minor differences[27] from the information submitted to WHO are as follows:

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
2. will authorize WHO[28] 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),[29] as well as information and documentation on any actions taken by WHO post-prequalification of the Product.

[25] 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.
[26] 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.
[27] 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.
[28] 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.
[29] Reportable changes to a WHO prequalified in vitro diagnostic medical device. Geneva: World Health Organization; 2016 (Document WHO/EMP/RHT/PQT/2016.01;

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.

For the Applicant

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

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 (name of applicant) seeking registration for the WHO-prequalified in vitro diagnostic product number (WHO prequalification number) in (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, (name of WHO PQ holder) and that (name of WHO PQ holder) agrees with the application of the Procedure in the country concerned.

For (name of WHO PQ holder)

Signature:

Name:

Title:

Place:

Date (dd/mm/yyyy):

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https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf, accessed 14 December 2020).