# Annex 4

## 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. Introduction

National assessment of applications for registration (marketing authorization) of in vitro diagnostics (IVDs) is a key regulatory process that enables national regulatory authorities (NRAs) to evaluate and monitor the quality, safety and performance of IVDs.

Consideration of the outcomes/results of WHO prequalification dossier assessments, performance evaluations and manufacturing site inspections by NRAs during the national decision-making process is an example of a regulatory approach based on reliance. Such reliance on WHO prequalification outcomes/results contributes substantially to savings in regulatory resources and improvements in the quality of regulatory decisions, while retaining the prerogative of NRAs to conclude their assessment with sovereign decisions that reflect their own judgement of the risk–benefit balance in terms of their specific country situation and legislation. Consideration of the WHO prequalification outcomes or results requires a system that will permit:

- assurance that the product for which the WHO prequalification decision was taken is the same as the product being assessed (see section 4.2) or, if it is not the same, that a clear understanding exists of the differences between the products subjected to assessment in the two regulatory environments;
- efficient use of available scientific expertise and human and financial resources to determine, with reasonable certainty, the risk–benefit profile of an evaluated product when used in a given country; and
- selection by each NRA of the approach that will make the best use of their resources, workload and competencies.

Approaches could range from completely independent data reviews and inspections to adoption of the prequalification outcomes/results without further review. One pragmatic approach is to verify whether the product submitted for registration is the same as the product already prequalified by WHO (see section 4.2) and to assess only those areas relating to the use of the product in the country concerned, and where failure to comply with regulatory standards could pose health risks. In the remaining areas, the WHO prequalification outcomes may be adopted.

Collaborative procedures have been developed and implemented with a view to accelerating the national registration and regulatory life-cycle of pharmaceutical products and vaccines prequalified by WHO or approved by reference authorities *(1, 2)*. On the basis of experience with the WHO Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines *(1)* the procedure set out in the current document is intended to facilitate and accelerate national registration processes and post-registration regulatory life-cycles of WHO-prequalified IVDs by enabling participating NRAs to take advantage of the expertise and outcomes of WHO assessment.

This collaborative procedure (hereafter referred to as "the Procedure") has been developed on the basis of the above considerations to promote timely access to WHO-prequalified products in countries, to ensure that "sameness" can be demonstrated (that is, that the product to be used in countries is the same as that prequalified by WHO) and to provide a model for the exchange of regulatory information between countries.

## 2. Purpose and scope of the Procedure

The Procedure aims to provide a convenient tool for NRAs wishing to enhance their pre-marketing evaluation and registration system by taking advantage of WHO prequalification assessment, in accordance with the *Overview of the WHO prequalification of in vitro diagnostics assessment: WHO prequalification of in vitro diagnostics (3)* and the *Essential principles of safety and performance of medical devices and IVD medical devices (4)*.

The objectives of this document are:

- to describe the Procedure for accelerating the national registration of WHO-prequalified IVDs based on exchange of dossier assessment, manufacturing site inspection and performance evaluation outcomes between WHO and participating NRAs; and
- to provide a resource for manufacturers or applicants and participating NRAs to implement facilitated national registration of WHO-prequalified IVDs.

Enhanced collaboration and information exchange between participating NRAs and WHO benefits all partners. Subject to the agreement of the concerned applicant or manufacturer of a WHO-prequalified IVD, participating NRAs will be able to access assessment, manufacturing site inspection and performance evaluation outcomes that are not in the public domain and that have been prepared in conformity with WHO guidance *(3)*. Such reports and relevant WHO documents will help participating NRAs make their decisions, and will assist in the training of national regulatory staff. At the same time, feedback from participating NRAs on the information and documentation received from WHO under the Procedure will allow WHO to improve its activities in this area and ensure that the outcomes of its dossier assessments are relevant to NRAs. Consequently, patients will benefit from this collaboration through faster access to IVDs found to be acceptable in principle for procurement by United Nations agencies and WHO Member States.

The Procedure will also benefit manufacturers of WHO-prequalified IVDs through faster and better harmonized regulatory approvals in participating countries, thus contributing to a reduction in the burden of additional assessments such as on-site inspections and performance evaluations.

The Procedure is applicable to IVDs that have been prequalified by WHO in line with its current procedures and standards[1] and that have been found to be acceptable in principle for procurement by United Nations agencies and WHO Member States as shown in the WHO list of prequalified IVD products.[2]

In addition to accelerating the assessment and registration of IVDs prequalified by WHO, the Procedure also covers the national registration and management of post-approval changes.

## 3. Terminology

For the purposes of the Procedure, the following definitions and descriptions apply. These terms may have different meanings in other contexts.

**Abridged assessment**: a limited independent assessment of specific parts of the dossier, or regulatory submission of data for suitability of use under local conditions and regulatory requirements, taking into account prior assessment (including dossier review

[1] See: https://www.who.int/diagnostics_laboratory/evaluations/en/
[2] See: https://www.who.int/diagnostics_laboratory/evaluations/201013_prequalified_product_list.pdf?ua=1

and/or independent performance evaluation) and inspection outcomes from WHO prequalification to inform the NRA decision.

**Applicant**: the legal person or institution that applies for registration of a product on behalf of the manufacturer.

**Collaborative procedure (Procedure)**: procedure for collaboration between WHO and participating NRAs in the assessment and accelerated national registration of WHO-prequalified IVDs.

**Manufacturer**: any natural or legal person[3] with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name, whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s).

**Participating authorities or participating NRAs**: NRAs that voluntarily agree to implement this Procedure and accept the task of processing applications for registration of WHO-prequalified IVDs in accordance with its terms.

**In vitro diagnostic (IVD) medical device**:[4] a medical device, used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

**Performance evaluation**: assessment and analysis of data to establish or verify the scientific validity, and the analytical and (where applicable) clinical performance of an IVD.

# 4. Principles and general considerations

## 4.1 Participating parties

The Procedure has three major stakeholders: participating NRAs, WHO and interested applicants or manufacturers who agree that the Procedure can be used for applications submitted to participating NRAs for national registration of their WHO-prequalified IVD. The marketing authorization in a given country will be issued by the NRA. Although institutions may be commissioned by NRAs to carry out performance evaluation as part of the overall marketing authorization assessment, this does not change the fact that the main stakeholder with regard to the Procedure is the NRA itself.

## 4.2 Sameness of the WHO-prequalified and nationally registered IVD

WHO and participating NRAs receive applications for the same IVD product. Within the context of the Procedure, the same product is characterized by:

- the same product name;
- the same regulatory version;
- the same product code(s);
- the same site of manufacture and quality management system;

[3] This natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for medical devices in the countries or jurisdictions in which the devices are intended to be made available or sold, unless this responsibility is specifically imposed on another person by the regulatory authority within that jurisdiction.

[4] IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles, and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

- the same data on quality, safety and performance;
- the same design, with the same components from the same suppliers; and
- the same information, labelling[5] and packaging, including instructions for use and intended use.[6]

## 4.3 Submissions format and content of product dossiers for NRAs

4.3.1 The technical data included in the dossier should be essentially the same as that approved for the WHO prequalification of the product.

In exceptional circumstances, data may be organized differently in line with specific national requirements.

4.3.2 However, participating authorities may require applicants to comply with specific additional national requirements or may accept abbreviated dossier submissions. Each participating authority is encouraged to reduce the scope of specific national requirements in order to align them with the Procedure and to harmonize the requirements with the international format and content of a regulatory dossier. Specific national requirements should be made public.

4.3.3 Advantages of a harmonized format include enabling the same dossier to be submitted across several participating NRAs, thus facilitating comparison, reliance, optimal utilization of assessment resources and reduced workload for participating NRAs and manufacturers or other applicants.

4.3.4 As a minimum, the technical documentation in the submission should be sufficient to enable a participating NRA to verify and ensure the sameness of the product, as defined above in section 4.2 of this Procedure, and to meet existing technical requirements for a specific country.

4.3.5 Should the applicant for national registration be a person or legal entity other than the manufacturer of the WHO-prequalified product, the relationship between the two parties must be clearly stated and agreement must be reached to the effect that the information requested by the participating NRA will be passed from the manufacturer via the applicant.

4.3.6 The translation of documents required in the national language is the responsibility of the manufacturer. The method and extent of verification of translation accuracy required are matters for decision by the individual participating NRAs.

## 4.4 Information shared under the Procedure

4.4.1 WHO, with the agreement of the applicant/manufacturer of the WHO-prequalified product (see Appendix 2), shares the full outcome of prequalification assessment – including dossier review, manufacturing site inspections and performance evaluation reports – with participating authorities under appropriate obligations of confidentiality and restrictions on use.

[5] Labelling includes labels and the instructions for use.

[6] The product information may be translated into another language provided the information content is the same as that approved by WHO.

4.4.2 With regard to sharing the outcomes/results of the dossier review, manufacturing site inspections and performance evaluations, only data owned by the applicant/manufacturer of the WHO-prequalified product and/or by WHO are shared. Sharing of any other data (for example, related to third parties) is subject to the additional agreement of the data owners concerned.

4.4.3 For the purpose of the Procedure, participating authorities accept the product documentation and reports in the formats in which they are routinely prepared by WHO as specified in *Overview of the WHO prequalification of in vitro diagnostics assessment: WHO prequalification of in vitro diagnostics (3)*. It should be noted, however, that participating authorities may require applicants to comply with specific requirements for local regulatory review. Each participating authority should make such specific requirements public.

4.4.4 WHO encourages participating NRAs not to perform repetitive dossier assessment of thoroughly assessed data but rather to focus on data verification so that they can be assured that the product submitted for registration is the same as the WHO-prequalified product. Nor is it recommended that participating NRAs re-inspect sites that have already been inspected and found to be compliant with WHO requirements. It is also not recommended to repeat any performance evaluations to determine sensitivity/specificity if such evaluations were carried out as part of the WHO prequalification assessment. Efforts should instead focus on market surveillance.

Results from the performance evaluation organized in the course of the WHO prequalification assessment will be included in the information package available to each participating authority.

4.4.5 The sharing of information related to the Procedure between WHO, applicants/manufacturers of WHO-prequalified products and participating NRAs is governed by Appendices 1–4 of this document. Completed Appendices 1 and 2 must be submitted to WHO without any change in their content. Provision of Appendices 3 and 4 can be substituted by the provision of the same information by other means.

## 4.5 Applicable national registration fees

The payment of fees by the applicants to participating authorities continues to follow standard national procedures. Similarly, the submission by manufacturers of product samples (if required or applicable) continues to follow the standard operating procedures defined in national legislation and/or as defined by the NRAs.

## 4.6 Participating authority commitments

4.6.1 Consistent with the terms of Appendix 1: Part A and Appendix 3: Part B, each participating authority commits itself:

- to treat any information and documentation provided to it by WHO pursuant to this Procedure as confidential in accordance with the terms of Appendix 1: Part A, and to allow access to such information and documentation only to persons:[7]
  - who have a need to know for the purposes of the dossier assessment, manufacturing site inspections, performance evaluation and accelerated

[7] This includes the focal point(s) and all other persons in the NRA who have access to any information and documentation provided by WHO.

registration of the product in question in the country, and any post-registration processes that may be required; and

- who are bound by confidentiality undertakings in respect of such information and documentation which are no less stringent than those set out in Appendix 1: Part A;

- to issue its national regulatory decision on registration of a given WHO-prequalified product (whether positive or negative) within 90 calendar days[8] of regulatory time.[9]

  If the applicant:
  - fails to reply within a reasonable time frame (for example, 90 days);
  - fails to outline a plan to obtain and provide the requested information; and/or
  - fails to provide additional data, or respond to other queries raised by NRAs, and delays the completion of missing parts of the documentation without any justification then the participating NRA is entitled to terminate the Procedure for that specific product and switch to the normal registration process. Such termination is communicated to the applicant and to WHO using Appendix 3: Part C or by providing the same information in another format.

4.6.2 These commitments are agreed to by each participating authority in writing to WHO by entering into the agreement for participation in the Procedure reproduced in Appendix 1: Part A and are reconfirmed for each IVD for which collaboration is being sought (see Appendix 3: Part B).

4.6.3 Each participating NRA nominates a maximum of three focal points and specifies their areas of responsibility (for example, manufacturing site inspections, dossier assessment or performance evaluation). These focal points will access the restricted-access website through which WHO will communicate all confidential information and documentation. The number of focal points can be increased upon a justified request by the participating NRA to WHO.

4.6.4 Focal points designated by the participating NRA must sign the undertaking reproduced in Appendix 1: Part B before they will be granted access to the restricted-access website. Any change in designated focal points must be communicated to WHO in writing without delay and must be accompanied by an undertaking (Appendix 1: Part B) signed by the new focal point(s).

4.6.5 To successfully operate the Procedure, it is important for participating authorities to establish a clear registration pathway for WHO-prequalified IVDs, including by making relevant information publicly available for applicants, and by developing and implementing

[8] Participating authorities should issue their national regulatory decision at the earliest opportunity after being given access to the confidential information and documentation on a given WHO-prequalified product. If a participating authority does not issue its decision within 90 calendar days of regulatory time and does not communicate valid reasons for the delay to WHO, WHO may follow up with the head of the NRA to clarify the situation. In emergency situations, the timeline should be reduced as much as possible to facilitate access to urgently needed products.

[9] 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.

standard operating procedures for internal use to facilitate regulatory decision-making based on available information from WHO.

## 4.7 Regulatory decision(s) on a WHO-prequalified IVD

The decision on whether to register a given product in a particular country remains the prerogative and responsibility of each participating authority. Accordingly, a participating authority may come to a different conclusion from that reached by WHO or can decide to terminate the Procedure for a specific product. Within 30 calendar days of having taken its decision, the participating authority reports this decision to WHO, together with the dates of submission and registration and, if applicable, any deviations from the WHO prequalification decision and the reasons for such deviations.[10] A decision to discontinue the Procedure for a specific product should also be reported to WHO. All decisions are reported through the restricted-access website by completing the form provided in Appendix 3: Part C or by providing the same information in another format. The participating NRA provides either a copy of the completed form or the corresponding information in the other format to the applicant.

## 4.8 Manufacturer commitments

4.8.1 Participation in the Procedure by a manufacturer of a WHO-prequalified IVD is voluntary and involves submission to a participating NRA of the expression of interest provided in Appendix 3: Part A. For each product, participation will be subject to acceptance by the manufacturer of the terms of the Procedure, including the confidential exchange of information and documentation between WHO and the participating NRA (see Appendix 2).

4.8.2 The manufacturer of the WHO-prequalified product can end their participation in the Procedure at any time, provided they inform WHO and the participating NRAs in writing of their decision to do so. In such a case, the participating NRA shall stop using all of the information disclosed to it for the relevant product(s) as per the terms of the participation agreement (see Appendix 1).

4.8.3 Participation in this Procedure does not exempt applicants for national registration and/or holders of national registration from the respective national regulatory requirements.

# 5. Steps in the Procedure for market authorization of a WHO-prequalified IVD

5.1 As a preliminary step, the NRA confirms its interest in participating in the Procedure by signing and submitting to WHO the agreement for participation in the Procedure provided in Appendix 1: Part A. The NRA also designates the focal points to be given access to the WHO restricted-access website. The designated focal points complete, sign and submit to WHO the confidentiality undertaking (Appendix 1: Part B). This step is updated as necessary (for example, if the NRA changes its designated focal points). Thereafter, WHO lists the participating NRAs on its public website.

[10] This refers to a decision not to approve the registration of a WHO-prequalified product and to a decision to approve the registration, but with deviations.

5.2 The applicant submits the application for national registration of a WHO-prequalified IVD to a participating NRA. The technical data included in the dossier should be essentially the same as the data in the dossier approved for the prequalification of the product, including changes (where applicable). The submission should be consistent with section 4.3 above. The applicant must provide the participating authority with:

- a product dossier complying with established national requirements and in line with section 4.3 above:
  - to the extent that national regulatory requirements allow, the technical content of the dossier should be essentially the same as that of the WHO-prequalified product. In specific cases the NRA may prefer a dossier which is abbreviated in line with national requirements;
  - if acceptable to NRAs, not only should the technical content of the dossiers be essentially the same, but the format in which data are presented should also closely follow the format in which dossiers are submitted to WHO – that is, a "Table of Contents" format;
- the expression of interest provided in Appendix 3: Part A;
- data according to country-specific requirements; and
- any fees that may be payable to the NRA pursuant to national requirements.

5.3 The applicant informs the participating NRA of their interest in following this Procedure by completing the expression of interest provided in Appendix 3: Part A. If the applicant for national registration is not the same as the manufacturer/holder of the WHO-prequalified IVD, the manufacturer of the WHO-prequalified IVD must confirm to the participating NRA and to WHO by means of an authorization letter (as per the form annexed to Appendix 3: Part A) that the applicant is acting for, or pursuant to rights derived from, the manufacturer of the WHO-prequalified IVD, and that the manufacturer agrees with the application of this Procedure in the country concerned.

5.4 Wherever possible, to minimize the workload of the participating NRA and facilitate the process, applicants should ensure that they express their interest in using the Procedure (Appendix 3: Part A) to the participating NRA and to WHO before submitting a national application for registration. In situations where the applicant wishes to apply the Procedure to an application already pending within the NRA, the applicant should first update the dossier to ensure that the technical part of the information is essentially the same as that approved by WHO.

5.5 For each application under this Procedure, the manufacturer of the WHO-prequalified IVD informs WHO of the submission of its application to the participating NRA(s) by providing WHO with a completed copy of Appendix 3: Part A. For each product and country, the manufacturer also provides WHO with its written consent for WHO to provide the product-related information and documentation, in compliance with the applicable confidentiality requirements, to the participating NRA of the country concerned. To this end the manufacturer completes, signs and submits to WHO the consent form provided in Appendix 2.

5.6 For each application, the participating NRA notifies WHO and the relevant applicant of its decision to accept or decline to apply this Procedure to the application (Appendix 3: Part B). It is at the discretion of each participating NRA to decide whether to apply the

Procedure to individual submissions. The Procedure applies only to applications that the participating NRA has accepted as complete.

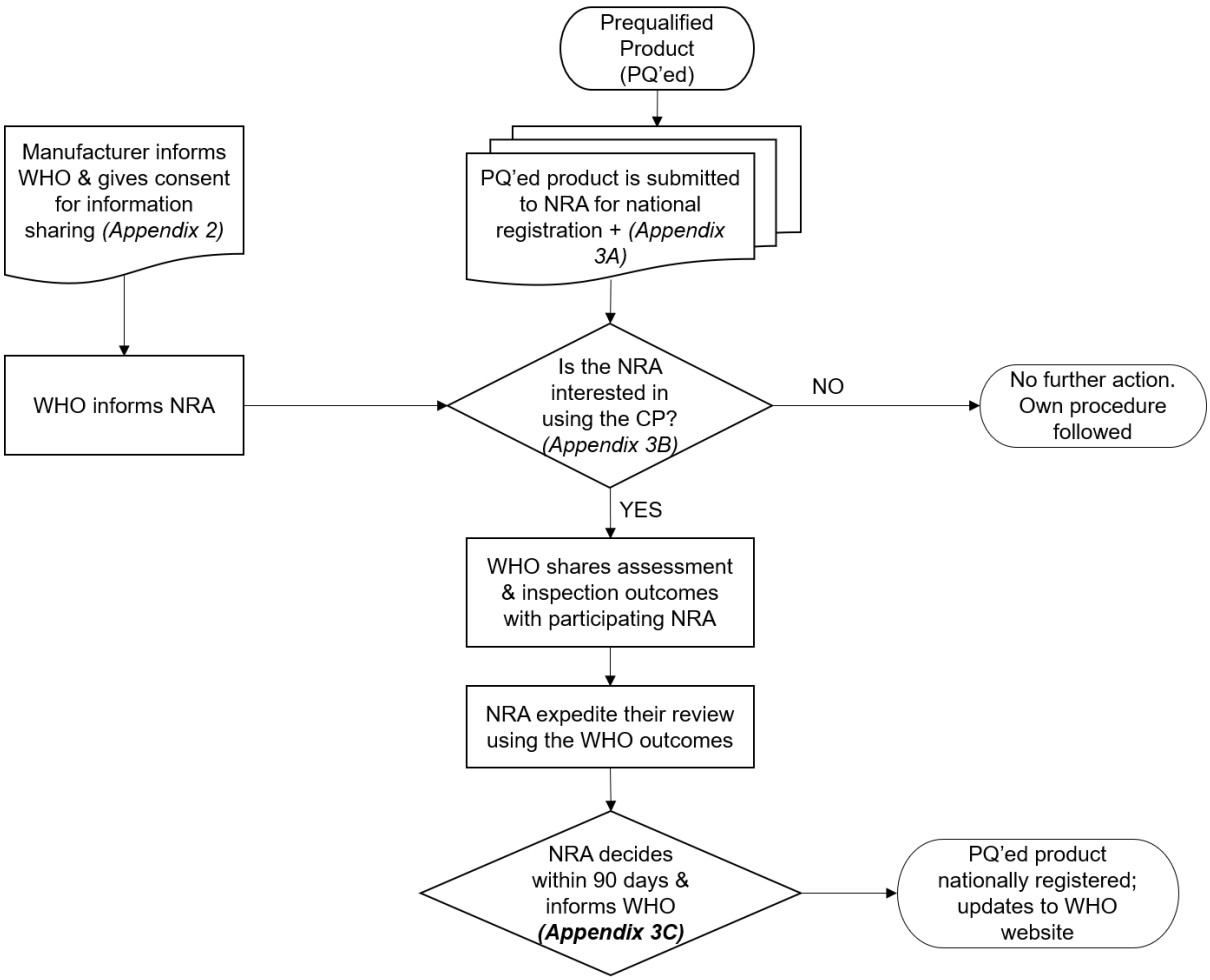
5.7 Within 30 calendar days of receipt of the manufacturer's consent, WHO shares with the participating authority the most recent product-related information, and dossier assessment, manufacturing site inspection and performance evaluation outcomes, through the restricted-access website. This information is subject to the obligations of confidentiality and restrictions on use, and may include dossier assessment report(s), change assessment report(s) (if applicable), manufacturing site inspection report(s), performance evaluation results and the letter of WHO prequalification. At the request of the participating authority, WHO will provide explanations and/or more-detailed information. If participating NRAs have significant concerns or questions which would preclude the registration of the prequalified IVD in their country, questions may be sent to WHO – preferably within 60 calendar days of the first day of regulatory time. WHO will facilitate resolution of the problem in cooperation with relevant parties.

5.8 After receiving the information and documentation from WHO, the participating authority undertakes an assessment of the product in question within the agreed 90-day turnaround time. One pragmatic approach is to verify whether the product submitted for registration is the same as the product already prequalified (see section 4.2 above) and to assess only those areas which relate to the use of the product in the country concerned, and where failure to comply with regulatory standards could pose health risks. In the remaining areas, the WHO prequalification outcomes may be adopted.

5.9 For each application, the participating authority is required to issue the relevant national decision within 90 calendar days of regulatory time. Within 30 days of having taken its decision, the participating authority reports this decision, together with an indication of the dates of submission, registration and, if applicable, the length of the non-regulatory time. The participating authority also reports any deviations from the WHO prequalification conclusion and the reasons for such deviations or, if a decision has been made to discontinue the Procedure for a product, the reasons for such discontinuation, to WHO. All decisions are reported through the restricted-access website by completing the form provided in Appendix 3: Part C or by providing the same information in another format. The participating NRA provides either a copy of the completed form or the corresponding information in the other format to the applicant. WHO lists IVDs registered by participating NRAs pursuant to this Procedure on its public website.

5.10 The steps in the Procedure for national registration of a WHO-prequalified IVD product are summarized in Fig. 1.

Fig. 1
**Steps in the Procedure for national registration of a WHO-prequalified IVD product**




## 6. Collaboration mechanisms for post-prequalification and/or post-registration changes

6.1 The requirements and procedures in case of a change – as defined in applicable WHO guidance *(5)* – may differ between participating authorities and WHO. This Procedure includes a change procedure which aims to promote consistency between changes accepted by WHO and changes accepted by participating authorities. There could be situations in which a manufacturer of a WHO-prequalified product submits a change application to WHO but not to the participating NRA or vice versa.

In such a situation the conditions of the national registration, which were initially "harmonized" with the WHO decision, may become essentially different through the life-cycle of the product. In this case, a product registered and procured in a participating country would no longer be the same as the WHO-prequalified product because the specifications, manufacturing sites and/or other essential parameters would no longer be the ones accepted by WHO.

Manufacturers of WHO-prequalified products and participating NRAs are expected to inform WHO of the changes and the reasons for them if, due to inconsistencies in changes, the nationally registered product is no longer the same as the WHO-prequalified product. Similarly, WHO will inform participating NRAs when such changes are accepted for WHO-prequalified products. It is important for the manufacturer to evaluate the potential effect the

change may have on the safety, quality and performance of the product. Certain changes – such as change of labelling into the local language with no impact on product quality, safety and performance – are not considered as reportable.

6.2 Applicants are required to submit to any relevant participating authorities without delay – at the latest 30 calendar days after acceptance of the changes by WHO – those changes which are subject to national regulatory requirements. Applicants should inform participating NRAs that the same application for change is being processed by WHO. The submission of changes to participating NRAs should be in line with national regulatory requirements.

6.3 WHO promptly shares with the relevant participating NRA (through the restricted-access website, and subject to the above-mentioned obligations of confidentiality and restrictions on use) the outcomes of change assessments and of manufacturing site inspections conducted subsequent to prequalification listing, as well as any field safety corrective action undertaken to maintain compliance with prequalification quality, safety and performance requirements. Participating authorities are encouraged to follow the outcomes of the WHO change assessments for nationally approved WHO-prequalified IVDs.

The obligations of manufacturers to report adverse events and other relevant post-marketing information to WHO are spelt out in WHO prequalification procedures. In addition to these procedures, manufacturers should follow the specific safety provisions of national regulations when reporting to NRAs.

6.4 If a change approved by the participating NRA results in the nationally registered product no longer being the same as the WHO-prequalified product (see section 4.2) or if a change to the WHO-prequalified product is not followed by the same change to the nationally registered product (in the event that the particular change is subject to national regulatory requirements) and, as a consequence, the nationally registered product is no longer the same, then:

- the manufacturer of the WHO-prequalified IVD informs WHO of the differences and the reasons for them; and
- the participating authority informs WHO of the situation by submitting the form provided in Appendix 4, clearly specifying the deviations.

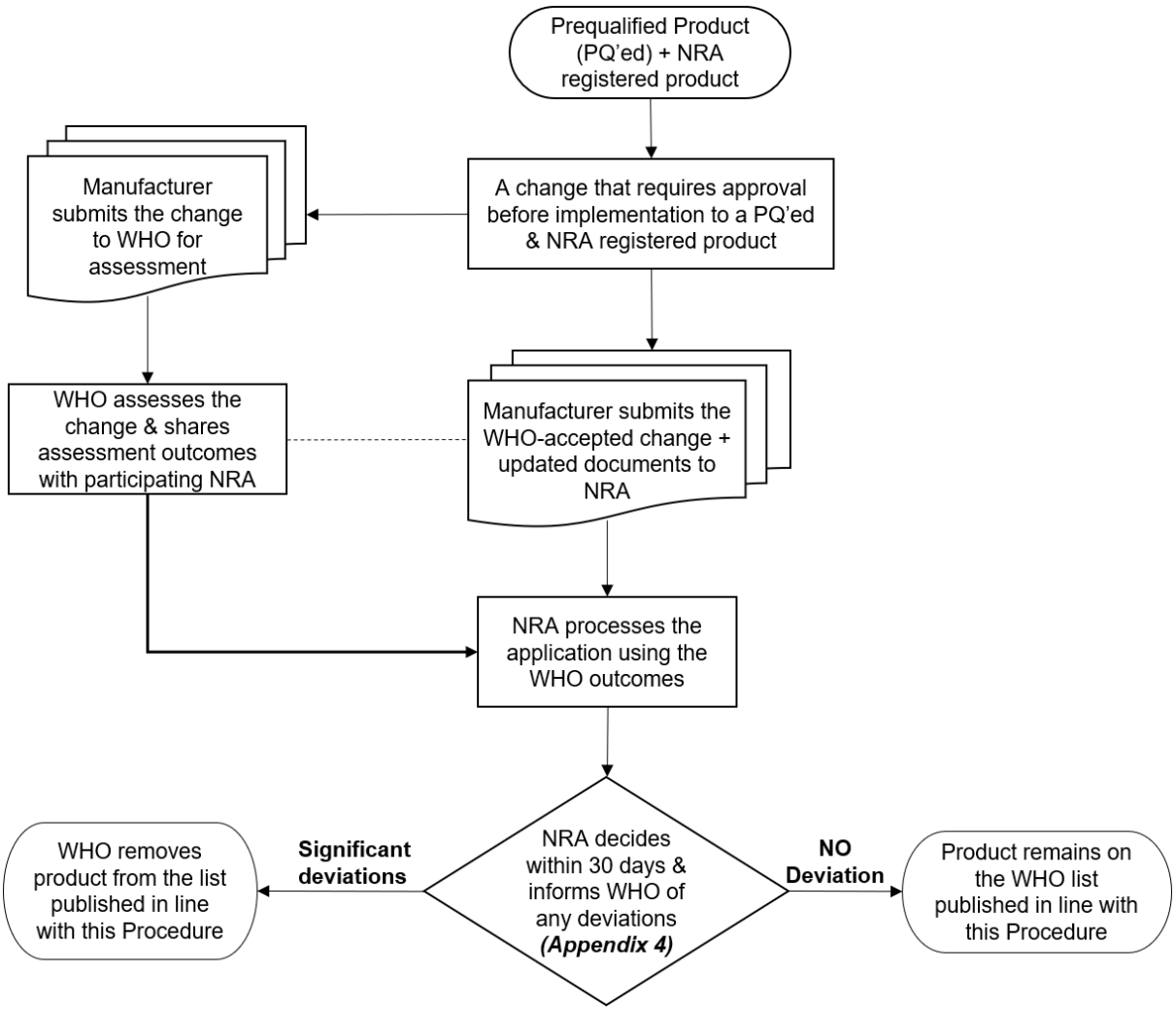
6.5 Within 30 days of obtaining access to the relevant information and documentation from WHO, each participating authority will inform WHO, through the restricted-access website, if and to what extent changes to a WHO-prequalified product are not followed by the same accepted changes to the nationally registered product and that, as a consequence, the nationally registered product is no longer the same as the WHO-prequalified product (see section 4.2 above). Changes approved by WHO will be considered by WHO as accepted by the participating NRA on a non-objection basis 30 days after the information-sharing described in section 6.3 above, unless and until the participating NRA informs WHO otherwise. Other participating NRAs that have registered the prequalified product in question pursuant to this Procedure will be made aware of such deviations through the restricted-access website.

6.6 WHO shall remove a product from the list of products approved under the Procedure if the nationally registered product is no longer the same as the WHO-prequalified product (see section 4.2 above). In addition, if a WHO-prequalified product has been registered in a

particular country pursuant to this Procedure and this has been made public by the NRA then any subsequent deviations should also be made public.

6.7 The steps for managing post-approval changes under this Procedure are summarized in Fig. 2.

Fig. 2
**Managing post-approval changes under this Procedure**




## 7. Withdrawals, suspensions or delisting of WHO-prequalified IVDs and national deregistration

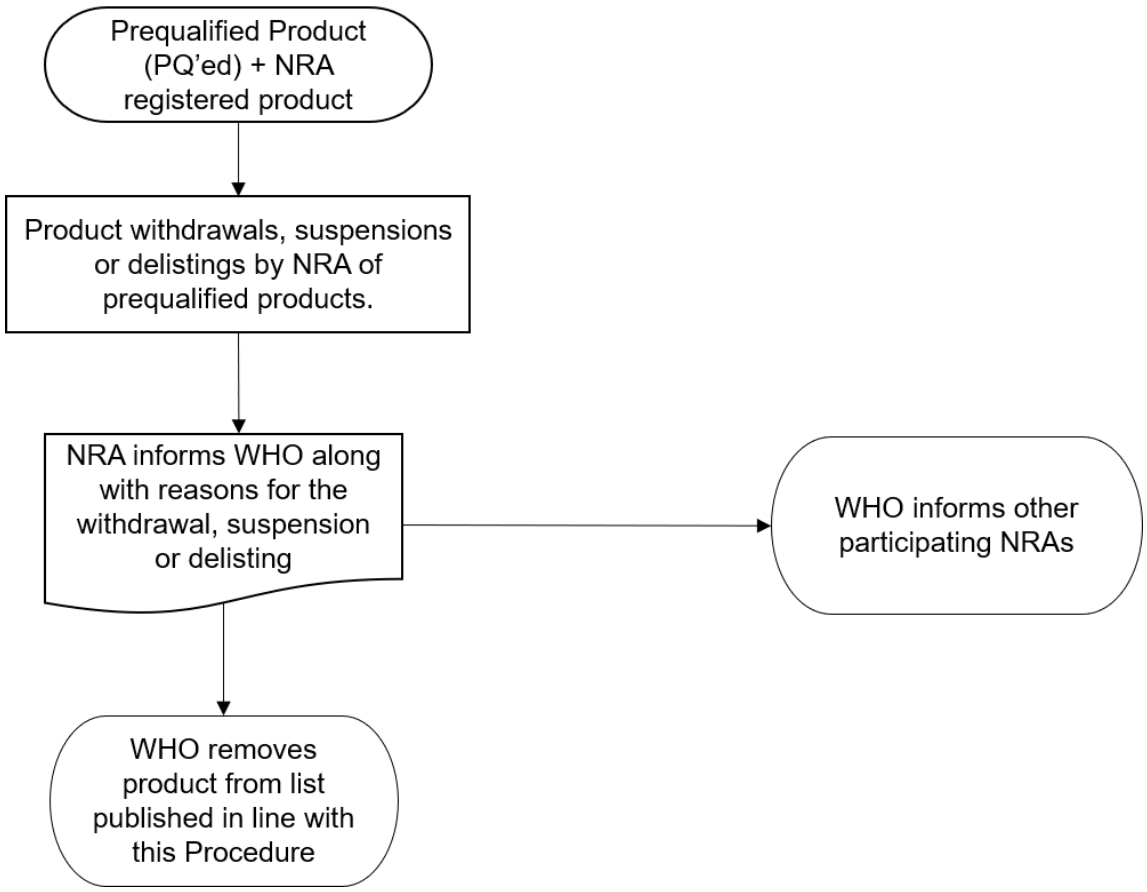
7.1 If a WHO-prequalified product is withdrawn by the manufacturer, or is suspended or delisted by WHO, then WHO will inform each participating authority that has approved the product or is in the process of reviewing the product pursuant to this Procedure of the withdrawal, suspension or delisting (together with the reasons for taking the action) through the restricted-access website, and subject to the obligations of confidentiality contained in Appendix 1: Part A.

7.2 In the case that a participating NRA deregisters or suspends the registration of a WHO-prequalified IVD for any reason, the participating authority will inform WHO of the decision (together with an indication of the reasons) through the restricted-access website. This information should be provided promptly whenever there are concerns about product quality, safety or performance and in all other cases within 30 days of the decision being taken. A participating authority is encouraged to consult WHO before adopting a decision about deregistration or suspension of registration of a WHO-prequalified product. Other participating NRAs who have registered the WHO-prequalified product in question pursuant to this Procedure will be made aware of such national deregistration or suspension through the restricted-access website.

7.3 In the case that a participating NRA deregisters or suspends registration of a WHO-prequalified product at the national level, or in the case that WHO suspends or delists a prequalified product, WHO will adjust the information on the product given on its website accordingly.

7.4 Fig. 3 summarizes the maintenance of registration status of a WHO-prequalified product. The participating NRA should inform WHO of any regulatory action taken nationally for a product registered through the Procedure. WHO will update the list of nationally registered products accordingly and inform other participating NRAs, where applicable, in cases of quality- or safety-related regulatory action.

Fig. 3
**Maintenance of registration status of a WHO-prequalified product**



## 8. References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# 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: Click or tap here to enter text ("the NRA")

Postal address: 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

Country: Click or tap here to enter text ("the Country")

Telephone number: Click or tap here to enter text (please include codes)

Email: Click or tap here to enter text

### 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").[11]

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

[11] 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.

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),[12] 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
- 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

[12] 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).

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[13] 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[14] as the WHO-prequalified product, or if and to the extent change

[13] 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.

[14] 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

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 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);[15]

- 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.[16] This same person should be designated for IVD-related inspections.

- Mr/Ms/Dr

First name (and initials): Click or tap here to enter text

Surname/family name: Click or tap here to enter text

Title in NRA: 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

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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.

[15] 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.

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

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

**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): Click or tap here to enter text

Surname/family name: Click or tap here to enter text

Title in NRA: 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

☐ A signed Undertaking is attached

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

First name (and initials): Click or tap here to enter text

Surname/family name: Click or tap here to enter text

Title in NRA: 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

☐ 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: 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

Attachments:

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

## Appendix 1: Part B

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

The undersigned:

- Mr/Ms/Dr

First name (and initials): Click or tap here to enter text

Surname/family name: Click or tap here to enter text

Title in NRA: Click or tap here to enter text

Name of NRA: Click or tap here to enter text ("the NRA")

Country: Click or tap here to enter text ("the Country")

Telephone number: Click or tap here to enter text (please include codes)

Email: Click or tap here to enter text

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.

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[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 2020).

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: | 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 2

## Consent of WHO prequalification holder for WHO to confidentially share information with the NRA under the Procedure

Reference is made to the attached expression of interest in the assessment and accelerated national registration 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") of the following WHO-prequalified IVD (hereafter referred to as "the Product") in:

Country: Click or tap here to enter text ("the Country").[19]

☐ IVD

**WHO prequalification details**

WHO prequalification (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:[20] Click or tap here to enter text

**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

The WHO PQ holder hereby consents to WHO providing the following information and documentation to the national regulatory authority (NRA) of Click or tap here to enter text [country] ("the NRA") for the assessment and accelerated registration of the Product in the country under the Procedure and to freely discuss the same with the aforesaid NRA for this purpose:

- the full WHO assessment and inspection outcomes (reports), results of performance evaluation and, if relevant, 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;

[19] Please complete a separate copy of this Appendix for each country.

[20] 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.

- information and documentation on subsequent changes (as defined in WHO guidance),[21] as well as information and documentation on any actions taken by WHO 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 assessment, 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.[22] Such consent is subject to the NRA having entered into an agreement with WHO as per Appendix 1: Part A to the Procedure and having agreed to conduct the assessment and consider the accelerated registration of the Product under the Procedure, by having submitted the form reproduced in Appendix 3: Part B to the Procedure to WHO.

The WHO PQ holder/Applicant commits to submit post-prequalification changes to WHO and any relevant participating authorities, respecting national regulatory requirements. Changes should be submitted to participating authorities at the latest 30 calendar days after acceptance of the changes by WHO. Participating authorities should be informed of the fact that the same application for a change is being processed by WHO. If a national change procedure results in the nationally registered product being no longer the same[23] as the WHO-prequalified product, or if a change to the 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, the WHO PQ holder/Applicant will inform WHO of the differences and the reasons for them.

**For the 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

[21] 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).

[22] In the case that certain data submitted to WHO by the WHO PQ holder in relation to the prequalification of the Product are not in their ownership, the WHO PQ holder specifies such data in an annex to this declaration of consent.

[23] 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.

# 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 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

**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

[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: 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[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:

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
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: 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

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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).

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?[30]

☐ 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**

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

**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

☐ 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 |

# Appendix 4

## Report on post-registration actions in respect of a product registered under the Procedure

☐ Change of the national registration resulting in the national registration conditions being inconsistent with the WHO prequalification conclusions

☐ Deregistration or suspension of the registration of the product

☐ Field Safety Corrective Action (FSCA) issued on the product

### Product details

Product name in national system: Click or tap here to enter text ("the Product")

National registration number: Click or tap here to enter text

Date of registration (dd/mm/yyyy): 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 national changes procedure has resulted in the nationally registered Product being no longer the same[31] as the WHO-prequalified product

| 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 |

☐ The changes notified to the NRA by WHO have not been followed by a change to the nationally registered Product and, as a consequence, the nationally registered Product is no longer the same[32] as the WHO-prequalified product

[31] 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.

| 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 |

☐ The Product has been deregistered or the registration of the Product has been suspended

Deregistration: ☐ Yes ☐ No

Suspension of registration: ☐ Yes ☐ No

Effective date (dd/mm/yyyy): Click or tap here to enter text

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

[32] 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.