



World Health Organization

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva 19 to 23 October 2020

COLLABORATIVE PROCEDURE BETWEEN THE WORLD HEALTH ORGANIZATION (WHO) AND NATIONAL REGULATORY AUTHORITIES IN THE ASSESSMENT AND ACCELERATED NATIONAL REGISTRATION OF WHO-PREQUALIFIED IN VITRO DIAGNOSTICS (IVDS)

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS) and by the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).

Publication of this draft is to provide information about the proposed *Guidelines for Collaborative Procedure between the World Health Organization (WHO) and National Regulatory Authorities in the assessment and accelerated National Registration of WHO-Prequalified In Vitro Diagnostics* to a broad audience and to improve transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulation of the ECBS. Written comments proposing modifications to this text MUST be received by 15 July 2020 using the Comment Form available separately and should be addressed to: Department of Health Products Policy and Standards (HPS), World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Comments may also be submitted electronically to the Responsible Officer: gunlud@who.int.

The outcome of the deliberations of the ECBS and ECSPP will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the second edition of the *WHO style guide* (KMS/WHP/13.1).

All rights reserved.

This draft is intended for a restricted audience only, i.e. the individuals and organizations having received this draft. The draft may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means outside these individuals and organizations (including the organizations' concerned staff and member organizations) without the permission of the World Health Organization. The draft should not be displayed on any website.

The designations employed and the presentation of the material in this draft do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this draft. However, the printed material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This draft does not necessarily represent the decisions or the stated policy of the World Health Organization.

Table of Contents

Background.....	4
Introduction	6
Aims and objectives of the Collaborative Procedure	6
Scope	7
Glossary	8
Principles and general considerations	10
Participating parties	10
Sameness of the prequalified product and nationally registered product.....	10
Submissions format and content of product dossiers to NRAs	11
Information shared under the Collaborative Procedure	12
Applicable national registration fees	13
Participating authority commitments	13
Regulatory decision(s) on a prequalified product	15
Manufacturer commitments	16
Steps in the collaboration for national registration of a prequalified in vitro diagnostic	17
Collaboration mechanisms for post-prequalification and/or post-registration variations/changes.....	24
Withdrawals, suspensions or delistings of prequalified IVDs and national deregistrations.....	28
References	30
Appendices	Error! Bookmark not defined.

1. Background

1.1 National assessment of applications for registration (marketing authorization) of in vitro diagnostics (IVDs) is the key regulatory process that enables a national regulatory authorities (NRAs) to evaluate and monitor the quality, safety, and performance of the IVDs. For most countries, the approach to registration of IVDs is a combination of the following two components:

- the NRA's own assessment of technical documentation combined with verification of compliance with relevant good practices through manufacturing site inspections (mostly focusing on quality management systems),
- consideration by the NRA of decisions and outcomes of assessments, performance evaluations and manufacturing site inspections made by NRAs in other countries or by the World Health Organization (WHO) Prequalification Team (WHO-PQT).

1.2 Consideration of the outcomes/results of assessments, performance evaluations and manufacturing site inspections by WHO-PQT, or by national regulatory authorities of other countries whose regulatory decisions are based on acceptable standards, substantially contributes to savings in regulatory resources and improvements in the quality of regulatory decisions, while retaining the prerogative of NRAs to conclude their assessment by sovereign decisions, which reflect their own judgement of the benefit–risk balance as it relates to their specific country situation and the legislation in place. Taking into consideration the regulatory decisions of other NRAs, or the prequalification by WHO-PQT, requires setting up a system that will permit:

- identification of reference authorities whose regulatory decisions are based on acceptable standards and identification of documents associated with such regulatory decisions, which are relevant to the regulatory environment in the country wishing to rely on such decisions;

- assurance that the product for which the decision has been taken by the reference NRA is the same (see section 3.2) as the product being assessed 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 decide, with reasonable certainty, on the benefit–risk profile of an evaluated product when used in a given country;
- the choice by each NRA of the approaches that will make best use of the resources, workload and competencies of individual NRAs.

1.3 Approaches could range from completely independent data reviews and inspections to adoption of the regulatory decisions of reference authorities or of the prequalification by WHO-PQT without any further scientific review. A pragmatic approach is to verify whether the product submitted for registration is the same (see section 3.2) as the product already approved by reference authorities or prequalified by WHO and assess only those areas which relate to use of the product in the country concerned and where failure to comply with regulatory standards could pose health risks. In the other areas, the outcomes of reference authorities or of WHO-PQT may be adopted.

1.4 Collaborative registration procedures (CRP) have been developed and implemented with a view to accelerate national registrations and the regulatory life-cycle of pharmaceutical products and vaccines prequalified by World Health Organization (WHO), or approved by reference authorities (1, 2). Based upon WHO's experience with the "*Collaborative Procedure between the World Health Organization (WHO) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines*", WHO has developed this Collaborative Procedure 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 the scientific assessment work conducted by WHO-PQT.

2. Introduction

This Collaborative Procedure has been developed based on the above-mentioned considerations to enhance timely access to WHO-prequalified products in countries, to ensure that the product in countries is the same as the one which is WHO-prequalified and to provide a model for regulatory information exchange between countries.

2.1. Aims and objectives of the Collaborative Procedure

2.1.1 This Collaborative Procedure aims to provide a convenient tool for NRAs wishing to enhance their premarketing evaluation and registration system by taking advantage of the WHO prequalification assessment, in-line with the *Procedure for WHO Prequalification of In Vitro Diagnostics* (3) and the *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices* (4).

2.1.2 The objectives of this document are to:

- Describe the Procedure for accelerating national registrations of WHO-prequalified IVDs in participating NRAs based on exchange of assessment, manufacturing site inspection and performance evaluation outcomes between WHO-PQT and the NRAs.
- Provide a resource for manufacturers or applicants with prequalified IVDs, and participating NRAs to implement facilitate national registrations for prequalified IVDs.

2.1.2 Enhanced collaboration and information exchange between NRAs and WHO-PQT benefits all partners. Subject to the agreement of the concerned applicant or manufacturer with a WHO-prequalified IVD, participating NRAs have access to assessment, manufacturing site

inspection and performance evaluation outcomes that are not in the public domain and that have been prepared in conformity with the WHO recommended standards on which the *Procedure for WHO Prequalification of In Vitro Diagnostics* are based (3). Such reports and relevant WHO documents help participating NRAs to make their decisions and also assist in training national regulatory staff. At the same time, feedback from participating NRAs on the information and documentation received from WHO-PQT under the Procedure allows WHO-PQT to improve its work and ensures that the outcomes of its assessments are relevant to NRAs. As a consequence, patients benefit from this collaboration by gaining faster access to IVDs that have been found acceptable in principle for procurement by United Nations (UN) agencies and WHO Member States. The collaborative registration procedure can be of particular relevance when implemented to expedite national approval of prequalified IVDs in emergency situations.

2.1.3 This Collaborative Procedure also benefits manufacturers of WHO-prequalified IVDs through faster and better harmonized regulatory approvals in participating countries, and contributes to alleviating the burden of additional national inspections on manufacturers and performance evaluations.

2.2.Scope

2.2.1 This Collaborative Procedure is applicable to IVDs that have been assessed and inspected by WHO-PQT in line with the procedures and standards available at http://www.who.int/diagnostics_laboratory/evaluations/en/ and that have been found to be acceptable in principle for procurement by UN agencies and WHO Member States, as listed in the *List of WHO prequalified IVDs*, available at http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

2.2.2 The Collaborative Procedure serves to accelerate the assessment and registration of IVDs prequalified by WHO-PQT based on both full assessment and abridged assessment.

2.2.3 This Collaborative Procedure covers national registrations and management of variations/post approval changes.

2.3. Glossary

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

abridged assessment. A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements whilst relying on prior assessment and inspection outcomes from a reference authority or WHO Prequalification to inform the local decision.

collaborative procedure or Procedure. Procedure for collaboration between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and interested national regulatory authorities (NRAs) in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostic medical devices (IVDs).

manufacturer. means any natural or legal person with responsibility for design and/or manufacture of a diagnostic with the intention of making the diagnostic available for use, under his name; whether or not such a diagnostic is designed and/or manufactured by that person himself or on his behalf by another person(s).

participating authorities or participating NRAs. NRAs that voluntarily agree to implement this collaborative procedure and accept the task of processing applications for registration of WHO-prequalified IVDs in accordance with the terms of the Procedure. A list of participating authorities is posted on the WHO-PQT website (http://www.who.int/diagnostics_laboratory/evaluations/en/).

in vitro diagnostic medical device (IVD)¹. A medical device, whether 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. IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

performance evaluation. Assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of an IVD medical device.

verification. The procedure by which a regulatory authority only confirms the product or submission, and ensures that the product for local marketing is equal or similar to that approved by the reference authority or prequalified by WHO-PQT.

¹ IMDRF/GRRP WG/N47 FINAL 2018. Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.

3. Principles and general considerations

3.1.Participating parties

This Collaborative Procedure has three major stakeholders: interested NRAs, WHO-PQT and those interested applicants² or manufacturers who agree that this Procedure be used for applications for national registration of their WHO-prequalified IVD submitted to participating NRAs. The marketing authorization in a given country will be done by the NRA. To the extent that institutions are commissioned by these NRAs (or the manufacturer/applicant) to perform laboratory evaluations as part of the overall assessment, then this does not change the fact that the main stakeholder vis-a-vis WHO is the NRA itself.

3.2.Sameness of the prequalified product and nationally registered product

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

- the same product name,
- the same specifications, including the same regulatory version and the same product code,
- the same site of manufacture and quality management system,
- the same data on quality, safety and performance,
- the same design, with the same components from the same suppliers,

- same information, labelling³ and packaging including instructions for use and intended use.⁴

3.3.Submissions format and content of product dossiers to NRAs

3.3.1 The dossier submission to the participating NRAs should be in a harmonized format as required by WHO-PQT or IMDRF format (table of contents). In exceptional situations data can be organized differently in line with specific national requirements, however, the technical data included in the dossier should be essentially the same as the prequalified product. There may be country specific differences in administrative data.

3.3.2 Note, however, that participating authorities may require applicants to comply with specific additional national requirements or may accept abbreviated dossiers. Each participating authority is encouraged to reduce the scope of specific national requirements to align them with the Procedure and harmonize its requirements with the international format and content of a regulatory dossier. Specific national requirements should be made public.

3.3.3 Advantages of harmonized format include enabling the same dossier to be submitted across several participating authorities thus facilitating comparison, reliance and optimal utilization of assessment resources and less workload by participating NRAs and applicants.

3.3.4 As a minimum, the technical data in the submission should be sufficient to enable participating authorities to verify and ensure sameness of the product as defined in section 3.2 in this Procedure and meet existing technical requirements for a specific country/region.

³ Labelling includes labels and the instructions for use.

⁴ The language of the product information may be different as long as the information content is the same as that approved by WHO-PQT.

3.3.5 Should the applicant for national registration be a different person or legal entity than the manufacturer of the WHO-prequalified product, the relationship should be clarified and agreements assuring information flow should be adjusted to reflect this situation.

3.3.6 Translation of documents required in the national language is the responsibility of the manufacturer. The method and extent of verification of translation accuracy are a matter of decision of individual participating NRAs.

3.4.Information shared under the Collaborative Procedure

3.4.1 WHO-PQT, with the agreement of the applicant/manufacturer of the WHO-prequalified product, shares the full outcome of prequalification assessments, manufacturing site inspections and performance evaluations, including final assessment and inspection reports, with participating authorities, under appropriate obligations of confidentiality and restrictions on use (see below).

3.4.2 As regards sharing the outcomes/results of assessments, 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 (e.g. related to third parties) is subject to additional agreement of the data owners concerned.

3.4.3 For the purpose of this Collaborative Procedure, participating authorities accept the product documentation and reports in the format in which they are routinely prepared by WHO in accordance with the *Procedure for 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.

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

3.5.Applicable national registration fees

Fees to be paid by the applicants to participating authorities continue to follow standard national procedures. Similarly, the submission by manufacturers of product samples– if required or applicable – continues to follow standard procedures as defined in national legislation and/or as defined by NRAs. Participating authorities are advised to refrain from additional performance evaluation for marketing authorization, instead such efforts should be focused on post-marketing. Results from the performance evaluation organized in the course of WHO’s prequalification assessment will be included in the information package available to each participating authority.

3.6.Participating authority commitments

3.6.1 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-PQT pursuant to this Collaborative 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:⁵

⁵ This includes the focal point(s) and all other persons in the NRA who have access to any information and documentation provided by WHO-PQT

- who have a need to know for the purpose of the assessment, manufacturing site inspections, performance evaluation and accelerated 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 reproduced in Appendix 1, Part A;
- to issue its national regulatory decision on registration of a given prequalified product (whether positive or negative) within 90 calendar days⁶ of regulatory time.⁷ If the applicant takes a long time to complete missing parts of the documentation without any justification, to provide additional data or to respond to other queries raised by NRAs, or if the applicant fails to provide the participating NRA with necessary information and cooperation, the participating NRA is entitled

⁶ Participating authorities should issue their national regulatory decisions at the earliest opportunity after being given access to the confidential information and documentation on a given prequalified product. Although a time limit of 90 days of regulatory time is defined in the Procedure, the decision should normally be taken within 60 days. This deadline can be extended to a maximum of 90 days if predefined dates of technical or decision-making meetings do not allow a participating authority to issue its decision within 60 days. If a participating authority does not issue its decision within 90 days of regulatory time and does not communicate valid reasons for the delay to WHO-PQT, WHO-PQT can follow up with the head of the NRA to clarify the situation. The timeline should be reduced as much as possible to facilitate access to products needed in case of emergency situations.

⁷ 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.

to terminate the Collaborative Procedure and switch to the normal registration process. Such termination is communicated to the applicant and to WHO-PQT using Appendix 3, Part C.

3.6.2 These commitments are provided by each participating authority to WHO-PQT in writing by entering into the agreement for participation in this Collaborative Procedure as reproduced in Appendix 1, Part A and are reconfirmed for each IVD for which collaboration is sought (see Appendix 3, Part B).

3.6.3 Each participating NRA nominates a maximum of three focal points and specifies their areas of responsibility (e.g., manufacturing site inspections, assessment or performance evaluation). These focal points will access the restricted-access website through which WHO-PQT 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-PQT.

3.6.7 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-PQT in writing without delay and must be accompanied by an undertaking (Appendix 1, Part B) signed by the new focal point(s).

3.6.8 To successfully operate the Procedure, it is important for participating regulatory authorities to establish clear registration pathways for WHO-prequalified IVDs, including by making publicly relevant information publicly available for applicants, and by developing and implementing standard operating procedures (SOPs) for internal use to facilitate regulatory decision based on available information from WHO-PQT or reference participating authorities.

3.7.Regulatory decision(s) on a prequalified product

The decision whether or not 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-PQT or can decide to discontinue the Collaborative Procedure for a specific product. Within 30 calendar days of having taken its decision, the participating authority reports this decision to WHO-PQT, together with the dates of submission and registration and, if applicable, any deviations from WHO-PQT's decision on prequalification and the reasons for such deviations⁸ and/or any decision to discontinue the Collaborative Procedure for a specific product. It does so through the restricted-access website by completing the form in Part C of Appendix 3 or providing the same information in another format. The participating NRA provides a copy of the completed form or the information to the applicant.

3.8.Manufacturer commitments

3.8.1 Participation in this Collaborative Procedure by manufacturers of a WHO-prequalified IVD is voluntary, through the submission to a participating NRA of the expression of interest reproduced in Part A of Appendix 3. For each product such participation will be subject to the manufacturer of the WHO-prequalified product accepting the terms of this Collaborative Procedure, including the confidential exchange of information and documentation between WHO-PQT and the participating NRA (see Appendix 2).

3.8.2 The manufacturer of the prequalified product can cease participation in this Collaborative Procedure at any time provided that the manufacturer informs WHO-PQT and the participating NRAs in writing of its decision. In such a case, the participating NRA shall cease all use of the information disclosed to it for the relevant product(s) as per the terms of the participation agreement (see Appendix 1).

⁸ 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.

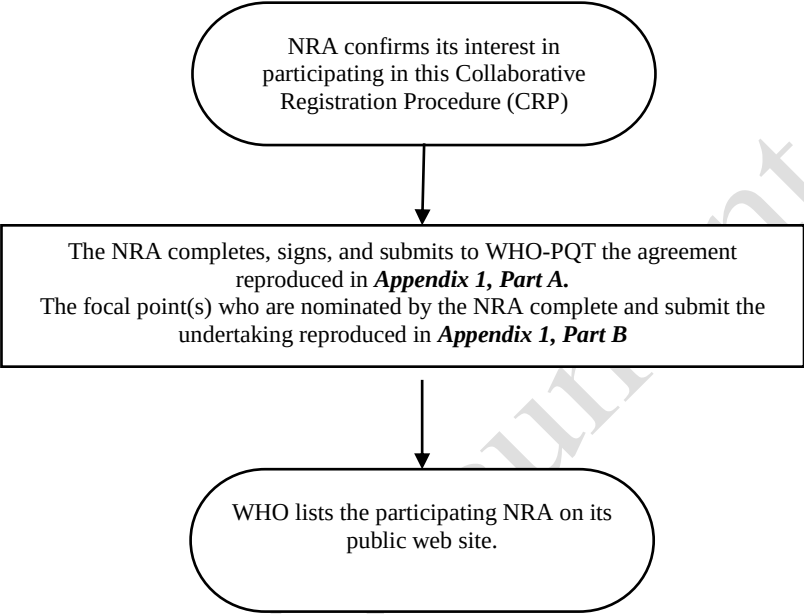
3.8.3 Participation in this Collaborative Procedure does not exempt applicants for national registration and/or holders of national registration from the respective national regulatory requirements. Participating authorities retain the right to assess submitted data and conduct site inspections and performance evaluations to the extent they deem appropriate. WHO encourages participating NRAs not to perform repetitive assessment of thoroughly assessed data, but rather to focus on data verification so that they can be assured that the same product is submitted for registration as that which is WHO-prequalified. It is highly recommended not to reinspect the sites that have already been inspected, and found to be compliant with WHO requirements, by WHO-PQT inspection teams. In addition, it is highly recommended not to redo performance evaluation where it has been carried out as part of the WHO prequalification assessment.

4. Steps in the collaboration for national registration of a prequalified in vitro diagnostic

4.1 As a preliminary matter, the national regulatory authority confirms to WHO-PQT its interest in participating in this Collaborative Procedure, and signs and submits to WHO-PQT the agreement for participation in this Collaborative Procedure (as reproduced in Appendix 1, Part A). The NRA also designates the focal points for access to the restricted-access website. The designated focal points complete, sign and submit to WHO-PQT the confidentiality undertaking (Appendix 1, Part B). This step is updated as necessary, for example, when the NRA changes the focal points. Thereafter, WHO-PQT lists the participating NRAs on its public website.

Figure 1, below, sets forth the principal steps for an NRA to participate in this Collaborative Procedure.

Figure 1: NRA Agreement to participate in the Procedure



4.2 The applicant submits the application for national registration (e.g., product dossier) for a WHO-prequalified IVD to a participating NRA. The technical part of the dossier is updated to reflect the data as approved by WHO-PQT during the initial prequalification procedure, and consecutive variation/change procedures (where applicable). The submission should be consistent with section 3.3. The applicant must provide the participating authority with:

- a product dossier complying with established national requirements and in-line with section 3.3:
 - To the extent that national regulatory requirements allow, the technical content part of the dossier should be essentially the same as the 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 same, but also the format in which data are presented should closely follow the format in which dossiers are submitted to WHO-PQT or Table of Contents (ToC) format.
- an expression of interest reproduced in Part A of Appendix 3;
- data according to country-specific requirements;
- any fees that may be payable to the NRA pursuant to national requirements.

4.3 The applicant informs the participating NRA of its interest in following this Collaborative Procedure by completing the expression of interest reproduced in Appendix 3, Part A. If the applicant for national registration is not the same as the manufacturer/holder of the WHO-prequalified IVD, then the manufacturer of the WHO-prequalified IVD must confirm to the participating NRA and to WHO-

PQT through 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 Collaborative Procedure in the country concerned.

4.4 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 Collaborative Procedure (Appendix 3, Part A) to the participating NRA and to WHO-PQT before submitting a national application for registration. In situations where the applicant wishes to apply the Collaborative Procedure to an application which is 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-PQT.

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

4.6 For each application, the participating NRA notifies WHO-PQT and the relevant applicant of the NRA's decision to accept or decline to apply this Collaborative Procedure to such application (Appendix 3, Part B). It is up to each participating NRA's own discretion to decide whether to apply the Procedure for individual submissions. The Collaborative Procedure applies only to applications that the participating NRA has accepted as complete.

4.7 Within 30 calendar days of receipt of the manufacturer's consent, WHO-PQT shares with the participating authority the most recent product-related information and 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 assessment report(s), variation/change assessment report(s) if applicable, manufacturing site inspection report(s), performance evaluation results, and the letter of prequalification. At the request of the participating authority, WHO-PQT provides 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-PQT, preferably within 60 calendar days from the first day of the regulatory time. WHO-PQT will facilitate the problem resolution in cooperation with relevant parties.

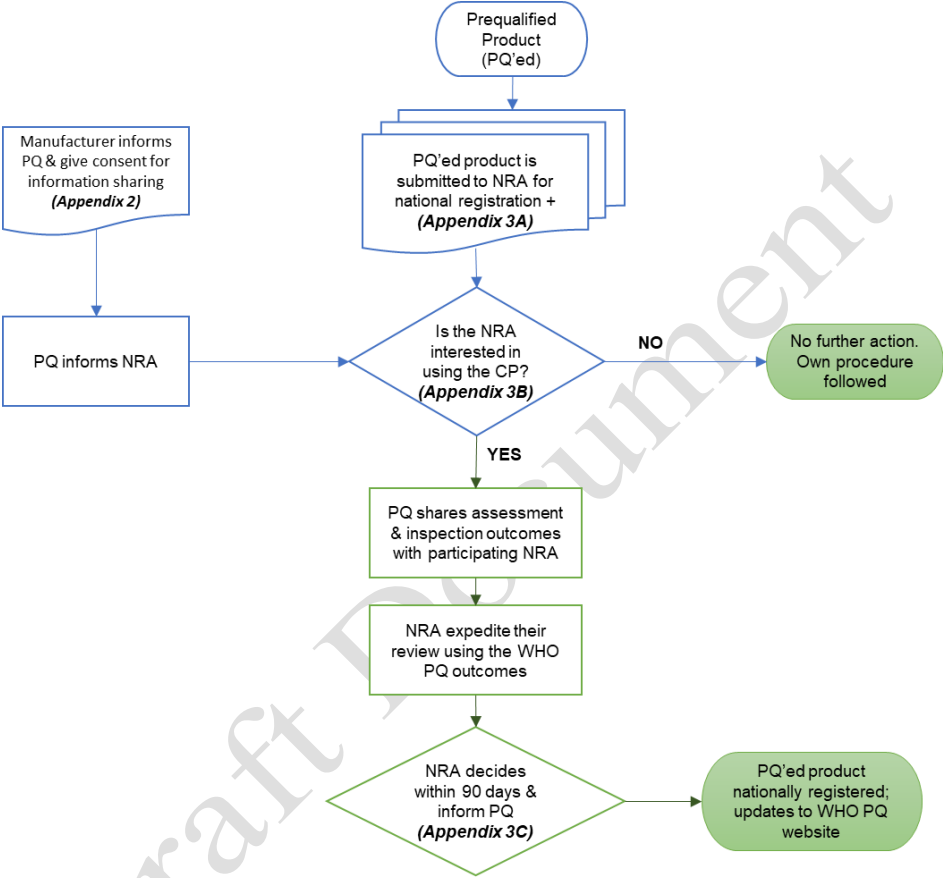
4.8 After receiving the information and documentation from WHO-PQT, the participating authority undertakes an accelerated assessment of the product in question which may be based, at the participating NRA's discretion, on the documentation provided by WHO and the manufacturer. Approaches could range from completely independent data reviews, manufacturing site inspections and performance evaluation, to adoption of regulatory decisions of reference authorities without any further scientific review. A pragmatic approach is to verify whether the product submitted for registration is the same (see section 3.2) as the product already prequalified and assess only those areas which relate to use of the product in the country concerned and where failure to comply with regulatory standards could pose health risks. In the other areas, the outcomes of WHO-PQT may be adopted.

4.9 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

474 authority reports this decision, together with an indication of the dates
475 of submission, registration and, if applicable, the length of the non-
476 regulatory time. The participating authority also reports any deviations
477 from WHO-PQT's conclusion and the reasons for such deviations, or, if
478 a decision has been made to discontinue the Collaborative Procedure
479 for a product, the reasons for such discontinuation, to WHO-PQT
480 through the restricted-access website. This report is provided to WHO-
481 PQT using Part C of Appendix 3 and is copied to the applicant. WHO-
482 PQT lists IVDs registered by participating NRAs pursuant to this
483 Collaborative Procedure on its public website.

484 The steps in the collaboration for national registration of a WHO-
485 prequalified IVD are summarized in Figure 2, below.

Figure 2: Steps in the Procedure to register a WHO-prequalified IVD product



5. Collaboration mechanisms for post-prequalification and/or post-registration variations/changes

5.1 The requirements and procedures in case of a variation/change (as defined in applicable WHO-PQT guidance (5)) may differ between participating NRAs and WHO-PQT. This Collaborative Procedure includes a variation procedure which is aimed at promoting consistency between changes accepted by WHO-PQT and changes accepted by participating authorities. There could be situations in which a manufacturer of a WHO-prequalified product submits a variation application to a participating authority and not to WHO-PQT or vice versa. In such a case the conditions of the national registration, which were initially “harmonized” with the WHO-PQT decision, may become essentially different through the product life cycle. In such a 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-PQT. The manufacturers of a prequalified product and participating NRAs are expected to inform WHO-PQT of the differences 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.

5.2 As a result, applicants are required to submit to any relevant participating authorities without delay, at the latest 30 calendar days after acceptance of the variation by WHO-PQT, those changes which are subject to national regulatory requirements. Applicants for national changes should inform participating NRAs that the same application for variation is being processed by WHO-PQT. Submission of changes to participating NRAs should respect national regulatory requirements.

5.3 WHO-PQT promptly shares with the relevant participating authorities (in each case, through the restricted-access website and subject to the above-mentioned obligations of confidentiality and restrictions on use), the outcomes of variation assessments and of related post-prequalification manufacturing site inspections and performance evaluations (if applicable) in cases in which a variation (including “notification” according to WHO-PQT’s variation procedures (4)) requires regulatory action (e.g. where product quality, safety, efficacy or patient information materials are concerned). Participating authorities are encouraged to follow the outcomes of the WHO variation procedures for nationally-approved WHO-prequalified IVDs.

5.4 If a national variation procedure results in the nationally-registered product being no longer the same (see section 3.2) as the WHO- prequalified product, or if a variation of the WHO-prequalified product is not followed by the same variation of the nationally-registered product (in the event that the particular variation is subject to national regulatory requirements) and, as a consequence, the nationally-registered product is no longer the same, then (i) the manufacturer of the WHO-prequalified IVD informs WHO-PQT of the differences and their reasons, and (ii) the participating authority informs WHO-PQT of the situation by submitting the form in Appendix 4, clearly specifying the deviations.

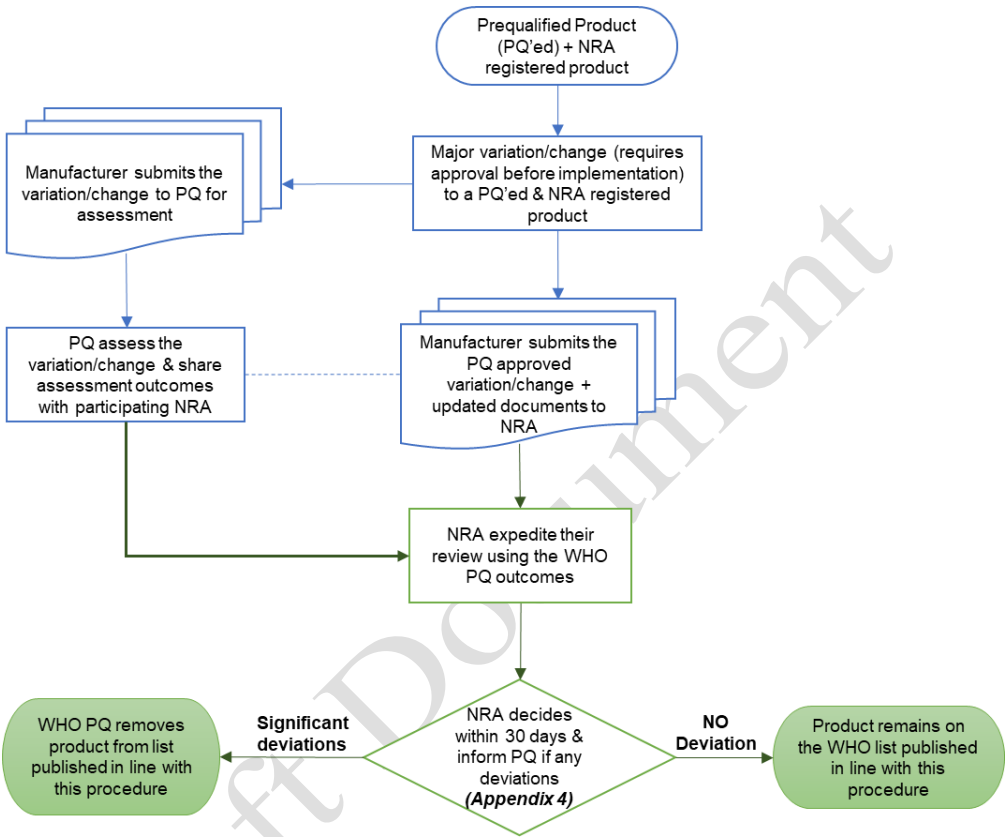
5.5 Within 30 days of obtaining access to the information and documentation from WHO-PQT, each participating authority informs WHO-PQT through the restricted-access website if and to what extent a variation of a WHO-prequalified product is not followed by the same accepted variation of the nationally-registered product and, as a consequence, the nationally-registered product is no longer the same (see section 3.2) as the WHO-prequalified product. The variation approved by WHO-PQT will be considered by WHO-PQT as accepted by the participating NRA on a non-objection basis 30 days after

information-sharing described in section 5.3 above, unless and until the participating NRA informs WHO-PQT otherwise. Other participating NRAs which have registered the prequalified product in question pursuant to this Collaborative Procedure will be made aware of such deviations through the restricted-access website.

5.6 WHO-PQT removes a product from the list published in line with this Procedure if the nationally-registered product is no longer the same (see section 3.2) as the WHO-prequalified product. In addition, if the fact that a WHO-prequalified product has been registered in a particular country pursuant to this Procedure has been made public, then any subsequent deviations should also be made public.

5.7 The steps for managing post-approval changes under this Collaborative Procedure are summarized in Figure 3, below.

Figure 3: Managing post approval changes under this Collaborative Procedure



6. Withdrawals, suspensions or delistings of prequalified IVDs and national deregistrations

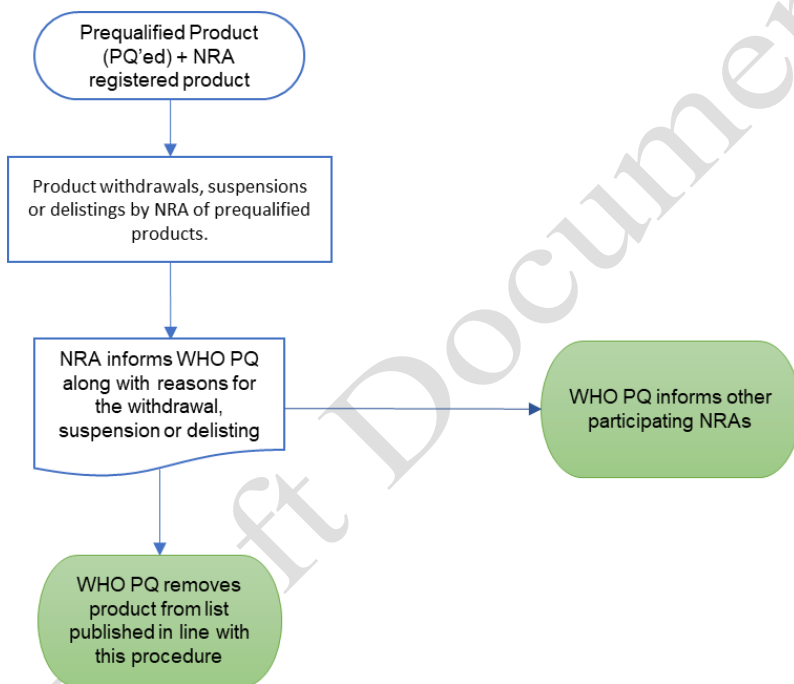
6.1 If a WHO-prequalified product is withdrawn by the manufacturer, or is suspended or delisted by WHO-PQT, WHO-PQT will inform each participating authority that has approved, or is in the process of reviewing the product pursuant to this Procedure, of the withdrawal, suspension or delisting and the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

6.2 In the case that a participating NRA deregisters or suspends the registration of a prequalified IVD for any reason, the participating authority informs WHO-PQT of the decision (together with an indication of the reasons), through the restricted-access website. The information should be provided promptly whenever there are concerns about product quality, safety or efficacy and in all other cases within 30 days. A participating authority is encouraged to consult WHO-PQT 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 Collaborative Procedure will be made aware of such national deregistration or suspension through the restricted-access website.

6.3 In the case that a participating NRA deregisters or suspends registration of WHO-prequalified product at the national level, or in the case that WHO-PQT suspends or delists a prequalified product, WHO-PQT adjusts accordingly the information about this product on its website.

6.4 Figure 4, below, 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 Collaborative Procedure. WHO will update the list of nationally registered products accordingly and inform other participating NRAs, where applicable, in case of a quality or a safety related regulatory action.

Figure 4: Registration maintenance



7. References

- 1) World Health Organization and WHO Expert Committee on Specifications for Pharmaceutical Preparations. 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 ((2016.In Fiftieth report of the WHO Expert Committee on specifications for pharmaceutical preparations. World Health Organization. Annex 8 (WHO Technical Report Series, No 996, pp 263-304). <http://www.who.int/iris/handle/10665/255338> (Last accessed 23 October 2018).
- 2) World Health Organization and WHO Expert Committee on Specifications for Pharmaceutical Preparations. Collaborative Procedure in the Assessment and Accelerated National Registration of Pharmaceutical Products and Vaccines Approved by Stringent Regulatory Authorities (2018). In Fifty-Second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Annex 11 (WHO Technical Report Series 1010, Annex 11, pp. 353-406). <http://apps.who.int/iris/bitstream/handle/10665/272452> (Last accessed 23 October 2018).
- 3) World Health Organization. ((2018Overview of the WHO . prequalification of in vitro diagnostics assessment: WHO :prequalification of in vitro diagnostics version 8. World Health Organization. <http://www.who.int/iris/handle/10665/259403>.
- 4) International Medical Device Regulators Forum (IMDRF) Good Regulatory Review Practices Group (2018). Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. International Medical Device Regulators Forum. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grp-essential-principles-n47.pdf> (Last accessed 15 April 2019)

- 646 5) World Health Organization. ((2016Reportable changes t .o a
647 WHO prequalified in vitro diagnostic medical device. World
648 Health Organization.
649 <http://www.who.int/iris/handle/10665/251915>.

Draft Document

Appendix 1

National regulatory authority participation agreement and undertaking for national regulatory authority focal point(s)

Appendix 1, Part A

Agreement to participate in the collaborative procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities (NRAs) in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics in vitro diagnostics

1. Details of 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

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

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

Email (please indicate contact details as appropriate for inclusion in the list of participating NRAs maintained on the WHO website): Click or tap here to enter text.

2. Scope of agreement

Applicants for national registration of a particular WHO-prequalified in vitro diagnostic products (hereafter referred to as “Applicants”) may express their interest to the NRA in the assessment and accelerated registration of this in vitro diagnostics product (“the Product”) in the Country under the “Collaborative Procedure between WHO-PQT and NRAs in the assessment and accelerated national registration of WHO-

prequalified in vitro diagnostics” (hereafter referred to as “the Procedure”).¹

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of the Product under the Procedure (by submitting the form reproduced in Part B of Appendix 3 attached to the Procedure to WHO-PQT through the restricted-access website), the NRA hereby confirms for each such Product that it will adhere to, and collaborate with the WHO-PQT and the Applicant for registration of the Product in accordance with the terms of the Procedure.

3. Confidentiality of information

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

- the full WHO-PQT assessment, performance evaluation, and inspection outcomes (reports);
- information and documentation on variations (as defined in WHO guidelines²), as well as information and documentation on any actions taken by WHO-PQT or NRAs post-prequalification of the Product;
- all such data, reports, information and documentation being hereinafter referred to as “the Information”.

As regards sharing the outcomes of assessments, inspections and performance evaluation, only data owned by the WHO PQ holder and

¹ If the applicant for national registration is not the same as the holder of the WHO prequalification (“WHO PQ holder”), the WHO PQ holder must confirm to the NRA and to WHO-PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the WHO PQ holder agrees with the application of the Procedure in the country concerned

² Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device. Geneva, Switzerland: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO. <https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=CDBE8667BEAC848C89DF76AF52CADA65?sequence=1>

WHO-PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

WHO-PQT 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 any Information provided by WHO-PQT as aforesaid as strictly confidential and proprietary to WHO-PQT, the WHO PQ holder/Applicant and/or third parties collaborating with WHO-PQT 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-PQT in strict confidence, and to take all reasonable measures to ensure that:

- the Information received from WHO-PQT shall not be used for any purpose other than the Purpose;
- the Information shall only be disclosed 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-PQT to the NRA under the Procedure; or

- 733 ▪ becomes part of the public domain or the subject of public
734 knowledge through no fault of the NRA; or
- 735 ▪ is required to be disclosed by law, provided that the NRA shall
736 in such event immediately notify WHO-PQT and the Applicant
737 in writing of such obligation and shall provide adequate
738 opportunity to WHO-PQT and/or the Applicant to object to such
739 disclosure or request confidential treatment thereof (provided
740 always, however, that nothing contained herein shall be
741 construed as a waiver of the privileges and immunities enjoyed
742 by WHO-PQT and/or as submitting WHO-PQT to any national
743 court jurisdiction).

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

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

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

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

766 **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:

- within 90 calendar days of regulatory time³ after obtaining access (through the restricted access website) to:
 - the data submitted to WHO-PQT for prequalification of the Product and owned by the WHO PQ holder,
 - the full WHO-PQT assessment, performance evaluation, and inspection outcomes (reports), the NRA undertakes to take a decision on the national registration of the Product;
- within 30 working days of the NRA's decision on national registration of the Product, the NRA undertakes to inform WHO-PQT 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 as Appendix 3, Part C to the Procedure to WHO-PQT through the restricted-access website;
- if a national variation procedure results in the nationally-registered product being no longer the same⁴ as the WHO-prequalified product, or if and to the extent a variation of a WHO-prequalified product is not followed by a variation of the

³ 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.

⁴ Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name, including proprietary name, the same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of the manufacturer and quality management system, the same data on quality and performance, the same intended use, same labelling and packaging, and the same instructions for use.

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-PQT thereof (together with an indication of the reasons for such deviations) within 30 days of the conclusion of the national variation procedure or within 30 days of having received access to the information and documentation provided by WHO-PQT, as the case may be (i.e. by completing and submitting the form attached to the Procedure as Appendix 4 to WHO-PQT through the restricted-access website);⁵

- the NRA undertakes to inform WHO-PQT 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 an Appendix 4, to WHO-PQT 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 restricted-access website

The NRA has designated the person(s) listed below to act as focal point(s) for access to WHO-PQT's 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-PQT without delay in writing and will be subject to the new focal point having signed and submitted to WHO-PQT the undertaking reproduced in Appendix 1, Part B to the Procedure. The NRA also undertakes to inform WHO-PQT if and as soon as a designated focal point ceases to be an employee of the NRA.

⁵ 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

819

820 **6. Focal point for inspections**

821 *If applicable, this should be the same focal point as for the “WHO-PQT*
822 *Collaborative Procedure with NRAs in inspection activities”*
823 *(<http://who.int/prequal>, “Inspections”). The same person should be*
824 *designated for inspections of in vitro diagnostics.*

825

826 1. Mr/Ms/Dr

827 First name (and initials): [Click or tap here to enter text](#)

828 Surname/family name: [Click or tap here to enter text](#)

829 Title in NRA: [Click or tap here to enter text](#)

830 Email: [Click or tap here to enter text](#)

831 Telephone: [Click or tap here to enter text](#)

832 ☐ A signed Undertaking is attached.

833 **7. Focal point(s) for dossier assessment**

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

839

840 2. Mr/Ms/Dr as a focal point for

841 Dossier assessment only ☐

842 Dossier assessment and performance evaluation ☐

843 First name (and initials): [Click or tap here to enter text](#)

844 Surname/family name: [Click or tap here to enter text](#)

845 Title in NRA: [Click or tap here to enter text](#)

846 Email: [Click or tap here to enter text](#)

847 Telephone: [Click or tap here to enter text](#)

848 ☐ A signed Undertaking is attached.

849

850 3. Mr/Ms/Dr as a focal point for laboratory evaluation

851 First name (and initials): [Click or tap here to enter text](#)

852 Surname/family name: [Click or tap here to enter text](#)

853 Title in NRA: [Click or tap here to enter text](#)

854 Email: [Click or tap here to enter text](#)

855 Telephone: [Click or tap here to enter text](#)

856 ☐ A signed Undertaking is attached.

857

858 **8. Miscellaneous**

859 The NRA agrees that WHO-PQT may list its name on the WHO-PQT
860 website as a participant in the Procedure. Except as provided
861 hereinbefore, neither party shall, without the prior written consent of
862 the other party, refer to the relationship of the parties under this
863 Agreement and/or to the relationship of the other party to the Product,
864 the Information and/or the Purpose, in any statement or material of an
865 advertising or promotional nature.

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

870 The parties shall use their best efforts to settle amicably any dispute
871 relating to the interpretation or execution of this Agreement. In the
872 event of failure of the latter, the dispute shall be settled by arbitration.
873 The arbitration shall be conducted in accordance with the modalities to
874 be agreed upon by the parties or in the absence of agreement, with the
875 UNCITRAL Arbitration Rules in effect on the date of this Agreement.
876 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 in vitro diagnostics.

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) (Appendix 1, Part B)

Appendix 1, Part B

Undertaking for 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”)

Email: Click or tap here to enter text

Telephone: Click or tap here to enter text

Applicants for national registration of WHO-prequalified in vitro diagnostics (hereafter referred to as “Applicants”) may express their interest to the national regulatory authority (NRA) in the assessment and accelerated national registration of such products under the *“Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics”* (hereafter referred to as “the Procedure”).¹

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO-PQT will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA, and the

¹ If the applicant for national registration is not the same as the holder of the WHO prequalification (the “WHO PQ holder”), the WHO PQ holder must confirm to the NRA and to WHO-PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned

NRA will communicate outcomes of the national registration procedure and post- registration actions in respect of such products to WHO-PQT, through a restricted-access website, which can be accessed only by the focal points designated by the NRA, including the undersigned. For the purpose of accessing the restricted-access website and downloading Information and uploading reports in accordance with and subject to the terms of the Procedure, WHO-PQT will provide the undersigned with a secret access code. The undersigned undertakes to treat this access code as strictly confidential and not to disclose it to any other person whatsoever. The undersigned furthermore undertakes to take all precautionary measures that may be needed to prevent any other person whatsoever from obtaining the aforesaid secret access code and from accessing the restricted-access website (i.e. except for the other designated focal points who have signed this Undertaking).

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

- the full WHO-PQT assessment and inspection outcomes (reports) and if relevant, also results of performance evaluation;
- information and documentation on subsequent variations (as defined in WHO guidelines²), as well as information and documentation on any actions taken by WHO-PQT or NRAs post-prequalification of the Product.

As regards sharing the outcomes of assessments, inspections and performance evaluation, only data owned by the WHO PQ holder and WHO-PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

The undersigned confirms that:

² Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device. Geneva, Switzerland: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO. <https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=CDDBE8667BEAC848C89DF76AF52CADA65?sequence=1>

1. the NRA has bound him or her to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1, Part A to the Procedure; and that
2. the aforesaid obligations of confidentiality and restrictions on use shall not cease on completion of the assessment and accelerated registration of any product in the Country, nor on completion of any post-registration processes that may be required, nor on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease having the right to access the restricted-access website when the NRA designates a new focal point to replace the undersigned or when the undersigned ceases to be an employee of the NRA.

This Undertaking shall not be modified except by mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes to promptly inform WHO-PQT 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](#)

981 Date (dd/mm/yyyy): Click or tap here to enter text

Draft Document

Appendix 2

Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure

Reference is made to the attached expression of interest in the assessment and accelerated national registration under the “*Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics*” (hereafter referred to as “the Procedure”) of the following WHO-prequalified in vitro diagnostic (hereafter referred to as “the Product”) in [Click or tap here to enter text \[country\]](#) (the “Country”).¹

☐ in vitro diagnostic

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](#)

Date of requalification (if applicable): [Click or tap here to enter text](#)

Name of WHO PQ holder:² [Click or tap here to enter text](#)

Application details:

Name of entity: [Click or tap here to enter text](#) (“the Applicant”)

¹ Please complete a separate copy of this Appendix for each country.

² If the applicant for national registration is not the same as the holder of WHO prequalification (“WHO PQ holder”), the WHO PQ holder must confirm to the NRA and to WHO-PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ

Street: [Click or tap here to enter text](#)

City and country: [Click or tap here to enter text](#)

Email: [Click or tap here to enter text](#)

Telephone: [Click or tap here to enter text](#)

The WHO PQ holder hereby consents to the WHO Prequalification Team (WHO-PQT) 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-PQT assessment and inspection outcomes (reports), results of performance evaluation and, if relevant, also assessment and inspections 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;
- information and documentation on subsequent variations (as defined in WHO guidelines³), as well as information and documentation on any actions taken by WHO-PQT post-prequalification of the Product;
- all such data, reports, information and documentation being hereinafter referred to as “the Information”.

As regards sharing the outcomes of assessments, inspections and performance evaluations, only data owned by the WHO PQ holder and WHO-PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.⁴

³ Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device. Geneva, Switzerland: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO. <https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=CDBE8667BEAC848C89DF76AF52CADA65?sequence=1>

⁴ In the case that certain data submitted to WHO-PQT by the WHO PQ holder in relation to the prequalification of the Product are not in his/her ownership, the WHO PQ holder specifies such data in an annex to this declaration of consent.

Such consent is subject to the NRA having entered into an agreement with WHO-PQT as per Part A of Appendix 1 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 Part B of Appendix 3 to the Procedure to WHO-PQT.

The WHO PQ holder/Applicant commits to submit post-prequalification variations to WHO-PQT and any relevant participating authorities respecting national regulatory requirements. Variations should be submitted to participating authorities at the latest 30 calendar days after acceptance of the variation by WHO-PQT. Participating authorities should be informed about the fact that the same application for a variation is being processed by WHO-PQT. If a national variation procedure the same⁵ as the WHO-prequalified product, or if a variation of the WHO- prequalified product is not followed by a variation of 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-PQT of the differences and their reasons.

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](#)

⁵ Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name, including proprietary name, the same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of the manufacturer and quality management system, the same data on quality and performance, the same intended use, same labelling and packaging, and the same instructions for use.

Appendix 3

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

Appendix 3, Part A

Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified in vitro diagnostic

In line with the “ Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics” (hereafter referred to as “the Procedure”), the undersigned Applicant¹ 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:

☐ in vitro diagnostic

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](#)

¹ If the applicant for national registration is not the same as the WHO prequalification (PQ) holder, the WHO PQ holder must confirm to the NRA and to WHO/Prequalification Team (PQT) by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned

- 1082 Email: [Click or tap here to enter text](#)
- 1083 Telephone: [Click or tap here to enter text](#)
- 1084 Date of application (dd/mm/yyyy): [Click or tap here to enter text](#)
- 1085 Product name in national system (if known): [Click or tap here to enter](#)
 1086 [text](#)
- 1087 National reference number (if known): [Click or tap here to enter text](#)
- 1088 **Product details for in vitro diagnostic**
- 1089 Product name: [Click or tap here to enter text](#)
- 1090 Product code(s): [Click or tap here to enter text](#)
- 1091 Regulatory version: [Click or tap here to enter text](#)
- 1092 Manufacturer: [Click or tap here to enter text](#)
- 1093 Manufacturing site(s): [Click or tap here to enter text](#)
- 1094 Packaging: [Click or tap here to enter text](#)
- 1095 **WHO prequalification details:**
- 1096 WHO PQ reference number: [Click or tap here to enter text](#)
- 1097 Date of prequalification (dd/mm/yyyy): [Click or tap here to enter text](#)
- 1098 WHO PQ holder: [Click or tap here to enter text](#)
- 1099 The Applicant confirms that the information and documentation
 1100 provided in support of the above-mentioned submission for national
 1101 registration is true and correct, that the product submitted for national
 1102 registration is the same² as the WHO-prequalified product and that the

² Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name, including proprietary name, the same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of the manufacturer and quality management system, the same data on quality and performance, the same intended use, same labelling and packaging, and the same instructions for use.

technical information in the registration dossier is the same³ as that approved by WHO-PQT during the initial prequalification procedure, and consecutive variation/change procedures. Minor differences⁴ from the information submitted to WHO-PQT are the following:

[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-PQT in accordance with the terms of the Procedure; and
2. will authorize WHO-PQT⁵ to provide the NRA 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-PQT assessment and inspection outcomes (reports), results of performance evaluation and if relevant, also assessment and inspections 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,

³ 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.

⁴ As defined in section 3.2. 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 language of product information.

⁵ If the applicant for national registration is not the same as the WHO PQ holder, then the authorization to WHO/PQT must be provided by the WHO PQ holder or their legal representative.

- information and documentation on subsequent variations (as defined in WHO guidelines⁶), as well as information and documentation on any actions taken by WHO-PQT post- prequalification of the Product.

As regards sharing the outcomes of 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 additional agreement of the data owners concerned.

3. authorizes the NRA to freely share and discuss with WHO-PQT 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 points' 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 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](#)

⁶ Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device. Geneva, Switzerland: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO. <https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=CDBE8667BEAC848C89DF76AF52CADA65?sequence=1>

Draft Document

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-PQT.]

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 PQ number) in Click or tap here to enter text (name of country) under the “Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO-PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified 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 *. For other fields, if there have been changes to the details as completed in Part A, please 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

Email: Click or tap here to enter text

Telephone: 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 in vitro diagnostic

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

1209

1210 **WHO prequalification details:**

1211 *WHO PQ reference number: [Click or tap here to enter text](#)

1212 Date of prequalification (dd/mm/yyyy): [Click or tap here to enter text](#)

1213 Name of WHO PQ holder: [Click or tap here to enter text](#)

1214

1215 **Please complete either section A or section B below:**

1216 ☐ **Section A**

1217 The NRA agrees to conduct the assessment and the accelerated
1218 registration of the above-mentioned product (“the Product”) under the
1219 Procedure and requests access to product-specific information, in
1220 accordance with and subject to the terms of the Procedure and the
1221 Agreement between WHO/ PQT and the NRA dated [Click or tap here](#)
1222 [to enter text](#) (dd/mm/yyyy).

1223 ☐ **Section B**

1224 The NRA has decided not to apply the Procedure to the above-
1225 mentioned Product for the following reasons: [Click or tap here to enter](#)
1226 [text](#)

1227 [Click or tap here to enter text](#)

1228

1229

1230 ***For the NRA of** [Click or tap here to enter text](#)
1231 (indicate country)

1232 Signature: [Click or tap here to enter text](#)

1233 Name: [Click or tap here to enter text](#)

1234 Title: [Click or tap here to enter text](#)

1235 Place: [Click or tap here to enter text](#)

1236 *Date (dd/mm/yyyy): [Click or tap here to enter text](#)

1237

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.

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](#)

1264 Email: [Click or tap here to enter text](#)

1265 Telephone: [Click or tap here to enter text](#)

1266

1267 Are the national registration conclusions different from prequalification
1268 outcomes?¹ ☐ Yes ☐ No

1269 **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

1270 Please specify whether registration is subject to specific commitments,
1271 the registration is provisional or conditional, use of the Product is
1272 limited by specific restrictions, or additional trials or additional data are
1273 required: [Click or tap here to enter text](#)

1274

1275 ☐ **Section B**

1276 Please complete as appropriate:

1277 ☐ The application for registration of the Product was rejected for
1278 the following reasons: [Click or tap here to enter text](#)

1279 ☐ The collaborative procedure was discontinued for this
1280 application for the following reasons: [Click or tap here to enter text](#)

1281

1282 **For the NRA**

1283 Signature: [Click or tap here to enter text](#)

1284 Name: [Click or tap here to enter text](#)

1285 Title: [Click or tap here to enter text](#)

1286 Place: [Click or tap here to enter text](#)

¹ This refers to deviations in indications, contraindications, intended use, special warnings and precautions for use, storage conditions and shelf life.

1287 Date (dd/mm/yyyy): [Click or tap here to enter text](#)
1288

Draft Document

Appendix 4

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

☐ Variation of the national registration resulting in the national registration conditions being inconsistent with the WHO-PQT prequalification conclusions

☐ Deregistration or suspension of the registration of 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 variation procedure has resulted in the nationally-registered Product being no longer the same¹ 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

¹ Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name, including proprietary name, the same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of the manufacturer and quality management system, the same data on quality and performance, the same intended use, same labelling and packaging, and the same instructions for use.

☐The variation notified to the NRA by WHO-PQT has not been followed by a variation of the nationally-registered Product and, as a consequence, the nationally-registered product is no longer the same¹ 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 Product has been deregistered or the registration of the Product has been suspended.

Deregistration: ☐Yes ☐No

Suspension of registration: ☐Yes ☐No

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

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](#)