WHO's abridged prequalification assessment for in vitro diagnostics

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Abbreviations

BLA	Biologics License Application
DoC	Declaration of Conformity
EC	European Commission
GHTF	Global Harmonization Task Force
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
IVD	in vitro diagnostic medical device
IVDD	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
JMHLW	Japanese Ministry of Health, Labour and Welfare
PMA	Premarket Approval
RRA	Recognized Regulatory Authority, as listed in Table 1 below
SMDR	Singapore Medical Device Register
TGA	Australian Therapeutic Goods Administration
WHO	World Health Organization

1. Introduction

This document has been prepared by the World Health Organization (WHO) to provide an overview of WHO's abridged prequalification assessment for in vitro diagnostic medical devices (hereinafter each, an "IVD" or "product"). This document supersedes *"Abridged prequalification assessment: prequalification of in vitro diagnostics, PQDx_173 version 5".* WHO's prequalification of IVDs is a comprehensive quality assessment of individual IVDs through a standardized procedure aimed at determining whether a product meets WHO's prequalification requirements, pursuant to and in accordance with document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics"*.

If a prequalification application is accepted by WHO, WHO's prequalification assessment can take place through one of two pathways—namely, full or abridged prequalification assessment—as determined by WHO.

An abridged prequalification assessment includes the following components:

- review of an abridged product dossier;
- inspection of a manufacturing site against all applicable requirements of International Organization for Standardization (ISO) 13485; and
- labelling review.

This document should be read in conjunction with document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics"* (hereinafter, the "PQ Procedure"), as well as with the other relevant documents set forth in Section 8 below. For the avoidance of doubt, all requirements, terms and conditions set forth in the PQ Procedure apply to WHO's abridged prequalification assessment of IVDs as well as to any products undergoing the same. The definitions contained in the PQ Procedure apply to the terms used in this document.

2. Intended audience

This document provides an overview of the abridged pathway under WHO's prequalification assessment of IVDs. Manufacturers wishing to apply for WHO's prequalification of their product(s) should read this document before doing so, in order to be prepared for WHO's abridged prequalification assessment, if applicable.

3. Rationale for WHO's abridged prequalification assessment

The rationale for WHO's abridged prequalification assessment is that a prior regulatory approval by a Recognized Regulatory Authority (or RRA) provides a level of assurance relating to the product's quality, safety and performance in countries where it is approved, but it cannot always provide the same assurance when the product is used in other settings, including resource-limited settings.

WHO's abridged prequalification assessment aims to avoid duplication of effort and promote efficiency. WHO will review the pre-submission form and supporting documentation to determine: (a) whether or not the product is eligible for and can be accepted to undergo WHO's prequalification assessment; and (b) assuming such acceptance, whether or not the product qualifies for an abridged prequalification assessment.

The abridged prequalification assessment consists of the following components:

- review of an abridged product dossier;
- inspection of a manufacturing site against all applicable requirements of ISO 13485[1]; and
- labelling review.

4. WHO's performance evaluation as a pre-requisite to WHO's abridged prequalification assessment

WHO's performance evaluation of an IVD is a prerequisite for certain IVDs (as described in document PQDx_298 "*Eligibility criteria for WHO's prequalification assessment of in vitro diagnostics")* to be submitted to and apply for WHO's prequalification assessment. Please refer to document PQDx_458 "*WHO's Performance Evaluation Procedure for In Vitro Diagnostics*" and document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics*" for more information about the terms, conditions and requirements

[1] As the same may be amended from time to time.

applicable to WHO's performance evaluation of IVDs and how it applies in connection with WHO's prequalification assessment of those products.

5. WHO's abridged prequalification assessment process

5.1. Eligibility for abridged prequalification assessment

Based on the information provided by the manufacturer as part of the pre-submission form and related documentation, WHO will determine, in its discretion, the appropriate pathway (i.e., abridged or full prequalification assessment) that will apply to an IVD. WHO will make such determination at the time it reviews the pre-submission form and will inform the manufacturer in writing.

For specific product types and/or intended uses, only full prequalification assessment may be available; in this case, the manufacturer will be notified in writing after WHO's review of the pre-submission form.

If WHO accepts a prequalification application, then the product is, in principle, eligible for WHO's abridged prequalification assessment if one of the following conditions is met:

1. The regulatory version of the product submitted for WHO's prequalification assessment has previously been stringently assessed (as defined below) and approved by any of the Recognized Regulatory Authorities (RRAs) listed in Table 1 below; or
2. The regulatory version of the product submitted for WHO's prequalification assessment has not been stringently assessed and approved by an RRA, but:
    a. there is another regulatory version of the product that has been stringently assessed and approved by an RRA; and
    b. in WHO's discretion, there are no substantial differences between those two regulatory versions (including, without limitation, substantial differences as to the product description, intended use, test procedure, labelling and instructions for use, quality management system, design, manufacturing site, key suppliers, verification/validation studies, and/or lot release criteria).

Conversely, a product is not eligible for abridged prequalification assessment if:

A. The regulatory version of the product submitted for WHO's prequalification assessment has not previously been stringently assessed and approved by an RRA, and there is no other regulatory version of the product that has been stringently assessed and approved by an RRA. The foregoing includes, but is not limited to, cases where the regulatory version of the product:
    i. has been previously assessed and approved by an RRA, but not according to an appropriate level of stringency (i.e., lower risk classification or different risk classes than those set forth in Table 1); and/or
    ii. has been previously assessed and approved by any regulatory authority or body other than an RRA listed in Table 1; or
B. The regulatory version of the product submitted for WHO's prequalification assessment is not the same as the regulatory version that has previously been

stringently assessed and approved by an RRA and, in WHO's discretion, there are substantial differences between the two regulatory versions.

For purposes of this document, the regulatory version of a product has been "stringently assessed and approved" only if such assessment and approval:

- has been performed by an RRA; and
- was not performed by an RRA based on a reliance mechanism (whereby the assessment was abridged or waived based on the recognition of a conformity assessment performed by a regulatory authority recognised by the RRA); and
- is for the specific risk classes set forth in Table 1 below. [2]

Recognized Regulatory Authority	Risk classes undergoing stringent assessment
Therapeutic Goods Administration, Australia	Class 3 and Class 4
Health Canada	Class III and Class IV
Notified bodies designated by European Union Member States or other countries under specific agreement	Annex II List A and List B (IVDD)[3] Class C and Class D (IVDR)
Ministry of Health, Labour and Welfare, Japan	Class III
Singapore Health Sciences Authority	Class C and Class D
Medicines and Healthcare products Regulatory Agency, United Kingdom	Annex II List A and List B, (Medical Device Regulations 2002)
Food and Drug Administration of the United States of America	Class II and Class III

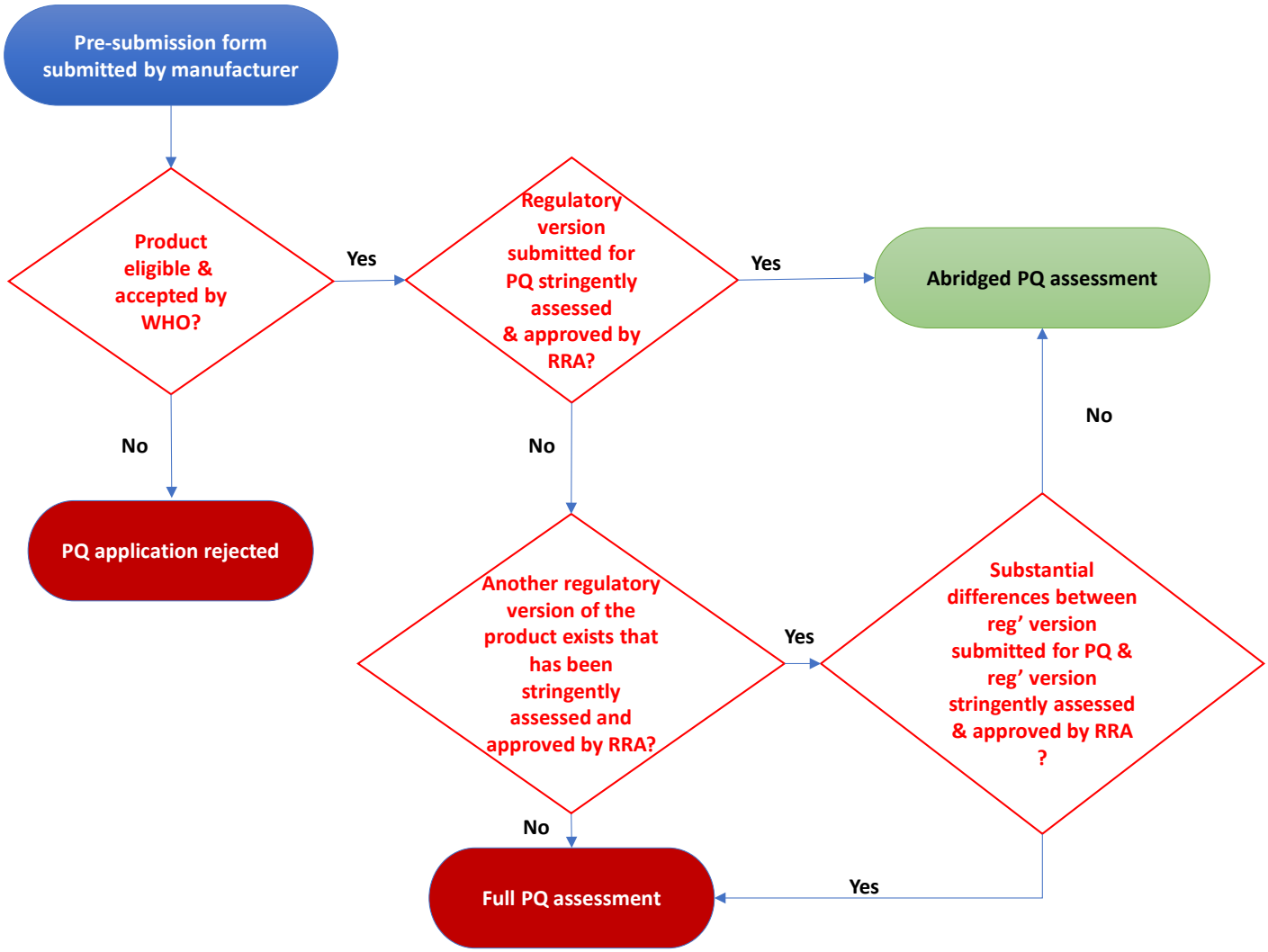
Table 1- Acceptable stringent assessments by Recognized Regulatory Authorities

If WHO accepts a prequalification application but determines that a product is not eligible for WHO's abridged prequalification assessment, then such product will be required to undergo a full prequalification assessment.

WHO reserves the right to shift from an abridged to a full prequalification assessment at any stage in WHO's prequalification assessment process, if the manufacturer fails or delays to submit satisfactory evidence that the product was stringently assessed and approved by a Recognized Regulatory Authority and/or if the product or evidence submitted does not meet WHO's requirements for abridged prequalification assessment.

[2] For the avoidance of doubt, if an RRA has assessed and approved a product for a lower risk classification or different risk classes than those set forth in Table 1 then—for purposes of WHO's prequalification. assessment—that product will not be considered to have been "stringently assessed and approved" by an RRA.
[3] The validity of certificates during the transition period will be reviewed to verify compliance with the EU IVDR transitional conditions.

Figure 1 below briefly summarizes the process for determining whether a product may undergo WHO's abridged prequalification assessment.



PQ= WHO's prequalification; Reg'= regulatory; RRA= recognized regulatory authority

Figure 1- Decision tree for determining if an IVD may undergo WHO's abridged prequalification assessment

5.2. Main differences between WHO's full and abridged prequalification assessment

WHO's full prequalification assessment process includes the following components:

- review of a full product dossier;
- inspection of a manufacturing site against all applicable requirements of ISO 13485[4]; and

[4] As the same may be amended from time to time.

- labelling review.

By contrast, WHO's abridged prequalification assessment includes the following components:

- review of an abridged product dossier;
- inspection of a manufacturing site against all applicable requirements of ISO 13485[5]; and
- labelling review.

5.3. Assessment components

5.3.1. Pre-submission stage

To apply for an IVD to undergo WHO's prequalification assessment, the manufacturer must complete and submit electronically to WHO a pre-submission form (using document PQDx_015 "*Pre-submission form*"), together with the necessary supporting documentation and requisite attachments, in accordance with PQDx_017 "*Instructions for completion of the pre-submission form"*.

The pre-submission form provides summary information about the product, its regulatory version and the manufacturer. The information provided in the pre-submission form and its attachments/supporting documentation will inform WHO in its decision on:

a. whether or not the product submitted for WHO's prequalification assessment is the same product as the one submitted in the manufacturer's Expression of Interest form for WHO's performance evaluation; and

b. whether or not the product submitted is eligible for WHO's prequalification assessment; and

c. if the product submitted is eligible for WHO's prequalification assessment, whether or not WHO's prequalification assessment can be abridged; and

d. determining the regulatory version accepted for WHO's prequalification assessment; and

e. the planning of each of the components of WHO's prequalification assessment process; and

f. determining the differences between existing regulatory versions of the product.

The pre-submission form and required documentation will be reviewed by WHO to determine, in its discretion and among other things: (i) whether the product is eligible for WHO's abridged prequalification assessment pursuant to the applicable requirements; and (ii) whether there is acceptable evidence (determined pursuant to Table 2 below) that the product has previously been stringently assessed and approved by an RRA for an acceptable risk class set forth in Table 1 above.

[5] As the same may be amended from time to time.

Recognized Regulatory Authority	Acceptable evidence of approval by the RRA for Global Harmonization Task Force (GHTF)/ International Medical Device Regulators Forum (IMDRF) Risk class C and D IVDs
Australia's Therapeutic Goods Administration	TGA Full Quality Assurance Certificate and Design Examination Certificate[6]; or TGA Production Quality Assurance Certificate and Type-Examination Certificate
Health Canada	Medical Device License for a class III or class IV IVD
Notified bodies designated by European Union Member States or other countries under specific agreement	Manufacturer's Declaration of Conformity (DoC) [7] EC Full Quality Assurance Certificate and EC Design Examination Certificate[8], issued under Annex IV of Directive 98/79/EC (IVDD) EC Production Quality Assurance Certificate issued under Annex VII and EC Type-Examination Certificate, issued under Annex V of Directive 98/79/EC (IVDD) EC Product Examination Certificate issued under Annex VI and EC Type-Examination Certificate issued under Annex V of Directive 98/79/EC[9] Certificate issued under Annex IX of Regulation 2017/746 (IVDR) Certificates issued under Annex X and XI of Regulation 2017/746 (IVDR)
Japan Ministry of Health, Labour and Welfare	JMHLW Minister's Approval Registration to JMHLW of Manufacturer (seizogyo touroku) Registration to JMHLW of Foreign Manufacturer (gaikoku seizogyosha touroku)
Singapore Health Sciences Authority	Listing on the Singapore Medical Device Register (SMDR) as Class C IVD[10] or Class D IVD
Medicines and Healthcare products Regulatory Agency, United Kingdom	Certificates issued under Annex IV (Full Quality Assurance, Product Design Dossier Examination), V (EC Type Examination), VII (Production Quality Assurance) of the Medical Devices Regulations 2002

[6] For TGA Class 4 devices.
[7] For products certified under Directive 98/79/EC (IVDD), the manufacturer must also provide documentary evidence that the transition to Regulation (EU) 2017/746 (IVDR) has been initiated, such as proof of application or contractual agreement with a designated Notified Body under the IVDR.
[8] For Annex II list A (IVDD) devices.
[9] For Annex II list B (IVDD) devices.
[10] Based on the full review by Singapore Health Sciences Authority.

Food and Drug Administration of the United States of America	Premarket Approval (PMA) letter or Biologics License Application (BLA) Premarket Notification 510(k)

Table 2: Acceptable evidence of approval by Recognized Regulatory Authorities for GHTF/IMDRF risk class C and D IVDs

For the avoidance of doubt, the other relevant terms and conditions of document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics*" (including, but not limited to, Section 6 (Applying for WHO's prequalification assessment) thereof) also apply to the pre-submission stage of the abridged prequalification assessment.

5.3.2. Decision to abridge WHO's prequalification assessment

WHO will determine, in its discretion, whether the product qualifies for WHO's abridged prequalification assessment pursuant to and in accordance with the requirements contained and/or referenced in this document.

If conditions 1 or 2 in Section 5.1 above are met, then WHO will in principle perform an abridged prequalification assessment of the product. Conversely, if none of those conditions are met, or if conditions A or B in Section 5.1 are met, then WHO will perform a full prequalification assessment of the product.

WHO will notify the manufacturer in writing of its decision on whether or not the product will undergo WHO's abridged prequalification assessment.

NOTE: In some cases, a product may have multiple regulatory versions and associated approvals and more than one of the different types of evidence specified in Table 2. Each of these approvals may support different aspects of WHO's prequalification requirements, which could further facilitate WHO's abridged prequalification assessment. Therefore, it is important for the manufacturer to provide WHO with all available evidence of previous and current stringent assessments and approvals by an RRA.

5.3.3. Abridged product dossier submission and review

If WHO determines that a product may undergo WHO's abridged prequalification assessment, WHO will invite the manufacturer to submit an abridged product dossier. In such case, the manufacturer must submit the abridged product dossier, according to the requirements and provisions set forth in document PQDx_018 "*Instructions for compilation of a product dossier – IMDRF ToC*", for WHO's screening and assessment.

For the avoidance of doubt, the other relevant requirements, terms and conditions of the PQ Procedure (including, but not limited to, Sections 6.4, 8.3 and 8.4.1 thereof) also apply to the abridged product dossier submission, screening and assessment.

5.3.4. Manufacturing site(s) inspection

If WHO determines that a product may undergo WHO's abridged prequalification assessment, and provided that the manufacturer has met all conditions set forth in Section 6.4 of the PQ Procedure, a manufacturing site inspection will take place. The manufacturing site inspection will be conducted subject to and in accordance with the relevant requirements, terms and provisions set forth in the PQ Procedure (including, but not limited

to, Section 8.4.2 thereof) and the information available on WHO's website at https://extranet.who.int/prequal/inspection-services/vitro-diagnostics-and-male-circumcision-devices.

5.3.5. Labelling review

If WHO determines that a product may undergo WHO's abridged prequalification assessment, and provided that the manufacturer has met all conditions set forth in Section 6.4 of the PQ Procedure, a labelling review will take place. The version of the product labelling that was submitted within the product dossier will be considered for purposes of WHO's abridged prequalification assessment.

All relevant requirements, terms and conditions of the PQ Procedure (including, but not limited to, Section 8.4.3 thereof) will apply to the product's labelling review and assessment.

6. Deadlines and requests for extensions

WHO's abridged prequalification assessment will be carried out in accordance with deadlines outlined on WHO's website available at https://extranet.who.int/prequal/vitro-diagnostics/timelines.

Whenever WHO requires additional information from the manufacturer in connection with WHO's abridged prequalification assessment, the manufacturer will be provided a deadline for the submission of the requested information. The manufacturer must use its best efforts to provide WHO with all requested information by such deadline.

WHO may grant the manufacturer additional time for the submission of the requested information in accordance with deadline extensions outlined on WHO's website https://extranet.who.int/prequal/vitro-diagnostics/timelines.

7. Outcome of WHO's abridged prequalification assessment

If a product is undergoing WHO's abridged prequalification assessment, WHO will take the prequalification decision (whether positive or negative) regarding that product only after:

(1) all components of WHO's abridged prequalification assessment of the product (i.e., abridged product dossier review, manufacturing site inspection and labelling review) have been completed; and

(2) If the IVD is also required to undergo WHO's performance evaluation (as per documents PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics*" and PQDx_459 "*Eligibility criteria for performance evaluation*"), WHO's performance evaluation of the product has also been completed.

For the avoidance of doubt, all relevant requirements, terms and conditions outlined in in the PQ Procedure (including, but not limited to, Section 11 and Section 12 thereof) shall apply in connection with the outcome of WHO's abridged prequalification assessment.

8. Relevant documents

This document must be read and understood in conjunction with other relevant documents applicable to WHO's prequalification assessment of IVDs which are available on the WHO website: https://extranet.who.int/prequal/vitro-diagnostics/prequalification-guidance including, without limitation, the following:

- Overview of WHO's prequalification procedure for in vitro diagnostics. Geneva: World Health Organization (PQDx_007);
- Information for manufacturers on manufacturing site inspections, available on WHO's website at https://extranet.who.int/prequal/inspection-services/vitro-diagnostics-and-male-circumcision-devices.
- Pre-submission form. Geneva: World Health Organization (PQDx_015).
- Instructions for completion the pre-submission form. Geneva: World Health Organization (PQDx_017).
- Instructions for compilation of a product dossier. Geneva: World Health Organization (PQDx_018 – IMDRF ToC).
- Product dossier checklist. Geneva: World Health Organization (PQDx_049).
- WHO's performance evaluation procedure for in vitro diagnostics. Geneva: World Health Organization (PQDx_458) available on WHO's website at https://extranet.who.int/prequal/ivd-performance-evaluation