World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE		
EVALUATE APPLICATIONS FOR PRODUCT PREQUALIFICATION		
Doc No: IMD/SOP/09	Version No: 2	Revise before: 15 Sept 2027
Effective date: 15 Sept 2024	Replaces: 01.06	Page 1 of 12
Approved by:	TL-VAX, date: 28 Aug 2024	UH-PQT, date: 4 Sept 2024
Once printed or copied from the Master, this document is no longer controlled and only valid on the day of printing or copying		

1. OBJECTIVE

1.1. This SOP describes the procedure for reviewing prequalification (PQ) applications.

1.2. The IMD-PQS Secretariat *(Secretariat)*, the IMD-PQS Working Group *(WG)* and by all *Technical Specialists (TS)* commissioned by the Secretariat follow these procedures set out in this SOP for evaluating PQ applications.

2. SCOPE

2.1. This SOP is applicable to any product or device offered for prequalification through the IMD-PQS initiative.

2.2. A product can only be prequalified if it complies with the relevant IMD-PQS performance specification and with the related IMD-PQS product verification protocol(s).

2.3. The SOP covers the PQ process of all immunization-related products or devices in the following categories before they can be added to the IMD-PQS database:

- E001: Cold rooms, freezer rooms, and related equipment
- E002: Refrigerated vehicles
- E003: Refrigerators and freezers
- E004: Cold boxes and vaccine carriers
- E005: Coolant-packs
- E006: Temperature monitoring devices
- E007: Cold chain accessories
- E010: Waste management equipment

3. CROSS-REFERENCES

Relevant KPI(s):	• KPI Website: https://extranet.who.int/prequal/about/who-prequalification-key-performance-indicators-kpis • % IMDs prequalified ≤ WHO target time for full assessment (120 days) • % IMDs prequalified ≤ Manufacturer target time for full assessment (30 days)
Background:	• https://extranet.who.int/pqweb/immunization-devices/product-evaluation-and-re-evaluation • https://extranet.who.int/pqweb/immunization-devices/process-overview

	• WHO/BCT/03.09: Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies. • Declaration of Interests (WHO Experts)
Under this SOP:	• IMD/TP/09a: Standard letter A - Invitation to apply for prequalification • IMD/TP/09b: Standard letter B - Prequalification information pack • IMD/TP/09c: Standard letter C - Request for missing information • IMD/TP/09d: Standard letter D - Evaluation notification • IMD/TP/09e: Standard letter E - Rejection • IMD/TP/09f: Standard letter F - Acceptance • Information brief to IMD PQ applicants v3: Revisions to the administration of payment of prequalification fees.
Other QMS documents:	• IMD/SOP/01: Development and publishing an IMD-PQS product performance specification. • IMD/SOP/02: Reviewing and revising an IMD-PQS product performance specification. • IMD/SOP/03: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/04: -Development and publishing an IMD-PQS product verification protocol. • IMD/SOP/05: Reviewing and revising an IMD-PQS product verification protocol. • IMD/SOP/06: Withdrawing an IMD-PQS product performance specification • IMD/SOP/10: Re-evaluating a prequalified IMD-PQS product • IMD/SOP/11: Removing a prequalified product from the IMD-PQS database

4. DEFINITIONS

Approved installer	A person or organization approved by the legal manufacturer or reseller as a competent installer of the system components and

	who has been appointed by the Employer to carry out the installation of the System.
Correspondence	Includes mail, fax and email.
Device	A medical device such as a syringe or temperature monitor for example.
Evaluator	An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of IMD-PQS prequalified products.
IMD-PQS Secretariat	The WHO IMD-PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization devices and products, as well as product alerts. It ensures that the standards that apply to equipment maintenance, manufacturing and product testing are current. The Secretariat also coordinates product feedback reports and learnings from product field monitoring. The Secretariat holds ultimate responsibility for the IMD-PQS process and takes all final IMD-PQS decisions, including the decision to award prequalified status to a product or device
IMD-PQS Working Group (WG)	The IMD-PQS WG is comprised of the WHO (IMD-PQS and Expanded Programme on Immunization), the United Nations Children's Fund (UNICEF) Supply and Programme Divisions, the Gavi, the Vaccine Alliance Secretariat, specialist agencies, partner organizations and other key stakeholders. In an advisory capacity through the WG structure, these actors offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices
In writing	Communication by letter, fax or email. (A hard copy will be kept on file.)
Legal manufacturer	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that

	person themself or on their behalf by a third party (Definition derived from Article 1 2.(f) of the EU Medical Device Directives). A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's name. A manufacturer that is contracted in this way is typically known as an Original Equipment Manufacturer, or OEM.
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
Product	In this document, where the word 'product' is used on its own, it includes device.
Production-run product	"Samples" of the product submitted for IMD-PQS prequalification that are commercial-run / production-run products, NOT prototypes or models of products.
Reseller	A commercial entity, licensed to act on behalf of a legal manufacturer and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Verification protocol	An IMD-PQS product verification protocol describes in detail how the performance of a class of immunization-related products will be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure. See *IMD/SOP/04: Development and publishing an IMD-PQS product verification protocol*.

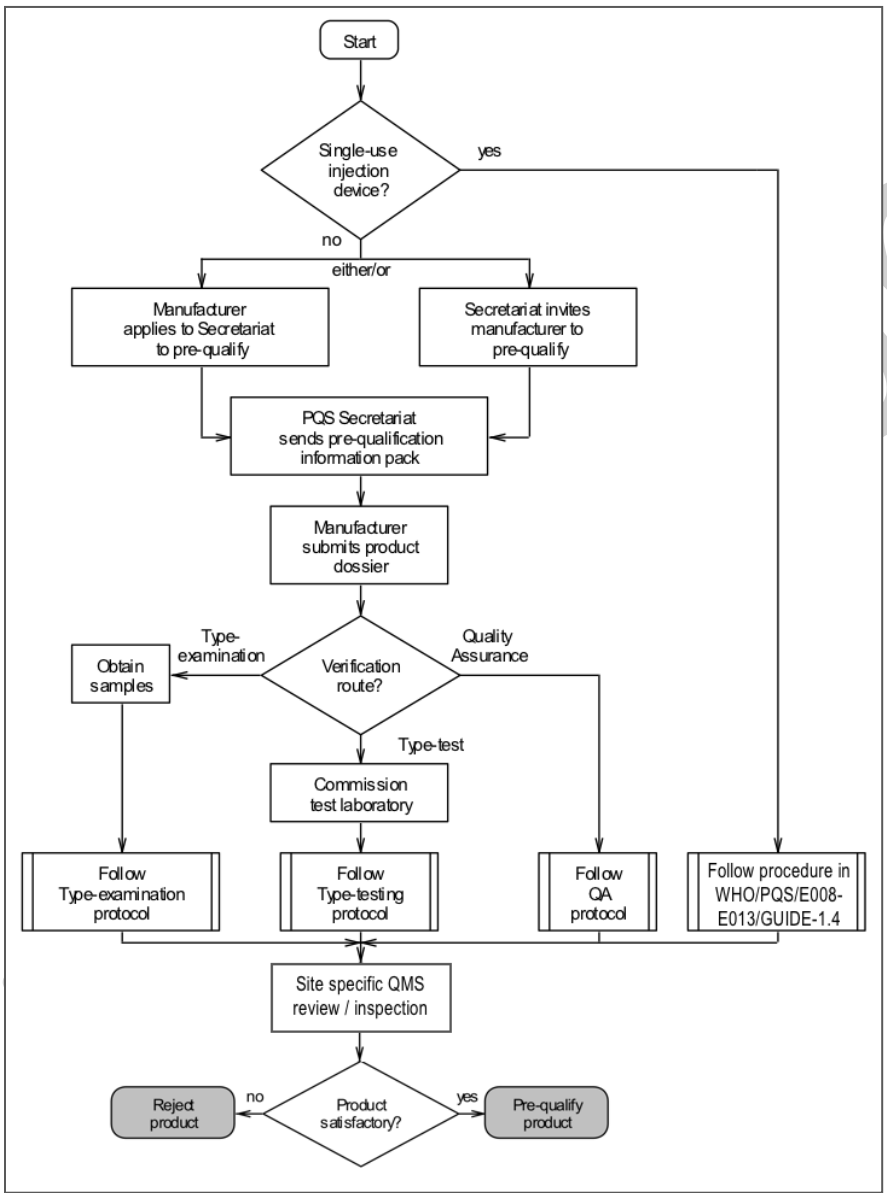
5. RESPONSIBILITIES

IMD-PQS Working Group (WG)	• Reviews product application dossiers; and • Makes recommendations to Secretariat
Technical Specialist (TS)	• Reviews product application dossiers as directed by the Secretariat; and • Makes recommendations to Secretariat
IMD-PQS Secretariat	• Receives dossiers from applicants, establishes and maintains a register that records the details of all applications for product prequalification;

	• Convenes Working Group (WG) members and/or Technical Specialists (TS) to review dossiers; • Reviews product application dossiers; • Corresponds with applicants should any clarifications related to the application be required; • Takes the final decision to approve or reject prequalified status for a product; • Informs applicants (product manufacturers) of their decision; and • Publishes approved products on the IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 – Prequalification process



7. PROCESS INSTRUCTIONS

7.1. Prequalification register (Secretariat)

7.1.1. The Secretariat establishes and maintains a register which records details of every application for product prequalification.

7.1.2. Copies of all correspondence with manufacturers are kept in the register. The register is organized according to the following hierarchy:

<IMD-PQS product category> : <manufacturer> : <product>

7.2. Cost recovery (Secretariat)

7.2.1. WHO charges manufacturers when screened product applications are accepted for dossier assessment. WHO invoices the applicant once the product application has been submitted via the WHO ePQS platform. Evaluation of the product dossier will not begin until the fee has been paid in full, in US Dollars, upon receipt of the invoice. Payment should be made within 30 days of receipt of the invoice from WHO

7.2.2. The Secretariat prepares and maintains an up-to-date schedule of charges for this work, which will be sent out to all applicant manufacturers with the *prequalification information pack* (detailed in IMD/TP/09b).

7.3. Confidentiality (Secretariat, WG, Evaluators)

7.3.1. WHO treats all information to which they will gain access during the evaluation, or otherwise in connection with the discharge of their responsibilities in regard to the prequalification of IMD-PQS products, as confidential.

7.3.2. WHO requires evaluators of product dossiers to likewise treat all information as confidential. The secretariat handles external evaluators as temporary advisors.

7.3.3. In addition, the evaluators of product dossiers are required to sign a Declaration of Interest.

7.3.4. A sample template of the confidentiality and Declaration of Interest undertaking for evaluators of product dossiers is available on Declaration of Interests (WHO Experts).

7.3.5. If, based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they discharge their functions exclusively as advisers to WHO.

7.4. Single-use injection devices (Secretariat)

7.4.1. All applications relating to single-use injection devices are processed strictly in accordance with the procedure described in document WHO/BCT/03.09: *Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies.*

7.4.2. As with other IMD-PQS products, the Secretariat keeps copies of all correspondence with applicant manufacturers in the Prequalification Register.

7.5. Obtain applications (Secretariat)

7.5.1. The Secretariat is responsible for obtaining prequalification applications. There are two ways in which this can be done:

7.5.1. An unsolicited application may be received directly from a manufacturer; or

7.5.1. The Secretariat may approach a potentially suitable manufacturer, in writing or by email, and formally invite him to apply for prequalification.

7.5.2. *Standard letter A* is used as the basis for this approach (IMD/TP/09a).

7.5.3. With the exception of a direct invitation to submit a product for prequalification evaluation, WHO IMD-PQS may only convene with manufacturers (or resellers) of WHO-IMD prequalified products or devices.

7.6. Product dossier (Manufacturer)

7.6.1. All manufacturers who seek prequalification submit a product dossier to the Secretariat.

7.6.2. This contains all the required information and production-run product samples (where required) that are listed in the relevant IMD-PQS performance specification under the heading *product dossier (*See *IMD/SOP/01: Developing and publishing a IMD-PQS product performance specification*. *IMD/TP/01a*, item 8).

7.6.3. The Secretariat screens the dossier for completeness before it is evaluated.

7.6.4. If the dossier is incomplete, the Secretariat contacts the manufacturer in writing and gives a single opportunity to provide the missing information or material.

7.6.5. If, after a reasonable period has elapsed, the manufacturer fails to supply the missing information or production-run product, the dossier is rejected.

7.7. Product Evaluation (Secretariat)

7.7.1. *Product verification* is carried out in accordance with the route relevant to the product: either *type-examination, type-testing* or *full quality assurance.*

7.7.2. In the case of type-testing, the manufacturer nominates an independent and IMD-PQS accredited testing laboratory which undertakes the work.

7.7.3. In the other two cases (*type-examination* or *full quality assurance)*, the Secretariat either carries out an in-house evaluation, outsource the work to an external evaluator, or forms a group from the IMD-PQS Working Group.

7.7.3. *Standard letter D* is used for this purpose (IMD/TP/09d).

7.7.3. If it is evident from the information set out in the dossier that the product will not be satisfactory, then there is no purpose in moving on to the testing stage.

7.7.3. In such situations, use the rejection option set out in the standard letter. This option should only be used in cases where there is no doubt that the product will fail to comply.

7.8. Evaluation results (Secretariat)

7.8.1. The Secretariat monitors the evaluation process and receives the evaluation results.

7.8.2. If the results are *unsatisfactory,* the Secretariat contacts the manufacturer in writing of the outcome of the evaluation and informs that the product is not suitable in its current form using.

7.8.2. *Standard letter E* is used as the basis for this (IMD/TP/09e).

7.8.2. A copy is also sent to UNICEF Supply Division.

7.8.3. In the event of any dispute or disagreement between the manufacturer and WHO arising from or relating to the prequalification assessment process, an SOP established by WHO for the handling of such disputed and disagreements is followed to discuss and resolve the issue.

7.8.4. If the results are *satisfactory,* the Secretariat approves prequalification of the product or device.

7.9. Approval process (Secretariat)

7.9.1. The Secretariat (alone) takes the final decision to approve prequalification of a product or device, or not.

7.10. Publication (Secretariat)

7.10.1. If the Secretariat *approves* prequalification, the manufacturer is notified in writing of the outcome of the evaluation; they are informed that the product has been granted IMD-PQS prequalification status and that it will be listed on the IMD-PQS database/catalogue.

7.10.2. Copies of this notification are sent to UNICEF Supply Division, filed in the Prequalification Register and filed in the Product Performance Register (See IMD/SOP/11: *Removing a prequalified product from the IMD-PQS database* Clause 7.1). *Standard letter F* is used for this purpose (IMD/TP/09f).

7.10.3. A new IMD-PQS website entry is then created for the product, overwritten with the words:

NEW PRODUCT AS AT <DD.MM.YY>

7.10.4. The overwriting remains on the website for a minimum period of six months, after which it is deleted.

7.10.5. Notification of the addition is also posted on the TechNet-21 forum.

7.11. DISTRIBUTION (Secretariat)

This SOP is distributed to the following individuals and groups:

- IMD-PQS Secretariat,
- IMD-PQS WG,
- WHO Expanded Programme on Immunization (EPI),
- UNICEF Supply Division and UNICEF Programme Division,
- Each Technical Specialist commissioned to work on any aspect of the product prequalification process,
- All relevant manufacturers,
- IMD-PQS and TechNet-21 websites.

8. RECORDS

8.1. The Secretariat saves register of dossier applications in WHO ePQS-Box / Sharepoint: Folder “1. Current dossiers”.

8.2. The Secretariat saves register of dossier applications in WHO ePQS-Box / Sharepoint: Folder "Applications archive".

8.3. The Secretariat saves register of prequalified products in WHO ePQS-Box / Sharepoint: Folder "1_PQS Database".

8.4. The Secretariat saves letters of rejection in WHO ePQS-Box / Sharepoint: Folder "Rejection letters".

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	1. ATT team was changed to QSS team due to the reorganization in the IVB Department. 2. The code VML was changed to IMD-PQS in the SOP No.s for easy reference. 3. The person responsible for giving no-objection clearance for the specifications was identified as the QSS Coordinator.	Drafted by O. Afsar Approved by U. Kartoğlu	06/01/2007
01	1. Hyperlink to each IMD-PQS category added in the 'Purpose' clause. 2. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 3. IMD-PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures). 4. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 5. Footnote defining 'Exceptional circumstances' added in sub-clause 7.2. 6. Clause 7.11 'Distribution' edited to include complete group of stakeholders.	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

	7. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 8. Removal of sub-clause 'Pre-qualification information pack'		
02	1. Updating to new RPQ format 2. New department, unit and team names 3. Changed supervisors name from Group Lead to Team Lead 4. Assignment of IMD as code for the product stream on PQ of immunization devices and equipment and used for numbering of QMS documents 5. Inclusion of KPIs and their targets where applicable 6. Transforming some annexes into templates related to the SOP 7. PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)	Approved by I. Gobina	01/2024