World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE		
REMOVE A PREQUALIFIED PRODUCT FROM THE IMD-PQS DATABASE		
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Approved by:	TL-VAX, date: 31 Oct 2024	UH-PQT, date: 31 Oct 2024
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1. OBJECTIVE

1.1. A product may only be prequalified if it complies with the relevant IMD-PQS performance specification and with the related IMD-PQS product verification protocol.

2. SCOPE

2.1. This SOP is applicable to any product or device prequalified through the IMD-PQS initiative, with the exception of syringes.

2.2. Circumstances can subsequently arise which make it necessary to remove a prequalified product from the database.

2.3. This SOP identifies these circumstances and describes the removal procedure.

2.4. The IMD-PQS Secretariat (Secretariat), and the IMD-PQS Working Group (WG) follow these procedures set out in this SOP for re-evaluating prequalified IMD-PQS products.

2.5. The SOP covers the process of all immunization-related products or devices in the following categories before they can be removed from the IMD-PQS database (*Syringes are prequalified on the basis of ISO standards, as described in the World Health Organization document: "Prequalification of single-use injection devices under the IMD-PQS system: Guidelines for manufacturers"*):

- 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):	Nil
Background:	• https://extranet.who.int/pqweb/immunization-devices/product-evaluation-and-re-evaluation
Under this SOP:	• IMD/TP/11a: Standard letter A - Notification of product removal

Other QMS documents:	• IMD/SOP/03: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/06: Withdrawing an IMD-PQS product performance specification • IMD/SOP/09: Evaluating a prequalified IMD-PQS product • IMD/SOP/10: Re-evaluating a prequalified IMD-PQS product

4. DEFINITIONS

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

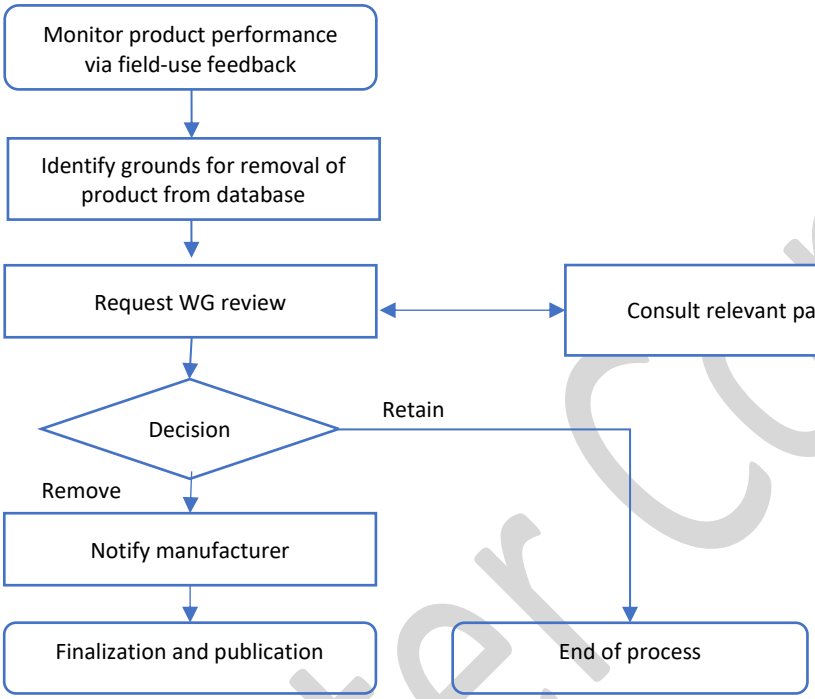
	meet countries' EPI needs for high-quality cold chain equipment and devices.
In writing	Communication by letter, fax or email. A hard copy will be kept on file.
Legal manufacturer	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device 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.
Performance Specification	An IMD-PQS product performance specification is a published standard which sets out the detailed performance requirements for an immunization-related product. A performance specification defines the functional requirements of a product and describes the environment within which it must operate. It also describes any interface and inter-changeability requirements. Although it should set out clear verification criteria, it must not attempt to describe how the functional requirements are to be met. Rather, stimulating the device manufacturer to determine how the functional requirements may be best met creates room for innovation.
Product	In this document, where the word 'product' is used on its own, it includes device.
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 products being considered for removal from the IMD-PQS database; • Makes recommendations to Secretariat
IMD-PQS Secretariat	• Establishes and maintains a register which records the performance of prequalified products and prequalified manufacturers; • Takes the final decision to retain, suspend or remove a product's prequalified status; • Removes all dependent prequalified products from the IMD-PQS database if an IMD-PQS performance specification and/or a verification protocol is withdrawn; and • Publishes withdrawal of a product's prequalified status 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



7. PROCESS STEPS

7.1. Product Performance Register (Secretariat)

7.1.1. The performance of each prequalified product and each prequalified manufacturer listed on the IMD-PQS database is regularly monitored.

7.1.2. The Secretariat establishes and maintains a register to record these data and investigates complaints of unsatisfactory performance.

7.1.3. The register is organized according to the following hierarchy:

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

7.1.4. The Secretariat obtains performance information from the following sources:

7.1.4.1. UNICEF Supply Division Quality Assurance Centre (QAC) reports;

7.1.4.2. Results of structured field performance monitoring;

7.1.4.3. Performance feedback from governments and donor agencies;

7.1.4.4. Manufacturers' *Change Notifications* (See *IMD/SOP/04: Development and publishing a IMD-PQS product verification protocol. IMD/TP/04a)*;
7.1.4.5. Manufacturers' *Product Defect Reports* (Ibid);
7.1.4.6. Questionnaires;
7.1.4.7. Anecdotal reports from the field; and
7.1.4.8. Relevant policy decisions.

7.2. Grounds for removing a product from the database (Secretariat)

7.2.1. There are five principal reasons why a product or group of products may need to be removed from the database.

7.2.2. **Unsatisfactory product**

7.2.2.1. If a prequalified product fails to perform satisfactorily as per the relevant product specification, the Secretariat is removes it from the IMD-PQS database. Grounds for taking this action include:

7.2.2.1.1. If the manufacturer changes the product in way which is unacceptable as per the requirements of the relevant product performance specification;
7.2.2.1.2. If the field performance is not in accordance with performance specification requirements;
7.2.2.1.3. If product quality is poor or inconsistent;
7.2.2.1.4. If there are product defects; or
7.2.2.1.5. If the product reliability is poor.

7.2.2.2. In cases where a specific design or manufacturing fault is widely reported, the Secretariat notifies the manufacturer, allowing a six-month period in which to rectify the fault and (if necessary) to re-verify the product. In the meantime, the product is suspended as described in *IMD/SOP/10: Re-evaluating a prequalified IMD-PQS product*.

7.2.3. **Unsatisfactory manufacturer**

7.2.3.1. If a manufacturer of prequalified products fails to perform satisfactorily, the Secretariat removes some or all of his products from the IMD-PQS database.
7.2.3.2. Grounds for taking this action include:

7.2.3.2.1. Bankruptcy, receivership, corruption or other financial irregularity;

7.2.3.2.2. Poor production quality control (e.g. reported by UNICEF Supply Division QAC;

7.2.3.2.3. Failure to meet agreed delivery schedules;

7.2.3.2.4. Poor after-sales service (e.g. reported by end-users);

7.2.3.2.5. An un-notified change of manufacturer or manufacturing site, resulting in one or more of the problems identified in Clauses 7.3.1 and 7.3.2.

7.2.4. **Major revision to performance specification/verification protocol**

7.2.4.1. Whenever there is a major revision to a performance specification or product verification protocol, the Secretariat determines a transitional period of at least one year (on a case-by-case basis) to enable manufacturers to re-verify their products. See IMD/SOP/02: *Reviewing and revising an IMD-PQS product performance specification* and IMD/SOP/05: *Reviewing and revising an IMD-PQS product verification protocol*. Manufacturers will have been invited to comment on the draft revision, so the effective transitional period is likely to be 15 to 18 months.

7.2.4.2. After a re-verification process, some products may no longer be compliant, and the Secretariat removes these products from the IMD-PQS database.

7.2.5. **Withdrawal of performance specification/verification protocol**

7.2.5.1. When a performance specification or verification protocol is withdrawn, all prequalified products conforming to that package are to be removed from the IMD-PQS database.

7.2.5.2. Manufacturers are notified of the withdrawal in accordance with the relevant SOPs (See IMD/SOP/03: *Withdrawing an IMD-PQS product performance specification* and IMD/SOP/6: *Withdrawing an IMD-PQS product verification protocol)*.

7.2.6. **WHO policy change**

7.2.6.1. From time to time, changes in WHO policy may make an entire group of products obsolete. A recent example of this is the decision no longer to recommend the use of reusable syringes.

7.2.6.2. When such a policy decision comes into force, the Secretariat removes all prequalified products affected by the policy decision from the IMD-PQS database.

7.2.6.3. Generally, there is a transitional period of months or even years leading up to the removal.

7.2.7. **Non-payment of prequalification or annual review fee**

7.2.7.1. The Secretariat suspends and eventually removes a product if fees are not paid.

7.2.7.1.1. After two months of non-payment from invoice date a product is suspended.

7.2.7.1.2. After four months of non-payment from invoice date a product will have IMD-PQS status removed.

7.3. Recommendation to remove a product (WG)

7.3.1. Upon the request of the Secretariat, the WG is responsible for delivering recommendations concerning the removal of an unsatisfactory or obsolete product.

7.3.2. Before doing so, it may need to consult with WHO EPI, UNICEF Programme Division and Supply Division and relevant experts on policy matters and technical issues.

7.3.3. The WG prepares a written case for removing the product and submits it to the Secretariat.

7.4. Approval process (Secretariat)

7.4.1. The Secretariat reviews the written case for product removal and makes the final decision to either to remove or to retain the product.

7.4.2. Final decision for removal of a product rests with the Secretariat.

7.5. Publication (Secretariat)

7.5.1. As soon as removal has been approved, the Secretariat notifies the product manufacturer of the decision using the general format of *Standard letter A* (IMD/TP/11a).

7.5.2. Notification is to be by letter, fax or by email. A copy is filed in the Performance Register.

7.5.3. In the event of any dispute or disagreement between the manufacturer and WHO arising from or relating to the prequalification reassessment process, an SOP (PQT/SOP/04) established by WHO for the handling of such disputed and disagreements is followed to discuss and resolve the issue.

7.5.4. The relevant IMD-PQS database website entry will be overwritten with the words:

PRODUCT WITHDRAWN ON <DD.MM.YY>

7.5.5. The overwritten entry remains on the website for a minimum period of six months, after which it is deleted.

7.5.6. Notification of the withdrawal is also posted on the TechNet-21 forum.

7.6. 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 prequalified products in WHO ePQS-Box / Sharepoint: Folder “1_PQS Database”.

8.2. The Secretariat saves letters of suspension in WHO ePQS-Box / Sharepoint: Folder “Suspension letters”.

8.3. The Secretariat saves product performance register in WHO ePQS-Box / Sharepoint: Folder "Complaints".

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
01.06	4. Hyperlink to each IMD-PQS category added in the 'Purpose' clause. 5. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 6. 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). 7. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 8. Clause 7.6 'Distribution' edited to include complete group of stakeholders. 9. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 10. Added sub-clause 7.2.6 'Nonpayment of prequalification or annual review fee'.	Drafted by P. Mallins Approved by I. Gobina	27/01/2017
02	1. Updating to new RPQ format 2. New department, unit and team names 3. Changed supervisors position from Group Lead to Team Lead	Approved by I. Gobina	01/2024

	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)		