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WHO Immunization Devices (IMD)
Prequalification of cold chain-related products

GUIDELINES FOR WHO IMD APPLICANTS & PREQUALIFICATION HOLDERS

- POCKET GUIDE-

OBLIGATIONS AND COMMITMENTS OF MANUFACTURERS AND RESELLERS OF IMD PREQUALIFIED PRODUCTS

ALL WHO IMD Product Categories

WHO Immunization Devices (WHO-IMD)
Performance, Quality and Safety () system
Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

Golden Rules of WHO IMD Prequalification

This "Pocket Guide" is an abridged version of the complete IMD Manufacturer Guidelines, which is the manual for product manufacturers or resellers (hereafter: "applicants") wishing to submit their immunization equipment and devices for WHO prequalification, and for existing Prequalification Holders wishing to maintain their prequalified status. WHO IMD wishes to draw applicants' and Prequalification Holders' attention to the following "Golden Rules" of IMD prequalification to help ensure a smooth, efficient and successful prequalification process.

1. WHO prequalified status is only possible through the WHO prequalification process.

There is no possibility to obtain prequalified status via a waiver based on other certification, in order to be eligible for procurement by United Nations agencies. Immunization equipment and devices may ONLY be evaluated under the WHO IMD programme in order to obtain prequalified status. As of Quarter 1 2025, the prequalification dossier review process is to be conducted via the **WHO ePQS online platform ONLY** (see Technical Guide, Annex 7).

2. WHO IMD standards are minimum requirements; they are NOT restrictive.

Applicants seeking prequalified status must be able to verify that their products fulfil the requirements defined in the relevant WHO IMD Product Specifications. However, exceeding these requirements with additional features, functionalities or other attributes that improve the product's performance, quality and safety as per user-needs is acceptable and encouraged.

3. Speedy replies to IMD requests for further information significantly improve the dossier review time.

The prequalification process typically requires some back-and-forth between IMD and applicants, to clarify information or collect additional documentation. The speed of each IMD prequalification dossier review depends heavily on the promptness, completeness and correctness of applicants' replies to IMD requests for further information. As of Quarter 1 of 2025 all exchanges related to prequalification applications will take place via WHO e.

4. One ePQS application per product, and per manufacturing site.

WHO IMD prequalifies PRODUCTS, not manufacturers/resellers. Applicants must submit ONE ePQS application FOR EACH product to be evaluated for prequalification. In addition, If the product is manufactured at more than one manufacturing site, ONE dossier must be submitted FOR EACH site.

5. Complaints, failures or changes to prequalified products must be reported in real-time.

Prequalification Holders are obliged to report complaints or product defects or failures to IMD as soon as the complaint comes to your attention ("**in real-time"**). It is essential that Prequalification Holders also keep WHO IMD fully informed about any changes made to products, to the manufacturing process or to the manufacturing site(s). Failure to do so may result in prequalified status being suspended or withdrawn. Complaints review and management is a strictly confidential process between WHO Immunization Devices and the Prequalification Holder.

Contacts

WHO Immunization Devices Prequalification website
https://extranet.who.int/pqweb/immunization-devices

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1. Introduction

This document is the abbreviated "Pocket guidelines" for WHO IMD applicants and Prequalification Holders. **The complete, long-form Guidelines for WHO IMD Applicants & Prequalification Holders** (hereafter "Full Guidelines") is available for download here[1]:

The "Pocket guidelines" summarizes the core processes and procedures of the WHO IMD prequalification programme **for all WHO IMD product categories**. It introduces the mandatory **obligations and commitments** of Prequalification Holders wishing to maintain WHO-prequalified status for their cold chain-related products.

The IMD prequalification lifecycle is comprised of **five procedural stages**:

Manufacturers and resellers may offer products which they believe will comply with current WHO IMD performance specifications[2] for the following categories of equipment:

- E001: Cold rooms, freezer rooms
- E002: Refrigerated vehicles
- E003: Refrigerators and freezers
- E004: Cold boxes and vaccine carriers
- E005: Coolant-packs
- E006: Temperature monitoring devices
- E007: Cold chain accessories
- E008: Single-use injection devices
- E010: Waste management equipment
- E013: Therapeutic injection devices

FURTHER INFORMATION
At the end of each section of this pocket guideline please review the "FURTHER INFORMATION" box for the links to the relevant sections in the complete, long-form Guidelines for WHO IMD Applicants & Prequalification Holders ("Full Guidelines").

[1] https://extranet.who.int/prequal/immunization-devices/prequalification-guidance-prospective-prequalification-holders
[2] https://extranet.who.int/pqweb/immunization-devices/performance-specifications

2. Background

WHO IMD: The immunization cold chain's first line of defense

The WHO Immunization Devices Secretariat (WHO IMD) oversees the prequalification of cold chain equipment and devices according to the relevant WHO Performance, Quality and Safety standards, in support of the WHO's Assessment of Medical Devices Team (AMD). WHO IMD provides technical expertise aimed at achieving a reliable, high-quality cold chain for the world's immunization programmes, by developing performance specifications and verification protocols (standards) and by applying these standards through the prequalification process.

- WHO IMD standards are minimum requirements; they are not restrictive.
- WHO IMD standards have been developed over many years in response to the evolving needs of end-users (national immunization programmes), with prioritization driven by programme needs.
- Prequalification Holders contribute via feedback on performance issues, by taking appropriate corrective action and by informing WHO of emerging technologies that may be suitable for challenging operating environments.

Glossary Page 5-6 Full Guidelines
Frequently asked questions (FAQs) Page 8-9 Full Guidelines
Map of IMD Prequalification Holders Section 2 Full Guidelines
IMD Standard Operating Procedures (SOPs) Section 7 Full Guidelines
Website links to all IMD Standards Section 5 Full Guidelines

3. Procedural guide - overview

Prequalification indicates that the product is technically satisfactory for procurement by United Nations agencies for the purpose for which it is intended, and subject to any limitations set out in the IMD database or the IMD Product Catalogue[3]. T**he granting of IMD prequalified status does not constitute a guarantee of purchase**. Individual UN procurement agencies reserve the right to impose additional conditions and limitations. **There is no possibility to obtain prequalified status via a waiver based on other certification: only the WHO IMD product evaluation may grant prequalified status.**

Any legal manufacturer of an immunization-related product or device belonging to a that WHO prequalifies, and which complies with one of the IMD Performance Specifications & associated Verification Protocols may submit a product for prequalification. Products offered by a reseller may also be considered for prequalification if a formal licensing arrangement has been made with the legal manufacturer.

ePQS Portal

As of Quarter 1 of 2025, ALL IMD prequalification applications, and post-prequalification variations must be submitted via the **WHO ePQS (e-prequalification system) online platform.**

The application **pre-submission form**, the **Annual Review** of prequalified products and the **extra-ordinary review process**, continue via email submissions / communications.

IMPORTANT: WHO ePQS – "electronic **P**re**Q**ualification **S**ystem" **does not** refer to the IMD "WHO Immunization Devices, Performance, Quality and Safety".

[3] https://extranet.who.int/prequal/immunization-devices/who-catalogue-prequalified-immunization-devices

Prequalification timelines and fees

PRE-SUBMISSION TIMELINE: Potential applicants may submit a pre-submission form at any time. IMD will contact applicants within 30 DAYS§ of receiving a complete pre-submission form.

PREQUALIFICATION APPLICATION TIMELINE: Applicants may submit an application upon receipt of a favorable response to a pre-submission form. IMD will render a decision based on a complete application dossier submitted via the WHO ePQS portal within 60 DAYS§, of receipt, (or within 90 DAYS§ for category E001).

§ IMD response time **depends on the speed and completeness of applicant responses** to IMD requests for further documents or information.

Three different fees will be due over the lifetime of an IMD prequalified product: 1. Prequalification evaluation fees; 2. Laboratory testing fees; 3. Annual Review fees. The amount of each fee varies per category of product.

Applicants are also responsible for the cost of any **production-run products** (samples) that may be required as a part of the application evaluation.

Lastly, in some cases, **inspections** may be carried out in connection with an IMD prequalification application. Although not considered a "fee", inspections are conducted on a full "**real cost-recovery**" basis.

Table of prequalification-related fees Section 3.3 Full Guidelines

Stages of the prequalification process life-cycle Section 3.4 Full Guidelines

The 5 stages of the IMD prequalification life-cycle

Stage 1 - Product application pre-submission (screening)

Potential applicants must begin by submitting a complete pre-submission form. The IMD ***pre-submission form*** is available for download on the WHO IMD Website: "Pre-submission form"[4].

The purpose of the pre-submission stage is to screen potential applications to establish whether they correspond to an active IMD product category, i.e. a product that answers the needs of country immunization programmes. Pre-submission screening also allows IMD to identify whether a proposed product is likely to meet the programme's performance, quality and safety criteria. The information provided in the pre-submission form will assist WHO in determining whether the product is eligible for WHO prequalification assessment.

The applicant must submit the pre-submission form, using the correct file name conventions, **by email** to Dr. Isaac Gobina (gobinai@who.int) and Mr. Paul Mallins (mallinsp@who.int).

[4] https://extranet.who.int/prequal/sites/default/files/document_files/Product Dossier Presubmission Form.pdf

Stage 2 – Product application: submission of product dossier

If IMD deems the product or device eligible for prequalification evaluation, it will invite the applicant to submit **a full prequalification application**, via the WHO ePQS platform. **Complete guidance for submitting an application via ePQS is** available here[5].

The IMD Secretariat will send the applicant **a tailored information pack** via email. The information pack contains the **complete application instructions** and required documentation for their application, including: the relevant Performance Specifications, Verification Protocols, an **Application Review Template***[6] and WHO's Terms & Conditions[7], along with other related material specific to the product and its prequalification application. A signed copy of the Terms & Conditions must be included in each product prequalification application dossier.

The "***Application review template***" documents a product's compliance with each of the specifications as laid out in the relevant product specification(s), as well as the communication exchanges between the applicant and the IMD Secretariat that take place throughout the dossier review process.

ePQS Portal

The application must be made via the **WHO ePQS platform**. ePQS Registration form: "ePQS - User Registration and accessing the ePQS Portal" Applications may be created in WHO ePQS **at any time,** once the applicant has received an invitation and an application information pack from the IMD Secretariat.

One dossier must be submitted **FOR EACH product**.

If the product is manufactured at more than one manufacturing site, one dossier must be submitted **FOR EACH site**.

Laboratory testing

Laboratory testing is required for the *majority* of products submitted for IMD prequalification. For syringe categories E008 and E013, in-house testing by the product manufacturer is acceptable in lieu of testing by an accredited laboratory. The type of laboratory testing required for each product is defined in the relevant Verification Protocol and depends on the **volumes** that would be deployed and whether the product is **safety-critical** or not. Laboratory testing results MUST be submitted to using the "IMD Laboratory Report Template[8]".

Field testing

In some cases, the results of additional testing of a product or device in its intended operating environment must be included in the application dossier. WHO is responsible for identifying product types for which field-testing is either mandatory or desirable and will specify the appropriate generic testing method for each product type. Applicants should ask WHO whether their product will require field testing on a case-by-case basis. Field-testing provides product manufacturers with information to validate performance in use case conditions and improve product design and suitability. It can also help end-users to select products that are best suited to their needs and operating environments.

[5] https://extranet.who.int/prequal/key-resources/documents/who-IMD-ePQS-learning-materials-IMD-pq-holders-applicants

[6] https://extranet.who.int/prequal/immunization-devices/application-dossier-requirements

[7] https://extranet.who.int/prequal/sites/default/files/document_files/WHO IMD Terms and Conditions_3.pdf

[8] https://extranet.who.int/prequal/key-resources/documents/who-vax-IMDlaboratory-test-report-template

Stage 3 – Prequalification application review and evaluation

ePQS Portal Each product application dossier is screened for completeness before being evaluated, to make sure that all the required information and documentation have been submitted.

If the application is incomplete, the applicant will be contacted via the e-Box correspondence platform and will be provided **a single opportunity** to provide the missing information or material. The applicant must supply the missing information or production-run product(s) within two weeks. If, after this period has elapsed, the applicant fails to do so, the application will be rejected.

During dossier evaluation, the IMD Secretariat will inform applicants whether any clarifications or additional information is required before a final decision regarding prequalification can be taken. If clarification or additional information is required of the applicant during the dossier evaluation phase, the applicant must ensure to respond with the complete information requested. **The number of rounds of review for an application is strictly limited to three rounds**. In the case that the application is not approved after three rounds of review, the application will be rejected. If the applicant chooses to resubmit, the process begins again: the screening and dossier evaluation will recommence from the beginning, as will the review timelines. Any new application must be accompanied by the payment of a new dossier review fee.

Once a product prequalification application has been accepted it will undergo review by a group of technical specialists who will evaluate the application dossier and test results, as well as share its recommendations as to whether the product meets the relevant IMD equipment performance specifications. The IMD Secretariat and technical specialists treat all information pertaining to an application **with the strictest confidence**.

Detailed IMD procedural guide Section 3 Full Guidelines
ePQS Technical Guidance Annex 7 Full Guidelines
Pre-submission form and checklist Section 4.1 Full Guidelines
Prequalification application contents checklist Section 4.2 Full Guidelines
Generic list of supporting documents Section 3.4.3.2 Full Guidelines
Types of laboratory testing Section 3.4.3.6 Full Guidelines
WHO-accredited laboratories Section 3.4.3.6 Full Guidelines
Product field testing criteria & information Section 3.4.3.7 Full Guidelines
Required file name conventions Annexes 2 & Annex 3 Full Guidelines
Website links to all category-specific guidance Section 6 Full Guidelines
Prequalification Terms & Conditions Annex 1 Full Guidelines

Stage 4 – Prequalification and maintaining prequalified status

ePQS Portal After fully evaluating an application, IMD will inform applicants via the e-Box correspondence platform whether any clarifications or additional information is required before a final decision can be taken.

If the results of the evaluation and verification are **SATISFACTORY**, WHO IMD will inform the applicant via the WHO ePQS platform, including a copy of the verification report. The successful applicant is granted the denomination of IMD Prequalification Holder.

If the evaluation and/or verification results are **UNSATISFACTORY,** IMD will inform the applicant via the WHO ePQS platform that the product is not suitable in its current form.

Maintaining prequalified status - reporting product or manufacturing variations

Once a product has been prequalified, and as long as no serious complaints have been received from product users, it will maintain its prequalified status for up to 12 months, or until the next scheduled Annual Review of products.

Each Prequalification Holder must keep WHO IMD fully informed about any changes, or "variations" made to: the product itself; manufacturing process of the product; or manufacturing site of the product.

ePQS Portal

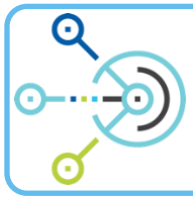
Product and manufacturing variations must be reported via the WHO ePQS platform as of Quarter 1 of 2025. Refer to the detailed technical guide in Annex 7 of the Full Guidelines for instructions variations-reporting via WHO e.

Inspections

In cases where inspections are necessary, they may be carried out by WHO IMD and/or carried out in collaboration with the WHO Prequalification Unit's (PQTs) Inspection Services team[9]. Inspections carried out by IMD for Prequalification Holders are predominantly Quality Management Systems (QMS) compliance verifications related to ISO/IEC 9001 (categories E001, E002, E003, E004, E005, E006, E007, E010) and ISO/IEC 13845 (categories E008 and E0013) and/or quality issues and complaints.

The aim of the Inspection is to confirm compliance of the manufacturer with relevant good practices and international standards and adherence to dossier information. This may be: via an initial on-site inspection; by leveraging the outputs of inspections conducted by national regulatory authorities operating to equivalent standards and stringency to those of WHO; or in addition, Inspection Services may conduct subsequent inspections to verify that a product-related site continues to be compliant with the required norms and standards.

The inspection process is conducted via formal correspondence with WHO Prequalification Inspection Services, via WHO e.



Maintaining prequalified status: Post-PQ changes and Inspections Section 3.4.5 Full Guidelines

Stage 5 - Post-prequalification commitments and obligations

IMD depends on Prequalification Holders and the wider immunization community to share feedback on WHO IMD products in order to fulfil its mission to ensure the availability of quality, reliable products for the storage, transport and administration of prequalified vaccines for national immunization programmes.

The performance of prequalified products is continually reviewed through the formal IMD review procedures and throughout the procurement process at UN procurement agencies.

[9] https://extranet.who.int/prequal/inspection-services

WHO IMD Prequalification Holders commit to **fulfil three types of post-prequalification commitments:**

1. **IMD Post-market Monitoring (PMM) requirements,**
2. **IMD Annual Review of products, and**
3. **Extra-ordinary IMD review process (if necessary).**

1. Post-market monitoring (PMM) requirements

Post-market monitoring (PMM) is a crucial part of WHO IMD' work. PMM depends on Prequalification Holders and the wider immunization community to collect and share information and operational feedback about product performance in immunization operating environments.

Prequalification Holders must submit product performance reports, failures and complaints either with the IMD product complaints & feedback reporting form).

Mandatory complaints and failures reporting

Prequalification Holders are obliged to report complaints, problems and failures to WHO IMD **in real time** throughout the period of prequalification (not only during the annual review) using the dedicated complaints & feedback reporting form. Complaints and failures may include, but are not limited to: production defects, poor performance, product recalls and reported complaints. Reports of performance issues or failures will NOT lead automatically to the suspension of a product's prequalified status.

When reporting equipment failures or complaints to IMD, Prequalification Holders of category E003 products (ONLY) are required to refer to the WHO IMD "Post-market Monitoring (PMM) Taxonomy[10]".

User feedback and reports

Prequalification Holders are **actively encouraged** to collect user feedback via the IMD product complaints & feedback reporting form including positive performance reports and to promptly communicate these reports to IMD.

Quality assurance and CAPAs

Prequalification Holders are also expected to ensure quality assurance and/or implement corrective and preventative actions (CAPAs), as needed as part of their quality management system.

In addition to collecting performance reports and product defect reports, Prequalification Holders are required to analyze product performance information as part of the annual review of their products. This is also a requirement of the quality management system, as stipulated by the International Organization for Standardization (ISO).

2. The IMD Annual Review process

All prequalified products must undergo a formal annual review, to verify that they continue to meet prequalification performance, quality and safety requirements. The annual re-evaluation exercise takes place each year in April and covers all products in the database of prequalified immunization devices, irrespective of the original date of prequalification.

[10] https://extranet.who.int/prequal/key-resources/documents/e003-cold-chain-taxonomy

The purpose of the annual review is to: verify that certificates are up to date; to check whether the product design or manufacturing process has changed; and to check whether any significant defects or failures have been noted.

Kindly note: the World Health Organization (WHO) reserves the right to delist companies and/or products from the WHO IMD Catalogue if insufficient, invalid or fraudulent information is submitted as a part of the Annual Review.

Currently, the Annual Review of Prequalified products takes place **via email-submission**. The IMD Secretariat will contact Prequalification Holders in January and again in February with detailed instructions about relevant submission documents. Important - products may only be re-evaluated once the invoice has been paid and proof of payment has been provided. Products for which the invoice has not been paid by the submission deadline will be automatically removed from the list of WHO-prequalified immunization devices.

Prequalification Holders must submit the required elements by email to Dr. Isaac Gobina (gobinai@who.int), Mr. Paul Mallins (mallinsp@who.int) and Mr. Albertus Knopper (knoppera@who.int).

The subject line of the email should clearly indicate "IMD ANNUAL REVIEW OF PRODUCTS".

Individual PDF or Word files should not exceed 10 MB in size.

ePQS Portal

In the future, the Annual Review will take place via the WHO ePQS Platform. Guidance will be provided at that time.

3. The Extra-ordinary IMD review process

If serious problems arise with a prequalified product that (may) put vaccine potency at risk, the IMD Secretariat may deem an extra-ordinary review process to be necessary. The Prequalification Holder must provide all information requested of them.

An extra-ordinary prequalification review will take place immediately if: major changes have been made to the product; the Prequalification Holder has failed to notify WHO of complaints received about the product that may put vaccine potency at risk; UN agencies or product users have reported receipt of non-compliant products; complaint investigations have indicated significant quality or safety defects.

How can a product lose its IMD Prequalified status?

A product's IMD prequalified status may be lost or removed in several ways. The status may be: withdrawn by the product manufacturer, suspended or definitively removed by IMD, or the product may become obsolete.

Chart illustration: Post-prequalification commitments and obligations Section 3.4.6 Full Guidelines
Post-market monitoring (PMM) requirements Section 3.4.6.1 Full Guidelines
Failures reporting Taxonomy E003 Section 3.4.6.1.1 Full Guidelines
IMD Annual Review of products Section 3.4.6.2 Full Guidelines
Annual Review checklist Section 4.3 Full Guidelines
Annual Review file name conventions Annex 4 Full Guidelines
IMD Extraordinary review process Section 3.4.6.3 Full Guidelines
Paths to losing prequalified status Section 3.5 Full Guidelines