



WHO IMD PQS  
IMMUNIZATION DEVICES  
PREQUALIFICATION

WHO/VAX/IMD/PQS/GUIDE 2.0  
Distribution: Public

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

# GUIDELINES FOR WHO IMD-PQS APPLICANTS & PREQUALIFICATION HOLDERS

- POCKET GUIDE -

OBLIGATIONS AND COMMITMENTS OF MANUFACTURERS AND RESELLERS  
OF IMD-PQS PREQUALIFIED PRODUCTS

**ALL WHO IMD-PQS Product Categories**

WHO Immunization Devices (WHO-IMD)  
Performance, Quality and Safety (PQS) 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-PQS 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-PQS wishes to draw [applicants’](#) and [Prequalification Holders’](#) attention to the following “Golden Rules” of IMD-PQS 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-PQS programme in order to obtain prequalified status. As of Q3 2024, the prequalification dossier review process is to be conducted via the **WHO ePQS online platform ONLY** (see Technical Guide, Annex 7).

### 2. WHO IMD-PQS 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-PQS [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-PQS requests for further information significantly improve the dossier review time.

The prequalification process typically requires some back-and-forth between IMD-PQS and [applicants](#), to clarify information or collect additional documentation. The speed of each IMD-PQS prequalification dossier review depends heavily on the promptness, completeness and correctness of [applicants’](#) replies to IMD-PQS requests for further information. As of Quarter 3 of 2024 all exchanges related to prequalification applications will take place via WHO ePQS.

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

WHO IMD-PQS 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-PQS as soon as the complaint comes to your attention (“**in real-time**”). It is essential that [Prequalification Holders](#) also keep WHO IMD-PQS 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.

## Contacts



WHO Immunization Devices Prequalification website  
<https://extranet.who.int/pgweb/immunization-devices>



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## 1. Introduction



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

The “Pocket guidelines” summarizes the core processes and procedures of the WHO IMD-PQS prequalification programme **for all WHO IMD-PQS 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-PQS prequalification lifecycle is comprised of **five procedural stages**:



Manufacturers and resellers may offer [products](#) which they believe will comply with current [WHO IMD-PQS performance specifications](#)<sup>2</sup> for the following categories of equipment:

E001: Cold rooms, freezer rooms

E006: Temperature monitoring devices

E002: Refrigerated vehicles

E007: Cold chain accessories

E003: Refrigerators and freezers

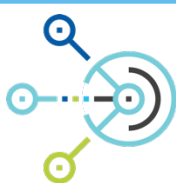
E008: Single-use injection devices

E004: Cold boxes and vaccine carriers

E010: Waste management equipment

E005: Coolant-packs

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-PQS Applicants & Prequalification Holders (“Full Guidelines”)**.

<sup>1</sup> <https://extranet.who.int/prequal/immunization-devices/prequalification-guidance-prospective-prequalification-holders>

<sup>2</sup> <https://extranet.who.int/pgweb/immunization-devices/performance-specifications>

## 2. Background

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

The WHO Immunization Devices Secretariat (WHO IMD-PQS) 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 Vaccines Assessment Team (VAX). WHO IMD-PQS 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-PQS standards are minimum requirements; they are not restrictive.
- WHO IMD-PQS standards have been developed over many years in response to the evolving needs of end-users (national immunization programmes),
- [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-PQS Prequalification Holders [Section 2 Full Guidelines](#)

IMD-PQS Standard Operating Procedures (SOPs) [Section 7 Full Guidelines](#)

Website links to all IMD-PQS Standards [Section 5 Full Guidelines](#)

IMD-PQS Terms & Definitions (formatted blue) [Annex 6 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-PQS database or the [IMD-PQS Product Catalogue](#)<sup>3</sup>. **The granting of IMD-PQS 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-PQS [product](#) evaluation may grant prequalified status.**

Any [legal manufacturer](#) of an immunization-related [product](#) or [device](#) belonging to a [country](#) that WHO [prequalifies](#), and which complies with one of the IMD-PQS 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](#).



As of Quarter 3 of 2024, ALL IMD-PQS 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 PreQualification System” **does not** refer to the IMD-PQS “WHO Immunization Devices, Performance, Quality and Safety”.

<sup>3</sup> <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-PQS will contact [applicants](#) within 30 DAYS<sup>§</sup> 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-PQS will render a decision based on a complete application dossier submitted via the WHO ePQS portal within 60 DAYS<sup>§</sup> of receipt, (or within 90 DAYS<sup>§</sup> for category E001).

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



**Three different fees** will be due over the lifetime of an IMD-PQS 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-PQS prequalification application. Although not considered a “fee”, inspections are conducted on a full “**real cost-recovery**” basis.

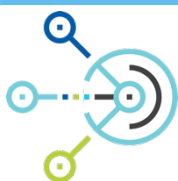


Table of prequalification-related fees [Section 3.3 Full Guidelines](#)  
Stages of the prequalification process life-cycle [Section 3.4 Full Guidelines](#)

## The 5 stages of the IMD PQS prequalification life-cycle

### Stage 1 - Product application pre-submission (screening)

[Potential applicants](#) must begin by submitting a complete pre-submission form. The IMD-PQS **pre-submission form** is available for download on the WHO IMD-PQS Website: “[Pre-submission form](#)”<sup>4</sup>.

The purpose of the pre-submission stage is to screen potential applications to establish whether they correspond to an active IMD-PQS product category, i.e. a product that answers the needs of country immunization programmes. Pre-submission screening also allows IMD-PQS 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](mailto:gobinai@who.int)) and Mr. Paul Mallins ([mallinsp@who.int](mailto:mallinsp@who.int)), copying [pqsinfo@who.int](mailto:pqsinfo@who.int).

<sup>4</sup> [https://extranet.who.int/prequal/sites/default/files/document\\_files/Product\\_Dossier\\_Presubmission\\_Form.pdf](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-PQS 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.

The IMD-PQS 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**<sup>\*5</sup> and **WHO's Terms & Conditions**<sup>6</sup>, 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 PQS “**Application review template**” collects and tracks information about the product’s compliance with each of the required specification clauses as laid out in the relevant product specification(s), and the communication exchanges between the applicant and the IMD-PQS Secretariat that will take place throughout the dossier review process.



The application, including the required documentation and using required file name conventions, must be made via the **WHO ePQS platform**. 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-PQS 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-PQS prequalification. 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 PQS using the “**IMD-PQS Laboratory Report Template**”<sup>7</sup>.

### **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.

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<sup>5</sup> <https://extranet.who.int/prequal/immunization-devices/application-dossier-requirements>

<sup>6</sup> [https://extranet.who.int/prequal/sites/default/files/document\\_files/WHO IMD-PQS Terms and Conditions 3.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/WHO%20IMD-PQS%20Terms%20and%20Conditions%203.pdf)

<sup>7</sup> <https://extranet.who.int/prequal/key-resources/documents/who-vax-imd-laboratory-test-report-template>



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.

### Stage 3 – Prequalification application review and evaluation



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 ePQS-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

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 laboratory test results, as well as share its recommendations as to whether the **product** meets the relevant IMD-PQS equipment performance specifications. The IMD-PQS Secretariat and technical specialists treat all information pertaining to an application **with the strictest confidence**.



Detailed IMD-PQS procedural guide [Section 3 Full Guidelines](#)  
ePQS Technical Guide: Online applications instruction [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



After fully evaluating an application, IMD-PQS will inform **applicants** via the ePQS-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-PQS 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-PQS Prequalification Holder**.

If the evaluation and/or verification results are **UNSATISFACTORY**, IMD-PQS 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-PQS fully informed about any changes, or “variations” made to: the **product** itself; manufacturing process of the **product**; or manufacturing site of the **product**.



**Product** and manufacturing variations must be reported via the WHO ePQS platform as of Quarter 3 of 2024. Refer to the detailed technical guide in Annex 7 of the Full Guidelines for instructions variations-reporting via WHO ePQS.

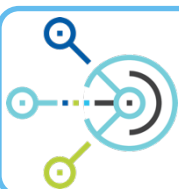
### **Inspections**

In cases where inspections are necessary, they may be carried out by WHO IMD-PQS and/or carried out in collaboration with the WHO Prequalification Unit’s (PQTs) **Inspection Services team**<sup>8</sup>. Inspections carried out by IMD-PQS 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 ePQS.



**Maintaining prequalified status: Post-PQ changes and Inspections**  
[Section 3.4.5 Full Guidelines](#)

### **Stage 5** - Post-prequalification commitments and obligations

IMD-PQS depends on **Prequalification Holders** and the wider immunization community to share feedback on WHO IMD-PQS **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-PQS review procedures and throughout the procurement process at UN procurement agencies.

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

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

<sup>8</sup> <https://extranet.who.int/prequal/inspection-services>



## **1. Post-market monitoring (PMM) requirements**

Post-market monitoring (PMM) is a crucial part of WHO IMD-PQS' 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-PQS product complaints & feedback reporting form](#).

### **Mandatory complaints and failures reporting**

[Prequalification Holders](#) are obliged to report complaints, problems and failures to WHO IMD-PQS **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-PQS, [Prequalification Holders](#) of category E003 [products](#) (ONLY) are required to refer to the WHO IMD-PQS "[Post-market Monitoring \(PMM\) Taxonomy](#)<sup>9</sup>".

### **User feedback and reports**

[Prequalification Holders](#) are **actively encouraged** to collect [user](#) feedback via the [IMD-PQS product complaints & feedback reporting form](#) including positive performance reports and to promptly communicate these reports to IMD-PQS.

### **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-PQS 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.

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.

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<sup>9</sup> <https://extranet.who.int/prequal/key-resources/documents/e003-cold-chain-taxonomy>



Kindly note: the World Health Organization (WHO) reserves the right to delist companies and/or products from the WHO IMD-PQS 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-PQS Secretariat will contact [Prequalification Holders](#) in January and again in February with detailed instructions about relevant submission documents.



[Prequalification Holders](#) must submit the required elements by email to Dr. Isaac Gobina ([gobinai@who.int](mailto:gobinai@who.int)) and Mr. Paul Mallins ([mallinsp@who.int](mailto:mallinsp@who.int)), copying [pqsinfo@who.int](mailto:pqsinfo@who.int).

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

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



In the future, the [Annual Review](#) will take place via the WHO ePQS Platform. Annex 7 of the Full Guidelines will be updated in the course of 2024/5 with instructions for submitting an [Annual Review](#) dossier via the ePQS platform. The core information and documentation required for each submission will remain the same as 2023, although the format is different on the ePQS platform.

### **3. The Extra-ordinary IMD-PQS review process**

If serious problems arise with a prequalified [product](#) that (may) put vaccine potency at risk, the IMD-PQS 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-PQS Prequalified status?**

A [product's](#) IMD-PQS 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-PQS, 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-PQS 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-PQS Extraordinary review process [Section 3.4.6.3 Full Guidelines](#)

Paths to losing prequalified status [Section 3.5 Full Guidelines](#)