World Health Organization

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

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)

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Contacts

WHO IMD-PQS information

pqsinfo @ who.int

Isaac Gobina, IMD-PQS Technical Officer

gobinai @ who.int

Paul Mallins, IMD-PQS Technical Officer

mallinsp @ who.int

Lauren Goodwin, IMD-PQS Programme Manager

lgoodwin @ who.int

Gemma Huckerby, IMD-PQS Communications Manager

huckerbyg @ who.int

WHO Immunization Devices Prequalification website

https://extranet.who.int/pqweb/immunization-devices

Glossary

The following acronyms may be relevant to IMD-PQS applicants and Prequalification Holders.

Note: A full *Terms & Definitions* is provided in Annex 5

AC	Alternating Current
ANSI	American National Standards Institute
AQL	Acceptable Quality Limit
CCE	Cold chain equipment
CE	Conformité Européenne
CEN	Conseil Européen pour la Normalisation
CFC	Chloro-fluoro-carbon
CTC	Controlled Temperature Chain
DC	Direct Current
EEPROM	Electrically erasable, programmable, read-only memory
EHC	Energy Harvest Control
EHT	Essential Health Technologies
EMAS	European Union Eco-Management and Audit Scheme
EMS	Equipment Monitoring Standards
EN	Euro Norm
EPI	Expanded Programme on Immunization
EU	European Union
EVM	Effective Vaccine Management initiative
EVSM	Effective Vaccine Store Management initiative
HDPE	High Density Polyethylene
HFC	Hydro Fluorocarbon
HIP	High Impact Polystyrene
IAPSO	Inter-Agency Procurement Services Office (UN agency)
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ILR	Ice-lined Refrigerator
ISO	International Standards Organization
IVB	Immunization, Vaccine and Biologicals (WHO Department)
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
LDPE	Low Density Polyethylene
LPG	Liquid Petroleum Gas
MHP	Access to Medicines and Health Products Division
MOH	Ministry of Health
NGO	Non-governmental Organization
NIST	United States National Institute of Standards and Technology
ODP	Ozone Depletion Potential
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PIS	Product Information Sheets
PMM	Post-Market Monitoring
PQS	Performance, Quality, Safety
PQT	Prequalification Unit
PV	Photovoltaic

PVC	Polyvinyl Chloride Plastic
PW	Peak Watt
QA	Quality Assurance
QMS	Quality Management System
QSS	Quality, Safety and Standards
RH	Relative humidity
RPQ	Regulation and Prequalification Department
RTMD	Remote Temperature Monitoring Device
SAGE	Strategic Advisory Group of Experts
SDD	Solar Direct Drive
SIGN	Safe Injection Global Network
SOP	Standard Operating Procedure
TLAC	Technologies and Logistics Advisory Committee
TPP	Target product profile
UL	Underwriters Laboratories
ULT	Ultra-Low Temperature
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNICEF-SD	United Nations Children's Fund – Supply Division
UPS	Uninterruptible Power Supply
UV	Ultra-violet light
V	Volt
VAX	Vaccines & Immunization Devices Assessment Team
VIP	Vacuum Insulated Panels
VP	Verification Protocol
VVM	Vaccine Vial Monitor
W	Watt
WHO	World Health Organization

Golden Rules of WHO IMD-PQS Prequalification

This Manufacturer Guideline is a complete 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 Quarter 1 of 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-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 1 of 2025 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 their 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.

Frequently Asked Questions

How much does it cost to apply for IMD-PQS prequalification?

WHO recovers the cost of dossier evaluation through fees charged to the applicant. **Dossier evaluation fees** are set per category of IMD-PQS products. Refer to Section 3.3.1 of this guideline for dossier evaluation fees per category of IMD-PQS product.

As of January 2024, the dossier evaluation fees must be paid in full once the dossier has been accepted for evaluation. Payment should be made within 30 days of receipt of the invoice from WHO. **The commencement of dossier evaluation will be triggered by a confirmation of payment of the invoiced fees**.

IMD-PQS will, in most cases, request the applicant to send the required production-run products (not prototypes or models of products) to one of the WHO-accredited testing laboratories for evaluation against the relevant IMD-PQS verification protocol. Laboratory fees vary.

Applicants whose products are successfully prequalified by WHO IMD-PQS will **also be charged an annual review fee** for each prequalified product. Annual review fees are also set per category of product. Refer to Section 3.3.3 of this guideline for annual review fees.

How long is the prequalification dossier review process? How quickly will my product be prequalified?

Pre-submission: The IMD-PQS Secretariat will reply to a complete pre-submission within 30 days. The purpose of the pre-submission is to screen potential prequalification applications.

Application: The Secretariat will render a decision on a complete prequalification application (via the WHOs ePQS system) within 60 days, except for category E001 in which case 90 days.

The speed of the IMD-PQS prequalification dossier review process from start to prequalification depends heavily on the promptness, completeness and correctness of applicants' replies to IMD-PQS requests for further information. IMD-PQS total response time excludes wait-times whilst applicants are gathering and submitting the requested additional information.

Are laboratory testing costs included in the cost of prequalification?

No, laboratory testing fees are to be paid directly to the relevant testing laboratory by the applicant seeking prequalification. Laboratory fees vary.

Which is the officially appointed laboratory for product testing?

WHO accredits laboratories that are qualified to test one or several IMD-PQS categories. WHO accredits a laboratory only if it can demonstrate to a competent third-party accreditation body that it meets international standards.

The current list of WHO-accredited laboratories is provided in on the IMD-PQS website[1]. Accredited laboratories are presented by location and by IMD-PQS category accreditation(s). Prequalification Holders and WHO PQS-accredited laboratories should use the following template when submitting test results to IMD-PQS: PQS Laboratory Report Template[2].

[1] https://extranet.who.int/prequal/immunization-devices/accredited-laboratories
[2] https://extranet.who.int/prequal/key-resources/documents/who-vax-imd-laboratory-test-report-template

What are the different stages of the prequalification process?

The key stages for applicants to observe, to ensure an efficient and successful prequalification application are:

1. completion of the **pre-submission form**[3], described in Section 3.4.2;
2. a comprehensive **prequalification application**[4] including laboratory testing results (required for most products) and/or field testing (in some cases) described in Section 3.4.3; and
3. **prompt and complete responses** to any subsequent requests for information by IMD-PQS during the product application review process.

The complete stages of the prequalification process are explained in detail in Section 3.4 of this guideline, illustrated by flowcharts.

Complete dossiers will be evaluated by technical specialists appointed by the IMD-PQS Secretariat.

Once a product has been approved for prequalification, IMD-PQS will inform the applicant of this decision. Details of the approved product are then "published " on the IMD-PQS website[5].

In order for a product to *retain* prequalified status, Prequalification Holders must successfully meet **post-prequalification commitments** and **obligations**, as described in Section 3.4.6.

Can product manufacturers (or resellers) request a meeting with WHO IMD-PQS?

Outside of the prequalification process, WHO IMD-PQS only convenes with Prequalification Holders, that is: manufacturers (or resellers) of WHO-IMD prequalified products or devices.

Prospective applicants (manufacturers or resellers interested in pursuing prequalification) should begin by reviewing the existing relevant IMD-PQS product specification(s) and, if appropriate, submitting a pre-submission form (by email to the IMD PQS Secretariat).

[3] https://extranet.who.int/prequal/key-resources/documents/who-imd-pqs-prequalification-pre-submission-form
[4] https://extranet.who.int/prequal/epqs-portal
[5] https://extranet.who.int/prequal/immunization-devices

1. Introduction

These **IMD-PQS Prequalification Guidelines** (hereafter: "Guidelines") are addressed to **applicants** & **IMD-PQS Prequalification Holders** and describe the processes and procedures of the World Health Organization (WHO) Prequalification of Immunization Devices (IMD), Performance, Quality & Safety programme (PQS) **for ALL WHO IMD-PQS product categories**.

The Guidelines provide complete information about the prequalification **requirements**, **obligations and commitments** for new applicants and for Prequalification Holders wishing to maintain WHO-prequalified status for their cold chain-related products, for procurement by United Nations (UN) agencies. The IMD-PQS prequalification lifecycle is comprised of **five procedural stages**:

Product application pre-submission (screening)

Product prequalification application

Dossier review & evaluation

Prequalification

Post-prequalification commitments & obligations

Applicants may offer products which they believe will comply with current WHO IMD-PQS performance specifications for the following categories of equipment:

- E001: Cold rooms, freezer rooms & 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
- E008: Single-use injection devices
- E010: Waste management equipment
- E013: Therapeutic injection devices

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 in support of the WHO's Vaccines Assessment Team (VAX), within the WHO's Department of Regulation and Prequalification (RPQ).

WHO IMD-PQS provides technical expertise aimed at achieving access to reliable, high-quality cold chain products for the world's immunization programmes. It does this through developing performance specifications and verification protocols (standards) for cold chain and other immunization-related equipment and devices, and by applying these standards through the prequalification process. WHO IMD-PQS standards are minimum requirements; they are not restrictive. By selecting from the list of prequalified equipment, UN procurement agencies, governments and NGOs can be sure that they are purchasing products that are fit for purpose.

WHO IMD-PQS standards have been developed over many years in response to the evolving needs of end-users (national immunization programmes), and in consultation with stakeholders, industry and testing laboratories. They are the result of a long-established and rigorous procedure for evaluating and prequalifying suitable equipment. Links to a complete set of the WHO IMD-PQS Standard Operating Procedures (SOPs) are provided in Section 7 of this Guideline.

Prequalification Holders contribute to WHO's goal of expanding and extending access to quality-assured, reliable products that help safeguard vaccine potency by:

- manufacturing products in accordance with IMD-PQS specifications;
- sharing feedback on equipment performance issues and taking appropriate corrective action;
- informing WHO of emerging technologies that may be suitable for challenging operating environments.

As of 2024, WHO IMD-PQS lists products prequalified by 83 Prequalification Holders, spread across all 6 WHO regions.

3. Procedural guide

3.1 Introduction to IMD-PQS prequalification

3.1.1 What does 'IMD-PQS prequalification' mean?

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 Catalogue (available here[6]). **The grant of IMD-PQS prequalified status does not constitute a guarantee of purchase**. The Prequalification Holder is entirely responsible for making a commercial arrangement with a potential purchaser, and for ensuring that the quality of the specific product(s) delivered is acceptable to that purchaser. In this context, the word 'purchaser' means any one of the UN agency procurement units, including UNICEF, IAPSO, UNFPA, WHO & PAHO.

Applicants and Prequalification Holders should also be aware that the **individual UN procurement agencies reserve the right to impose additional conditions and limitations** when seeking offers for the supply of prequalified products.

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.

3.1.2 Can my company be considered?

Any manufacturer of an immunization-related product or device, belonging to a category that WHO prequalifies, may submit a product for prequalification. WHO prequalifies products that are offered by the legal manufacturer of the product. Products offered by a reseller may also be considered for prequalification if a formal licensing arrangement has been made with the legal manufacturer regarding the marketing, distribution, warranty arrangements and product maintenance, either globally, or within a large geographical area.

3.1.3 What products or devices are eligible for prequalification?

Products offered by applicants must comply with one of the IMD-PQS Performance Specifications & Verification Protocols. Products and devices are eligible for prequalification once they have been formally submitted to WHO and have passed the requisite verification process. Prequalified products will be added to the WHO IMD-PQS Catalogue of prequalified products. IMD-PQS will only prequalify one version of a product or device sourced directly from the legal manufacturer or licensed reseller. Re-badged or re-packaged variants will not be considered.

3.1.4 What are the stages of the IMD-PQS prequalification process?

The prequalification lifecycle consists of five stages:

1. Applicant submits a **product application pre-submission**;
2. Applicant **submits a complete product prequalification application**;
3. WHO IMD-PQS conducts the **dossier review and product evaluation**;
4. If the dossier and product evaluation is satisfactory, **prequalification is granted**;
5. In order for a product to *retain* prequalified status, Prequalification Holders must successfully meet **post-prequalification commitments**.

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

3.1.5 How can I apply for IMD-PQS prequalification for my product or device?

NEW

ePQS WHO e-prequalification platform

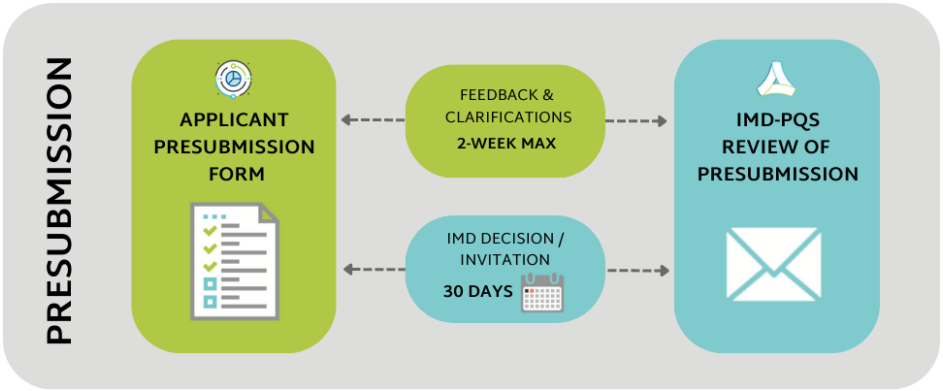
As of Quarter 1 2025, IMD-PQS applications for prequalification must be submitted via the **WHO ePQS ("e-Prequalification system") platform** (excluding the pre-submission screening), as must reports of post-prequalification product variations and changes. WHO ePQS user guidance for IMD-PQS applicants and Prequalification Holders is provided throughout these guidelines, and **step-by-step instructions** are provided in Annex 7: "*WHO IMD ePQS Technical Guide*".

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

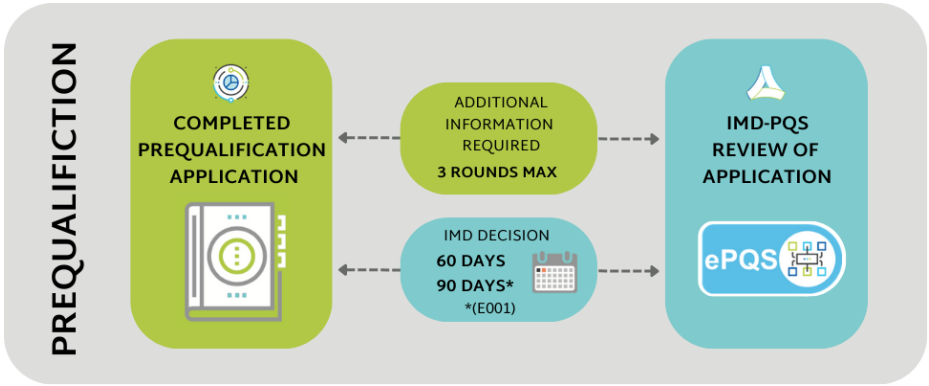
IMPORTANT: WHO e*PQS* – "electronic **P**re**Q**ualification **S**ystem" **does not** refer to the IMD-*PQS* "WHO Immunization Devices, Performance, Quality and Safety".

3.2 Prequalification application timelines & IMD-PQS response times

Stage 1 – Pre-submission (screening): IMD-PQS will contact applicants within 30 DAYS§ after receiving a complete pre-submission form.



Stage 2 - Prequalification application: IMD-PQS will render a decision to the applicant 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-PQS response times **depends on the speed and completeness of applicant replies** to IMD-PQS requests for further documents or information: response time excludes wait-times whilst applicants are gathering and submitting the requested additional information.

3.3 Cost of WHO IMD-PQS prequalification

Three different fees will be due over the lifetime of an IMD-PQS prequalified product:

3.3.1 Prequalification application evaluation fee

WHO levies a non-refundable, cost-recovery fee for application dossier evaluation. Application evaluation fees are set per category of products. The fees for all categories of products are provided in Section 3.3.5 of this Guideline.

WHO will invoice 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.

In some cases, IMD-PQS may request applicants to provide production-run product examples of the product (not prototypes or models) as a part of the application dossier submission. In such cases the applicant is responsible for bearing the cost of the production-run products provided, and of their shipping.

3.3.2 Laboratory testing fee

IMD-PQS will, in most cases, request the applicant to send the required production-run products (not prototypes or models of products) to one of the WHO-accredited testing laboratories, for evaluation against the relevant IMD-PQS Verification Protocol. The applicant will be required to pay for laboratory testing; it is NOT covered by the IMD-PQS application evaluation fee. **Laboratory fees vary.**

3.3.3 Annual review of prequalified products fee

Prequalification Holders are also charged a fee for the annual product review. Fees are due for EACH product submitted for Annual Review, in order to maintain prequalified status for the following 12 months.

WHO will invoice the annual review fees to the Prequalification Holder by 31 March, for each prequalified product that was listed in the IMD-PQS Product Catalogue up to the 31 December of the previous year. **The annual product review will not commence unless payment of the invoiced annual fees has been confirmed.** Payment should be made within 30 days of receipt of the invoice from WHO.

3.3.4 Inspections: cost recovery

In some cases, inspections may be carried out in connection with an IMD-PQS prequalification application, or carried out in close collaboration with the Prequalification Unit's (PQTs) Inspection Services team.

Although not considered a "fee", inspections are conducted on a full "**real cost recovery**" basis (the Prequalification Holder is required to reimburse the cost of the inspection).

3.3.5 Table of Prequalification Application Review and Annual Review Fees

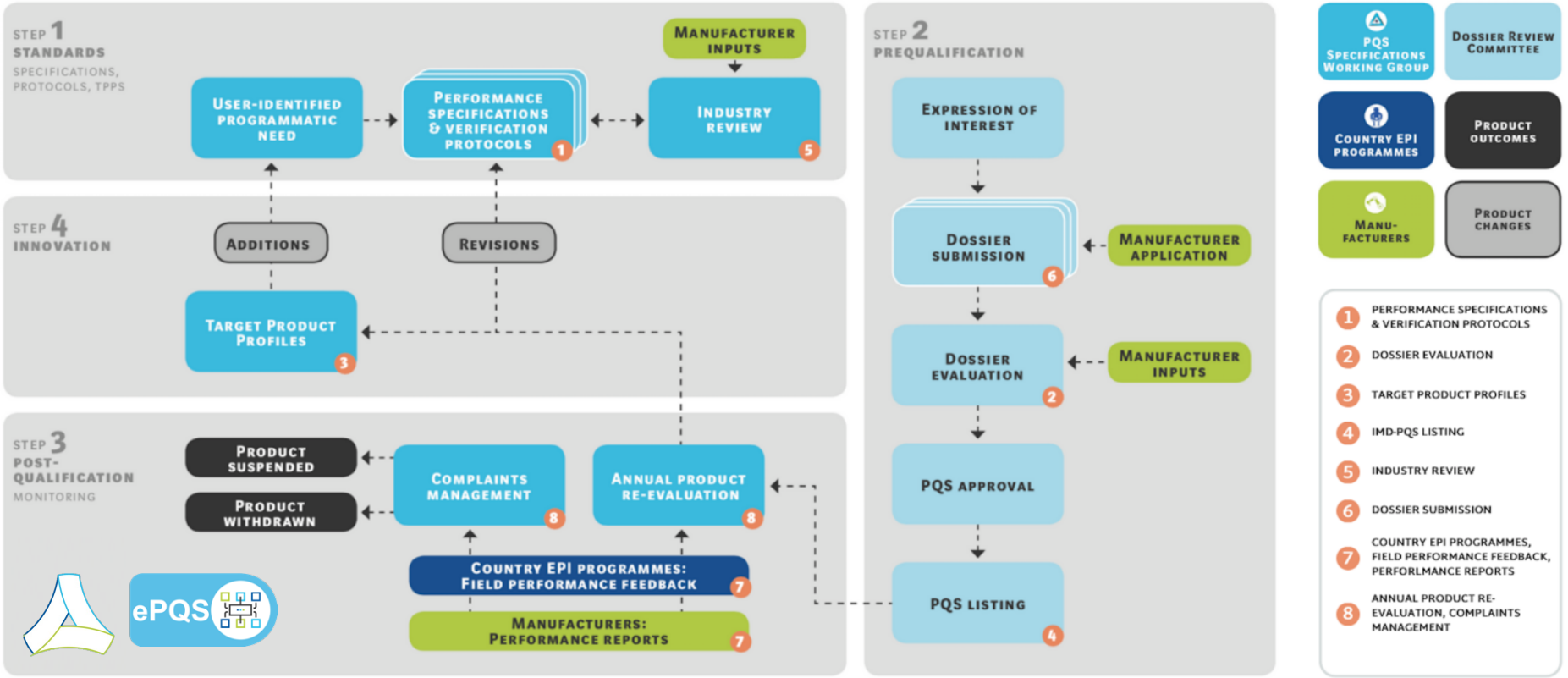
CATEGORY	Dossier evaluation fee (US$)	Annual review fee (US$)
E001 - Cold rooms, freezer rooms & related equipment	2,400	1,400
E002 - Refrigerated vehicles	2,400	1,400
E003 - Refrigerators and freezers	2,400	1,300
E004 - Cold boxes and vaccine carriers	2,000	1,200
E005 - Coolant-packs	600	300
E006 - Temperature monitoring devices	2,400	1,200
E007 - Cold chain accessories	2,400	1,200
E008 - Single-use injection devices	3,000	1,600
E010 - Waste management equipment	2,400	1,200
E013 - Therapeutic injection devices	3,200	1,600

3.4 Stages of the prequalification lifecycle

The following flow chart illustrates the five stages of the IMD-PQS lifecycle.

Detailed procedural explanation for applicants and the obligations and commitments of Prequalification Holder for each stage are provided in the sections that follow in this guide.

3.4.1 Overview: complete IMD-PQS prequalification lifecycle



3.4.2 Stage 1 - Product application pre-submission

Potential applicants must begin by submitting a complete pre-submission form[7]. 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., that answers the needs of national 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. **Completion of the pre-submission form is obligatory**.

Applicants should refer to the relevant IMD-PQS Performance Specification(s)[8] and Verification Protocol(s)[9] to assess whether their product or device corresponds to an IMD-PQS Product Category or Sub-Category, and whether a full application is warranted.

The pre-submission screening process requires applicants to provide the following information and documentation:

- Applicant company information
- Authorised contacts for the applicant
- Product name & manufacturers/resellers own product reference
- Name and number of the reference IMD-PQS Product Specification
- Previous product testing information
- Licensing information and documents
- Certification information and documents
- WHO history of product
- Prequalification Holder declaration

A checklist of this supporting documents is provided in Section 4.1 of this guide.

3.4.2.1 Method to submit pre-submission forms to WHO IMD-PQS

The pre-submission process remains external to the WHO ePQS platform.

The applicant must submit the following elements by email to Dr. Isaac Gobina (gobinai@who.int) and Mr. Paul Mallins (mallinsp@who.int), copying pqsinfo@who.int.

- the completed pre-submission form,
- including a cover email, in English,
- accompanied by the required documentation.

The subject line of the email should clearly indicate "PRESUBMISSION FORM".

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

[7] https://extranet.who.int/prequal/key-resources/documents/who-imd-pqs-prequalification-pre-submission-form
[8] https://extranet.who.int/prequal/immunization-devices/performance-specifications
[9] https://extranet.who.int/prequal/immunization-devices/verification-protocols

3.4.2.2 *File name conventions: pre-submission forms*

WHO IMD-PQS prequalification pre-submissions now require all documents submitted to **adhere to specific file name conventions.** The list of the required file name conventions can be found in Annex 2 of this guide.

Pre-submissions received containing documents with incorrectly-named files will be returned for correction before dossier evaluation may commence.

3.4.2.3 *IMD-PQS response times: pre-submission process*

The IMD-PQS Secretariat will render a decision on a complete pre-submission within 30 days. Refer to Section 3.2 "Stage 1" above.

3.4.3 Stage 2 - Product application: submission of product dossier

If the IMD-PQS Secretariat 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[10], including (but not limited to) the elements listed in Section 3.4.3.2.

The IMD-PQS Secretariat will send the applicant **an information pack** via email. The information pack contains the **complete application instructions** and documentation including: the relevant Performance Specifications, Verification Protocols, an "Application Review Template" and WHO's Terms & Conditions[11] along with other related material specific to the product and its prequalification.

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**.

Applicants must additionally review the complete instructions for submission contents provided in the **relevant WHO IMD-PQS Performance Specification(s),** included in the information pack received from the IMD-PQS Secretariat.

In addition to the documentation and information provided in the application dossier, applicants **may be required** to test products using one of three types of **laboratory testing** (Section 3.4.3.6) , and/or field-testing (Section 3.4.3.7) for further information on product testing requirements and to know if your product is concerned.

3.4.3.1 *Application tracking and communication: "Application review template"*

IMD-PQS "***Application review templates***" 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 IMD-PQS Secretariat will provide the template to applicants via the WHO ePQS system if, following pre-submission, the Secretariat deems the product or device eligible for prequalification evaluation. The templates are also available for download here[12].

[10] https://extranet.who.int/prequal/epqs-portal
[11] https://extranet.who.int/prequal/sites/default/files/document_files/WHO IMD-PQS Terms and Conditions_3.pdf
[12] https://extranet.who.int/prequal/immunization-devices/application-dossier-requirements

3.4.3.2 *Generic list of supporting documents: application for WHO IMD prequalification*

GENERIC list of supporting documents required for a prequalification application

A checklist of the following supporting documents is also provided in Section 4.2 of this document. Applicants must also refer to the **relevant Performance Specification(s)** and to the **category-specific instructions sent by the IMD-PQS Secretariat** following a successful pre-submission and on receipt of an invitation to submit a full prequalification application.

- Completed **'Application review template'**[13], including the required indications that the product successfully meets the category and product criteria as set out in the relevant product specification and verification protocol(s).
- **Cover letter**, in English, expressing interest in participating in WHO prequalification and confirming that the information submitted in the product dossier is "true and correct".
- **A comprehensive set of photographs** including a three-quarter view of the product or device, external surfaces of the unit, and interior layout (where relevant).
- **Certified copies of all type-approvals** obtained for the product and/or its components, including CE marking and similar.
- **Certified copies of the legal manufacturer's ISO certificates,** as specified in the relevant WHO IMD-PQS equipment performance specification(s).
    - If you are a product reseller applying for prequalification, you must provide your own ISO certificates and those of the original product manufacturer as well.
- **Laboratory test report(s)** proving conformity with the relevant WHO IMD-PQS equipment performance specification(s) and verification protocol(s), using the Laboratory test report template[14] (see Section 3.4.3.6 for information on laboratory testing).
- **Signed copy of the WHO IMD-PQS Terms & Conditions,** recognizing that by submitting a product for prequalification you agree by its articles: IMD-PQS Terms & Conditions.
- **Field testing report(s)** IF REQUIRED according to the relevant IMD-PQS verification protocol(s), (see Section 3.4.3.7 for information on Field testing).
- **Details of the compatible solar power system** IF REQUIRED by the relevant WHO IMD-PQS performance specification.

In addition, to be sent by postal / delivery courier:

- **Production-run products**, if required for testing by the relevant WHO IMD-PQS equipment performance specification: categories E006, E008, E010 and E013 only.

3.4.3.3 *Method to submit a prequalification application to WHO IMD-PQS*

The preceding documents must be **uploaded** to the WHO ePQS platform**,** to complete the **online** prequalification application.

Applications may be created in WHO ePQS **at any time,** once the applicant has received an invitation and information pack from the IMD-PQS Secretariat via the ePQS platform.

For complete instructions on applications via the WHO ePQS platform, please refer to the WHO ePQS Technical Guide in Annex 7 of this document.

[13] https://extranet.who.int/prequal/immunization-devices/application-dossier-requirements
[14] https://extranet.who.int/prequal/key-resources/documents/who-vax-imd-laboratory-test-report-template

3.4.3.4 File name conventions: prequalification application

WHO IMD-PQS prequalification applications now require all documents submitted to **adhere to specific file name conventions.** Please refer to Annex 3 for the list of required file name conventions. Applications containing documents with incorrectly-named files will be returned for correction.

3.4.3.5 IMD-PQS response times: prequalification application (WHO ePQS)

The IMD-PQS Secretariat will render a decision on a complete application, via the WHO ePQS platform, within 60 days for products of all IMD-PQS categories except E001, where the decision will be rendered within 90 days. Refer to Section 3.2 above.

3.4.3.6 Product 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.

Laboratory testing results MUST be submitted to PQS using the "IMD-PQS Laboratory Report Template[15]".

Laboratory testing results must be uploaded to the product application created on the WHO ePQS platform[16].

The specific requirements of laboratory testing depend on the **volumes** that would be deployed and whether the product is **safety-critical** or not.

The three types of laboratory testing are:

- ***Type-examination,*** an inspection of a product production-run product. Required for items that are not programme-critical;
- ***Independent type-testing,*** an inspection and a rigorous test of a production-run product. Required for programme-critical product; and
- ***Full quality assurance,*** an inspection of the production site carried out against a pre-defined checklist. Required for complex, programme-critical products involving site-specific design and on-site installation work.

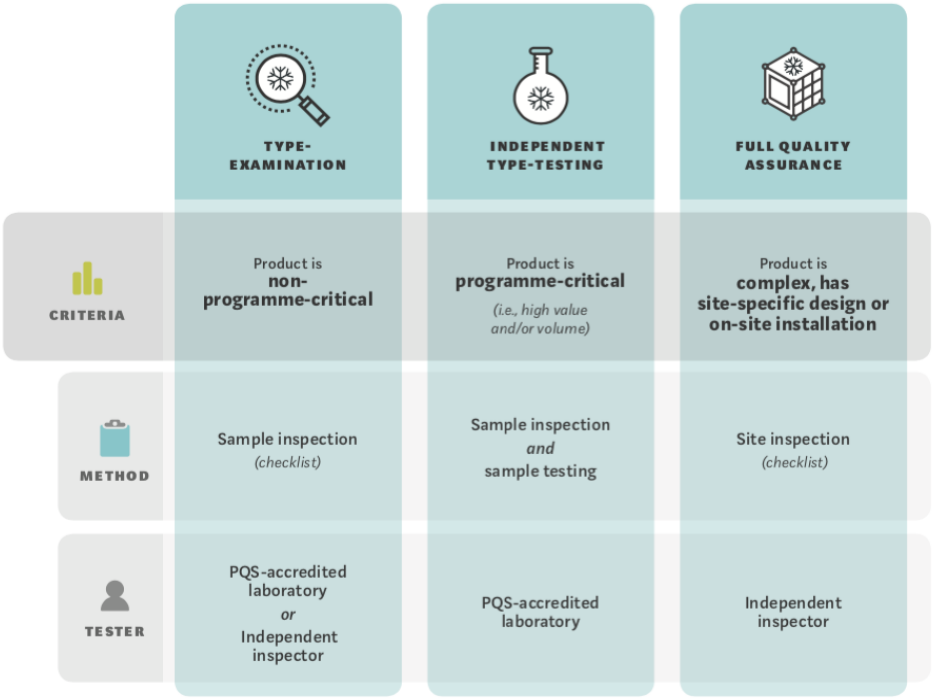
All independent type-testing must be carried out by an accredited testing laboratory. Type-examination or full quality assurance can be carried out either by an accredited laboratory or by an independent specialist appointed by IMD-PQS.

For some of the IMD-PQS product categories more than one type of laboratory testing may be required. The IMD-PQS Secretariat will inform applicants of the type(s) of laboratory testing that will be required for each prequalification application.

A list and a map of WHO-accredited laboratories are provided on the IMD-PQS website[17].

[15] https://extranet.who.int/prequal/key-resources/documents/who-vax-imd-laboratory-test-report-template
[16] https://extranet.who.int/prequal/epqs-portal
[17] https://extranet.who.int/prequal/immunization-devices/accredited-laboratories

Overview: Types of laboratory testing for IMD-PQS prequalification



3.4.3.7 *Product Field testing*

In some cases, the results of additional testing of a product or device in its intended operating environment may be required to 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.

Field-testing will always be required for:

- products that require the establishment of a new IMD-PQS category, and for
- products that are based on technologies that are new to the Expanded Programme on Immunization.

Field-testing may also be needed where products or devices:

- are safety-critical or are to be used in very large quantities
- require specific tests not covered under existing protocols
- require specific user training acceptance by end-users or operators
- have a history of technical failures.

Applicants should ask WHO whether their product will require field testing on a case-by-case basis. Field testing will always require a **Study Protocol** that has been approved by the IMD-PQS Secretariat in advance of the testing. Field-testing provides 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. Further information on the steps of field testing are available on the IMD-PQS Website[18] and in the IMD-PQS "Generic Guide to Field Testing"[19].

Field-testing results must be uploaded as a part of the product prequalification application created on the WHO ePQS platform as of Quarter 1 2025. Field testing results are accepted via email until this time.

[18] https://extranet.who.int/prequal/immunization-devices/product-testing-support-manufacturers
[19] https://extranet.who.int/prequal/key-resources/documents/imd-pqs-generic-guide-field-evaluation

3.4.4 Stage 3 - Prequalification application screening 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 cloud file sharing ("Box") correspondence platform and will be provided with a single opportunity to provide the missing information or material,
- the applicant must **provide 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 review the application dossier and laboratory test results, as well as share its recommendations as to whether products meet 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**.

During dossier evaluation, the IMD-PQS 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:

- applicants 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.

The application submission and evaluation process can be straightforward, provided the dossier is complete, prepared as per the latest performance specifications and all licences are up to date. If field evaluation and/or other validation of a product is required, results and/or laboratory tests outcomes must be included in the dossier (see Section 3.4.3.6 and Section 3.4.3.7 above).

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

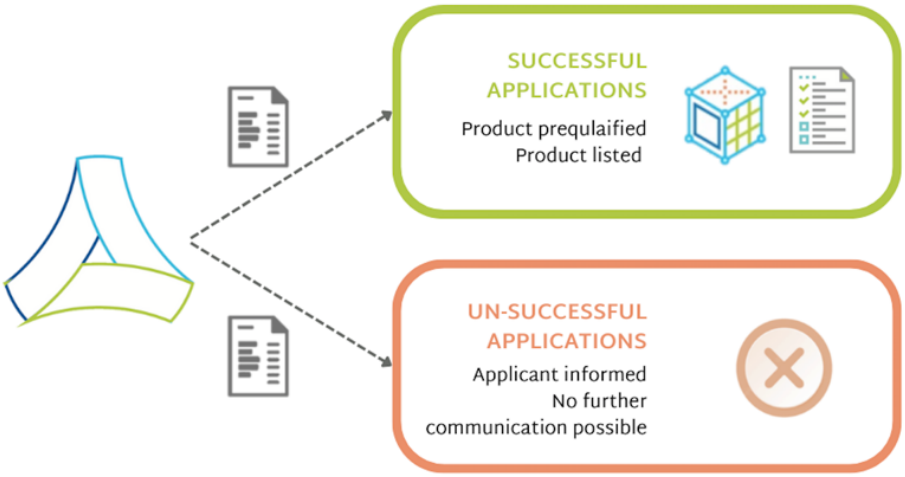
3.4.4.1 Application review decision

After fully evaluating an application, IMD-PQS will inform applicants whether any clarifications or additional information is required before a final decision regarding prequalification can be taken. IMD-PQS will inform applicants via the WHO ePQS platform correspondence platform (See Annex 7 for detailed instructions on WHO ePQS).

If the results of the evaluation and verification are **SATISFACTORY**, WHO IMD-PQS will inform the applicant and will forward a copy of the verification report. The successful

applicant is granted the denomination of IMD-PQS Prequalification Holder. Any remaining concerns will be noted therein and must be addressed prior to the next Annual Review.

If the evaluation and/or verification results are **UNISATISFACTORY,** IMD-PQS will inform the applicant that the product is not suitable in its current form. A copy of the verification report shall be sent. WHO IMD-PQS' decision is final and no correspondence with unsuccessful applicants will be entered into.



3.4.5 Stage 4 - Prequalification

Once a product has been approved for prequalification, IMD-PQS will inform the applicant of this decision by electronic correspondence via the WHO ePQS platform. Details of the approved product are then "published[20]" on the IMD-PQS website and in the IMD-PQS Product Catalogue[21].

3.4.5.1 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 the next scheduled Annual Review of products (see Section 3.4.6.2) (whichever occurs first). A 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.

Important note: a change to the manufacturing location/site automatically removes prequalified status and requires a new prequalification application and a new IMD-PQS PQ number/product code.

Product and manufacturing changes and variations must be reported via the WHO ePQS platform as of Quarter 1 2025. Please refer to the detailed technical guide in Annex 7 below for instructions on how to report changes.

[20] https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products
[21] https://extranet.who.int/prequal/immunization-devices/download-catalogue

3.4.5.2 *Inspections*

In cases where inspections are necessary, they may be carried out by IMD-PQS and/or in collaboration with the Prequalification Unit's (PQTs) Inspection Services team[22].

Inspections carried out of 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.

Inspection Services consists of a team of expert inspectors and an IMD-PQS Secretariat support group who contribute to the prequalification process and complement the work of all Product Streams by organizing, coordinating and conducting inspections in order to assess and verify compliance of a manufacturer / CRO / laboratory with relevant international standards and norms in connection with a prequalification application.

The aim of the inspection is to confirm Prequalification Holders' compliance with relevant good practices, international standards and adherence to information submitted in the prequalification application. Inspections may be carried out:

- via an initial on-site inspection, or
- 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.

Further information is available on the

- WHO Prequalification Inspection Services[23] website.
- Inspection procedures[24].

Inspections are conducted on a full "**real cost recovery**" basis (the Prequalification Holder is required to reimburse the cost of the inspection).

3.4.6 Stage 5 - Post-prequalification commitments & obligations

IMD-PQS depends on Prequalification Holders and the wider immunization community to share feedback on IMD-PQS prequalified 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.

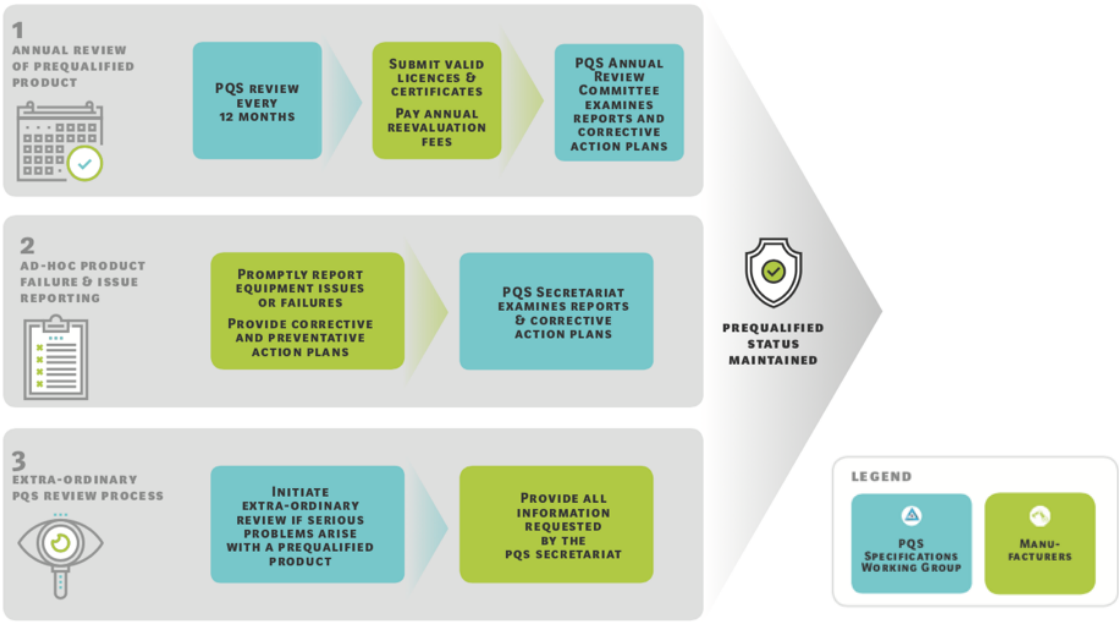
The performance of prequalified products is continually reviewed through the formal IMD-PQS review procedures and throughout the procurement process at UN and other procurement agencies.

[22] https://extranet.who.int/pqweb/inspection-services
[23] https://extranet.who.int/pqweb/inspection-services/what-we-do
[24] https://extranet.who.int/pqweb/inspection-services/vaccines

Prequalification Holders agree to **fulfil three types of post-prequalification commitments:**

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

Summary: Post-prequalification commitments & obligations



3.4.6.1 Post-market monitoring (PMM) requirements

Post-market monitoring (PMM) is a crucial part of WHO IMD-PQS' work. It is mandatory for all Prequalification Holders to provide feedback on product performance and safety. The success of IMD-PQS post-market monitoring depends on Prequalification Holders and the wider immunization community to collect and share information and operational feedback about product performance in immunization operating environments to:

- contribute information for the prequalification of appropriate products,
- ensure that WHO endorsement of the performance, quality and safety of prequalified products remains valid,
- provide insight into the reasons for equipment failure, which can inform and improve performance specifications and verification protocols,
- ensure timely feedback to Prequalification Holders to enable corrective and preventative actions, and
- collect information that can be used to improve countries' vaccine management systems.

Reports of performance issues or failures will NOT automatically lead to the suspension of a product's prequalified status.

3.4.6.1.1 Complaints and failures reporting

Prequalification Holders are obliged to report complaints, problems and failures to IMD-PQS as soon as the complaint comes to their attention throughout the period of prequalification (not only during the annual review) using the dedicated IMD-PQS prodct complaints & feedback reporting form.

Complaints and failures may include, but are not limited to: production defects, poor performance, product recalls, reported complaints. Reports of performance issues or failures will NOT lead automatically to the suspension of a product's prequalified status.

3.4.6.1.2 Mandatory E003 Taxonomy for performance reporting

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[25]" (et la Taxonomie en Français[26])

3.4.6.1.3 User feedback and reports

Prequalification Holders are also **strongly encouraged** to collect user feedback, including positive performance reports, user experience reports and product defect reports, and to promptly communicate these reports to the IMD-PQS Secretariat via the complaints & feedback reporting form.

3.4.6.1.4 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 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). Prequalification Holder analysis of product performance as a part of the annual review means that the root-causes of technology issues or product defects can be identified and addressed.

3.4.6.1.5 Method to submit product performance, failures and complaints reports

Prequalification Holders must submit product performance failures and complaints reports, either:

- with the IMD-PQS complaints& feedback reporting form, or
- by email to Dr. Isaac Gobina (gobinai@who.int) & Mr. Paul Mallins (mallinsp@who.int), copying pqsinfo@who.int.

[25] https://extranet.who.int/prequal/key-resources/documents/e003-cold-chain-taxonomy
[26] https://extranet.who.int/prequal/key-resources/documents/e003-taxonomie-chaine-de-froide

3.4.6.2 *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. This means that in the first year following prequalification, a product may be re-evaluated less than 12 months after it has been prequalified.

The purpose of the annual review is threefold:

- to verify that certificates are up to date,
- to check whether the product design or manufacturing process has changed,
- to check whether any significant defects or failures have been noted.

An overview of the requirements of the Annual Review submission is provided in Section 4.3 of this guideline. A sample submission package[27] is available for view on the IMD-PQS website. Amongst other information, Prequalification Holders must report all complaints and performance issues as part of their Annual Review.

Kindly note: the World Health Organization (WHO) reserves the right to delist companies and/or products from the WHO IMD-PQS Catalogue[28] if insufficient, invalid or fraudulent information is submitted as a part of the Annual Review.

3.4.6.2.1 File name conventions: Annual Review of products

WHO IMD-PQS Annual Review requires all documents submitted to **adhere to specific file name conventions.** The list of the required file name conventions can be found in Annex 4 of this guidelines.

Submissions received containing documents with incorrectly-named files will be returned for correction before dossier evaluation may commence.

3.4.6.2.2 Methods to submit the Annual Review dossier

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) and Mr. Paul Mallins (mallinsp@who.int), copying 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 this Guideline will be updated in the course of 2025 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.

[27] https://extranet.who.int/prequal/immunization-devices/annual-review

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

3.4.6.3 *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 Holders 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.

3.5 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	The Prequalification Holder decides to remove the product from the PQS-Catalogue. This may be done at any time, in writing, to IMD-PQS.
Suspended	IMD-PQS responds to an unresolved performance issue identified with the product.
Definitively Removed	The result of an unresolved "suspension"; the product is definitively removed from the list of IMD-PQS-prequalified products.
Made obsolete	The IMD-PQS performance specification of reference is changed or withdrawn and the product's technical specifications are not updated accordingly.

Typical reasons that could lead to the loss or removal of prequalified status include (refer to Annex 1):

- a change in the manufacturing site with or without notifying WHO of the intention to do so,
- a change to the product in an unacceptable way (one that negatively affects the performance of the product) with or without notifying WHO of the intention to do so,
- a failure on the part of the Prequalification Holder to provide evidence of annual license renewal(s) for the product or any other relevant time expiring documentation,
- if WHO receives reports from the UN procurement agencies showing that production quality control is poor or inconsistent,
- if the functioning of the product in the field is shown not to be meeting the performance requirements,
- if the Prequalification Holder enters into bankruptcy or receivership.

4. Checklists of application contents

Applicants should refer to the following checklists to ensure that they submit the correct and complete information to the IMD-PQS Secretariat at each stage.

4.1 Product application pre-submission (screening) overview

Refer to Section 3.4.2 of this Guideline for detailed information on the pre-submission process.

Pre-submission must be made via email (see Section 3.4.2.1), by submitting a completed "pre-submission form[29]" and the required documentation.

FILE NAME CONVENTIONS: The following pre-submission dossier elements MUST be submitted using the file name conventions indicated in Annex 2 of this Guideline.

• Applicant information
• Authorised contacts for the applicant
• Product name and manufacturer's own product reference for WHO prequalification assessment
• Name and number of the reference IMD-PQS product specification
• Product testing information
• Licencing information
• Certification information
• WHO history of product
• Prequalification Holder declaration

4.2 Prequalification application summary checklist

Refer to Section 3.4.3 of this Guideline for detailed information on the prequalification application process. Prequalification applications must be made via the WHO ePQS platform[30].

Following a successful "pre-submission", applicants will receive a complete information package from the IMD-PQS Secretariat with detailed instructions on how to apply for prequalification for their specific product.

Applicants must also review the complete instructions for submission contents provided in the **relevant WHO IMD-PQS performance specification[31]**.

FILE NAME CONVENTIONS: The following prequalification dossier elements MUST be submitted using the file name conventions indicated in Annex 3 of this Guideline.

[29] https://extranet.who.int/prequal/key-resources/documents/who-imd-pqs-prequalification-pre-submission-form
[30] https://extranet.who.int/prequal/epqs-portal
[31] https://extranet.who.int/prequal/immunization-devices/performance-specifications

1. Completed **'Application review template[32]'**, including the required indications that the product successfully meets the category and product criteria as set out in the relevant product specification and verification protocol(s).	
2. Cover letter, in English, expressing interest in participating in WHO prequalification and confirming that the information submitted in the product dossier is "true and correct".	
3. A comprehensive set of photographs including a three-quarter view of the product or device, external surfaces of the unit, and interior layout (where relevant).	
4. Certified copies of all type-approvals obtained for the product and/or its components, including CE marking and similar.	
5. Certified copies of the legal manufacturer's ISO certificates, as specified in the relevant WHO IMD-PQS equipment performance specification(s). If you are a product reseller applying for prequalification, you must provide your own ISO certificates and those of the original product manufacturer as well.	
6. Laboratory test report(s) proving conformity with the relevant WHO IMD-PQS equipment performance specification(s) and verification protocol(s) (see Section 3.4.3.6 for information on laboratory testing).	
7. Signed copy of the WHO IMD-PQS Terms & Conditions, recognizing that by submitting a product for prequalification you agree by the IMD-PQS Terms & Conditions.	
8. Field testing report(s) IF REQUIRED according to the relevant IMD-PQS verification protocol(s), (see Section 3.4.3.7 for information on Field testing).	
9. Details of the compatible solar power system IF REQUIRED by the relevant WHO IMD-PQS performance specification.	
10. Production-run products (not prototypes or models of products) if required by the relevant WHO IMD-PQS equipment performance specification: categories E006, E008, E010 and E013 only.	

Dossier evaluation fee: WHO levies a non-refundable, cost-recovery fee for application evaluation. Application evaluation fees are set per category of product or device. The fees for each category of product are provided in Section 3.3.5 of this Guideline.

WHO will invoice the applicant once the product application has been submitted via the WHO ePQS platform. The dossier evaluation fees must be paid in full once the dossier has been accepted for evaluation. Payment should be made within 30 days of receipt of the invoice from WHO. **Evaluation of the product dossier will not begin until the fee has been paid in full, in US Dollars, upon receipt of the invoice.**

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

4.3 IMD-PQS Annual Review summary checklist

Refer to Section 3.4.6.2 of this Guideline for a description of the Annual Review process. Annual Review submissions must be made by email submission to the IMD-PQS Secretariat. In the future Annual Review submissions will be via the WHO ePQS platform[33].

Detailed instructions will be provided in the *WHO IMD-PQS "Invitation to submit a product for Annual Review"*, which is sent annually by email to every Prequalification Holder.

FILE NAME CONVENTIONS: The following Annual Review submission elements MUST be submitted using the file name conventions indicated in Annex 4 of this Guideline.

• **Company licence** for the product manufacturer	
• **Company licence** for the product reseller *(if relevant)*	
• **Notarised translations of licences** that are not in English or French	
• **All relevant ISO certifications** (see relevant performance specification(s))	
• **Notarised translations of certificates** where the original is not in English or French	
• **Copy of IMD-PQS Product Data Sheet** (as per the IMD-PQS Product Catalogue)	
• *If the data sheet needs to be corrected or updated with product information* please provide **a hand-annotated, scanned or photocopied version of the Product Data Sheet** that describes these required changes.	

Additional important information:

- Scope of submissions: Please **ONLY** submit the specific forms and documentation that are requested, and no additional documentation; submitting additional documentation slows down the review.

- Reporting PMM data: Reporting PMM data (complaints and CAPA information) is not only encouraged as a part of the Annual Review of IMD-PQS-prequalified products, it is **MANDATORY**. Reporting complaints and CAPA information is also a sign of a healthy and well-functioning quality management system.

- Failure reporting taxonomy: Prequalification Holders of products in IMD-PQS category E003 are required to refer to the **WHO PQS post-market monitoring (PMM) taxonomy**[34] (et la **Taxonomie en Français**[35]) to describe and detail all failures in Table 4 of Form B. The taxonomy is also provided in this package of Annual Review submission documents, in English and in French.

- Product data sheet changes: In the case that you need to request changes to the Product Data Sheets, you will now be required **to report separately** the changes that relate to administrative data, and the changes that related to product technical information in the tables provided in the Annual Review submission pack.

[33] https://extranet.who.int/prequal/epqs-portal
[34] https://extranet.who.int/prequal/key-resources/documents/e003-cold-chain-taxonomy
[35] https://extranet.who.int/prequal/key-resources/documents/e003-taxonomie-chaine-de-froide

5. PQS Performance Specifications & Verification Protocols

This section provides the website links to access the performance specifications, verification protocols and other reference documents for each of IMD-PQS product category.

IMPORTANT: Always refer to the IMD-PQS website for the most up to date and complete list of standards.

WHO IMD-PQS Performance Specifications (all categories)

LINK IN FULL: https://extranet.who.int/pqweb/immunization-devices/performance-specifications

Presentation: Drop down menu organized by product category.

WHO IMD-PQS Verification Protocols (all categories)

LINK IN FULL: https://extranet.who.int/prequal/immunization-devices/verification-protocols

Presentation: Drop down menu organized by product category.

6. Additional category-specific guidance

This section provides the website links to access **additional category-specific guidance documents** that contain important information for the preparation of a product prequalification application, listed below.

IMPORTANT: Always refer to the IMD-PQS website for the most up to date and complete list of guidance materials.

CATEGORY-SPECIFIC GUIDANCE

All category specific guidance is provided on the IMD-PQS website:

LINK IN FULL: https://extranet.who.int/prequal/immunization-devices/product-categories-general-introduction

7. IMD-PQS Standard Operating Procedures (SOPs)

This section provides the website link to access the WHO IMD-PQS Standard Operating Procedures (SOPs).

IMPORTANT: Always refer to the IMD-PQS website for the most up to date and complete list of SOPs.

WHO IMD-PQS Standard Operating Procedures (SOPs)

LINK IN FULL: https://extranet.who.int/pqweb/immunization-devices/standard-operating-procedures

8. Annexes

Annex 1 – Standard Terms & Conditions

The Terms & Conditions can be downloaded on the IMD-PQS website here:
https://extranet.who.int/prequal/key-resources/documents/who-imd-terms-conditions-0

World Health Organization

WHO/PQT/VAX/IMD/T&C 1.0
January 2024

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

WHO IMD PQS Standard Terms & Conditions

APPLICABILITY: The Terms & Conditions set out below will apply to all IMD-PQS Prequalification Holders or *prospective* Prequalification Holders.

PREQUALIFICATON HOLDER **OBLIGATIONS:** Prequalification Holders and *prospective* Prequalification Holders should familiarize themselves with this document and ensure that they comply fully with the on-going reporting requirements set out therein. Failure to do so may result in the suspension or withdrawal of prequalified status.

PREQUALIFICATON HOLDER **MANDATORY SIGNATURE:** At the application stage, *prospective* Prequalification Holders must **countersign** these Terms & Conditions as acknowledgement that they understand and agree to be bound by them. The signature zone is found at the end of the document.

STANDARD TERMS & CONDITIONS
1. **Manufacturer intellectual property declaration:** You confirm that you are the legal manufacturer of, and that you have intellectual property ownership of, the IVD to be prequalified. If you have concluded agreements or otherwise established arrangements with any third-party regarding production and/or distribution of the product, you must clearly state the same in the product dossier. In addition, you are responsible for obtaining all cooperation, assistance and information from such third party as are necessary or reasonably requested by WHO in connection with the prequalification process.
2. **Dossier review:** 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 and will be provided with a single opportunity to submit the missing information or material. If, after a reasonable period has elapsed, the applicant fails to supply the missing information or sample, the application will be rejected. Complete applications will be retained for evaluation.
3. **Acceptable products:** An immunization device (IMD) which has been accepted to proceed in the prequalification assessment must be identical to the IMD described in the pre-submission form and any issues identified at the pre-submission stage must be addressed as part of the eventual product dossier submission. The IMD to be prequalified must be a commercially available product.
4. **Dossier Examination Fee:** The Dossier Examination Fee is non-refundable and must be paid in full in US Dollars, upon receipt of the invoice, before WHO can begin formal evaluation of the dossier.

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5. **Evaluation procedure:** The WHO unit responsible for the evaluation will be independent from all UN agency procurement units. Every product, device or service will be evaluated against the relevant IMD PQS performance specification and product verification protocol(s), current at the time of the evaluation. The applicant will receive a formal decision from WHO, via the e-prequalification (ePQS) portal, advising on the outcome of the evaluation process with regard to each product(s) submitted for prequalification.

   You understand and agree that WHO will have absolute, exclusive, unfettered control over the manner in which the prequalification assessment is carried out, including the publication of the results of the prequalification assessment, regardless of the outcome.

6. **Communication related to ongoing dossier evaluation:** WHO staff will provide all relevant information to your authorized contact as the product proceeds through the prequalification process.

7. **Laboratory testing:** You understand and agree that, where laboratory testing is specified in the relevant product verification protocol, these test will be carried out on production-run products (not prototypes or models of products), supplied by the applicant, in a WHO-accredited laboratory. All the tests specified will be carried out each and every time a product is submitted for testing.

   An applicant whose product has failed one or more of the tests is entitled to resubmit a revised product for the complete sequence of tests; the applicant is not entitled to resubmit solely for the tests that his product has previously failed.

8. **Provision of production-run products:** You understand and agree that sufficient quantities from different lots of the IVD, as defined in the relevant performance evaluation protocol, shall be provided at no charge to the WHO evaluating sites, for the performance evaluation of your product. The product shall be sent ***Free Domicile***, and detailed shipping instructions shall be given to you in due time.

9. **Field testing:** You understand and agree that, in some specific 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 mandatory, and will specify the appropriate generic testing method for each product type.

10. **Inspections:** You understand and agree that, subject to a successful review of the product dossier, an inspection of the manufacturing site(s) may be conducted to assess the adequacy and effectiveness of the quality management system under which your product is manufactured. You agree to grant the inspection team unfettered access to the manufacturing site(s) in question and to all relevant documents and records. You also agree to make available relevant staff to provide additional information to, and answer questions of, the inspection team.

11. **Meaning of prequalification:** The granting of prequalified status following a successful evaluation process indicates that the product or device is technically satisfactory for use in national immunization programmes, subject to any limitations set out on the IMD-PQS website or catalogue. There is no possibility to obtain prequalified status via a waiver based on other certification: only the WHO IMD PQS product evaluation may lead to prequalification.

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- The granting of prequalified status does not guarantee that an acceptable commercial arrangement can be reached between the supplier of the product or device and the purchaser; nor does it guarantee that the quality of the delivered product or device will be acceptable to the purchaser. In this context the word, 'purchaser' includes, but is not limited to, national immunization programmes or more than one of the UN agency procurement units, including UNICEF, PAHO, UNDP/IAPSO, UNFPA and WHO.
- Once granted, the ongoing maintenance of prequalified status is wholly dependent on the satisfactory fulfilment of a variety of post-prequalification obligations and requirements on the part of the prequalification-holder. Refer to Clause 8 of these Terms & Conditions.

12. **Publication:** Following satisfactory evaluation, the product, as manufactured at the specified manufacturing site, will be included in the list of 'prequalified' IMD-PQS products and WHO will inform the interested UN agency procurement unit(s) accordingly. Details of the product will then be posted on the IMD-PQS website and will be published in the IMD-PQS catalogue.

13. **Maintaining prequalified status:** Once granted, a product's prequalified status will be maintained until 31st May (the next IMD-PQS Annual Review) without need for further testing as long as there and no major product changes, serious complaints or other faults and issues identified via post-market monitoring (PMM), IMD-PQS WHO quality management (QMS) investigations or via any other source validated by WHO.

    → **IMD-PQS Prequalification Holders are obliged to report ALL product issues, including but not limited to reported product defects, product failures and performance complaints, in real time and without hesitation to the IMD-PQS Secretariat throughout the period of prequalification-holding, not only during the annual review.**

    It is essential that Prequalification Holder also keep WHO IMD-PQS fully informed about any administrative or technical changes relative to the product(s) or to the manufacturing process. In this way, the IMD-PQS endorsement of the performance, quality and safety of all prequalified products available for procurement remains valid. Prequalification Holders should also be aware that a change specifically to the manufacturing location/site automatically removes prequalified status and requires a new prequalification application and a new IMD-PQS PQ number/product code.

    Re-evaluation of prequalified products may be required in any of the following cases:

    - omission(s) by the Prequalification Holder in the initial evaluation procedure or during the follow-up activities, in relation to the requirements, including compliance with quality system standards and failure to notify complaints;
    - A batch(es) of supplied product(s) are documented by WHO, Ministries of Health, or one or more of the UN agencies or organizations, not to be in compliance with the agreed specifications of the product or to reveal failure(s) regarding safety, performance or quality of the device;
    - the investigation or report of any product-related defects or performance complaints validated by WHO that concludes that the quality and/or safety of the product does not meet performance requirements;

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- planned or ad-hoc QMS inspections of manufacturing facilities reveal non-conformities with the ISO 9001 or ISO 13485 and/or the specific requirements of WHO performance specifications and verification protocols. Non-conformities will necessitate the satisfactory implementation of corrective or preventive action plans (CAPAs) to avoid the removal of prequalified status.

14. **Monitoring of complaints:** You understand and agree that WHO will investigate reported complaints (from any source) concerning a product, in collaboration with the Prequalification Holder. WHO will maintain a database of complaints.

15. **Confidentiality undertaking:** WHO will treat, and will require evaluators of product dossiers to treat 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 products in the strictest confidence. In addition, the evaluators of product dossiers will be required to sign a Declaration of Interest with WHO VAX-IMD, including signature of Annex C: Confidentiality Undertaking. 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 will discharge their functions exclusively as advisers to WHO.

16. **Scope of WHO responsibilities:** For the sake of good order, we should like to emphasize that it is not in WHO's mandate to issue any approvals, certificates or licenses for IMDs. This responsibility lies with the regulatory authority of each country. Furthermore, WHO does not, as a matter of policy, endorse any specific commercial product over others. As mentioned above, the purpose of the WHO Prequalification of Immunization Devices is to provide guidance to WHO Member States and interested UN agencies in their procurement decisions. In this regard, please note that the results of the prequalification assessment, the participation in the WHO prequalification process, the inclusion of any product in the list of prequalified IMDs and/or the WHO name and emblem, may not be used for commercial and/or promotional purposes. WHO will not accept any liability or responsibility whatsoever for an injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with the procurement, distribution and use of any product, as to which WHO has published the assessment results and/or which is included in the WHO list of prequalified IMDs.

17. **WHO Privileges & Immunities**: You understand and agree that, by virtue of WHO's status as a specialized agency of the United Nations, WHO, its officials and experts performing missions for WHO (including, e.g., the prequalification inspectors) enjoy privileges and immunities under national and international laws and conventions, including the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the "1947 Convention"). Nothing contained in or relating to this Letter of Agreement or the prequalification assessment will constitute or be deemed as a waiver of any of the privileges or immunities which WHO, its officials and/or experts performing missions for WHO enjoy pursuant to the 1947 Convention or otherwise under any national or international law, convention or agreement, and/or as submitting WHO, its officials and/or experts aforesaid to any national court jurisdiction.

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18. The following disclaimer applies to all products that are accepted for inclusion on the IMD-PQS database.

Disclaimer: Inclusion in the list of IMD PQS-prequalified products does not constitute an endorsement, or warranty of fitness, of any product for a particular purpose, including in regard to its safe and appropriate use in immunization programmes. Furthermore WHO does not warrant or represent that: 1) the database is complete or error free and/or that 2) the products that have been found to meet the standards recommended by WHO, will continue to do so and/or that 3) the products listed have obtained regulatory approval for use in every country of the world or that its use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. In addition, WHO wishes to alert procurers (including but not limited to UN procurement agencies) that the improper storage, handling and transportation of products may affect their quality, efficacy and safety. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of products included in the list.

APPLICANT MANDATORY SIGNATURE

If you agree to these Terms & Conditions, please arrange for a duly authorized representative to countersign below on behalf of your company and return it to us, in the manner described below, as part of the product dossier submission.

You must complete, sign and upload a copy of these Terms & Conditions to the WHO e-Prequalification (ePQS) platform, as a part of a complete online prequalification application. The dossier evaluation fees must be paid in full once the dossier has been accepted for evaluation. Payment should be made within 30 days of receipt of the invoice from WHO. The commencement of dossier evaluation will be triggered by a confirmation of payment of the invoiced fees.

Only upon WHO's receipt of the product dossier, this signed Terms & Conditions and the proof of payment of the first fee referred to under paragraph 4 above, will the product dossier be screened for completeness.

→ Mandatory signature on next page

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Prequalification Holder COMPANY full legal name:
(In English, printed)

Prequalification Holder company REPRESENTATIVE full name:
(In English, printed)

Commercial PRODUCT name:
(In English, printed)

SIGNATURE of company representative:

Date (DD – MM – YYYY)

Place (Town, Country)

Annex 2 – Mandatory file name conventions - Pre-submission Form

Document type	FILE NAME PER DOCUMENT
Applicant Company Licence	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **< "APPLICANT LICENCE">** For example: "Acme-Extracool2000-E003RF01.1-APPLICANT LICENCE"
ISO Certificates	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **< "ISO number (#)">** For example: "Acme-Extracool2000-E003RF01.1-ISO 9001"
Applicant declaration form (pre-submission)	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"PRESUBMISSION DECLARATION">** For example*:* " Acme-Extracool2000-E003RF01.1-PRESUBMISSION DECLARATION"

Annex 3 – Mandatory file name conventions - Prequalification Application Documentation

DOCUMENT TYPE	EXTENSION OF FILE NAME PER DOCUMENT
Cover letter of expression of interest	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"COVER LETTER">** For example: "Acme-Extracool2000-E003RF01.1-COVER LETTER"
COUNTERSIGNED COPY of WHO IMD-PQS letter of invitation	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"COUNTERSIGNED INVITATION">** For example: "Acme-Extracool2000-E003RF01.1-COUNTERSIGNED INVITATION"
Catalogue product photograph (for the IMD-PQS product data sheet and catalogue)	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"CATALOGUE PRODUCT PHOTOGRAPH">** For example: "Acme-Extracool2000-E003RF01.1-CATALOGUE PRODUCT PHOTOGRAPH "
A **comprehensive set of photographs** showing all relevant features or aspects.	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"PRODUCT PHOTOGRAPH"> - < # of series ("#1, #2, etc.)> - <Angle of photograph ("DOOR OPEN *or* LID OPEN *or* APPLIANCE CLOSED *or* EXTERNAL SURFACES *or* INTERIOR LAYOUT *or* COMPRESSOR SYSTEM *or* COOLING SYSTEM *or* CLOSE UP THERMOMETER *or* CLOSE UP INDICATOR LIGHT *or* CLOSE UP CONTROLS *or* CLOSE UP SECURING MECHANISM *or* OTHER")>** For example: "Acme-Extracool2000-E003RF01.1- PRODUCT PHOTOGRAPH-1-DOOR OPEN"
Certified photocopies of all type-approvals obtained for the appliance	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"TYPE APPROVAL"> - <"Certificate Number (#)">** For example: "Acme-Extracool2000-E003RF01.1- TYPE APPROVAL-10001AOAB"
Certified photocopies of the manufacturers' current **ISO 9001** quality system certification	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<"ISO 9001">**

	For example: “Acme-Extracool2000-E003RF01.1-ISO9001”
Certified photocopies of the manufacturer’s **ISO 14001** certification *IF applicable.*	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<“ISO 14001”>** For example: “Acme-Extracool2000-E003RF01.1-ISO14001”
Laboratory test report(s)	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<“LABORATORY TEST REPORT”> - < Test name>** For example: “Acme-Extracool2000-E003RF01.1-LABORATORY TEST REPORT-HUMIDITY TEST ”
Signed copy of IMD-PQS Terms & Conditions	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<“IMD TERMS CONDITIONS”>** For example: “Acme-Extracool2000-E003RF01.1-IMD TERMS CONDITIONS”
Details of the compatible **solar power system** *IF applicable.*	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **<“SOLAR SYSTEM DETAILS”>** For example: “Acme-Extracool2000-E003RF01.1-SOLAR SYSTEM DETAILS ”

FOLLOWING THE INITIAL APPLICATION

Application Review Template	<Applicant Company Name> - <Applicant Product Name> - <WHO IMD-PQS Product Specification Reference> - **< “APPLICATION REVIEW TEMPLATE>”** For example: “Acme-Extracool2000-E003RF01.1-APPLICATION REVIEW TEMPLATE ”

Annex 4 – Mandatory file name conventions - IMD-PQS Annual Review submissions

Document type	EXTENSION OF FILE NAME PER DOCUMENT
Manufacturer/reseller declaration form	< Manufacturer or Reseller COMPANY NAME > - < IMD-PQS Product CODE > - < YEAR of Annual Review Reference> - <**DECLARATION FORM**> For example: "Acme-E003021-2025-DECLARATION FORM"
Company Licence - Manufacturer	< Manufacturer or Reseller COMPANY NAME > - < IMD-PQS Product CODE > - < YEAR of Annual Review Reference> - ***<"MANUFACTURER LICENCE">*** For example: "Acme-E003021-2025-MANUFACTURER LICENCE"
Company Licence - Reseller	<Manufacturer or Reseller COMPANY NAME> - <IMD-PQS Product CODE> - <YEAR of Annual Review> - ***<"RESELLER LICENCE">*** For example: "Acme-E003021-2025-RESELLER LICENCE"
ISO Certificates	<Manufacturer or Reseller COMPANY NAME> -<IMD-PQS Product CODE> - <YEAR of Annual Review> - ***<"ISO number (#)">*** For example: "Acme-E003021-2025-ISO9001"
Notarised translation(s) of Licence(s)	<Manufacturer or Reseller COMPANY NAME> - <IMD-PQS Product CODE> - <YEAR of Annual Review> - ***<"NOTARISED TRANSLATION LICENCE">*** For example: "Acme-E003021-2025-NOTARISED TRANSLATION LICENCE"
Notarised translation(s) of Certificate(s)	<Manufacturer or Reseller COMPANY NAME> - <IMD-PQS Product CODE> - <YEAR of Annual Review> ***<"NOTARISED TRANSLATION CERTIFICATE"> - <"ISO number (#)">*** For example: "Acme-E003021-2025-NOTARISED TRANSLATION CERTIFICATE-ISO9001"
IMD-PQS Product Data Sheet	<Manufacturer or Reseller COMPANY NAME> - <IMD-PQS Product CODE> - <YEAR of Annual Review> - ***<"PRODUCT DATA SHEET">*** For example: "Acme-E003021-2025-PRODUCT DATA SHEET"

***Annotated* IMD-PQS Product Data Sheet**	<Manufacturer or Reseller COMPANY NAME> - <IMD-PQS Product CODE> - <YEAR of Annual Review> - ***<"ANNOTATED DATA SHEET">*** For example: "Acme-E003021-2025-ANNOTATED DATA SHEET "

Annex 5 – Terms & Definitions

The following definitions apply to ALL PQS categories **E001, E002, E003, E004, E005, E006, E007, E008, E010, E013** and are highlighted in blue throughout.

Applicants and Prequalification Holders must also refer to the *"Terms & Definitions"* provided in the corresponding PQS performance specification and verification protocol for their product(s).

A Master List of all WHO IMD-PQS Terms & Definitions[36] is also available on the IMD-PQS website.

Access	The ability of national EPI programmes to procure high-performing, quality and safe immunization devices and equipment, that respond to their own particular programmatic needs.
Annual Review	The 12-monthly review which all PQS prequalified manufacturers are required to pass in order to remain on the register of prequalified companies.
Appliance	A cold chain-related device or piece of equipment designed to perform a specific task.
Applicant	Legal manufacturer or licensed reseller of a product, in the process of submitting that product for prequalification assessment by the WHO IMD-PQS Secretariat.
Certification body	A government department or agency or third-party organization that provides services for conformity assessment following completion of an independent assessment verification and qualification process.
Certified copy	Wherever a certified copy or certified photocopy is requested, the copy must be certified as a true copy of the original document by a person registered to practice law in the legal manufacturer's or licensed reseller's country of origin and must be endorsed with the legal practitioner's official stamp and signature. Self-certification of documents is not acceptable.
Cold chain equipment (CCE)	Equipment used to maintain the temperature of vaccines or other medical products and samples in an acceptable range. This definition includes, but is not limited to refrigerators, refrigerated rooms, carriers and cold boxes.
Correspondence	Includes mail, fax, email and the WHO ePQS platform.
Device	A cold chain-related product, unless specifically described as an 'injection device'.
Employer	The organization that contracts with the legal manufacturer or reseller who will supply the system components and the installation and maintenance advisory services described in the relevant IMD-PQS Product Specification or Verification Protocol. The employer will typically contract with an installer who will install and commission the installation under the supervision of a QA assessor and also with a maintenance contractor who will maintain the installation.
Equipment Monitoring System (EMS)	Component assemblies for advanced monitoring and communication of cold chain equipment (CCE) performance, events and alarms across administrative levels of the cold chain.

[36] https://extranet.who.int/prequal/key-resources/documents/who-vax-imd-terms-definitions

Evaluator	An individual or organization (including a WHO-accredited testing laboratory) responsible for evaluating or assessing any aspect of a product as described in the relevant IMD-PQS Product Specification or Verification Protocol.
Installation	The complete physical installation of the equipment as described in the relevant IMD-PQS Product Specification and its companion Verification Protocol, and as per all the procurers' requirements, together with the commissioning (carrying out of all necessary tests and procedures) as specified in the WHO standards, to ensure that the product or device is able to function as intended.
Installer	A person or organization who has been appointed by the employer to carry out the installation of a device, appliance or system.
In writing	Correspondence by mail, fax, email or the WHO ePQS platform.
Maintenance contractor	A person or organization contracted by the employer to maintain the installation.
Manufacturer	The legal manufacturer.
Montreal Protocol	Montreal Protocol on Substances that Deplete the Ozone Layer.
Legal manufacturer	Legal manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or product before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.
Performance Specification	WHO IMD-PQS issued Standard that lays out the characteristics, features and functionality of a product that may be considered for WHO IMD-PQS prequalification. Performance Specifications are minimum requirements. However, going beyond 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.
Period of grace	Period allowed to provide information or to complete a transaction, after formal notice in writing has been given.
Prequalification Holder	A manufacturer or licenced reseller that is legally responsible for a product that has been granted (at the current time) WHO IMD-PQS prequalified status. All Prequalification Holder must fulfil all the IMD-PQS post-prequalification obligations. In addition, the IMD-PQS Secretariat only maintains communication with, and may only convene meetings with Prequalification Holders or prequalification applicants.
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.
Product	A cold chain-related product.

QA Assessor	The person or organization appointed by the employer to assess the suitability of candidate installers, to evaluate their proposals and to monitor the assembly and commissioning of the installation on site.
QA	Quality assurance.
Quality System	A quality system that has been certified by the appropriate regulatory or notified body as specified in the relevant IMD-PQS Performance Specification. This quality system must be in current and continuous compliance.
Region	A contiguous geographical area within which the legal manufacturer or Reseller is able to provide the full range of services described in the relevant performance specification.
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.
User	The person responsible for the day-to-day operation and monitoring of a device or appliance.
User-intervention	Any activity that is required to be executed by appliance users (e.g., healthcare workers) in order to ensure vaccine protection against freezing temperatures or other undesirable conditions. Activities could include, but are not limited to, basket storage, the requirement to use storage compartment covers, thermostat/fuel adjustment, placement of removable liners or barriers, charging a battery, or thermally conditioning the appliance or components thereof.
Verification protocol	A verification protocol describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure.

Annex 6 – Information brief: Revisions PQ fees payment administration

Information brief to applicants/manufacturers of immunization-related devices and products: Revisions to the administration of payment of prequalification fees.

Since 2017, WHO levies fees for dossier evaluation and the annual product review for each prequalified product https://extranet.who.int/prequal/immunization-devices/prequalification-procedures-and-fees-immunization-devices#collapse92 . The dossier evaluation and annual fees are set per category of products or devices. The fees are administered to applicants or manufacturers at specific time points as per applicable amount for each product or device as stipulated in the terms and conditions.

This brief is to inform applicants and manufacturers about an update on procedures for handling of prequalification (PQ) fees for immunization-related products or devices that has been made as part of our quality management system. The update was to strengthen the alignment and consistency of internal procedures and practices in handling PQ fees for various products. It is important to note that the **applicable fees per category of products or devices remain the same and are not affected by this revision** of internal quality procedures. The following changes have been implemented:

- **Dossier evaluation fee**: The dossier evaluation fees must be paid in full once the dossier has been accepted for evaluation. Payment should be made within 30 days of receipt of the invoice from WHO. The commencement of dossier evaluation will be triggered by a confirmation of payment of the invoiced fees.
- **Annual review fee:** WHO will invoice the annual product review fees to the applicant or manufacturer by 31 March for each prequalified immunization-related product or device that was on the prequalification catalogue (list) up to the 31 December of the previous year. Payment should be made within 30 days of receipt of the invoice from WHO. The annual product review will not commence unless payment of the invoiced annual fees has been confirmed.

WHO takes this opportunity to inform applicants and manufacturers that the above outlined changes to the administration of PQ fees will **be effective from 1st January 2024**. Any feedback and queries for further clarifications on these changes can be sent by email to pqsinfo@who.int with a copy to prequalfees@who.int.

This information brief is available to download on IMD-PQS website here[37].

[37] https://extranet.who.int/prequal/key-resources/documents/fees-payments-requirements-who-imd-pqs-prequalification-holders

7.1 Introduction to the WHO ePQS platform

E-prequalification: purpose & benefits of "ePQS"

WHO Immunization Devices now prequalifies products and devices via the WHO's online "e-**P**re**Q**ualification **S**ystem" (ePQS), alongside the WHOs other prequalification divisions (vaccines, medicines, in-vitro diagnostics, and vector control products).

WHO ePQS consolidates, streamlines and safeguards all information and communication exchanges related to core prequalification and post-prequalification processes, helping to improve the efficiency and quality of these vital WHO prequalification functions.

The ePQS platform will be active for registrations, new applications and post-prequalification processes as of Quarter 1 2025.

Links to general ePQS user guides

In addition to the current guide, the WHO has produced general ePQS user guides, including how to register, navigate and use the system. WHO IMD-PQS strongly recommends all IMD-PQS prequalification applicants and Prequalification Holders to read these general guides.

The guidance documents can be accessed towards the bottom of the following page of the WHO Prequalification Team website, under "General Portal Information": https://extranet.who.int/prequal/epqs-portal.

7.2 How the "ePQS" platform works

The ePQS system provides prequalification applicants (product manufacturers and resellers) a one-stop online portal to submit and manage prequalification assessment, and post-prequalification product variations**.** Product annual reassessment. (Annual Review) will be included in the ePQS system in future.

In additional to application and information submissions, the ePQS platform supports all communication between applicants, Prequalification Holders and the WHO prequalification divisions and external experts related to the workflows (applications, post-prequalification variations) via a cloud file sharing system integrated into ePQS system.

Key components of the WHO ePQS platform for external applicant users:

- ***The "application wizard"***

  Applications for prequalification, as well as submissions for post-prequalification product variations take place via the "Application Wizard".

- ***Cloud file-sharing facility (" Box")***

  A cloud file-sharing facility manages the uploading, storage and sharing of documents between external applicants, WHO prequalification divisions and external experts or partners. The company providing this cloud file-sharing facility is called "Box". The file-sharing takes place via an "External Correspondence" folder, accessible via document tabs within each ePQS *Case Record* or *Product Record.* (Please refer to the Glossary of ePQS terms in Section 7.4 below).

7.3 Navigating the “ePQS” user journey

1. WHO ePQS landing page: https://extranet.who.int/prequal/epqs-portal

World Health Organization | Prequalification of Medical Products

Contact us | Glossary and Acronyms | FAQ | Complaints | Feedback

Product Streams | Events | News | ePQS | About

ePQS Portal

The **ePQS Portal** is the externally-facing Salesforce Community site of the WHO Prequalification Unit’s new ePQS system. ePQS is a platform for the processing of Prequalification Information for medicines, diagnostics, vector control products, vaccines, immunization devices, quality control laboratories and inspections.

Within the portal, users will have the ability to:

- View Salesforce records relevant to the user
- Submit applications
- Upload and download documents securely
- View and monitor notifications for pending activities

Registered users will be able to access the Portal at this link: https://who.my.site.com/ePQS/s/login/

Guidance notes related to the features of the portal, processes around applications, document submissions, and many other topics will be progressively posted to this webpage.

Webinars will be announced soon and regular clinics will be held post-go live to support users, answer questions, and identify issues in order to make continuous improvements.

NOTE: The portal will be opened from January 2024 and commence with user registrations thereon.

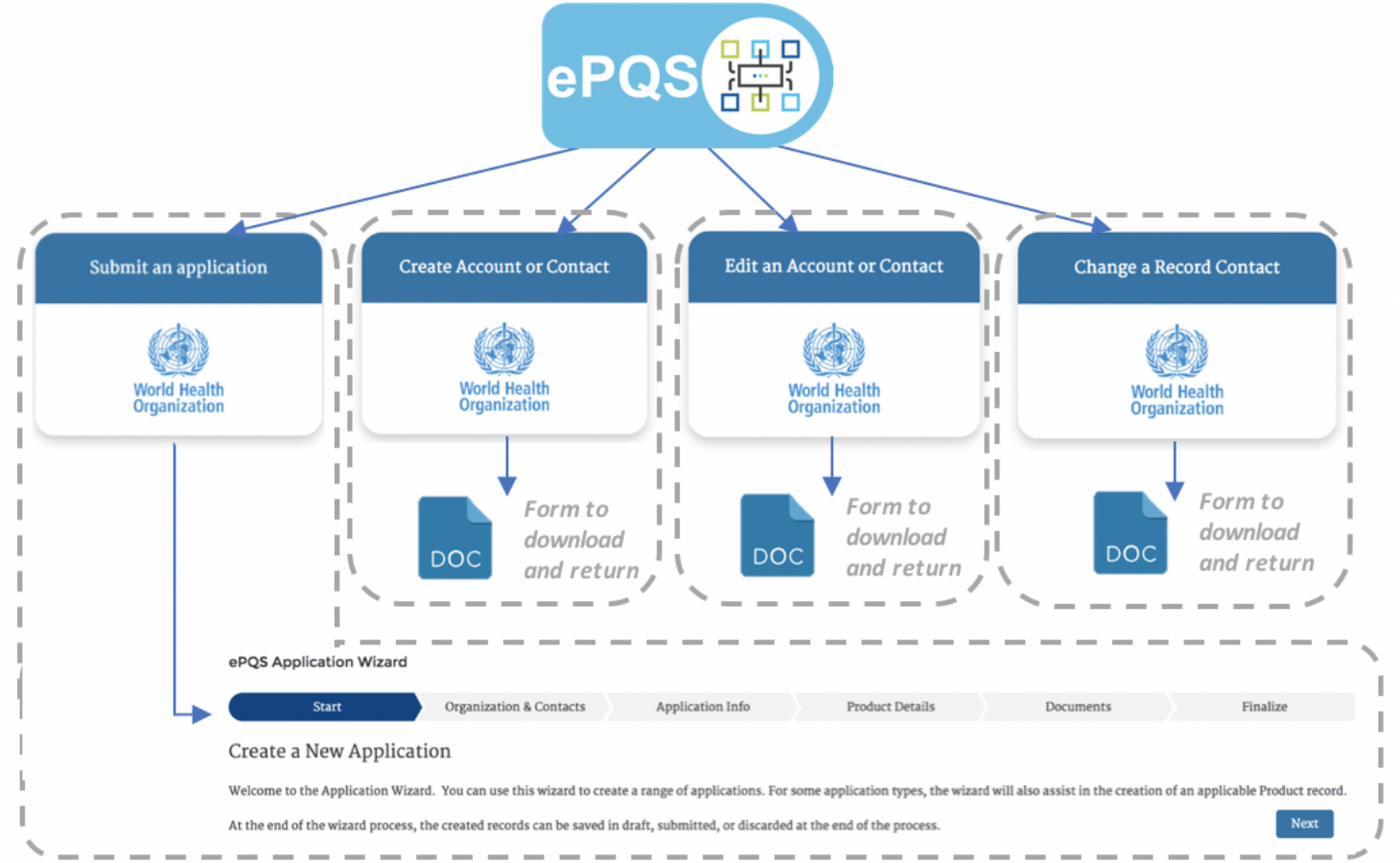
General Portal Information

ePQS - Accounts Contacts Users and Record Visibility
ePQS - Creating or editing a Contact or Account
ePQS - Portal Introduction and Features
ePQS - Terms and Conditions of use (4 October 2023)
ePQS - User Registration and accessing the ePQS Portal

The following diagrams illustrate the two components of ePQS for external applicant and users; the "**ePQS" platform;** and the **"Box" cloud file sharing system**.

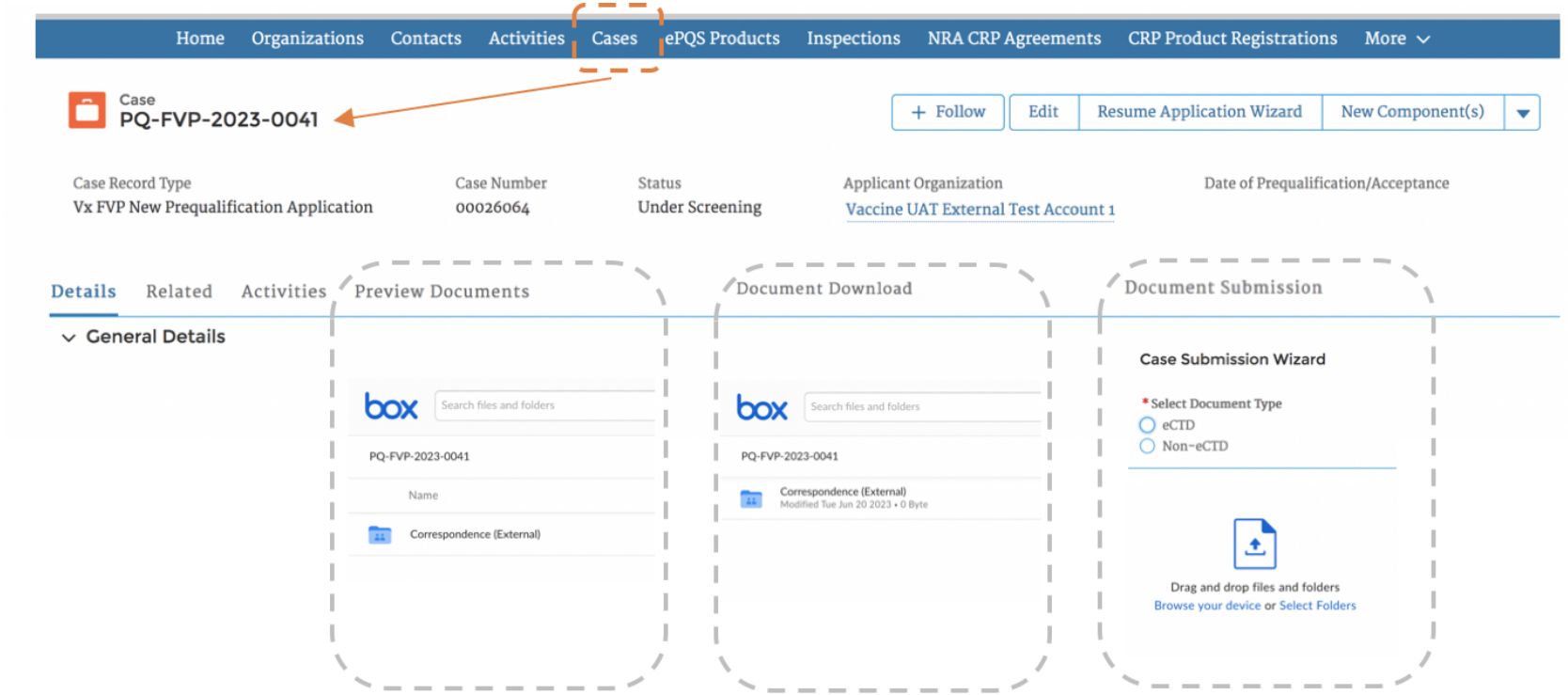
2. WHO ePQS user pathways:

The ePQS platform facilitates applications and associated processes via an "Application Wizard", and allows users to manage accounts and contacts.



3. Integrated “Box” cloud file-sharing user pathways:

The cloud file sharing system (“Box”) facilitates back and forth communication between WHO IMD-PQS and external users, via the transfer of documents, files and folders.



7.4 Glossary: ePQS external applicant user journey

WHO ePQS	World Health Organization e-Prequalification system: a platform for all WHO prequalification applications and post-prequalification processes.
WHO IMD-PQS	WHO Immunization Devices, Performance, Quality and Safety programme
Application	New application for product prequalification. Submitted via the Application Wizard.
Applicant organization	The legal entity submitting a prequalification application or post-prequalification commitment
Application number	Unique code assigned to each new application in ePQS, in the format "PQ-IMD-202X-XXXX". Identical to the "ePQS Case ID".
Application wizard	ePQS process assistant: a user interface that leads users through each ePQS process via sequence of prompted, explained steps.
Activity	Any system activity taken in relation to an ePQS *case*.
Case	Every prequalification application or associated application (E.g. Annual Review, post-prequalification product variants) begins with the creation of a *case*.
Case number	Once opened, each case is assigned an 8-digit case number.
Case owner	The originator of the case, i.e., the Applicant in the case of a new application for product prequalification.
Case history	A log of all case-related actions undertaken within ePQS. Case history can be found under the Cases > Related tab.
ePQS Case ID	Once opened, each case will be assigned an ID in the format "PQ-IMD-YEAR-XXXX"
Case record type	For each WHO IMD case the record type will be either "*Vx IMD Applicati*on", or "*Vx IMD Post-PQ change*", or "*Vx IMD Reassessment*". These terms are defined below.
Details	A tab on each *Case* main page that displays the case general details, such as identifier information, as well as case progress and system information. See "Cases" > "Details". Note: for detailed product information/application contents refer to the "ePQS Products" > "Related" > "IMD Product Variants" > "IMD Variant Ref."> page.
eCTD	electronic Common Technical Document
External ID	Subsequent to the successful application for prequalification, WHO IMD-PQS will assign an External ID in the tradition format of the "PQS Product code": "IMD-E0XX-XXX"
IMD product	Section of the prequalification application that contains the basic information about a product submitted for review. For example, the product name, description and type and applicant organization.
IMD product variant	Sub-section of the unique product prequalification application that contains the record of all of the detailed product technical specifications.
IMD variant reference	Code assigned to each unique IMD product variant page (see previous definition). The "IMD Variant Ref." is displayed in the

	format: “IMDV-XXXXX”. See: “ePQS Products” > “Related” > “IMD Product Variants” > “IMD Variant Ref.”>.
(WHO) Product ID number	Once a prequalification application is completed and submitted in the application wizard, a product will be assigned an ID number in the format: “P-XXXXX”.
Product name	Name given to the Product by the Applicant upon creation of a Product Record (new application).
Product site	Location and facility at which a product is manufactured.
Product specifications	Stage in the Application Wizard that requires users to insert the characteristics, features, and functionality of a product.
Product status	As each application passes through the evaluation process the status will be updated from: Draft, to Under Screening, Under Assessment, to Decision Phase. Thereafter a product status may be: Prequalified, or On Hold, or Suspended. Previously prequalified products may also be Withdrawn or Delisted.
Product sub-type	For IMD-PQS the “*product sub-types*” are the **IMD-PQS Categories** (E001, E002, E003 etc. through E013)
Product type	For IMD-PQS the “*product type*” is “Immunization Devices” (IMD)
Record	A single instance of object data, e.g., Product Record, Case Record, Contact Record, Account Record.
Record status	There are four record statuses depending on the progress of the record : draft; active; inactive; discarded.
Vx IMD	This refers to WHO Vaccines Prequalification, Immunization Devices. WHO Immunization Devices belongs to the WHO Vaccines team, within WHO prequalification.
Vx IMD Application	IMD-PQS ePQS Application type meaning: “New application for product prequalification”. See Section 3.4.3 of this guideline
Vx IMD Post-PQ change	IMD-PQS ePQS Application type meaning: “Post-prequalification variation, a change to product or manufacturing process”. See Section 3.4.5.1 of this guideline.
Vx IMD Reassessment	IMD-PQS ePQS Application type meaning: “IMD Annual Review of prequalified products”. See Section 3.4.6.2 of this guideline.

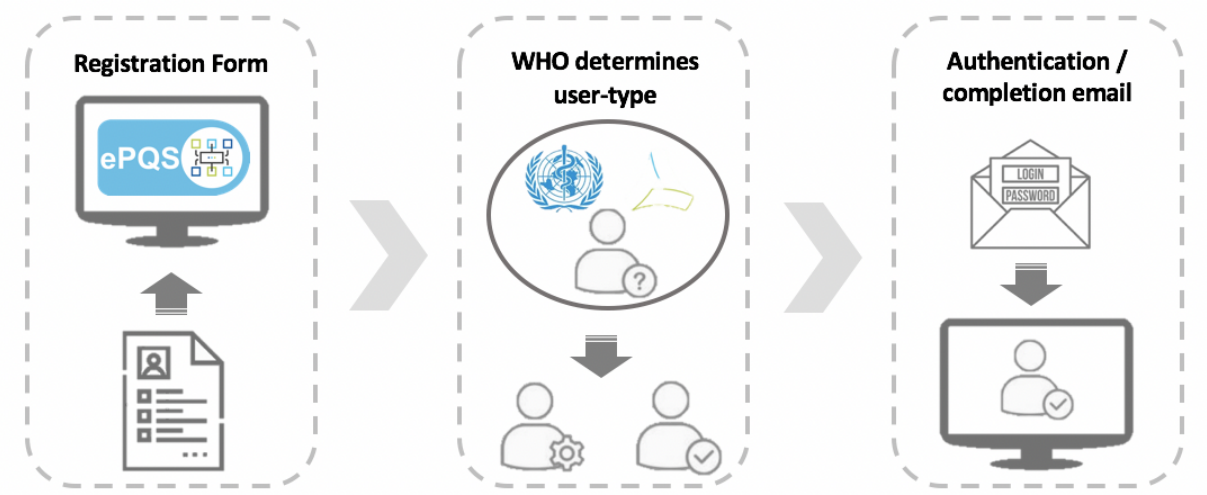
7.5 Step by step guide

Getting started: Creating your external user account

New users can download the registration form on the ePQS landing page: https://extranet.who.int/prequal/epqs-portal.

The WHO responsible teams will determine the correct "user type" and trigger an authentication email to the new external user, which will contain instruction for completing the sign-up process.

The complete guide to registration is available here: https://extranet.who.int/prequal/key-resources/documents/epqs-user-registration-and-accessing-epqs-portal



Submitting an application for prequalification

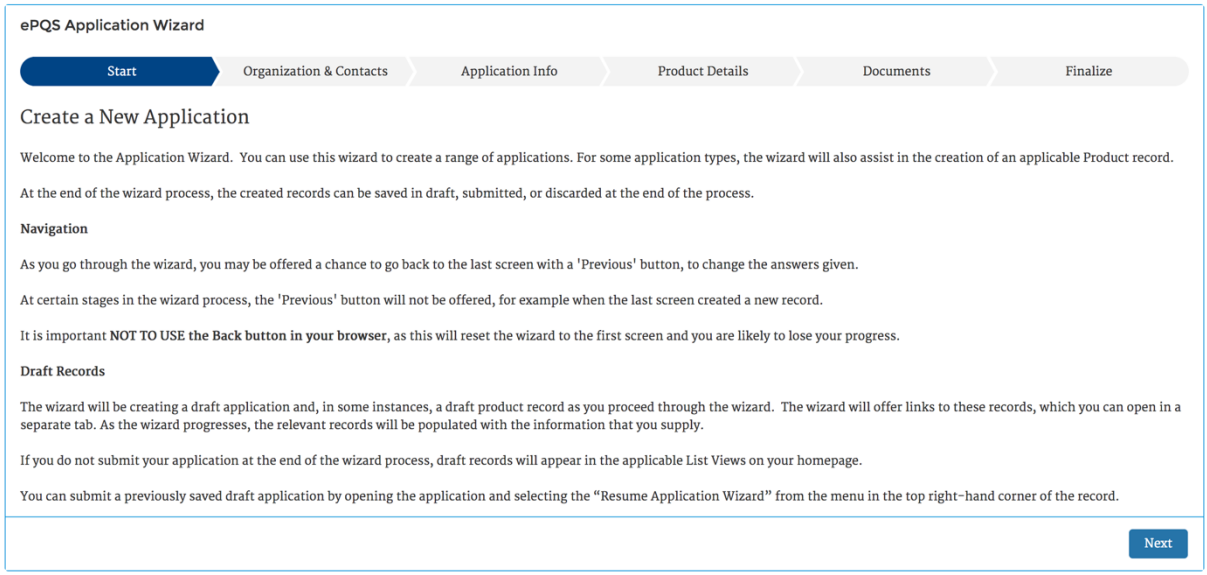
Once an account has been created, external applicants may proceed to submit an application for prequalification.

The ePQS login page can be found at: https://who.my.site.com/ePQS/s/login

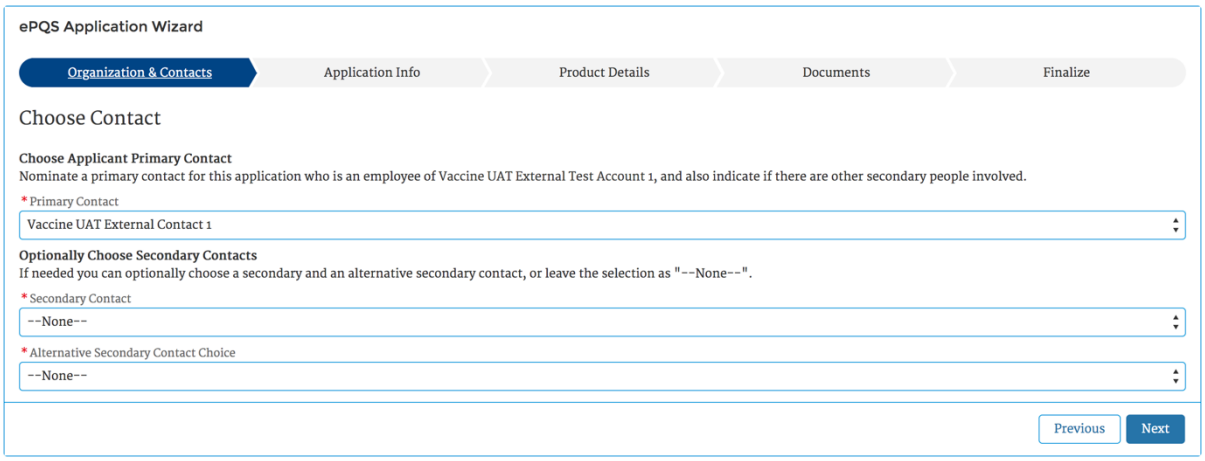
The "Application Wizard" tool provides step-by-step instructions for how to complete the application. **The key data-input screens are reproduced here below.**

Please also refer to the "Glossary of ePQS" terms in Section 7.4 of this Annex 7, below).

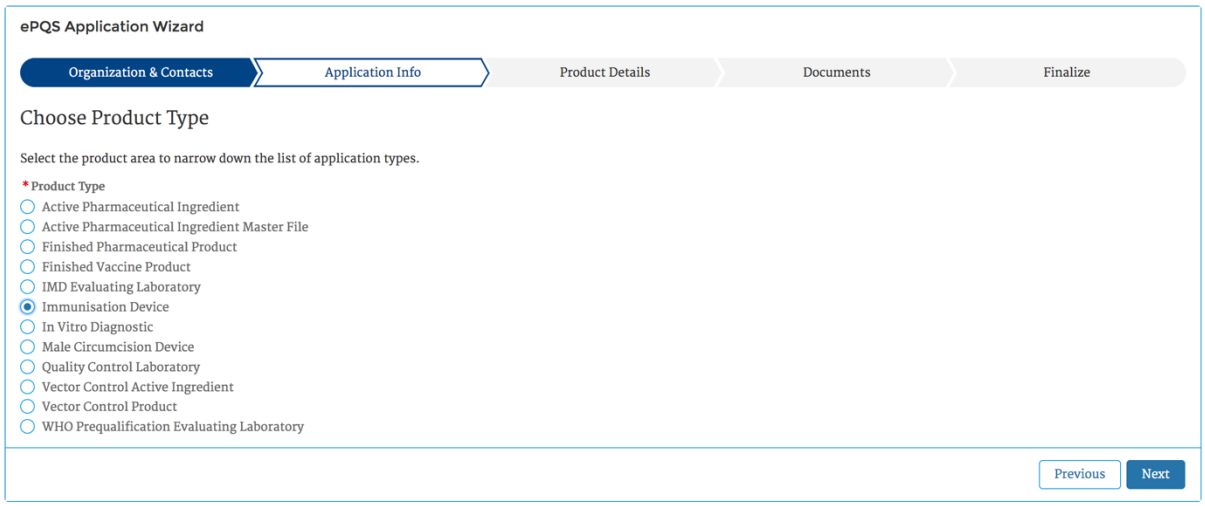
The wizard welcome page provides an overview of the process:



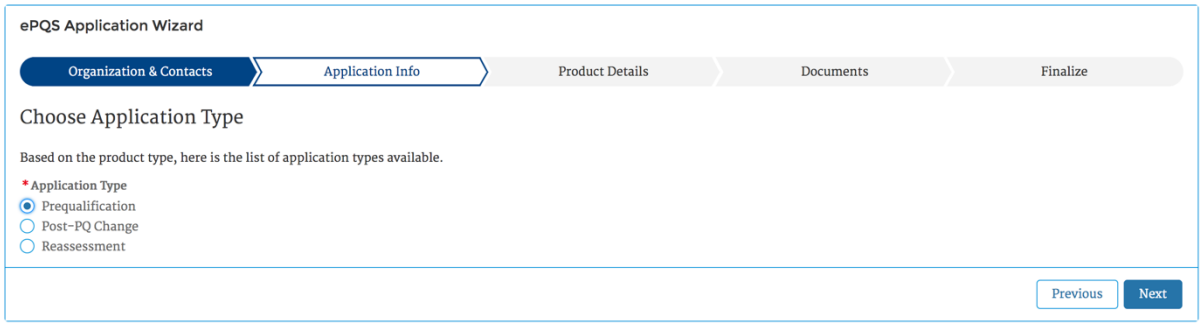
Applicants will first be prompted to select the relevant contacts:



Next, select "Immunization Device" as the product type:

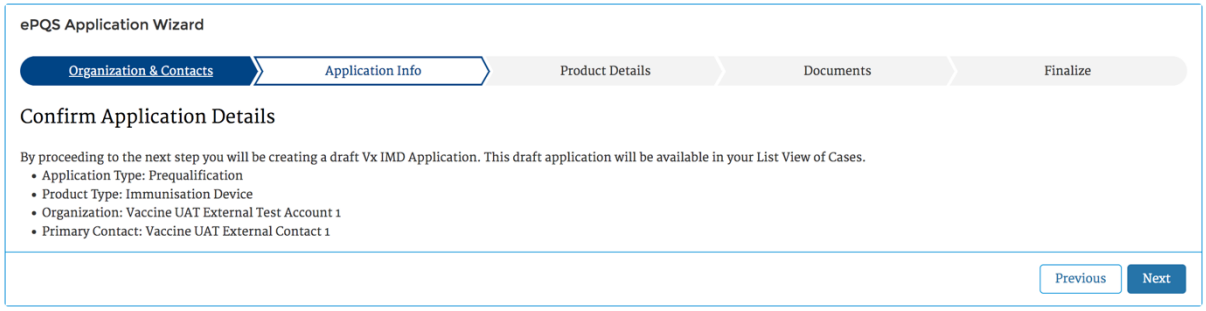


Next, select “Prequalification” as the application type:

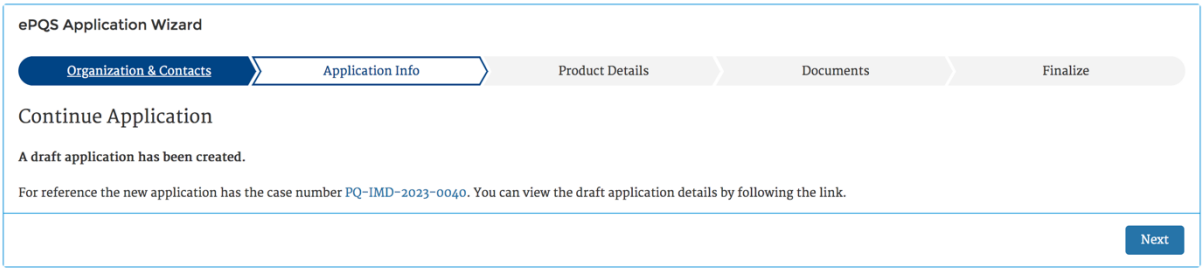


The Wizard will ask for confirmation of the application details:

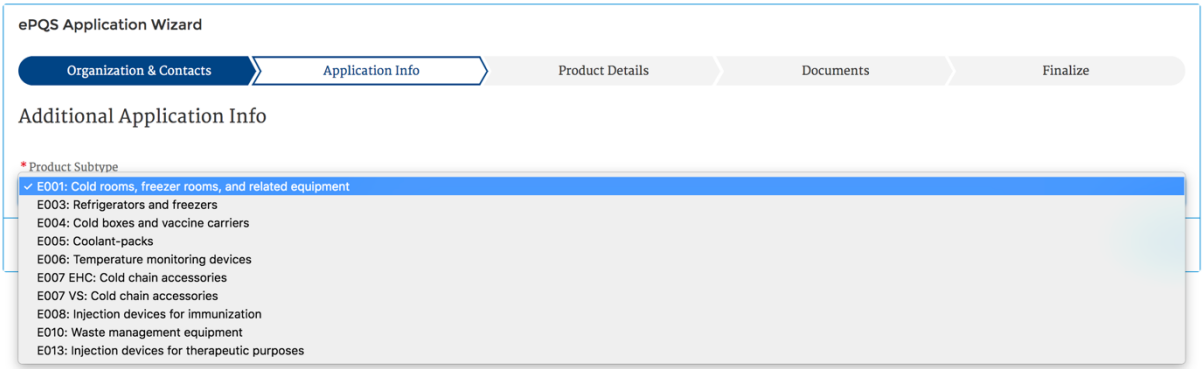
*Note: WHO-IMD applications are classified as “**Vx IMD**” (Vaccines – Immunization Devices) within the ePQS system.*



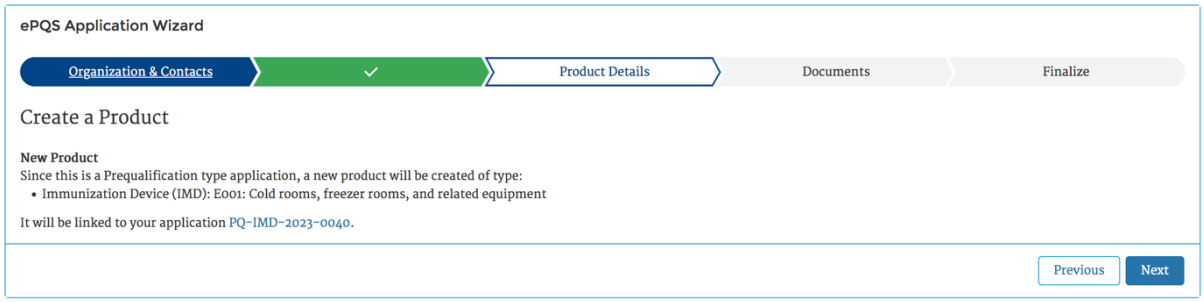
The Wizard will provide you with your case number. Make a note of this reference number:



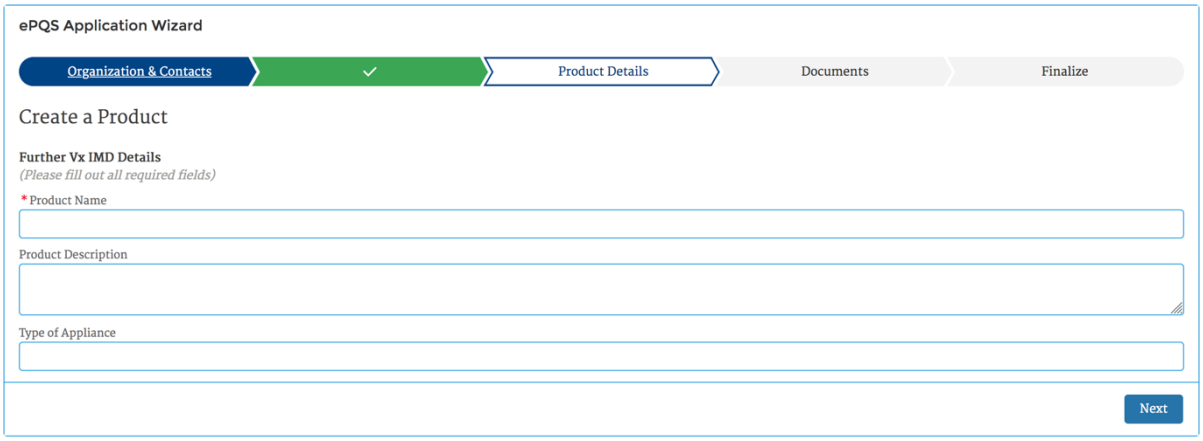
Next, select the “Product Subtype” (the IMD-PQS Product Category) to which you wish to submit your product for prequalification assessment:



The Wizard will provide you with your application number (which is the same as your case number):

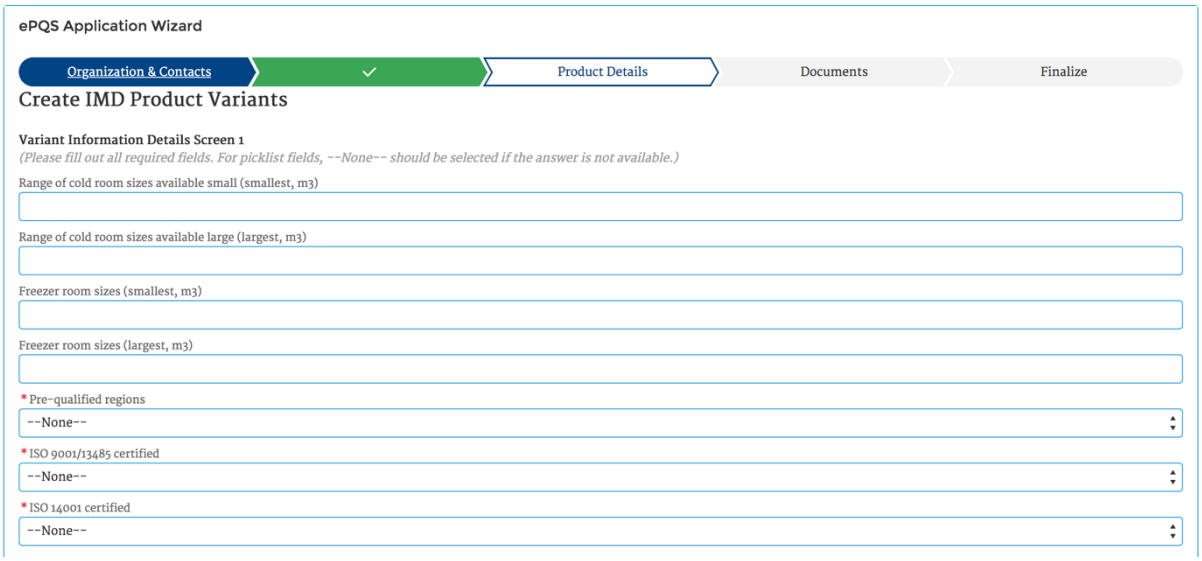


Input a product name of your choice, a description, and the type of appliance (free text):

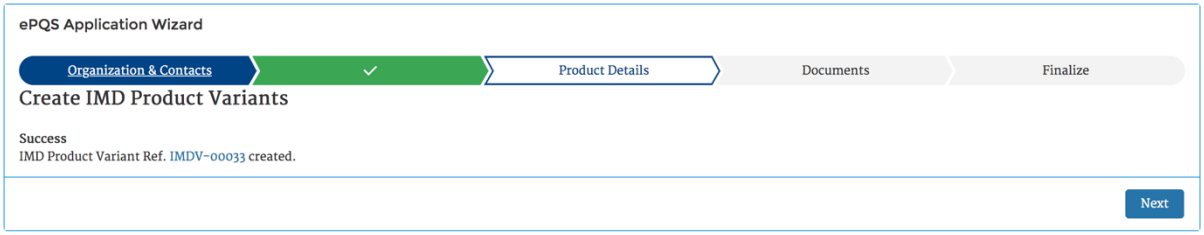


The following section of the application requires the input of the full product specifications (called the "IMD Product Variant" page, additional to the "IMD Product" in the previous section).

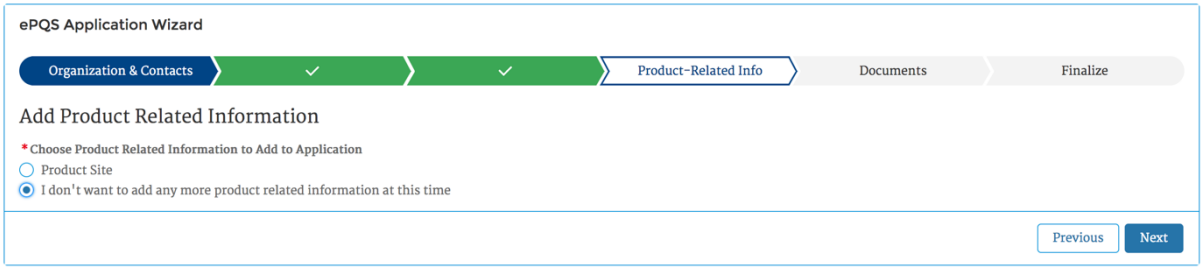
All fields are mandatory unless not applicable for your product. There are multiple Variant Information Detail Screens for each category of product:



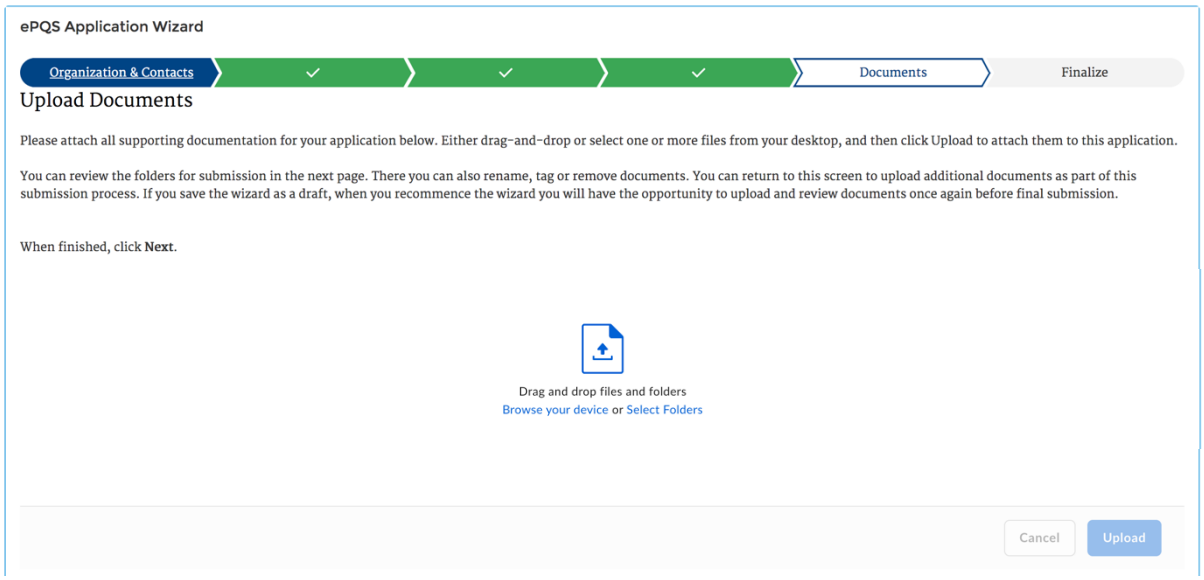
Once the Variant Information Detail Screens are completed, the wizard will provide the “IMD Product Variant Ref.”. Make a note of this reference number:



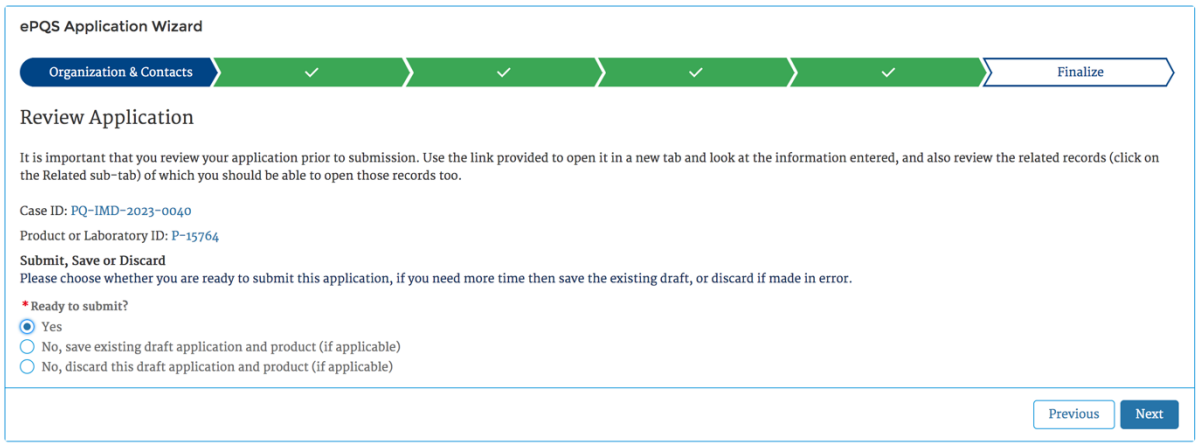
Next, you have the choice to provide information about the “product site” (the site of product manufacture). Note: select “I don’t want to add any more product related information at this time” at this stage:



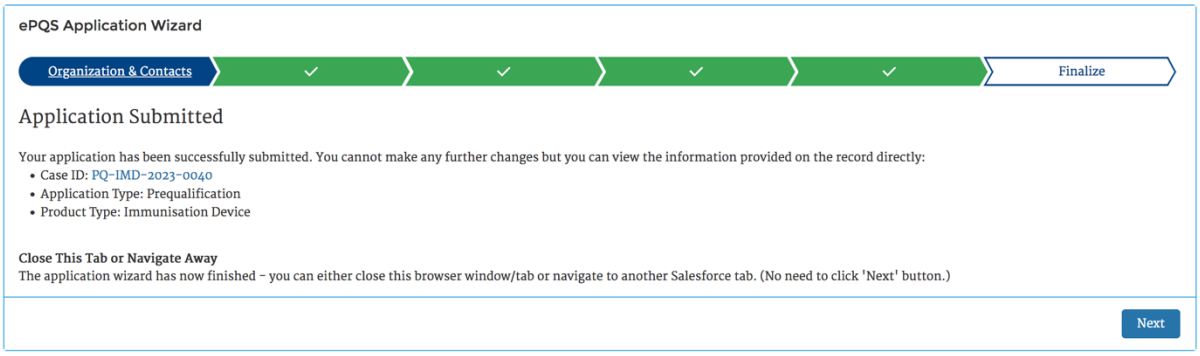
The final stage of the Wizard allows applicants to upload the (mandatory) documents. IMPORTANT: Please refer to Section 3.4.3 of this Guideline for a generic list of the documentation that must be provided for a complete application. Applicants must also refer to the relevant IMD-PQS Performance Specifications and to the ‘Information Pack’ received from the IMD-PQS Secretariat included in their ‘Invitation to Apply for Prequalification’:



Once the complete documentation has been uploaded to the submission, the Wizard will provide the option to submit, save draft or discard draft:



Once "submit" has been selected, the Wizard will confirm your Case ID. **Your application is complete.** The IMD-PQS Secretariat will contact you via the ePQS "Box" cloud file-sharing system with any further requests for information and with information about next steps.



Requesting a post-prequalification product variation or change

The Post-prequalification product change (variation) functionality will be available on WHO ePQS as of Q1 2025. This Guide will be updated accordingly and republished at that time.

Submitting an annual review dossier

Currently the Annual Review of Prequalified products takes place **via email-submission**. The IMD-PQS Secretariat contacts Prequalification Holders in January and again in February with detailed instructions and the relevant submission documents.

The Annual Review of products functionality will be available on WHO ePQS in future and these guidelines will be updated accordingly.

7.6 WHO ePQS Frequently Asked Questions

Why is WHO prequalification moving to the online ePQS portal?

The ePQS platform is an initiative of the WHO Regulation and Prequalification Department (RPQ). Prequalification applications for all RPQ product streams will be managed via the ePQS platform as of Quarter 1 2025, including Vaccines, Medicines, In-vitro Diagnostics and Vector Control Products, along with Inspection Services.

The ePQS portal provides one online gateway for prequalification. It consolidates, streamlines and safeguards all information and communication exchanges related to core prequalification and post-prequalification processes, helping to improve the efficiency and quality of these vital WHO prequalification functions.

Within the portal, users will have the ability to:

- view records relevant to the user,
- submit applications,
- upload and download documents securely,
- view and monitor notifications for pending activities.

How do I register to begin using ePQS?

All ePQS platform users must begin by registering for access to the portal.

To register:

- Users must first download the registration form on the ePQS login page: https://who.my.site.com/ePQS/s/login/
- Users must return the completed form to the email address: ePQS@who.int.

Additional activities may be required by the prospective user, depending on the circumstances of registration.

ALL users must read and agree to the ePQS Terms and Conditions[38] as a part of the registration process.

Step-by-step registration instructions are provided in the following ePQS Guidance document "External Guidance - User Registration and Accessing the ePQS Portal[39]".

What business processes can I complete with ePQS?

For the prequalification of immunization devices (IMD-PQS), **ALL** new applications for prequalification of a new product or device must be made via the ePQS platform as of Quarter 1 2025. This includes all communications and sharing of mandatory documentation with the IMD-PQS Secretariat related to prequalification. Comprehensive information related to inspections, audits and laboratory testing will also be maintained within the product records on the ePQS platform.

[38] https://extranet.who.int/prequal/key-resources/documents/epqs-terms-and-conditions-use-4-october-2023
[39] https://extranet.who.int/prequal/key-resources/documents/epqs-user-registration-and-accessing-epqs-portal

Post-prequalification product variations (changes) must be carried out via the ePQS platform as well. A notification will follow when other processes are available on the portal.

What are the features and functionalities of the ePQS portal?

The platform offers the following features and functionalities to facilitate the prequalification-related processes:

- Global search facility
- Notification "Bell" icon
- Menu bar of major record types
- Filterable list views
- Application Wizard
- Outstanding/pending activities tab
- Document submission, preview and download
- Contacts & accounts
- Personalized commonly-used lists
- FAQs and training materials

How will ePQS affect how I communicate with the WHO IMD-PQS Secretariat?

As described in these IMD-PQS applicant and Prequalification Holder guidelines, the first contact with the IMD-PQS Secretariat for a new application for prequalification remains by email (Prequalification pre-submission). If the Secretariat deems that an application is warranted, the Secretariat will instruct the applicant to register on the ePQS platform. Thereafter all communication related the prequalification application, up to and including the final decision, will pass through the ePQS platform.

Communication between applicants or Prequalification Holders and the IMD-PQS Secretariat will take place via the folder named "External Communications" within each user account. Guidance information about the functioning of the ePQS platform, including official communication between the applicants or Prequalification Holders and the IMD-PQS Secretariat, is available on the WHO ePQS main page: https://extranet.who.int/prequal/epqs-portal. Refer also the guidance above relating to the cloud file sharing and document transfer tool.

Post-prequalification product changes (variations) will also begin to be processed exclusively through the ePQS platform, and the IMD-PQS Annual Review (product reassessment) will be processed through the ePQS platform in time.

What kind of information is stored on the ePQS platform?

The ePQS platform is designed to house comprehensive information related to all new and existing IMD PQS-prequalified products, throughout their entire lifecycle.

The ePQS platform stores information related to all user accounts, contacts and complete records of all prequalification applications and post-prequalification-related processes. Prequalification or post-prequalification-related records include all product information and data, a history of decision processes, as well as all communications between the IMD-PQS Secretariat and applicants and Prequalification Holders; documents uploaded or exchanged relating to the prequalification or post-prequalification processes. Information related to inspections, audits and laboratory testing will also be maintained within the product records on the ePQS platform.

How can I get additional support or guidance about how to use the ePQS platform?

Additional guidance is being rolled out by the dedicated WHO ePQS team and is available here: https://extranet.who.int/prequal/epqs-portal. Webinars and user-support clinics will also be offered on this page through 2025.

Complete FAQs and ePQS training materials are also available with the ePQS platform, once the user registration is completed.

Finally, limited individual support and assistance can be provided by the IMD-PQS Secretariat to applicants and Prequalification Holders during the roll-out phase of the ePQS portal.

Revision History Form

Guideline number		WHO/PQS/E003/GUIDE 2.0	
Date of original issue 1.0: August 2007 Date of second issue, version 2.0: July 2024			
REVISIONS			
Date	**Change**	**Reason for revision(s)**	**Authorized by**
21.05.2010	General update	Specifications and VPs revised.	**DM**
01.11.2023	Complete revision	Evolution of IMD-PQS processes & procedures; evolution of prequalification department structure/organization; introduction of the WHO Prequalification ePQS platform.	**IG**