Performance, Quality & Safety

World Health Organization

WHO IMD-PQS Annual Review 2026

PREQUALIFICATION HOLDER – GENERAL INTRODUCTION

OVERVIEW

The IMD-PQS Annual Review is an activity aimed at collecting information on changes in prequalified products and Prequalification-Holders, as well as data on product performance.

IMD-PQS has widened its focus from a qualification process based on certificate and licence reviews, towards the improvement of products through manufacturing change transparency, CAPAs with more detailed failure reports and risk mitigation, and certificate verification.

A Pre-review of submissions take place four weeks before the Annual Review (on, or shortly after the submission deadline). Should the Prequalification Holder be required to provide further information or documentation they will be advised two-to-three weeks prior to the Annual Review.

FEES & PROOF OF PAYMENT

As of 2025, the WHO requires Annual Review fees to be acquitted BEFORE the review takes place. Fees are only charged for products that you wish to re-qualify; there are no fees for products that you wish to withdraw.

ENSURE TO INCLUDE THE PROOF OF PAYMENT OF THE INVOICE OF EACH PRODUCT YOU WISH TO SUBMIT FOR RE-EVALUATION IN YOUR SUBMISSION.

GENERAL INSTRUCTIONS

"Prequalification Holder" refers to any product manufacturer OR reseller of a WHO prequalified product.

The 2026 IMD-PQS Annual Review includes **two separate submission packages:**

(1) **Manufacturer Submission Package** – for Prequalification Holders who are the product manufacturer. "Manufacturer" means "Legal manufacturer", 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[1].

OR

[1] Definition derived from Article 1 2(f) of the EU Medical Device Directives

(2) **Reseller Submission Package** – for Prequalification Holders who are the product reseller. "Reseller" means 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.

Please carefully select the correct submission package that corresponds to your relationship with the prequalified product.

Both submission packages (for product resellers AND manufacturers) require the Prequalification Holder to complete and submit an IMD-PQS **Company Review Form A** (CRF) and an IMD-PQS **Product Review Form(s) B** (PRF), and to submit certified copies of requested mandatory documents by 07 March, 2025.

Reseller responsibility for manufacturer information: A product reseller is required to submit information and documents regarding the original product manufacturer. **The reseller is responsible** for contacting the product manufacturer to obtain the relevant information and documents.

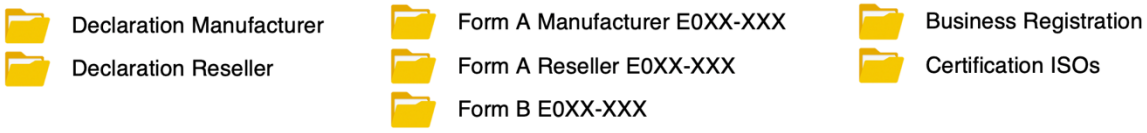
Licensing and certification requirements:

- Applicants must provide an **Original Business Registration** document. This is the only acceptable "business licence". If the document in not in English, a notarised translation mist also be supplied.
- Applicants are reminded that they are obliged to provide a spec**ific web-link to a certificate authentication page** for each mandatory certificate. (A general web link is not sufficient.)
- Business registration documents and certificates must be **valid until at least the 14th July 2026**. For licences and certificates that are NOT valid until 14th July 2026, a copy of a Renewal Request letter addressed to the relevant authority must be submitted also.
- Lastly, applicants are reminded that they should NOT submit licences or certification for any entity other than the Prequalification Holder and OEM (if there is one). Documentation related to sub-contractors, for example, should NOT be submitted.

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

File naming conventions: All files and folders must be provided with the following name conventions : <Form name> <Category Number Product Number> For example: **"Form A E008_113"**. Submissions provided with incorrect file naming will be returned.

Example of file names & submission organization:



IMPORTANT REMINDERS

Confidentiality:	All information provided by the Prequalification Holder will be treated in the strictest confidence.
Completeness:	Prequalification Holders are reminded that incomplete submissions cannot be revalidated and will be pending further action. A checklist of required submission documents is included in the Prequalification Holder Declaration.
Licence/certificate renewal	Prequalification Holders are requested to ensure business licences and manufacturing certificates are valid, are accompanied by a notarised translation and, when renewal is required, to ensure that valid documents are provided to the IMD-PQS Secretariat in line with the AR submission deadline.
Prequalification Holder Declaration:	Prequalification Holders are reminded of the requirement to sign and date the Prequalification Holder Declaration form in order to validate their submission. Products cannot be recommended for re-validation in the absence of this signature.
Taxonomy (E003):	Prequalification Holders are reminded that IMD-PQS requires that the product performance Taxonomy (released 2020) be used to report all performance failures of IMD-PQS prequalified products in category E003 – including as a part of the Annual Review requirement. Taxonomy: https://extranet.who.int/prequal/key-resources/documents/whopqtvaximdpmm-taxonomy-v10

END