 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	IN VITRO DIAGNOSTIC ASSESSMENT TEAM	
Guidance		
EXTERNAL GUIDANCE – Instructions for submitting a product dossier or CAP		
Comes under SOP No:		
Doc No:	Version No: 1.0	Revise before: November 2027
Effective date: November 2025	Replaces: n/a	Page 1 of 7
Approved by: Susie Braniff		
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1.0 INTRODUCTION:

This document will be made available on the IN VITRO DIAGNOSTIC ASSESSMENT TEAM website to provide instructions to manufacturers on how to submit a product dossier, product dossier screening supplement, corrective action plan (CAP), amendment or commitment to prequalification-related material using the ePQS portal.

2.0 REVISION HISTORY

SOP version	Effective date	Reason for revision	Prepared by
1.0	11/11/2025	New document	LF

**SUBMISSION OF AN IVD PRODUCT DOSSIER OR
SCREENING/CAP/AMENDMENT/COMMITMENT TO
PREQUALIFICATION MATERIALS**

- 1. Scope**
- 2. Prerequisites**
- 3. Accessing the Portal**
- 4. Submitting dossier documents**
Using the Wizard

1. Scope

This guide outlines the procedures for the submission of a product dossier, supplement, CAP, amendment or commitment to prequalification by a manufacturer on the ePQS portal.

2. Prerequisites

Submission wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>. This requires a grant of access to the ePQS portal first. To seek registration, apply via the form here: <https://who.my.site.com/ePQS/s/login/>.

3. Accessing the Portal

Submission wizards are accessed via the ePQS Portal – Registered users can access the Portal at here: <https://who.my.site.com/ePQS/s/login/>

To create or edit a Contact or Account, please refer to **Creating or editing a Contact or Account.pdf**

4. Submission of a product dossier, dossier supplement, or Corrective Action Plan/Amendment (IVD)

After you have received a Letter of Agreement/Letter of Prioritization, Dossier Screening Request letter, Dossier Review letter requesting a corrective action plan (CAP), or CAP or Amendment request letter from WHO PQ-IVD, you may log into your ePQS account and from the home page click on “ePQS Products” in the top bar.

The screenshot shows the top navigation bar of the WHO ePQS system. The 'ePQS Products' menu item is highlighted with an orange border. Below the navigation bar are four main action buttons, each featuring the WHO logo: 'Submit an application', 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact'. Below these buttons is a section titled 'COMMONLY USED LISTS' with a vertical list of links: 'Medicine Storage Conditions', 'WHO Vaccine Names', 'Medicines Pharmaceutical Ingredients', 'VC Active Ingredients / Synergist Name', 'QCLm Generic Name (INN)', and 'Post-Prequalification Changes'. To the right of this list is a large blue button labeled 'View ePQS Registered Accounts'. Below the 'COMMONLY USED LISTS' section is the word 'FEATURED'.

Click the link of the WHO Product ID (PQDx number) relating to the product you wish to submit documents for.

In the Product page, find the Original Application number, and click on the linked original application number assigned to the submission, e.g. 00027402.

ePQS Product
PQDx 1234-567-00

Product Type	Applicant Organization	Product Assessment Procedure	Date of Application Submission	Date of Prequalification/Acceptance
In Vitro Diagnostic		Prequalification - Standard	24/10/2024	

Details | Related | Document | Activity | Chatter | Audit Trail

Comments

Information

WHO Product ID	PQDx 1234-567-00	Product Status	Under Screening
Product Name	Random HIV Test	Original Application	00027402
Product Type	In Vitro Diagnostic	Date Application Accepted for Assessment	
Product Subtype		Reason for Product Suspension	
Responsible team	Diagnostics Team	Date of Product Suspension	
Product Assessment Procedure	Prequalification - Standard	Date of Prequalification/Acceptance	
Applicant Organization		Date of Product Cancellation...	ⓘ
Applicant Organization (Legal)		Reason for Product Cancellation...	ⓘ
Primary Contact			

Alternatively, if you know the case number, you may access it directly via the Cases tab in the top bar of the ePQS portal landing page.

Regardless of how you access the Application via the portal, ensure the Application case selected is correct and relates to the product for which you wish to upload the information by verifying the information described in the Details tab, e.g. WHO Product ID (the PQDx number assigned to the product and application), Product Name, etc., e.g., through the case:

Home | Organizations | Contacts | Activities | **Cases** | ePQS Products | Inspections | NRA CRP Agreements | CRP Product Registrations

Case
PQ-IVD-2024-0029

+ Follow | Edit | Resume Application Wizard

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Dx IVD New Prequalification Application	00026808	Under Screening		

Details | Related | Activities | Preview Document | Document Download | Document Submission

General Details

ePQS Case ID	PQ-IVD-2024-0029	Case Owner	ePQS Dx IVD Queue
WHO Product ID ⓘ	PQDx 18972645-027-00	Status	Under Screening
Product Name	HIV IVD	WHO Application Number	PQ-IVD-2024-0029
Product type	In Vitro Diagnostic	Applicant Organization	

Use the “Document Submission” tab to start the document submission wizard for the case

Case PQ-IVD-2024-0029 + Follow Edit Resume Application Wizard New Component(s) ▼

Case Record Type: Dx IVD New Prequalification Application | Case Number: 00026808 | Status: Under Screening | Applicant Organization: [redacted] | Date of Prequalification/Acceptance: [redacted]

Details | Related | Activities | Preview Document | Document Download | **Document Submission**

Case Submission Wizard

Welcome to Document Submission Wizard. Please click on **Next** to proceed for Case#00026808

Next

[About Us](#) | [Contact Us](#) | [Privacy Policy](#) | [Legal Disclaimer](#)

And follow the wizard instructions to upload the requested dossier files: initial dossier, screening supplements, CAPs and amendments as requested in the most recent letter from WHO Prequalification of IVDs.

Case PQ-IVD-2024-0029 + Follow Edit Resume Application Wizard New Component(s) ▼


Case Record Type: Dx IVD New Prequalification Application | Case Number: 00026808 | Status: Under Screening | Applicant Organization: [redacted] | Date of Prequalification/Acceptance: [redacted]

Details | Related | Activities | Preview Document | Document Download | **Document Submission**



Case Submission Wizard

Document Review

Please review the documents and folders you intend to upload. You may navigate through the folder structure, renaming and deleting folders as necessary. If you wish to upload further documents or folders please use the Previous button to return to the Upload document page. Document type meta-data may also be added to individual documents by opening these document and adding the metadata value via the document menu that appears. If you do not wish to process to upload document as this time, please delete the files and folders displayed. By proceeding you will complete the submission process

 Search files and folders

2024-09-13-22:15 ☰

Name	Modified	Size
 TSS-5 9789241513715-eng.pdf	Today by WHO_JWT	329.03 KB
 TSS-6 9789241515160-eng.pdf	Today by WHO_JWT	912.22 KB

Previous Press to submit & complete process

You can start again if needed by following the directions on the screen that follows submission:

The screenshot displays a web application interface for a case submission wizard. At the top, the case ID is 'PQ-IVD-2024-0029'. Below this, there are several fields: 'Case Record Type' (Dx IVD New Prequalification Application), 'Case Number' (00026808), 'Status' (Under Screening), 'Applicant Organization' (with a dropdown arrow), and 'Date of Prequalification/Acceptance' (with a date picker). A navigation bar includes 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The main content area is titled 'Case Submission Wizard' and contains the message: 'You have successfully completed the process. You can start all over again by clicking the Start Over Button'. A 'Start Over' button is located at the bottom right of this area. At the very bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

When you have finished uploading the dossier documents to Box, send an email to the Officer with whom you were communicating during the Presubmission stage and to diagnostics@who.int to notify them that the material has been uploaded.

NOTE: uploaded documents and other information cannot be seen once submitted.

For submission of commitment material and other materials related to prequalified products, please follow the instructions provided to you in the letter in which the request was made. If you should have any difficulties in submitting the requested information in this manner, please contact diagnostics@who.int for help.