

WHO PREQUALIFICATION OF MEDICINES

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Overview

WHO Pre-Qualification (PQ) of medicines is a **service provided by WHO to assess the quality, safety and efficacy of medicinal products**. The focus was originally on medicines for treating HIV, tuberculosis and malaria. The WHO prequalification procedure is a mechanism that seeks to ensure a supply of quality-assured products, particularly for use in low-income countries. The key prequalification activities for medicines include assessment of product dossiers, inspection of manufacturing and clinical sites, and organization of quality control testing of products.

Medicines key prequalification activities are:

- assessment of product dossiers (for finished pharmaceutical products (FPPs) or master files (for active pharmaceutical ingredients (APIs))
- inspection of manufacturing and clinical sites
- organization of quality control testing of products.

Below you can find links to the WHO landing page for PQ, pre- and post-qualification procedures and most importantly guidance documents to support the pre-qualification.

Link to Documents

[Medicines | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)

[Guidance Documents | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)