



# PQM Technical Assistance for Manufacturers of Second-line Anti-Tuberculosis Medicines

The Promoting the Quality of Medicines (PQM) program is assisting the Global Drug Facility (GDF) in its efforts to increase the availability of quality-assured second-line anti-tuberculosis (TB) medicines at an affordable price. To expedite the process of prequalification with the World Health Organization (WHO)—and thereby expand the pool of viable manufacturers—PQM provides technical assistance to interested companies at no cost to the manufacturer on preparing medicines dossiers, evaluating manufacturing practices, providing gap analysis, and guiding them through the facility inspection process. PQM is a cooperative agreement of the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention.

## What Is the WHO Prequalification Programme?

WHO initially developed the Prequalification Programme for the United Nations (UN) to ensure that medicines procured by its agencies meet international standards of quality, safety, and efficacy. WHO establishes a “List of Prequalified Medicinal Products” from which UN agencies can safely choose and that other organizations purchasing medicines in bulk can use for guidance.

## Why Is This Assistance Available?

Currently, there are not enough WHO-prequalified second-line anti-TB medicines manufacturers or a sufficient supply of products to treat patients with multidrug-resistant TB (MDR-TB). In order to ensure good quality products, UN procurement agencies; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and many other international and nongovernmental organizations (NGOs) mandate that only medicines prequalified by WHO, or approved by stringent regulatory agencies, are suitable for procurement. The increase of MDR-TB in certain regions has created a need for additional prequalified medicines to be made available.

## Why Should a Manufacturer Be Interested in Pursuing Prequalification?

A manufacturer’s WHO-prequalified medicine is considered acceptable for procurement by UN organizations, such as UNICEF and UNITAID; in addition, other organizations use the “prequalified list” to guide their procurement decisions. Consequently, manufacturers of prequalified products may be invited by UN agencies, WHO member states, or NGOs to submit tenders for a bulk supply of their product. More countries are now recognizing the need for quality assurance in anti-TB medicines manufacturing and are moving toward more stringent control in procurement and importation.

## How Does PQM Help Get Products Prequalified?

PQM plays a supporting role to interested manufacturers by working collaboratively with them to

- Prepare their product dossier for submission to the WHO Prequalification Programme in a manner that fulfills the requirements;
- Facilitate discussions with WHO to remedy incomplete dossiers or respond to WHO comments; and
- Guide a company on-site to comply with the principles and guidelines of WHO good manufacturing practices (GMP).

*See Reverse Side*

## [www.usp.org](http://www.usp.org)

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# Opportunity for Technical Assistance Available to Second-line Anti-Tuberculosis Medicine Manufacturers

## What Products Are Included in This Offer for Technical Assistance?

Manufacturers that wish to receive technical assistance from PQM may submit their Expressions of Interest to the WHO prequalification team on the following products:<sup>1</sup>

- Amikacin, 500 mg/2 ml solution for injection ampule or vial; 1 g powder for injection ampule or vial\*
- Capreomycin, 1 g powder for injection, vial\*
- Cycloserine, 250 mg capsule
- Ethionamide, 250 mg tablet/capsule
- Kanamycin, 500 mg or 1 g powder for injection, vial\*
- Levofloxacin, 250 mg tablet/capsule; 500 mg or 750 mg tablet
- Moxifloxacin, 400 mg tablet/capsule
- Ofloxacin, 200 mg or 400 mg tablet/capsule
- Para-Aminosalicylic Acid (PAS), 4 g granules, sachets
- Para-Aminosalicylic Acid (PAS) Sodium, 100 g granules, jar; 4 g or 9.2 g granules, sachets; powder for oral solution, sachets
- Prothionamide, 250 mg tablet/capsule
- Terizidone, 250 mg or 300 mg capsule/tablet

\* with or without diluent water for injection 5 ml vial

Once the GDF has authorized a manufacturer to receive technical assistance, PQM will review their product dossier(s) for completeness, consistency, and credibility and will determine whether the information fulfills the WHO assessment criteria.

<sup>1</sup> 11<sup>th</sup> Invitation to manufacturers of antituberculosis medicines to submit an Expression of Interest (Eoi) for product evaluation to the WHO Prequalification Programme (June 2012). Viewed August 21, 2012, at [http://apps.who.int/prequal/info\\_applicants/eoi/EOI-Tuberculosis\\_V11.pdf](http://apps.who.int/prequal/info_applicants/eoi/EOI-Tuberculosis_V11.pdf).

## Does Working with PQM Ensure My Product Will Be Prequalified?

Working with PQM does not guarantee WHO prequalification status for any medicine; however, it offers manufacturers the opportunity to initially present a stronger, higher quality dossier. Whether assessing preliminary dossiers, conducting GMP inspections, or testing samples for quality, PQM will provide the necessary resources to complement the WHO Prequalification Programme. The stronger the dossier, the more quickly and smoothly it will be processed by the WHO prequalification team.

## How Does PQM Make This Assistance Available to Manufacturers?

PQM has been reaching out to potential manufacturers of second-line anti-TB medicines through a series of workshops held in regions of the world with a high burden of TB or where medicines manufacturers are working to improve their GMP and seek WHO prequalification. Workshops are conducted in collaboration with WHO and GDF, providing manufacturers an opportunity to learn more about the process, procedures, and requirements of the WHO program; GDF efforts to increase access to anti-TB medicines; and the technical assistance PQM can offer. Participants can interact with workshop facilitators and receive clarification on key technical issues and hear from other companies that are working toward WHO prequalification with PQM technical assistance.

Interested manufacturers can learn more about the WHO Prequalification Programme by visiting the WHO website at <http://apps.who.int/prequal>.

## FOR FURTHER INFORMATION

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