I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2011 an application for Ethionamide 250 mg Tablets* (TB 242) to be assessed with the aim of including Ethionamide 250 mg Tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Ethionamide 250 mg Tablets was assessed according to the 'Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process. The countries of origin of the assessors involved with Ethionamide 250 mg Tablets were Congo, Georgia, South Africa, Spain, Sweden, Switzerland, Tanzania and Uganda.

Licensing status:
Ethionamide 250 mg Tablets has been licensed / registered in India (the country of origin).

2. Steps taken in the evaluation of the product

Sept 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2011	The company's response letter was received.
Nov 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2012	The company's response letter was received.
March 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Sept 2012	The quality data were reviewed and found to comply with the relevant WHO requirements
Oct 2012	Product dossier accepted (quality assurance)
Dec 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
19 Dec 2012	Ethionamide 250 mg Tablets was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is under local DRA responsibility.
Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Micro Labs Limited (Unit: ML-03)
92, Sipcot Industrial Complex
Hosur – 635126
Tamilnadu
INDIA

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GCP and GLP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
www.who.int/prequal/