I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2004 an application for Ethionamide 250 mg Tablets [*] (TB133) to be assessed with the aim for acceptance of Ethionamide 250 mg Tablets on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

Ethionamide 250 mg Tablets were 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 for the assessors involved with Ethionamide 250 mg Tablets are Canada, China, Estonia, Finland, Germany, Hungary, Netherlands, South Africa, Spain, Switzerland and United Kingdom.

Licensing status:

Ethionamide 250 mg Tablets has been licensed / registered in the following countries:

Sri Lanka	DR-024513
Moldova	14458
Kazakhstan	3676-07
Kyrgyzstan	P-2004-551KP-2754
Ukraine	UA/2425/01/01
Guatemala	2001-05829
Kenya	18820
Turkmenistan	004276
Russia	П No 11943/01
Georgia	R-002098
Nepal	2152
Malaysia	MAL06091362A
Uzbekistan	B-250-95 40907

[*] 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.

2. Steps taken for the assessment of the product

June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2004	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
March 2005	The company's response letter was received.
April 2005	During the meetings of the assessment team, the additional safety and efficacy were reviewed and further information was requested.
May 2005	The company's response letter was received.
May 2005	During the meetings of the assessment team, the additional safety and efficacy as well as the quality data were reviewed and further information was requested.
November 2005	The company's response letters were received.
November 2005	During the meetings of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
March 2007	The company's response letters were received.
April 2007	During the meetings of the assessment team, the additional safety and efficacy data as well as the additional quality data were reviewed and further information was requested.
May 2007	The company's response letters were received.
May 2007	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
July 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
September 2007	The company's response letters were received.
September 2007	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
September 2007	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
21 December 2007	Ethionamide 250 mg Tablets was accepted to the list for prequalified medicines.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Macleods Pharmaceuticals Ltd
Plot No. 25 - 27,
Sr. No. 366,
Premier Ind. Estate,
Kachigam, Daman (U.T),
India
Tel: +91-0260 2244337
Fax: +91-0260 2241565

Commitments for Prequalification

The Applicant committed to put production scale batches on long-term stability testing and provide the data as soon as available; any out-of-specification results during the ongoing study should immediately be reported to WHO.

Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP and GCP.

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/