I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2011 an application for [TB230 trade name]* (TB230) to be assessed with the aim of including [TB230 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB230 trade name] 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.

Steps taken in the evaluation of the product

Jan 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2011 April 2011	During and in between the meetings of the assessment team the quality data were reviewed and further information was requested.
April 2011	The company's response letter was received.
April 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Oct 2012	The quality data were reviewed and found to comply with the relevant WHO requirements
Nov 2012	Product dossier accepted (quality assurance)
16 Nov 2012	[TB230 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Macleods Pharmaceuticals Limited
Unit II, Plot No. 25-27
Survey No. 366, Premier Industrial Estate
Kachigam, Daman (U.T.)
India

Commitments for Prequalification

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

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.
Not inspected for GCP/GLP. Previous site inspections by WHO showed acceptable outcome.

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

Medicinal product subject to medical prescription.

Further information is available at:

http://www.who.int/prequal