Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2005 an application for [TB159 trade name]* (TB159) to be assessed with the aim of including [TB159 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB159 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.

2. Steps taken in the evaluation of the product

March 2005	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2005	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
December 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2006	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
March 2006	The company's response letter was received.
March 2006	During the meetings of the assessment team, the additional safety and efficacy data as well as the quality data were reviewed and further information was requested.
July 2006	The company's response letters were received.
September 2006	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.
November/ December 2006	The company's response letters were received.
December 2006	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements. The additional safety and efficacy data were reviewed and further information was requested.
Jan 2007	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Jan 2007	The company's response letter was received.
Jan 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.
23 March 2007	[TB159 trade name] was accepted to the list for prequalified medicines.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release
Macleods Pharmaceuticals Ltd
Unit II, Plot No. 25 - 27,
Sr. No. 366,
Premier Ind. Estate,
Kachigam, Daman – 396210
India

Commitments for Prequalification
Since long-term stability data were generated on primary batches, the applicant committed to put three production scale batches on long-term stability testing and to provide the data as soon as available; any out-of-specification results obtained during the study should immediately be reported to WHO.

Inspection status
The sites inspected were 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:
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products