Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceutical Limited submitted in 2005 an application for [TB154 trade name]* (TB154) to be assessed with the aim of including [TB154 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB154 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.
April 2005	During the meeting of the assessment team, the safety and efficacy data 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 data as well as the quality data were reviewed and further information was requested.
September 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 found to be in compliance with the relevant WHO requirements.
December 2005	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
January 2006	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
March 2006	The company's response letter was received.
March 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
July 2006	The company's response letter was received.
July 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
August 2006	The company's response letter was received.
September 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
November 2006	The company's response letter was received.
November 2006	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
January 2007	The company's response letter was received.

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

January 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
February 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.
23 March 2007	[TB154 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

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Premier Ind. Estate,
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India
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Inspection status

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