Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

Submission of the dossier

The company Lupin Ltd submitted in 2008 an application for [TB199 trade name][*] (TB199) to be assessed with the aim of including [TB199 trade name] in the list of prequalified medicinal products for tuberculosis treatment.

[TB199 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 for the assessment of the product

Sept 2008	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2008	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Dec 2008	The company's response letter was received.
Jan 2009	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March /April 2009	The company's response letters were received.
May 2009	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
July 2009	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2010	The company's response letter was received.
July 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2011	The company's response letter was received.
Feb 2011	The manufacturers of two of the API's were inspected for compliance with WHO requirements for GMP.
March 2011	The company's response letter was received.
March 2011	During the meeting of the assessment team the additional efficacy data and quality data were reviewed and further information was requested.
April 2011	The company's response letter was received.
May 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
June 2011	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
June 2011	The company's response letters were received.
July 2011	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
July 2011	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP.

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

July 2011	The company's response letter was received.
Sept 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2011	The company's response letters were received.
Nov 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2012	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
June 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.
July / Aug 2012	The company's response letters were received.
Aug 2012	In between the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Dec 2012	The quality data were reviewed and found to comply with the relevant WHO requirements
Dec 2012	Product dossier accepted (quality assurance)
11 Jan 2013	[TB199 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:
Lupin Limited
A-28/1, MIDC Industrial area
Chikalthana
431210 Aurangabad
India

Commitments for Prequalification
None

Inspection status
The sites inspected were found to be compliant 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