Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2008 an application for [TB206 trade name]* (TB206) to be assessed with the aim of including [TB206 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB206 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

December 2008	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2009	In between the meetings of the assessment team the applicant's response letter was received. The additional quality/safety and efficacy data were reviewed and further information was requested.
October 2009	The applicant's response letter was received.
November 2009	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
January 2010	The applicant's response letter was received.
January 2010	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2010	The applicant's response letter was received.
September 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2011	The applicant's response letter was received.
May 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2011	The applicant's response letter was received.
January 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2012	The applicant'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 applicant'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 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2013	The applicant's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The applicant's response letters were received.

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

July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2014	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and f found to comply with the relevant WHO requirements.
June 2014	Product dossier accepted (quality assurance)
13 June 2014	[TB206 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

Lupin Limited
A-28/1, MIDC Industrial Area,
Chikalthana
Aurangabad-431210
India

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