Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Ltd submitted in 2006 an application for [TB177 trade name]* (Ethambutol hydrochloride 400 mg tablets) to be assessed with the aim of including [TB177 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB177 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

November 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2005	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2007	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
May 2007	The company's response letter was received.
May 2007	During the meetings of the assessment team, the additional efficacy data as well as quality data were reviewed and further information was requested.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2007	The company's response letters were received.
November 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April 2008	The company's response letters were received.
May 2008	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
August 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

September 2008	The company's response letter was received.
November 2008	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
December 2008	The company's response letter was received.
January 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
May 2009	The company's response letter was received.
July 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
October 2009	The company's response letter was received.
October 2009	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
January 2010	The company's response letter was received.
January 2010	During the meetings of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements
08 April 2010	[TB177 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, M.I.D.C. Industrial Area

Chikalthana

431 210 Aurangabad

India

Inspection status

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

Not inspected for GCP. Previous inspections by a stringent regulatory authority were acceptable.

API supported by a CEP. Inspection of the manufacturing site waived based on risk assessment.

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/prequal/medicines/prequalified/finished-pharmaceutical-products