Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2010 an application for [TB223 trade name][1] (TB223) to be assessed with the aim of including [TB223 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB223 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

July 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept 2010	The company's response letter was received.
Sept 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2011	The company's response letter was received.
March 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2011	The company'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.
July 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Sept 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2013	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2013	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

	requested.
Nov 2014	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
Dec 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Dec 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
April 2016	The additional quality data were reviewed and further information was requested.
July 2016	The company's response letter was received.
July 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	Product dossier accepted (quality assurance)
07 Dec 2016	[TB223 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:

Micro Labs Limited
15/A, II Phase, Kumbalgodu Industrial Area
Bangalore - 560074
Karnataka, India.

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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/