Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2012 an application for [TB259 trade name][*] (TB259) to be assessed with the aim of including [TB259 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB259 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

September 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and furth information was requested.
November 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2013	The company's response letter was received.
December 2013	The company's response letter was received.
January 2014	During the meeting of the assessment team the additional quality and efficacy data were review and further information was requested.
May 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2014	The company's response letter was received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed and furthe information was requested.
December 2014	The company's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and furthe information was requested.
April 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and furthe information was requested.
June 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2015	The company's response letters were received.

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

January 2016	During the meeting of the assessment team the additional quality and efficacy data were review and further information was requested.
January 2016	The company's response letter was received.
February 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and furthe information was requested.
March 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2016	The company's response letter was received.
May 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2016	Product dossier accepted (quality assurance)
07 September 2016	[TB259 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

Macleods Pharmaceuticals Limited
Phase II, Unit II, Plot No. 25 – 27
Survey No. 366
Premier Industrial Estate
Kachigam
Daman – 396210
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/prequal/medicines/prequalified/finished-pharmaceutical-products