Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2010 an application for [TB231 trade name]* (TB231) to be assessed with the aim of including [TB231 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB231 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

Jan 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jan / March 2011	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2011	The company's response letter was received.
May 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
Feb 2012	The company's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2012	The company's response letter was received.
Nov 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.
April 2013	The company'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.

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

May 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2014	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2015	The company's response letter was received.
Jan2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2016	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb / March 2016	The company's response letters were received.
April 2016	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April / May 2016	The company's response letters were received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2016	The company's response letter was received.
Aug 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Sept 2016	Product dossier accepted (quality assurance)
15 Sept 2016	[TB231 trade name] was included in the list ofprequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments 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

Oxalis Labs
Village Theda,
P.O Lodhimajra, Baddi,
Distt. Solan,
Himachal Pradesh, 174101,
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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products