Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2015 an application for [TB302 trade name]* (TB302) to be assessed with the aim of including [TB302 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB302 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

March 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
May 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional efficacy data and the quality data were reviewed and further information was requested.
April 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
June 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
September 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
January 2016	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February and March 2016	The company's response letters were received.
March 2016	During the meeting of the assessment team the additional efficacy data and the additional quality data were reviewed and further information was requested.
September 2016	In between the meetings of the assessment team the company's response letter was received. The additional safety and efficacy data were reviewed and further information was requested.
August 2016	The company's response letter was received.

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

September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2016	The company's response letters were received.
November 2016	During the meeting of the assessment team the additional 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.
February 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May and July 2017	The company's response letters were received.
July 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
August 2017	Product dossier accepted (quality assurance)
31 August 2017	[TB302 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
Unit II, Phase II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam, Daman, 369 210
India

Oxalis Labs
Village Theda
P.O. Lodhimajra, Baddi
Distt. Solan
Himachal Pradesh, 174101
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