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 the 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 for the assessment 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.
Jan 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.
Aug 2016	The manufacturer of one 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	The manufacturer of one 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 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.
Sept 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

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

	was requested.
Aug 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company's response letters were received.
Nov 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.
Feb 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.
Aug 2017	Product dossier accepted (quality assurance)
31 Aug 2017	[TB302 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturers 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

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP, GCP and 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