Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2016 an application for [TB322 trade name][*] (TB332) to be assessed with the aim of including [TB322 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB322 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

June 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
May 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and July 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2017	The company's response letters were received.
March 2017	During the meeting of the assessment team the additional quality, safety and efficacy data were reviewed and further information was requested.
April 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional safety and efficacy data were reviewed an further information was requested.
May and June 2017	The company's response letters were received.
July 2017	During the meeting of the assessment team the additional quality, safety and efficacy data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
August 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 2017	The company's response letter was received.
September 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
December 2017	The company's response letter was received.
January 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2018	The company's response letter was received.
March 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2018	In between the meetings of the assessment team the company's response letters were received. The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2018	Product dossier accepted (quality assurance)
17 July 2018	[TB322 trade name] was included in the list of prequalified medicinal products.

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

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 -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