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 [TB309 trade name]* (TB309) to be assessed with the aim of including [TB309 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB309 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 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March and May 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2015	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	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional quality and additional efficacy 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 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.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
September 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
December 2016	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The 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 quality data were reviewed and further information was requested.

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

May 2017	The company's response letters were received.
July 2017	During the meeting of the assessment team the additional quality 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 manufacturers of one API were inspected for compliance with WHO requirements for GMP.
August 2017	The company's response letters were received.
August 2017	The additional quality data were reviewed and further information was requested.
September 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The company's response letters were received.
November 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2017	Product dossier accepted (quality assurance)
12 December 2017	[TB309 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– 369 210

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

FPP manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

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