Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2014 an application for [TB297 trade name][*] (TB297) to be assessed with the aim of including [TB297 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB297 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

Jul 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Dec 2014	The applicant's response letter was received.
Jan 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2014 and Jan 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Apr 2015	The applicant's response letters were received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2015	The applicant's response letter was received.
Jul 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2015	The applicant's response letter was received.
Sep 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2015	The applicant'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.
Dec 2015	The applicant'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 2016	The applicant'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
Jun 2016	The applicant's response letter was received.

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

Jul 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2016	The applicant's response letter was received.
Nov 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
Jul 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Oct 2017	The applicant's response letter was received.
Nov 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2017	The applicant's response letters were received.
Nov 2017	The quality data were reviewed and found to comply with the relevant WHO requirements
Dec 2017	Product dossier accepted (quality assurance)
12 Dec 2017	[TB297 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Macleods Pharmaceuticals Limited
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P.O. Lodhi Majra
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Himachal Pradesh, 174101
India
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Fax: +91-1795 661452

Inspection status

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

3. (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