Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2019 an application for [TB369 trade name][*] (TB369) to be assessed with the aim of including [TB369 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB369 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

November 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April and June 2019	The quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September and October 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
August 2020	The applicant's response letter was received.

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

September 2020	A desk review for evaluation of compliance for the bioequivalence study for GCP met WHO requirements.
October 2020	The additional quality data were reviewed and further information was requested.
October and November 2020	The applicant's response letters were received.
November 2020 and January 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
February 2021	The additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021 and February 2022	The additional quality data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
April 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2022	Product dossier accepted (quality assurance)
13 May 2022	[TB369 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
At Oxalis Labs,
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India

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Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP/GCP. 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products