Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2018 an application for [TB359 trade name][*] (TB359) to be assessed with the aim of including [TB359 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB359 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

May 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May and July 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 2018	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	A desk review for evaluation of compliance of one manufacturer of the API for GMP was conducted and it met WHO requirements.
April 2019	The applicant's response letters were received.
May 2019	During the meeting of the assessment team the additional quality and safety and efficacy data were reviewed and further information was requested.
June 2019	The applicant's response letters were received.
July 2019	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.

February 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality and safety and efficacy data were reviewed and further information was requested.
April 2020	The applicant's response letters were received.
May 2020	During the meeting of the assessment team the additional quality and safety and efficacy data were reviewed and further information was requested.
June 2020	The applicant's response letter letters were received.
July 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2020	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2020	The applicant's response letter was received.
January 2021	The additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	The additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
February 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2021	Product dossier accepted (quality assurance)
02 March 2021	[TB359 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,
G Block -Tablet Section,
Village Theda,
P.O. Lodhimajra,
Tehsil Baddi, Dist. Solan,
Himachal Pradesh, 174101, India

Inspection status

The FPP site inspected was found to be in compliance with WHO requirements for GMP.

API site not inspected for GMP. Previous site inspections by WHO were acceptable.

Not inspected for GLP /GCP. Previous site inspections by WHO 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/