Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2021 an application for [TB391 trade name][*] (TB391) to be assessed with the aim of including [TB391 trade name] in the list of prequalified medicinal products for treatment of drug-resistant tuberculosis caused by *Mycobacterium tuberculosis*.

[TB391 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

August 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and November 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2021	The applicant's response letter was received.
January 2022	The applicant's response letter was received.
January 2022	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.
May 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2022	The applicant's response letter was received.

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

September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2022	Product dossier accepted (quality assurance)
14 November 2022	[TB391 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,
Plot No.50 to 54A,
SEZ, Phase II
Pithampur,Dist.: Dhar
Madhya Pradesh, 454774
India

Inspection status

Desk review of the API site found it to be in compliance with WHO requirements for GMP.

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

Desk review of the CRO found it to be in compliance with WHO requirements for GCP/GLP.

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