Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2022 an application for [TB398 trade name]* (TB398) to be assessed with the aim of including [TB398 trade name] in the list of prequalified medicinal products for treatment and prophylaxis of tuberculosis.

[TB398 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 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and June 2022	The assessment team reviewed the quality data and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November and December 2022	The additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.
February 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2023	The applicant's response letter was received.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2023	Product dossier accepted (quality assurance)
02 September 2023	[TB398 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

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Inspection status

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

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