Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2018 an application for [TB356 trade name] to be assessed with the aim of including [TB356 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB356 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

January 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2018	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
June 2018	The applicant's response letter was received.
August 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2018	The applicant's response letter was received.
October 2018	The additional quality data were reviewed and further information was requested.
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	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.
April 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2019	The applicant's response letter was received.
August 2019	The additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
October 2019	The additional quality data were reviewed and further information was requested.
October 2019	The applicant's response letter was received.
October 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2019	Product dossier accepted (quality assurance)
22 October 2019	[TB356 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Micro Labs Limited,
Unit 3, 92 Sipcot Industrial Complex,
Hosur 635 126,

Tamil Nadu,
India.

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

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

2. Conditions or restrictions regarding supply and use

To be decided by the national medicines regulatory authority in accordance with national legislation.

Further information is available at:
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products