Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Ltd, Chikalthana, Aurangabad, India submitted in 2018 an application for [TB360 trade name][*] (TB360) to be assessed with the aim of including [TB360 trade name] in the list of prequalified medicinal products for tuberculosis.
[TB360 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
June 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
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
September 2018	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
October 2018	The applicant's response letter was received
November 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
18 January 2019	The applicant's response letter was received
March and April 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
October 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.
February 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2020	The applicant's response letter was received.

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

May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
June 2020	The applicant's response letter was received.
July and August 2020	The additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
October 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
December 2020	The additional quality data were reviewed and further information was requested.
May 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2021	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
July 2021	The applicant's response letter was received.
August 2021	The additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
August 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2021	Product dossier accepted (quality assurance)
20 August 2021	[TB360 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

Lupin Limited
A-28/1, MIDC Area, Chikalthana
Aurangabad 431210
India

Inspection status

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

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable and previous site inspections by WHO were acceptable.

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

Inspection of API manufacturer waived based on risk assessment

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