Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in YYYY an application for [TB376 trade name]* TB376) to be assessed with the aim of including [TB376 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB376 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

March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP.
July 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
July and October 2019	The quality data were reviewed and further information was requested.
January 2020	The applicant's response letters were received.
January 2020	During the meeting of the assessment team the additional safety and efficacy data and the additional quality data were reviewed and further information was requested.
February 2020	The applicant's response letter was received.
March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 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.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.

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

August 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team 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.
December 2020	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
March and June 2021	The additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
October 2021	The additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2021	Product dossier accepted (quality assurance)
19 November 2021	[TB376 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

EPIP, SIDCO Industrial Complex

Kartholi, Bari Brahmana

Jammu & Kashmir 181 133

India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a biowaiver applies.

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