Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2018 an application for [TB365 trade name]* (TB365) to be assessed with the aim of including [TB365 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB365 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

July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2018	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
February 2019	The quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team 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.
November 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.
December 2019	The applicant's response letter was received.
February 2020	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.
February 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2020	Product dossier accepted (quality assurance).
16 March 2020	[TB365 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

Mylan Laboratories Limited
Plot No. 11, 12 & 13
Indore Special Economic Zone
Pharma Zone
Phase II, Sector III
Pithampur, District Dhar
Madya Pradesh, 454 775
India.

Inspection status

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

A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.

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/