Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited, submitted in 2015 an application for [TB321 trade name][1], (TB321) to be assessed with the aim of including [TB321 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB321 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

October 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November 2015 January 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
April 2016	The company's response letters were received.
May 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2016 and July 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2016	The company's response letter was received.
September 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2016	Product dossier accepted (quality assurance)
07 December 2016	[TB321 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Cipla Limited

Unit IV, Plot no. 9 & 10

Pharma zone, Phase II

Indore special economic zone

Pithampur

Madhya Pradesh – 454 775, India

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

Inspection status

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

Not inspected for GLP /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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products