Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2014 an application for [TB299 trade name]* (TB299) to be assessed with the aim of including [TB299 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB299 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

November 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2015	The quality data were reviewed and further information was requested.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements forGMP.
Septmber 2015	The company's response letter was received.
September 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
October 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2015	The company's response letter was received.
January 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2015	The company's response letter was received.
May2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2015	The company's response letter was received.
May 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2016	Product dossier accepted (quality assurance)
11 July 2016	[TB299 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Hetero Labs Limited, Unit – V
Sy No. 439, 440, 441 & 458
TSIIC Formulation SEZ
Polepally village, Jadcherla Mandal
Mahaboob Nagar District
Telangana
India

Commitments for Prequalification

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

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.
Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

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