Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Shasun Limited submitted in 2015 an application for [TB306 trade name]* (TB306) to be assessed with the aim of including [TB306 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB306 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

January 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
February 2015	The company's response letter was received.
March 2015	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January and March 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2015	The company's response letter was received.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements forGMP.
June 2016	Product dossier accepted (quality assurance)
30 June 2017	[TB306 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

Strides Pharma Science Limited (Formulation division)
Unit II, R.S. No 32, 33 and 34, PIMS Road
Periyakalapet, Puducherry, 605 014
India

Inspection status

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

2. 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