Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company MSN Laboratories Private Limited submitted in 2017 an application for [TB341 trade name]* (TB341) to be assessed with the aim of including [TB341 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB341 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

16 October 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2017	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
March 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data and the additional efficacy data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
October 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The company's response letter was received.
January & February 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The company's response letter was received.
May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2018	Product dossier accepted (quality assurance)
19 June 2018	[TB341 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

MSN Laboratories Private Limited - Formulation Division
Unit-II, Survey Nos. 1277, 1319 to 1324
Nandigama (Village & Mandal)
Rangareddy District
Telangana - 509228
India

Inspection status

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

Commitments for Prequalification

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

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/medicines/prequalified/finished-pharmaceutical-products