Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2017 an application for [TB350 trade name]* (TB350) to be assessed with the aim of including [TB350 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB350 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 2015	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements
May 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and August 2017	The quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
January 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	The company's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2018	The company's response letter was received.
July and September 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2018	The company's response letters were received.
October 2018	The additional quality data were reviewed and further information was requested.
November 2018	The company's response letter was received.
November 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2018	Product dossier accepted (quality assurance).
18 December 2018	[TB350 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

Lupin Limited
EPIP, SIDCO Industrial Complex
Kartholi, Bari Brahmana
Jammu (J&K)- 181133,India
Tel: +91-1923-220046/220672/220676
Fax:+91-1923-220177

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

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