Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2010 an application for [TB227 trade name][*] (TB227) to be assessed with the aim of including [TB227 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB227 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

September 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2010	During the meeting of the assessment team, the safety and efficacy data as well as the quality data were reviewed and further information was requested.
January 2011	The company's response letters were received.
January 2011	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2011	The company's response letter was received.
November 2011	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
December 2011	The company's response letter was received.
December 2011	During the meeting of the assessment team, the additional quality data were reviewed and found to comply with the relevant WHO requirements.
December 2011	Product dossier accepted (quality assurance)
22 December 2011	[TB227 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

Cipla Ltd,
Unit VII, III, IV
Plot No: L-147 to L147-1 & L139 to L-146
Verna Industrial Estate,
Goa – 403722, India

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

Inspection status

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

Not inspected for GCP. Previous site inspections by WHO showed acceptable outcome.

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