Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cadila Pharmaceuticals Limited submitted in 2013, an application for [TB276 trade name][*] to be assessed with the aim of including [TB276 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB276 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

July 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July and Nov 2013	During the meetings of the assessment team the quality data were reviewed, and further information was requested.
March 2014	The company's response letters were received.
March 2014	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
May 2014	The company's response letters were received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2014	The company's response letter was received.
Sept 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.

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

Jan 2015	Product dossier accepted (quality assurance)
29 Oct 2015	[TB276 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Cadila Pharmaceuticals Limited
Main Pharma Block
1389, Trasad Road
Dholka – 382225, Ahmedabad
Gujarat State, 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 GCP/GLP. 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/prequal/