Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cadila Pharmaceuticals Ltd., India submitted in 2002 an application for [TB015 trade name]* (TB015) to be assessed with the aim of including [TB015 trade name] in the list of prequalified medicinal products for treatment of tuberculosis {abbreviated indications}.

[TB015 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 2002	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
November 2002	In between the meetings of the assessment team the applicant's response letters were received. The additional quality data and safety and efficacy data were reviewed and further information was requested.
January 2003	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
March 2003	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
May 2003	In between the meetings of the assessment team the applicant's response letter was received. 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.
July 2003	In between the meetings of the assessment team the applicant's response letter was received. The quality data were reviewed and found to comply with the relevant WHO requirements.
13 November 2003	[TB015 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
1389 Trasad Road
Dholka – 382 225
Ahmedabad, Gujarat, 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, GLP and GCP.

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