Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2007 an application for [TB179 trade name]* (TB179) to be assessed with the aim of including [TB179 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB179 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 2006	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2007	During the meeting of the assessment team, the safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
March 2007	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2007	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
May 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
September 2007	The company's response letter was received.
September 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
November 2007	The company's response letter was received.
February 2008	The company's response letter was received
March 2008	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
23 April 2008	[TB179 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

Macleods Pharmaceuticals Limited
Plot No. 25-27

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

Survey No. 366
Premier Industrial Estate
Kachigam,
Daman – 396 210
India

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/prequal/medicines/prequalified/finished-pharmaceutical-products