Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2007 an application for [TB183 trade name][*] (TB183) to be assessed with the aim of including [TB183 trade name] in the list of prequalified medicinal products for the initial treatment of tuberculosis due to *Mycobacterium tuberculosis*.

[TB183 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 for the assessment of the product

Nov 2005	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Oct 2006	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2007	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept/Nov 2007	During the meeting of the assessment team, the safety and efficacy data as well as the quality data of the dossier were reviewed and further information was requested.
Nov 2007	The company's response letter was received.
Nov 2007	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
Feb 2008	The company's response letter was received.
March 2008	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
June 2008	The company's response letter was received.
July 2008	During the meeting of the assessment team, the additional quality data of the dossier were reviewed and further information was requested.
Aug 2008	The company's response letter was received.
Sept 2008	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
22 October 2008	Rifampicin/Isoniazid/Ethambutol hydrochloride 150mg/75mg/275mg Tablets was accepted for the list of prequalified medicines.

[*] 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:

Macleods Pharmaceutical Limited
Plot No. 25-27, Survey No. 366
Premier Industrial Estate
Kachigam, Daman – 396 210 (UT)
India
Tel: + 91 0260 2244337
Fax: + 91 0260 2241565

Commitments for Prequalification

None

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Not inspected for GCP due to previously demonstrated compliance.

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