Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2013 an application for [TB226 trade name][*] (TB226) to be assessed with the aim of including [TB226 trade name] in the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB226 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

November 2010	During the meeting of the assessment team the 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.
January 2011	The company's response letter was received.
January 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2011	The company's response letter was received.
May 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2011	The company's response letter was received.
September 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2011	The company's response letter was received.
January 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2012	In between the meetings of the assessment team a company's response letter was received The additional quality data were reviewed and further information was requested.
June 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2013	The company's response letters were received.
October 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2013	Product dossier accepted (quality assurance)
04 Nov 2013	[TB226 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Macleods Pharmaceuticals Limited
Unit II, Plot No. 25-27
Sr. No. 366, Premier Industrial Estate
Kachigam, 396 210 Daman,
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 in compliance with WHO requirements for GMP.
Not inspected for GCP/GLP since a biowaiver applies.

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