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 [TB278 trade name][*] (TB278) to be assessed with the aim of including [TB278 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB278 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

Feb 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2013	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
Nov 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2013	The company's response letter was received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2014	The company's response letter was received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2014	The company's response letter was received.
Oct 2014	The quality data were reviewed and found to comply with the relevant WHO requirements
Oct 2014	Product dossier accepted (quality assurance)
24 Oct 2014	[TB278 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

Macleods Pharmaceuticals Limited
Block-N2
Village Theda

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

Post Office Lodhimajra
Tehsil Baddi
District Solan
Himachal Pradesh – 174101
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP/GCP. 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products