Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2012 an application for [MA091 trade name]* (MA091) to be assessed with the aim of including [MA091 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA091 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

February 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2011	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
June 2011	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
March 2012	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2012	The company's response letter was received.
September 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2012	The company's response letter was received.
November 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2013	The sites relevant for study of bioequivalence were inspected for compliance with WHO requirements for GLP and GCP.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2013	The company's response letter was received.

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

July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2013	The company's response letter was received.
September 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2013	Product dossier accepted (quality assurance)
21 October 2013	[MA091 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
Unit II, Phase II/Phase III, Plot No. 25 – 27
Survey No. 366
Premier Industrial Estate
Kachigam
Daman – 396210
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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products