Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2016 an application for [MA134 trade name]* (MA134) to be assessed with the aim of including [MA134 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA134 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 2016	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2017	The company's response letter was received.
January 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2016 + February 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2018	The company's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	The company's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The company's response letter was received.
May and August 2018	The additional quality data were reviewed and further information was requested.
September 2018	The company's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2018	The company's response letter was received.
September 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2018	Product dossier accepted (quality assurance).

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

31 October 2018	[MA134 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Micro Labs Limited
Plot No S-155 to S-159 & N1
Phase-III and Phase IV
Verna industrial estate, Verna
Goa - 403722, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

2. Conditions or restrictions regarding supply and use

To be decided by the national medicines regulatory authority in accordance with national legislation.

Further information is available at:
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products