Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2016 an application for [MA124 trade name][*] (MA124) to be assessed with the aim of including [MA124 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA124 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 2014	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
February 2016	The applicant's response letter was received.
March 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2016	The applicant's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The applicant's response letter was received.
September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2017	The applicant's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October and December 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
January 2018	The applicant's response letter was received.
January 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2018	Product dossier accepted (quality assurance)
22 February 2018	[MA124 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, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited,
Plot no. D-7 (Unit 1)
MIDC Industrial Area
Kurkumbh
Dist: Pune 413 802
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, GLP and GCP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product not subject to medical prescription.

Further information is available at:
https://extranet.who.int/prequal/