Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2014 an application for [MA115 trade name]* (MA115) to be assessed with the aim of including [MA115 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA115 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 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Oct 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Feb 2015	The company's response letter was received.
March 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2015 and March 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
April 2016	The company'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.
June 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

Aug 2016	The company's response letter was received.
Aug 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2016	Product dossier accepted (quality assurance).
17 July 2017	[MA115 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

Cipla limited

Unit IV, Plot no. 9 & 10

Pharma zone, Phase II

Indore special economic zone

Pithampur (MP)-454775

India

Inspection status

The sites inspected were found to be compliant with WHO requirements.

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