Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2015 an application for [MA120 trade name]* (MA120) to be assessed with the aim of including [MA120 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA120 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 one API was inspected for compliance with WHO requirements for GMP.
April 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept and Nov 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested,
April 2016	The company's response letters were received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2016	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.
Aug 2016	The company's response letter was received.
Sept 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	Product dossier accepted (quality assurance).
17 July 2017	[MA120 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 and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla limited

Village Upper Malpur

P.O. Bhud, Tehsil Nalagarh

District Solan

Himachal Pradesh 173205

India

Inspection status

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

Not inspected for GCP/GLP since a biowaiver applies.

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