Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2008, an application for [MA064 trade name]* (artemether/lumefantrine 20mg/120mg tablets) to be assessed with the aim of including [MA064 trade name] in the list of prequalified medicinal products for malaria.

[MA064 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

October 2007	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2008	During the meeting of the assessment team the efficacy and safety aspects of the dossier were reviewed and further information was requested.
June 2008	The quality data were reviewed and further information was requested.
June 2008	The company's response letter was received.
July2008	During the meeting of the assessment team the efficacy and safety aspects of the dossier were reviewed and found to be in compliance with the relevant WHO requirements.
July 2008	The manufacturer of one FPP was inspected for compliance with WHO requirements for GMP.
October 2008	The company's response letters were received.
December 2008	The additional quality data were reviewed and further information was requested.
February 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team, the additional quality data were reviewe and further information was requested.
May 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team, the additional quality data were reviewe and found to be in compliance with the relevant WHO requirements.
May 2009	[MA064 trade name] was included in the list of prequalified medicines.
July 2009	The site relevant for the first bioequivalence study was inspected by WHO inspectors and was found not to be in compliance with WHO requirements for GLP and GCP.

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

July 2009	A WHO Notice of Concern was issued and the company committed to submitting a new bioequivalence study.
February 2010	A new bioequivalence study conducted at a different site was submitted.
March 2010	During the meeting of the assessment team the additional data were reviewed and further information was requested.
April 2010	The company's response letter was received.
May 2010	The additional data on the new bioequivalence study were reviewed and found to be in compliance with the relevant WHO requirements.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Ltd.
Manufacturing division Plot No. A-33/1/2 & A-42
Patalganga Industrial Area
Dist: Raigad
410 220 Patalganga
Maharashtra
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP. Previous site inspections by WHO were acceptable.

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/prequal/