Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2013 an application for [MA102 trade name] * (MA102) to be jointly assessed by WHO/EAC with the aim of facilitating the national registration in the EAC countries of [MA102 trade name] once jointly accepted and included in the list of prequalified pharmaceutical products for the treatment of malaria.

[MA102 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

20 Jan 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
July 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2013	The applicant's response letters were received.
Sept 2013	During the meeting of the assessment team the safety and efficacy data and the additional quality were reviewed and further information was requested.
Sept + Oct 2013	The applicant's response letters were received.
Nov 2013	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
Dec 2013 + Jan 2014	The applicant's response letters were received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
Feb 2014	The applicant's response letters were received.
Feb 2014	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements
March 2014	Product dossier accepted (quality assurance)
8 April 2014	[MA102 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 II, A-42, MIDC
Patalganga, District: Raigad

Maharashtra state
India

Inspection status

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

Not inspected for GLP /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/medicines/prequalified/finished-pharmaceutical-products