Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2013 an application for [MA103 trade name] (MA103) to be jointly assessed by WHO/EAC with the aim of facilitating the national registration in the EAC countries of [MA103 trade name] once jointly accepted and included in the list of prequalified pharmaceutical products for the treatment of malaria.

[MA103 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

Jan 2011	The manufacturer of one the API's was inspected for compliance with WHO requirements for GMI
May 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Oct 2013	The company's response letter was 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	The company's response letter was 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 t relevant WHO requirements.
Feb 2014	The manufacturer of one of the API's 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.
Feb 2014	The company's response letter was received.
March 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2014	Product dossier accepted (quality assurance)
08 April 2014	[MA103 trade name] was included in the list of prequalified medicinal products.

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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 compliant with WHO requirements for GMP.

Not inspected for GLP/GCP. Previous site inspections by WHO showed acceptable outcome.

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