I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2010 an application for Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) CiplaTablets[*] (MA078) to be assessed with the aim of including the product in the list of prequalified medicinal products for the treatment of Malaria.

Artesunate and mefloquine tablets were 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. The countries of origin of the assessors involved with Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) CiplaTablets are Canada, Germany, Netherlands, South Africa, Spain, Sweden and Switzerland.

Licensing status:
Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) CiplaTablets have been licensed / registered in the following countries:

- India MF-589/2011
- Malaysia MAL 1203581A
- Myanmar 1709AA4816

2. Steps taken for the assessment of the product

March 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2010	Safety and efficacy data have been reviewed and further information was requested.
Aug 2010	The company's response letters were received.
June – Oct 2010	During the meetings of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
Dec 2010	The company's response letters were received.
Jan 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2011	The manufacturer of the API 1 was inspected for compliance with WHO requirements for GMP.
Feb 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
June 2011	The company's response letters were received.
July 2011	During the meeting of the assessment team the additional safety and efficacy and quality data were reviewed and further information was requested.
Sept 2011	The company's response letters were received.
Sept 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Dec 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The company's response letters were received.
March 2012	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 under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Aug 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2012	Product dossier accepted (quality assurance)
12 Sept 2012	Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets were included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturers of the finished product and responsible for batch release:

Cipla Limited,
A-42, MIDC,
Patalganga, 410220
Dist: Raigad.
Maharashtra
India
Phone : (9122) 23082891
Fax: (9122) 23070013
E-mail: dsingh@cipla.com

Commitments for Prequalification

None.

Inspection status

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

For the sites not inspected, previous inspections either by a stringent regulatory authority or by WHO showed acceptable outcome with respect to GMP, GLP and GCP.

2. (Advice on) conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
http://www.who.int/prequal/