Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2013 an application for [MA099 trade name]* (MA099) to be assessed with the aim of including [MA099 trade name] in the list of prequalified medicinal products for the treatment of uncomplicated malaria due to *Plasmodium falciparum.*

[MA099 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

Dec 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2013	The applicant's response letter was received.
May 2013	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
June 2013	The applicant's response letter was received.
July 2013	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Aug 2013	The applicant's response letter was received.
Sep 2013	The applicant's response letter was received.
Sep 2013	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.
Oct 2013	The applicant's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The applicant'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.

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

Feb 2014	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
March 2014	The applicant's response letter was received.
April 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2014	Product dossier accepted (quality assurance)
16 May 2014	[MA099 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

Mylan Laboratories Limited
F-4, F-12, Malegaon M.I.D.C.
Sinnar, Nashik – 422113
Maharashtra state, India

Inspection status

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

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products