Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Global PTE Limited submitted in 2013 an application for [MA110 trade name] (MA110) to be assessed with the aim of including [MA110 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA110 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

June 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November 2013	During the meeting of the assessment team the quality were reviewed and further information was requested.
January 2014	The applicant's response letters were received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2014	The applicant's response letter was received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
November 2014	The applicant's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2015	The applicant's response letter was received.
April 2015	The applicant's response letter was received.
May 2015	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
June 2015	The applicant's response letter was received.
July 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2015	The additional quality data were reviewed and further information was requested.
August 2015	The applicant's response letters were received.
August 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

February 2017	The applicant's response letters were received.
March 2017	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data and additional quality data were reviewed and further information was requested.
March 2017	The applicant's response letter was received.
May 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	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.
September 2017	The applicant's response letter was received.
October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The applicant's response letter was received.
December 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2017	Product dossier accepted (quality assurance)
12 December 2017	[MA110 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

Strides Pharma Science Limited
KRS Gardens
Tablet Block
36/7, Suragajakkanahalli,
Indlavadi cross,
Anekal Taluk
Bangalore – 562 106
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