Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Arcolab Limited submitted in 2011 an application for [MA088 trade name][*] (MA088) to be assessed with the aim of including [MA088 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA088 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

October 2009	The manufacturer of one of the API's was inspected for compliance with WHO requirements GMP.
May 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
August 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2011	The company's response letter was received.
November 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
December 2011	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
March 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2012	The company's response letter was received.
November 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2012	The company's response letter was received.
January 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2013	The company's response letter was received.
February 2013	In between the meetings 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.

February 2013 March 2013	The company's response letters were received.
March 2013	The safety and efficacy data and the quality data were reviewed and found to comply with the relevant WHO requirements.
April 2013	Product dossier accepted (quality assurance)
24 June 2013	[MA088 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

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

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product

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 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products