Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co. Ltd submitted in 2014 an application for [MA113 trade name][*] (MA113) to be assessed with the aim of including [MA113 trade name] in the list of prequalified medicinal products for the preventive treatment of malaria

[MA113 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

January 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January + March 2014	During the meetings of the assessment team the quality data were reviewed and furthe information was requested.
June 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2015	The company's response letter was received.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2016	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
September 2016	The company's response letter was received.
September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
April 2017	The company's response letter was received.
September 2017	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.

October 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The company's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2018	The company's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2018	The company's response letter was received.
October 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2018	Product dossier accepted (quality assurance)
31 October 2018	[MA113 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

Guilin Pharmaceutical Co. Ltd.
Oral solid dosage workshop (OSD-I)
No. 43 Qilidian Road
Guilin
Guangxi, China, 541004

Inspection status

The sites inspected were found to be compliant 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