Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co. Ltd submitted in 2015 an application for [MA117 trade name]* (MA117) to be assessed with the aim of including [MA117 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA117 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

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

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

February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	The company's response letter was received.
April 2018	The additional quality data were reviewed and further information was requested.
May 2018	The company's response letter was received.
May 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2018	The additional quality data were reviewed and further information was requested.
July 2018	The company's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	The company's response letter was received.
August 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2018	Product dossier accepted (quality assurance)
21 August 2018	[MA117 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
No. 43 Qilidian Road
Guilin
Guangxi
China 541004

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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/prequal/medicines/prequalified/finished-pharmaceutical-products