Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd. submitted in 2019 an application for [MA153 trade name]* (MA153) to be assessed with the aim of including [MA153 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA153 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

May 2018	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
October 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2019	The applicant's response letter was received.
May 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and July 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
April 2020	The additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.

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

November 2020 and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
April 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2021	Product dossier accepted (quality assurance)
13 April 2021	[MA153 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 I
No. 43, Qilidian Road, Guilin 541004
Guangxi
China

Inspection status

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

Not inspected for GCP/GLP since a biowaiver applies.

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