Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd, Oral Solid Dosage Workshop, Guilin, Guangxi, China submitted in 2019 an application for [MA151 trade name][1] to be assessed with the aim of including [MA151 trade name] in the list of prequalified medicinal products for the treatment of malaria.
[MA151 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

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

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

June 2020	The applicant's response letter was received.
August 2020	The additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
September 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2020	Product dossier accepted (quality assurance.
16 September 2020	[MA151 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

Guilin Pharmaceutical Co., Ltd
Oral Solid Dosage Workshop 1
No. 43, Qilidian Road, Guilin 541004
Guangxi, China.

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, 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/prequal/