Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd, No. 43, Qilidian Road, Guilin 541004, Guangxi, China submitted in 2017 an application for [MA141 trade name][1] to be assessed with the aim of including [MA141 trade name] in the list of prequalified medicinal products for the treatment of malaria.
[MA141 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

Sept 2017	During the meeting of the assessment team the safety and efficacy and the quality data were reviewed and further information was requested.
Jan 2018	The applicant's response letter were received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The additional efficacy data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2018	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
July 2018	The applicant'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.
Oct 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2019	The applicant's response letter was received.
Jan 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2019	The applicant's response letter was received.
Sept 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2019	The applicant's response letters were received.
Sept 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2019	The applicant's response letters were received.
Oct 2019	The additional quality data were reviewed and further information was requested.
Oct 2019	The applicant's response letters were received.
Oct 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2019	Product dossier accepted (quality assurance).
19 Nov 2019	[MA141 trade name] was included in the list of prequalified medicinal products.

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

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 site inspected was found to be in compliance with WHO requirements for GMP.

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/