Part 7: Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Guilin Pharmaceutical Co., Ltd, Guangxi, submitted in 2016 an application for [MA131 trade name][1] to be assessed with the aim of including [MA131trade name] in the list of prequalified medicinal products for the treatment of malaria.
[MA131 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2016	The applicant's response letter was received.
Jan 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Jan 2017	The applicant's response letter was received.
March 2017	The applicant'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. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	The applicant'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.
Nov 2017	The applicant's response letter was received.
Jan 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2018	The manufacturer of the APIs were inspected for compliance with WHO requirements for GMP.
May 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
Aug 2018	The applicant's response letter was received.
Sept 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.
Oct 2018	The applicant's response letter was received.

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

Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 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 letter was received.
Oct 2019	The additional quality data were reviewed and further information was requested.
Oct 2019	The applicant's response letter was received.
Oct 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2019	Product dossier accepted (quality assurance)
19 Nov 2019	[MA131 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 have an impact on the benefit-risk profile of the medicinal product.

Inspection status
The sites inspected were found to be compliant with WHO requirements for GMP, GCP and 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/