# Steps before prequalification

## I BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Guilin Pharmaceutical Co. Ltd submitted in 2010 an application for [MA083 trade name][*] (MA083) to be assessed with the aim of including [MA083 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA083 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

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| February 2010 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| July 2010 | During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested. |
| September 2010 | The company's response letter was received. |
| September 2010 | During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested. |
| September 2010<br>November 2010 | The company's response letters were received. |
| November 2010 | During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested. |
| February 2011 | The company's response letters were received. |
| March 2011<br>May 2011 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| June 2011 | The company's response letter was received. |
| July 2011 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 2011 | The company's response letter was received. |
| September 2011 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| November 2011 | The company's response letter was received. |
| November 2011 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| May 2012 | The company's response letters were received. |
| May 2012 | During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested. |
| June 2012 | The company's response letters were received. |
| July 2012 | The safety and efficacy and the quality data were reviewed and found to comply with the relevant WHO requirements. |
| August 2012 | The manufacturer of the API 1 and 2 was inspected for compliance with WHO requirements for GMP. |
| September 2012 | Product dossier accepted (quality assurance) |
| October 2012 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP. |
| 16 November 2012 | [MA083 trade name] was included in the list of prequalified medicinal products. |

[*] 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.
OSD-I
No. 43 Qilidian Road
Guilin, Guangxi
541004 Guilin
China
Tel: +86-773-3675053
Fax: +86-773-3675053

### 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.

Not inspected for GCP (biowaiver).

## 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

http://www.who.int/prequal