# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Guilin Pharmaceutical Co. Ltd. submitted in 2006 an application for Artesun® (MA051) to be assessed with the aim of including Artesunate 60 mg for Injection in the list of prequalified medicinal products for the treatment of malaria.

Artesun® 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. The countries of origin for the assessors involved with Artesunate 60 mg for Injection were Canada, Ethiopia, Germany, Hungary, South Africa, Swizerland, and Uganda.

**Licensing status:**

Artesunate 60 mg for Injection has been licensed/registered in the following countries by national procedure:
P.R.China : State approved No. H10930195

## 2. Steps taken for the assessment of the product

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| June 2006 | During the meeting of the assessment team, the safety and efficacy data of the dossier were reviewed and assessment was started |
| March 2007 | During the meeting of the assessment team, the quality data of the dossier were reviewed and further information was requested. |
| November 2007 | The company's response was received |
| January 2008 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| August 2008 | The company's response was received. |
| September 2008 | The manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| November 2008 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| March 2009 | The company's response was received. |
| May 2009 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| October 2009 | The company's response was received. |
| November 2009 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| January 2010 | The company's response was received. |
| April 2010 | During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. |
| June 2010 | The company's response was received. |
| August 2010 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| September 2010 | During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements |
| September 2010 | Clinical assessment of the product was undertaken and found to support prequalification of the product |
| 5 November 2010 | Artesunate 60 mg for Injection 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.
No. 43 Qilidian Road
Guilin
Guangxi
China

Commitments for Prequalification

None.

Inspection status

The sites inspected were 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:

www.who.int/prequal