## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2013 an application for [MA100 trade name]* (MA100) to be assessed with the aim of including [MA100 trade name] in the list of prequalified medicinal products for the treatment of uncomplicated malaria due to Plasmodium falciparum.

[MA100 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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| Dec 2011 | The manufacturer of one API was inspected for compliance with WHO requirements for GMP. |
| April 2012 | The manufacturer of one API was inspected for compliance with WHO requirements for GMP. |
| June 2012 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| March 2013 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP. |
| March 2013 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested. |
| March 2013 | The applicant's response letter was received. |
| May 2013 | During the meeting of the assessment team the additional efficacy data and the quality data were reviewed and further information was requested. |
| May 2013 | The applicant's response letter was received. |
| May 2013 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| Aug 2013 | The applicant's response letter was received. |
| Sept 2013 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Oct 2013 | The applicant's response letter was received. |
| Nov 2013 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Jan 2014 | The company's response letters were received. |
| Jan 2014 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2014 | The company's response letters were received. |
| April 2014 | The quality data were reviewed and found to comply with the relevant WHO requirements. |

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

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| April 2014 | Product dossier accepted (quality assurance) |
| 16 May 2014 | [MA100 trade name] was included in the list of prequalified medicinal products. |

# II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

## 1. Manufacturer and Inspection status

**Manufacturer of the finished product and responsible for batch release**

Mylan Laboratories Limited
F-4, F-12, Malegaon M.I.D.C.
Sinnar, Nashik – 422113
Maharashtra state, India

**Inspection status**

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP (biowaiver).

## 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/pqweb