## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company {DotWP-Applicant} submitted in 2020 an application for [MA171 trade name]* (MA171) to be assessed with the aim of including [MA171 trade name] in the list of prequalified medicinal products for malaria prevention during the malaria season (seasonal malaria chemoprevention, SMC) in patients aged 1 year to 10 years.

[MA171 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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| July 2020 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| August 2020 | A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements. |
| August 2020 | The applicant's response letter was received. |
| September 2020 | A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements. |
| September 2020 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| July and October 2020 | The assessment team reviewed the quality data and further information was requested. |
| April 2021 | The applicant's response letter was received. |
| May and June 2021 | The assessment team reviewed the additional quality data and further information was requested. |
| June 2021 | A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements. |
| August 2021 | The applicant's response letter was received. |
| September 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| November 2021 | The applicant's response letter was received. |
| November 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| January 2022 | The applicant's response letter was received. |
| January 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |

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

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| April 2022 | The applicant's response letter was received. |
| May 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| June 2022 | The applicant's response letter was received. |
| June 2022 | The manufacturers of one API were inspected for compliance with WHO requirements for GMP. |
| July and October 2022 | The assessment team reviewed the additional quality data and further information was requested. |
| October 2022 | The applicant's response letter was received. |
| October 2022 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| October 2022 | Product dossier accepted (quality assurance) |
| 04 November 2022 | [MA171 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**

Macleods Pharmaceuticals Limited,
Unit II, Phase II,
Plot No 25 - 27, Survey No 366,
Premier Industrial Estate,
Kachigam, Daman
396210, India

**Inspection status**

API manufacturer was inspected and found to be in compliance with WHO requirements for GMP.

API and FPP manufacturer were inspected through desk assessment and found to be in compliance with WHO requirements for GMP.

The site inspected through desk review was found to be in compliance with WHO requirements for GLP and GCP

## 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/medicines/prequalified/finished-pharmaceutical-products