## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2019 an application for [MA159 trade name][*] (MA159) to be assessed with the aim of including [MA159 trade name] in the list of prequalified medicinal products for intermittent preventive treatment of malaria.

[MA159 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

| | |
|---|---|
| October 2018 | A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements |
| September 2019 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| November 2019 | The applicant's response letter was received. |
| November 2020 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| September + December 2019 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| August 2020 | A desk review for evaluation of compliance of the manufacturer of the APIs for GMP was conducted and it met WHO requirements. |
| August 2020 | The applicant's response letter was received. |
| September 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| September 2020 | A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements. |
| November 2020 | The applicant's response letter was received. |
| November 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| January 2021 | The applicant's response letter was received. |
| January and May 2021 | During the meetings of the assessment team the additional quality data were reviewed and further information was requested. |
| June 2021 | The applicant's response letter was received. |
| June 2021 | The additional quality data were reviewed and further information was requested. |
| June 2021 | The applicant's response letter was received. |
| June 2021 | 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.

| | |
|---|---|
| June 2021 | Product dossier accepted (quality assurance). |
| 1 July 2021 | [MA159 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**

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable.

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