I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2016 an application for [MA127 trade name][1] (MA127) to be assessed with the aim of including [MA127 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA127 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

March 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2016	The applicant's response letter was received.
July 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2016	The applicant's response letter was received.
November 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2017	The applicant's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
December 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The manufacturer of the APIs were inspected for compliance with WHO requirements for GMP.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

October 2018	The applicant's response letter was received.
April 2019	The additional quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
April 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2019	Product dossier accepted (quality assurance)
15 May 2019	[MA127 trade name] 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:

Macleods Pharmaceuticals Limited
Phase II and Phase III, Unit II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam, Daman,
396 210, India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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