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 [MA152 trade name][*] (MA152) to be assessed with the aim of including [MA152 trade name] in the list of prequalified medicinal products for the treatment of severe malaria caused by *Plasmodium falciparum*, in adults and children.

[MA152 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

December 2017	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
May 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February + April 2019	The quality data were reviewed and further information was requested.
June + July 2019	The applicant's response letters were received.
August 2019	The additional quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019 + January 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 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.
October 2020	The applicant's response letters were received.
December 2020 + March 2021	The additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
April 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.

April 2021	Product dossier accepted (quality assurance)
13 April 2021	[MA152 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
Phase I, Unit II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam, Daman,
369 210, India

Inspection status

Not inspected for GCP/GLP. No bioequivalence study was required due to the nature of the pharmaceutical formulation.

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