Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2023 an application for [MA194 trade name][*] (MA194) to be assessed with the aim of including [MA194 trade name] in the list of prequalified medicinal products for malaria.

[MA194 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

June 2022	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and October 2023	The quality data were reviewed by the assessment team and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2024	The applicant's response letter was received.
March 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2024	The applicant's response letter was received.
April 2024	The additional quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.
May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2024	The applicant's response letter was received.
May 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2024	Product dossier accepted (quality assurance)
29 May 2024	[MA194 trade name] was included in the list of prequalified medicinal products.

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

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

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

Not inspected for GCP/GLP since a biowaiver applies.

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