Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2020 an application for [MA176 trade name]* (MA176) to be assessed with the aim of including [MA176 trade name] in the list of prequalified medicinal products for malaria.

[MA176 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

September 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
December 2020	The applicant's response letter was received.
December 2020	The additional safety and efficacy data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2020 and February 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meetings 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 meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
May 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2022	The applicant's response letter was received.

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

September 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP
November 2022	The applicant's response letter was received.
November 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.
January 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2023	The applicant's response letter was received.
May and June 2023	The additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
December 2023	The additional quality data were reviewed and further information was requested.
December 2023	The applicant's response letter was received.
December 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2023	Product dossier accepted (quality assurance)
22 December 2023	[MA176 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

Block N2, Village Theda,

P. O. Lodhi Majra,

Tehsil Baddi,

Distt. Solan,

Himachal Pradesh, 174101,

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