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 [MA158 trade name][*] (MA158) to be assessed with the aim of including [MA158 trade name] in the list of prequalified medicinal products for intermittent preventive treatment of malaria.

[MA158 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.
September + December 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
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.
June 2021	Product dossier accepted (quality assurance).
01 July 2021	[MA158 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,

Unit II, Phase II,

Plot No 25 - 27, Survey No 366,

Premier Industrial Estate,

Kachigam, Daman

396210, India

Inspection status

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

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