Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2018 an application for [MA143 trade name][*] (MA143) to be assessed with the aim of including [MA143 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA143 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

February 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May 2018	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
May 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2018	The applicant's response letter was received.
October 2018	The additional quality data were reviewed and further information was requested.
November 2018	The applicant's response letter was received.
December 2018	The additional quality data were reviewed and further information was requested.
January 2019	The applicant's response letter was received.
February 2019	The manufacturers of the two APIs were inspected for compliance with WHO requirements for GMP.
June 2019	The additional quality data were reviewed and further information was requested.
July 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
August 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2019	Product dossier accepted (quality assurance)

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

22 August 2019	[MA143 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
At, Oxalis Labs
Village Theda
P.O. Lodhimajra
Tehsil Baddi, Dist. Solan
Himachal Pradesh-174101, India
Tel: +91-1795 661400
Fax: +91-1795 661452

Inspection status

The 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/