Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2017 an application for [MA137 trade name]* (MA137) to be assessed with the aim of including [MA137 trade name] in the list of prequalified medicinal products for Malaria.

[MA137 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.
May 2017	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2017	The applicant's response letter was received.
July 2017	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
July and August 2017	The applicant's response letters were received.
September 2017	During the meeting of the assessment team the additional quality and safety and efficacy data were reviewed and further information was requested.
October 2017	The applicant's response letters were received.
November 2017	During the meeting of the assessment team the additional 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.
March 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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 additional quality data were reviewed and further information was requested.
July 2018	In between the meetings of the assessment team the applicant's response letter was

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

	received. The additional quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2019	The applicant's response letter was received.
July 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2019	Product dossier accepted (quality assurance)
22 August 2019	[MA137 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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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