Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Universal Corporation Limited submitted in 2020, an application for [MA166 trade name]* (MA166) to be assessed with the aim of including [MA166 trade name] in the list of prequalified medicinal products for malaria prophylaxis.

[MA166 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

May 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and July 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2020	The applicant's response letters were received.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November and December 2020	The additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
April 2021	The additional quality data were reviewed and further information was requested.
June 2021	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	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 2021	The applicant's response letter was received.
November 2021	During the meeting 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 meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.

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

March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
June 2022	Three manufacturers of two APIs were inspected for compliance with WHO requirements for GMP.
May and July 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2022	The applicant's response letter was received.
August 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2022	Product dossier accepted (quality assurance)
22 August 2022	[MA166 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
Universal Corporation Limited
Club Road, Plot No. 13777
P.O.Box 1748-00902
Kikuyu
Kenya

Inspection status
The sites inspected and desk-reviewed 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products