Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Beijing Holley-Cotec Pharmaceuticals Co. Limited submitted in 2021 an application for [MA177 trade name]* (MA177) to be assessed with the aim of including [MA177 trade name] in the list of prequalified medicinal products for treatment of uncomplicated malaria.

[MA177 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	The manufacturers of the APIs were inspected for compliance with WHO requirements for GMP.
September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and October 2021	The assessment team reviewed the quality data were and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
January 2022	The applicant's response letters were received.
January 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
January and March 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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 sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2022	The applicant's response letter was received.
July 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
August 2022	The applicant's response letter was received.
September 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
October 2022	The additional quality data were reviewed and further information was requested.

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

November 2022	The applicant's response letter was received.
November 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2022	Product dossier accepted (quality assurance)
July 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
10 October 2023	[MA177 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

KBN-Zhejiang Pharmaceutical Co. Limited
340 Yunhai Road, Economic Development Zone
Jiaxing City
Zhejiang Province
China

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/prequal/medicines/prequalified/finished-pharmaceutical-products