Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company S Kant Healthcare Ltd submitted in 2018 an application for [MA145 trade name]* (MA145) to be assessed with the aim of including [MA145 trade name] in the list of prequalified medicinal products for intermittent preventive treatment of malaria.

[MA145 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

September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2018	A desk review for evaluation of compliance of the manufacturer of the APIs for GMP was conducted and it met WHO requirements.
November 2018	The applicant's response letter was received.
November 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.
March 2019	The applicant's response letter was received.
March and May 2019	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	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.
April 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

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

May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 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.
September 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.
December 2020	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
April 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2021	Product dossier accepted (quality assurance)
12 April 2021	[MA145 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

S Kant Healthcare Ltd

Plot No. 1802-1805

G.I.D.C. Phase III,

Vapi 396 195

Gujarat,

India

Inspection status

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

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

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