Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2017 an application for [MA136 trade name]* to be assessed with the aim of including [MA136 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA136 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

April 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2016	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2017	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and furthe information was requested.
November 2017	The company's response letter was received.
November 2017 and January 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
February 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	Product dossier accepted (quality assurance)
19 June 2018	[MA136 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Ipca Laboratories Limited

Plot no. 255/1, Village Athal

Silvassa 396 230

Dadra and Nagar Haveli (U. T.) 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