I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ipca Laboratories Limited submitted in 2017 an application for [MA135 trade name][1] (MA135) to be assessed with the aim of including [MA135 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA135 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

Feb 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan and March 2017	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2017	The company's response letter was received.
Sept 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2018	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
Jan 2018	The company's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The company'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.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2018	The company's response letter was received.
July 2018 and Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2018	The company's response letter was received.
Nov 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2018	Product dossier accepted (quality assurance)
18 Dec 2018	[MA135 trade name] was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Ipca Laboratories Limited
Sejavta, Ratlam
Madhya Pradesh, 457002
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/prequal/