Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ajanta Pharma Limited submitted in 2016 an application for [MA128 trade name]* (MA128) to be assessed with the aim of including [MA128 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA128 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

November 2014	The manufacturer of both APIs was inspected for compliance with WHO requirements for GMP.
April 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements forGMP.
July 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2016 and September 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2016	The company's response letter was received.
September 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
October 2016	The company's response letter was received.
November 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2016 and December 2016	The company's response letters were received.
January 2017	The safety and efficacy data and the quality data were reviewed and found to comply withthe relevant WHO requirements.
April 2017	Product dossier accepted (quality assurance)
21 April 2017	[TB128 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

Ajanta Pharma Ltd.
B-4-5-6, MIDC
Industrial Area
Paithan,
Aurangabad, 431148
Maharashtra, India.

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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP/GCP. (Biowaiver)

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