Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ajanta Pharma Limited submitted in 2013 an application for [MA111 trade name][*] (MA111) to be assessed with the aim of including [MA111 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA111 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

January 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
December 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
July 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2013	The company's response letter was received.
August 2013	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2013	The company's response letter was received.
January 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2014	The company's response letter was received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2014	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
June 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2014	The company's response letters were received.
July 2014	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.

August 2014	The company's response letter was received.
August 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2014	Product dossier accepted (quality assurance).
6 October 2014	[MA111 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 Limited
B-4-5-6, MIDC Industrial Area
Paithan, Aurangabad, 431148
Dist: Aurangabad
Maharashtra, India.

Ajanta Pharma Limited
Z/103/A, Dahej SEZ-II
Bharuch, Gujarat-392130
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The API manufacturers were found to be in compliance with WHO requirements for GMP.

FPP manufacturer was not inspected for GMP compliance with respect to [MA111 trade name]. Recent inspections by WHO covering other products produced at the site showed an acceptable outcome.

No GCP/GLP inspection was conducted with respect to [MA111 trade name]. Recent site inspections by WHO covering studies conducted on other products showed an acceptable outcome.

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