Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ajanta Pharma Limited submitted in 2012 an application for [MA092 trade name][*] (MA092) to be assessed with the aim of including [MA092 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA092 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

March 2011	The manufacturer of the one of the APIs was inspected for compliance with WHO requirements for GMP.
May 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested. The additional efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2012	The company's response letter was received.
September 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2012	The company's response letter was received.
November 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2012	Product dossier accepted (quality assurance)
19 December 2012	[MA092 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments 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.

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

Written commitments of the manufacturer

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

Inspection status

The API manufacturer inspected was found to be compliant with WHO requirements for GMP.

FPP manufacturer not inspected for GMP. Previous site inspections by WHO showed acceptable outcome.

Not inspected for GLP /GCP. Previous site inspections by WHO showed 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