Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi-Aventis submitted in 2007 an application for [MA057 trade name] * (MA057) to be assessed with the aim of including [MA057 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA057 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

September 2006	The manufacturer of the API (amodiaquine) was inspected for compliance with WHO requirements for GMP.
March 2007	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
May 2007	During the meeting of the assessment team, quality aspects of the dossier and the safety and efficacy data were reviewed and further information was requested.
July 2007	During the meeting of the assessment team, the preclinical data were reviewed and further information was requested.
January 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2008	The company's response letter was received.
March/July 2008	During the meetings of the assessment team, the additional quality as well as safety and efficacy data were reviewed and further information was requested.
September 2008	During the meeting of the assessment team, safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
October 2008	Quality data were reviewed and found to be in compliance with the relevant WHO requirements.
14 October 2008	[MA057 trade name] was accepted for the list of prequalified medicines.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

MAPHAR Laboratories
Boulevard ALKIMIA N°6
Quartier industriel Sidi Bernoussi 20250 Casablanca
Morocco
Phone No: + 212 22 67 88 00
Fax No: + 212 22 67 80 56

Sanofi-Aventis Maroc
Route de Rabat R.P.1 –
BP2611 - Aïn Sebaâ

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

20250 Casablanca
Morocco
(for batch release)
Phone No: + 212 22 66 20 20
Fax No: + 212 22 66 90 51

Inspection status

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

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