Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novartis Pharma AG submitted in 2012 an application for [MA108 trade name]* (MA108) to be assessed with the aim of including [MA108 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA108 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

June 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2014	The quality data were reviewed and further information was requested.
March 2015	The company's response letter was received.
April 2015	The quality data were reviewed and further information was requested.
June 2015	The company's response letter was received.
July 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2015	Product dossier accepted (quality assurance).
15 July 2015	[MA108 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

Novartis Saglik,
Gida ve Tarim Urunleri San. Ve Tic. A.S.,
Yenişehir Mahallesi Ihlara Vadisi Sokak
No. 2, Pendik, Istanbul, TR 34912, Turkey

Inspection status

The API site inspected was found to be in compliance with WHO requirements for GMP.

FPP site not inspected for GMP. Previous site inspections by a stringent regulatory authority were acceptable.

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

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

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