Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Swiss Pharma Nigeria Limited submitted in 2021 an application for [MA180 trade name][*] (MA180) to be assessed with the aim of including [MA180 trade name] in the list of prequalified medicinal products for prophylaxis of malaria.

[MA180 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 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
November 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
December 2021 and January 2022	The quality data were reviewed by the assessment team and further information was requested.
January 2022	The applicant's response letter was received.
January 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March and May 2023	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2023	The applicant's response letter was received.
August 2023	The additional quality data were reviewed and further information was requested.
August 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

February 2024	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
August 2023	Product dossier accepted (quality assurance)
16 August 2024	[MA180 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

Swiss Pharma Nigeria Ltd
5 Dopemu Road
Agege-Lagos
Ikeja 463
Nigeria

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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