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 [DI014 trade name]* (DI014) to be assessed with the aim of including [DI014 trade name] in the list of prequalified medicinal products for acute and persistent paediatric diarrhoea.

[DI014 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

November 2021 and January 2022	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
May 2022	The applicant's response letter was received.
July 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.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
September 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 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 and February 2023	The additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
March 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 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.

April 2023	Product dossier accepted (quality assurance)
02 May 2023	[DI014 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
Nigeria

Inspection status

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

FPP manufacturer inspected were found to be acceptable for prequalification of this product.

Not inspected for GCP/GLP since a biowaiver applies.

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