Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company PharmEvo Private Limited submitted in 2017 an application for [DI009 trade name][*] (DI009) to be assessed with the aim of including [DI009 trade name] in the list of prequalified medicinal products for treatment of diarrhoea.

[DI009 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 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2017	The applicant's response letter was received.
November 2017	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
September and November 2017	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
September 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2023	The applicant's response letter was received.
May 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2023	The applicant's response letter was received.
June 2023	The additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
June 2023	The additional quality data were reviewed and further information was requested.

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

June 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2023	Product dossier accepted (quality assurance)
12 July 2023	[DI009trade 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

PharmEvo (Pvt) Ltd.

A-29, North Western Industrial Zone

Port Qasim, Karachi 75020.

Pakistan

Inspection status

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

The FPP manufacturer was inspected and found to be in compliance with WHO requirements for GMP.

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