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 [DI010 trade name]* (DI010) to be assessed with the aim of including [DI010 trade name] in the list of prequalified medicinal products for the treatment diarrhoea.

[DI010 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
September and November 2017	During the meetings of the assessment team the quality data were reviewed and further information was requested.
January 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.
August 2018	The applicant's response letter was received.
October 2018	The additional quality data were reviewed, and further information was requested.
November 2018	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.
March 2019	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. The analytical facilities, relevant for the acceptability of the biowaiver were 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 letters were received.
June 2023	The additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letters were received.
June 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
July2023	Product dossier accepted (quality assurance)
12 July 2023	[DI010 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

PharmEvo (Private) Limited
A-29, North Western Industrial Zone
Port Qasim,
Karachi-75020
Pakistan

Inspection status

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

FPP manufacturer inspected and was 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