Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company The ACME Laboratories Limited, submitted in 2020 an application for [DI013 trade name][*] (DI013) to be assessed with the aim of including [DI013 trade name] in the list of prequalified medicinal products for the treatment of diarrhoea in children.

[DI013 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

February 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January + March 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
May 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July and October 2021	The additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
October 2021	The additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
October 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2021	Product dossier accepted (quality assurance)
02 November 2021	[DI013 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

The ACME Laboratories Limited
Solid Dosages Unit, Dhulivita
Dhamrai, Dhaka-1350
Bangladesh

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

Inspection status

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

The CRO inspected was found to be in compliance with WHO requirements for 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/prequal/medicines/prequalified/finished-pharmaceutical-products