Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Indoco Remedies Limited submitted in 2022 an application for [NT016 trade name][*] (NT016) to be assessed with the aim of including [NT016 trade name] in the list of prequalified medicinal products for treatment of certain helminthic infections.

[NT016 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

August 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2022	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January and February 2023	The quality data were reviewed by the assessment team and further information was requested.
February 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional safety and efficacy were reviewed and further information was requested.
April 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.
May 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
September 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.

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

January and March 2024	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
March 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2024	The applicant's response letter was received.
May 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2024	The applicant's response letter was received.
August 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2024	The applicant's response letters were received.
August 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2024	Product dossier accepted (quality assurance)
30 August 2024	[NT016 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

Indoco Remedies Limited
Village Katha, P.O. Baddi
Tehsil: Nalagarh, Dist.: Solan
Himachal Pradesh - 173 205
India

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/prequal/medicines/prequalified/finished-pharmaceutical-products