Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merck Healthcare KGaA submitted in 2021 an application for [NT013 trade name]* (NT013) to be assessed with the aim of including [NT013 trade name] in the list of prequalified medicinal products for neglected tropical diseases.

[NT013 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	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
July 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
July and September 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 2021	The applicant's response letters were received.
November 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November and December 2021	The additional 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.
July 2022	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
September 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 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 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 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.
September 2023	The applicant's response letter was received.

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

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 and December 2023	The additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
February 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2024	Product dossier accepted (quality assurance)
22 February 2024	[NT013 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

Merck S. A. de C.V
Calle 5, No. 7
Fraccionamiento Industrial Alce Blanco
Naucalpan de Juárez
C.P. 53370
Mexico

Inspection status

A desk review for evaluation of the manufacturer of the API was conducted and found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of the manufacturer of the FPP was conducted and found to be in compliance with WHO requirements for GMP.

The sites inspected were found to be in compliance with WHO requirements for 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