Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratorios Liconsa S.A. submitted in 2019 an application for [NT007 trade name]* (NT007) to be assessed with the aim of including [NT007 trade name] in the list of prequalified medicinal products for treatment of parasitic infestation.

[NT007 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 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
August 2019	The applicant's response letter was received.
July + November 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2019 + January 2020	During the meetings of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
June 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2020	The applicant's response letter was received.
November + December 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February + April 2021	The applicant's response letters were received.
March + April 2021	The additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	The additional 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.
May 2021	The applicant's response letter was received.

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

May 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2021	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
June 2012	Product dossier accepted (quality assurance)
01 July 2021	[NT007 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

Laboratorios Liconsa, S.A.
Avda. Miralcampo, No. 7
Polígono Industrial Miralcampo
19200 Azuqueca de Henares
Guadalajara 19200
Spain

Inspection status

The bioequivalence study sites inspected were found to be in compliance with WHO requirements for GCP/GLP.

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

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