Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Zydus Lifesciences Limited submitted in 2023 an application for [NT017 trade name]* (NT017) to be assessed with the aim of including [NT017 trade name] in the list of prequalified medicinal products for leishmaniasis.

[NT017 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

April 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
May and June 2023	The assessment team reviewed the quality data and further information was requested.
June 2023	The applicant's response letter was received.
July2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 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.
September 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
October 2023	The applicant's response letter was received.
November and December 2023	The additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
January 2024	The applicant's response letter was received.
January 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	[NT017 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

Zydus Lifesciences Limited

Kundaim Industrial Estate,

OSD Block – II, Plot No.203-213,

Kundaim, Goa-403 115, India

Inspection status

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

Not inspected for GLP/GCP. 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/prequal/medicines/prequalified/finished-pharmaceutical-products