Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company LEKHIM Joint Stock Company, Kyiv, Ukraine submitted in 2017 an application for [TB353 trade name][*] (TB353) to be assessed with the aim of including [TB353 trade name] in the list of prequalified medicinal products for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis*.

[TB353 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

November 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2017 and February 2018	The quality data were reviewed and further information was requested.
February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
March 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional safety and efficacy were reviewed and further information was requested.
August 2018	The applicant's response letter was received.
September 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional safety and efficacy were reviewed and further information was requested.
October 2018	The additional quality data were reviewed and further information was requested.
December 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

February 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March and April 2019	The applicant's response letters were received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	The applicant's response letter was received.
September 2019 and January 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2021	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2020	Product dossier accepted (quality assurance)
08 September 2021	[TB353 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

Technolog Private Joint Stock Company
8, Stara prorizna street, Uman City
Cherkassy Region, 20300
Ukraine

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