Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Svizera Labs Pvt Ltd submitted in 2021 an application for [TB392 trade name]* (TB392) to be assessed with the aim of including [TB392 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB392 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 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
December 2021	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2021 and March 2022	During the meetings of the assessment team the quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
November 2022 and January 2023	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2023	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
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.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
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.
July 2023	The applicant's response letter was received.
September and	During the meetings of the assessment team the additional quality data were reviewed and

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

November 2023	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.
November and December 2023	The applicant's response letters were received.
November 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2023	The applicant submitted additional safety and efficacy data.
November 2023	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
December 2023	In between the meetings of the assessment team the applicant's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
December 2023	Product dossier accepted (quality assurance)
22 December 2023	[TB392 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

Svizera Labs Pvt. Ltd.
Plot no. D16/6, TTC Industrial Area,
MIDC, Turbhe,
Navi Mumbai 400703,
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

A desk review for evaluation of compliance with GMP was conducted for the API manufacturer and it met WHO requirements.

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