I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Svizera Europe B.V. submitted in 2007 an application for [TB192 trade name][*](TB192) to be assessed with the aim of including [TB192 trade name]in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB192 trade name] was assessed according to the 'Procedure for 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 2007	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2008	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2008	The applicant's response letters were received.
September 2008	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
November 2008	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2009	The applicant's response letters were received.
August 2009	In between the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2011	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
June 2011	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
September 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2011	The applicant's response letters were received.
November 2011	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
February 2012	The manufacturer of one of the API's was inspected for compliance with WHO requirements for GMP.
February 2012	The applicant's response letters were received.
March 2012	The applicant's response letters were received.
March 2012	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
April 2012	In between the meeting of the assessment team the company's response letters were received. The additional quality data were reviewed and further information was requested
May 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP.
May 2012	The applicant's response letters were received.
May 2012	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.

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

July 2012	The applicant's response letters were received.
July 2012	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
July 2012	The applicant's response letters were received.
September 2012	The safety and efficacy data and the quality data were reviewed and found to comply with the relevant WHO requirements.
December 2012	Product dossier accepted (quality assurance)
19 December 2012	[TB192 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 D-16/6, TTC Industrial Area, MIDC,
Turbhe, New Mumbai – 400703
India

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products