Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Svizera Europe BV submitted in 2007 an application for [TB193 trade name] * (TB193) to be assessed with the aim for acceptance of [TB193 trade name] on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[TB193 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

Nov 2007	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Mar 2008	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jun 2008	The company's response letter was received.
Jul 2008	The company's response letter was received.
Sep 2008	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Nov 2008	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2008	The company's response letter was received.
Feb 2009	The company's response letters were received.
Mar 2009 Apr 2009	During and in between the meetings of the assessment team the additional safety and efficacy data and the quality data were reviewed and further information was requested.
Jun 2009	The company's response letter was received.
Aug 2009	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2011	The manufacturer of the one of the APIs was inspected for compliance with WHO requirements for GMP.
Apr 2011	The company's response letter was received.
May 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Jun 2011	The manufacturer of the one of the APIs was inspected for compliance with WHO requirements for GMP.
Jun 2011	The company's response letter was received.
Jul 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Jul 2011	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Sep 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

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

Sep 2011	The company's response letter was received.
Sep 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Oct 2011	The company's response letters were received.
Nov 2011	During the meeting of the assessment team the additional safety and efficacy data and quality data were reviewed and further information was requested.
Feb 2012	The manufacturer of the one of the APIs was inspected for compliance with WHO requirements for GMP.
Feb 2012	The company's response letter was received.
Mar 2012	The company's response letter was received.
Mar 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Apr 2012	The company's response letters were received.
Apr 2012	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jul 2012	The company's response letters were received.
Jul 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sep 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Dec 2012	Product dossier accepted (quality assurance)
19 Dec 2012	Rifampicin 150 mg/Isoniazid 75 mg/Pyrazinamide 400 mg/Ethambutol Hydrochloride 275 mg Tablets USP was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacture, Commitments and Inspection status

Manufacture of the finished product and responsible for batch release

Svizera Labs Private Ltd
Plot D-16/6, TTC Industrial Area
Turbhe
Navi Mumbai 400 703
India

Inspection status

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