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 [TB189 trade name]* (TB189) to be assessed with the aim of including [TB189 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB189 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 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 safety and 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.
February 2009	The applicant's response letters were received.
March 2009	During the meeting of the assessment team the additional quality/safety and efficacy data were reviewed and further information was requested.
June 2009	The applicant's response letters were received.
July 2009	During the meeting of the assessment team the additional quality/safety and efficacy data were reviewed and further information was requested.
October 2010	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2010	The applicant's response letter was received.
January 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
February 2011	The applicant's response letter was received.
March 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
April 2011	The applicant's response letters were received.

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

May 2011	During the meeting of the assessment team the additionalquality/safety and efficacy data were reviewed and further information was requested.
June 2011	The applicant's response letters were received.
June 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
July 2011	During the meeting of the assessment team the additional quality/safety and efficacy data were reviewed and further information was requested.
August 2011	The applicant's response letter was received.
September 2011	During the meeting of the assessment team the additionalsafety and efficacy data were reviewed and further information was requested.
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 quality data were reviewed and further information was requested.
November 2011	The applicant's response letter was received.
November 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2012	The applicant's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The applicant's response letter was received.
April 2012	In between the meetings of the assessment team the applicant's response letter was received. The additional qualitydata were reviewed and further information was requested.
April 2012	The applicant's response letter was received.
May 2012	During the meeting of the assessment team the additionalquality data were reviewed and further information was requested.
July 2012	The applicant's response letter was received.
July 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2012	Product dossier accepted (quality assurance)
19 December 2012	[TB189 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 Private Limited

Plot D-16/6, TTC, Industrial Area

Turbhe,

Navi 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