Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Dong-A Pharmaceutical Co. Ltd. submitted in 2011 an application for [TB236 trade name]* (TB236) to be assessed with the aim of including [TB236 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB236 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

May 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2011	The applicant's response letters were received.
July 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2011 I	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
Nov 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Dec 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2011	The company'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.
May 2012	The company's response letter was received.
June 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2012	The company's response letter was received.
Aug 2012	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Oct 2012	In between the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Oct 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2012	A company's letter with additional data was received. The quality data were reviewed and found to comply with the relevant WHO requirements

Nov 2012	Product dossier accepted (quality assurance).
16 Nov 2012	[TB236 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

Dong-A Pharmaceutical

Cheon-an Plant : 404, Chaam-dong, Cheonan-city,

Chungcheongnam-do,

Korea

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