Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Laboratories Ltd submitted in 2012 an application for [TB253 trade name][*] (TB253) to be assessed with the aim of including [TB253 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB253 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

April 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Sept 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2012	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2013 March 2013	The company's response letters were received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2013	The company's response letters were received.
Sept 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP.
Oct 2013	Product dossier accepted (quality assurance)
04 Nov 2013	[TB253 trade name] was included in the list of prequalified medicinal products.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[1] Formerly Ranbaxy Laboratories Ltd.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1 Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

MSN Laboratories Private Limited (Formulations division)
Plot No. 42, Anrich Industrial Estate
Bollaram, Medak District
Pin code- 502 325
Andhra Pradesh, India

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be compliant 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:

http://www.who.int/prequal