I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Ltd submitted in 2008 an application for Isoniazid/Rifampicin 150 mg/150 mg Tablets* (TB195) to be assessed with the aim of including Isoniazid/Rifampicin 150 mg/150 mg Tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Isoniazid/Rifampicin 150 mg/150 mg Tablets 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. The countries of origin of the assessors involved with Isoniazid/Rifampicin 150 mg/150 mg Tablets were Canada, Germany, Ghana, Hungary, Netherlands, South Africa, Spain, Switzerland, Tanzania, United Kingdom, Zambia and Zimbabwe.

Licensing status:
Isoniazid/Rifampicin 150 mg/150 mg Tablets has not been licensed / registered in other countries.

2. Steps taken in the evaluation of the product

March 2008	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2008	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2008	The company's response letter was received.
July 2008	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Oct 2008	The company's response letter was received.
Nov 2008	The company's response letter was received.
Nov 2008	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Jan 2009	The company's response letter was received.
Jan 2009	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2009	The company's response letter was received.
March 2009	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
Feb 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2010	The company's response letter was received.
Nov 2010	During the meeting of the assessment team the additional 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. Throughout this WHOPAR the proprietary name is given as an example only.

Feb 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.
Oct 2011	The company's response letter was received.
Dec 2013	The additional quality data were reviewed and further information was requested.
Dec 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Feb 2012	The company's response letter was received.
March 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letters were received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	In between the meetings of the assessment team the company's response letters were received. The quality data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013	Product dossier accepted (quality assurance)
29 Jan 2013	Isoniazid/Rifampicin 150 mg/150 mg Tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Lupin Limited
A-28/1, M.I.D.C Industrial Area
Chikalthana
431 210 Aurangabad
India

Commitments for Prequalification

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

Inspection status

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

Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

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