I BACKGROUND INFORMATION ON THE PROCEDURE

2. Submission of the dossier

The company Cadila Pharmaceuticals Limited submitted in 2002 an application for Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets* (TB009) to be assessed with the aim of including Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Ethambutol hydrochloride/Isoniazid 400mg/150mg 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 Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets were Brazil, Canada, China, Estonia, Ethiopia, Finland, Germany, Hungary, Netherlands, Philippines, Spain, South Africa, Uganda, United Kingdom.

2. Steps taken for the assessment of the product

September 2002	During the meeting of the assessment team, the safety and efficacy data as well as quality data were reviewed and further information was requested.
November 2002	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
January 2003	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2003	During the meeting of the assessment team, the additional efficacy and quality data were reviewed and further information was requested.
May 2003	During the meeting of the assessment team, the additional efficacy and quality data were reviewed and further information was requested.
July 2003	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
January 2004	During the meeting of the assessment team, the additional efficacy and quality data were reviewed and further information was requested.
May 2005	The company's response letters were received.
May 2005	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
June 2005	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
August 2005	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. Steps taken for the assessment of the product (cont.)

November 2005	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
October 2006	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2009	The company's response letter was received.
February 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April 2009	The company's response letter was received.
May 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
July 2009	The company's response letters were received.
July 2009	During the meeting of the assessment team, the additional efficacy and quality data were reviewed and further information was requested.
September 2009	The company's response letters were received.
September 2009	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements. The additional efficacy data were reviewed and further information was requested
November 2009	The company's response letter was received.
November 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
January 2010	The company's response letter was received.
January 2010	During the meeting of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
28 April 2010	Ethambutol hydrochloride/Isoniazid 400mg/150mg 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:

Cadila Pharmaceuticals Limited
1389, Dholka 387 810
District : Ahmedabad
Gujarat State
India
Tel: + 91 2714 221483-83
Fax: + 91 2714 220315
E-mail: mona.gogia@cadilapharma.co.in

Commitments for Prequalification

None

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:
www.who.int/prequal/