I BACKGROUND INFORMATION ON THE PROCEDURE

2. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2005 an application for Para-aminosalicylate sodium delayed-release granules 60% w/w* (TB156) to be assessed with the aim of including Para-aminosalicylate sodium delayed-release 60% granules in the list of prequalified medicinal products for the treatment of tuberculosis.

Para-aminosalicylate sodium delayed-release granules 60% w/w 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 Para-aminosalicylate sodium 60% granules were Canada, China, Ethiopia, Hungary, Netherlands, Spain, United Kingdom and Zimbabwe.

Licensing status:

Para-aminosalicylate sodium delayed-release granules 60% w/w has been licensed / registered in the following countries: Belarus, Kenya and Russia

2. Steps taken for the assessment of the product

July 2005	During the meeting of the assessment team, the safety and efficacy data as well as the quality data were reviewed and further information was requested.
March 2007	The company's response letter was received.
March 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2007	The company's response letter was received.
September 2007	During the meetings of the assessment team, the additional quality data were reviewed and further information was requested.
November 2007	The company's response letters were received.
November 2007	During the meeting of the assessment team, the additional quality and efficacy data were reviewed and further information was requested.

* 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.)

January 2008	The company's response letters were received.
January 2008	During the meeting of the assessment team, the additional quality data were reviewed and found to be in compliance with the relevant WHO requirements
May 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
May 2009	The company's response letter was received.
June 2009	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2009	During the meetings of the assessment team, the additional efficacy data were reviewed and found to be in compliance with the relevant WHO requirements
December 2009	During the meeting of the assessment team, the additional efficacy data were reviewed and further information was requested.
14 Dec 2009	Para-aminosalicylate sodium 60% granules 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:

Macleods Pharmaceuticals Ltd
Phase II
Plot 25-27
Sr No. 366, Premier Ind. Estate
Kachigan, Daman (U.T.)
396 21 India

Commitments for Prequalification

None.

Inspection status

The applicant was inspected and found to be in compliance with WHO requirements for GMP. Not inspected for GCP due to previously demonstrated compliance.

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/