I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Olainfarm JSC submitted in 2010 an application for P-Aminosalicylic acid 5.52 g powder* (TB229) with the aim of including p-Aminosalicylic acid 5.52 g powder in the list of prequalified medicinal products for treatment of tuberculosis.

P-Aminosalicylic acid 5.52 g powder 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 p-Aminosalicylic acid 5.52 g powder were Germany and South Africa.

Licensing status:
p-Aminosalicylic acid 5.52 g powder has been licensed / registered by least one regulatory authority in one of the ICH regions and in Belarus, Kazakhstan, Moldova and Ukraine .

2. Steps taken for the assessment of the product

January 2011	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
March 2011	The company's response letter was received.
March 2011	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
22 March 2011	p-Aminosalicylic acid 5.52 g powder was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

JSC Olainfarm
5, Rupnicu St.
Olaine
LV-2114
Latvia

Inspection status
Not applicable

Commitments
None

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