I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Biocom JSC submitted in 2011 an application for Cycloserine 250 mg Capsules* (TB222) to be assessed with the aim of including Cycloserine 250 mg Capsules in the list of prequalified medicinal products for the treatment of tuberculosis.

Cycloserine 250 mg Capsules 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 Cycloserine 250 mg Capsules were Botswana, Canada, Congo, Ethiopia, Germany, the Netherlands, South Africa, Switzerland, Uganda and Zambia.

Licensing status:

Cycloserine 250 mg Capsules has been licensed / registered in the following countries:
Azerbaijan Republic, DV № 12-0385
Republic of Armenia, N 10255
Republic of Kazakhstan, RK-LS-5№019385
Turkmenistan, LS-A№010094

2. Steps taken for the assessment of the product

July 2010	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2012	The company's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality 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 additional quality data were reviewed and further information was requested.
July 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Aug 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2013	The company's response letter was received.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

June 2013	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
July 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2013	Product dossier accepted (quality assurance)
20 Aug 2013	Cycloserine 250 mg Capsules 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:

Biocom JSC
54 Chapaevsky Cr
355016 Stavropol
Russian Federation

Commitments for Prequalification

In-use data were not submitted with the application, and applicant committed to conduct confirming in-use studies on the production batches.

Inspection status

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

Not inspected for GCP and GLP. No bioequivalence study conducted (the product was designed by technology transfer of the innovator product).

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/