I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Antibiotice SA submitted in 2013 an application for Sinerdol ISO, capsules, 300 mg/150 mg[1] (TB270) to be assessed with the aim of including Sinerdol ISO, capsules, 300 mg/150 mg in the list of prequalified medicinal products for the treatment of tuberculosis.

Sinerdol ISO, capsules, 300 mg/150 mg 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 Sinerdol ISO, capsules, 300 mg/150 mg capsules were Germany and South Africa.

Licensing status:
Sinerdol ISO, capsules, 300 mg/150 mg has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

Jan 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Feb 2013	The company's response letter was received.
Feb 2013	The quality data were reviewed and found to comply with the relevant WHO requirements
28 Feb 2013	Sinerdol ISO, capsules, 300 mg/150 mg was included in the list of prequalified medicinal products.

[1] 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.