I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Antibiotice S. A. submitted in 2013 an application for Sinerdol 300 mg hard capsules[1] (TB269) to be assessed with the aim of including Sinerdol in the list of prequalified medicinal products for the treatment of tuberculosis.

Sinerdol 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. Based on the data submitted the team of assessors advised that Sinerdol is included in the list of prequalified medicinal products.
Sinerdol was listed on 28 February 2013.

Sinerdol's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

February 2022	WHO letter of request for requalification was sent to the applicant.
April 2022	The application letter was received.
July 2022	The assessment team reviewed the submitted data and further information was requested
October 2022	The applicant's response letter was received.
April 2023	The submitted data were reviewed and found to comply with the relevant WHO requirements.
02 May 2023	Requirements of requalification were met. Sinerdol 300 mg hard capsules remained on the list of prequalified medicinal products.

[1] 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.