I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Antibiotice SA submitted in 2013 an application for Pyrazinamide Atb 500 mg tablets [1] (TB267) to be assessed with the aim of including Pyrazinamide in the list of prequalified medicinal products for the treatment of tuberculosis.

Pyrazinamide Atb 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 Pyrazinamide Atb is included in the list of prequalified medicinal products. Pyrazinamide Atb was listed on 28 February 2013.

Pyrazinamide Atb uncoated tablets '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.
May 2022	The assessment team reviewed the submitted data and further information was requested
July 2022	The applicant's response letter was received.
December 2022	The assessment team reviewed the submitted data and further information was requested
December 2022	The applicant's response letter was received.
January 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
29 January 2024	Requirements of requalification were met. Pyrazinamide Atb 500 mg tablets 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.