I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Antibiotice SA. submitted in 2013 an application for Isoniazid Atb 300 mg, tablets [1] (TB266) to be assessed with the aim of including Isoniazid Atb 300 mg, tablets in the list of prequalified medicinal products for treatment of tuberculosis.

Isoniazid Atb 300 mg, tablets 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 Isoniazid Atb 300 mg, tablets is included in the list of prequalified medicinal products. Isoniazid Atb 300 mg, tablets was listed on 28 February 2013.

Isoniazid Atb 300 mg, tablets' 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 2023	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. Isoniazid Atb 300 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.