I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novartis South Africa (Pty) Limited submitted in 2002 an application for Rimactazid 150 mg/75 mg tablets [1]) (TB085) to be assessed with the aim of including Rimactazid in the list of prequalified medicinal products for treatment of tuberculosis.

Rimactazid 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 Rimactazid is included in the list of prequalified medicinal products. Rimactazid was listed on 14 September 2004.

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

The marketing authorization holder is Sandoz A/S (Denmark).
The applicant is Sandoz Private Limited (Mumbai, India).

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

August 2024	WHO letter of request for requalification was sent to the applicant.
October 2024	The application letter was received.
November 2024	The assessment team reviewed the submitted data and further information was requested.
January 2025	The applicant's response letter was received.
March 2025	The assessment team reviewed the submitted data and further information was requested.
April 2025	The applicant's response letter was received.
April 2025	The assessment team reviewed the submitted data and further information was requested.
June 2025	The applicant's response letter was received.
June 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
04 June 2025	Requirements of requalification were met. Rimactazid 150 mg/75 mg tablets remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-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.