I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

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

Rimactazid 150 mg / 75 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. Based on the data submitted the team of assessors advised that Rimactazid 150 mg / 75 mg is included in the list of prequalified medicinal products. Rimactazid 150 mg / 75 mg was listed on 14 September 2004.

Rimactazid 150 mg / 75 mg 's conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

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

Licensing status:
Rimactazid 150 mg / 75 mg has been licensed / registered in Sweden.

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

March 2016	WHO letter of request for requalification was sent to the applicant.
June 2016	The application letter was received.
April 2017	The assessment team reviewed the submitted data and further information was requested.
January 2018	The applicant's response letter was received.
April 2018	The assessment team reviewed the submitted data and further information was requested.
June 2018	The applicant's response letter was received.
Feb 2019	The assessment team reviewed the submitted data and further information was requested.
March 2019	The applicant's response letter was received.
June 2019	The submitted data were reviewed and found to comply with the relevant WHO requirements.
26 June 2019	Requirements of requalification were met. Rimactazid 150 mg / 75 mg remained on 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.

[2] "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"