I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Olainfarm JSC submitted in 2010 an application for p-Aminosalicylate sodium 5.52 g powder for oral solution [1] (TB229) to be assessed with the aim of including p-Aminosalicylate sodium 5.52 g powder in the list of prequalified medicinal products for treatment of tuberculosis.

p-Aminosalicylate sodium 5.52 g powder 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 p-Aminosalicylate sodium 5.52 g powder is included in the list of prequalified medicinal products
p-Aminosalicylate sodium 5.52 g powder was listed on 22 March 2011.

The holder of the marketing authorization changed to Olpha AS in October 2024.

p-Aminosalicylate sodium 5.52 g powder '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

March 2016	WHO letter of request for requalification was sent to the applicant.
February 2017	The application letter was received.
September 2017	The assessment team reviewed the submitted data and further information was requested
December 2017	The applicant's response letter was received.
January 2018	The assessment team reviewed the submitted data and further information was requested
Apil 2024	The applicant's response letter was received.
May 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
08 May 2024	Requirements of requalification were met. p-Aminosalicylate sodium 5.52 g powder for oral solution 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.