

## I BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company RIEMSER Pharma GmbH submitted in 2017 an application for PETEHA 250 mg, film-coated tablets <sup>1)</sup> (TB345) to be assessed with the aim of including PETEHA in the list of prequalified medicinal products for the treatment of tuberculosis

PETEHA 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 PETEHA is included in the list of prequalified medicinal products. PETEHA was listed on 14 March 2018.

The name of the applicant changed to Esteve Pharmaceuticals GmbH in July 2022.

PETEHA ‘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

August 2024	WHO letter of request for requalification was sent to the applicant.
March 2025	The application letter was received.
August 2025	The assessment team reviewed the submitted data and further information was requested
September 2025	The applicant’s response letter was received.
September 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
16 September 2025	Requirements of requalification were met. PETEHA 250 mg, film-coated 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>

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<sup>1</sup> 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.