I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

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

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

Product name 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.

2. Steps taken in the evaluation of the product

March 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
December 2017	The company's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
March 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
14 March 2018	PETEHA 250 mg, film-coated tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

*formerly RIEMSER Pharma GmbH

[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