I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2020 an application for Pretomanid Tablets 200 mg [1] (TB386) to be assessed with the aim of including Pretomanid Tablets 200 mg in the list of prequalified medicinal products for the treatment of MDR/XDR tuberculosis.

Pretomanid Tablets 200 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.

2. Steps taken in the evaluation of the product

July 2020	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2020	The company's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The company's response letter was received.
November 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
25 November 2020	Pretomanid Tablets 200 mg was included in 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