I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company RIEMSER Pharma GmbH, Germany submitted in 2017 an application for TERIZIDON[1] (TB346) to be assessed with the aim of including TERIZIDON in the list of prequalified medicinal products for the treatment of tuberculosis.

TERIZIDON 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.
Dec 2017	The company's response letter was received.
Jan 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 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	TERIZIDON 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