I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Venus Pharma GmbH submitted in 2019 an application for Meropenem 1 g Powder for Solution for Injection or Infusion[1] (TB384) to be assessed with the aim of including Meropenem 1 g Powder for Solution for Injection or Infusion in the list of prequalified medicinal products for the treatment of tuberculosis.

Meropenem 1 g Powder for Solution for Injection or Infusion 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.

Licensing status:
Meropenem 1 g Powder for Solution for Injection or Infusion has been licensed / registered in The United Kingdom.

2. Steps taken in the evaluation of the product

Feb 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
03 March 2020	Meropenem 1 g Powder for Solution for Injection or Infusion 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.