I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shionogi B.V. submitted in 2023 an application for Fetcroja 1 g powder for concentrate for solution for infusion[1] (MR001) to be assessed with the aim of including Fetcroja in the list of prequalified medicinal products for the treatment of multi-drug resistant bacterial infections.

Fetcroja 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

November 2023	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2024	The company's response letter was received.
February 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
22 February 2024	Fetcroja 1 g powder for concentrate for solution for infusion was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://www.ema.europa.eu/en/medicines/human/EPAR/fetcroja
EMEA/H/C/004829

[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