I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Products Limited, UK, submitted in 2017 an application for Rocephin 1g for injection or infusion[1] (HA692) to be assessed with the aim of including Rocephin 1g Powder for solution for injection or infusion in the list of prequalified medicinal products for the treatment of bacterial infections in HIV/AIDS patients.

Rocephin 1g Powder 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 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2017 January 2018	The company's response letters were received.
February 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
22 February 2018	Rocephin 1g Powder for solution for injection or infusion 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

[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.