I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company LABORATORIO REIG JOFRE, S.A submitted in 2022 an application for Benzetacil 1.200.000 UI powder and solvent for suspension for injection [1] (RH103) to be assessed with the aim of including Benzetacil 1.200.000 UI in the list of prequalified medicinal products for the treatment of reproductive health conditions.

Benzetacil 1.200.000 UI 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

January 2023	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2023	The company's response letter was received.
March 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
21 March 2023	Benzetacil 1.200.000 UI powder and solvent for suspension for injection 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