I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company BIAL-Portela & C[a], S.A. submitted in 2022 an application for Misofar 200 micrograms vaginal tablets[1] (RH105) to be assessed with the aim of including Misofar in the list of prequalified medicinal products for of reproductive health conditions in women.

Misofar 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

February 2023	The submitted 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.
27 March 2023	Misofar 200 micrograms vaginal tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified-lists

[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.