I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company BIAL-Portela & Cª, S.A. submitted in 2021 an application for Misofar 25 micrograms vaginal tablets [1] (RH099) to be assessed with the aim of including Misofar in the list of prequalified medicinal products for the treatment 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.
Based on the data submitted the team of assessors advised that Misofar is included in the list of prequalified medicinal products.
Misofar 25 micrograms vaginal tablets was listed on 16 December 2021.

2. Steps taken in the re-evaluation of the product

July 2026	WHO letter of request for requalification was sent to the applicant.
August 2026	The application letter was received.
August 2026	The submitted data were reviewed and found to comply with the relevant WHO requirements.
12 August 2026	Requirements of requalification were met. Misofar 25 micrograms vaginal tablets remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

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