I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Inresa Arzneimittel GmbH submitted in 2016 an application for Magnesium sulfate 50% Inresa[1] (RH062) to be assessed with the aim of including Magnesium sulfate 50% Inresa in the list of prequalified medicinal products for treatment of reproductive health conditions in women.

Magnesium sulfate 50% Inresa 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 Magnesium sulfate 50% Inresa is included in the list of prequalified medicinal products. Magnesium sulfate 50% Inresa was listed on 15 August 2016.

Magnesium sulfate 50% Inresa's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

January 2024	WHO letter of request for requalification was sent to the applicant.
February 2024	The application letter was received.
March 2024	The assessment team reviewed the submitted data and further information was requested.
August 2024	The applicant's response letter was received.
August 2024	The assessment team reviewed the submitted data and further information was requested.
October 2024	The applicant's response letter was received.
October 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
30 October 2024	Requirements of requalification were met. Magnesium sulfate 50% Inresa remained on the list of prequalified medicinal 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.