I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Martindale Pharma submitted in 2017 an application for Magnesium Sulfate 50%w/v Solution for Injection[1](2ml) (RH073) to be assessed with the aim of including Magnesium Sulfate 50%w/v Solution for Injection in the list of prequalified medicinal products for the treatment of reproductive health conditions in women.
Magnesium Sulfate 50%w/v Solution for Injection 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.

Licensing status:
Magnesium Sulfate 50%w/v Solution for Injection has been licensed / registered in the United Kingdom.

2. Steps taken in the evaluation of the product

March 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
Nov 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2017	The company's response letters were received.
Nov 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
12 Dec 2017	Magnesium Sulfate 50%w/v Solution for Injection was included in the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.