I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Labesfal, Laboratórios Almiro S.A. submitted in 2018 an application for Sulfato de Magnésio Labesfal Solução Injectável 5000 mg/10 ml Solução injectável[1] (RH072) to be assessed with the aim of including Sulfato de Magnésio in the list of prequalified medicinal products for for the treatment of reproductive health conditions in women.

Sulfato de Magnésio 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:
Sulfato de Magnésio has been licensed / registered in Portugal.

2. Steps taken in the evaluation of the product

May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
19 June 2018	Sulfato de Magnésio 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