# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Inresa Arzneimittel GmbH submitted in 2012 an application for Magnesiumsulfat 50% Inresa [1] (RH062) to be assessed with the aim of including Magnesiumsulfat 50% Inresa in the list of prequalified medicinal products for the treatment of. (pre-) eclampsia.

Magnesiumsulfat 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. The countries of origin of the assessors involved with Magnesiumsulfat 50% Inresa were Germany and South Africa.

**Licensing status:**

Magnesiumsulfat 50% Inresa has been licensed / registered in Germany.

## 2. Steps taken in the evaluation of the product

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| July 2016 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| 15 Aug 2016 | Magnesiumsulfat 50% Inresa 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