I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Linepharma International Limited submitted in 2014 an application for Mifepristone Linepharma 200 mg tablet[1] (RH051) to be assessed with the aim of including Mifepristone Linepharma 200 mg tablet in the list of prequalified medicinal products for medical termination of a developing intra-uterine pregnancy.

Mifepristone Linepharma 200 mg tablet 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 Mifepristone Linepharma 200 mg tablet were Germany, South Africa and Switzerland.

Licensing status:
Mifepristone Linepharma 200 mg tablet has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

May 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2014	The company's response letter was received.
Sept 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
06 Oct 2014	Mifepristone Linepharma 200 mg tablet 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