I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company EXELGYN submitted in 2015 an application for Mifegyne 200 mg tablets [1] (RH061) to be assessed with the aim of including Mifegyne 200 mg tablets in the list of prequalified medicinal products for medical termination of a developing intra-uterine pregnancy.

Mifegyne 200 mg tablets 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 Mifegyne 200 mg tablets were Germany and South Africa.

Licensing status:
Mifegyne 200 mg tablets has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

April 2015	The quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
April 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
23 May 2016	Mifegyne 200 mg tablets 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