I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2015 an application for Fall Back Solo® [1] (RH058) to be assessed with the aim of including Fall Back Solo® in the list of prequalified medicinal products for emergency contraception for women.

Fall Back Solo® 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 Fall Back Solo® were Germany and South Africa.

Licensing status:
Fall Back Solo® has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

Oct 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
16 Dec 2015	Fall Back Solo® 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