I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer Oy, Turku, Finland, submitted in 2009 an application for Jadelle sine inserter 2 x 75 mg implant [1] (RH017) to be assessed with the aim of including Jadelle Sine Inserter in the list of prequalified medicinal products for female contraception .

Jadelle Sine Inserter 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.

Jadelle Sine Inserter 's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

April 2016	WHO letter of request for requalification was sent to the applicant.
April 2016	The application letter was received.
April 2016	The submitted data were reviewed and found to comply with the relevant WHO requirements.
01 June 2016	Requirements of requalification were met. Jadelle sine inserter 2 x 75 mg implant remained on the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.