I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer Schering Pharma AG submitted in 2007 an application for Microlut[1] (RH002) to be assessed with the aim of including Microlut in the list of prequalified medicinal products for female contraception.
After prequalification the marketing authorization holder changed to Jenapharm GmbH & Co. KG.

Microlut 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.

Microlut'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

December 2015	WHO letter of request for requalification was sent to the applicant.
March 2016	The application letter was received.
March 2016	The assessment team reviewed the submitted data and further information was requested.
June 2016	The applicant's response letter was received.
December 2016	The submitted data were reviewed and found to comply with the relevant WHO requirements.
28 September 2017	Requirements of requalification were met. Microlut 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.