I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2013 an application for Levonorgestrel and Ethinyl Estradiol Tablets USP[1] (RH042) to be assessed with the aim of including Levonorgestrel and Ethinyl Estradiol Tablets USP in the list of prequalified medicinal products for female contraception.

Levonorgestrel and Ethinyl Estradiol Tablets USP 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.
Based on the data submitted the team of assessors advised that Levonorgestrel and Ethinyl Estradiol Tablets USP is included in the list of prequalified medicinal products. Levonorgestrel and Ethinyl Estradiol Tablets USP was listed on 26 August 2013.

Levonorgestrel and Ethinyl Estradiol Tablets USP 's conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

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

February 2022	WHO letter of request for requalification was sent to the applicant.
April 2022	The application letter was received.
September 2022	The assessment team reviewed the submitted data and further information was requested
December 2022	The applicant's response letter was received.
February 2023	The submitted data were reviewed and found to comply with the relevant WHO requirements.
08 March 2023	Requirements of requalification were met. Levonorgestrel and Ethinyl Estradiol Tablets USP 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.