I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd, submitted in 2013 an application for Freya 21[1] (RH037) to be assessed with the aim of including Freya 21 in the list of prequalified medicinal products for contraception for women on 14 August 2013.

After prequalification the applicant changed to Mylan Laboratories Limited, India.

Freya 21 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 Freya 21 is included in the list of prequalified medicinal products.

Freya 21 '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

February 2022	WHO letter of request for requalification was sent to the applicant.
March 2022	The application letter was received.
June 2022	The assessment team reviewed the submitted data and further information was requested
July 2022	The applicant's response letter was received.
November 2022	The submitted data were reviewed and found to comply with the relevant WHO requirements.
11 November 2022	Requirements of requalification were met. Freya 21 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.