I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Jenapharm GmbH & Co. KG submitted in 2017 an application for Microgynon 28 150 micrograms / 30 micrograms coated tablets[1] (RH082) to be assessed with the aim of including Microgynon 28 in the list of prequalified medicinal products for reproductive health conditions in women.

Microgynon 28 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 Microgynon 28 is included in the list of prequalified medicinal products. Microgynon 28 was listed on 24 October 2017.

Microgynon 28'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

January 2024	WHO letter of request for requalification was sent to the applicant.
April 2024	The application letter was received.
May and June 2024	The assessment team reviewed the submitted data and further information was requested.
August 2024	The application letter was received.
September 2024	The assessment team reviewed the submitted data and further information was requested.
October 2024	The application letter was received.
January 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
14 January 2025	Requirements of requalification were met. Microgynon 28 150 micrograms / 30 micrograms coated tablets remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-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.