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[1] (RH082) to be assessed with the aim of including Microgynon 28 in the list of prequalified medicinal products for contraception for 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.

2. Steps taken in the evaluation of the product

September 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
October 2017	The company's response letter was received.
October 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
24 October 2017	Microgynon 28 was included in the list of prequalified medicinal products.

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/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