I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company N.V. Organon submitted in 2022 an application for Cerazette 75 microgram film-coated tablets[1] (RH102) to be assessed with the aim of including Cerazette in the list of prequalified medicinal products for contraception for women.

Cerazette 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

November 2022 and January 2023	During the meetings of the assessment team the quality data were reviewed and further information was requested.
February 2023	The company's response letter was received.
May 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
05 May 2023	Cerazette 75 microgram film-coated tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

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