I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer AG, submitted in 2021 an application for Mirena 20 micrograms/24 hours intrauterine delivery system [1] (RH100) to be assessed with the aim of including Mirena in the list of prequalified medicinal products for reproductive health conditions in women.

Mirena 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

December 2021	The assessment team reviewed the submitted data and further information was Requested.
March 2022	The company's response letter was received.
March 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
17 March 2022	Mirena 20 micrograms/24 hours intrauterine delivery system was included in 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