# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Bayer Schering Pharma AG Berlin, Germany, submitted in 2010 an application for Noristerat [1] (RH022) to be assessed with the aim of including Noristerat in the list of prequalified medicinal products for contraception for women.

After prequalification the marketing authorisation holder changed to Bayer plc United Kingdom.

Noristerat 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.

Noristerat'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

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| December 2016 | The submitted data were reviewed and found to comply with the relevant WHO requirements. |
| 28 September 2017 | Conformance to the requirements of prequalification was verified.<br>Noristerat 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.