

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 Noristerat¹ (RH022) to be assessed with the aim of including Noristerat in the list of prequalified medicinal products for contraception for women.

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.

Based on the data submitted the team of assessors advised that Noristerat is included in the list of prequalified medicinal products. Noristerat was listed on 05 October 2011.

Noristerat’s conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

2. Steps taken in the re-evaluation of the product

January 2025	WHO letter of request for requalification was sent to the applicant.
May 2525	The application letter was received.
May 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
19 May 2025	Requirements of requalification were met. Noristerat 200 mg, solution for intramuscular injection 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.