

## I BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Bayer Oy submitted in 2009 an application for Jadelle® sine inserter 2 x 75 mg implant <sup>1</sup> (RH017) to be assessed with the aim of including Jadelle in the list of prequalified medicinal products for reproductive health.

Jadelle 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 Jadelle is included in the list of prequalified medicinal products. Jadelle was listed on 23 September 2009.

Jadelle ‘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

January 2025	WHO letter of request for requalification was sent to the applicant.
April 2025	The application letter was received.
April 2025	The assessment team reviewed the submitted data and further information was requested
May 2025	The application letter was received.
June 2025	The assessment team reviewed the submitted data and further information was requested
July 2025	The application letter was received.
July 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
17 July 2025	Requirements of requalification were met. Jadelle® sine inserter 2 x 75 mg implant 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>

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<sup>1</sup> 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.