

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company N.V. Organon submitted in 2010 an application for Desolett 28 tablets¹ (RH025) to be assessed with the aim of including Desolett in the list of prequalified medicinal products for female contraception.

Desolett 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 Desolett is included in the list of prequalified medicinal products. Desolett was listed on 29 September 2010.

The name of the supplier changed to Merck Sharp & Dohme BV, Haarlem, Netherlands, in June 2015. The Marketing Authorization Holder changed to N.V. Organon, Netherlands, in 2021.

Desolett ‘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

August 2024	WHO letter of request for requalification was sent to the applicant.
October 2024	The application letter was received.
March 2025	The assessment team reviewed the submitted data and further information was requested
June 2025	The applicant’s response letter was received.
July 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
15 July 2025	Requirements of requalification were met. Desolett 28 tablets 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.