STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company N.V. Organon submitted in 2010 an application for Desolett 28 tablets* (RH025) with the aim of including Desolett 28 in the list of prequalified medicinal products for contraception for women.

Desolett 28 tablets 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.

The name of the supplier changed to Merck Sharp & Dohme BV, Haarlem, The Netherlands in June 2015.

The Marketing Authorization Holder changed to N.V. Organon, Netherlands, in 2021

Desolett 28 tablets'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

December 2015	WHO letter of request for requalification was sent to the applicant.
March 2016	The application letter was received.
February 2017	The assessment team reviewed the submitted data and further information was requested
April 2017	The applicant's response letter was received.
January 2018	The submitted data were reviewed and found to comply with the relevant WHO requirements.
02 February 2018	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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

* Trade names are not prequalified by WHO. This is under local Drug Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.