I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company NV Organon submitted in 2013 an application for Implanon NXT, 68 mg implant subdermal use [1] (RH036) to be assessed with the aim of including Implanon NXT in the list of prequalified medicinal products for contraception for women.

Implanon NXT 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 Implanon NXT is included in the list of prequalified medicinal products. Implanon NXT was listed on 23 May 2013.

Implanon NXT '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

February 2022	WHO letter of request for requalification was sent to the applicant.
July 2022	The application letter was received.
January 2023	The assessment team reviewed the submitted data and further information was requested
February 2023	The applicant's response letter was received.
April 2023	The assessment team reviewed the submitted data and further information was requested
June 2023	The applicant's response letter was received.
June 2023	The submitted data were reviewed and found to comply with the relevant WHO requirements.
20 June 2023	Requirements of requalification were met. Implanon NXT, 68 mg implant subdermal use 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