# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Pfizer N. V. - S.A, Belgium, submitted in 2009 an application for Depo-Provera, 150 mg/mL suspension for injection[1] (vials) (RH018) to be assessed with the aim of including Depo-Provera in the list of prequalified medicinal products for contraception for women.

Depo-Provera, 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 Depo-Provera is included in the list of prequalified medicinal products. Depo-Provera, 150 mg/mL suspension for injection (vials)was listed on 20 August 2010.

The name of the supplier was changed to "Pfizer AB", (Sweden) in 2021.

Depo-Provera'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

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| August 2024 | WHO letter of request for requalification was sent to the applicant. |
| October 2024 | The application letter was received. |
| October 2024 | The assessment team reviewed the submitted data and further information was requested. |
| December 2024 | The application letter was received. |
| December 2024 | The submitted data were reviewed and found to comply with the relevant WHO requirements. |
| 16 December 2024 | Requirements of requalification were met.<br>Depo-Provera, 150 mg/mL suspension for injection (vials) 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.