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, 150 mg/mL suspension (vials) for injection in the list of prequalified medicinal products for contraception for women.

Depo-Provera, 150 mg/mL suspension for injection (vials) 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.

Depo-Provera, 150 mg/mL suspension for injection's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

The name of the supplier was changed to "Pfizer AB", (191 90 Sollentuna, Sweden) in 2021.

2. Steps taken in the re-evaluation of the product

December 2015	WHO letter of request for requalification was sent to the applicant.
April 2016	The application letter was received.
August 2017	The assessment team reviewed the submitted data and further information was requested
May 2018	The application letter was received.
November 2018	The assessment team reviewed the submitted data and further information was requested
May 2020	The application letter was received
July 2020	The assessment team reviewed the submitted data and further information was requested
October 2020	The application letter was received
January 2021	The submitted data were reviewed and found to comply with the relevant WHO requirements.
18 January 2021	Requirements of requalification were met. 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.