WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Depo-Provera, 150 mg/mL suspension for injection, (vials) [1]

Medroxyprogesterone acetate 150 mg/mL suspension for injection

Depo-Provera, 150 mg/mL suspension for injection, (vials), was submitted by Pfizer N. V. - S.A, Belgium in 2009 to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for reproductive health conditions in women on 20 August 2010.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information https://extranet.who.int/prequal/medicines/rh018

The reference Stringent Regulatory Authority (SRA) changed from Belgium (FAMHP) to Sweden (MPA) in May 2018.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by the Swedish Medical Products Agency ("Läkemedelsverket" https://lakemedelsverket.se/english/) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.
However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Store the vial in the upright position. Do not store above 30°C. Do not refrigerate or freeze.
- The shelf-life at this storage condition is 48 months.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (https://lakemedelsverket.se) resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.
(https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel?id=19761001000038)

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet
The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "Läkemedelsverket" approved texts, are included in this WHOPAR.

This WHOPAR for Depo-Provera, 150 mg/mL suspension for injection, (vials), is comprised of parts 2, 3, 4, 5 and 7
For products for which the WHO recommended uses differ from those authorized by the reference authority, additionally parts 3a, 4a and 5a are included.

Depo-Provera, 150 mg/mL suspension for injection, (vials), is a so called progestogen-only contraceptive, containing the synthetic hormone medroxyprogesterone acetate.
Its WHO recommended use is for long-acting, reversible contraception for women.

The efficacy and safety profile of medroxyprogesterone acetate is well established based on extensive clinical experience for contraception in women,

Summary of Prequalification Status for Depo-Provera, 150 mg/mL suspension for injection, (vials)

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list,	20 August 2010	listed	18 January 2021	listed
Dossier Evaluation	July 2010	MR	January 2021	requalified

MR: meets requirements
The table represents the status of relevant completed activities only.