

**5.11 MEDROXYPROGESTERONE ACETATE,
Suspension for injection 150 mg in 1 mL pre-filled
syringe,
Depo-Provera[®],
Pfizer Australia Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule (Unrestricted Benefit) listing of medroxyprogesterone acetate 150 mg/mL pre-filled syringe (Depo-Provera[®]) (herein referred to as medroxyprogesterone PFS) under the same circumstances as the currently listed medroxyprogesterone acetate 150 mg/mL injection, vial forms (Depo-Provera[®], Depo-Ralovera[®]) (herein referred to as medroxyprogesterone vial).
- 1.2 The submission stated that medroxyprogesterone vial will be phased out in 2024 once medroxyprogesterone PFS is PBS-listed. The sponsor intends to submit a delisting request for medroxyprogesterone vial for consideration at the March 2024 PBAC meeting. The pre-PBAC response noted that the timing of delisting remains uncertain.

2 Background

Registration status

- 2.1 Medroxyprogesterone PFS was Therapeutic Goods Administration (TGA) registered on 3 May 2023 for the same indications as medroxyprogesterone vial. The Product Information and Consumer Medicines Information of medroxyprogesterone vial were updated to include medroxyprogesterone PFS.

Previous PBAC consideration

- 2.2 Medroxyprogesterone PFS has not been previously considered by the PBAC.

3 Requested listing

3.1 The submission requested the following new listing, under the same circumstances as the currently listed medroxyprogesterone vial.

3.2 *Add new medicinal product in italics as follows:*

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
MEDROXYPROGESTERONE					
medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial	3118D	1	1	1	Depo-Ralovera Depo-Provera
<i>medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe</i>	<i>NEW</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>Depo-Provera</i>

3.3 The submission noted that medroxyprogesterone PFS is simpler to administer than medroxyprogesterone vial, because there is no need to withdraw the suspension from a vial into a syringe. The submission claimed that this is more efficient in clinical settings, which is particularly relevant in remote communities where medroxyprogesterone acetate is a preferred form of contraception among Aboriginal and Torres Strait Islander women.

4 Comparator

4.1 The submission did not specifically nominate a comparator. The pre-PBAC response nominated the medroxyprogesterone vial as the appropriate nominated comparator (i.e the therapy that prescribers would most replace in practice with medroxyprogesterone PFS).

4.2 The submission stated that medroxyprogesterone PFS and medroxyprogesterone vial have the same formulation (including excipients), dosage form, strength/concentration, indications and patient groups, route and site of administration, and dosage. Therefore, a bioequivalence study was not required by the TGA. The TGA approval letter confirms that the only differences between the two forms are the container type (with consequential changes to manufacturing processes), shelf-life and storage conditions.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

Pricing consideration

- 5.3 The submission requested an approved ex-manufacturer price (AEMP) for medroxyprogesterone PFS which is equivalent to medroxyprogesterone vial, noting that the existing Depo-Provera injection vial has a brand premium. The pre-PBAC response confirmed that the sponsor is not requesting a brand premium for medroxyprogesterone PFS.

Economic analysis

- 5.4 The submission did not include an economic analysis.

Estimated PBS usage and financial implications

- 5.5 The submission did not provide a financial estimate workbook. It was not clear from the submission whether the replacement of the vial form with the PFS is likely to have an impact on overall use of medroxyprogesterone on the PBS. The pre-PBAC response confirmed no financial impact is expected to the PBS/RPBS for the new listing, noting that the AEMP requested for the new listing is equivalent to the medroxyprogesterone vial. The pre-PBAC response further clarified that the formulation, dosage, pack size and dispensing details of the medroxyprogesterone vial and PFS are the same, therefore any vial replaced by the PFS in practice will result in a nil financial impact to the PBS/RPBS.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of medroxyprogesterone PFS (Depo-Provera®) on the General Schedule (Unrestricted Benefit) under the same circumstances as the PBS-listed medroxyprogesterone vial (Depo-Provera®, Depo-Ralovera®).
- 6.2 The PBAC considered that the nomination of medroxyprogesterone vial as the comparator was appropriate. The PBAC noted that a bioequivalence study was not required by the TGA, and that the TGA approval letter confirmed that medroxyprogesterone PFS and medroxyprogesterone vial are the same except for the container type (with consequential changes to manufacturing processes), shelf-life and storage conditions.
- 6.3 The PBAC advised that the equi-effective doses were:
- Medroxyprogesterone acetate 150 mg/mL PFS = medroxyprogesterone acetate 150 mg/mL vial
- 6.4 The PBAC noted that the sponsor intends to delist the medroxyprogesterone vial once medroxyprogesterone PFS is PBS-listed and the timing of the delisting request remains uncertain.
- 6.5 The PBAC noted the submission's request for an AEMP for medroxyprogesterone PFS which is equivalent to the medroxyprogesterone vial, and that a brand premium was not requested for the new listing.

- 6.6 The PBAC considered that the listing of medroxyprogesterone PFS would likely not result in increased utilisation of medroxyprogesterone, and that the listing was therefore likely to have no financial impact.
- 6.7 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, the medroxyprogesterone vial and medroxyprogesterone PFS should be considered equivalent for the purposes of substitution (i.e., ‘a’-flagged in the Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purposes of substitution).
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because medroxyprogesterone PFS is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the comparator, and is not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item.

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
MEDROXYPROGESTERONE					
medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe	NEW	1	1	1	Depo-Provera

	<p>Administrative Advice: Pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe and pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial are equivalent for the purposes of substitution.</p>
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- 7.2 Flow on changes to existing medroxyprogesterone acetate 150mg vial (PBS item code 3118D) to include the above administrative advice.

This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.