

**OOS SEMAGLUTIDE,
Solution for injection 2 mg in 1.5 mL pre-filled pen
(s19A);
Solution for injection 4 mg in 3 mL pre-filled pen
(s19A),
Ozempic® (UK),
Medsurge Healthcare Pty Ltd Purpose**

1 Purpose

- 1.1 To seek the PBAC’s advice on the temporary PBS listing of section 19A (s19A) products sponsored by Medsurge Healthcare Pty Ltd (Medsurge) to manage the shortage of PBS subsidised semaglutide injections (Ozempic). The s19A products detailed below have been approved for supply under subsection 19A(1) of the *Therapeutic Goods Act 1989* until the date mentioned in Table 1.

Table 1: Listed product in shortage and s19A product

Listed product in shortage		Reported shortage
Ozempic®	Semaglutide, solution for injection 2 mg in 1.5 mL pre-filled pen (injection) Semaglutide, solution for injection 4 mg in 3 mL pre-filled pen (injection)	15 April 2022 to 31 December 2022
s19A product		s19A expiry
Ozempic®(UK)	Semaglutide, 0.25 mg solution for injection in pre-filled pen Semaglutide, 1 mg solution for injection pre-filled pen	31 October 2022

2 Background

- 2.1 Semaglutide is a GLP-1 analogue used in the treatment of type 2 diabetes, available on the PBS for use in combination with metformin and/or sulfonylurea or with insulin.
- 2.2 Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk), the sponsor of the only PBS listed semaglutide product, Ozempic®, has notified the TGA of a shortage due to an unexpected increase in consumer demand, due to off-label prescribing for obesity management. The TGA and the sponsor have published a joint statement advising prescribers to limit prescribing to patients with type 2 diabetes. There has been limited availability of Ozempic in Australia since 15 April 2022 and this has in turn recently caused a shortage of another PBS listed GLP-1 analogue, dulaglutide (Trulicity®).

- 2.3 Ozempic is available in two forms, the first contains a 2 mg solution in a 1.5 mL pre-filled pen (for dose escalation and maintenance therapy) and the second is a 4 mg solution in a 3 mL pre-filled pen (for maintenance therapy only).
- 2.4 From 1 January 2021 to 31 December 2021, 491,185 scripts of Ozempic were dispensed under the PBS and the average monthly script volume was 23,375 (the current year-to-date average is 48,933 scripts/month) for the 3 mL pen and 17,557 for the 1.5 mL pen (the current year-to-date average is 35,863 scripts/month). The total PBS and RPBS expenditure for the 2021 calendar year was \$49.33 million and the year-to-date expenditure up until 30 June 2022 was \$56.81 million.
- 2.5 Tables 2 and 3 below shows the prescription volume and expenditure for both forms of Ozempic for each patient category for the 2021 calendar year and the year-to-date (until 30 June 2022) respectively.

Table 2: Patient category share of prescriptions for Ozempic (item codes 12075M and 12080T from 1 January 2021 to 31 December 2021.

	PBS				RPBS		Total
	General – Ordinary	General – Safety Net	Concessional- Ordinary	Concessional – Free Safety Net	RPBS – Ordinary	RPBS – Safety Net	
Services	175,268	18,324	128,859	100,419	3,174	3,317	429,361
Benefit (\$)	\$16,348,002	\$2,350,272	\$16,370,210	\$13,410,159	\$403,104	\$444,964	\$49,326,711

Table 3: Patient category share of prescriptions for Ozempic (item codes 12075M and 12080T from 1 January 2022 to 30 June 2022.

	PBS				RPBS		Total
	General – Ordinary	General – Safety Net	Concessional- Ordinary	Concessional – Free Safety Net	RPBS – Ordinary	RPBS – Safety Net	
Services	224,089	6,601	227,666	39,008	6,543	1,423	505,330
Benefit (\$)	\$20,740,411	\$855,362	\$28,948,517	\$5,247,057	\$828,855	\$192,205	\$56,812,407

Source: Medicare statistics website (http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp)

- 2.6 The TGA has provided approval for the short-term import and supply of the UK approved version of Ozempic to assist with the local product shortages.

3 Requested Listing

- 3.1 The s19A products and the PBS listed products in shortage have the same drug form and pricing quantity. Medsurge has requested a limited temporary listing for < 500 packs of the 0.25 mg solution for injection in pre-filled pen and < 500 packs of the 1 mg solution for injection pre-filled pen.
- 3.2 It is noted that the volume of packs the s19A sponsor is able to supply will account for around 1% of the PBS market. The sponsor has also requested an increase of approximately % in the AEMP for the s19A products (\$111.44 for the ARTG products compared to \$ for the s19A products). It is also noted that \$111.44 is the published price for Ozempic, which is subject to Special Pricing Arrangements.

3.3 The details of the requested listing are set out in Table 4.

Table 4: Details of requested s19A listing

Out of Stock	AEMP (Current listing)	s19A products	s19A expiry	Requested AEMPs	Estimated financial impact
Semaglutide, Solution for injection 2 mg in 1.5 mL pre-filled pen (injection), Ozempic	\$111.44	Ozempic 0.25 mg solution for injection in pre-filled pen (UK)	31 October 2022	\$ ¹	\$ ¹
Semaglutide, Solution for injection 4 mg in 3 mL pre-filled pen (injection), Ozempic	\$111.44	Ozempic 1 mg solution for injection pre-filled pen (UK)	31 October 2022	\$ ¹	\$ ¹

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

4 PBAC advice

- 4.1 The PBAC recommended the temporary listing of the s19A products Ozempic 0.25 mg solution for injection in pre-filled pen (UK) and Ozempic 1 mg solution for injection pre-filled pen (UK) on the PBS at the same ex-manufacturer price as the two forms of PBS-listed semaglutide which are currently in shortage.
- 4.2 The PBAC considered that there is a clinical need to maintain supply of semaglutide on the PBS. The PBAC considered that the temporary listing should apply for the duration of the subsection 19A(1) approval.
- 4.3 The PBAC noted reports that the increase in consumer demand for semaglutide has been driven by off-label prescribing for obesity management and this has resulted in the current shortages.
- 4.4 The PBAC did not support listing at the requested price as it considered that the s19A listing should not come at an increased cost.
- 4.5 The PBAC noted that while the s19A sponsor is not Novo Nordisk, the s19A product would be sourced from the same manufacturer and that the requested price did not appear well justified from a cost of goods perspective.
- 4.6 The PBAC advised under section 101(4AACD) of the Act that the temporary listing for Ozempic, semaglutide 0.25 mg solution for injection in pre-filled pen (UK) should be treated as equivalent to the currently listed brand of semaglutide, solution for injection 2 mg in 1.5 mL pre-filled pen for the purpose of substitution at the pharmacy level.
- 4.7 The PBAC advised under section 101(4AACD) of the Act that the temporary listing for Ozempic 1 mg solution for injection pre-filled pen (UK) should be treated as equivalent to the currently listed brand of semaglutide, solution for injection 4 mg in 3 mL pre-filled pen (injection) for the purpose of substitution at the pharmacy level.

Outcome:

Recommended

5 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.

6 Sponsor's Comment

Since the worldwide shortage of diabetes medicine, Ozempic® (semaglutide) started earlier this year, Medsurge sought a section 19a (S19A) approval from the Therapeutics Goods Administration (TGA) to source overseas-registered semaglutide products. Medsurge was granted a temporary S19A approval and has worked diligently to fill a critical need for patients with type 2 diabetes.

Australian local supply of OZEMPIC® 1 mg semaglutide (rys) 1.34 mg/mL solution for injection pre-filled pen AUST R: 315107, and OZEMPIC® 0.25/0.5 mg semaglutide (rys) 1.34 mg/mL solution for injection pre-filled pen AUST R: 308324 supplied by Novo Nordisk is subsidised on the Pharmaceutical Benefits Scheme (PBS) for treatment of type 2 diabetes.

Sourcing overseas medicines under an S19A requires the local sponsor to apply to the Pharmaceutical Benefits Advisory Committee (PBAC) to approve a temporary variation in cost to the original Pharmaceutical Benefits Scheme pricing. Unfortunately, PBAC recommended that PBS listing be granted at the current local supply price.

Medsurge sources the semaglutide products from various overseas supply partners, not directly from the manufacturer, which is considerably more expensive. Medsurge does not have control over the pricing set by the overseas partners. In addition, the rising cost of shipping, air freight, duties, currency conversion and small batch quantities add to the increased expense of sourcing critical medicines from overseas wholesalers. Therefore, Medsurge are unable to supply overseas products at the expected local market prices.

Medsurge understands S19A product listing will not ensure supply of this medicine is directed to patients with the greatest clinical need, however it is no different to the Registered product version. Use of this product is the responsibility of the Prescriber.

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Medsurge continues to engage with TGA, PBAC and other health professional organisations to find a favourable solution for all stakeholders, whilst still sourcing sufficient S19A supply to fulfil the current demand until the shortage is resolved.

Medsurge acknowledges the importance of access to Ozempic® for patients living with diabetes and other chronic health conditions and we are taking this shortage very seriously.