

**5.22 INSULIN ASPART,
Injections (human analogue), cartridges, 100 units
per mL, 3 mL, 5,
Truvelog®
Injections (human analogue), pre-filled pen, 100 units
per mL, 3 mL, 5,
Truvelog Solostar®,
Sanofi-Aventis Australia Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 3 submission sought listing of a new biosimilar brand of insulin aspart (Truvelog) in the form of 100 IU/mL cartridge (Truvelog®) and 100 IU/mL pre-filled pen (Truvelog Solostar®), for the treatment of diabetes mellitus, under the same circumstances as the PBS-listed forms of the reference biologic NovoRapid (NovoRapid FlexPen® and NovoRapid Penfill®).

2 Background

Registration status

- 2.1 Truvelog was TGA registered on 15 October 2020 for the treatment of diabetes mellitus, and determined to be a biosimilar to the reference brand NovoRapid. Truvelog has the same TGA indication as NovoRapid.

3 Requested listing

- 3.1 The submission requested listing Truvelog under the same circumstances as the existing unrestricted listings of NovoRapid.
- 3.2 The submission requested that Truvelog be 'a' flagged against corresponding forms of the reference brand NovoRapid and proposed inclusion of an administrative note encouraging the use of biosimilar medicines for treatment-naïve patients.

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

- 4.1 The submission nominated NovoRapid as the main comparator. This was appropriate.

For more detail on PBAC's view, see section 6 PBAC outcome.

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.

Clinical trials

5.3 The submission presented a summary of the GEMELLI 1 (EFC 15081) study, a randomised, open label study comparing safety and efficacy of SAR341402 (Truvelog) to NovoRapid in adult patients with diabetes mellitus also using insulin glargine.

5.4 The GEMELLI 1 study formed part of the TGA submission to register Truvelog as a biosimilar to NovoRapid. The TGA Delegate's Overview noted that the data provided is adequate to support the registration of Truvelog as a biosimilar to NovoRapid and that the disposable pens are also sufficiently similar for patients to know how to use the device without the need for re-education.

5.5 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.6 The submission claimed that Truvelog was biosimilar to NovoRapid.

5.7 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was adequately supported by the data.

Pricing considerations

5.8 The submission requested listing Truvelog on a cost-minimisation basis to NovoRapid.

5.9 Although not a matter for PBAC, the PBAC noted the Sponsor planned to submit a request for Ministerial Discretion to reduce the 'First New Brand' statutory price reduction under the National Health Act 1953 of up to 25%, to ■%.

Table 1: Current prices for NovoRapid and prices for Truvelog with █% and 25% reduction

NovoRapid FlexPen/PenFill – Current ex-manufacturer price
\$36.23 (1 pack containing 5 units)
Truvelog/Truvelog SoloStar – Proposed ex-manufacturer price (█% SPR)
\$█ (1 pack containing 5 units)
Truvelog/Truvelog SoloStar – Proposed ex-manufacturer price (25% SPR)
\$27.17 (1 pack containing 5 units)

Source: table 3, p6 of the submission

Abbreviations: DPMQ: dispensed price maximum quantity, SPR: statutory price reduction

Estimated PBS utilisation and financial implications

- 5.10 Table 2 presents the estimated extent of use and the net financial implications to the PBS/RPBS. The financial estimates assume a █% statutory price reduction is applied with the listing of Truvelog.
- 5.11 The submission estimated that 300,000 to < 400,000 scripts for Truvelog would be supplied over the first six years of listing (10,000 to < 20,000 in Year 1 to 70,000 to < 80,000 in Year 6).
- 5.12 The submission estimated the net financial impact to the PBS/RPBS for the listing of Truvelog is a net cost saving over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).
- 5.13 As a Category 3 submission, the financial estimates have not been independently evaluated.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	█ ¹	█ ²	█ ³	█ ⁴	█ ⁴	█ ⁵
Drug costs to PBS/RPBS						
Cost of Truvelog to the PBS	█ ⁶	█ ⁶	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Cost of Truvelog to the RPBS	█ ⁶	█ ⁶	█ ⁶	█ ⁶	█ ⁶	█ ⁶
Cost of affected PBS/RPBS listing						
Cost of affected PBS listings (NovoRapid)	-█ ⁶	-█ ⁶	-█ ⁷	-█ ⁷	-█ ⁷	-█ ⁷
Cost of affected RPBS listings (NovoRapid)	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶
Estimated net financial implications						
Net cost PBS / RPBS	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶	-█ ⁶

Source: utilisation and cost model workbook from the submission

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ 10,000 to < 20,000

² 40,000 to < 50,000

³ 50,000 to < 60,000

⁴ 60,000 to < 70,000

⁵ 70,000 to < 80,000

⁶ \$0 to < \$10 million

⁷ \$10 million to < \$20 million

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a new biosimilar brand of insulin aspart in the form of 100 IU/mL cartridge (Truvelog) and 100 IU/mL pre-filled pen (Truvelog Solostar) under the same circumstances as the PBS-listed reference brands NovoRapid Penfill and NovoRapid Flexpen. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Truvelog and Truvelog Solostar would be acceptable if they were cost-minimised to NovoRapid Penfill and NovoRapid Flexpen respectively.
- 6.2 The PBAC advised that the equi-effective doses are: Truvelog 100 IU/mL cartridge = NovoRapid Penfill 100 IU/mL cartridge and Truvelog Solostar 100 IU/mL pre-filled pen = NovoRapid Flexpen 100 IU/mL pre-filled pen.
- 6.3 The PBAC noted that the TGA determined Truvelog to be biosimilar to the reference brand NovoRapid based on the clinical evidence presented in the submission. The PBAC noted the TGA delegate considered Truvelog Solostar and NovoRapid Flexpen to be sufficiently similar for patients to know how to use the device without the need for re-education.

- 6.4 The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953* (“the Act”), that Truvelog Solostar should be treated as equivalent to NovoRapid Flexpen for the purposes of substitution (i.e. ‘a’ flagged).
- 6.5 The PBAC noted that Truvelog and NovoRapid Penfill cartridges are designed to be used with specific insulin delivery systems and compatible sterile needles. On this basis, the PBAC advised under Section 101 (4AACD) of the Act that Truvelog and NovoRapid Penfill cartridges should not be treated as equivalent for the purposes of substitution.
- 6.6 The PBAC considered that the ‘Biosimilar prescribing policy’ administrative note should be included:
- Prescribing of the biosimilar brand, Truvelog/Truvelog Solostar, is encouraged for treatment naive patients.*
- Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).*
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Truvelog is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over NovoRapid, or 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 2009* for Pricing Pathway A were not met.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new trade products (Truvelog and Truvelog Solostar) to existing listings for NovoRapid Penfill and NovoRapid Flexpen as follows:
- 7.2 Add equivalence indicators to the trade products ‘Truvelog Solostar’ and ‘NovoRapid Flexpen’ as follows:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
INSULIN ASPART					
insulin aspart 100 units/mL injection, 5 x 3 mL cartridges	8435Y	5	5	1	Novorapid Penfill 3 mL Truvelog
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse					
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit					
Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand, Truvelog, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
INSULIN ASPART					
insulin aspart 100 units/mL injection, 5 x 3 mL pen device	12254Y	5	5	1	NovoRapid Flexpen ^a Truvelog Solostar ^a
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse					
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit					
Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand, Truvelog Solostar, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).					
Administrative Advice: Pharmaceutical benefits that have the brand Truvelog Solostar 100 units/mL injection, 5 x 3 mL and pharmaceutical benefits that have the brand Novorapid Flexpen 100 units/mL injection, 5 x 3 mL are equivalent for the purposes of substitution.					

These restrictions 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.