5.17 AFLIBERCEPT, Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL), Eydenzelt®, Celltrion Healthcare Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule Authority Required listings of a new aflibercept biosimilar (Eydenzelt®) for the treatment of subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM) on a cost-minimisation basis and under the same conditions as its reference biologic (Eylea®).

2 Background

2.1 Eydenzelt was TGA registered on 24 March 2025 and was determined to be a biosimilar medicine to the reference brand (Eylea).

2.2 The TGA approved indication for Eydenzelt is as follows: "Eydenzelt 2mg (aflibercept) is indicated in adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV)." The submission stated that the approved indication is synonymous to the term 'subfoveal CNV due to PM' used in the PBS listing of Eylea.

2.3 The submission also stated that there are several other indications for Eydenzelt which the sponsor will request TGA approval for once patent issues are resolved.

3 Requested listing

3.1 The submission requested listing Eydenzelt under the same circumstances as Eylea for the CNV due to PM indication only.

3.2 The submission also requested that the listings for Eydenzelt be consistent with the biosimilar uptake driver policy.

3.3 As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

3.4 Add brand to existing items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
AFLIBERCEPT					
aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe	12141B	1	1	2	Eylea[a] *Eydenzelt*[a]
aflibercept 2 mg/0.05 mL injection, 0.05 mL vial	12131L	1	1	2	Eylea[a] *Eydenzelt*[a]
Administrative Advice: ***Biosimilar prescribing policy*** *Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.*					
Administrative Advice *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
AFLIBERCEPT					
aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe	13139M	1	1	2	Eylea[a] *Eydenzelt*[a]
aflibercept 2 mg/0.05 mL injection, 0.05 mL vial	13151E	1	1	2	Eylea[a] *Eydenzelt*[a]

3.5 The submission requested that Eydenzelt be considered equivalent ('a' flagged) to Eylea for the purpose of substitution (for equivalent injection devices that contain the same injectable mg dose per volume).

3.6 The submission noted that Eylea is currently subject to a Special Pricing Arrangement. Therefore, the current confidential effective prices are not known to the sponsor.

3.7 Eydenzelt will have the same drug, form and manner of administration as the existing aflibercept brand and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing aflibercept brand as per Section 85C of the *National Health Act 1953.*

3.8 The Secretariat has added administrative advice reflecting the biosimilar uptake policy (i.e. encouraging biosimilar prescribing for treatment-naïve patients) to the initial listings for CNV.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

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

Clinical evidence

4.3 As per the Product Information, the TGA has confirmed that "Eydenzelt (for 2 mg dosing) is a biosimilar medicine to the reference product Eylea (aflibercept) (for 2 mg dosing). The evidence for comparability supports the use of Eydenzelt for the listed indication."

4.4 The submission stated that the equi-effective doses are: 1 mg Eydenzelt = 1 mg Eylea.

Pricing matters

4.5 Although not a matter for the PBAC, the listing of the first new biosimilar brand of aflibercept may trigger a statutory 'first new brand' price reduction of up to 25%.

Estimated PBS usage and financial implications

4.6 Listing of biosimilar brands does not change overall utilisation of the drug.

4.7 Eydenzelt is expected to substitute for Eylea and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

5.1 The PBAC recommended the General Schedule Authority Required listings of a new aflibercept biosimilar (Eydenzelt®) for the treatment of subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM) on a cost-minimisation basis and under the same conditions as its reference biologic (Eylea®).

5.2 The PBAC advised the equi-effective doses to be 1 mg Eydenzelt = 1 mg Eylea.

5.3 The PBAC noted that the TGA has confirmed that Eydenzelt is a biosimilar medicine to Eylea.

5.4 The PBAC noted that in their pre-PBAC response, the sponsor confirmed that initial treatment should remain Authority Required (Written/Online) and continuing treatment should be Authority Required (Streamlined) (in other words, the same restriction levels as Eylea).

5.5 The PBAC also noted that the submission requested the addition of administrative advice reflecting the biosimilar uptake driver that encourages biosimilar prescribing for treatment-naïve patients. The PBAC considered that the application of that biosimilar uptake driver to Eydenzelt would be clinically appropriate.

5.6 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Eydenzelt and Eylea should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits).

5.7 The PBAC considered that the listing of Eydenzelt would not result in a net cost to the PBS as it would likely substitute for Eylea and not increase the overall market utilisation.

5.8 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Eydenzelt is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Eylea, and is not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

5.9 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

6 Recommended listing

6.1 As the submission requested the same restrictions as the existing brand, the full restrictions have not been reproduced.

6.2 Add Eydenzelt biosimilar listing, with schedule equivalence ('a' flag) to Eylea for the CNV due to PM indication only.

6.3 Amend existing listings as follows:

- Add the Eydenzelt brand – Authority Required listing of Eydenzelt, with the Authority type for each treatment phase to be consistent with Eylea.
- Apply the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients for listings with initial treatment phases:

  Prescribing of the biosimilar brand where available is encouraged for treatment naïve patients.

  Encouraging biosimilar prescribing for treatment naïve 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 Medicines webpage *(www.health.gov.au/health-topics/medicines)*

Amend existing listing as follows (additions are in italics):

MEDICINAL PRODUCT medicinal product pack			PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
AFLIBERCEPT							
aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe			12141B	1	1	2	Eylea[a] *Eydenzelt[a]*
aflibercept 2 mg/0.05 mL injection, 0.05 mL vial			12131L	1	1	2	Eylea[a] *Eydenzelt[a]*
Prescribing rule	*33164*	***Administrative Advice:*** ***Biosimilar prescribing policy*** *Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.*					
	29791	***Administrative Advice*** *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
AFLIBERCEPT					
aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe	13139M	1	1	2	Eylea[a] *Eydenzelt[a]*
aflibercept 2 mg/0.05 mL injection, 0.05 mL vial	13151E	1	1	2	Eylea[a] *Eydenzelt[a]*

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.