

5.15 GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND DOCOSAHEXAENOIC ACID AND LOW IN PHENYLALANINE

Sachets containing oral powder 40 g, 30 (PKU GMPPro Delight), PKU GMPPro Delight®, Danone Nutricia ANZ

1 Purpose of Submission

- 1.1 The Category 3 submission requested a General Schedule Restricted Benefit listing of glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine (PKU GMPPro Delight®) sachets containing oral powder 40 g, under the same circumstances as glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine (PKU Sphere20®) sachets containing oral powder 35 g for the dietary management of phenylketonuria (PKU).
- 1.2 Listing was requested on the basis of cost minimisation approach versus PKU Sphere20. The Secretariat noted, despite the submission's cost minimisation approach, the AEMP sought for GMPPro Delight was higher than the AEMP of the comparator, PKU Sphere 20, per gram of protein equivalent (PE).

2 Background

- 2.1 PKU GMPPro Delight is a low volume, concentrated, methionine-free protein substitute containing 5 grams of PE per sachet for the dietary management of PKU. It is expected that PKU GMPPro Delight will largely be used to treat children from 3 years of age, and adults with PKU.

Registration status

- 2.2 The sponsor of PKU GMPPro Delight confirmed it meets the requirements for foods for medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.
- 2.3 As PKU GMPPro Delight is marketed as a nutritional product and not a therapeutic good, it is not registered in the Australian Register of Therapeutic Goods.

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Previous PBAC consideration

- 2.4 PKU GMPPro Delight has not been previously considered by the Pharmaceutical Benefits Advisory Committee (PBAC) for the dietary management of PKU.
- 2.5 In November 2022, the PBAC had recommended the General Schedule Restricted Benefit listing of PKU Sphere20 (glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine) for the dietary management of PKU.

3 Requested listing

- 3.1 The submission requested for PKU GMPPro Delight to be listed under the same conditions as the current PBS-listed PKU Sphere20 (PBS item code: 11071Q) (i.e., a section 85 General Schedule Restricted Benefit listing for PKU).

Add new medicinal product as follows:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE						
glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 40 g sachets		NEW	4	4	5	PKU GMPPro Delight
Concept ID	Category / Program: ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒ Medical Practitioners ☒ Nurse Practitioners					
	Restriction type: ☒ Restricted benefit					
	Restriction Summary 4295 / Treatment of Concept: 4295					
	Indication: Phenylketonuria					

4 Comparator

- 4.1 The submission nominated PKU Sphere20 as the main comparator. The submission considered the nutritional profile of PKU GMPPro Delight is similar to the nutritional profile of PKU Sphere20, with the only differences being the protein source and inclusion of dietary fibre in PKU GMPPro Delight (details of the nutritional profile are provided in Table 2).
- 4.2 The PBAC could only recommend listing PKU GMPPro Delight at a higher price than the alternative therapy or therapies if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies (*National Health Act 1953*, section 101(3B)). The alternative therapy in this case is PKU Sphere20.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer inputs

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

Clinical evidence

5.3 No clinical trials were presented in the submission comparing PKU GMPPro Delight to the comparators.

5.4 The submission cited 19 publications (Table 1) in support of the listing of PKU GMPPro Delight. The submission stated the publications show the inclusion of glycomacropeptide (GMP) and docosahexaenoic acid (22:6n-3, DHA) in PKU GMPPro Delight, when compared to traditional amino-acid diets, may promote satiety, have prebiotic properties and address dietary deficiencies common in PKU subjects.

Table 1: Publications presented in the submission

First Author	Publication title	Publication citation
van Calcar, S.C., et al.	Food products made with glycomacropeptide, a new low phenylalanine whey protein, provide a new alternative to amino acid-based medical foods for nutrition management of phenylketonuria	J Acad Nutr Diet, 2012. 112: p. 1201-1210
Ney, D.M., et al.	Nutritional management of PKU with glycomacropeptide from cheese whey	J Inherit Met Dis, 2009. 32: p. 32-39
Bruck, W.M., et al.	Effects of bovine alpha-lactoglobulin and casein glycomacropeptide-enriched infant formulae on faecal microbiota in healthy term infants	J Paediatr Gastroenterol Nutr, 2006. 43: p. 673-679
van Calcar, S.C., et al.	Improved nutritional management of phenylketonuria by using a diet containing glycomacropeptide compared with amino acids	Am J Clin Nutr, 2009. 89: p. 1068-77
Etzel, M.R.	Manufacture and use of dairy protein fractions	J Nutr, 2004. 134: p. 996S-1002S
Sanjurjo, P., et al.	Dietary Threonine Reduces Plasma Phenylalanine Levels in Patients With Hyperphenylalaninemia	J Pediatr Gastroenterol Nutr, 2001. 36: p. 23-26
van Spronsen, M.J., et al.	Large neutral amino acids in the treatment of PKU: from theory to practice	J Inherit Met Dis, 2010. 33(6): p. 671-676
Smith, Q.R.	Blood–brain barrier amino acid transport	Introduction to the Blood–Brain Barrier, W.M. Pardridge, Editor. 1998, Cambridge University Press: Cambridge. p. 188-197.
Lim, K.W., et al.	Acceptable Low-Phenylalanine Foods and Beverages Can Be Made with Glycomacropeptide from Cheese Whey for Individuals with PKU	Mol Genet Metab, 2007. 92(1/2): p. 176-178
Ney, D.M., et al.	Glycomacropeptide for nutritional management of phenylketonuria: a randomized, controlled, crossover trial	Am J Clin Nutr, 2016. doi:10.3945/ajcn.116.135293.
Zaki, O.K., et al.	The use of glycomacropeptide in dietary management of phenylketonuria	J Nutr and Met. http://dx.doi.org/10.1155/2016/2453027

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First Author	Publication title	Publication citation
Solversen, P.M., et al.	Glycomacropeptide, a low-phenylalanine protein isolated from cheese whey, supports growth and attenuates metabolic stress in the murine model of phenylketonuria	Am J Physiol Endocrinol Metab, 2012. 302(7): p. E885-95
Ney, D.M., et al.	Dietary glycomacropeptide supports growth and reduces the concentrations of phenylalanine in plasma and brain in a murine model of phenylketonuria	J Nutr, 2008. 138: p. 316-322.
Ney, D.M., et al.	Advances in the nutritional and pharmacological management of phenylketonuria	Curr Opin Clin Nutr and Metab Care, 2014. 17(1): p. 61-68
MacLeod, E.L., et al.	Breakfast with Glycomacropeptide Compared with Amino Acids Suppresses Plasma Ghrelin Levels in Individuals with Phenylketonuria	Mol Genet Metab, 2010. 100(4): p. 303-308.
Sawin, E.A., et al.	Glycomacropeptide is a prebiotic that reduces Desulfovibrio bacteria, increases cecal short-chain fatty acids, and is anti-inflammatory in mice	American Journal of Physiology - Gastrointestinal and Liver Physiology, 2015. 309(7)
Ahring, K., et al.	Dietary management practices in phenylketonuria across European centres	Clin Nutr, 2009. 28(3): p. 231-6
Scriver, C.R. and Kaufman, S.	Hyperphenylalaninaemia: phenylalanine hydroxylase deficiency	The Metabolic and Molecular Bases of Inherited Disease, C.R. Scriver, Beaudet, A. L., Sly, W. S., Valle, D., Childs, B., Kinzler, K. W., Vogelstein, B., Editor. 2001, McGraw-Hill Medical: New York. p. 1667-1724
Montoya Parra, G., et al.	Status of nutrients important in brain function in phenylketonuria: a systematic review and meta-analysis	Orphanet Journal of Rare Diseases, Volume 13, p. 101.

Source: Reference of the submission

Clinical claim

- 5.5 The submission claimed the nutritional composition of PKU GMPPro Delight is therapeutically equivalent to PKU Sphere20 and is expected to deliver comparable clinical outcomes. The submission provided a comparison of the nutritional profile of PKU GMPPro Delight with PKU Sphere20 (Table 2).
- 5.6 The submission stated one 160 ml serving (40 g powder in 140 ml water) PKU GMPPro Delight provides 519 kJ/ 122 kcal, 20 g protein equivalent (PE); 36 mg phenylalanine (PHE), and 100 mg docosahexaenoic acid (DHA).
- 5.7 The submission stated PKU Sphere20 provides 20 g PE per 35 g sachet; 36 mg of PHE.
- 5.8 The submission stated that the main protein source in PKU GMPPro Delight is casein-derived GMP compared to whey-derived GMP in PKU Sphere20, which may increase patient adherence due to a neutral taste.
- 5.9 The submission stated that PKU GMPPro Delight includes dietary fibre compared to PKU Sphere20, which does not contain any dietary fibre.

Table 2: Nutritional composition PKU GMPPro Delight, and main comparators, PKU Sphere20

		PKU SPHERE20 (Red Berry)	PKU GMPRO DELIGHT 20 TROPICAL	PKU GMPRO DELIGHT BERRY
		Per 35 g	Per 40 g sachet	Per 40 g sachet
Energy	KJ	508	519	517

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		PKU SPHERE20 (Red Berry)	PKU GMPRO DELIGHT 20 TROPICAL	PKU GMPRO DELIGHT BERRY
	kcal	120	122	122
Fat	g	1.6	0.5	0.5
of which saturates	g	0.6	0.16	0.16
DHA	mg	110	100	100
Carbohydrate	g	18*	8.9	8.8
of which sugars	g	2.5	4	4.3
Protein equivalent	g	20	20	20
Salt	g		0.64	0.64
Fibre	g	–	2.1	2.1
Vitamin A (RE)	µg	241	359	359
Vitamin D	µg	4.2	9.76	9.76
Vitamin E (αTE)	mg	4.91	5.59	5.59
Vitamin K	µg	21	24.3	24.3
Vitamin C	mg	28	59.7	59.7
Thiamin	mg	0.52	0.56	0.56
Riboflavin	mg	0.52	0.64	0.64
Niacin	mg	3	7.1	7.1
Vitamin B6	mg	0.49	0.66	0.66
Folic Acid	µg	91	73.1	73.1
Vitamin B12	µg	1.4	1.38	1.38
Biotin	µg	11	22.2	22.2
Pantothenic acid	Mg	1.8	2.67	2.67
Sodium	Mg	283	257	257
	Mmol		11.2	11.2
Potassium	Mg	206	675	675
	mmol		17.3	17.3
Chloride	mg	7	<12	<12
	mmol		0.34	0.34
Calcium	mg	353	582	582
	mmol		14.5	14.5
Phosphorus	mg	367	423	423
	mmol		13.7	13.7
Magnesium	mg	101	124	124
	mmol	2.1	5.12	5.12**
Iron	mg	6.6	7.05	7.05
Zinc	mg	6.6	6.6	6.6
Copper	mg	0.52	0.57	0.57
Manganese	mg	0.35	0.88	0.88
Selenium	µg	27	24.2	24.2
Chromium	µg	10	31.3	31.3
Molybdenum	µg	18	28.5	28.5
Iodine	µg	74	69.6	69.6
Choline	mg	178	203	203
L-Alanine	g	0.83	0.92	0.92
L-Arginine	g	0.96	1	1
L-Aspartic Acid	g	1.31	1.1	1.1
L-Cystine	g	0.24	0.043	0.043
L-Glutamic Acid	g	–	2.4	2.4

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		PKU SPHERE20 (Red Berry)	PKU GMPRO DELIGHT 20 TROPICAL	PKU GMPRO DELIGHT BERRY
L-Glutamine	g	2.7	–	–
Glycine	g	0.71	1.2	1.2
L-Histidine	g	0.7	0.66	0.66
L-Isoleucine	g	1.42	1.3	1.3
L-Leucine	g	3.02	2.6	2.6
L-Lysine	g	0.95	2	2
L-Methionine	g	0.28	0.63	0.63
L-Phenylalanine	g	0.036	0.036	0.036
L-Proline	g	1.6	1.372	1.372
L-Serine	g	1.01	0.91	0.91
L-Threonine	g	2.29	2.1	2.1
L-Tryptophan	g	0.4	0.36	0.36
L-Tyrosine	g	2.25	2	2
L-Valine	g	1.14	1.7	1.7
Osmolality	mOsm/Kg	900	1070	1090
Osmolarity	mOsm/L	-	890	910

Source: pp12-13 of submission

*Noted by NPWP as the value per 100 g, correct value is 6.3 g per sachet (paragraph 6.4 refers).

**Stated as 5.12; 13.7 corrected from the Product Documentation Sheet

5.10 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

5.11 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Pricing and considerations

5.12 As a Category 3 submission, the economic analysis has not been independently evaluated.

5.13 The submission stated that it had presented a cost-minimisation approach (CMA) of PKU GMPPro Delight compared with PKU Sphere20. However, the cost analysis showed different prices per gram of PE of \$0.76 for PKU Sphere20 and \$0.825 for PKU GMPPro Delight at the approved ex-manufacturer price (AEMP).

5.14 The requested AEMP per maximum quantity PE (\$2,142.93) of PKU GMPPro Delight is higher than the comparator PKU Sphere20 (\$1,984.72). The submission stated this price was 'very close per gram of protein equivalent' (

5.15 Table 3: Calculated costs versus comparator

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	PKU Sphere20	PKU GMPPro Delight
Presentation	35g	40g sachets
Units	30	30
Maximum Quantity of boxes (packs)	4	4
g protein equivalent per serve	20	20
Therapeutic relativity based on protein equivalent	1	1
Total protein equivalent for maximum quantity g	$30 \times 4 \times 20 = 2,400$	$30 \times 4 \times 20 = 2,400$
AEMP per box	\$456.92	\$495
AEMP per Max Qty	$4 \times \$456.92 = \mathbf{\$1,827.68}$	$4 \times \$495 = \mathbf{\$1,980}$
AEMP per g protein equivalent	\$0.76	\$0.825
PTP per box (Price to pharmacy)	\$470.46	$\$2,034.24/4 = \mathbf{\$508.54}$
PTP x Max Qty	$\$1,827.68 + 54.14 = \mathbf{\$1,881.82}$	$\$1,980 + 54.14 = \mathbf{\$2,034.14}$
Price per unit (PTP / unit)	$\$470.46/30 = \mathbf{\$15.68}$	$\$508.54/30 = \mathbf{\$16.95}$
Wholesale markup	\$54.14	\$54.14
Pharmacist AHI fee Tier 2: \$4.62, plus 5% of the amount where the price to pharmacists exceeds \$100.00, per maximum quantity supplied	AHI Fee for Max Qty Tier 2 = Tier 1 \$4.91 + 5% of \$1881.82-\$100 = \$4.91 + \$89.09 = \$94.00	AHI fee for max Qty > \$2,000 = Tier 1 fee (\$4.91) + \$95.00 = \$99.91
Dispensing fee	\$8.88	\$8.88
DPMQ	PTP Max Qty \$1,881.82 + AHI Fee \$94.00 + Disp Fee \$8.88 = DPMQ \$1,984.70 (0.02c diff may be in the diff dispensing fee when submitted) = \$1,984.72	PTP Max Qty \$2,034.14 + AHI Fee \$99.91 + Disp fee \$8.88 = DPMQ \$2,142.93

Source: from Table 5, p27 of submission

Note: Rounding applied in the AEMP and PTP calculations

5.16) and reflected updated formulation and manufacturing costs.

5.17 The price of PKU GMPPro Delight in comparison to the nominated comparator is presented in Table 3: Calculated costs versus comparator.

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Table 3: Calculated costs versus comparator

	PKU Sphere20	PKU GMPro Delight
Presentation	35g	40g sachets
Units	30	30
Maximum Quantity of boxes (packs)	4	4
g protein equivalent per serve	20	20
Therapeutic relativity based on protein equivalent	1	1
Total protein equivalent for maximum quantity g	$30 \times 4 \times 20 = 2,400$	$30 \times 4 \times 20 = 2,400$
AEMP per box	\$456.92	\$495
AEMP per Max Qty	$4 \times \$456.92 = \mathbf{\$1,827.68}$	$4 \times \$495 = \mathbf{\$1,980}$
AEMP per g protein equivalent	\$0.76	\$0.825
PTP per box (Price to pharmacy)	\$470.46	$\$2,034.24/4 = \mathbf{\$508.54}$
PTP x Max Qty	$\$1,827.68 + 54.14 = \mathbf{\$1,881.82}$	$\$1,980 + 54.14 = \mathbf{\$2,034.14}$
Price per unit (PTP / unit)	$\$470.46/30 = \mathbf{\$15.68}$	$\$508.54/30 = \mathbf{\$16.95}$
Wholesale markup	\$54.14	\$54.14
Pharmacist AHI fee Tier 2: \$4.62, plus 5% of the amount where the price to pharmacists exceeds \$100.00, per maximum quantity supplied	AHI Fee for Max Qty Tier 2 = Tier 1 \$4.91 + 5% of \$1881.82-\$100 = \$4.91 + \$89.09 = \$94.00	AHI fee for max Qty > \$2,000 = Tier 1 fee (\$4.91) + \$95.00 = \$99.91
Dispensing fee	\$8.88	\$8.88
DPMQ	PTP Max Qty \$1,881.82 + AHI Fee \$94.00 + Disp Fee \$8.88 = DPMQ \$1,984.70 (0.02c diff may be in the diff dispensing fee when submitted) = \$1,984.72	PTP Max Qty \$2,034.14 + AHI Fee \$99.91 + Disp fee \$8.88 = DPMQ \$2,142.93

Source: from Table 5, p27 of submission

Note: Rounding applied in the AEMP and PTP calculations

Drug cost/patient/year: \$25,715.16

- 5.18 The estimated drug cost per patient per year would be \$25,715.16, based on the submission's calculated DPMQ of \$2,142.93 and 12 scripts per year. The actual cost may vary due to differences in individual patient needs.

Estimated PBS usage and financial implications

- 5.19 The submission proposed a market share approach to predict the utilisation and estimate the financial implications of listing PKU GMPro Delight.
- 5.20 The submission claimed the requested price was based on the AEMP of PKU Sphere20 listed in the PBS in November 2022 however, as noted in paragraph 5.14, the AEMP sought for PKU GMPro Delight was higher than the current AEMP of PKU Sphere20.
- 5.21 The submission did not provide a completed UCM model, relying instead on the claim that the listing would result in a nil financial impact to the PBS.

6 NPWP Consideration

- 6.1 The NPWP supported the listing of PKU GMPPro® Delight on the PBS under the same conditions as PKU Sphere20 for the dietary management of PKU, on a cost-minimisation basis to PKU Sphere20, at an equivalent cost per gram of PE.
- 6.2 The NPWP advised that PKU Sphere20 is the most appropriate comparator for PKU GMPPro Delight.
- 6.3 The NPWP considered PKU GMPPro Delight to be therapeutically comparable and expected it to provide non-inferior clinical benefits and safety compared to PKU Sphere20.
- 6.4 The NPWP noted that the nutrition information for PKU Sphere20 (Red Berry flavour) provided in the submission (see Table 2) was incorrect in relation to the total carbohydrate content. The value listed (18 g) reflects the amount per 100 g of PKU Sphere20 rather than per sachet. The correct total carbohydrate content is 6.3 g per sachet (35 g), consistent with the nutritional information published on the Vitaflo Australia Pty Limited website.
- 6.5 The NPWP considered that, while PKU GMPPro Delight has higher iron and additional fibre content that may offer potential nutritional benefits for some patients, there was no clinical evidence to support superior safety or effectiveness compared with PKU Sphere20.
- 6.6 The NPWP noted that the intended population for PKU GMPPro Delight is for patients over the age of 3 years, whereas the comparator PKU Sphere20 is for patients over the age of 4 years. The NPWP considered there to be potential advantages of expanding access to PBS subsidised nutritional products for the treatment of PKU in patients between the age of 3 and 4 years, who are currently ineligible for treatment with the comparator, PKU Sphere20.
- 6.7 The NPWP noted that the osmolarity of PKU GMPPro Delight is higher than that of PKU Sphere20, but differences in osmolarity were unlikely to affect preparation volume or treatment adherence. The NPWP also noted the submission's claim that PKU GMPPro Delight may offer a more neutral taste that could influence individual patient preference and adherence, but there was no evidence of significant clinical benefit to justify a price premium compared with PKU Sphere20.

7 PBAC Outcome

- 7.1 The PBAC recommended a General Schedule Restricted Benefit listing of glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine (PKU GMPPro Delight®) sachets containing oral powder 40 g for the dietary management of phenylketonuria (PKU) under the same circumstances as glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine (PKU Sphere20®) sachets containing oral powder 35 g for the same indication.
- 7.2 The PBAC considered that PKU GMPPro Delight should be cost-minimised to PKU Sphere20, the comparator accepted by the NPWP at an equivalent price per gram of PE.
- 7.3 The PBAC considered that the Listed Drug name in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* for PKU GMPPro Delight should align with the Listed Drug name for PKU Sphere20, which currently includes reference to 'long chain polyunsaturated fatty acids'.
- 7.4 The PBAC noted and accepted PKU Sphere20 as the appropriate main comparator.
- 7.5 The PBAC noted and supported the NPWP advice that PKU GMPPro Delight is expected to provide non-inferior clinical benefits and safety compared to PKU Sphere20.
- 7.6 The PBAC advised that PKU GMPPro Delight is suitable for prescribing by nurse practitioners.
- 7.7 The PBAC recommended that the Early Supply Rule should not apply, as it has been the PBAC's view that general nutrients be exempt.
- 7.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because PKU GMPPro Delight is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over PKU Sphere20, 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.
- 7.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

8.1 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE					
glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 40 g sachets	NEW	4	4	5	PKU GMPro Delight
Concept ID	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒ Medical Practitioners ☒ Nurse Practitioners				
	Restriction type: ☒ Restricted benefit				
	Restriction Summary 4295 / Treatment of Concept: 4295				
	Indication: Phenylketonuria				

This restriction 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.