14.03(j) WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE
Oral powder 400 g, Kindergen®, Nutricia Australia Pty Ltd

1 Purpose of Application

1.1 The Committee Secretariat Submission requested a formulation change to Kindergen® to conform to new European compositional standards.

2 Background

2.1 Kindergen was listed on the PBS on 1 August 2002 for chronic renal failure in infants and young children. Kindergen underwent minor formulation changes in 2011, to which the PBAC had no objection.

2.2 The sponsor previously stated in its December 2001 submission that Kindergen is not a therapeutic good but a "Food for Special Medical Purposes" (FSMP) regulated under the Australia New Zealand Food Standards Code 2.9.7.

2.3 The submission requested a change to the formulation of Kindergen to comply with the compositional standards specified in the European Union (EU) Commission Delegated Regulation (EU) 2016/127 for infants (IF) and follow-on formulae (FOF) and the European Union (EU) Commission Delegated Regulation (EU) 2016/128 for Food for Special Medical Purposes (FSMP).

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

3 Requested listing

3.1 The submission proposed no changes to the existing listing (PBS item code 8587Y).

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Other relevant matters

4.3 The key differences between the current and new formulation of Kindergen were:

- additions of organic acids, dietary fibre (GOS and FOS), vitamin E, folate, and arachidonic acid (AA) and docosahexaenoic acid (DHA);
- increases in the level of calcium, iodine, choline and inositol;
- addition of allergens in the new formulation

4.4 There are changes in the guidance of Kindergen usage according to age range in the new formulation. The new formulation of Kindergen is suitable as a sole source of nutrition for infants and as a supplementary feed for children over 1 year of age, instead of a complete nutritional support or supplementary feeding for both infants & children in the old formulation of Kindergen.

4.5 The full changes to the formulation of Kindergen are presented in Table 1.

Table 1: Nutritional composition changes to Kindergen

Parameter	Unit per 100g	Old value Kindergen	New value Kindergen
Energy value	kJ	2104	2083
Energy Value	kcal	503	498
Carbohydrate	g	59.0	57.6
Sugars	g	6.1	8.0
Glucose	g	1.2	2.2
Maltose	g	4.1	3.8
Lactose	g	0.8	1.99
Polysaccharides	g	47.1	48.7
Organic Acids	g		0.88
Fat	g	26.3	25.9
Saturated Fat	g	8.6	9.1
Monounsaturated fat	g	11.9	12.3
Polyunsaturated fat	g	4.5	4.3
Dietary Fibre (GOS & FOS)	g	0	2.8
Calcium	mg	112	229
Phosphorus	mg	93.0	115
Iron	mg	4.8	7.47
Copper	ug	450	370
Manganese	mg	0.45	0.05
Molybdenum	ug	30.5	12.0
Chromium	ug	12.5	5.91
Iodine	ug	52.0	94.6
Vitamin D3	ug	5.4	11.9
Vitamin E	mg	NA	9.01
Vitamin E Alpha-tocopherol	ug	2.8	9.18
Vitamin K	ug	25.4	33.4

Parameter	Unit per 100g	Old value Kindergen	New value Kindergen
Thiamin (B1)	mg	0.35	0.75
Riboflavin (B2)	mg	0.45	1.00
Pantothenic acid (B5)	mg	2.1	3.98
Vitamin B6	mg	0.45	0.53
Folic Acid	ug	82.0	83.7
Folate	ug	NA	139
Vitamin B12	ug	0.90	1.00
Biotin	ug	23.0	18.9
Vitamin C	mg	52.0	66.2
Choline	mg	37.6	156
Inositol	mg	21.0	124
Taurine	mg	27.0	34.9
Linoleic Acid (LA)	g/100gFA	16.5	14
Alpha linoleic acid (ALA)	g/100gFA	1.5	1.36
Arachidonic acid (AA)	g/100gFA	0	0.51
Docosahexaenoic acid (DHA)	g/100gFA	0	0.51
Osmolarity	mOsmol/l	180	235
Osmolality	mOsmol/kg water	215	280
Age range		Kindergen is designed to provide complete nutritional support or supplementary feeding for infants & children.	Suitable as a sole source of nutrition for infants and as a supplementary feed for children over 1 year of age.
Allergens		Allergen listed for: -Milk and products thereof (including lactose)	Allergen listed for: -Milk and products thereof (including lactose) -Fish and products thereof -Soybeans & products thereof.

Estimated PBS usage & financial implications

4.6 The submission did not request a change of the price of Kindergen.

4.7 The minor submission estimated there to be no financial implications to the PBS/changes in PBS usage as the submission listing does not affect the current quantities, brand name, packaging, pack sizes or shelf life.

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

5 NPWP consideration

5.1 The NPWP noted the requested change to formulation for Kindergen due to new European compositional standards.

5.2 The NPWP noted that the manganese levels were low when compared to Australian adequate intake (AI) levels, but considered that it would not be of concern as drinking water, vegetables and cereals were the main dietary sources for manganese.

5.3 The NPWP noted the revised formulation had included a range of changes to the nutritional profile, including carbohydrate and fatty acid content, as well as to the

vitamin, mineral and micronutrient profile. The NPWP considered that the nutritional values spreadsheets and comparison with appropriate FSANZ and EU Food standards included in the submission were informative and agreed it would be useful for submissions to continue to present information in this format.

5.4 The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients and supported the request to change the formulation.

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

6 PBAC Outcome

6.1 The PBAC recommended continuing the Restricted Benefit listing of whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose, Kindergen®, for the dietary management of chronic renal failure in infants and young children following its reformulation due to changes in European compositional standards.

6.2 The PBAC noted the NPWP had no concerns that the changes in formulation would pose a risk to the health and safety of patients.

6.3 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 No change to the existing listing.

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.