

**14.03(d) CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS,
Oral powder 400 g,
Energivit[®],
Nutricia Australia Pty Ltd**

1 Purpose of Application

- 1.1 The Committee Secretariat listing requested a change to the formulation of the carbohydrate, fat, vitamins, minerals and trace elements formula, Energivit[®], in order to comply with new European compositional standards.

2 Background

- 2.1 Energivit was first listed on the PBS on 1 February 2000 for proven inborn errors of protein metabolism.
- 2.2 The submission requested a change to the formulation of Energivit to meet new European Commission Delegated Regulations on Infant and Follow-on Formulae [Commission Delegated Regulation (EU) 2016/127] and Food for Special Medical Purposes (FSMP) [Commission Delegated Regulation (EU) 2016/128]. Regulation 2016/128 sets out new maximum and minimum levels of vitamin and mineral substances for products that will provide a sole source of nutrition, and new maximum levels of vitamins and minerals for products that are not a sole source of nutrition. This regulation also requires additional nutrient declarations on the packaging with the intent to guarantee appropriate use of the product. Further information on the compositional changes are presented in Section 4.

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

3 Requested listing

- 3.1 The submission proposed no changes to the current listing of Energivit (PBS item 8369L).

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a committee secretariat submission.

Consumer comments

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

Nutritional profile changes

4.3 The main changes to the nutritional profile proposed in the submission relate to the fatty acid profile, as well as an increase in selenium, iodine, vitamin A, vitamin and choline and a decrease in manganese and linoleic acid (LA). These and other changes are presented in Table 1.

Table 1: Summary of changes to Energivit

Type of parameter (units of measurement per 100g)	Old formulation	New formulation
Carbohydrate (g)	66.7	66.9
Sugars (g)	6.0	6.1
Glucose (g)	1.3	1.4
Maltotriose (g)	6.7	
Polysaccharides (g)	54.0	60.0
Organic Acids (g)		0.83
Saturated Fat (g)	7.6	9.7
Monounsaturated Fat (g)	11.6	11.2
Polyunsaturated Fat (g)	4.6	4.1
Phosphate (mg)		920
Copper (mg)	0.43	0.42
Manganese (mg)	0.43	0.029
Selenium (µg)	15.5	17.7
Iodine (µg)	83.0	98.0
Vitamin A (µg RE)	392	408
Vitamin D3 (µg)	8.7	11.2
Vitamin E (mg α TE)	4.6	9.23
Folic Acid (µg)	55	55
Folate (µg)		91.7
Vitamin B12 (µg)	1.2	1.21
Vitamin C (mg)	49	48.9
Choline (mg)	91	145
Inositol (mg)	98	98.1
Linoleic Acid (LA) (g/100gFA)	17.53	13.7
Alpha Linolenic Acid (ALA) (g/100gFA)	1.73	1.38
Arachidonic Acid (AA) (g/100gFA)	0	0.50
Docosahexaenoic Acid (DHA) (g/100gFA)	0	0.50

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Type of parameter (units of measurement per 100g)	Old formulation	New formulation
Osmolarity (mOsmol/l)		190
Osmolarity (mOsmol/kg water)	190	210
Potential Renal Solute Load (mOsmol/l)		61
pH		6.6

Source: Energivit Minor Submission, Table 1 pg. 3-4

- 4.4 The submission also stated that there would be a decrease in shelf life from 24 months to 18 months with the reformulation.

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

5 NPWP Consideration (and sponsor's further clarification)

- 5.1 The NPWP noted the requested change to formulation for Energivit, for proven inborn errors of protein metabolism, due to new European compositional standards.
- 5.2 The NPWP noted that the levels of folate were relatively low for the 7-12 months age group (69% RDI), however it considered that this would not be an issue in practice due to the high fruit and vegetable intake of the patient group.
- 5.3 The NPWP noted the addition of docosahexaenoic acid (DHA) and amino acids (AA) to Energivit.
- 5.4 The NPWP noted the revised formulation had included a range of changes to the nutritional profile, including 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 future similar submissions to present information in this format.
- 5.5 The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients and accepted 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 carbohydrate, fat, vitamins, minerals and trace elements formula, Energivit, following its reformulation due to changes in European compositional standards.
- 6.2 The PBAC noted that the NPWP was not concerned that the levels of folate were relatively low for the 7-12 months age group due to the high fruit and vegetable intake of the patient group.
- 6.3 The PBAC noted the NPWP had no concerns that the changes to formulation would

pose a risk to the health and safety of patients.

- 6.4 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.