14.03b WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE
Oral powder 400 g,
Sachets containing oral powder 100 g,
Renastart®,
Vitaflo Australia Pty Ltd

1 Purpose of Application

1.1 The Committee Secretariat submission requested a change to the formulation of whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose (Renastart®), for the dietary management of chronic kidney disease (CKD) in infants and young children.

2 Background

2.1 Renastart was listed on the PBS in March 2009 starting with the 100 g sachets (PBS item 9382T). The 400 g cans have been listed since December 2013 (PBS item 2870C).

2.2 The submission requested a change to the formulation of Renastart without impact to its PBS listing to meet the recently published European Union regulations (Commission Delegated Regulation (EU) 2016/127, and Commission Delegated Regulation (EU) 2016/128) and CODEX guidelines (FAO/UNU/WHO, Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. Revision: 2007). 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.

2.3 The submission stated that the reformulated Renastart complies with EU and CODEX guidelines with the exception of several micronutrients (potassium, chloride, calcium, phosphorus and vitamin A) which are often required in lower amounts in the dietary management of CKD in infants and young children.

2.4 The submission confirmed that Renastart 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. The submission also stated that

Renastart complies with Standard 2.9.1: Infant Formula Standards Code (the Standard), with discrepancies.

2.5 In separate correspondence to the Secretariat, the Sponsor has requested to delist (and remove PBS item code 9382T) 100 g sachets. The submission stated it has not sold this form since February 2014.

3 Requested listing

3.1 The submission proposed no changes to the current listings for Renastart (PBS item codes 2870C and 9382T).

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.

Clinical trials

4.3 As a Committee Secretariat submission requesting a formulation change, no clinical trials were presented in the submission.

Other relevant matters

4.4 The submission requested no changes to the current pricing arrangements for Renastart. The formulation change results in 672kJ more being dispensed per maximum quantity for the 400 g cans (the AEMP for the maximum quantity currently is $1237.36)[1].

4.5 The main changes to the nutritional profile comparing the old formulation to the new, included an increase to the levels of choline, which was slightly above the recommended range according to the Standard.

4.6 The submission stated Clause 27 of Division 3, Subdivision 2 of the Standard which relates to Infant Formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions, allows an infant formula product to be specifically formulated to satisfy a condition stated above, provided that all other respects comply with the division. The submission stated that Renastart is an infant formula, specially formulated for CKD (modified electrolyte, modified micronutrients, modified protein, high calorie density). Although lower in protein and higher in kilojoules than stated as

[1] The AEMP is for dispensing of Renastart 6 x 400 g cans. The maximum quantity packs that can be dispensed is 4, therefore the AEMP for the maximum quantity is represented as (6 x 400 g cans) x 4 packs.

a requirement of Clause 31, this variation is acceptable as per Clause 27. The protein and caloric content was not significantly altered from the old formulation to the new.

4.7 Other changes included minor increases to the levels of iodine, selenium, and chromium, as well as a decrease in the levels of aspartic acid and glutamine.

Table 1: Overview of key Renastart formulation changes

Type of change/parameter (grams per 100kcal)	Old formulation	New formulation	Comparator (Kindergen)
Energy (kcal/100mL)	99	100	101
Protein	1.5	1.5	1.5
Fats (total)	4.8	4.8	5.3
Docosahexaenoic acid (DHA) Arachidonic acid (ARA) Linoleic acid α-linoleic acid	16 30 560 60	23 40 746 60	- - 830 79

Sources: Summarised from Pg. 10 of the Submission, Appendices 1-4 from the Submission.

4.8 Renastart was within the Standard's recommendation for total fatty acids (Clause 23) and had no change to its content from the old formulation to the new.

4.9 The submission noted that Renastart contains no fibre. Renastart also contains no fluoride complying with the standard recommendation of <17mcg/100kJ (Clause 19 of the standard, Appendix 4 to the submission).

Estimated PBS usage & financial implications

4.10 The submission did not request a change of the price of Renastart.

4.11 The Committee Secretariat submission estimated there to be no financial implications to the PBS/changes in PBS usage as the submission did not expect the reformulation would change the existing patient population.

5 NPWP Consideration (and sponsor's further clarification)

5.1 The NPWP noted the requested change to formulation for Renastart to meet international guidelines and standards for nutritional content of supplementary products for children and infants.

5.2 The NPWP noted the revised formulation had increased the choline content to a more appropriate level for the indicated population and although this is above the Infant Formula Standard 2.9.1 recommended levels, was within an acceptable range. The NPWP also specifically noted other changes to the formulation, including vitamin D and chromium.

5.3 The NPWP approved of the request to change the formulation and noted it had no other concerns that the changes would pose a risk to the health and safety of patients. *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, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose, Renastart, for the dietary management of chronic kidney disease (CKD) 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 advised that its previous advice for whey protein formula regarding Nurse Practitioner Prescribing, the Early Supply Rule and interchangeability advice under Section 101 (3BA) of the *National Health Act 1953* remained appropriate.

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.