

## **6.15 AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Oral powder 400 g (EleCare LCP)**

**EleCare® LCP,**

**Abbott Australasia Pty Ltd**

### **1 Purpose of Submission**

- 1.1 The Category 3 submission requested the amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids (EleCare® LCP) continue to be listed on the PBS under the existing conditions following a change to the source of docosahexaenoic acid (DHA) within the formulation.

### **2 Background**

#### ***Registration status***

- 2.1 The submission claimed that EleCare LCP, using the new source of DHA, continues to meet the requirements set out under *the Australia New Zealand Food Standards (FSANZ) Code – Standard 2.9.1: Infant Formula Products*. As EleCare LCP is marketed as a nutritional product rather than a therapeutic good, it is not registered in the Australian Register of Therapeutic Goods.

#### ***Previous PBAC consideration***

- 2.2 EleCare LCP was recommended by the PBAC at its November 2009 meeting and is currently listed as an Authority Required (Telephone/Online) benefit for the treatment of:
- Cows' milk anaphylaxis,
  - Severe cows' milk protein enteropathy with failure to thrive,
  - Combined intolerance to cows' milk protein,
  - Soy protein and protein hydrolysate formulae,
  - Cows' milk protein enteropathy,
  - Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein,
  - Severe intestinal malabsorption including short bowel syndrome

### **3 Requested listing**

- 3.1 The submission stated that there will be a change to the source of DHA from *C. cohnii* oil (referred to as DHA-A) to *Schizochytrium* sp.oil (referred to as DHA-B) for the existing listings of EleCare LCP.
- 3.2 The submission requested no changes to the existing listing of EleCare LCP (items 9339M, 9340N), including no change to the price of EleCare LCP.
- 3.3 The submission stated that the source of DHA was the only change to the formulation and therefore did not provide nutritional composition information. The nutritional profile comparison between the currently listed EleCare LCP with DHA-A and the proposed EleCare LCP with the new source of DHA-B was requested and was subsequently found to be identical in ingredients, strengths, and quantities.

### **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 The submission stated that FSANZ had concluded that the composition of oil derived from DHA-B is comparable to other traditional sources of DHA in its 2017 Risk and Technical Assessment of Alternative DHA-rich Algal Oil for Infant Formula Products. In this assessment, FSANZ stated DHA-B had demonstrated evidence of bioequivalence to DHA-A in baby piglets and human infants. FSANZ concluded that the Applicant had provided sufficient technical data to ensure that DHA-B is suitable as an additional, alternative or replacement DHA oil source in infant formula products. The primary difference between the two sources of DHA is the ratio of DHA to eicosapentaenoic acid (EPA). However, the compositional differences between DHA-A and DHA-B were considered nutritionally insignificant by FSANZ in its review (Food Standards Australia New Zealand, 2017).

#### ***Estimated PBS usage and financial implications***

- 4.4 The submission stated there would be no change to the market utilisation due to the change in DHA source of EleCare LCP.
- 4.5 As a Category 3 submission, neither the economic analysis nor the financial estimates analysis has been independently evaluated.

### **5 NPWP Consideration**

- 5.1 The Nutritional Products Working Party (NPWP) supported the continued listing of EleCare LCP with a new source of DHA on the PBS under the existing conditions.
- 5.2 The NPWP considered that changing the source of the DHA component of EleCare LCP from *C. cohnii oil* to *Schizochytrium sp.oil* was safe and appropriate.
- 5.3 The NPWP considered the change in source of DHA is unlikely to change the clinical effectiveness or safety profile of the product.
- 5.4 The NPWP noted that the quantities of ingredients between the previous and current formulations had not been provided at the time of NPWP consideration and requested clarification that the quantity of DHA would remain the same between the two formulations. It has since been confirmed that the quantities will remain the same.

## **6 PBAC Outcome**

- 6.1 The PBAC recommended that EleCare LCP continue to be listed on the PBS under the same conditions as the current listing.
- 6.2 The PBAC agreed with NPWP advice that the new source of DHA-B is safe and appropriate and that the change in source of DHA is unlikely to change the clinical effectiveness or safety profile of the product.
- 6.3 The PBAC considered that the submission's assumption of no change to the market utilisation due to the change in DHA source of EleCare LCP was reasonable.
- 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 changes to the listing were recommended.

## **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.