

## 6.14 TRIGLYCERIDES MEDIUM CHAIN FORMULA

### Sachets containing oral powder 16 g, 30 MCT Pro-Cal<sup>®</sup>, Vitaflo Australia Pty Ltd.

#### 1 Purpose of Application

- 1.1 The minor submission requested changes to the formulation, label description and new age restriction for the existing Authority Required (STREAMLINED) listing of MCT Pro-Cal.

#### 2 Requested Listing

- 2.1 The submission requested to add an age range of 3 or older to the existing listing. No other changes to the existing listing were proposed.
- 2.2 The requested changes to the formulation and label description is summarised in the table below:

**Table 1. Difference in nutritional contents and label description for the current and the new triglycerides medium chain formulation**

Previous Quantitative Ingredient List	g/100g	Amended Quantitative Ingredient List	g/100g
Vegetable Oil (Coconut and palm kernel oils)	62.9	Medium Chain Triglyceride (MCT) Oil	63.4
Glucose Syrup	21.3	Dried Glucose Syrup	21.5
Sodium Caseinate (from milk)	14.2	Sodium Caseinate	13.5
Dipotassium phosphate	1.3	Stabilizer (E340)	1.4
Anticaking Agent (E341iii)	0.25	Anticaking Agent (E341)	0.25

Source: page 3 of submission

#### 3 Background

- 3.1 The sponsor of MCT Pro-Cal<sup>®</sup> has previously indicated that the product meets the requirements for foods that have medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*

##### **Sponsor hearing**

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

##### **Consumer comments**

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

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

## **4 Pricing considerations**

- 4.1 The submission did not request a price change for the existing listing. The requested changes are expected to be cost neutral to the PBS as the request was to change the content of the current formulation.

## **5 NPWP Consideration**

- 5.1 The Nutritional Product Working Party (NPWP) considered that the requested amendments to the nutritional content would not impact on the nutritional value of the product for the listed indications and supported the continued listing of MCT Pro-Cal® on the PBS.
- 5.2 The NPWP noted that the current listing was silent on age restriction. The NPWP noted that MCT Pro-Cal® is currently being used in infants with liver failure, and that the addition of an age restriction to 3 years or over may impact on this patient population. The NPWP noted that the rationale behind age request was unclear, other than that the submission indicated it was to comply with the European Union Additives Regulation (p3 of submission).
- 5.3 The NPWP requested further clarification from the Sponsor on the rationale behind the age restriction request, however was generally supportive of remaining silent on age in the restriction and considered patient eligibility based on age (amongst other factors) should remain a clinical judgement.
- 5.4 In the pre-PBAC response, the sponsor acknowledged and supported the NPWP's advice and withdrew its request for an additional age restriction on the listing of MCT Pro-Cal®.

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the continued listing of triglycerides medium chain formula (MCT Pro-Cal®) with the minor change in nutritional profile and changes in the label description.
- 6.2 The PBAC noted the Nutritional Product Working Party (NPWP) considered that the changes in the new formula would not impact on the nutritional value of the product, and supported the continued listing of MCT Pro-Cal® on the PBS.
- 6.3 The PBAC noted the submission requested an addition of an age range to 3 or greater to the current restriction based on the change in one component that now no longer meets the European Union Additives Regulations for use in children below 3 years of age and noted this request was withdrawn in the Pre-PBAC response.

- 6.4 The PBAC agreed with the NPWP that the requested age restriction should be clinically justified under an Australian context. The PBAC considered the restriction should remain silent on age requirement.
- 6.5 The PBAC recommended the Early Supply Rule should continue to not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.6 The PBAC noted MCT Pro-Cal® is currently able to be prescribed by nurse practitioners, similar to other nutritional products.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **7 Recommended listing**

No change to the existing listing

## **8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## **9 Sponsor's Comment**

The sponsor had no comment.