

## **6.15 PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES**

### **Oral powder 450 g (Aptamil Gold + Pepti-Junior), Aptamil Gold + Pepti-Junior<sup>®</sup>, Nutricia Australia Pty Limited**

#### **1 Purpose of Application**

- 1.1 The minor submission sought to amend the current Authority Required (STREAMLINED) listing by updating the nutritional profile of protein hydrolysate formula with medium chain triglycerides (Aptamil Gold + Pepti-Junior). No changes to existing indications or restrictions were requested.

#### **2 Requested Listing**

- 2.1 The submission outlined changes in the nutritional composition for the protein hydrolysate formula with medium chain triglycerides.
- 2.2 No changes to the existing listing were requested by the sponsor.

*For more detail on PBAC's view, see section 7 PBAC outcome.*

#### **3 Background**

- 3.1 The sponsor of Aptamil Gold + Pepti-Junior 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, and has not advised otherwise in this submission.

#### **4 Consideration of 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.

##### ***Clinical trials***

- 4.3 As a minor submission, no clinical trials were presented in the submission.
- 4.4 The purpose of the submission was to amend the nutritional profile of the currently listed product.
- 4.5 The Nutritional Product Working Party (NPWP) was requested to advise on the

appropriateness of the updated nutritional content, including changes in fat, minerals and vitamins.

- 4.6 In consideration of the submission, the NPWP noted that the submission provided a comparison between the current and the new formulation.
- 4.7 The NPWP considered that the amendments on fat, minerals and vitamins in the new formula would not impact on the nutritional value of the product and the product should be retained on the PBS.

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the continued listing of protein hydrolysate formula with medium chain triglycerides (Aptamil Gold + Pepti-Junior) with the minor change in nutritional profile.
- 5.2 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 Aptamil Gold + Pepti-Junior on the PBS.
- 5.3 The PBAC recommended the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 5.4 The PBAC noted Aptamil Gold + Pepti-Junior is currently able to be prescribed by nurse practitioners, similar to other nutritional products.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

### **Outcome:**

Recommended

## **6 Recommended listing**

- 6.1 No change to the existing listing

## **7 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.

## **8 Sponsor's Comment**

The sponsor had no comment.