

## **14.03 TRIGLYCERIDES, LONG CHAIN with GLUCOSE POLYMER**

### **Oral liquid 250 mL, 18, Oral liquid, 1L, 6 ProZero<sup>®</sup>, Vitaflo Australia Pty Limited**

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

- 1.1 The minor submission sought notify the PBAC of a minor change in the sodium chloride content (not affecting the nutritional properties) of ProZero products for proven inborn errors of metabolism.

#### **2 Requested Listing:**

- 2.1 The submission did not request changes to existing listings.
- 2.2 The sponsor advised changes to the sodium chloride content of ProZero products as shown in the table below.

**Table 1: Difference in sodium and chloride content for current and new ProZero formulations**

<b>ProZero</b>	<b>Current Formulation</b>	<b>New Formulation</b>	<b>Units</b>
Sodium	41	33	mg/100ml
Chloride	63	40	mg/100ml

Source: ProZero submission, updated table provided by sponsor

- 2.3 The sponsor also notified of a minor change to micronutrient values of ProZero, specifically to note that the calcium content was only from inherent ingredient sources at very low levels, which are not nutritionally significant or relevant for the intended use of the product.

#### **3 Background**

- 3.1 ProZero was PBS listed on 1 March 2010 for proven inborn errors of metabolism for patients who are unable to meet their energy requirements with permitted food and formulae.

#### **4 Pricing considerations**

- 4.1 There are no pricing considerations for this item as the nutritional properties of ProZero have not changed.

## **5 NPWP Consideration**

- 5.1 The Nutritional Products Working Party (NPWP) considered that the reduction of the sodium and chloride levels in the product would not change the ability of the product to meet the nutritional needs of patients with proven inborn errors of metabolism and supported the request.

## **6 PBAC Outcome**

- 6.1 The PBAC noted the change to the formulation processed by the Secretariat and noted the listing of ProZero would not be altered by this change.

## **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.