

**6.07 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE,
Oral liquid, 87 mL, 30 (PKU Cooler 10);
Oral liquid, 130 mL, 30 (PKU Cooler 15);
Oral liquid, 174 mL, 30 (PKU Cooler 20);
PKU Cooler® 10, PKU Cooler® 15, PKU Cooler® 20,
Vitaflo Australia Pty Ltd.**

1 Purpose of Application

- 1.1 The minor submission sought to amend the current Restricted Benefit listing by updating the nutritional profile of PKU Cooler® and requesting the listing of a new flavour, PKU Cooler® Yellow (Mango Breeze), for the dietary management of phenylketonuria

2 Requested Listing

- 2.1 The submission outlined changes in the nutritional composition for all flavours of PKU Cooler® to align with international nutritional recommendations. No changes to the price per gram of protein equivalent (PE) have been requested.
- 2.2 The submission additionally requested the listing of a new flavour of all strengths of PKU Cooler®. This is not a matter requiring PBAC consideration.
- 2.3 No changes to the current listing were requested by the sponsor

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

3 Background

- 3.1 The sponsor of PKU Air® confirms that it 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*.
- 3.2 The PBAC previously considered the product at the November 2004 meeting. The PBAC recommended the listing of PKU Cooler® (formerly known as PKU Express Active®) on a cost-minimisation basis against PKU Express®, Easiphen® and XPMaximum® at an equivalent cost per gram of protein equivalent.

4 Comparator

- 4.1 The minor submission nominated PKU Air® and PKU Lophlex LQ® as the main comparators. Both brands are oral liquids which are PBS-listed for the dietary management of phenylketonuria.

- 4.2 The sponsor has also provided a similar submission requesting changes to the formulation and an additional brand of PKU Air® (agenda item 6.06 refers).

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 The purpose of the submission was to amend the nutritional profile of the currently listed product.
- 5.5 Since the listing, the sponsor stated that the source of docosahexaenoic acid (DHA) has changed, which has led to an insignificant amount of eicosapentaenoic acid (EPA). The sponsor has therefore removed EPA from the nutritional label, while the DHA content remains unchanged.
- 5.6 The NPWP was requested to advise whether the absence of EPA is nutritionally appropriate.
- 5.7 The sponsor has also amended the micronutrient content of the product in order to align with international nutritional recommendations, such as the Australian and New Zealand Nutrient Reference Values (ANZ NRV) and the European Food Safety Authority Dietary Reference Values (EFSA DRV). The key difference between the current and new formulation is a general decrease in vitamins, minerals, and trace elements, but the amino acid profile remains unchanged. The NPWP was requested to advise whether the changes to the nutritional profile are nutritionally appropriate.
- 5.8 In consideration of the submission, the NPWP noted that:
- The updated changes to the nutritional profile were clinically appropriate and in line with international nutritional recommendations.
 - The NPWP considered that the reduction in folic acid and niacin raised some concern as in Item 6.06 but that this was of minimal clinical concern as such patients are often prescribed other sources to supplement these nutrients.

The NPWP supported the change in the nutritional profile of the currently listed PKU Cooler®.

Estimated PBS usage & financial implications

- 5.9 The submission did not request a change to the current DPMQs (\$976.46 for PKU Cooler® 10, \$1,465.62 for PKU Cooler® 15, and \$1,952.34 for PKU Cooler® 20). The net cost to the PBS as a result of the requested changes is expected to be nil.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the continued listing of PKU Cooler® with the above change in nutritional profile, for the dietary management of phenylketonuria. The PBAC noted that no price change was requested by the sponsor and therefore there were nil financial consequences.
- 6.2 The PBAC noted that the NPWP raised some concerns about the reduced amounts of folic acid and niacin. However, it was considered that this change was of minimal clinical concern as additional supplements can be prescribed and was therefore not an impediment to continued listing of PKU Cooler®.
- 6.3 The Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.4 Nutritional products are currently included for prescribing by nurse practitioners.
- 6.5 The PBAC noted that this submission does not meet the criteria for an Independent Review. Independent Review is not available in response to a request to modify or extend an existing listing.

Outcome:

Recommended

7 Recommended listing

- 7.1 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.