Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

13 August 2019

INC SUBMISSION ON ACCESS REGULATIONS FOR AMINO ACID FORMULA (AAF)

INTRODUCTION

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing infant formula and toddler milk drinks (formulated supplementary foods for young children) in Australia and New Zealand
INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula and toddler milk drink industry in Australia and New Zealand.

INC is a responsible group that voluntarily restricts its marketing practices infant formula products to support government policies for the protection and promotion of breastfeeding.

Members:

- A2 Infant Nutrition Ltd
- Aspen Nutritionals Australia Pty Ltd
- Danone Nutricia Early Life Nutrition
- Fonterra Co-operative Group Ltd
- H J Heinz Company Australia Ltd and H J Heinz Company (New Zealand) Ltd
- Nestlé Australia Ltd and Nestlé New Zealand Limited
- Synlait Milk Ltd

Associate Members:

- Abbott Australasia Pty Ltd
- Adams Australia Pty Ltd
- Australian Dairy Park
- Bakels Edible Oils (NZ) Ltd
- Bayer Ltd
- Blend and Pack
- Bodco Dairy Ltd
- Bubs Australia Ltd
- Mataura Valley Milk Ltd
- NIG Nutritionals
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Nu-Mega Ingredients
- Oceania Dairy Limited
- Reckitt Benckiser
- Saputo Dairy Australia Pty Ltd

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- Burra Foods
- Cargill Australia
- Dairy Goat Co-operative Ltd
- DSM Pty Ltd
- Freedom Foods
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Great Ocean Ingredients
- Jamestrong Packaging Pty Ltd
- Snow Brand Aust Pty Ltd
- Spring Sheep Milk Co
- Tatura Milk Industries
- The H&H Group
- Wattle Health Australia Ltd
- Westland Co-operative Dairy Company Ltd
- Winston Nutritional New Zealand
- Yashili Dairy New Zealand

INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.

We welcome the opportunity to provide written comment to PHARMAC in response to the request for feedback to ***Proposal to change access to amino acid infant formula***.

Yours sincerely

Jan Carey
Chief Executive Officer

The Infant Nutrition Council (INC), in response to the call for consultation regarding proposed changes to access criteria for amino acid infant formula (AAF), wishes to highlight several issues. These issues have the potential to negatively impact New Zealand patients and families and not deliver against PHARMAC's ambition of equitable access to medicines, should the proposal be adopted on 1 July, 2020.

In relation to the changes proposed by PHARMAC, we note the following:

1. The intent to segment access criteria based on whether the patient is below or above 12-months of age.
2. The exclusion of general practitioners and dietitians from being able to make AAF applications on behalf of patients over 12-months of age.
3. AAF applications for patients 12-months + to be made exclusively by a paediatrician, including paediatric gastroenterologists and paediatric immunologists.
4. Reference to the cost of AAF formula being roughly three times that of eHF, combined with inappropriate prescribing practices for AAF versus eHF (ie over-prescription of AAF).

The intent to segment access criteria based on whether the patient is below or above 12-months of age.

a) This proposed change is fundamentally problematic since current ASCIA guidelines recommend that although children should be reviewed around 12 months of age, it takes until 3-5 years of age for most children to outgrow their cow's milk allergy.[1]
b) Based on the above, we would question the merit of an AAF access approach based on age segmentation rather than the assessment of an individual patient's clinical needs.

The exclusion of general practitioners and dietitians from being able to make AAF applications on behalf of patients over 12-months of age.

a) Dietitians are qualified healthcare professionals with specific knowledge and training to manage the nutritional needs of patients, including infants and children.
b) Dietitians play a key role in caring for infants and children with often highly complex conditions such as Food Protein-Induced Enterocolitis Syndrome (FPIES), Eosinophilic Esophagitis (EoE), as-well-as multiple food protein allergies. They are therefore expertly placed to provide continuity of care for patients both under and over 12-months of age.
c) Should dietitians be excluded from AAF applications for infants 12-months of age or over, this may adversely impact continuity of care and could potentially result in compromised health outcomes for patients.
d) Because of a patient being forced to transition from a dietitian or vocationally registered general practitioner to a paediatrician at 12-months of age, unnecessary stress or anxiety may be experienced by both patients and families due to the lack of continuity of care and / or the need to transition to a new and unknown healthcare specialist.

AAF applications for patients 12-months + to be made exclusively by a paediatrician, including paediatric gastroenterologists and paediatric immunologists.

a) PHARMAC's acknowledgement that the adoption of the proposal may cause an increased level of referrals to paediatricians.
b) PHARMAC notes that, from clinical advice, the number of patients over the age of 12 months for whom AAF is required would be 'small'.

[1] https://www.allergy.org.au/images/pcc/ASCIA_PCC_Cows_milk_dairy_allergy_2019.pdf

c) In respect of point (a) above, we would suggest that in the interests of clarity and accuracy that the number of patients over the age of 12 months for whom AAF is required is quantified.
d) Quantification of the above will enable a more robust assessment of the capability of available paediatric resources to manage the additional workload created as a by-product of adopting the revised AAF access proposal.
e) Should an assessment of available paediatric resources show any deficiency, we would highlight the level of stress and anxiety this may cause families seeking a referral when their child reaches 12-months of age. Perhaps more importantly, we point to the potential for delays in ongoing treatment as families seek out a specialist paediatrician upon their child turning 12-months of age.
f) It is entirely possible that a cost burden may be imposed upon families if forced to seek specialist paediatric consultation. This may come in the form of both out of pocket costs, travel costs and time imposition should families be unable to locate an available specialist in their local area.

Reference to the cost of AAF formula being roughly three times that of eHF, combined with inappropriate prescribing practices for AAF versus eHF (ie over-prescription of AAF)

a) Given the extent to which infants rely (sometimes exclusively) on AAF or eHF formula for their nutrition, it is of concern to the INC that management of expenditure is cited as a key driver for this proposal. While we understand the need to manage expenditure in an environment of rising costs, this should not be done in a manner that may cause unintended negative health, social or economic consequences for families.
b) We would suggest PHARMAC explore alternatives to alleviate expenditure burden. One example being education for healthcare professionals to correctly diagnose CMPA and prescribe appropriate infant nutrition. This might prove a particularly salient tactic given PHARMAC's view that AAF is being over prescribed.

The INC extends its thanks for PHARMAC for the opportunity to consult on this important change to access criteria for the funding of Amino Acid Formula.

Should you have any questions regarding this submission, please contact Jan Carey, INC CEO at jancarey@infantnutritioncouncil.com or on +61 412 514 735.