Attachment 1

Consultation Paper on P1028 – Infant Formula: to revise and clarify standards relating to infant formula comprising category definitions, composition and labelling

Submission from Dr Melinda White; A/Director Dietetics and Food Services, Queensland Health, Lady Cilento Children's Hospital, CHQ HHS

Q2. What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory (IFPSMP)? If you support creation of a separate category for IFPSMP, should products developed for pre-term and low birthweight infants be included or retained as a separate subcategory? Please provide your rationale.

Option 2 is preferable where products for transient gastroenterological conditions should be removed from IFPSDU and transferred to the standard infant formula category for the following reasons:

- There is limited scientific evidence for the clinical effectiveness of these products with the exception of low lactose products for medically diagnosed chronic lactose intolerance.
- If these products are consumed they will not cause harm to the infant population.
- Excluding them from the IFSDU category provides clear differentiation from specialised infant formula products that do have proven clinical effectiveness.
- FSANZ will be seen to support the unsubstantiated clinical claims of these formulas if they are included in the IFPSDU category.
- If formula companies feel strongly that their product does have scientific merit there should be an avenue for application to submit their product for inclusion into the IFPSDU category.

Once the category 'products for transient gastroenterological conditions' is removed, the other categories should be collapsed in one category 'Products for Special Medical Purpose's' IFPSMP for the following reasons:

- Many of these products will have multiple clinical treatment applications and clinical indication cross over i.e. the protein source is amino acids and the fat source MCT making them indicated for CMPA and malabsorption. Most products that have extensive protein hydrolysis also have fat manipulation. This makes them difficult to categories according to clinical indication.
- This category can then be dived to more accurately to reflect the composition of products on the market i.e. amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides. This is similar to the PBS naming convention.
- All of these products are for 'special medical purposes' including premature formulas which contain specific micronutrient profiles to prevent the development of clinical conditions such as metabolic bone disease and iron deficiency therefore used for a medical purpose.

- Products in this category would all fit the criteria for blanket labelling 'Should be used under direction of a suitably qualified health professional'

Q3 Do you support including a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

A definition for IFPSDU is not required if all formulas are placed in the IFPSMP category and IFPSMP definition is used.

Q4 If you support including a subcategory definition for IFPSMP in the Code is the proposed definition of IFPSMP appropriate; if not, what should it say?

The definition is appropriate for IFPSMP and would cover the protein substitute and premature and low birthweight formulas which would be collapsed into the IFPSMP category.

Q5 Are there any issues with the current definition for protein substitutes?

An elemental infant formula implies that all the macronutrients are elemental i.e. monosaccharides, medium chain fats and amino acids. Formulas can have amino acids and polysaccharides and long chain fats. Amino-acid based infant formula is more accurate definition of these product rather than elemental formula.

Q6 Is there a benefit to defining one or more of the following in the Code: – Hypo-allergenic formula – Partially hydrolysed formula – Extensively hydrolysed formula – Amino acid-based infant formula? If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

The benefit of including definitions is that it helps direct the clinical indication, note that hypo-allergenic formula and partially hydrolysed formula are the same in terms of protein composition. The key element for each definition is peptide length and proportion of peptides of a certain length.

Q7 Are there any issues with the current definition for pre-term products?

No

Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

There is no benefit for age and weight parameters as health professionals will use these products when they are clinically indicated i.e. you may use them for fluid restricted term infants in PICU or to fortify breast milk of term failure to thrive infants.

Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants? What are the uses of these products other than premature or low birthweight infants?

These products contain more protein, energy, iron and Vitamin D than standard infant formula and breast milk. I do use premature infant formula occasionally and more commonly breast milk fortifier for fluid restricted term infants in PICU or with cardiac disorders, as they contain the additional energy and protein to

meet requirements of critically ill infants. We also use infatrini, a high energy infant formula which would need to be covered in the IFPSMP category.

Q12 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?

Q14 Are any specific compositional requirements (energy/macronutrient etc.) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?

Q15 What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

All formula in the IFPSMP category should meet the criteria as standard infant formula with the exception of the specific nutrient modification for the clinical indications. A majority of formulas that would fit under the category IFPSMP are manufactured in the EU rather than the US therefore these products align more with EU formula regulations.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

A post discharge formula for premature infants is available without prescription to the public (premgro) however it has a different nutritional composition to pre-term infant formula which is not available in pharmacies or via the PBS, it is for hospital use only.

Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

I would support a statement that similar to 'the product must be used under medical supervision' however 'medical' implies a Doctor whereas recommendations from a child health nurse or dietitian would be equally valid, change the wording from 'medical' to 'suitably qualified health professional'