NEW ZEALAND COLLEGE OF MIDWIVES (INC)

28 September 2017

Consultation paper – Proposal P1028: Infant formula

Regulation of infant formula – infant formula products for special dietary use

Feedback from: New Zealand College of Midwives
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The New Zealand College of Midwives is the professional organisation for midwifery. Members are employed and self-employed and collectively represent 90% of the practising midwives in this country. There are around 2,900 midwives who hold an Annual Practising Certificate (APC). These midwives provide maternity care to on average 60,000 women and babies each year. New Zealand has a unique and efficient maternity service model which centres care around the needs of the woman and her baby. It provides women with the opportunity to have continuity of care from a chosen maternity carer (known as a Lead Maternity Carer or LMC) throughout pregnancy and for up to 6 weeks after the birth of the baby, and 92% of women choose a midwife to be their LMC. Primary maternity services provided by LMC midwives are integrated within the wider primary care and maternity services of their region or locality. The College offers information, education and advice to women, midwives, district health boards, health and social service agencies and the Ministry of Health regarding midwifery and maternity issues. Midwives interface with a multitude of other health professionals and agencies to support women to achieve the optimum outcome for their pregnancies, health and well-being.

NEW ZEALAND COLLEGE OF MIDWIVES (INC)

28 September 2017

To: Food Standards Australia New Zealand

Proposal P1028: Infant formula

The opportunity to provide a submission about the revision and clarity of standards relating to infant formula was welcomed by the New Zealand College of Midwives (the College).

Midwives protect, support and promote breastfeeding, and also provide information to parents on all aspects of infant feeding, including the use of breast-milk substitutes, and we consider that standards for all products should align with international standards, and also the International Code of Marketing of Breast-Milk Substitutes and subsequent, relevant World Health Assembly resolutions. The College considers formula product safety and protection of infant health and wellbeing, short and long-term, to be paramount, and therefore, appropriate regulation without commercial influence is essential. The College also considers that all formulas for special medical purposes should never be available as over-the-counter options; rather they should always require a prescription. Infants require ongoing long-term medical supervision for the duration of the use of special formula. Prescription only products will also hopefully eliminate infants without diagnosed disease, disorder or condition being unnecessarily fed on 'special' formulas without medical indication. This a particularly salient point, as just as we are not aware of any research evidence about the long-term effects of special formulas on medically diagnosed infants who require them, we are also unclear about outcomes for infants fed these products unnecessarily. What we do know is that if breastfeeding is discontinued infants, their mothers, and society, face numerous disadvantages. It should also be noted that breastfeeding is contraindicated in very few situations.

The College considers the International Code of Marketing of Breast-Milk Substitutes and subsequent, relevant World Health Assembly resolutions to be foundation documents, and we support the aim of the Code which is, *"to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."* [1]

With these issues in mind the feedback on the questions posed by FSANZ is below.

Questions to submitters

Q1 Are any other overseas regulations relevant to IFPSDU?

The College notes that there are new 2016 EU 'Foods for Special Medical Purposes' (FSMP) regulations, and also note that EU companies have four years to comply.[2] We are unclear in our understanding about why changes take this length of time, and recommend that FSANZ take infant vulnerability and safety into account when the timing of any changes of formulation are required.

The College also considers the World Health Assembly resolution 63.23, adopted in 2010 to be significant, in that it states health claims do not count as permitted information, and are prohibited unless explicitly approved. The WHA issued a call for action:

"to end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation." [3]

Q2 What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? 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.

The College is unclear as to why FSANZ considers it inappropriate for the safety and composition of infant formula products for special dietary (IFPSDU) use to be specified. Given the vulnerability of infants we think that the lack of any systematic process for reviewing safety of products to be a serious and potentially damaging omission. The College support the development of a special subcategory and also consider that products for preterm and low birthweight infants should be included in this category. None of the products included in this special category should be marketed to parents, nor should they be available for purchase by parents either in retail stores, or online from any source, including manufacturers' websites. Details of the special product category should be available only to health professionals, for the purpose of prescription for valid medical reasons. The rationale for this thinking is based on safety, and also the need to reduce inappropriate marketing to parents. We consider over the counter/internet access to products for special dietary use to be in the category of unethical direct marketing (of medication) to consumers. The special subcategory of products should also require industry to be accountable for both short and long-term safety, and short and long-term evidence of effectiveness. The College is mindful of research evidence which indicates that some formula marketed for 'special' purposes (which is still marketed for these purposes currently) has been the subject of research and systematic review, and been found to be ineffective.4 We are also aware of products that have caused severe health problems in infants, for example the recent issues with hypophosphatemia and bone disease associated with elemental formula.5 The College considers that industry is accountable for dietary sufficiency, effectiveness, and safety of products, just as the pharmaceutical industry is accountable for medication demonstrating safety and efficacy. A special category of what we consider to be pharmaceutical formulas would enable better supervision, accountability, surveillance, collection of data, science and evidence, and therefore better promote safety.

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?

The College consider that we have answered this question in Q2

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?

Using medical purposes in the definition would further support the specialised category for these products. As previously mentioned this would clearly differentiate these products and make it possible to regulate claims, evidence, surveillance and effectiveness.

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

As referred to in Q2 the College recommends urgent re-evaluation of all hydrolysed formula in light of research evidence confirming its ineffectiveness. We would like to see independent research evidence for the efficacy and short and long-term safety of all formulas that have claims made related to medical conditions. The College notes that a Cochrane Review about infant formulas containing hydrolysed protein for the prevention of allergic disease and food allergy has recently been withdrawn.6 Reasons for withdrawal are described as being due to data entry error. The original review stated:

"We found no evidence to support short-term or prolonged feeding with a hydrolysed formula compared with exclusive breast feeding for prevention of allergy. Very low-quality evidence indicates that short-term use of an EHF compared with a CMF may prevent infant CMA. In infants at high risk of allergy not exclusively breast fed, very low-quality evidence suggests that prolonged hydrolysed formula feeding compared with CMF feeding reduces infant allergy and infant CMA. Studies have found no difference in childhood allergy and no difference in specific allergy, including infant and childhood asthma, eczema and rhinitis and infant food allergy. Very low-quality evidence shows that prolonged use of a partially hydrolysed formula compared with a CMF for partial or exclusive feeding was associated with a reduction in infant allergy incidence and CMA incidence, and that prolonged use of an EHF versus a PHF reduces infant food allergy."

As the reviewed results may or may not be favourable to the claims made by hydrolysed formula makers, the College recommends that this FSANZ review takes into consideration how important this updated review may be to the safety, heath, and wellbeing of infants, and act accordingly once the results are known.

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 College would like to emphasise that independent evidence of efficacy and short and long-term safety should be available for all the products mentioned above. As referred to in Q2 and Q5 the College recommends urgent re-evaluation of all hydrolysed formula in light of research evidence confirming its ineffectiveness and the results of the revised Cochrane Review which are not available as yet.

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

The College considers the definition should be expanded to protect infants who are being fed these products unnecessarily, and for longer periods than necessary. Initiation of product use and the duration of the prescribed intervention need consideration. Despite the definition of preterm being birth before thirty-seven weeks the College does not consider formula-fed late-preterm infants a group who require special formula products. The issue of over-feeding preterm infants requires some consideration, as does the as yet unanswered question as to exactly which nutrients besides protein are specifically necessary for the healthy growth and neurodevelopment of very low or low birthweight infants. More research is obviously necessary, and again the College would like to point out that industry should be responsible for the claims they make, in respect to infant safety and product efficacy. Marketing to health professionals should also avoid inflated health and nutrition claims. A Cochrane Review in 2016 found that recommendations to prescribe post-discharge formula for preterm infants after discharge from hospital, was not supported by available evidence.[7]

It should be noted that breastfeeding and breast milk confer immunological protection, developmental support, and reduced risks of necrotising enterocolitis and sepsis for vulnerable preterm/low birthweight infants. The rising rates of mothers initiating lactation and providing milk for their NICU infants, with the added support, if needed, from human milk banks, is likely to increase, as is the support from neonatologists and paediatricians.

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

The benefits may be the potential avoidance of unnecessary prescribing of these products for infants who do not need them and the potential support of breastfeeding. Moderate to late preterm infants who are not breastfed will generally not require any special formula products. Including age and weight parameters does not preclude experienced clinicians making informed decisions about individual formula fed infants, but it may provide guidance and 'food for thought' for less experienced practitioners who may not be fully aware of the importance of breastfeeding, and/or the lack of evidence to support preterm formula use for moderate to late preterm infants. Given the results of the Cochrane Review noted in Q7, the College also considers that guidance as to the length of time a formula fed, growing preterm infant is on a special formula also requires attention.

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?

As yet the research appears to be inconclusive in regards to the benefits of fortified formula products added to breast milk for breastfed preterm/low birth weight infants, so the College would question the suggestion that these products may have other uses, until robust research evidence suggests otherwise. A 2016 Cochrane Review found that multi-nutrient fortification increases growth rates of preterm infants during their initial hospital admission, but that they did not provide consistent evidence on effects on longer-term growth or development. Authors recommended additional trials to resolve this issue. [8] The College understands that the use of fortifiers is by no means standard routine practice in all NICU settings in terms of age of infant, amount of fortifier (which is generally used in an unscientific way and not individualised to infant needs – one packet or two packets is the usual measurement), age of infant when

prescribed, and length of time of usage. Given the uncertainty about the efficacy of these products the College recommend caution in regards to other uses.

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

All formula products should be clearly labelled and described, regardless of type, and should be described in a clear way that does not make misleading claims.

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?

The College considers that scientific evidence of safety, benefit and efficacy for all products, formulation and ingredient is essential. The approach recommended by the College would be one where there is a requirement of industry to provide robust proof of short and long-term safety before any product is given to any infant. We also consider that there should be future liability for industry in respect to any adverse effects. The precautionary principle, and eliminating, or limiting, the risk of harm to infants is necessary, as is accountability of industry and appropriate consequences if harm is caused.

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

As previously mentioned in Q7, a Cochrane Review in 2016 found that recommendations to prescribe post-discharge formula for preterm infants after discharge from hospital, was not supported by available evidence. However, if a medical practitioner is suggesting the use of these products then the only access should be via medical prescription. Over the counter purchasing is inappropriate.

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.

Any product developed for infants for medical conditions should be used only under medical supervision, and be available only on prescriptions which need to be regularly renewed after ongoing infant medical assessment. This is in view of the need to ensure safety and efficacy, and to support ongoing monitoring of the short and long term effects of all products. The College strongly supports inclusion of the 'under medical supervision only' statement. We also support appropriate prescribing, and note that the cost of foods for special medical purposes has increased significantly. As reported by the First Steps Nutrition Trust, increases in costs in London alone recently were 212%.[9] The College supports including all formulas with specific health claims to support medical conditions in this category. This includes those aimed at parents of infants with potential reflux, constipation, allergies, or colic, for example. A serious barrier to prescribing formula for medical reasons is the lack of objective, scientific, free from commercial influence information accessible to paediatricians and general practitioners, and the resulting inadequacy of knowledge about breastfeeding and independent research. This results in breastfeeding women being told to stop breastfeeding unnecessarily, and unnecessary 'special' formula prescriptions. Generally the only information doctors have access to is via industry representatives.

The development of resources such as those created by the First Steps Nutrition Trust in the UK, are invaluable information documents both for health professionals and parents, and the College would like to see similar resources available in Australia and New Zealand.[10] First Steps Nutrition is an independent public health nutrition charity.

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

The safe preparation guidelines for all powdered infant formulas are provided by the World Health Organisation.

Conclusion

The College considers that the three primary objectives of Section 18 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act) should inform any revision decisions about formula milk products:

1. The protection of public health and safety.

2. The provision of adequate information relating to food to enable consumers to make informed choices.

3. The prevention of misleading or deceptive conduct.

As a final comment the College notes that the FDA issued draft guidance for industry on substances that are in contact with infant formula or human milk.[11] We have been unable to source the final guidance issued by the FDA, but note that the draft, which is concerned with chemical safety, describes the exposure of developing infants to food contact substances via their infant formula feeds. We would be interested to know whether FSANZ has similar guidance and if so, whether this has been taken into consideration in regards to formulas specifically designed for medical conditions.

The College would like to thank FSANZ for their consultation processes on regulatory issues related to infant formula products. The College is grateful to have a voice in these consultations, and supports FSANZ in their ongoing efforts to source the science and evidence to strengthen regulations and standards to protect the health and safety of infants.

Yours faithfully

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