P1028 Regulation of Infant formula – Infant formula products for special dietary use

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The Dietitians Association of Australia (DAA) is the national association of the dietetic profession with over 6000 members, and branches in each state and territory. DAA is a leader in nutrition and advocates for food and nutrition for healthier people and healthier nations. DAA appreciates the opportunity to provide feedback on P1028 Regulation of Infant formula – Infant formula for special dietary use by FSANZ.

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DAA interest in this consultation

DAA is the peak professional body for dietitians in Australia and responsible for the Accredited Practising Dietitian (APD) program as the basis for self-regulation of the profession.

DAA advocates for a safe and nutritious food supply in which the community has confidence and which meets the nutritional needs of all Australians, including groups with special needs.

DAA strongly supports breastfeeding for all healthy infants as breastfeeding provides the optimal nutrition for the healthiest start in life. DAA acknowledges the need to ensure a safe substitute for human milk for infants who are not breastfed. As experts in nutrition, APDs provide nutritional advice to caregivers to ensure the nutritional needs of infants are met through the diet in a safe and appropriate manner.

Recommendations

- DAA supports the proposed approach to retain the provisions for infant formula for special dietary use (IFPSDU) in Standard 2.9.1, and the introduction of a definition for IFPSDU.
- DAA recommends the name for Standard 2.9.1 Division 4 be amended to 'Infant formula products for special medical purposes (IFPSMP)' along with the removal of the subcategories under Division 4. This proposed naming aligns with the Codex and EU naming of this category, and better reflects the nature of products within this category.
- For similar reasons, DAA does not support the creation of a subcategory 'Products for special medical purposes' under Standard 2.9.1 Division 4. DAA is also not supportive of a subcategory 'Products for transit gastroenterological conditions' as there is a lack of quality evidence to support the efficacy of the products that would fall into this category.
- DAA supports a labelling requirement on pre-term formula that 'the product must be used under medical supervision' and recommends this statement be applied to all products under the IFPSDU category.

Discussion

Overall, DAA supports the proposed approach to retain the provisions for infant formula for special dietary use (IFPSDU) in Standard 2.9.1 given the requirement for IFPSDU to comply with the provisions of Standard 2.9.1. DAA also supports the introduction of a definition for IFPSDU as outlined in the 'Proposed category

definition' in the consultation paper 2.3.1.3 to provide clarity for the regulation of products in this category (Q3).

DAA notes that the proposed definition for IFPSDU is in line with the Codex/EU definition of 'Formula/Food for Special Medical Purposes'. However, the name for Standard 2.9.1 Division 4 'Infant formula products for special dietary use (IFPSDU)' is not in line with the Codex and EU naming of the category, and the current name of IFPSDU for Division 4 can be ambiguous. Therefore, DAA recommends amending the name for Standard 2.9.1 Division 4 from 'IFPSDU' to 'Infant formula products for special medical purposes (IFPSMP)' and the removal of the subcategories under Division 4 (Q5-8, Q10-11) to further align with the Codex and EU's naming and definition of this category. We have further outlined below rationales for this recommendation:

- Our proposed new name 'Infant formula products for special medical purposes (IFPSMP)' for Division 4 is a better reflection of the nature of the products in this category, regardless of whether they are for reflux, lactose intolerance, preterm birth or inborn error of metabolism etc. These products are for special medical purposes in relation to a specific disorder, disease or medical condition;
- The use of these products is required to be under medical supervision regardless of their subcategory in of Division 4 of Standard 2.9.1;
- These products are for special medical purposes and are not alternative dietary choices. The proposed changes help to avoid confusing or misleading consumers and may help to avoid inappropriate self-prescribed use;
- The removal of the subcategories facilitates future innovation and new product development, without the need to create new subcategories in future;
- Our proposed changes promote harmonisation of categorisation and regulatory oversight of these products with Codex and EU regulation.

DAA does not support the creation of a subcategory 'Products for special medical purposes' under Standard 2.9.1 Division 4 (Q2 & Q4) for similar reasons outlined in the response above recommending amendment of the name for Division 4 from IFPSDU to IFPSMP and the removal of the subcategories. Furthermore, the inclusion of a subcategory 'Products for special medical purposes' under Standard 2.9.1 Division 4 implies only products assigned to this IFPSMP subcategory are for medical purposes whereas products in other subcategories in Division 4 are not for medical purposes. This contradicts the 'Proposed category definition' in the consultation paper 2.3.1.3 for the category IPFSDU. It may also have a flow on effect on the regulation of products in the non–IFPSMP subcategories which may lead to compromising the safety of the products in the non–IFPSMP subcategories.

In addition, DAA does not support the creation of a subcategory 'Products for transit gastroenterological conditions' as a result of the proposed subdivision of the current IFPSDU subcategory 'Products formulated for metabolic, immunological, renal, hepatic and malabsorptive conditions' (Standard 2.9.1-14) into two subcategories. Our reasons are outlined below:

- Currently there is a lack of quality evidence to support the efficacy of the products that fall into this subcategory. The benefits and necessity of these products remain uncertain.
- The creation of such subcategory risks medicalising behaviours that may be normal infant behaviour (e.g. crying, frequent waking and varying bowel habits), and therefore has the potential to undermine breastfeeding. Caregivers trying to diagnose or self-manage conditions and infant behaviours, may believe that an infant (that is breastfed or formula fed) demonstrating these behaviours will benefit from swapping to these formulas.
- A critical review of the marketing claims of infant formula products in the US indicated claims encourage those parents who perceive their infants to be fussy, gassy, or colicky to purchase modified formulas as a remedy, even though there is insufficient available research to support this.[1]

DAA is supportive of the labelling requirement for a statement that 'the product must be used under medical supervision' on pre-term formula (Q26). Furthermore, DAA recommends that this statement should be applied to all products under the IFPSDU/IFPSMP category with additional wording indicating that 'the product is not for general use' regardless of whether the products are marketed to the general public or available for general sale (Q28). Our reasons are outlined below:

- The 'Proposed category definition' for the IFPSDU/IFPSMP specifies that the product is specifically formulated to be used under medical supervision;
- This requirement is aligned with the Codex, EU and US regulation on labelling requirements for such special infant formula products;
- This requirement helps to inform consumers that the use of these products should be under medical supervision even if the products are available for purchase on the market.

Finally, DAA would like to highlight concern that the highly technical nature of the issues and the volume of the work required to address the issues raised in the P1028 IFPSDU consultation paper may hinder responses from relevant health care professionals who do not have the time and resources necessary to adequately address the issues. Health care professionals such as paediatric dietitians, maternal child health nurses and midwives, and paediatricians play a vital role in educating and supporting parents to provide appropriate nutrition for their infants and young children. It is imperative to ensure that the expertise and views of these key health

care professionals are appropriately represented in the consultation process before any decisions are made regarding changes to the regulation of IFPSDU. It may be useful to determine an alternative way of accessing the views of these important stakeholders.

References

1. Belamarich PF, Bochner RE, Racine AD. A critical review of the marketing claims of infant formula products in the United States. Clinical Pediatrics; 2016; 55(5), 437-442.