INDUSTRY CONSULTATION
Standard 2.9.5 – Food for Special Medical Purposes

Abbott Nutrition is grateful for the opportunity to provide feedback on the recent Industry Consultation for draft Standard 2.9.5 – Food for Special Medical Purposes.

Please find below comments addressing FSANZ specific questions and additional comments for consideration.

Questions for stakeholders:

1. Do you have any comments/concerns with the proposed definition of food for special medical purposes?

Response 1:

Abbott Nutrition does not oppose the definition suggested in the Draft (dated: November 2011) of the Food for Special Medical Purposes standard.

Abbott Nutrition strongly opposes Food for Special Medical Purposes becoming a prescribed name in labelling under Standard 2.9.5 or elsewhere in the Food Standards Code. The FSMP definition proposed by FSANZ adequately and clearly describes how products within this category are "represented" thereby distinguishing them from general and other special purpose foods. Common labelling practices for FSMP products around the world include a statement that the product should be used under the supervision of a medical practitioner – a statement that is a clear indication the product is considered FSMP.

Should FSMP become a prescribed name, there would be significant implications to the Abbott Nutrition product range currently available within Australia and New Zealand, ultimately affecting over 75% of the portfolio. Any labelling rework required as a result FSMP becoming a prescribed name would result in either a cost being passed on to the end consumer or the evaluation of continued supply of product into the Australian and New Zealand market.

Questions for stakeholders:

2. Does the modification to draft Standard 2.9.5 clarify the restriction on sale?

3. Does the revised restriction on sale capture existing practices with the sale of FSMPs?

4. Please comment on the feasibility and appropriateness of a requirement for a written request.

Response 2:

Abbott Nutrition recognises FSANZ requirement to mitigate the risk by restricting the access of FSMP however this does not agree with the proposed changes to Clause 4 of the latest Draft standard.

- Clause 4 a) provides clarity as to the healthcare facilities permissible to sell FSMP.
- Clause 4 b), while the intent is clear, this clause places limitations on healthcare professionals other than medical practitioners or dietitians, that would be suitably qualified to sell or recommend a FSMP product. E.g. speech pathologist and a thickened fluid FSMP; nursing practitioners providing services to home patients. Greater clarity is required here to ensure that there are no undue limitations placed on those who can sell/prescribe FSMP products
- Clause 4 c) does not add to providing clarity to the intent of this Clause

Response 3:

- Clause 4 a) captures existing facilities and businesses that sell FSMP product to consumers

Abbott Nutrition notes that across several Oral and Enteral Nutrition State/Territory tenders, eligible customers include, but are not limited to, community centres, government schools and child care centres. All listed eligible customers would have access to purchase FSMP product and sell to a customer where health professional advice may or may not be available.

- Clause 4 b) does not adequately capture existing practice of current healthcare professionals selling/prescribing FSMP. Abbott Nutrition recommends this is reworded to include *'or other suitably qualified healthcare professional'*
- Clause 4 c) does not represent current practice of the sale of FSMP products

Response 4:

Abbott Nutrition strongly disagrees with the proposed requirement of a written request as described in Clause 4 c) in order for a consumer to purchase FSMP products.

Within State Government Tender requirements, programs such as the Home Enteral Nutrition program (HEN) require written "registration" in order to access product. This practice was established as a cost management program for home patients to access product outside of retail pharmacy at significantly reduced prices, rather than for risk mitigation.

Clause 4 c) suggests that customers not suitable for the HEN program would require permission from a healthcare professional or appropriate facility before being able to purchase a FSMP product. In addition, Clause 4 c) creates some ambiguity as to who requires permission – the customer to purchase or the person/business to sell.

In addition to this, Abbott Nutrition, based on extensive experience with the HEN program, would suggest that enforcement agencies may find it difficult to monitor and police requirements for a written request.

Abbott Nutrition believes that there are many practical issues that would be difficult to resolve in implementing this approach. Whilst not exhaustive some of these issues include:

- The establishment of a process to formalise the requirement of a written request
- Education of healthcare professionals as to the new requirement of a written request; for example, who will educate the GPs (circa 20,000 in Australia alone)?
- How will the existing end consumers be informed/educated of the new requirements?
- How will a consistent practice of all points of sale of FSMP products be established to ensure the intent of the written request is fulfilled?

Notwithstanding the above, even if a practical, implementable process was established to address the issue of effectively managing the risk profile of FSMP products what is the basis for concern regarding risk management of FSMP products in the Australian and New Zealand context versus other countries around the world? In the following countries not only is a written request not required for the products, the products are available in food and grocery outlets as well as pharmacies. (Note: Pharmacy channels in these countries have been established primarily to allow for medical food/FSMP product reimbursement):

i) USA
ii) Spain
iii) Canada

iv) Mexico
v) India
vi) Indonesia
vii) Singapore
viii) Taiwan
ix) South Africa

For implementation of FSMP in the EU and Member State, the EU directive makes no reference to channels of distribution.

Questions for stakeholders:

5. Please provide any comments on the proposed labelling requirements for FSMPs in inner packages.

Response 5:

Abbott Nutrition has completed a review of inner packaging labels currently available in the ANZ market. The inner packages of these products all meet the proposed labelling requirements.

While Abbott Nutrition does not oppose the suggested labelling requirements of inner packages, we would recommend the inclusion of LOT/batch identification and expiry date to ensure traceability.

Questions for stakeholders:

6. Please provide any comments on the proposed labelling requirements for FSMPs not in a package and for transportation outers containing FSMPs.

Response 6:

Abbott Nutrition supports the requirement for transportation outers to include, whether printed on the transportation shipper or by way of sticker, the name of the product (unless clearly discernible through the outer), LOT/Batch identification and local supplier details.

In addition, Abbott Nutrition agrees that the recommendation by FSANZ to include Sub-clause 2(2) whereby FSMPs *not in a package* are exempt from labelling requirements.

Questions for stakeholders:

7. Please provide any comments on the proposed approach not to apply Standard 1.3.2, the Transitional Standard for Health Claims (1.1A.2) and Standard 1.2.7 (when gazetted) to FSMPs.

8. Please provide comments on whether therapeutic claims should be prohibited or not (noting the requirement in draft Standard 2.9.5 to state the medical purpose of FSMPs), with your reasons why/why not.

Response 7:

Abbott Nutrition agrees with the proposed approach not to apply Standard 1.3.2., 1.1A.2 and 1.2.7.

Response 8:

Abbott Nutrition is of the position that therapeutic claims should *not be prohibited* on the label of a FSMP product. Based on the class of these products, the label requires some type of claim in conjunction with the indication. Claims are currently limited to the disease state or condition for which the product is indicated.

Questions for stakeholders:

9. Please provide any comments on the proposed approach to apply the advisory and warning statements listed above to FSMPs.

Response 9:

Abbott Nutrition has no objection to the proposed approach for use of the current advisory and warning statements for polyols and polydextrose.

Questions for stakeholders:

10. Please provide comment on whether any of the proposed labelling requirements are likely to impact on costs to industry and consumers, or on the availability of FSMP products (see summary table of the proposed labelling in the Labelling Requirements Update Page 20). If so, please specify the labelling requirement of concern and provide details e.g. what is the impact, the number and type of products likely to be affected, and estimated costs.

Response 10:

Listing contraindications and precautions –

- Abbott Nutrition is unclear as to what specific contraindications and precautions would be required to be listed outside of the advisory and mandatory statements already required/suggested

There would be significant additional costs associated with the over-labelling or label rework of products currently shared with other Abbott Nutrition Affiliates – this would affect over 75% of the current Abbott Nutrition ANZ product range. Ultimately this cost would need to be passed on to the end user.

Questions for stakeholders:

11. Can you provide further information on how nutrient levels declared in nutrition information panels are derived? e.g. are these based on an average of the amount of addition in each product range, or on the minimum amount of a substance added? Is the amount determined analytically or by calculation?

Response 11:

Abbott Nutrition sources product from both the USA and Europe.

Labels of EU origin reflect the *average quantity* across the shelf life of the product and takes into consideration the amount added as an ingredient in addition to what is inherent in the major product ingredients, i.e. oil and proteins. These values are determined through both calculation and analytical confirmation.

USA origin labels reflect the *minimum quantity* across the entire shelf life of the product and takes into account both the added ingredient values and inherent values from major ingredients, i.e. oil and proteins. These values are determined through both calculation and analytical confirmation. Several USA origin labels do declare *average quantities*

which are reflective of the entire shelf life. These values are also determined by calculation and analytical confirmation.

Abbott Nutrition conducts nutrient analyses routinely to ensure label compliance.

Questions for stakeholders:

12. FSANZ is interested in feedback as to whether this new paragraph 1.3(b) will ensure that VLED products are not captured by draft Standard 2.9.5.

Response 12:

To prevent any ambiguity, Abbott Nutrition recommend including a clause specifically referencing *products formulated as very low energy dense* are not considered FSMP.

Additional Comments:

Chromium picolinate –

Abbott Nutrition is seeking clarification on the permission to allow the use of Chromium Picolinate in FSMP products. It is noted on Page 17 of the November 2011 – Consultation Paper that chromium picolinate has been assessed as a suitable form of trivalent chromium and no maximum limit would apply to FSMP products. We note that chromium picolinate has not been listed within Schedule 1 of the new 2.9.5 draft within the November consultation document.