Reforms to the regulatory framework for complementary medicines

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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 the consultation *Reforms to the regulatory framework for complementary medicines* by Therapeutic Goods Administration (TGA).

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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. For some, dietary intake may not provide enough nutrition and supplements may be required. It is of interest to DAA and its members to know that these supplements are high quality, efficacious, backed by sound science and have accurate labels. A strong regulatory framework for complementary medicines will assist APD's to assess a client's nutritional status, assess potential nutrient, food, drug, herb interactions and provide appropriate advice to both the client and other members of the client's healthcare team.

Recommendations

DAA supports the objectives of the reforms to the complementary medicines regulatory framework as outlined on page 6 of the consultation.

DAA supports requirements for appropriate high quality independent scientific evidence to substantiate health claims and efficacy of ingredients and products.

DAA recommends ongoing monitoring and evaluation processes should be considered to ensure the reforms are implemented as expected.

DAA recommends that comparisons to the nutrient content of foods should not be permitted by complementary medicines. DAA have provided further comments and specific recommendations on the consultation paper within the discussion.

Discussion

Section 3 Assessment pathways for complementary medicines

Establishing a risk-based hierarchy for therapeutic indications

3.1 Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways?

DAA supports the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways.

DAA recognises this proposed pathway is similar to FSANZ's general level health claim (GLHC) self-substantiation pathway in that those manufacturers wanting to make GLHC's outside the approved FSANZ list of GLHC's can do so provided they hold a systematic literature of the evidence (Standard 1.2.7 Schedule 6)[1].

DAA supports the TGA's proposal to review the evidence specifically for efficacy of the complementary medicine. This proposed pathway will further assure dietitians of the proven benefits of complementary medicines beyond traditional use via an assessed scientific evidence base.

3.2 Do you envisage any difficulties with criteria used to include or exclude products from the new pathway?

DAA does not envisage any difficulties with the criteria used to include or exclude products from the new pathway.

3.3 What other considerations may need to be taken into account in implementing the new pathway?

DAA suggests evidence of any drug, complementary medicine, food and nutrient interactions be assessed and made available to health care professionals.

Approaches to establishing efficacy

3.4 Do you agree with the proposed methods to establish efficacy for products included via the new pathway?

DAA supports the new approach of a pre-market assessment of the evidence for a product as a whole rather than the sum of the individual parts. This is in line with the food health relationships that needs to be established for general and high level health claims under FSANZ[1]. Assessing clinical evidence of the effects of a product as a whole will help determine the quality of the product, the bioavailability of ingredients purported to provide an effect within that product and any interactions between the ingredients of the product. Inherent in this specification is that products will be required to demonstrate quality formulation meaning the product contains enough of the active ingredient(s) to support the proposed effect.

3.5 Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?

DAA supports the proposed approach to transition current listed products with a restricted representation exemption to the new approval pathway.

Evidence requirements

3.6 Are the evidence requirements appropriate for the new pathway?

DAA recommends the efficacy of complementary medicines should be substantiated by high quality independent scientific evidence such as randomised control trials in humans, systematic reviews (and meta analyses) for the product as a whole and for individual ingredients. This is to ensure public safety of these products/ingredients and maintain trust in the TGA and the assessment process.

DAA assumes there are TGA guidelines available for complementary medicine manufacturers that explain how to undertake and present these reviews, but these should be specified within the framework. Chemical characterisation of the final product (not just the ingredients) is required to demonstrate that the physicochemical properties of the final product are supported by evidence to support the purported physiological effect.

3.7 Do the proposed levels of assessment align with the proposed risk-based hierarchy?

DAA supports that products with a higher indication level should require a higher level of rigor for the evidence e.g. category D evidence (RCTs and systematic reviews) for Intermediate and high level indications. However, DAA believe that only one RCT in support of the evidence of effect is not sufficient. It would not be possible to exclude bias based on the results of one study alone. Although providing guidance on the minimum number of studies required is useful, it is unlikely a single study would provide the basis for substantiation. The weight of evidence for and against effects must be determined and this will be product, effect and study/cohort dependent.

3.8 What other considerations may need to be taken into account in implementing the new pathway?

DAA recommends the TGA consider ongoing monitoring and evaluation to ensure implementation of the new pathway is working as expected. Ideally, the evidence base will be reviewed every 5 years by the sponsor/TGA.

Section 4. Implementing a list of permitted indications

Criteria for permitted indications

4.1 Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?

DAA supports the criteria for inclusion of a low level indication on the permitted indications list, as:

- These criteria will ensure that only indications appropriate for listed medicines, and that are compliant with the regulatory requirements, will be accepted for inclusion on the permitted list.
- Products containing higher level indications require approval through a pre-market assessment process (i.e. the new pathway or registration).

DAA acknowledges the new indications list has yet to be developed but will include stakeholder consultation.

4.2 What other considerations should be taken into account in implementing the permitted indications list?

DAA recommends criteria be applied to complementary medicines so that comparisons between complementary medicines and foods cannot be made. DAA also recommends that these comparisons are not suitable for inclusion in the permitted indications list.

- DAA acknowledges comparisons between complementary medicines cannot be made however it is unclear whether comparisons between foods and complementary medicines are permitted.
- FSANZ Standard 1.2.7[1] does not allow comparisons of the vitamin and mineral content between foods, or comparisons of foods with therapeutic goods.

Implementation of the permitted indications list

4.3 Is Option 2 for selecting indications for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications?

DAA supports option 2 as it provides rigor to the indications process by providing an approved list to choose from while allowing some flexibility for manufacturers. DAA believe this will help prevent exaggerated or inappropriate claims or claims lacking appropriate scientific substantiation.

4.4 What other considerations should be taken into account in implementing the permitted indications list?

DAA recommends the TGA consider ongoing monitoring and evaluation to ensure implementation of the permitted indications list is working as expected.

Section 5. Claiming evidence of efficacy

Criteria for the use of a claimer

5.1 Do the proposed criteria for the use of a claimer address the objectives for the recommendation?

DAA supports the proposed criteria, as outlined in section 5 of the consultation, for the use of a claimer.

Use of a claimer

5.3 Will the use of a claimer on complementary medicines have any unintended consequences?

DAA supports that a claimer may only be used on complementary medicine labels and/or other product promotional materials following TGA approval as part of a pre-market assessment process.

DAA have not identified unintended consequences of the use of a claimer on complementary medicines.

Presentation of claimers

5.4 Should the claimer be presented as a visual identifier as well as a statement?

DAA supports presentation of the claimer as a visual logo as well as a statement such as 'Evidence has been reviewed by the TGA' to allow for quick identification of those products that have been assessed and provide consumers with assurances as to the quality and efficacy of the product.

DAA recommends implementation of the claimer should be accompanied by a consumer education campaign by the TGA to raise awareness of this new initiative. DAA also recommends adequate monitoring and evaluation should be considered.

5.5 Do you have any views on the possible wording or design of the label claimer?

DAA suggests the TGA consider the consumer research garnered when the Health Star Rating was developed for guidance on label style, placement, etc. Information is available on the Health Star rating website- www.healthstarrating.gov.au.

Section 6. Incentives for Innovation

While DAA does not have an opinion on the commercial issues within section 6 of the consultation, consideration would need to be made as to how any exclusivity period could be inclusive of independent external peer review of the evidence, particularly around new ingredients.

References

1. Food Standards Australia New Zealand. Australia New Zealand Food Standards Code – Standard 1.2.7 – Nutrition, health and related claims. Canberra: FSANZ; 2017. Available from: https://www.legislation.gov.au/Details/F2017C00068