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Therapeutic Goods Administration  
Department of Health

Submission by the ATMS – Consultation: Sports supplements. Proposed clarification that certain sports supplements are therapeutic goods

The Australian Traditional-Medicine Society (ATMS) is Australia's peak national professional association of natural medicine practitioners. ATMS is a multi-disciplinary association representing around 10,000 accredited practitioners throughout Australia, including practitioners of naturopathic and nutritional medicine, many of whom recommend, or whose clients, use sports supplements.

This consultation raises the issue of the food-medicine interface, which is a matter of importance to the ATMS because the proper regulation of both foods and medicines is required to ensure that public safety is maintained. Where any form of dietary supplement is used by consumers, both healthcare practitioners and consumers should be able to rely on the quality, safety, effectiveness of the product, and the dosage instructions provided by the manufacturer.

It has become increasingly obvious of late that a growing number of sports supplements that are regulated as foods are effectively being marketed as therapeutic goods, and without the protections that are provided by the therapeutic goods regulations, these products pose a risk to consumers because of the questionable quality, safety and effectiveness. Clearly, any supplement that is advertised for a health benefit or for some form of physiological enhancement is a therapeutic good and while Food Standards Australia New Zealand (FSANZ) does an effective job at regulating foods, and the Therapeutic Goods Administration (TGA) does an effective job at regulating medicines, advertisers have taken advantage of the possibilities inherent in the grey area that currently exists between the definitions of foods and medicines. It is because the ATMS is committed to the health and wellbeing of the Australian public, that we welcome the opportunity to comment on this issue.

#### Consultation Questions

*1. Do you support the proposal for certain sports supplements to be declared to be therapeutic goods? What are the reasons for your answer?*

The ATMS supports the proposal for certain sports supplements to be declared to be therapeutic goods. Currently there is sufficient ambiguity in the definition of a food, as this relates to the *Food Standards Australia New Zealand Act 1991* that use can and is being made of this to allow some advertisers to promote foods as medicines, and by so doing, are putting consumers at risk through a lack of appropriate regulation of these products.

*2. Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers? What are the reasons for your answer?*

The ATMS is of the view that the proposed declaration would not have an impact on the availability and choice of sports supplements for consumers. Manufacturers may incur an extra compliance cost because of the re-classification of some products from foods to medicines, but this extra cost should not be significant enough to influence product availability and therefore choice.



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*3. Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines? What are the reasons for your answer?*

The ATMS is of the view that the proposed declaration will provide greater clarity for industry as to whether their products should be marketed as foods or medicines. This is the logical consequence of the proper classification of some sports supplements as therapeutic goods.

*4. Are you aware of products on the market that would not be captured by the proposed declaration but should be? What are the reasons for your answer? Please provide specific details and the rationale for why these products should be therapeutic goods.*

The ATMS is not currently aware of any products on the market that would not be captured by the proposed declaration but should be.

*5. Are you aware of products on the market that would be captured by the proposed declaration but should not be? What are the reasons for your answer? Please provide specific details and the rationale for why these products should not be therapeutic goods.*

The ATMS is not currently aware of any products on the market that would be captured by the proposed declaration but should not be.

*6. What impact would the proposed declaration, if made, have on your business? If there would be a positive impact, what are the reasons for your answer? If there would be a negative impact, please provide the following information (identified as confidential in the consultation submission cover sheet):—the number of products affected  
—operational impacts on your business  
—approximate costs that these changes may impose on your operation*

As a professional membership association, the ATMS will not be directly impacted by the proposed declaration, if made. However, because the re-classification of some sports supplements as therapeutic goods will require sponsors to ensure that these products comply with the requirements set out in the Therapeutic Goods Act and Therapeutic Goods Advertising Code, ATMS members who recommend these products to clients can expect a greater level of confidence that these products are low risk, contain only the ingredients listed on the product label, and will provide the clinical benefits as advertised.

*7. Do you have any other comments related to the consultation?*

The "Decision tree" depicted on page 14 of the consultation document provides a clear and useful description of the process that the TGA is proposing to establish and should form an integral part of any education offering to product sponsors who are considering whether their products are foods or medicines.

ATMS notes the Position Statement, November 2019 Sports Supplement Consultation by Complementary Medicines Australia and broadly supports that Position Statement.

Other than this, the ATMS has no other comments to make on this issue but again would like to thank the TGA for the opportunity to contribute to this consultation.