



Member Alert

Consultation on Sports Supplements Regulatory Reform

Dear Members and industry stakeholders,

Complementary Medicines Australia is working closely on the newly announced Therapeutic Goods Administration (TGA) [public consultation](#): “**Proposed clarification that certain sports supplements are therapeutic goods**”. It provides a draft “[Therapeutic Goods \(Declared Goods\) Order 2020](#)” that would declare a large proportion of sports supplements as therapeutic goods via an instrument made under section 7 of the *Therapeutic Goods Act 1989*.

CURRENT STATUS OF SPORTS SUPPLEMENTS

The size of the sports nutrition sector is currently measured at \$1.11 billion dollars¹, and CMA’s five year projection predicts further healthy growth in this category (not including the influence of any Government reforms).

Currently, many sports and recreation supplements are sold as either foods or consumer goods (if not meeting the definition of a medicine or “therapeutic good”), often supplied in Australia under food standards, including;

- [Standard 2.9.4 - Formulated Supplementary Sports Foods](#);
- [New Zealand Food \(Supplemented Food\) Standard 2016](#); and to some extent;
- Standard 2.6.2 - Non-alcoholic Beverages and Brewed Soft Drinks (electrolyte drinks and bases).
- Standard 2.9.3 - Formulated Meal replacements and Formulated Supplementary Foods

A small percentage of sports supplements and electrolyte products are alternatively included in the TGA’s Australian Register of Therapeutic Goods (or ‘[ARTG](#)’) as listed medicines. The TGA have a tool that helps companies decide whether a product is a food or therapeutic good, the [Food Medicine Interface Guidance Tool](#).

PROPOSED “CLARIFICATION” THROUGH DECLARED THERAPEUTIC GOODS ORDER

The consultation proposes to clarify that, under the existing regulatory regimes for therapeutic goods and foods, certain products will be “clarified” as requiring Government regulation under the Therapeutic Goods Act framework, if they are “used, advertised, or presented for supply” in a particular way. This is with the view that certain products seen to be making certain claims are already therapeutic goods, and that these goods should be under a national system of regulatory controls. The consultation excludes some products, which will still be considered foods.

As food products are already permitted to make health claims under certain circumstances, and the proposal captures products that are currently regulated as foods (whether compliant or non-compliant), it is arguable that this is NOT a clarification but rather, it is a change of regulation for many products.

The consultation has been launched separately, and without coordination with Food Standards Australia New Zealand or [FSANZ’s review](#) of the Formulated Supplementary Sports Foods standard (2.9.4).

¹ Euromonitor International Australia, 2019. Complementary Medicines Market Data 2017-2018, Sydney: Euromonitor International Australia.

FURTHER DETAIL

The proposed Declared Therapeutic Goods Order includes:

- **goods for oral administration**
- **that are represented (expressly or by implication) as being for**
- **improvement or maintenance of physical or mental performance in sport, exercise or any other recreational activity;**

WHERE those products meet any of the below:

- is a tablet, capsule or pill
- any product that:
 - Contains any substance in [a Schedule of the Poisons Standard](#) or
 - Contains any substance in the [WADA prohibited list](#) or
 - Contains any other relevant substance, as decided by the TGA;
 - **OR**, have an equivalent pharmacological action to three kinds of substances above (including an active principle, precursor, derivative, salt, ester, ether or stereoisomer)
- **OR, when used according to the directions of use:**
 - Contains an amount of substance exceeding a restriction in the [Permissible Ingredients Determination](#)
 - Contain an amino acid or substance exceeding that specified in S29—18 or S29—19 of the [Food Standards Schedule 29](#).

CMA ACTIONS IN RESPONSE TO THE CONSULTATION

CMA members voice will be represented in this consultation. CMA is:

- examining in-depth the interaction between the current regulations and the proposed regulations;
- facilitating an industry working group of affected members who are sponsors, manufacturers, suppliers, or other business owners in the sports supplements category;
- reviewing the appropriateness of the consultative engagements;
- exploring the outcomes and requirements associated with various regulatory outcomes;
- seeking responses from affected members and working with NZ counterparts;
- developing a checklist and proforma for members to help measure effect on products with flow on effects to manufacturing, jobs, and businesses;
- coordinating an industry-wide impact view;
- engaging with Government parliamentary and executive representatives; and
- coordinating a united industry policy in response to the Government proposal.

JOINING COMPLEMENTARY MEDICINES AUSTRALIA

For industry stakeholders not currently a member of the CMA, it is highly encouraged that you get in contact with us and explore how we can best represent your views and concerns in relation to this matter. CMA promotes appropriate industry regulation and advancement. CMA is the award-winning peak body for the complementary medicines industry, representing stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals, researchers and educators.

Member Join form: A member joining form is included at the end of this alert.
Joining benefits: <http://cmaustralia.org.au/Join>
Joining enquiries: members@cmaustralia.org.au (Natasha Flynn).
Technical queries: technical@cmaustralia.org.au (Lucy Lang).
Contact line: 02 6260 4022 (international: +612 6260 4022)

ENDS

Complementary Medicines Australia

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Complete all information required for your application and **Return** to the CMA Membership Team at members@cmaustralia.org.au

Please indicate the Membership category you are applying to:

Member

Select a Membership Category from the list:

Finished Products
(brand owner/sponsor/manufacturer)
Raw Material Supplier
Distributor/Wholesaler
Retailer

Associate Member

Select a Membership Category from the list:

International
Association
Industry Consultant
Corporate Retailer

If you need assistance with completing this application form, please contact our Membership team, via members@cmaustralia.org.au or call us on (02)6260 4022

REGISTRATION AND OWNERSHIP

Company Name:	<input type="text"/>		
Trading Name(s):	<input type="text"/>		
ACN:	<input type="text"/>	ABN:	<input type="text"/>
Postal Address:	<input type="text"/>		
Website:	<input type="text"/>		
Phone:	<input type="text"/>	Fax:	<input type="text"/>
Primary Contact Name:	<input type="text"/>		
E-mail:	<input type="text"/>		
Mobile:	<input type="text"/>		

NET ANNUAL REVENUE

What was your organisation's net annual revenue for the past, full financial year:

If you fall under the Association membership category, net annual revenue does not apply to Associations.

Please provide the number of existing members in your Association:

PLEASE DO NOT SEND PAYMENT WITH YOUR APPLICATION
A tax invoice will be mailed to your nominated address following approval.

RELEVANT LEGAL ISSUES

Have any of your senior management, or Directors of the organisation been convicted of a criminal offence against a law of the Commonwealth or of an Australian State or Territory?

Yes

No

Has the organisation had its licence to manufacture or trade cancelled or suspended in part or in full?

Yes

No

If Yes, please provide details on a separate sheet

DECLARATION AND SIGNATURE

I confirm that I have read and understood the CMA Information Kit prior to completing this application.

I understand that the information submitted within this application has been provided on a confidential basis and will not be used by CMA for purposes other than building a profile of the complementary medicine industry generally, and in specific circumstances detailed above.

I confirm that I have read and understood the CMA Marketing & Supply Code of Practice and, on behalf of the applicant, declare that the applicant agrees to operate in accordance with the CMA Marketing & Supply Code of Practice.

I acknowledge that all members of CMA are obliged to comply with the CMA Constitution at all times, and that failure to do so may result in the termination of membership.

I acknowledge that the information given within this application will be used to determine the correct category and fee of CMA Membership. Should this information change, I acknowledge that an increase or decrease in membership fees may result.

I give approval that, for the purposes of considering this application for CMA Membership, CMA may make such enquiries with Commonwealth and/or State/Territory authorities as deemed necessary. In addition, I understand that CMA may seek the views of its members and others to inform judgement as deemed necessary.

I declare that the information provided in this application is true and complete and understand that CMA reserves the right to vary or reverse any decision on CMA membership based on incomplete or incorrect information.

Company Name:

(Applicant)

Name:

(Authorised Person*)

Position Title:**Date:****Signature:**

(Authorised Person*)

* The Authorised Person should be a senior executive officer of the organisation, i.e. Executive Director, Managing Director, CEO etc

CMA is committed to maintaining the privacy of all members. All information provided will be used in accordance with relevant privacy legislature and is understood to be provided on a commercial in confidential basis.

Applicants can elect to have their details displayed on the CMA website and supplied to relevant third party preferred suppliers.

CMA reserves the right to audit any information provided by an applicant, or to request further documentation if required.

Thank you for your membership application to Complementary Medicines Australia. This will now be assessed and you will receive notice of the outcome within 20 working days of receipt.