
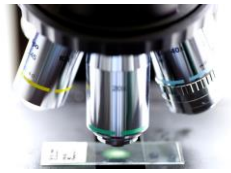


Member Alert

Sports Supplements – Key Points to Consider for Submissions

Dear Member,

Complementary Medicines Australia has been working closely on the public consultation by the Therapeutic Goods Administration: "**Proposed clarification that certain sports supplements are therapeutic goods**". The Government have not responded to calls for an extension on this consultation, therefore submissions **close 3 December 2019**.

Overview of CMA's Response and Key Points for Members.

Members are welcome to consider including the key points in this alert as part of their submission.

The TGA's consultation is inherently confusing as it mixes up policy issues of products that are already illegal (such as illegal prescription medicines), athletes requirements, as well as a major re-set to the Food-Medicine Interface, which are different policy concerns.

It is commendable that issues of safety and quality are under examination and these areas should be subject to appropriate levels of regulation. There are areas where the food-medicine interface deserves additional consideration and consultation. However, the Government regulatory scheme must be able to adequately serve the needs of consumers, businesses, and serve the growth of the Australian industry locally and internationally. CMA are concerned that the consultation as outlined does not serve these goals, or meet standards for appropriate clarity of regulation and appropriate regulation of various product categories.

Issues and concerns with the consultation are outlined below. A return to consultation would be welcomed with broad policy options supported by a best practice regulatory approach. Members are welcome to consider key points below for inclusion in submissions.

Key Points - Industry and Economic Effects.

1. Many products contain formulations that have been safely used for years would not be eligible to survive due to limitations in either the TGA or FSANZ substances framework. Others would not be able to find the required type of manufacturer, or would not be able to sell products with lower potencies and higher prices.
2. The personal importation scheme would continue to import many of these products as dietary supplements from international countries with attractive advertising, claims, and low cost. They are easily ordered and delivered rapidly under modern e-commerce platforms that compete aggressively for consumers' attention. Border Force cannot prevent this

"personal importation" of non-Scheduled products. Consumers would be less protected than if industry and Government can agree on an appropriate food-medicine interface and regulatory scheme.

3. The combined effect of the above is that sponsors, specialist retailers, manufacturers and distributors would lose a significant amount of their products and turnover. Many of these would not survive this environment or some may move offshore. It is widely expected that hundreds of millions of dollars of Australian economy and manufacturing would be handed to international businesses without any significantly improved protection of Australians.
4. As the TGA's proposed declaration takes legal hierarchy over any AU/NZ Food Standard, this consultation affects many NZ products that are currently sold under the Trans Tasman Free Trade Agreement under the NZ Supplemented Foods Standard. This effect should not occur without wider consultation under COAG.
5. The proposed actions are a large increase in regulation and out of alignment with Government's commitment to decreasing regulation and growing Australian businesses internationally.

A full description of expected impacts above is described in CMA's Position Statement.

Key Points – Policy, Regulatory Framework, and Legislative issues.

1. **The stated premise of the consultation does not reflect the nature of the consultation. It is not a clarification, but a change of regulatory status for many affected products.**

   While there are a small amount of products that may have been considered therapeutic goods, the majority of those affected by the proposed Declaration have always been considered foods. The premise that these products are already therapeutic goods and that therefore this is a "clarification" is not correct. Those products which can be considered to be foods under existing Food Standards or traditional foods would undergo a distinct regulatory change of status. This may be justified in more limited circumstances than the consultation currently proposes, which affects a large number and many types of goods.

2. **The proposed consultation re-opens wide policy questions on how the food-medicine interface is regulated, but by focusing only on a subset of products, it creates other issues.** The proposed declaration:

   - **Captures as medicines, products that were not intended to be captured.** This includes health foods with health claims, formulated caffeinated beverages, certain subcategories of tablets and capsules for food or recreational use, etc.
   - **Captures as medicines, products that should not be captured**, including many sports nutrition supplements that are currently not fully aligned to the Foods Standard specifications but which may not need to become medicines, or which are waiting on an update and review of particular Food Standards.
   - **Excludes as medicines, many products that are already Listed Medicines on the ARTG**. Products that are listed medicines and are undivided preparations with permitted indications that are the same or similar to the therapeutic uses outlined in the document would no longer be required to be medicines. This has not been mentioned in the consultation document and therefore businesses have not been transparently and adequately consulted about how this de-regulation would affect their interests.

3. **The consultation and proposed legislation has been confusing and out of step with usual Government and community expectations for consultation and legislation.**

   - The legislation is confusing as it includes reference to products that are already illegal (products with Scheduled substances) or with undeclared ingredients. Enforceable actions are already available against such products and is commonly undertaken on a regular basis.
   - The inclusion of the definition of 'therapeutic use' in the proposed Declaration is confusing, as it captures foods with health claims. This does not clarify but further confuses the food-medicine interface for businesses and manufacturers. It negates and creates ambiguities with other Government policy, which is that many foods can include health claims.
   - The legislation includes reference to substances listed by the World Anti-Doping Authority, a non-Government foundation based in Canada. While the regulatory scheme and regulatory decisions (such as Scheduling medicines and poisons) may be *informed* by WADA prohibited list, the regulatory status of individual products in Australia cannot be determined by an international, non-Government body.
   - The legislation names 'relevant substances' which acts as a replacement for proper Scheduling mechanisms under the Government's well established 'Scheduling Policy Framework' which sets out the national policy for applying restrictions on all "poisons".
   - The proposed legislation disallows the use of substances that have an "equivalent pharmacological action" when this is out of step with Government approaches to substances and the ability to clearly apply legislative rules. Stakeholders are not able to ascertain whether one substance would or would not be included in this category. In all other categories where a group of substances have a common pharmacological effect, that effect can still vary considerably (such as opioids) and those substances are appropriately Scheduled and regulated individually, not as a group.

4. **Where products have been affected (as described above) but this has not been adequately identified or described in the consultation paper, the consultation has not been transparent about its full effects.**

   The confusion of what is and is not captured by the draft Declaration and therefore the full meaning and effect of the legislation against different product categories has confused the community. The community, meaning both consumers and businesses, haven't been adequately consulted on what type of products they *want* to have access to, and what attributes those products should have. Consumers are likely unaware that products changed to therapeutic goods will not have the type of presentation or information they are used to and seek out.

5. **The consultation mixes together a number of different policy regulation issues that need separate consideration.**
   a. **Enforcement of illegal or undeclared substances**. This should be considered separately to the food-medicine interface.
   b. **WADA and athletes**. This should also be considered separately to the issue of the food-medicine interface. Medicinal regulation does not offer the type of guarantee

required for professional competition, therefore any product, whether food or medicine, still must be separately certified for athletes outside of any regulatory scheme.

c. **How to approach novel substances** at the food-medicine interface.
d. **The adequacy of the Food Standards to meet modern requirements.**
e. **The adequacy of the current Food-Medicine Interface for all types of supplementary products.**

6. **The consultation raises much larger questions about the Food-Medicine Interface which go beyond sports supplements.**
   By combining a set of claims with a set of product types, as mentioned above, the consultation both captures products that were intended and also excludes products that are already medicines. This is a major change to the FMI, which needs to be considered in its full depth and complexity as to what it is included and what can be excluded, regardless of whether its use is related to sport.

7. **The premise of the consultation, that the regulatory status of a product can change on how it is advertised, is not feasible as third party advertisers could change the regulatory status of a product.**
   The presentation of the product and associated explicit or implied claims are able to change the regulatory status of a product without the involvement of the sponsor. This is not a feasible approach to product regulation.

8. **The TGA consultation is out of step with FSANZ, who are currently reviewing the Formulated Supplementary Sports Foods Standard under Proposal 1010**, available here: https://www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx

   As the content of the FSSF Standard would affect the regulatory framework of a variety of products described in the TGA's proposed Declaration, the two consultations cannot occur out of step as it changes the regulatory status of products significantly and stakeholders are unable to fully respond without knowing the FSANZ changes.

9. **Complex considerations and large impacts, with insufficient consultation time.**

   This is a very large consultation, involving thousands of products for hundreds of businesses, with many complex rules that a number of stakeholders are not closely familiar with. The Government has not provided stakeholders sufficient consultation time to understand the full impact of this proposal on their businesses, or to conduct a full assessment of how their products have been affected. This has also been in the lead up to the busiest time of year for businesses.

Key Points – Returning to an improved consultation

Return to consultation offers the Government, industry and consumers many potential benefits:

- A modernised and globally agile framework for Australian industry to respond to new patterns of trade and commerce;
- A flexible access scheme for Australian consumers and industry to substances and products, while still ensuring safe and high quality products.

CMA's Summary Recommendations to Government

CMA recommends:

1. **A different consultation with**:
    - **Four broad policy options**, consulted with stakeholders beforehand (an Australian Government best practice regulatory approach).
    - **COAG consultation** (Council of Australian Governments).
2. **A thorough assessment of direct evidence** conducted by Government on the case for regulatory change, including laboratory elucidation of claims around contamination.
3. **A thorough assessment of impact** so that all regulatory costs, whether arising from new regulations or changes/legislated clarification to existing regulations, are quantified using the Regulatory Burden Measurement (RBM) framework.
4. **Following Australian Government principles and process** of a **coordinated whole-of-Government approach** and **Treasury's De-Regulation Taskforce**, supporting reduced regulatory barriers for Australian businesses growing investment and trade.

Four broad policy options (Best Practice Regulation)

Our first recommendation above recommends consulting with industry on four broad policy options based on Best Practice Regulation, outlined in "The Australian Government Guide to Regulation".

Broad options that could be discussed include (but are not limited to):

- **No change** in regulation / No change in regulation combined with improved enforcement;
- **An overall re-assessment of the operation of the Food-Medicine Interface for all goods** (may result in more appropriate regulation for all products);
- A **food standard specifically intended for this supplement category**;
- **A unique regulatory body** for supplements;
- **Revision of Food Standard 2.9.4 and improved harmonisation of the food-medicine interface** involving TGA, FSANZ, state and territory food enforcement and industry;
- **An exemption under section 7 that certain goods are not therapeutic goods** in relation to a set of sports supplement products, in harmonisation with improved compliance and Border Force mechanisms for 'lower risk' products. This would clarify a portion of food type products at the interface that pose the least risk to consumers without the need for them to transition to the therapeutic goods regulatory framework;
- **Collaboration with other bodies to effectively introduce or improve a voluntary scheme in relation to the WADA prohibited list** so that a subset of the sector may effectively compete to supply the needs to this sub-set of professional athlete consumers;
- **Or, a combination of the above,** ensuring that Australia remains safe but competitively poised to thrive in the global market.

Assessing Impacts on your Products

It is necessary to provide evidence that you have products that will be affected by this Consultation, either directly (and why) or indirectly (and why), and information or evidence on how this will affect your business and the consumers that take your products. CMA strongly recommends that businesses that manufacture or distribute products in Australia review every product for oral consumption within your range, using the TGA's Decision Tree which is included in the Consultation Document and reproduced in our Position Statement. OR the TGA's draft Declaration can be used.

Every product for oral consumption includes:

- Products sold under any FSANZ or NZ food standard (including Formulated Supplementary Sports Foods, Formulated Caffeinated Beverages and any other); and
- Any other health or nutrition product that is not already listed with the TGA.

Currently we are estimating a figure of around 40% of sports and health food supplements with health claims (directly affected) and 60-80% (indirectly affected). (*Please note Regarding the TGA's "Decision Tree", any products that are already in the Poisons Standard (such as prescription medicine ingredients) or with undeclared active ingredients would already be considered illegal or non-compliant, so such products, if or where they exist, shouldn't be included in calculations*.)

NOTE: If your product is captured by the descriptions in the TGA's proposed Section 7 Declaration (see the Declaration and/or the TGA's Decision Tree), your product would become a medicine (therapeutic good) even if it complies with any Food Standard (or is a traditional food). In other words, if a product met the description specifically outlined in a TGA Section 7 Declaration, it legally overrides any Food Standard, even if the product complies with that Food Standard.

Preparing a Submission to the TGA's Consultation

It is essential that affected businesses and interested consumers respond to the TGA Consultation to provide a thorough picture to Government. The TGA publish submissions if you give them permission. You may choose to give permission to publish part of your submission, and you can ask them to not publish parts of your submission that contain confidential or sensitive parts of your submission (eg about your specific products, business turnover or employee numbers). It may be easier to write a public and non-public section of your submission.

Submission responses can include any relevant information, such as:

- Information, views, evidence, and/or examples, to support or refute the TGA's proposed case for increased regulation. This could include specific product examples.
- Response to safety concerns stated by the TGA's consultation.
- Any perceived problems or issues with the proposed legislation, including how clear it is for everyday businesses to be able to follow the "food-medicine interface" and understand where your product is supposed to fit and how to comply.
- Alternative solutions to safe regulatory oversight of this sector while allowing businesses

to thrive, especially under Scott Morrison's Deregulation Taskforce goals. For example, the types of solutions mentioned in our Broad Policy Options.

- Any other relevant information on how consumers, business, the community, and Australia's economy is affected. For example, scientific and technical, economic, Government considerations, international obligations, business and consumer information.
- How you think this fits with the Scott Morrison's Government objectives of reducing regulatory burden for businesses and encouraging exports.
- Your technical and financial ability to transition to TGA regulations and TGA GMP manufacturing, and advertising and requirements for evidence (see above – Understanding TGA regulation of Supplements).
- Broader policy implications for Australia within global trade and commerce of this sector.
- It is important to identify specific benefits or costs to you, or even your suppliers or customers. These may be financial or non-financial. If possible, please attempt to quantify these costs and benefits on how this will change your business. Provide evidence where possible. This is important – the Government is required to quantify the regulatory impact (burden and/or savings) of any proposed changes.
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Members of CMA are welcome to mention their support for the CMA position statement/submission in their written response.