Complementary Medicines Australia submission to the Australian Government's Therapeutic Goods Administration consultation:

Proposed clarification that certain sports supplements are therapeutic goods

December 2019

To:

Sports Supplements Consultation
Complementary Medicines and OTC Medicines Branch
Therapeutic Goods Administration

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the TGA's consultation on the consultation and draft Section 7 Declaration that amends the operation of the Food-Medicine Interface ('FMI'), particularly in regards to products that promote mental or physical performance, or advocates use in sports or recreation. We also note the proposal has impacts on goods other than those specifically recognised as sports supplements, including a percentage that are currently Listed Medicines on the TGA's Australian Register of Therapeutic Goods (ARTG).

CMA is committed to a vital and sustainable complementary medicines and healthcare sector, and represents stakeholders across the value chain – including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. CMA advocates for industry advancement, including appropriate regulation that balances the needs of safe, high quality products with advancing the successes of Australian businesses and economy, locally and globally.

The consumer demand for complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare. Australia has also emerged as the leading exporter to China, over larger and more powerful global competitors. Over the last few decades the Australian complementary medicines sector has evolved into a world-class industry in its field, supporting domestic skilled jobs, research, manufacturing and exports. Our industry is reversing the trend of many local manufacturing industries, attracting manufacturing and investment in Australia, and it is critical that Government policy and regulation maintains a cautious, balanced approach that has served our industry and community well to date.

Summary Overview

It is commendable that issues of safety and quality of all supplement categories are under examination. There are areas where the food-medicine interface needs additional consideration and consultation.

CMA is concerned outlined in this submission include that the consultation, in trying to address certain concerns about a small percentage of products, has cast the net on products very in such a way that key goals on improving safety on a small handful of products are overshadowed by large unintended consequences; further, that the consultation and draft legislation does not meet community needs around clarity of policy and appropriate regulation of various product categories.

This submission focuses primarily on the policy, framework, and legislative issues. Our Position Statement provided to you and published on our website several weeks ago and attached to this submission focuses on the consumer, industry and economic effects.

A return to consultation would be welcomed with *four broad policy options* supported by a best practice regulatory approach.

Overview - Industry and Economic Effects.

The Government regulatory scheme must also be able to adequately serve the needs of consumers, businesses, and serve the growth of the industry locally and internationally. CMA is concerned that the effect of the consultation, whether implemented now or in the next few years, will have large unintended consequences on Australian businesses and the economy, without advancing or potentially worsening the safety of everyday Australians. It appears likely to hand an important sector directly to legal personal importation through e-commerce platforms that aggressively target Australian consumers online with low prices and rapid product delivery.

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.
4. It is 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.
5. 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.
6. 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 discussion on the above impacts and concerns are outlined in detail in our CMA Position Statement.

Overview – Policy Approach

It should be recognised that this short but major consultation has been confusing for the wider community as evidenced by not only engagement with industry members but all of the community evidenced by general and social media. such as goods that are already illegal (such as illegal prescription medicines), athletes' requirements surrounding professional competition when using supplements, as well as a major re-set to the Food-Medicine Interface, and includes duplication with other legislation, overall resulting in deep confusion amongst consumers, businesses, and the general community as to what products are changing, how and why. Separate policy concerns could be examined to some extent each on their own merit, this is expanded upon in this submission.

The details and breadth of proposed legislative instrument is highly complex in application, making it difficult for many who are not closely familiar with regulation to understand its impacts. It has also been confusing even for those that do, with various new but significant effects presenting themselves in the details over time, that were not immediately apparent.

One issue is the unintended inclusion and exclusion of goods from the Food-Medicine Interface.We have found that there have been very few experienced stakeholders who have been aware (outside of CMA advice) that a Section 7 Declaration specifying particular goods 'overrides' any FSANZ food legislation, even where those goods are fully compliant with a specific AU/NZ Food Standard. There have also been very few who have identified that this would *downregulate* a large number of undivided preparations that are already Listed Medicines. Due to this, it is unlikely that the Government will receive a full picture of the impact in this consultation.

In short, there are unintended consequences, ambiguity, confusion and a lack of clarity on certain aspects through this consultation that are seriously problematic considering that a change to the regulatory framework of any product costs a business many thousands or tens of thousands of dollars per product and may even impact the viability of their business and significantly affect consumer choice. These major framework regulatory changes cannot be made lightly.

It is also 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. There hasn't been sufficient consultation time to understand the full impact of this proposal on them as consumers, or as businesses to conduct a full assessment of how their products have been affected.

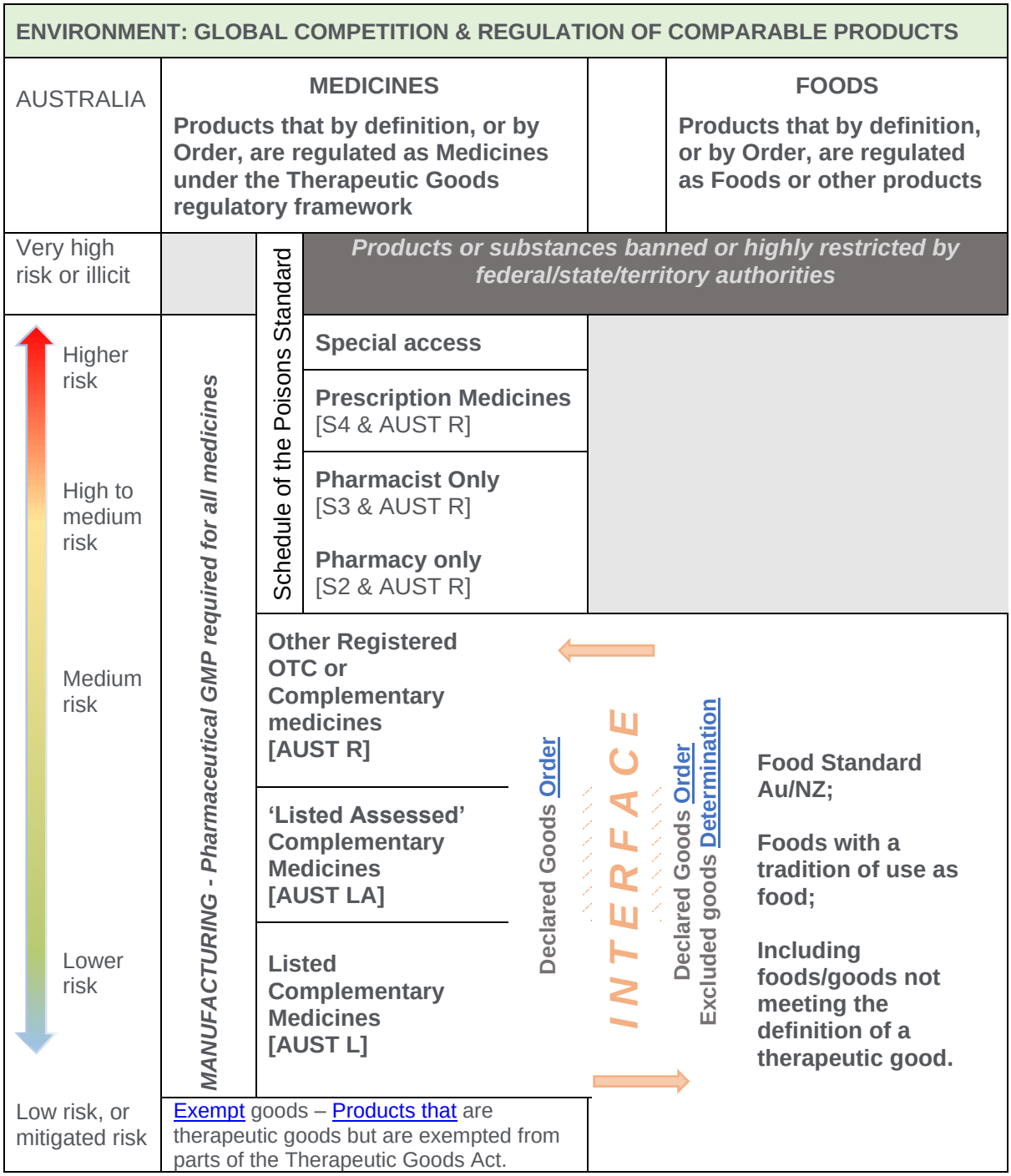
A Note on a Transition Period.

Much of the response to-date surrounding the community's concerns have revolved around providing a transition period. A transition is critical, following any agreed upon change to regulation, however a transition period does not solve many of the key policy issues outlined in response to this consultation.

Resolution of the key issues with industry and wider community first is key; we propose setting the transition period aside as a phase 2 consideration.

For context: the Food-Medicine Interface.

Figure 1. A Mind Map of Regulatory Interface of goods for oral use.



Fundamental Policy Issues with Consultation

The Government have a responsibility to provide an effective, transparent and accountable regulatory framework within which industry can work efficiently.

A core issue with this consultation is that the proposed legislative has duplicative aspects and mixes together a number of issues, is long, complex, and extremely difficult to apply particularly as it is not obvious to stakeholders that this document would take hierarchy over a number of products that are compliant with particular Food Standards (other than Standard 2.9.4 identified in the consultation).

The mixing of issues and the content of draft legislation has confused the community, as evidenced by the response to the consultation across media types, as to which products are affected and why. Mixing policy issues of illegal substances, athlete doping issues, with how to manage the food-medicine interface is confusing – the answer to illegal substances for example, does not automatically mean that many foods should be turned into medicines. The consultation has unfortunately not revealed some of the effects the intended legislation would have. The confusion applied in a regulatory context, is going to result in inadvertent compliance problems and costs that will tie up businesses in further difficult red tape and threaten viable operation, particularly for SMEs. Increasing difficulty in nderstanding and applying rules and increasing red-tape is moving in the opposite direction to the Government's principles under Treasury's Deregulation Taskforce.

We welcome a return consultation on how to best manage a modern, agile, FMI for all goods.

Table 1. Identified issues with policy approach in the proposed Declaration.

Issue 1. Unregistered products with illegal Scheduled medicines, including prescription medicines are already illegal.
Any product, whether food, therapeutic good, or other, that contains illegal prescription or Scheduled substances is already an illegal product subject to compliance and enforcement. The Government regularly apply enforcement controls to such goods at various interfaces in Australia and at the border. If there is any lack of clarity about how and why this is the case for certain substances, it could be addressed through improved Government guidance. It does not necessarily require that most products for mental or physical performance, or pre or post workout goals for example, need to come under medicinal controls. The mixing of this illegal substances issue with a change to the food-medicine interface policy in the consultation has been unnecessary and confusing. *If* it is necessary for the Government to clarify in legislation that foods containing certain Scheduled substances are medicines, that could be approached as a separate consultation and legislation to the FMI issue. Any foo product, not only a sport supplement, with a Scheduled substance may be considered a medicine. However there are other issues that need to be considered separately in such a consultation - for example, foods are permitted to contain a higher level of certain naturally occurring components (such as arbutin) than therapeutic goods, so this policy approach needs consideration as a separate item on its own merits.

Issue 2. Novel substances and Scheduling issues of novel substances.

The inclusion of two items in the Declaration are significantly problematic from a regulatory policy perspective:

- Item 1(iii) 'relevant substances' (four substances specified)
- Item 1(iv) – '*a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer.'*

These both act as a "defacto" style Scheduling mechanism outside of the Scheduling Policy Framework (SPF), which is Australia's national policy for applying restrictions on all "poisons".

The 'relevant substances' provision does this by making these substances "therapeutic goods" in the Declaration when they are not approved substances, thereby setting up a purposeful restriction on those substances to the community that cannot be appealed under any established legislative mechanisms. While it may be necessary to restrict certain substances to the community in particular ways, it is clearly unacceptable to do this within a Section 7 Declaration. There is a well-established national policy of restricting substances to different levels under the SPF that involves two specific rounds of community consultation, as well as recommendations by a Committee of experts before any decisions on increasing or decreasing restrictions on substances by the general community are progressed.

'Equivalent pharmacological action' (etc) groups together substances under a pharmacological banner, for which businesses cannot reasonably predict to what extent the Government might or might not consider it equivalent. This proposal is far too ambiguous and difficult as a regulatory concept for management by stakeholders to consider including in legislation, it 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 and those substances are appropriately Scheduled and regulated individually, not as a group.

The above inclusions in the proposal are trying to address a regulatory problem around novel substances, much of which should be dealt with through the SPF if appropriate. Outside of SPF, the question remains of how to approach novel substances, and the safety of novel substances, from both the food and medicine perspective. Food Standards Australia New Zealand (FSANZ) have an established approach to novel substances in foods.

For novel substances that should be *medicines* because they have a distinct pharmacological action that is not nutritive in nature, or are not naturally derived from foods (as caffeine is), there may be a better mechanism for approaching this policy problem that does not involve problematic policy approaches described above. For example, non-nutritive, non-naturally-occurring substances are unlikely to be a food, but are also unlikely to enter the SPF quickly. An alternative mechanism could be the development of a list of novel substances that are considered to be specifically medicinal, but which are noted as 'yet to be assessed' for either Listed Medicines or the SPF. In other words, their presence is transparently acknowledged as substances that are medicinal, but the purpose is not yet classified. This kind of approach would require a robust criteria to ensure novel substances appropriate for food regulation are NOT included in this list. Key issues for the wider supplements and sports industry are that:

- The process to assess novel medicinal substances must be rapid in order to remain internationally competitive and accessible, for Australian to remain globally competitive with the supplements market.
- The majority of substances available globally as dietary supplements should be made available to Australian consumers unless there is a specific safety issue, as consumers demand these products and will find other (sometimes black market) mechanisms to access them; it is safer to have them accessible and regulated within a scheme than operating outside of it. The ability to serve consumer demands by remaining competitive and innovative on the global platform is considered critical by the sports industry in particular and has formed part of the preference for the food regulatory system.

Issue 3. Professional requirements of athletes and anti-doping

Athletes have unique challenges in consuming any oral product under the strict conditions set out for them in professional competition. However, it is also clear that the Australian Sports Anti-Doping Authority (ASADA) cannot recommend that TGA-listed products are any safer than any other products.

The legislation refers to substances listed by the World Anti-Doping Authority (WADA) a non-Government foundation based in Canada. While regulatory decisions made within the Australian regulatory scheme (such as Scheduling medicines and poisons) might be informed by WAD information, the regulatory status of individual products in Australia cannot be determined by an international, non-Government body with a list that can change at any time.

Athletes are better served by a voluntary batch-by-batch certification scheme such as those that already exist – HASTA or Informed Sport – and an improved education campaign. This also benefits industry by allowing a subset of businesses to cater to this specialised, high value market.

Issue 4: Inadequately consulting with the consumer base on what they want

In regards to Items 2 and 3 above and the general confusion surrounding this consultation, 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 accustomed to and seek out.

An example of this includes thermogenic or metabolically stimulating (or 'burn') products, which have been identified as a target in media. The vast majority of these products will be ineligible to exist under the extremely stringent clinical trial requirements for weight loss related claims in the TGA's Evidence Guidelines for Listed Medicines. This is one of the most popular categories that consumers demand access to as part of workout expectation, even if the evidence is not based on a percentage of weight loss from a 3-6 month double-blind clinical trial. The elimination of this category in Australia may be seen as desirable to a small subset of stakeholders, but the large cohort of consumers who access these products purposefully have not been transparently informed that these products, and other products, will be ineligible and will disappear from shelves over time. They will turn to international e-commerce platforms for the same products, placing them at more risk after destroying the local industry. This is not a good policy outcome, and Government should not introduce changes without full transparency of effects to everyday consumers.

Issue 5: The premise of the consultation, does not reflect the nature of the consultation that it is not a clarification, but a change of regulatory status for many affected products at the FMI, and it is occurring out of step with FSANZ, who are currently reviewing the Formulated Supplementary Sports Foods Standard 2.9.4 under Proposal 1010.

It must be noted that the Food Standard 2.9.4 in the spotlight was developed to accommodate sports nutrition products. While there are a small number of products that may still have been considered therapeutic goods, the majority of those affected by the proposed Declaration have always been treated as foods as regulators in Federal State and Territory jurisdictions. The presumed premise that these products are already therapeutic goods and that therefore this is a "clarification" isn't, therefore, a meaningful argument to the affected sector except for a limited handful of products. Other 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 is currently proposed.

Food Standard 2.9.4 Formulated Supplementary Sports Foods is under review 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.

Issue 6: The premise that the regulatory status of a product can change based advertising, 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, a wholly unfeasible approach to product regulation.

Issue 7: Duplication of other therapeutic goods legislation and definition is inherently confusing

The legislation duplicates other requirements that Scheduled substances are therapeutic goods, as outlined in Issue 1 above. Another seriously ambiguous and confounding issue is the repetition of the core part of the definition of a therapeutic good in Column 3 of the instrument, which creates a hierarchy that makes a broader definition repeated and subordinate to a minimised definition, which does not make legislative or policy sense for stakeholders. Hierarchy:

Step 1. Therapeutic Goods Act – Definition of therapeutic good ("therapeutic use" etc).
Step 2. Section 7 Declaration, Column 2 – "*goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or any other recreational activity*"
Step 3. Section 7 Declaration, Column 3 – " *when the goods are used, advertised, or presented for supply: (a) for therapeutic use; or (b) in a way that is likely to be taken to be for therapeutic use*."

The proposal also clouds the ability of business stakeholders to understand when they can legally make a functional food with health claims. There are valid functional foods with health claims that will be captured by this proposal, affecting many large businesses (including our members) and small businesses all around Australia. These products will be open to legal and regulatory action for having a 'therapeutic good' even when they have a food which is a significant upregulation.

Fundamental Issues with Product Categorisation

The specific consultation and proposed Declaration should not move forward as there are a number of issues with regulatory product categorisation at the Food-Medicine Interface.

We welcome the re-opening of a broad consultative approach around the Food-Medicine Interface as its own topic and discussion, once the issues of already illegal goods and sports doping are set aside and dealt with appropriately as related but separate issues.

However, the current consultation should not move forward as, by focusing on only a sub-set of products (sports supplements) – independently of the FSANZ P1010 review – the proposed instrument has created a set of undesirable and in some cases unintentional upregulations and downregulations of product categories that are unable to be addressed with minor tweaks to the proposed Declaration.

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. If the FMI interface is to be re-examined for up and down regulatory effects, this needs to be performed properly and wholly for all goods existing closely on either side of the FMI to ensure a modern, unambiguous and successful platform for Australian businesses and consumers.

Table 2. Identified issues with product categorisation in the proposed Declaration.

The Consultation captures as medicines, products that were not intended to be captured or should not be captured.
The following product categories would be either unintentionally captured or captured in a way that makes it impossible for businesses to reasonably navigate. A. **Formulated Caffeinated Beverages of all kinds including soft drinks**. The application of the proposed Declaration means that many products compliant with the Food Standard – Formulated Caffeinated Beverages, including viable compliant products, even well-known soft drinks, would be captured. This is likely unintentional, but to carve out an exemption for soft drinks or similar would create a seriously problematic double-standard for these foods and other products due to the allowance of claims and substances. B. **Functional foods with acceptable food health claims**, that have naturally occurring plant- or animal-based compounds which would be considered to be captured by any of the many substance restrictions outlined in either the Schedules to the Poisons Standard (eg naturally occurring arbutin, coumarin, etc etc), the Permissible Ingredients Determination, or the Schedule to the Food Standard. This huge and complex interface becomes far too complex, messy and confusing for small businesses or even larger businesses to reasonably navigate.

C. **A number of sports nutrition supplements that should remain foods**. There are nutritive products that are not fully aligned to the Foods Standard specifications but which should remain foods. Some of these are waiting on an update and review of the Formulated Supplementary Sports Food Standard under FSANZ Proposal P1010. A particular example of this is a variety of amino acids, particularly branched chain amino acids, that are used either individually or as an addition to protein powders.

   Under the proposal, the unavailability of the substances in either the therapeutic goods framework or the food framework, means that substances and products that have been used safely and widely by the community for years or decades, become unavailable as certain nutritive substances are not approved in the quantities despite widespread and frequent safe use. The significant restriction of the quantity of these products will simply drive consumers away from Australian business to personal importation on e-commerce platforms.

D. **Certain types of tablets and capsules.** While the Declaration purposefully intends to capture some tablets and capsules and there are likely appropriate reasons for many to be captured, there are others that should not be. Examples include:

   - ✓ weight management of any kind, including sugar substitutes
   - ✓ recreational use that isn't therapeutic in nature
   - ✓ certain functional foods (e.g. chlorella) presented in tablet form, which are intended as nutritive food supplements, but could unintentionally be construed as being taken for therapeutic use by this Declaration.

The Consultation excludes as medicines, all or almost all oral powders, liquids (or other undivided preparations) that are already Listed Medicines on the ARTG.

As stated by the consultation, '*a product cannot simultaneously be both food and medicine in law.*'

The following products would **no longer be required** to be medicines:

- ✓ **Listed Medicines** (they do not exceed the ingredient restrictions) *that are*
- ✓ **Oral undivided preparations** - powders, liquids, etc; *and have*
- ✓ **Indications** consistent with the therapeutic uses outlined in the document *(which are all therapeutic uses due to the inclusion of the '(a) for therapeutic use; or (b), etc).*

This down-regulates all oral powders, liquids, etc, on the TGA's ARTG to foods. It is a very major regulatory change that 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.

This issue of itself requires a return to the consultative table at the broader policy level.

Position

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

- A modernised and globally agile framework and Food-Medicine Interface 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 they demand, while still ensuring safety and high-quality products.

CMA recommends:

1. **A 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.

Broad policy options

The first recommendation above includes consultation on *broad policy options* as outlined in "The Australian Government Guide to Regulation". Options 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**;
- **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.

POSITION STATEMENT

November 2019

Sports Supplements Consultation

In respect of the Australian Government public consultation by the Therapeutic Goods Administration, closing 3 December 2019: '*Proposed clarification that certain sports supplements are therapeutic goods'*.

Complementary Medicines Australia

Complementary Medicines Australia is the leading expert association exclusively committed to a vital and sustainable complementary medicines and complementary healthcare product industry. In 2019, CMA won the Association Forum's Award for the top Association of the Year, in recognition of its industry advancement and services to its members.

CMA represents stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, importers, consultants, retailers, allied health professionals, researchers and educators.

Complementary Medicines Australia promotes appropriate industry regulation and advancement to ensure that consumers have access to complementary medicines and products of the high quality and wide choice, whilst protecting, enhancing, and growing our industry both in Australia and globally.

EXECUTIVE SUMMARY

The Therapeutic Goods Administration ('TGA') has released a public consultation paper that specifically proposes to declare a change to the food-medicine interface such that specified kinds of sports nutrition supplements are clarified as medicines (therapeutic goods). The declaration would move a proportion directly into the therapeutic goods regulatory scheme under the *Therapeutic Goods Act 1989*.

Complementary Medicines Australia acknowledges the untimely and accidental death of a man from a concentrated caffeine supplement of unknown origin. We wish to ensure that the gravity of this tragic occurrence is welcomed with a commensurate and collaborative industry and Government response, without being overshadowed by disunity through consultation.

Working with affected stakeholders, it has become evident that the proposal as it stands will be unable to meet the needs of the sports nutrition community. Serving the demands of millions of consumers and contributing over a billion dollars to the economy, stakeholders estimate that the proposed change would remove at least 40% of existing products after implementation with a cascading or domino effect, due to manufacturing and other regulatory impacts, to 60-80% of the sector from the economy along with hundreds of businesses and thousands of jobs.

The supplements industry is in growth. It is not expected that the demand for such products by consumers will alleviate and it is expected that this loss of business will be handed to US and other international counterparts who serve Australian customers easily and rapidly through online portals with less oversight and care than local manufacturers and retailers. Specialty retailers are expecting that turnover will be affected such that they will be forced to close and remaining manufacturers and distributors will be stimulated to either close or move offshore to distribute through alternate mechanisms.

While the case for added regulation must examine any safety issues, under the current proposal an increase in use of the personal importation scheme due to international product availability and far lower prices will potentially have far more serious outcomes on consumer health and safety than the existing status. With a rare few exceptions that were not clearly linked to local products, there has to date been limited adverse events under common community use. The replacement of local businesses and retailers – those who directly engage with and understand the needs of the Australian sports and exercise community – with online international suppliers, will create unintended consequences with a limited ability to recover.

It is necessary to approach this consultation with due care. Industry seek a solution that will be responsible for consumers while meeting the Government's commitment on addressing regulatory barriers to invest, create jobs and grow the economy. A change of regulation to this degree requires involvement by state, territory, and local governments. CMA proposes re-examining the case for regulation under the Council of Australian Governments (COAG). Further, it is critical that a broad range of policy options is available in order to find a solution that will support the needs of committed Australian consumers and businesses who seek to thrive responsibly and safely.

Contents

Consultation

The consultation on sports supplements released by the Therapeutic Goods Administration is currently provided as a **Commonwealth consultation** and is proposing under section 7 of the *Therapeutic Goods Act 1989*, that a specified set of goods will now be declared as medicines.

- **Regulatory Impact Statement** (RIS): A requirement to assess the impact of the proposed policy on affected stakeholders is yet to be determined. Affected stakeholders include consumers and businesses such as retailers, manufacturers, sponsors, distributors. Costs and offsets of regulation need agreement by the Office of Best Practice Regulation (OBPR).

- **Timeframe**: Stakeholders have been given between **22 October and 3 December 2019** to respond. Stakeholders have provided that this timeframe is too short for both affected businesses and consumers to fully understand and respond to the wide implications.

Government Case for Action: why is this consultation occurring?

The consultation paper provides commentary on its purpose:

Regulatory scheme and governing body: The consultation proposes to amend the regulatory status of these products to address a stated uncertainty surrounding these products that currently sit at the "food-medicine interface" (see page 11). The consultation provides a view that certain uses of the products for performance in sports and exercise are "therapeutic" use, in which case, they should be regulated as "medicines" rather than "foods". Medicines have a very different set of Federal Government and State/Territory controls and requirements than foods.

Consumer use and safety: The consultation paper discusses concerns around consumer safety and proposes a mechanism to ensure that these products are *'regulated appropriately to safeguard public health and safety'*; including to address;

- Concerns or claims that some sports supplements have been found to include unlabelled or potentially dangerous substances or adulterants, such as, banned substances, prescription-only medicines, amphetamine-like substances, novel substances with a safety profile unexamined by Government authorities, substances prohibited in the list published by the World Anti-Doping Agency (WADA); or substances that occur naturally in food but in higher concentrations than found in traditional food.
- Concerns associated with a presumed level of under-reporting of adverse events.
- Claims or reports of adulteration of such supplements with either substances banned in sports, stimulants, or other substances.
- Concerns that consumers might be using products inappropriately or using too many.
- Concerns that sports supplements may have played a role in recent deaths, such as the death of a woman with an undiagnosed metabolic disorder to process a high protein diet.

Complementary Medicines Australia – Overview Assessment

Clarification to, or Change of Regulation?

The consultation paper raises that this is a clarification of the food-medicine interface. However the proposed Declaration includes reference to products that would *already* be considered therapeutic or illegal goods under existing legislation, notably, products with scheduled substances in the Poisons Standard. Therefore such products have not been included in any impact considerations discussed in this Position Statement.

The consultation and proposed legislation is clearly declaring a *new and specific* set of products to be captured as therapeutic goods, of which many to date have been accepted as *Formulated Supplementary Sports Foods* (FSANZ Food Standard 2.9.4) or other types of foods.

The food-medicine interface has been sometimes challenging to navigate, however, the regulation has remained relatively stable for many decades, with only a very small percentage of products being approached to change from one category to another. Consequently, the proposed Section 7 Declaration is viewed by the sports supplements industry not as a clarification but as a very specific change in policy, as it changes the regulatory framework for these goods. This will have far-reaching impacts and ramifications for consumer availability of products as well as the ongoing sustainability of maintaining businesses.

Discussion around the responsible use of supplements must occur with all affected stakeholders in the community with sufficient time to understand any implications, including a loss of available products to retailers, health care practitioners, nutritionists, and personal trainers.

The proposed Declaration overrides Food Standards and traditional foods

When the proposed Declaration's description applies to a product, it has the effect of legally overriding any AU or NZ Food Standard, or other product supplied as a food. Therefore the scope of the consultation, as it worded very widely, appears to not only override products currently sold as *Formulated Supplementary Sports Foods* (Standard 2.9.4) but has the scope to capture a wide proportion of health foods and products in other standards, including *Formulated Caffeinated Beverages* (Standard 2.6.4). This would increase the impact by tens or hundreds of millions of dollars, and further remove the ability of the community to access existing products.

Regulatory Harmony for Businesses & Consumers – Local & Global

There is some interaction in the sports supplements space with other complementary medicines that are listed with the TGA, although they are often viewed as often differentiated consumer segments in retail presentation and supply. Overall, the role of regulation between sports supplements, listed complementary medicines, and other food and nutrition products must not be rushed, must be coherent, and discussed in detail with the breadth of stakeholders, particularly industry – as issues of regulation and over-regulation are becoming magnified as all such consumer goods are now extremely sensitive to global e-commerce trends.

The Case for Regulation – Safe Supply of Sports Supplements

Complementary Medicines Australia and the wider Australian sports supplement community support responsible use of supplements, whilst maintaining the ability to meet consumer demand and compete internationally. This is not automatically commensurate with a large change in regulation that will have highly significant impact. Any case for regulation demands full examination of the issues. Below is a summary of several issues presented by consultation.

- **ILLEGAL OR BANNED PRESCRIPTION MEDICINES, OR UNDECLARED TOXIC OR DANGEROUS SUBSTANCES OR PROHIBITED LIST OF ANTI-DOPING SUBSTANCES**

Such products are already are already illegal or subject to Government compliance and enforcement. Proposing regulatory actions against products that have either undeclared substances or substances that are banned or restricted by a Schedule in the Poisons Standard (such as Prescription medicines), are not a new protection. This status could be made clearer in Government guidance, rather than duplicated in law, confusing other issues under discussion.

- **INAPPROPRIATE USE OF PURE OR CONCENTRATED CAFFEINE**

While foods have not to date expressly prohibited higher strength caffeine, this is currently under an urgent declaration at a proposed maximum limit of 5%. Medicines have never been able to provide a source of concentrated caffeine, but recent regulations further restrict any allowances for caffeine to under 100mg per 3 hourly dose and between 1–4 % concentration in powders and liquids. This is *less* than a strong cup of coffee or a formulated caffeinated beverage.

As mentioned earlier, the proposed declaration also has the capability of overriding the status of other food products, including Food Standard 2.6.4: *Formulated Caffeinated Beverages*. If the consultation is reworded to exclude these products, another possible unintended consequence of that would be that some existing supplements would re-formulate under this Standard, which increases the risk of excess consumption. Both alternatives highlights concern with the provision in the TG Act that permits legislative incompatibility and ambiguity for industry stakeholders by declaring products as 'medicines' when they are otherwise permissible under Food Standards.

- **ANABOLIC STEROIDS OR ANDROGENIC ACTIVITY**

The consultation refers to a particular paper which alleges 6 out of 112 supplements available in Australia contain substances with androgenic activity. It isn't clear which of these supplements were purchased online, whether those online purchases were from overseas websites, or even whether the androgenic activity could be directly attributed to a Scheduled or pharmacological dose of anabolic steroids. This is of relevance as industry stakeholders provide that it would simply be economically unfeasible to provide steroids in supplements that cost approximately one third of the price of the raw material price of anabolic steroids, and therefore, that this issue is a plausible case for wide up-regulation. The evidence and reasoning requires further product analysis by Government in order to justify the case for change. If contamination is occurring, it may be through certain sites with products that are identifiable at particular price points, for which there will be other solutions than a large increase of regulation for a wide category of goods.

- **SUBSTANCES THAT OCCUR NATURALLY IN FOOD BUT IN HIGHER CONCENTRATIONS IN SPORTS SUPPLEMENTS**

This is a key category that the sports supplements wish to retain under existing regulatory frameworks or a similar approach, based on widespread and common use, with the key example including the use of certain amino acids. The proposed framework under the Declaration would not permit these products due to substance restrictions or lack of specific approval and therefore availability, despite evidence of widespread safe use to date. The sector is opposed to taking such a drastic upregulation in relation to these types of goods which have been typically considered nutritional products. It is worth noting that many other products in Food Standards also commonly contain substances in higher concentrations that naturally occur in foods.

- **NOVEL SUBSTANCES**

The use of novel substances is a regulatory challenging category that needs further examination in light of local approaches to novel substances under both food and TG regulation, as well as global approaches, while ensuring a level playing field across all categories. The sector have expressed that in order for the sports supplement consumer goods segment to compete against global players, it is critical that Australia is capable of maintaining timeliness in innovation.

Bypassing the Scheduling Policy Framework

The proposed legislation includes a provision to restrict "**relevant substances**" determined at the TGA's discretion. This hands the Government the power to rapidly restrict substances with minimal community or expert consultation. There isn't an application mechanism to have them removed from this list. Such a proposal inappropriately bypasses normal mechanisms under the **Scheduling Policy Framework**, which '*sets out the national policy for applying access restrictions on all "poisons'"*[1], and is a relatively robust Government mechanism to increase or decrease restrictions on any substances in demand by the community.

- **TABLETS, CAPSULES & PILLS**

The capturing of tablets, capsules and pills as 'therapeutic goods' when presented for sports, exercise, recreational or other therapeutic use, could capture a wide amount of tablets, capsules and pills that is not intended, and many businesses in the food, listed complementary medicine, and sports supplements space are strongly opposed to the inclusion of this as it is presented. If it is acknowledged that other foods and nutrition products can be capsules tablets or pills, then it does not automatically follow that certain sports nutrients are automatically medicines if they tabletted or encapsulated. The similar TGA consultation in 2009 adequately captured the extensive regulatory issues with capturing this wide category as therapeutic goods.

[1] Therapeutic Goods Administration Scheduling Basics webpage: AHMAC - Scheduling policy framework for medicines and chemicals, 18 January 2018

An overview of interface between foods and therapeutic goods schemes.

The consultation has stated a primary goal of clarifying a set of goods that are currently close to an interface between different regulatory frameworks. To understand the estimated impacts to the sector described in this paper, it helps stakeholders to broadly understand this interface.

Figure 1. Mind Map of current Regulatory Interface of goods for oral use.

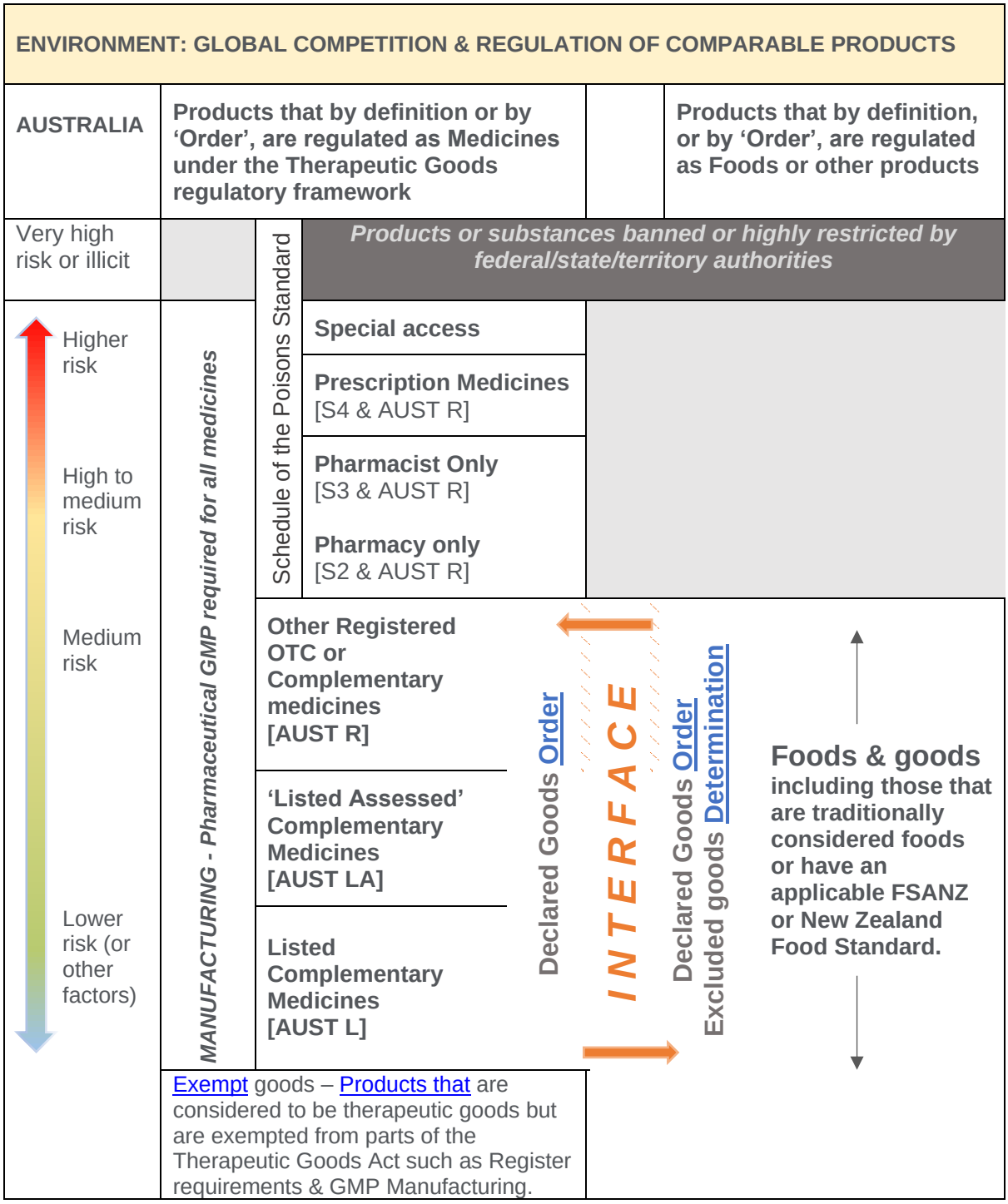
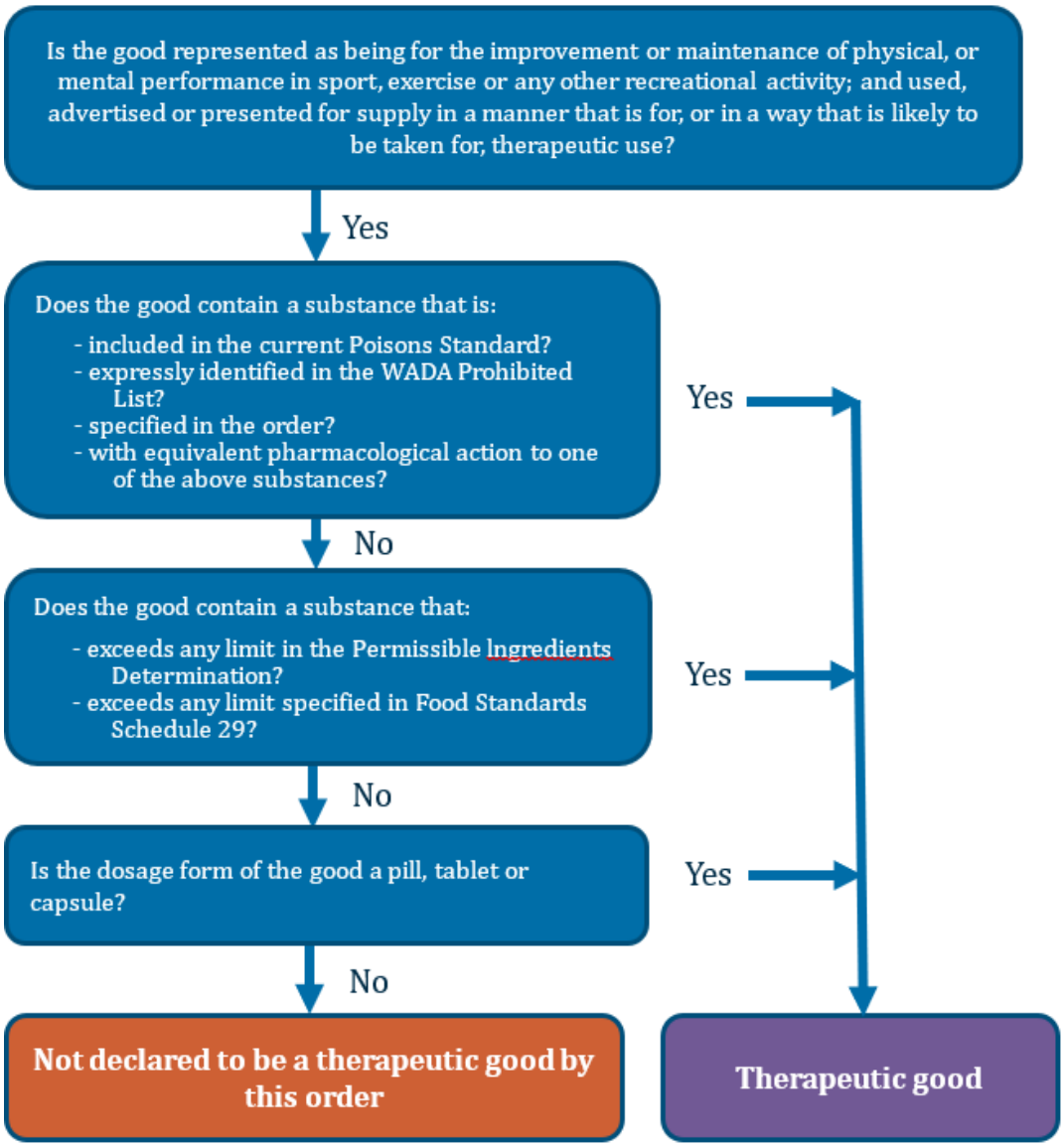


Figure 2. TGA Decision tree[2] (Products intended to be declared therapeutic goods)



Remaining non-therapeutic-goods:

- Oral powders or liquids within substance specifications of FSANZ Food Standard 2.9.4
- Oral powders or liquid that contains a substance approved by the TGA for listed medicines if in unrestricted quantities - *with or without* therapeutic/sports claims (NOTE)[3]
- Tablets capsules pills *without* any sport or therapeutic claims or implied presentation.

[2] Australian Government – Therapeutic Goods Administration - *Consultation: Sports supplements; Proposed clarification that certain sports supplements are therapeutic goods*; Version 1.0, Oct 2019
[3] NOTE clashes with current regulations that enables certain therapeutic powders/liquids on the TGA ARTG.

Figure 3. Products captured by the proposed legislation. (*Note: not including any goods already considered illegal, e.g. are in a Poisons Standard or contain undeclared substances*).

Products that will be **unable to transition**	• All products that are currently available through FSANZ/State/Territory food laws, but whose key substances or quantities are unavailable through the TGA list of Permissible Ingredients or Food Standard limits. • The TGA framework would not currently able to accommodate the needs of these products or transition ingredients into the framework.
Products that may be able to transition with **reformulation into therapeutic goods**	• Many products will be unable to transition to or find a TGA GMP licensed manufacturing line capacity. • Cost of goods under TGA regulation expected to increase 2.0x or more. • Many products will not survive the price competition with overseas websites supplying higher potency, lower price, higher claim goods for import. • A number of nutrient products likely to fail to transition due to stringency of TGA evidence guidelines and inability to develop desired products.
Limited products that may be able to transition by reformulating to **powdered/liquid supplementary foods**	• Reformulation away from tablets/capsules reduces consumer choice, further driving to overseas products. • Formulated Caffeinated Beverages as an alternative remains under question in this consultation. • Reduced desired substances and potency will drive customers to overseas e-commerce platforms.

Snapshot of Impact to the Australian Community

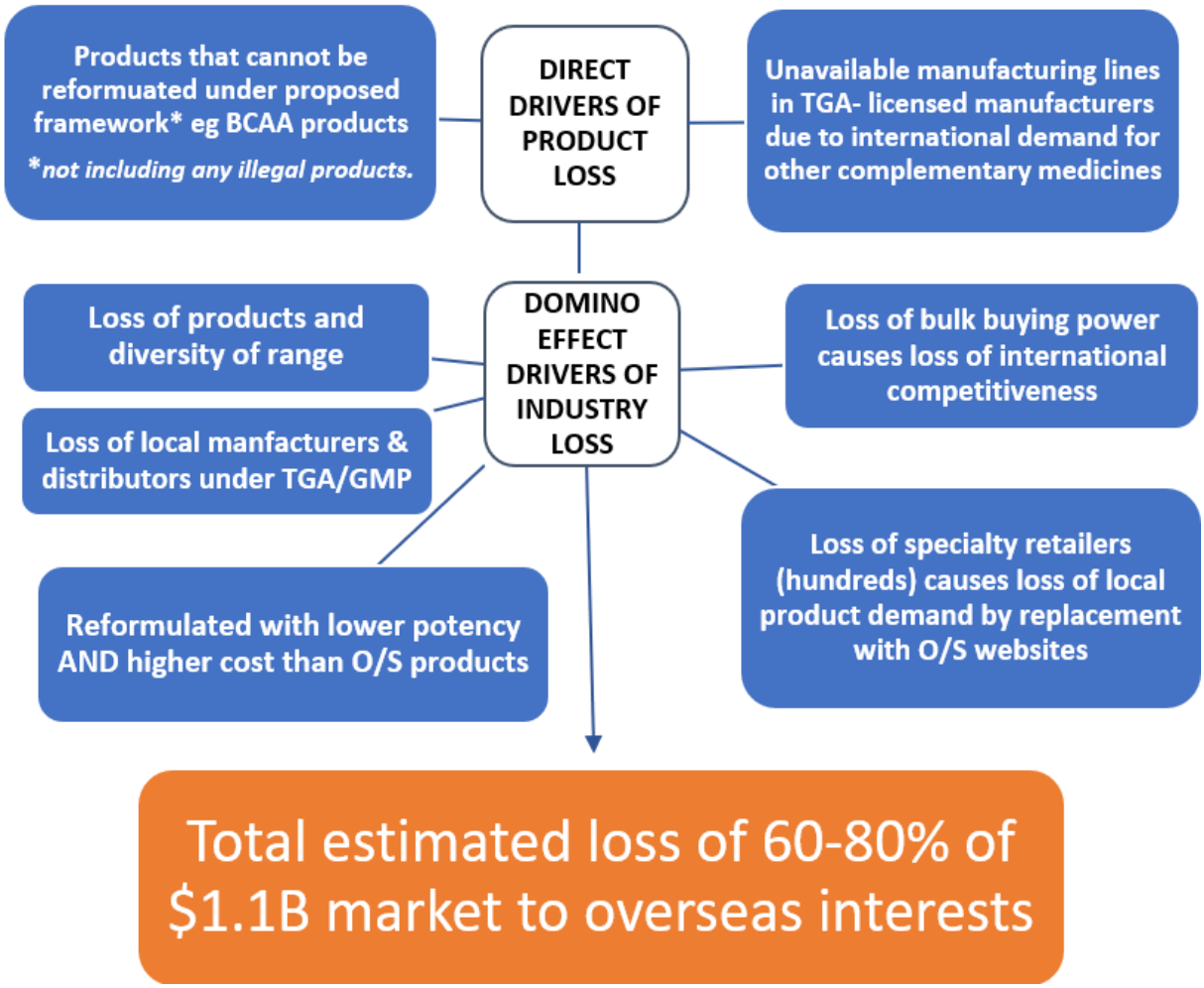
A brief overview of the expected impact is included below based on industry member feedback. The sector widely support safety and Government discussions through appropriate consultation, but it is important to explore the impacts of the "single option" presented. We urge the government to return to a suite of broader options under COAG consultation, and to conduct a thorough impact assessment so all direct and indirect costs to consumers and businesses, are quantified under the Regulatory Impact Assessment and Burden Measures framework.

SNAPSHOT: PRODUCTS

An immediate loss of around 40% of products, with a domino effect of up to 80% from other losses – such as retailers, exporters, bulk buying power.

The impact has been estimated by CMA based on feedback from industry stakeholders using the above TGA Decision Tree and estimating how it intersects with the dominance of current product types (for example, branched chain amino acids are a prominently affected category).

Figure 4: Snapshot of Impact. NOTE: There are potential additional impacts to other health food products or Food Standard products not included in the below.



SNAPSHOT - CONSUMERS:

Unintended or unknown safety consequences from personal importation from accessible online websites; and a loss of support from local retailers.

Due to the extensive and wide-ranging effects on suppliers described below, consumers will largely turn to international suppliers of sports supplements to retain access to the supplements they demand, with the presentation that they seek and at a price point they can afford. As sports supplement specialty retailers close, all consumers will be driven to using these platforms from even less regulated jurisdictions, creating more significant safety issues than that which the consultation proposes to address. Retailers in particular are closely involved in their communities and take great care with product recommendation, unlike international online platforms.

SNAPSHOT: SUPPLIERS, MANUFACTURERS, DISTRIBUTORS:

A loss of between 25% - 100% has been estimated by these businesses.

This includes business reductions and closures as well as offshore relocations. Sponsors, distributors and suppliers will be hard hit by the loss of products and retailer customers, and will have significantly reduced ability to effectively compete in the global market to serve the demands of customers, who seek the combined factors below to remain loyal customers:

1) Ability to deliver the desired substance & quantity
2) Presentation meets expectations
3) Price point; and
4) Diversity of offered range (ability to purchase multiple products together).

Possibly the hardest hit will be Australian manufacturers, who are largely unable to transfer to pharmaceutical level GMP, either inherently or on a cost-recovered basis, and who will lose key bulk purchasing power that enables competitive success. Local manufacturers supplying products globally risk losing significant and growing export market share as they will either close, or move off-shore so they may compete by distributing under personal importation.

SNAPSHOT: RETAILERS:

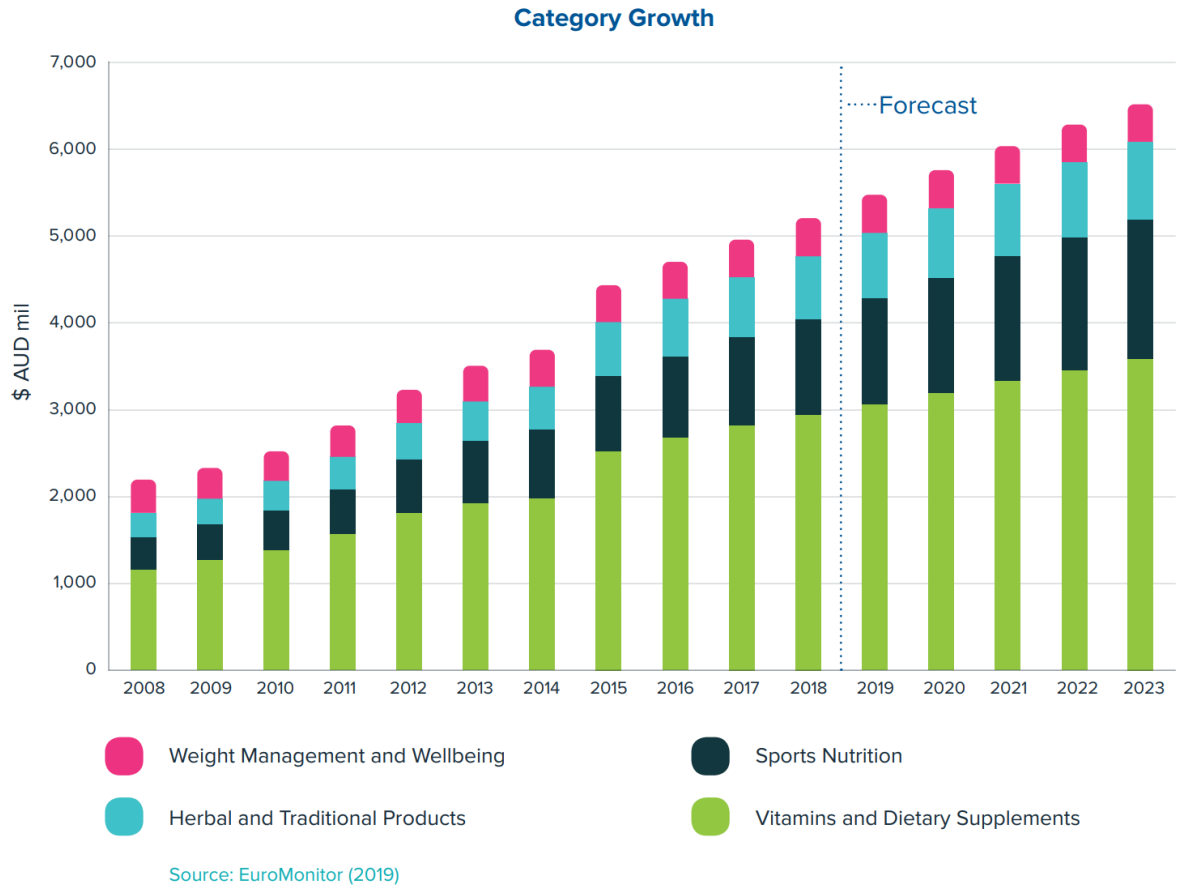
250-400 specialty stores with a projected 50 – 90% loss of outlets.

Current estimates are that, of the hundreds of specialty retail outlets that solely or primarily supply sports supplements, will face closure rates of between 50 – 90% due to a significant loss of product on shelves, and an attendant lack of turnover to meet minimum overheads. It is expected to be accelerated by consumer expectations in this category to purchase a range of supplements (such as 3-5) at one time to meet their needs and performance demands. Therefore the loss of a single product sale can represent the loss of 3-5x sales due to consumers seeking a one-stop shop through international e-commerce websites. This adds to the domino effect collapsing Australian small business outlets.

Background to Impact – A sector snapshot.

Below are figures derived from Euromonitor scan data of product sales. The industry sector, based on their knowledge and available turnover figures, believe that the below figures are conservative, and they do not capture all other products that may be impacted by the proposal.

Figure 4. Sports nutrition/supplements category relative to other categories*.



*Note that the weight management category includes products that would be captured within the sports supplement sector.

Figure 5. Growth of total market for sports supplements in preceding 10 years[4].

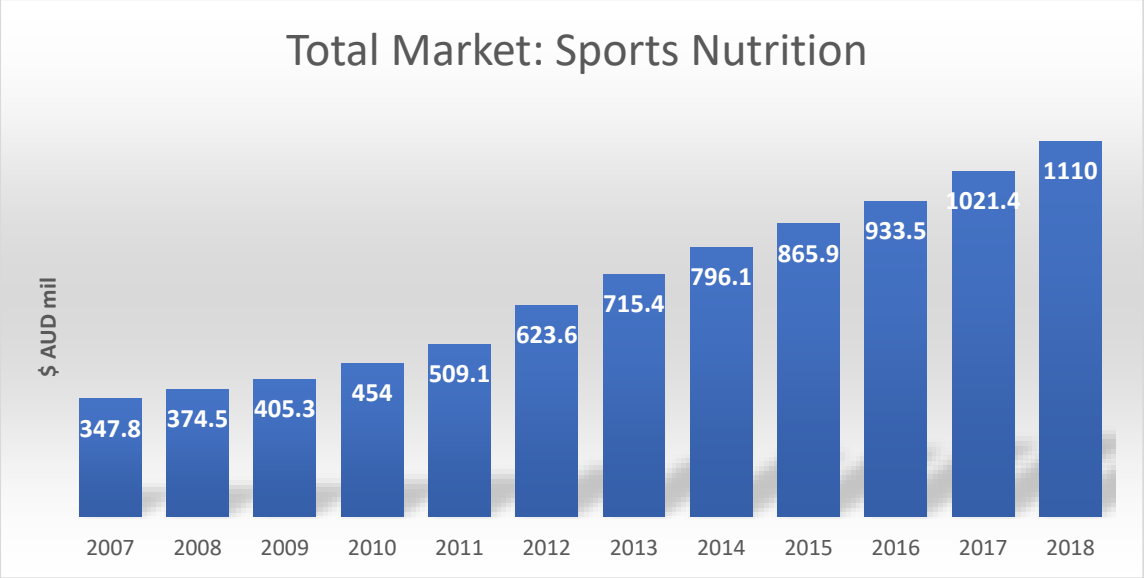
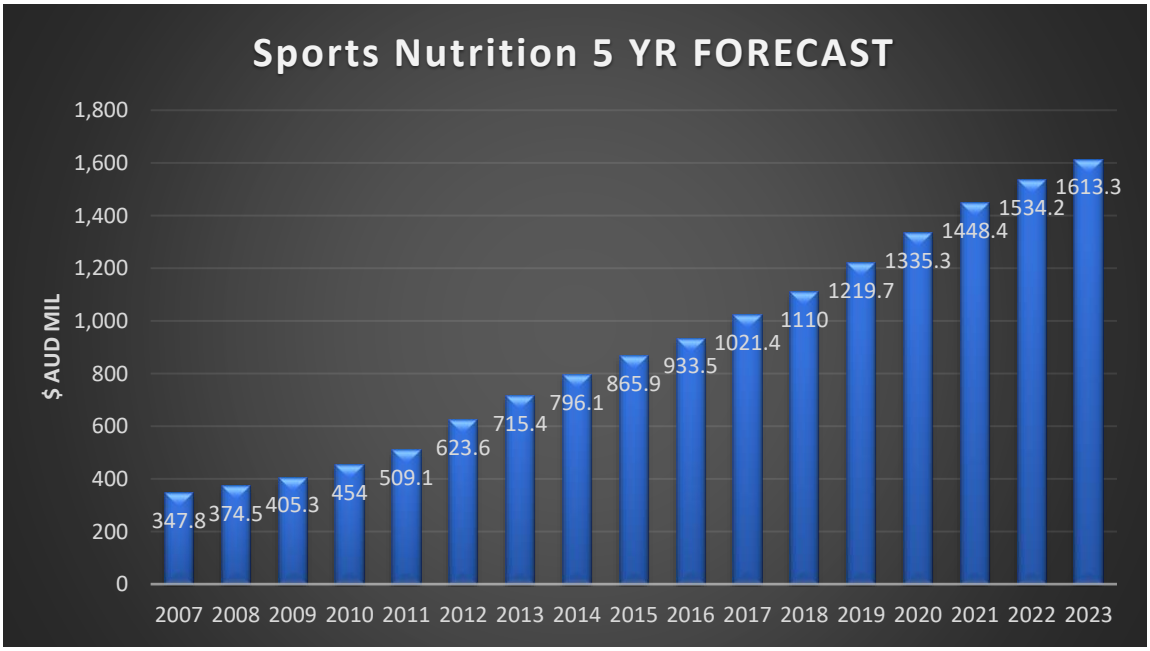
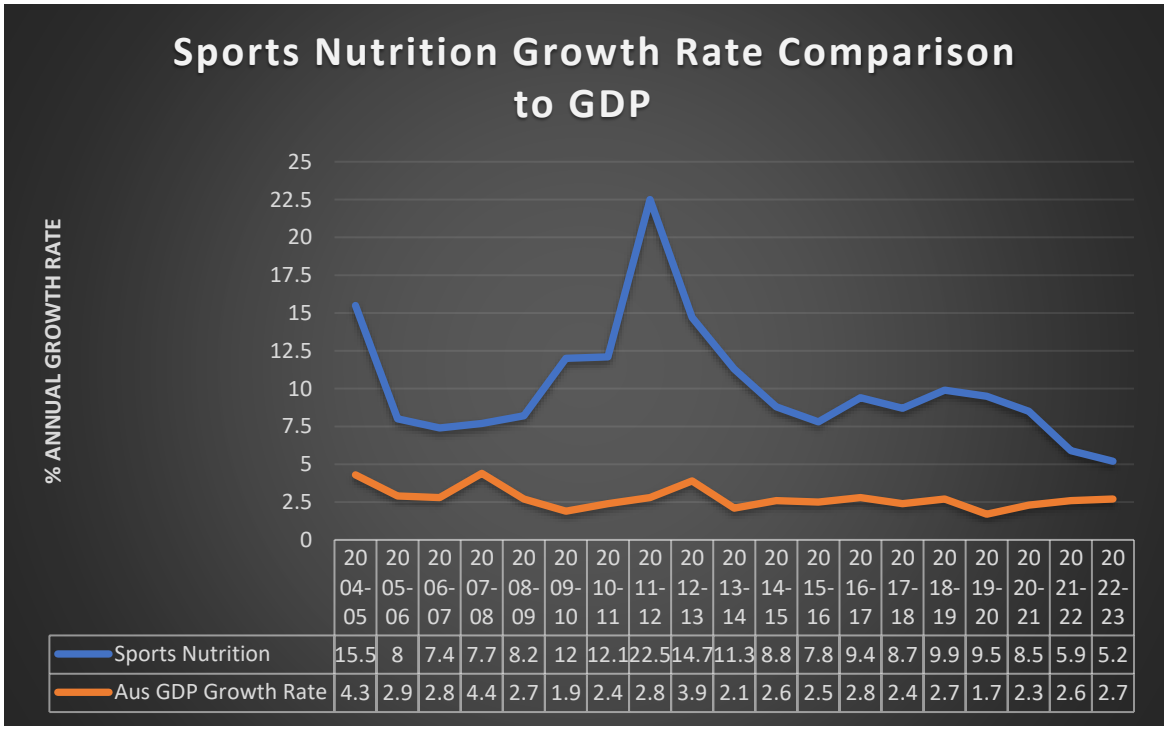


Figure 6. Projected 5 year forecast for the sports supplements sector[5].



[4] Euromonitor International Australia (2019), Complementary Medicines, Market Data 2017-2018, Sydney: Euromonitor International Australia.
[5] 5 year nominal Euromonitor forecast.

Figure 7. Growth Rate of sector relative to GDP, 2004 to 2023 (projected)[6].



	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23
Sports Nutrition	15.5	8	7.4	7.7	8.2	12	12.1	22.5	14.7	11.3	8.8	7.8	9.4	8.7	9.9	9.5	8.5	5.9	5.2
Aus GDP Growth Rate	4.3	2.9	2.8	4.4	2.7	1.9	2.4	2.8	3.9	2.1	2.6	2.5	2.8	2.4	2.7	1.7	2.3	2.6	2.7

[6] GDP data from Australian Bureau Statistics data and the 5 yr forecast from IMF

Regulatory & Cost impact of increased regulation on transitioned products

The complementary medicines sector in Australia has experienced a large increase in demand internationally, which has significantly impacted the availability of manufacturing lines in TGA-licensed GMP facilities in Australia and accredited facilities overseas. This has severely limited the ability of the existing complementary medicine industry with products on the ARTG to innovate smaller batches of product and do small product runs. Smaller businesses are already being turned away from capacity at TGA GMP contract manufacturers. In short, there is simply not the manufacturing capacity to absorb additional products within the sports supplement space.

Nor are purpose-built Australian manufacturers of sports supplements equipped to meet the demands of the TGA GMP licensing scheme. This severely and significantly restricts the capacity for Australian businesses to conduct normal product development and meet the market. Due to the extremely limited availability and therefore competition for manufacturing lines in TGA GMP certified manufacturing facilities, this cost could rise higher.

Based on estimates from manufacturers experienced in both the food space and the TGA GMP space, it is estimated that the cost of goods will be 2-2.5x higher than existing production.

Table 1. Cost/impact comparison of manufacturing a product as a Medicine or Food.

TGA Requirement	Food Requirement
Requirement: Comply with TGA Federal GMP Manufacturing Licence. Very difficult to achieve for new and existing food supplement manufacturers. High level PIC/S GMP requirements: Analysis, Validation and Product Quality Reviews on a regular basis, Cleaning Validation, Stability protocols, Calibration, Air handling management, very high documentation requirements, specifically qualified personnel with training in GMP/QC.	**Requirement:** Local State/Territory Food Authorities – generally a notification to food authority. Facility requirements are HAACP – Cleaning Certification and others basic requirements commensurate with risk management.
Inspections: Regular high level GMP inspections and associated high costs and resource implications through TGA.	**Inspections**: Minor cost, minor interruption of workflow.
Resource: High even for low risk (listed) medicines.	**Resource:** Low and generally commensurate with level of risk.
Ingredient cost: Must use pharmaceutical grade for all ingredients – usually 2x or more the cost of food grade ingredients. E.g., gelatine, sugar.	**Ingredient cost:** Food grade ingredients – acceptable quality but lower cost.

IMPACT – Adverse consequences on products and businesses.

The proposed declaration under section 7 of the Act provides the incorporation of products under the Therapeutic Goods Act, when these products for sports, exercise or recreational purposes have to date, with few rare exceptions, not been regulated or enforced as medicines.

Four of five case studies in the consultation are acknowledged as potentially falling under Food Standard 2.9.4 Formulated supplementary sports foods (with the fifth case study proposed to remain a food – whey protein). Excluding any products that may already be illegal (such as undeclared or Scheduled substances), the therapeutic goods regulatory scheme remains currently unable to accommodate many of the existing top selling sports supplements that have been regularly used for many years, due to substances or doses that have been used safely by many consumers in existing products not having been assessed by the regulator for use in medicines that are included on the listed (low risk) part of the Register.

There are many unscheduled substances in use that have not been considered for the purposes of section 26BB of the Therapeutic Goods Act- the 'Permissible Ingredients Determination'. Ingredients take years of development to enter into this process and further take lengthy evaluation and approval times, before product development could even begin.

There are significant implications here if the Government were to consider access to and continuation of the existing lower risk products currently considered foods. The TGA would have to undertake assessment of new substances as cost-recovered work – no single business would be liable to submit a new ingredient application to transition. TGA evaluator resources and their ability to maintain business-as-usual would come under threat, and industry would not have any assurance that the substances would pass the assessment.

Further, as outlined above, the manufacturing sector and the sports supplement sector are not currently able to accommodate the number of sports supplements available into the existing number and size of GMP facilities. There is currently not the manufacturing capacity or timeframe available in licensed GMP facilities to support the influx of such products, further, extended development timeframes would be expected. GMP manufacturers have been at capacity to an extent that contracts for existing products listed onto the ARTG as part of the therapeutic goods scheme are already being refused for further batch production due to exceeding of capacity.

In addition to the above, manufacturers have been considering commercial decisions on facility development based on local and international regulatory frameworks. These facilities and attendant regulatory compliance obligations take many years to set up and are at risk where there are large-scale, short time-frame proposals such as this announced.

As the therapeutic goods regulatory scheme nor the number of licensed GMP manufacturers currently are expected to be able to support these products, the current single consultation option has been seen as the presentation of a pre-disposed policy outcome with high loss on businesses, job, and Australian domestic and global trade, but which do not address the issues that occurred with the tragic caffeine overdose of a young man. As described earlier, there may

be interactions with this particular proposed legislation, market forces, and the Formulated Caffeinated Beverages Standard in unintended ways that haven't been fully considered as to the policy and safety.

Australian suppliers, manufacturers and sponsors of these products would be stimulated to move offshore to the USA or other jurisdictions and continue to supply consumers on an equal playing field with existing international competitors. This scenario creates a net economic loss for Australia, with little difference to consumers except that products are purchased online with far greater frequency than instore.

Whether the change is ultimately considered a change or clarification, it remains clear that there will be a very significant impact that requires proper Government analysis and assessment considering the widespread implications, which deserve application of best practice regulatory principles of four broad policy options considered feasible by stakeholders, including a Regulatory Impact Assessment with Regulatory Burden Measurement and offsets if and where any increased regulations are proposed to apply.

For New Zealand, see below on NZ & the Trans Tasman Mutual Recognition Agreement.

IMPACT – Adverse consequences on consumers.

Based on sector feedback, the following adverse consequences and adverse impacts are expected upon consumers:

- Consumer dissatisfaction over unavailability of in-demand products; change in form (reduced availability of tablets and capsules); increase in price of in-demand products in Australia, with cost of goods expected to double.
- Significantly increased use and reliance on international websites for product supply, with less regulatory and safety oversight than locally manufactured goods. Higher risk of inappropriate purchase and use of sports supplements.
- Consumer dissatisfaction at significant reduction in Australian manufacturers and suppliers and the inability to support Australian Made as these products become increasingly unavailable and manufacturers close or move offshore.

The key concern is that the implications of the policy proposal will not have the intended effects of protecting consumers as it aims to, for the reasons that a variety of products that are highly sought after will become unavailable in Australia. Consumers of sports supplements generally demand a suite of around 3-5 supplements to complement their fitness routines, which may consist of a pre-workout formula, a metabolic supplement, a recovery tonic and a protein supplement. Consumers will be unable to access the range of in-demand products at retailers. As cost of other goods rise, ranges shrink, and retail outlets close, all consumers will therefore be driven to importation from already accessible and prominent websites as their one-stop shop for supplements.

Personal advice and support from trained and experienced staff working in retail outlets will no longer be available and consumers will rely solely on internet supply from international providers, which heightens their safety risk.

The chance that a concentrated form of caffeine came from personal importation of an international product, where such products abound, is far more likely than it coming from a local manufacturer or distributor, especially under new changes[7] announced by FSANZ and the TGA.

There is also the policy issue as many Australian goods captured by the reform are currently operating in a competitive space with each other, providing better price availability to consumers. Australian consumers must be able to access products at an affordable price point, as well as a competitive price point relative to our international competitors. It is important that the cost of supplementary or functional food is affordable and accessible to all in the community. Price-conscious consumers or those seeking specific products should not be stimulated to risk their health with unknown and varied international online suppliers.

IMPACT – Adverse consequences on retailers.

Retailers have expressed that there will be a high risk to the survival of specialty sports supplement retailers. The owners of these specialty stores are dedicated to the sports and fitness industry and will likely be devastated by the impact to their small businesses. We place a conservative estimate based on feedback to date at around 250-400 specialty stores, but more may be implicated.

Retailers are facing incredible stress under current economic conditions. While we predict the reduction of around 40-80% of existing products over the short to long term, even a conservative reduction of 10-20% will create such disruption to a retail turnover that it is likely to cause immediate job losses and probable loss of the survival of most specialty sports retail outlets.

Whilst retailers have some option to try and diversify, this is firstly risky and secondly, it moves into the retail operating space of other retailers, including health food stores and other specialty retailers who are also struggling to survive in a retail environment now overshadowed by a global economic downturn and alternative e-commerce options for consumers.

Spending time in some of these specialty sports supplements stores demonstrates that the business owners and employees provide a specialised and valuable service to their customers. Like gymnasiums, they are often a hub of activity for those in the sports and exercise community, and that this will be another loss for consumers replaced by globally dominating e-commerce platforms.

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[7] Therapeutic Goods Administration - High-moderate risk changes to permissible ingredients – Caffeine, 3 September 2019.

Alignment with the Government's De-Regulation Agenda

The Deregulation Taskforce is being held by the Department of Treasury, and, for example, includes 'reducing regulatory burden for food manufacturers with an initial focus on exporting'.

The press release by the Morrison Government of **12 September 2019** announced the first three priority areas for its Deregulation Taskforce:

- 'The Taskforce will work with state and territory governments, and businesses themselves, to identify and address the most significant **regulatory barriers** to investment for selected industries, to continue the Coalition Government's commitment to reduce red tape and unnecessary regulation, making it easier for businesses to invest, create jobs and grow the economy.
- The Taskforce will walk in the shoes of business, collaborating with them and states and territories on three key priorities including reducing the regulatory burden for food manufacturers with an initial focus on exporting, making it easier for sole traders and micro businesses to employ their first person and getting major infrastructure projects up and running sooner.
- A better regulatory environment will help businesses lower their costs, save time and improve their competitiveness, while major infrastructure projects will help get us home sooner and safer. The Taskforce will pay particular attention to the degree of regulatory complexity, the length of time for approvals and duplication across levels of government.'

The **Deregulation's Taskforce Terms of Reference** relevantly include that;

Working with governments and business, the Deregulation Taskforce will outline high-priority areas for reform to address unnecessary regulatory barriers to investment in Australia, focussing on key sectors and activities for in-depth examination on a rolling basis. In doing so it will identify:

- the **main regulatory barriers to investment and to new business models** from the perspective of business;
- the **degree of complexity and length of time** regulatory approvals and appeals processes take; and
- **duplication, interaction and cumulative burden of regulation** imposed within and across Commonwealth, state, territory and local jurisdictions.

Resources:

Deregulation Taskforce review homepage

Treasurer Press Release: Delivering Deregulation for Australian Business

Deregulation Taskforce Terms of Reference

Industry Sector Reaction and Response

The sector have viewed the current consultation, with a single policy option as a set outcome, which doesn't examine the range of policy options that are open and available to Government, as insufficient to examine the issues at hand or meet the needs of community and businesses. In particular, affected industry members feel that the policy and consultation hasn't considered critical factors, including how local businesses, innovation and trade is maintained in an environment of rapid global trade and distribution of sports supplements.

After many years of a relatively stable approach to sports supplements, the affected sector view this as a significant up-regulatory approach that will capture the major percentage of an industry currently worth around $1.1B in direct product sales. The indirect effects upon the economy is expected to be significantly higher in respect of associated loss of support businesses, local trade and international exports. Therefore, the sector are firmly opposed to this proposal and the method of consultation that has been presented.

Considering the expected high loss of small and large businesses, trade, and jobs, and an expected devastating impact on small business owners in particular, the sector wish to return to the table on this issue, in a manner that appropriately involves affected stakeholders and Complementary Medicines Australia, the peak industry body.

The sector has expressed a willingness to work with Government on identified concerns or issues, within a policy approach that does not hand our industry to international suppliers, but supports and grows Australian businesses and consumer choice. A consultation approach is sought that is commensurate with the significance and broad community use of this sector.

New Zealand & the Trans Tasman Mutual Recognition Agreement

The Trans-Tasman Mutual Recognition Arrangement (TTMRA), drives regulatory coordination and contributes to both the Australian and New Zealand Governments' strategic objective of creating a single trans-Tasman market for the sale of goods and the registration of occupations.

Any products that have been specified in the proposed Section 7 Declaration that are currently manufactured under the **New Zealand Food Standard : Supplemented Food Standard 2016** by New Zealand's Ministry of Primary Industry and imported into Australian under the TTMRA will now be legally declared therapeutic goods in Australia, and will no longer be eligible for import and sale in Australia unless they are fully listed or registered goods on the TGA's ARTG complying with all new medicine requirements.

As it is not expected that many products will be able to transition to these requirements, this will have a large impact on New Zealand manufacturers and importers and affect Australia's trade relationship with New Zealand under the TTMRA.

Council of Australian Governments

COAG's role is to initiate, develop and monitor the implementation of policy reforms of national significance, which require cooperative action by Australian governments. Given COAG is the intergovernmental forum whose role is to facilitate cooperation between the Commonwealth Government and state and territory and local governments in specific policy areas, this case meets the objectives of the COAGs role and roles of their councils.

The regulation of supplements generally including sports supplements and the scale of impact of the proposed change involves a variety of intergovernmental considerations:

- A loss of several billion dollars from local industries and the economy requires further involvement at a minimum from Austrade and the Department of Industry, Innovation and Science.
- The declaration affects multiple millions of dollars of trade with NZ under the TTMRA.
- Most products captured by the consultation, including their manufacturing facilities, are regulated and inspected by State & Territory authorities.
- Existing businesses, facilities, and specialised equipment in-development are subject to State grants and grants under application.
- Specialty retailers have provided that the loss of products under this proposal will mean that the store turnover will no longer support business viability of hundreds of outlets, a matter for State, Territory and local governments.

Broad Policy Options

Complementary Medicines Australia supports a best practice regulatory approach, as outlined by the Department of Prime Minister and Cabinet, of four broad policy options. Potential options are:

- 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.

Interaction with Complementary Medicines on the ARTG

We note that the consultation will now “de-regulate” some existing products (certain undivided preparations) that are already included as listed medicines on the TGA’s Australian Register of Therapeutic Goods. The effects of this level of deregulation have not been highlighted or discussed in the consultation, even though there are potentially important implications for those businesses who are currently supplying these products, particularly those products that are supplying to international markets using established therapeutic goods export arrangements.

We further note that there is some interaction and overlap between sports nutrition supplements and TGA complementary medicines in general, and that Scott Morrison’s cabinet is in support of de-regulatory options and overall reduction of red-tape for Australian businesses. There may be scope for, and we would be willing to discuss, wider regulatory and de-regulatory options across various categories as part of an expanded consultation on sports supplements, the food-medicine interface, and the Department of Treasury’s Deregulation Taskforce.

Note: Prohibited list by World Anti-Doping Authority (WADA)

The proposal to reference non-government sources, such as the prohibited list by WADA, as a mechanism to change the regulatory status of goods is a concern for Australian Government legislation. As the WADA list is subject to change at any time, there will not be consultation or notice for affected industry stakeholders about the regulatory framework of their goods. While the WADA list is an important consideration for athletes, this proposal does not acknowledge that undeclared substances are already subject to compliance and enforcement, or that the inclusion of this as a therapeutic goods regulatory requirement would not automatically guarantee athlete’s protection. There are alternative, voluntary batch by batch certification mechanisms for interested industry members to seek to serve the needs of elite athletes. Currently the Australian Sports Anti-Doping Authority advice is that athletes should only use supplements which have been screened under voluntary programs for prohibited substances by an independent company, such as HASTA or Informed Sport.

Complementary Medicines Australia - Recommendations

Complementary Medicines Australia notes that the small amount of products containing illegal, undeclared, or dangerous substances are already subject to compliance and enforcement actions. We note that interim measures are available or being undertaken.

However, the consultation captures a vast majority of remaining sports supplements which are not high risk. The change of regulatory status will create significant damage (60-80%) to the remaining businesses in Australia representing a $1.1billion industry, and change consumer access to overseas websites, likely increasing net safety risks to the community.

We also note that this consultation has additional implications for products that are already regulated as complementary medicines, and for both TGA- and food- licensed manufacturers, and for products that currently meet existing food standards. We note that Food Standard 2.9.4, which significantly interacts with this category, is currently under review by FSANZ. Under a whole-of-Government approach, this should be coordinated.

CMA supports the replacement of the current consultation in favour of a best practice regulatory approach through the development of four broad policy options and examines an appropriate "whole of Government" approach with FSANZ and interrelated industries, including foods and listed complementary medicines. This may include examining suitable de-regulatory options under the Deregulation Taskforce.

Due to State, Territory and local implications, any approach must be supported under consultation through the Council of Australian Governments, by engaging collaboratively with affected stakeholders and representative peak bodies (including Complementary Medicines Australia), the Department of Industry, Treasury, Austrade, FSANZ, New Zealand, etc.

Summary recommendations:

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.

Version	
1.0 / 19 November 2019	Published
1.1 / 20 November 2019.	Added Note on WADA list and minor corrections.
1.2 / 3 December 2019	Additional policy option added: An overall re-assessment of the operation of the Food-Medicine Interface for all goods (may result in more appropriate regulation for all products);

Position Statement Disclaimer

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