



Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Sports supplements

Proposed clarification that certain sports supplements are therapeutic goods

Version 1.0, October 2019

TGA Health Safety
Regulation



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Abbreviations used

Abbreviation	Meaning
ARTG	Australian Register of Therapeutic Goods
The Code	Food Standards Code
FMI	Food-Medicine Interface
FSANZ	Food Standards Australia New Zealand
FSANZ Act	<i>Food Standards Australia New Zealand Act 1991</i>
SME	Small-Medium Enterprise
TGA	Therapeutic Goods Administration
TG Act	<i>Therapeutic Goods Act 1989</i>
WADA	World Anti-Doping Agency

Introduction

In Australia, food and medicines are regulated under separate legislated frameworks commensurate with the intended use and potential risks that those products pose to public health and safety.

Whether a product for oral consumption is a food or a medicine in law can depend on the specific combination of ingredients, claims and overall presentation. For instance, two products with the same formulation may be characterised differently—one as a food and the other as a medicine—depending on their claims, artwork and other aspects of their packaging. However, a product cannot simultaneously be both food and medicine in law.

‘Sports supplements’ is a broad category of products that straddles the interface between the food and medicine regulatory frameworks—the so-called ‘food-medicine interface’ (FMI). These products often carry explicit or implied claims relating to sport, fitness or recreational performance, and are likely to be marketed and consumed for therapeutic use, yet some of the products may still be considered to be food under law. This is because Food Standard 2.9.4 - [Formulated supplementary sports foods](#) in the Food Standards Code may be taken to apply to them. As a consequence of that standard, some products that are represented as sports supplements are not presently considered to be therapeutic goods within the meaning of the *Therapeutic Goods Act 1989* (the TG Act) (refer to [Regulation of foods in Australia](#) below).

Medicines are subject to a national system of controls established under the TG Act to assure quality, safety and efficacy according to the risk those medicines pose to consumers. The nature of and therapeutic claims associated with many sports supplements, which are often also found to contain higher risk ingredients not suitable for food, demands that those products are, where appropriate, regulated as medicines.

Two recent studies on sports supplements available in Australia highlight the importance of ensuring appropriate sports supplement regulation:

- In 2016, life science company LGC analysed 67 leading brand sports supplements available in Australia. One in five products contained one or more substances banned in sport. Two products were found to contain such high levels of unlabelled stimulants that they were considered to pose a significant health risk to athletes along with a significant risk of failing a doping test¹.
- In 2017, researchers from the University of Otago and the University of Technology Sydney screened 116 sports supplements available in Australia, including protein powders, pre-workout formulations, fat metabolisers, vitamins and herbal extracts. More than 1 in 20 supplements contained anabolic steroids that were not declared on the product labels. The research concluded there is a real health risk and doping violation risk for athletes consuming sports supplements².

This consultation

The Government is seeking to resolve much of the uncertainty around the regulatory status of sports supplements to ensure those products are regulated appropriately to safeguard public health and safety.

¹ LGC, [Australian Sports Supplement Survey \(2016\)](#).

² Cooper, ER et al. (2018) [Androgen Bioassay for the Detection of Nonlabeled Androgenic Compounds in Nutritional Supplements](#). *International Journal of Sport Nutrition and Exercise Metabolism*, 28(1):10-18.

This consultation seeks comment on a proposed approach—the making of an order (‘the proposed declaration’) under subsection 7(1) of the TG Act to declare that certain sports supplements, when used, advertised or presented for supply in a particular way, are therapeutic goods (in this case, medicines). Submissions received in response to this consultation will inform the decision by the TGA about making the order and what form it should take.

For guidance on how to provide feedback please refer to [How to submit your feedback to the TGA](#).

Subject to claims for your submission not to be published, all submissions and consultation outcomes will be published on the TGA website.

Background

Regulation of foods in Australia

The regulation of food in Australia is a joint responsibility of the Commonwealth and the states and territories.

Food Standards Australia New Zealand (FSANZ) is responsible for the New Zealand Food Standards Code (the Code), a set of national standards for food under the *Food Standards Australia New Zealand Act 1991*.

State and territory government food authorities and local councils enforce the Code through their respective legislation, deal with complaints about food and investigate food safety issues. The Department of Agriculture enforces food laws at Australia’s borders in relation to imported food.

Regulation of therapeutic goods in Australia

The TGA, a part of the Department of Health, is responsible for regulating therapeutic goods (including medicines, medical devices and biological products) under the TG Act and relevant regulations to ensure those goods are safe and fit for their intended purpose.

Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) to be lawfully supplied in, imported into, or exported from Australia, unless those goods are otherwise the subject of an exemption, approval or authority under the TG Act. There are two tiers of regulatory requirements for inclusion of medicines in the ARTG that correspond to the degree of risk based on a product’s ingredients, therapeutic indications (claimed health benefits) and presentation:

- lower risk medicines (e.g. most complementary medicines such as vitamin and mineral supplements) are listed in the ARTG, identified by an AUST L number on their label, and are available for self-selection by consumers
- higher risk medicines (e.g. all prescription medicines) are registered in the ARTG, are identified by an AUST R number on their label, and may be accessed over-the-counter or only with a prescription in pharmacies.

The regulatory requirements for medicines include:

- licensing or approval of manufacturing facilities to ensure medicines are manufactured in accordance with good manufacturing practice (GMP)

- restrictions over the types and amounts of ingredients to ensure medicines are acceptable in terms of safety and quality prior to marketing and supply, for example:
 - listed medicines are only permitted to contain certain low risk ingredients that are specified in a legislative instrument known as the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) ('the Permissible Ingredients Determination')
 - only registered medicines may be permitted to contain a substance included in a Schedule to the [Poisons Standard](#), a legislative instrument that consists of decisions regarding the classification of medicines and poisons into schedules for inclusion in the relevant legislation of the states and territories
- sponsors must have evidence to support the indications (specific therapeutic uses) and claims for the medicine (i.e. that it does what it says it does)
- requirements for labelling that support safe and effective use of medicines by consumers
- requirements for advertising to ensure it is not misleading or unsafe
- post-market monitoring of complaints about advertising, medicine defects and adverse events.

The [Australian Border Force](#) enforces the laws relating to medicines imported at Australia's borders. Some medicines are only available with a prescription, some medicines may only be imported by a medical professional and some substances may not be imported at all - refer to [Can I import a medicine for personal use?](#).

The food-medicine interface

Some products are at the interface of the food and medicines frameworks, meaning that it is not immediately evident which regulatory framework applies to them without a detailed assessment of their formulation, claims and presentation. Minor changes to one or more of these attributes may result in the products changing from being medicines to food, or vice versa, in law. Refer to case studies provided in [Regulatory status of sports supplements](#) for examples of different types of product presentations.

This situation arises, in part, from the interplay between:

- (i) the definitions of '*therapeutic goods*' and '*therapeutic use*' in the TG Act, and
- (ii) the permission, in the Code, for health claims to be made for some foods.

Sub-section 3(1) of the TG Act relevantly provides that **therapeutic goods** mean:

'goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use'

with **therapeutic use relevantly** defined as:

use in or in connection with 'influencing, inhibiting or modifying a physiological process in persons'.

However, products are **not** therapeutic goods if those goods are (emphasis added):

'(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of sub-section 4(1) of the Food Standards Australia New Zealand Act 1991)'.

Goods likely to be taken for the purpose of influencing, inhibiting or modifying a physiological process in persons are therapeutic goods, **unless**—in the absence of a relevant declaration under section 7 of the TG Act—there is an existing **food standard** for these goods.

The Code permits some foods to carry certain health claims that could simultaneously cause those products to be taken to be for therapeutic use according to the definition in the TG Act. This can give rise to ambiguity or confusion as to whether the products are food or medicine.

The TGA has published a [Food-Medicine Interface Guidance Tool](#) to guide manufacturers and importers of products as to whether their goods are regulated as therapeutic goods or food.

Regulatory status of sports supplements

'Sports supplements' is a broad category of products promoted for performance related to sport, fitness or other physical activity, that differ markedly in terms of ingredients, instructions for use, labelling and dosage forms (e.g. powder, drink, tablet or capsule).

Sport supplements often present at the FMI because the Code includes a 'Special Purpose Foods' standard for Formulated Supplementary Sports Foods:

Food Standard 2.9.4 – Formulated Supplementary Sports Foods*, defines these formulated supplementary sports food as:

'a product that is specifically formulated to assist sports people in achieving specific nutrition or performance goals'.

* note: Standard 2.9.4 is currently under review- refer to www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx

The existence of Food Standard 2.9.4 can mean that a product that is 'specifically formulated to assist sports people in achieving specific nutrition or performance goals' is a food. Sports supplements can therefore be foods or medicines, generally depending on how they are presented for supply.

The reference to a product being for assisting with achieving **either nutritional or performance goals** may cause a broader range of products to be considered to be foods than would ordinarily be considered to be so. In particular, products with claims related to *performance goals* that

meet the definition of therapeutic use that are of no or little nutritive value, *may* be considered to be foods, irrespective of the dosage form or other ingredients that they contain. As foods, those products fall outside the scope of the therapeutic goods regulatory framework that ensures the safe, efficacious and quality use of goods for therapeutic use.

How sports supplements may be viewed as food or medicines under the current regulatory frameworks is illustrated in the hypothetical Case Studies 1–5 below.

Case studies

Case study 1: Product containing a substance prohibited by World Anti-Doping Agency

A product that:

- is in the form of a powder to be made into a drink
- contains no explicit indications or claims on the label, but includes a brand “Fitness Max”, “Recovery” in the name, and an image of a muscular arm
- contains meldonium as an ingredient (not depicted on label)



Meldonium is included in the World Anti-Doping Agency (WADA) prohibited list for athletes.

However, Food Standard 2.9.4 does not exclude products that contain substances in the WADA prohibited substance list from being Formulated Supplementary Sports Foods.

Although the product does not have explicit claims on the label, it would be likely to be taken to be for the improvement or maintenance of physical or mental performance due to the words “Fitness Max” and “Recovery” in combination with the image of a muscular arm. As the representations on this product about therapeutic use, which are implied rather than explicit, could be seen as a claim or reference to a performance goal, the product is likely to be viewed as meeting Food Standard 2.9.4.

While this product has characteristics of a medicine, it would be likely to be considered to be a food (but may be a non-compliant food).

The proposed solution in this consultation paper would clarify that this product is a medicine.

Case study 2: Product providing a quantity of a substance significantly in excess of maximum one-day amount

A product that:

- provides an amount of choline that significantly exceeds the maximum amount for a formulated supplementary sports food in section S29—19 of the Food Standards Code – Schedule 29 – Special purpose foods
- is marketed as a ‘pre-workout’ product
- makes claims for ‘*ultimate performance*’, ‘*increase stamina*’ and ‘*boost energy*’



Choline naturally occurs in some foods, but this product provides an amount that is likely to be unsuitable for food. The product’s claims are clearly for therapeutic use. However, increasing stamina and boosting energy might also be considered ‘performance goals’.

Therefore, while this product clearly has characteristics of a medicine, Food Standard 2.9.4 may be considered to apply and the product is likely to be considered to be a food.

The proposed solution would clarify that this product is a medicine.

Case study 3: Product with substance of concern, a non-traditional dosage form and therapeutic claims

A product that:

- contains the active ingredient (Endurobol/GW-501516)
- makes claims for ‘*testosterone boosting*’, ‘*increase strength, stamina, endurance*’ and ‘*bulk muscle*’
- is presented in the form of a capsule



Endurobol is included in Schedule 10 to the Poisons Standard, reserved for substances of such danger to health as to warrant prohibition of sale, supply and use. However, while ingredients that are included in a schedule to the Poisons Standard are clearly inappropriate for inclusion in a product marketed as a food, the definition of Formulated Supplementary Sports Foods does not expressly exclude products which contain such substances.

Despite the above claims meeting the definition of therapeutic use, they may constitute ‘performance goals’ under Food Standard 2.9.4. Further, despite a capsule not representing a traditional form of food, Food Standard 2.9.4 does not exclude a good presented in the form of a capsule from being captured as a Formulated Supplementary Sports Food. Therefore, while this product is clearly a medicine, suppliers may assert that this product is a food (however, would likely be considered a non-compliant food).

The proposed solution would clarify that this product is a medicine.

Case study 4: Product providing nutrition

A product purported to be a food that:

- contains whey protein powder as the single ingredient
- makes claims for providing '*ultimate food for your muscles*' and '*lean muscle growth*'

Whey protein is a source of amino acids, nutrients normally obtained in the diet from food. A powder for preparation into a drink is a form commonly associated with food.

Although the above claims do meet the definition of therapeutic use, they reflect 'performance goals' covered by Food Standard 2.9.4. and therefore the product would likely be determined to be a food.

The proposed solution would *not* determine this product to be a medicine.



Case study 5: Product with a non-traditional dosage form and therapeutic claims

A product that:

- contains vitamins and minerals
- is presented in the form of a capsule
- makes claims for '*thermogenesis*', '*boost metabolism*', '*fat burning*'

The above claims meet the definition of therapeutic use, but likely also 'performance goals' in relation to Food Standard 2.9.4.

Despite a capsule not representing a traditional form of food, Food Standard 2.9.4 does not explicitly exclude a good presented in the form of a capsule from being a Formulated Supplementary Sports Food.

Therefore, while this product clearly has characteristics of a medicine, Food Standard 2.9.4 may be considered to apply and it could be considered to be a food.

The proposed solution would clarify that this product is a medicine.



Emerging issues with sports supplements

Consumer safety

Consumers of sports supplements actively seek a performance 'edge', are more likely to buy novel products³ and to consume multiple different products⁴.

Some sports supplements have been found to contain:

- illegal prescription medicines
- toxic or dangerous substances of known or likely concern, for example, the amphetamine-like substances, dimethylamylamine (1,3-DMAA)⁵ and Endurobol / GW-501516⁶.
- formerly registered prescription medicine substances withdrawn from sale for safety reasons
- novel substances with an unknown safety profile, such as synthetic caffeine derivatives Dynamine (methylxanthine) and TeaCrine (theacrine)
- substances included in the prohibited list published by the World Anti-Doping Agency (WADA)⁷
- substances that occur naturally in food but in higher concentrations than found in traditional food
- undeclared ingredients – including ingredients of the above types

In addition to the inclusion of the above high risk ingredients, sports supplements may also include claims that promote inappropriate (such as excessive) use of otherwise safe products in response to the consumer appetite for increased performance. The likelihood of unsafe use may also be exacerbated by the perception in the community of most sports supplements as foods, with a similar risk profile to other foods⁹. However, agitation, palpitations, insomnia and high blood pressure can result from overconsumption of caffeine products. Products with large amounts of protein or creatinine may cause raised blood urea or creatinine in an otherwise healthy individual. Androgen deficiency and hypogonadism may be result from the use of androgenic steroids⁸.

The potential risks to consumer safety posed by the above phenomena have been highlighted by recent deaths in Australia that have been linked to sports supplements (that were not included in the ARTG as medicines). In 2018, the death of a woman in Western Australia was attributed to

³ Food Standards Agency, *Food supplements consumer research* (May 2018)

www.food.gov.uk/research/research-projects/food-supplements-consumer-research.

⁴ Adverse effects of sports supplements in men, Martin et al, Australian Prescriber 2018

www.nps.org.au/australian-prescriber/articles/adverse-effects-of-sports-supplements-in-men

⁵ Department of Health, Therapeutic Goods Administration, *The TGA decision to ban DMAA* (3 August 2012) www.tga.gov.au/behind-news/tga-decision-ban-dmaa; Barbara Miller et al, *Aussie athletes test positive* (23 October 2010) www.abc.net.au/news/2010-10-23/aussie-athletes-test-positive/2308576.

⁶ Australian Sports Anti-Doping Authority, *Blog: GW1516 – Popular, but deadly* (23 October 2018) www.asada.gov.au/news/blog-gw1516-popular-deadly.

⁷ Published on the WADA website at www.wada-ama.org/en.

⁸ Adverse effects of sports supplements in men, Martin et al. Australian Prescriber 2018

www.nps.org.au/australian-prescriber/articles/adverse-effects-of-sports-supplements-in-men

an underlying metabolic disorder where her body was unable to metabolise her high protein diet that included protein-rich foods and various sports supplement protein powders⁹.

Given the nature of many sports supplements in relation to ingredients and claims, and the manner in which they are used, it is appropriate that many of them are subject to the national system of controls for therapeutic goods to safeguard consumers.

Jurisdictional responsibility

Confusion regarding their status as foods or medicines can result in products being present in the market without being subject to appropriate controls or in delays in regulatory authorities taking action where significant health and safety risks are detected. Given the above issues regarding consumer safety posed by sports supplements as a class of goods, this can put consumers at risk. This is of significant concern since adverse events associated with the use of supplements in the community are likely to be under-reported, which is exacerbated by community perceptions around supplements being 'foods' that pose a lower risk than medicines.

Proposal to declare that certain supplements are therapeutic goods

To clarify regulatory requirements for industry, thereby addressing many of the aforementioned issues, it is proposed to declare (under sub-section 7(1) of the TG Act) that sports supplements meeting certain criteria are therapeutic goods (the 'proposed declaration').

The proposed declaration is intended to remove much of the confusion about how these goods are regulated and facilitate swift regulatory action by the relevant regulator, especially in situations posing elevated risk to public health and safety.

What is a subsection 7(1) declaration?

Subsection 7(1) of the TG Act provides legal authority for the Secretary of Health or her delegate a declaration to be made that goods or classes of goods **are** or **are not** therapeutic goods, either generally, *or* when used, advertised or presented for supply in a particular way. Specifically, this declaration is made by a delegate of the Secretary of the Department of Health under legal authority provided under the TG Act.

In making a declaration under this subsection, the delegate must be satisfied that the relevant goods are therapeutic goods. In reaching that state of satisfaction, the delegate must disregard the paragraphs of the definition of therapeutic goods which relate to goods for which there is a food standard [within the meaning of sub-section 4(1) of the FSANZ Act]] or which have a tradition of use as a food in Australia or New Zealand (paragraphs (e) and (f) of the definition of therapeutic goods in subsection 3(1) of the TG Act). This means that the existence of food standard 2.9.4 and its terms are not relevant for the decision on whether to make a declaration that would clarify that some sports supplements are appropriately regulated as therapeutic goods (in this case, medicines).

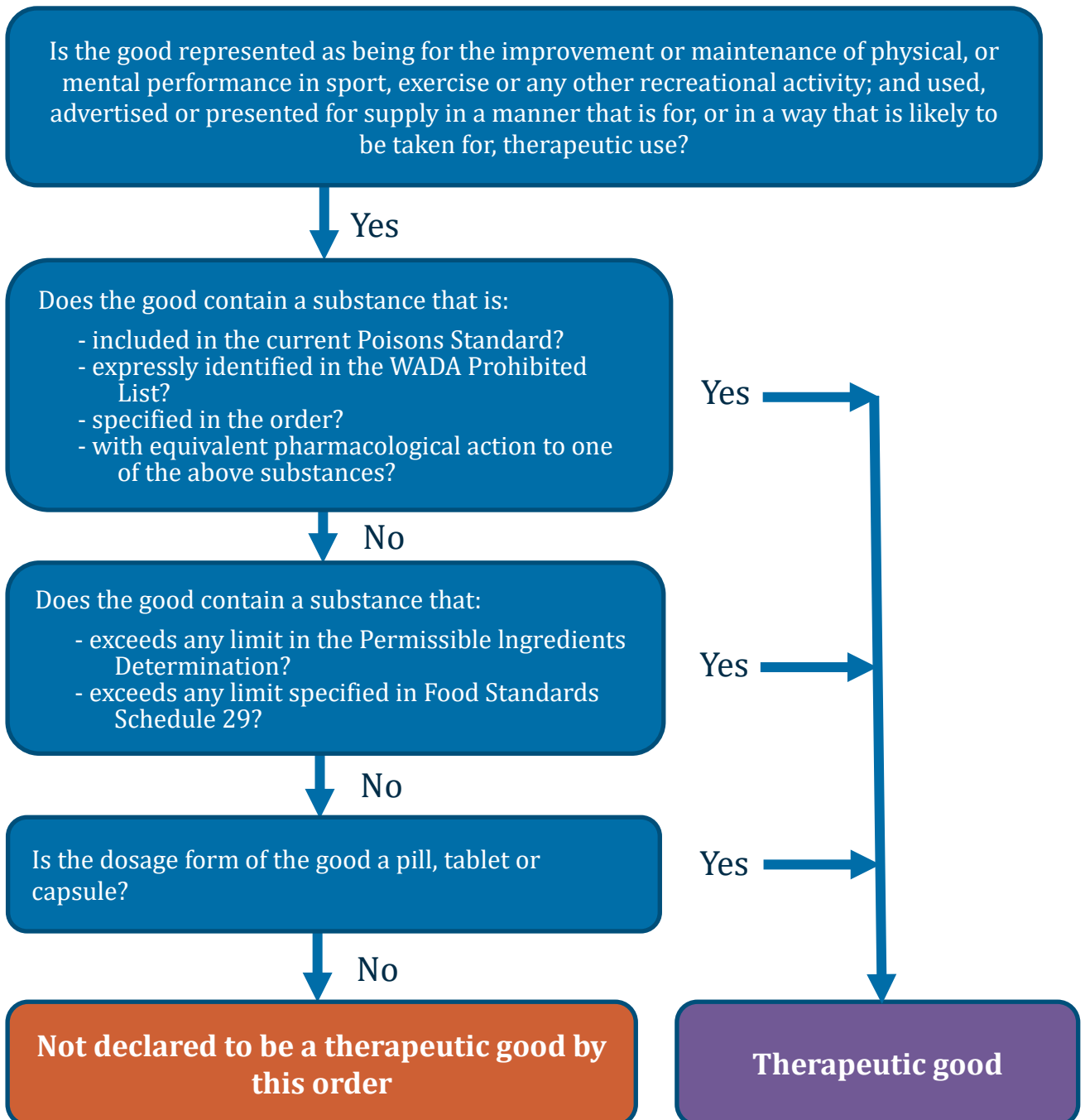
⁹ Deloitte, [Department of Health Sports Supplements Roundtable: Report on Discussions and Next Steps](#) (August 2018).

Proposed terms of the subsection 7(1) declaration

It is proposed that an order is made under subsection 7(1) of the TG Act in the form provided at **Attachment A**. The terms for which goods may be declared to be therapeutic goods are specified in Part 2 of Schedule 1 to the proposed declaration. These terms should in particular be read in conjunction with section 4 (Definitions) and section 5 (Declared goods - therapeutic goods) of the proposed declaration.

The following decision tree depicts how the proposed declaration would apply to a product in practice.

Decision tree



Outcomes of the proposed declaration

A declaration that sports supplements meeting the proposed terms are therapeutic goods (medicines) will provide greater clarity as to the regulatory status of these goods. In turn, this will ensure that they are efficiently subjected to the robust system of national controls or regulation relating to the quality, safety and efficacy of medicines, that is commensurate with them being for therapeutic use.


The controls (or regulations), in relation to sports supplements declared as therapeutic goods would, in particular, ensure that:





- products do not contain the wrong active ingredient, too much or too little active ingredient or variations across dosages, substandard ingredients, or contamination with other ingredients or microbes
- products only contain ingredients in amounts that have been assessed by the TGA and determined to be acceptable in terms of safety and quality, taking into account that some ingredients may also be consumed from the diet
- what the products are claimed to do is supported by evidence
- the advertising for the products does not promote excessive or inappropriate use or otherwise mislead about its anticipated benefits
- complaints about misleading or unsafe advertising are dealt with under the TGA's advertising complaints framework
- reports of defects or adverse events in relation to the products are rapidly handled by the TGA

Note: The proposed declaration is *not* intended to be applicable to products that *only* make claims for weight management that are not linked to physical or mental performance, e.g. some meal replacement products.

Status of particular types of sports supplements

The effect of the proposed declaration on different types of sports supplements is illustrated with reference to the earlier case studies as follows:

Effect of proposed section 7 declaration on different types of sports supplements	
<p>Case study 1</p> 	<p>Product would be a medicine because:</p> <ul style="list-style-type: none"> • claims and presentation mean that it is taken to be for therapeutic use in relation to exercise performance • contains a substance (meldonium) included in the WADA prohibited list

Effect of proposed section 7 declaration on different types of sports supplements	
<p>Case study 2</p> 	<p>Product would be a medicine because:</p> <ul style="list-style-type: none"> claims and presentation mean that it is taken to be for therapeutic use in relation to exercise performance contains a substance (choline) that is in excess of maximum amount allowed by section S29—19 of Food Standards Schedule 29
<p>Case study 3</p> 	<p>Product would be a medicine because:</p> <ul style="list-style-type: none"> claims and presentation mean that it is taken to be for therapeutic use in relation to exercise performance contains a substance (Endurobol) in a schedule to the current Poisons Standard
<p>Case study 4</p> 	<p>Product would not be a medicine as long as Food Standard 2.9.4 applies.</p>
<p>Case study 5</p> 	<p>Product would be a medicine because:</p> <ul style="list-style-type: none"> claims and presentation mean that it is taken to be for therapeutic use in relation to sport performance the dosage form is a capsule

Outcomes for consumers

If the declaration is made, and depending on the final terms of the declaration and when it comes into effect, consumers may see changes to some sports supplements on the market in relation to their formulation, claims, labelling and advertising.

Consumers will continue to be able to access products that are appropriately Formulated Supplementary Sports Foods and contain ingredients appropriate for food.

Sports supplements that are currently on the market but are unsafe or unsuitable for consumer use, (for example: due to containing substances that are scheduled in the current Poisons Standard) may become unavailable as the TGA takes regulatory action to remove them from supply.

Certain sports supplements may reappear on the market regulated as medicines as manufacturers change the manufacturing, formulation, labelling (including adding an AUST L or AUST R number to identify it as a medicine) or advertising of these products to meet regulatory requirements for therapeutic goods. If sports supplements are listed medicines in the ARTG, those supplements may be self-selected by consumers without the restrictions required for higher risk over-the-counter and prescription medicines. If sports supplements have high-risk substances and are registered in the ARTG, those supplements will have undergone a full pre-market evaluation of safety, quality and efficacy so consumers can have confidence in these products.

Regulating such products as medicines is expected to significantly minimise the risk to public health in relation to sports supplements and provide consumers with greater confidence in the safety of the products they are using. This will be enabled by swift compliance and enforcement action by the relevant authorities when safety concerns are identified and ensuring that sports supplements that are on the market are being subject to controls commensurate with their level of risk. In addition, by being subject to the labelling and advertising standards for therapeutic goods, consumers would also be aided in making more informed decisions when self-selecting sports supplements that have been declared to be therapeutic goods.

Outcomes for industry

A declaration that certain sports supplements are therapeutic goods will, if made, assist industry in knowing whether their products can be marketed as foods or medicines.

Generally, Formulated Supplementary Sports Foods subject to Food Standard 2.9.4 that contain ingredients appropriate for food and are in a form consistent with food should continue to be able to be marketed as food.

Manufacturers or suppliers of some sports supplements who recognise that their products that are purported to be foods are, in fact, therapeutic goods, will need to consider changing the manufacturing, formulation, labelling and/or advertising of these products. If the products are to be maintained on the market and are medicines, the products will need to be entered on the ARTG.

However, the proposal to clarify that these products (that are marketed with therapeutic claims and include substances or dosage forms that are not compatible with foods) are therapeutic goods is entirely consistent with the objects of the TG Act. Importantly, it is in the interest of the Australian public that products, which may pose actual and potential risks to consumer health and safety, are subject to the national system of controls relating to the quality, safety and efficacy of therapeutic goods, specifically the regulation of medicines.

Through supporting a high standard of quality, safety, efficacy and advertising, the proposed declaration is expected to increase consumer confidence in this class of products, which ultimately will benefit industry.

Further information for industry is available on the TGA's [summary of supplying therapeutic goods in Australia](#) and [basics of therapeutic goods regulation for small to medium enterprises \(SMEs\)](#).

How to comment on this consultation paper

The TGA invites comments from interested parties. Comments can address any or all of the issues discussed in this Consultation Paper.

It is preferred for submissions to be lodged using the [online questionnaire form](#).

Alternatively, submissions may be uploaded in either pdf or Microsoft Word format to the online consultation submission form. Hardcopy submissions can be sent with a printed coversheet to the address provided below.

Content of submissions

Your submission should include, unless confidential:

- your name and full contact details including: address, telephone number and, if applicable, facsimile and email address
- in the case of organisations; the level at which the submission was authorised

In addition, submissions can:

- include relevant evidence, and/or examples, to support the views expressed
- include any other relevant information, e.g. scientific and technical, economic, international obligations, business and consumer information
- identify and discuss any perceived omissions or alternative approaches, in addition to those included in the consultation paper

Questions included in online questionnaire form

In your submission, please consider the questions below and provide comments related to any other matter outlined in this consultation paper (note these questions can be answered via the [online questionnaire form](#)).

1. Do you support the proposal for certain sports supplements to be declared to be therapeutic goods?
What are the reasons for your answer?
2. Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers?
What are the reasons for your answer?
3. Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines?
What are the reasons for your answer?
4. Are you aware of products on the market that would not be captured by the proposed declaration but should be?
What are the reasons for your answer? Please provide specific details and the rationale for why these products should be therapeutic goods.
5. Are you aware of products on the market that would be captured by the proposed declaration but should not be?

What are the reasons for your answer? Please provide specific details and the rationale for why these products should not be therapeutic goods.

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

Confidentiality of submissions

If you wish any information contained in a submission to be treated as confidential, please clearly identify the information and outline the reasons why it is confidential, in the consultation submission cover sheet provided.

Questions relating to submissions

Any questions relating to submissions should be directed to the Complementary and Over the Counter Medicines Branch, by email to TGA.sports.supplements.consultation@health.gov.au.

Deadline for submissions

The deadline for receipt of submissions is close of business, Tuesday 3 December 2019.

Address for submissions

Hard copy submissions should be addressed to:

Sports Supplements Consultation
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
Department of Health
PO Box 100 WODEN ACT AUSTRALIA

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

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