

TGA Consultation: Proposed clarification that certain sports supplements are therapeutic goods

Submission by

Dr Ken Harvey MB BS, FRCPA AM

Associate Professor

with the assistance of

**Chiara Piazzese, Zoe Nikakis and
Chelsea Landwehr**

Summer School Scholarship Students

**School of Public Health and
Preventative Medicine**

Monash University

Submission endorsed by Friends of Science in Medicine



Proposed clarification that certain sports supplements are therapeutic goods

Summary

Some sponsors of sports supplements have used the ambiguity of regulations at the food-medicine interface to market unsafe products, evade regulation and put consumers at risk. The TGA is seeking comments from interested parties on a proposed approach to ensure sports supplements are regulated appropriately to safeguard public health and safety

1. Do you support the proposal for certain sports supplements to be declared to be therapeutic goods? **Yes**
2. Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers? **Yes**
3. Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines? **Yes**
4. Do you have any other comments related to the consultation? **Yes**

While we support the proposed declaration, we emphasise that it will do little to protect consumers unless the TGA ensure that the penalties applied for non-compliance outweigh the profit that comes from breaking the law.

In addition, to prevent consumers moving to overseas Internet sites to purchase illegal sports supplements, the TGA must strengthen its liaison with the Australian Border Force to seize illegal imports, increase its own education activities and work with consumer groups and magazine editors to provide relevant press releases and consumer stories for wider dissemination.

Introduction

The *Therapeutic Goods Act 1989* (the Act) defines a therapeutic good as a product likely to be taken for therapeutic use.¹ The latter is defined as, "influencing, inhibiting or modifying a physiological process in persons". Therapeutic goods have a number of constraints imposed on their supply, sale and promotion by the Act, associated regulations, and the Therapeutic Goods Advertising Code.² The Therapeutic Goods Administration (TGA) is the responsible regulator.³ The purpose of this regulatory process is to ensure acceptable standards for the quality, safety and efficacy of therapeutic goods.

However, the Act states that products are not therapeutic goods if there is a relevant Food Standards Australian New Zealand (FSANZ) standard.⁴ Standard: 2.9.4 is relevant. This defines Formulated Supplementary Sports Foods as "a product that is specifically formulated to assist sports people in achieving specific nutrition or performance goals".⁵ The standard is currently under review.⁶ FSANZ standards lack an advertising Code and are administered by State and Territory food authorities. Assisting performance goals (in the FSANZ standard) may involve influencing, physiological process (in the Act). This can give rise to ambiguity or confusion as to whether the

¹ <https://www.legislation.gov.au/Series/C2004A03952>

² <https://www.legislation.gov.au/Series/F2018L01524>

³ <https://www.tga.gov.au/>

⁴ <https://www.foodstandards.gov.au/code/Pages/default.aspx>

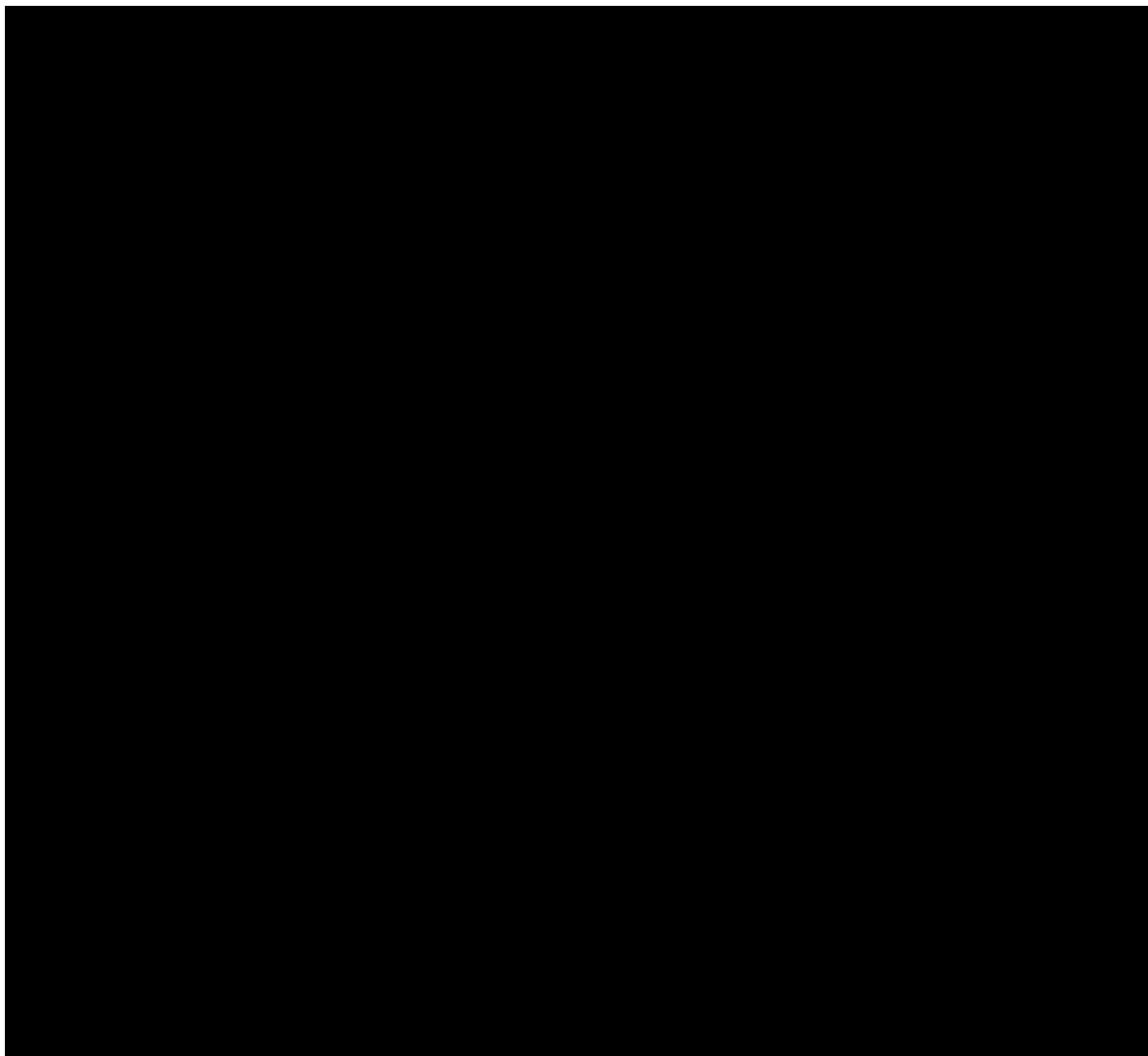
⁵ <https://www.legislation.gov.au/Series/F2015L00421>

⁶ <https://www.foodstandards.gov.au/code/proposals/Pages/P1010.aspx>

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products are food or medicine;⁷ an ambiguity which some sponsors of sports supplements have used to their advantage.

For example, [REDACTED] markets a range of supplements imported from the USA which they consider sports supplements (below).⁸



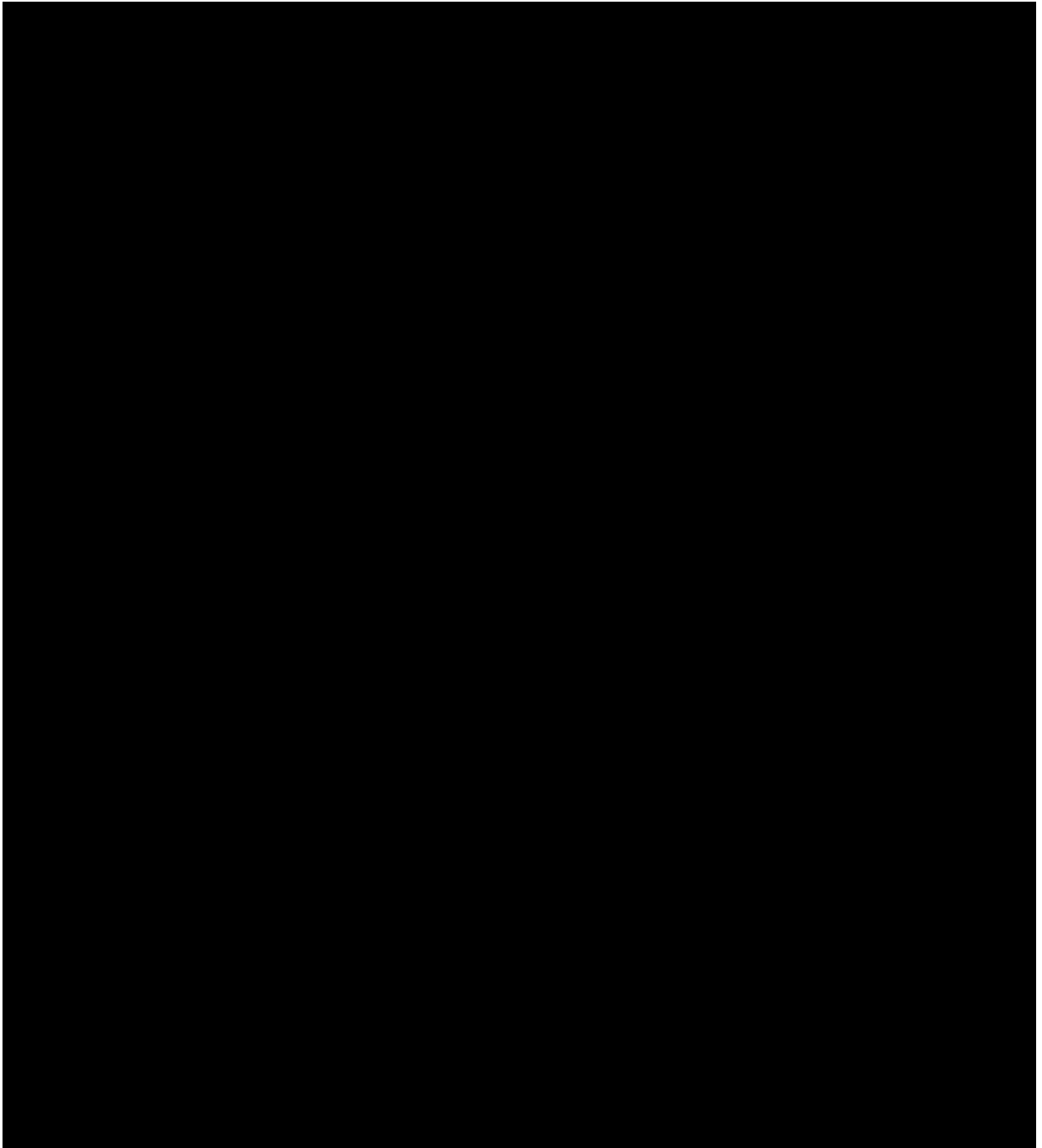
Some of these [REDACTED] contain dangerous scheduled drugs, such as selective androgen receptor modulators (SARMs), while others contain ingredients in listed therapeutic goods. None have gone through the TGA listing or registration process and thus they breach s.42DI(12) and many other sections of the Act and Code. A complaint about [REDACTED] [REDACTED] was submitted on 11 December 2018 [REDACTED] but has yet to have a published outcome.⁹ There are many other examples.^{10,11} Some are illustrated below.

⁷ <https://www.tga.gov.au/complementary-medicine-interface-issues#food>

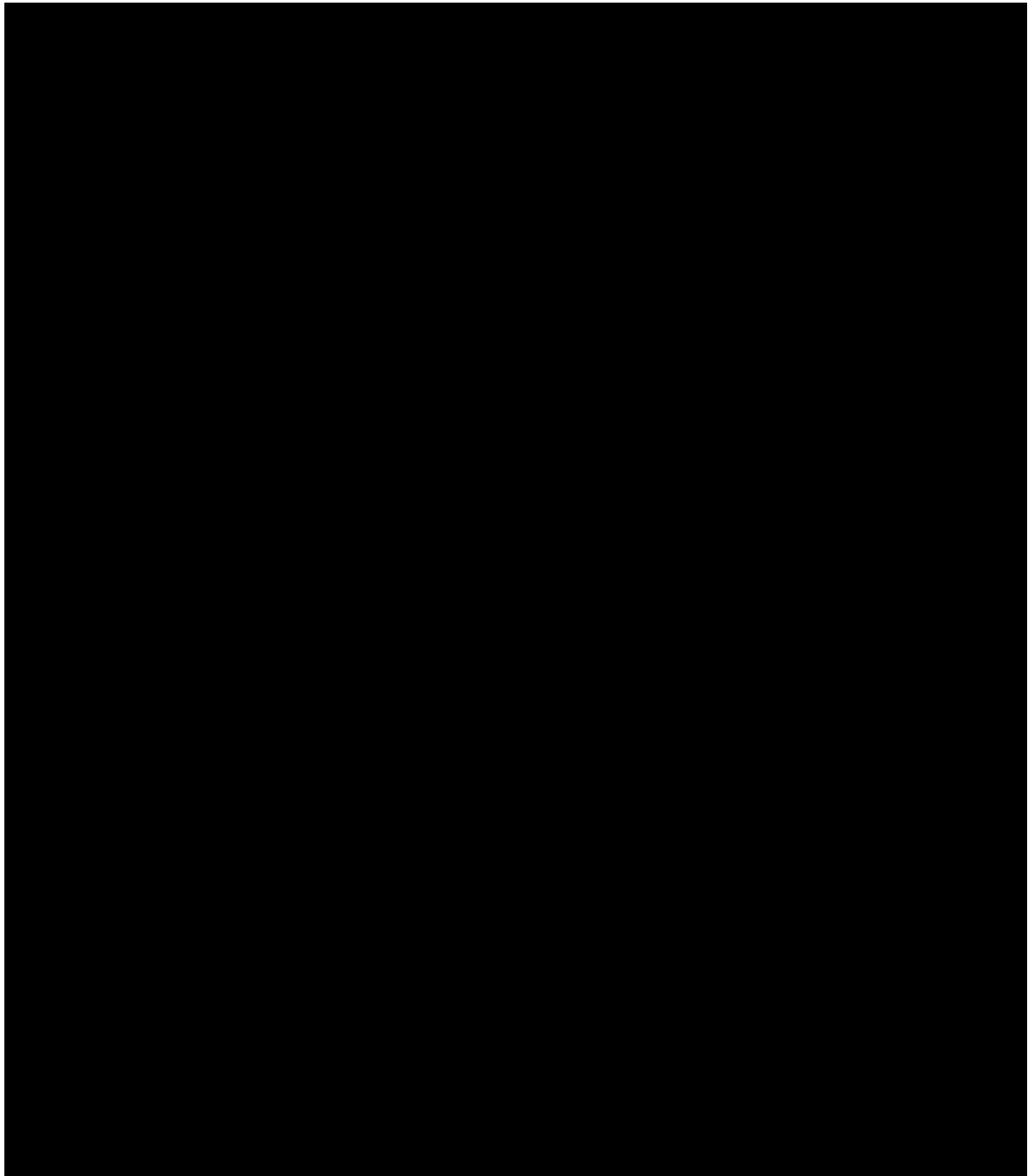
⁸

[REDACTED]

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The TGA is seeking comments from interested parties on a proposed approach to resolve some of the uncertainty around the regulatory status of sports supplements, to ensure they are regulated appropriately to safeguard public health and safety.¹²

¹² <https://www.tga.gov.au/consultation/consultation-proposed-clarification-certain-sports-supplements-are-therapeutic-goods>

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Questions asked

We respond to the following questions:

1. Do you support the proposal for certain sports supplements to be declared to be therapeutic goods? **Yes**

What are the reasons for your answer?

Sports supplements are increasing in popularity because of increased social interest in the body beautiful, fitness and exercise.

Sports supplements contain ingredients which are not naturally found in food and may include illegal performance enhancing substances and other harmful ingredients. These 'foods' must be appropriately regulated to ensure public health and safety. They should also be ethically promoted.

Sports supplements may:

- Promote excessive use of otherwise safe ingredients
- Contain substances that are prescription-only medicines or schedule 10 drugs under the Act
- Make therapeutic claims that cannot be considered "performance goals"
- Contain natural food substances in concentrations much higher than what is found in food
- Be in a tablet or capsule form.

Because sports supplements can alter human physiology the consumption of these products may lead to serious health concerns. Examples include excess creatinine consumption raising blood urea, and hormone deficiencies resulting from steroid use. The proposed declaration of sports supplements as therapeutic goods will ensure stricter regulation and safer consumption.

2. Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers? **Yes**

What are the reasons for your answer?

Under the proposed declaration, some companies will have to re-formulate, re-market or even entirely remove some products to comply with the new regulations.

This may lead to a perverse outcome where consumers turn to the Internet to obtain products from less regulated markets such as the U.S.A. This will need to be addressed as suggested under (7) below.

Regardless, removal of inappropriately formulated and advertised products should 'clean up' the sports supplement market and make way for newer, efficacious and approved supplements to the benefit of consumers.

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

What are the reasons for your answer?

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Currently the laws are unclear around what is required of industry, especially when formulating and advertising sports supplements. The decision tree suggested provides a number of criteria which enable industry to thoroughly analyse the components of each product and classify them accordingly as 'food' or 'therapeutic good' which will reduce some of the current ambiguity found with certain products. The categories demarcated in the decision tree are all necessary as they account for the most predominating aspects of these 'foods' which align them better as a 'therapeutic goods' that needs appropriate therapeutic regulation to minimise consumer harm.

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

While we support the proposed declaration, we emphasise that it will do little to protect consumers unless the TGA uses its new enforcement powers to remove illegal products from the market. Enforcement action is required for sponsors, advertisers and products that violate the regulations. Strict liability criminal penalties must be applied to ensure the penalties for non-compliance outweigh the profit that comes from breaking the law.

In addition, to prevent perverse outcomes, such as consumers turning to overseas Internet sites to purchase illegal sports supplements, the TGA should increase its liaison with the Australian Border Force (ABF) to seize illegal imports,¹³ increase its own education activities¹⁴ and liaise with consumer groups and magazine editors to provide interesting press releases and consumer stories for wider dissemination.¹⁵

2 December 2019

¹³ <https://www.tga.gov.au/alert/pure-biothroid-b-no1-tablets>

¹⁴ <https://www.tga.gov.au/buying-medicines-and-medical-devices-online>

¹⁵ <https://www.tga.gov.au/blogs/tga-topics/consumer-story-caitlin-and-medicinal-cannabis>