

P +64 9 477 5420
F +64 9 479 1486
HPSNZ.ORG.NZ

17 ANTARES PLACE
MAIRANGI BAY
AUCKLAND 0632

PO BOX 302 563
NORTH HARBOUR
AUCKLAND 0751



2nd December 2019

Sports Supplements Consultation
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To Whom It May Concern,

**Consultation Response: Proposed clarification that certain sport supplements are therapeutic goods.
DRAFT *Therapeutic Goods (Declared Goods) Order 2020***

**Category: High Performance Sport New Zealand
Sector: Sport**

High Performance Sport New Zealand (HPSNZ) is invested in the wellbeing and sporting performances of New Zealand athletes living and competing in New Zealand, Australia and worldwide. Given the relative ease of access to sports supplements and products through online purchasing and the close trade alliance between Australia and New Zealand, we consider ourselves a stakeholder for the Sports Supplement consultation being undertaken by TGA. Many of our athletes access products from, spend time in or live in Australia training and competing.

Our desire is to support New Zealand athlete performances, their safety and wellbeing. HPSNZ is committed to clean sport worldwide.

Rationale for comment

HPSNZ operates a Nutritional Supplements (NS) Programme aimed at managing the risks related to dietary and sports supplement products to ensure their safe and appropriate use. The programme focuses on protecting the health, integrity and wellbeing of our athletes. Through the NS Programme we have an increasing awareness of the complexity of sports supplements in terms of regulation and safety locally and internationally.

Statement of support

In principle, HPSNZ is strongly supportive of the interrogation of the classification of certain sports supplements to therapeutic goods and the move to clarify the market of products available to consumers.

Why

- Many sport supplement products contain labelled or unlabelled ingredients with unknown or known safety issues. This is a potential consumer safety risk, an athlete and supporting organisational integrity risk.
- It is difficult for consumers to understand the implications of product risk without extensive knowledge of ingredients, regulations and label claims. The proposed changes to regulation appear to address this issue.
- It provides greater clarity for the Food-Medicine interface.

Statement of concern #1

We support the new Proposal and wish to raise some questions to identify potential gaps or disadvantages for athletes that may arise from any change in sport supplement regulations. By forcing manufacturers to list products on the ARTG that contain WADA banned substances we are concerned that:

- Products containing WADA banned substances are still accessible 'over the counter' and continue to pose a potential safety risk for all consumers.

- Substances present on the WADA Prohibited List have a risk to health and are against the spirit of sport.
- Athletes subject to anti-doping may perceive that non-ARTG Listed products are free from WADA prohibited substances.

Note: Clear messaging has been provided to athletes by WADA and most National Anti-Doping Organisations regarding the need for athletes' vigilance with supplement product choice and use. Athletes are advised to select only third-party batch tested products with evidence of banned substance testing (Certificate of Analysis).

Statement of concern # 2

How will the proposed Therapeutic Goods (TG) (Declared Goods) Order be enforced particularly in relation to identifying the presence of banned substances?

Testing of sports supplements for WADA banned substances is expensive and carried out by a limited number of laboratories internationally. [Here](#) are some links to ISO accredited third party testing laboratories specifically testing sports supplements for banned substances.

- If TGA is to enforce the TG Order, what ingredients or substances will be tested to identify legitimacy of label ingredients? Noting that WADA update the Prohibited List annually and specifies analogues are included.
- In reference to case study 1, if a product containing meldonium is not declared on the label:
 - How will this be classified as a medicine if the ingredient is not declared and unknown?
 - How will TGA be able to stop such manufacturing practices if a manufacturer fails to declare the addition of such ingredients whether from poisons schedule of WADA Prohibited List, or inadvertent contamination?
- How will the proposed change in regulations affect accessibility to sports supplements such as creatine, beta alanine, caffeine, or other concentrated food ingredients sold in pill, tablet form or as single (or minimal) ingredient products? Will athletes require a prescription, and will practitioners require prescribing rights?
- There is a foreseeable risk that athletes will stockpile products. Customs will potentially be faced with an increased number of imported products at the border, and athletes could go 'underground' to access preferred products.

Statement of concern # 3

If changes occur to the regulations within months of the Tokyo Olympics, this poses a disadvantage and a disruption to well-developed strategies that have been practised by elite athletes. This could have a significant impact on athlete preparation and performance at the Tokyo Olympics. This will affect both New Zealand and Australian athletes and potentially the role of practitioners working with athletes (e.g. sport dietitians).

Statement of concern # 4

The market for foods containing sports supplement ingredients (e.g. hemp protein, whey protein, creatine and caffeine) is rapidly growing and evolving. Will these products be considered in terms of their potential to contain declared or undeclared ingredients/contaminants?

We look forward to greater clarity and safety for consumers, and especially athletes, who choose to purchase sports supplements.

Sincerely
