

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

3rd of December 2019

To whom this may concern,

Re: Consultation: Sports Supplements

We thank you for the opportunity to comment on the proposed changes relating to the classification of certain supplements as therapeutic goods.

The need for a level playing field is indeed overdue in relation sports foods and supplements in Australia and as a highly accomplished European company entering the Australian market, trying to navigate the current regulatory uncertainty surrounding sports products, we are extremely keen to be actively involved in helping to constructively shape the regulatory landscape of sports foods and supplements, to ensure the regulatory reforms are appropriate and proportionate. We along with much of the Australian industry, share the concern that there is strong potential for a further influx of non-regulated and therefore potentially unsafe sports products to continue to flood the market.

The changes if implemented as proposed would impact the availability, cost and choice of compliant supplements, due to the vast increase in manufacturing costs associated with the manufacture of Listed Medicines, which has seen an 80% increase in the manufacturing costs for the products we currently deem to be Listed Medicines, however should the number of products impacted increase significantly, it would jeopardise many compliant large and small businesses. We therefore believe the regulatory reform must be commercially pragmatic and include a pathway for the enforcement of non-compliant sports food products that will continue to fall intentionally or unintentionally outside the scope and tighter enforcement of Listed Medicines.

The following key points highlight areas where the proposed regulatory changes go beyond the food/medicine borderline for sports products and as such we do not support the proposal, including the *Therapeutic Goods (Declared Goods) Order 2020* as is currently drafted.

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Key Points from Consultation Documents:

Case Studies

Case study 1 (page 9) – it is not clear if the product would still be deemed a medicine, should it not contain Meldonium, a WADA prohibited substance. We strongly believe that should all the other ingredients fit within the updated FSANZ Standard 2.9.4, this product should not be deemed a medicine due solely to the brand and product name relating to fitness and recovery. Further justification of this point is detailed in other key points.

Case study 2 (page 10) – We strongly believe as per case study 1, that should the product sit within the updated FSANZ Standard 2.9.4 (e.g. Choline levels are adjusted accordingly), that this product should not be deemed to a medicine, solely based upon the time of consumption and the sports related claims, if the claims fit within the FSANZ nutrition, health and related claims. Again further justification of this point is detailed in other key points.

Goods or Classes of Goods

In the proposed *Therapeutic Goods (Declared Goods) Order 2020, Part 2 - Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way*, Column 2 refers to the following categories, which cannot be assessed without further clarification/details of the proposed amendments to S29-18 and S29-19 as part of the FSANZ Proposal P1010 the Review of Formulated Supplementary Sports Foods:

- (iii) a relevant substance;
- (vi) an amino acid in an amount that exceeds any limit for the amino acid specified in section S29—18 of the Food Standards Schedule 29 when used in accordance with the directions for use in relation to the goods;
- (vii) a substance in an amount that exceeds any limit for the substance specified in section S29—19 of the Food Standards Schedule 29 when used in accordance with the directions of use in relation to the goods

In light of the afore mentioned issue relating to the concurrent FSANZ Proposal P1010 the Review of Formulated Supplementary Sports Foods and the insertion of the open/undefined category “(iii) a relevant substance”, the inclusion of the term “maintenance” in relation to physical and/or mental performance, is reason for concern as it does not denote therapeutic use, nor should it be grounds to categorise products as therapeutic goods.

There are numerous examples of nutrition, health and related claims in FSANZ Schedule 4, under S4-5 (General level claims), where the current claims permitted on foods are related to the “maintenance” of physical or mental performance, for example:

Contributes to normal cognitive function
Contributes to normal energy production
Contributes to normal functioning of the nervous system
Contributes to normal iron transport and metabolism
Contributes to normal mental performance
Contributes to normal muscle function
Contributes to normal psychological function
Contributes to the growth of muscle mass

Contributes to the maintenance of muscle mass
Contributes to the reduction of tiredness and fatigue
Necessary for normal energy production
Necessary for normal energy release from food
Necessary for normal nerve and muscle function
Necessary for normal neurological function
Necessary for normal oxygen transport

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In addition to this, the current *Therapeutic Goods (Permissible Indications) Determination (No.2) 2019* includes the following two indications relating to the “improvement” of exercise and cognitive performance, however there is no equivalent indication for the “maintenance/support” of exercise and/or cognitive performance:

- Helps enhance/improve/promote/increase physical/exercise performance
- Enhance/improve/promote/increase cognitive performance

Thus, further supporting the need to update the section in the proposed *Therapeutic Goods (Declared Goods) Order 2020, Part 2 Goods or classes of goods* to state:

1 *goods for oral administration that are represented (expressly or by indication) as being for the improvement ~~or maintenance~~ of physical or mental performance in sport, exercise or any other recreational activity, and which...*

Use, Advertising or Presentation - Gaining Muscle

FSANZ Schedule 4 – Nutrition, health and related claims, includes the following two claims relating to the growth/maintenance of muscle mass, therefore “gaining muscle” should not be grounds to categorise products as therapeutic goods and as such “(c) gaining muscle” is not appropriate for inclusion in *Part 2, Column 3 - Use, advertising or presentation* of the proposed *Therapeutic Goods (Declared Goods) Order 2020*.

Protein

Specific health effect

- *Contributes to the growth of muscle mass*
- *Contributes to the maintenance of muscle mass*

(Page 27 - FSANZ Schedule 4)

Use, Advertising or Presentation – Losing Weight or Fat

FSANZ Schedule 4 – Nutrition, health and related claims, includes the following claim relating to weight loss and in addition there are also numerous notified health food relationships claims relating to weight loss, as permitted in FSANZ Standard 1.2.7. Therefore “losing weight or fat” should not be grounds to categorise products as therapeutic goods and as such “(h) losing weight or fat” is not appropriate for inclusion in *Part 2, Column 3 - Use, advertising or presentation* of the proposed *Therapeutic Goods (Declared Goods) Order 2020*.

Energy

Specific health effect

- *Contributes to weight loss or weight management*

Dietary context

- *Diet reduced in energy and including regular exercise*

(Page 26 - FSANZ Schedule 4)

Time of Use/Consumption

The time of use/consumption such as preparing for a workout or recovering after a workout, does not denote therapeutic use and should not be grounds to categorise products as therapeutic goods. Water should be consumed to prepare for a workout and also to recover from a workout, and bottled water is often marketed as such, not to mention many other foods such as Saline Salts or Electrolyte Drinks which are marketed to hydrate and recover before/after exercise, or as a revitaliser for sport/exercise. Therefore, the following two inclusions “(i) preparing for workout; (j) recovering from workout” are not appropriate for inclusion in *Part 2, Column 3 - Use, advertising or presentation* of the proposed *Therapeutic Goods (Declared Goods) Order 2020*.

Dosage Form

The inclusion of dosage forms such as “tablet” in *section b of column 2 – Goods or classes of goods*, in the proposed *Therapeutic Goods (Declared Goods) Order 2020*, could inadvertently stifle future food product development, as the relevant *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*, encompasses various tablet dosage forms, such as:

dispersible, in relation to a tablet, means an uncoated or film-coated tablet intended to be dispersed in water before administration, giving a homogeneous dispersion.

effervescent, in relation to a tablet, means an uncoated tablet generally containing acid substances and carbonates or hydrogen carbonates which react rapidly in the presence of water to release carbon dioxide, and that is intended to be dissolved or dispersed in water before administration.

This could impact future food product development, for example electrolyte drinks wishing to have an effervescent or dispersible tablet in the lid that drops into the drink at the point of consumption to provide visually appealing presentation of the drink, or perhaps a tablet that turns into a protein custard as a desert for sports people wishing to support physical performance, similar to ‘junket’ tablets that have been sold as a food since the 18th century. These two examples should be classified as foods, but would unintentionally fall within the Listed Medicine category, should the tablet dosage form be included in the *Therapeutic Goods (Declared Goods) Order 2020*.

Just as the original Standard 2.9.4 for Formulated Supplementary Sports Foods, could not have envisaged the development of the sports food and supplements category when the standard was developed, it is imperative that the sector is not stifled now and in the future, in the attempt to clean up the non-compliant players in the market.

Should you require further clarification to any of the points raised, or wish to consult on further related matters, please contact me.

Kind regards

Melanie Walter
Regulatory and Compliance Manager ANZ

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Appendix - Visual display of the key areas of concern in the proposed *Therapeutic Goods (Declared Goods) Order 2020, Part 2:*

Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way		
Column 1	Column 2	Column 3
Item	Goods or classes of goods	Use, advertising or presentation
1	<p>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, and which:</p> <p>(a) contain, or are represented (expressly or by implication) to contain, one or more of the following (however described or named):</p> <p>(i) a substance included in a schedule to the current Poisons Standard;</p> <p>(ii) a substance expressly identified on the WADA Prohibited List;</p> <p>(iii) a relevant substance;</p> <p>(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;</p> <p>(v) an ingredient in an amount that exceeds any limit for the ingredient specified in the Permissible Ingredients Determination when used in accordance with the directions for use in relation to the goods;</p> <p>(vi) an amino acid in an amount that exceeds any limit for the amino acid specified in section S29—18 of the Food Standards Schedule 29 when used in accordance with the directions for use in relation to the goods;</p> <p>(vii) a substance in an amount that exceeds any limit for the substance specified in section S29—19 of the Food Standards Schedule 29 when used in accordance with the directions of use in relation to the goods; or</p> <p>(b) are manufactured in the dosage form of a tablet, capsule or pill</p>	<p>when the goods are used, advertised, or presented for supply:</p> <p>(a) for therapeutic use; or</p> <p>(b) in a way that is likely to be taken to be for therapeutic use;</p> <p>including, but not limited to, one or more of the following therapeutic uses:</p> <p>(c) gaining muscle;</p> <p>(d) increasing mental focus;</p> <p>(e) increasing metabolism;</p> <p>(f) increasing stamina;</p> <p>(g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;</p> <p>(h) losing weight or fat;</p> <p>(i) preparing for workout;</p> <p>(j) recovering from workout</p>