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TGA (Therapeutic Goods Administration) Consultation: Sports Supplements

This review could potentially have the biggest impact to the nation's health food and wellness sector since the introduction of the Therapeutics Goods Act in 1989.

The supplement industry in Australia, is already, we believe the most regulated of its kind in the world, however we welcome any reforms which could make it safer.

This could mean updating compliance to cater for changes in the international marketplace, cross borders, personal importation and the worldwide web that have been introduced since the FSANZ/TGA created the industry standards in 1989.

But in light of the TGA's consultation document on Sports Supplements (Proposed clarification that certain sports supplements are therapeutic goods), there is widespread concern regarding the implications to the Australian manufacturing and retail industry and the flow-on effects for support industries (transport, construction, equipment engineers, farmers, etc).

Furthermore, the industry believes that the proposed changes will not improve quality nor safety of the sports supplement industry but rather increase risk.

We are disappointed with the tight turnaround for consultation on this critical review, with submissions due to close at 5pm on December 3.

There is a lot at stake for millions of Australians, so we need to ensure the TGA – and the Federal Government – get it right because:

- The retail industry in sport nutrition in Australia currently accounts for \$1.1 billion
- Up to 70,000 products could be impacted
- Tens of thousands of Australians are employed directly in the industry, and in related industries (manufacturing, farming, packaging, transport, engineers, construction, etc.)

This review follows concerns raised by the Federal Health Minister after two consumer deaths – one from using a pure caffeine powder, and another from a protein powder used by a consumer with an underlying renal protein condition.

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However, the TGA paper indicates that the two so-called 'problem' items of protein and caffeine DO NOT form part of this proposed TGA clarification.

The TGA is targeting foods that have 'an equivalent pharmacological action' to an array of ingredients, or those products that are in pill/capsule/tablet form.

We believe this would potentially greatly reduce the market and therefore restrict the consumer's right of choice, forcing them to import the products from unregulated overseas providers, decreasing safety – which is what the TGA is actually trying to improve.

With more consumers ordering on-line, the TGA proposal will also reduce the number of jobs in the industry. Qualified in-store staff, who have the potential to guide consumers safety, will disappear.

Australian retailers also have boundaries around advertising and claims to comply with FSANZ and TGA, but there is no control over buying direct from overseas.

TGA notes that many products in the market are adulterated with banned substances or contaminants. However, it is believed that these products are imports as Australian food and sport supplement manufacturers are unable to buy/import these raw ingredients. TGA's idea to manage imports is to check labels for banned substances, however many times the ingredient is not on the label (undeclared ingredients).

Why only a short 'consultation period for submissions?

TGA Regulation and Manufacture Status.

- Regulating products takes considerable time.
- Regulation does not make it safer, just paperwork – automated online registration against list of ingredients.
- Many TGA manufacturers have shut down (3 businesses in 2019), and there is a restricted number currently available to manufacture in Australia.
- Normal timeframe to have product approved was 24 hours, but now taking up to 90 days. Normal manufacturing timeframes with TGA-approved suppliers was 12 weeks, now closer to 24 weeks.

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- Expectation that if products DO require TGA listing then it could be a 1-2 year process, meaning many products will simply disappear from the Australian Market
- Getting a manufacturing site approved for TGA is complex, and TGA is very slow to discuss or even return calls to assist manufacturing businesses to attain this certification.

Everyone agrees, we want the safest industry possible – acknowledging the rules, regulations and testing is already in place to ensure this is already happening.

Perhaps the TGA looks at the Generally Recognised as Safe (GRAS) system, recognised in both the EU and the US.

Points to consider

- Maintaining Australian-manufactured safe, quality products
- Proposed changes would reduce Australian jobs in manufacturing, retail, construction, transport, equipment engineers and the already hard-hit farmers. Also, loss of tax income from businesses as the products will be purchased overseas.
- Supportive of FSANZ's initiative to regulate sales of pure caffeine.
- All capsules not necessarily therapeutic – e.g., Splenda tablets formulated for body composition goals – food or therapeutic?
- Use of capsules is enviro-friendly against resource-heavy sachets for small dose powders.
- TGA approved ingredients often include synthetics, GMO products or undesirable products from overseas and the use of 'clean' ingredients and excipients is not accepted potentially making the products unhealthy.

We are calling for extensive consultation with industry (retailers, manufacturers (FSANZ, TGA and cosmetics), distributors of finished goods and raw materials, regulatory affairs consultancy, universities conducting trials, agricultural industry, naturopaths, dieticians, AMA, and associated services (local and international courier companies, freight forwarders, border security).

A Regulatory Impact Statement must be created, and an approved strategy implemented because the economic impact of these changes will be unprecedented, and the Australian economy will not be able to absorb the cost burden and loss of revenue.

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Supplements likely to be impacted:

- All Australian-made supplemental foods in powder, liquid, capsule, tablet or pill
- Sports supplements
 - Fat loss
 - Muscle gain
 - Pre-workout
 - Post-workout
 - Mental performance
 - Stamina
 - Hormones
- Herbal products:
- Gut health products
- Stress
- Sleep aids
- Antioxidants
- Plant based nutrients and vitamin blends
- Super foods – apple cider vinegar, herbals, fruit powders, dolomite, clay
- Encapsulated – fibre, superfoods, spirulina, apple cider vinegar, herbal teas, chia seeds, plant oils
- Functional foods – fermented, plant based