Proposed clarification that certain sports supplements are therapeutic goods

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The Dietitians Association of Australia (DAA) is the national association of the dietetic profession with over 7500 members, and branches in each state and territory. DAA is a leader in nutrition and advocates for food and nutrition for healthier people and healthier nations. The DAA appreciates the opportunity to provide feedback on '*Clarification that certain sports supplements are therapeutic goods*' to the Therapeutic Goods Administration (TGA).

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DAA interest in this consultation

As the leading organisation of nutrition professionals in Australia, DAA has an interest in fostering food and nutrition knowledge and skills across the community. It is important that products are appropriately regulated as foods or therapeutic goods to ensure consumer safety and to support sportspersons to select sports supplements that support their health and performance.

The Accredited Practising Dietitian (APD) program managed by DAA is the basis for self-regulation of the dietetic profession in Australia. APDs support individuals and groups regarding food and nutrition for health and sports performance. APDs apply their knowledge of food and supplement regulation in the development and marketing of sports supplements.

Recommendations

1) Consumer safety should be the priority of the declared proposal to clarify that certain sports supplements are therapeutic goods.
2) TGA and FSANZ are each reviewing this area of regulation and should communicate transparently with each other in the course of changes to the regulation of sports foods and sports supplements.
3) TGA and FSANZ should each review their respective therapeutic and health claims processes to ensure that claims promoted to consumers are truthful and do not compromise consumer safety.
4) TGA should consider extending the definition of therapeutic goods beyond pills, tablets and capsules to consider how powders, gels, chewing gums, pastes, liquids, gummies and other product innovations (e.g. orally dissolving strips) fit into the food-medicine interface.
5) TGA should not allow products to contain substances in amounts higher than allowed in foods under Food Standards Code Schedule 29 without a risk management process.
6) TGA and FSANZ should work collaboratively to establish consistent nutritive limits for sports foods and supplements in the interest of consumer safety and to provide clear guidelines to food industry.
7) TGA should work with the appropriate authorities to ensure the safety of sports supplements purchased from online international retailers.

Discussion

Q1: Do you support the proposal for certain sports supplements to be declared to be therapeutic goods?

DAA considers the proposal to be appropriate as it has consumer health and safety as a priority. Further work needs to be done on the proposal to achieve its purpose of removing ambiguity at the food-medicine interface.

While TGA acknowledges there is a degree of uncertainty about regulation of sports supplements, it seems the approach taken does not address the overlapping definitions between sports foods and therapeutic goods. Rather, TGA's proposal is to use a range of additional product features (e.g. presence or amount of certain ingredients, form) to assess whether it is categorised as a food or therapeutic good. Addressing the overlap between the definitions of sport supplement and therapeutic good is essential to ensure clarity is provided to industry and consumers.

Food Standards Code (FSC) Standard 2.9.4 regarding formulated supplementary sports foods is currently under review by Food Standards Australia and New Zealand (FSANZ). Without the outcome of this review being published, it is difficult to know how TGA's proposed clarification may take effect. TGA and FSANZ should consider the implications of this proposal and the review of FSC Standard 2.9.4 occurring concurrently.

TGA and FSANZ both have processes allowing products to contain claims that are self-substantiated, with no peer-review of the purported evidence. Both agencies should review these processes to ensure that the health and therapeutic claims promoted to consumers are evidence-based and do not compromise consumer safety.

Q2: Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers?

This proposal may affect the availability of a small proportion of sports supplements currently on the market. However, consumer safety should be prioritised above business considerations.

The proposal may have the unintended effect of increasing marketing claims on these products. A product marketed as a formulated supplementary sports food cannot have nutrition content claims or general level health claims about vitamins and minerals according to FSC Schedule 4. However, the equivalent product marketed as a therapeutic good may have many possible claims about vitamins,

minerals and other nutritive substances. This could cause potential confusion to consumers. For example, currently on the market there are electrolyte capsules marketed as a formulated supplementary sports food which do not have vitamin and mineral claims, and similar electrolyte capsules marketed as a therapeutic good which have multiple claims for vitamins and minerals.

One possible solution may be to ensure consistency in the nutrition and health claims that could be made about these products regardless of whether they are regulated as a food or a therapeutic good. Consistency in allowed nutrition and health claims, regardless of the form of the product, would reduce consumer confusion.

Q3: Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines?

DAA agrees that the proposed declaration will reduce ambiguity at the food-medicine interface and help direct industry. However, the proposal must extend beyond pills, tablets and capsules to consider how powders, gels, chewing gums, pastes, liquids, gummies and other product innovations (e.g. orally dissolving strips) fit into the food-medicine interface. For example, under the proposal, two pre-workout products with the same amount of glucose and caffeine would be regulated differently if one were a pre-mixed liquid (a food) and the other a capsule (a therapeutic good).

The decision tree appears to make the determination that any sports food containing a substance in an amount exceeding any limits specified in FSC Schedule 29 would be classified as a therapeutic good. For example, two sports food bars could have the same ingredients in similar amounts, except one has excessive vitamins, minerals and other nutritive substances prohibited by FSC Standard 2.9.4-3. To the consumer, these products fulfil the same purpose but according to law, one is a food and one a therapeutic good. Safety limits in FSC Schedule 29 have been established to prevent harm to consumers. Thus, having therapeutic products available that exceed these limits would present significant risk to consumer safety. TGA and FSANZ should work collaboratively and transparently to establish consistent nutrient limits for sports foods and supplements in the interest of consumer safety and to provide clear guidelines to food industry. This should be reflected in a more robust decision tree.

Q4: Are you aware of products on the market that would not be captured by the proposed declaration but should be?

The proposal must extend beyond pills, tablets, capsules to consider how powders, gels, chewing gums, pastes, liquids, gummies and other product innovations (e.g. orally dissolving trips) fit into the food-medicine interface. Many of these products may be used in connection with "influencing, inhibiting or modifying a physiological process in persons," for example fat-loss promoting gummies, caffeine-containing chewing gum or liquid caffeine shots.

Q5: 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.

As discussed in response to question 3, under the proposed declaration non-compliant formulated supplementary sports food products have the potential to be sold as compliant therapeutic goods. TGA and FSANZ must communicate transparently to ensure no loopholes exist that would allow a non-compliant food to be sold as a compliant therapeutic good (e.g. sports food bar with added vitamin or mineral exceeding provisions of Schedule 29-16).

Q6: What impact would the proposed declaration, if made, have on your business?

Not applicable. DAA recommends that consumer safety should be prioritised over the impact on businesses developing and distributing sports supplements.

Q7: Do you have any other comments related to the consultation?

The consultation paper does not contain information on the implementation or monitoring and evaluation of the proposed changes, nor does it provide a timeline for these processes. DAA recommend this plan be made publicly available.

DAA recommend that TGA work with the appropriate authorities to ensure the safety of sports supplements for consumers purchasing online from international retailers.

DAA recommend that the labelling of allergens be identical across these types of products to protect allergenic consumers. Many of these products contain common allergens such as milk, soy, tree nuts and peanuts. *Therapeutic Goods Order 92 – Standard for labels of non-prescription medicines* requires the labelling

of many of the allergens in the FSC Standard 1.2.3. However, it does not include lupin, which has cross-reactivity with peanuts. It also only requires a gluten declaration if it is present at more than 20 ppm, whereas for foods, any detectable gluten containing cereals, with limited exceptions, must be declared.

Consumers may not easily tell the difference between a sports product regulated as a formulated supplementary sports food or a therapeutic good. To protect consumers in regard to food allergy, it is critical that allergens be treated consistently across both regimes.