Consumers Health Forum of Australia

SUBMISSION

Therapeutic Goods Administration Consultation: Proposed clarification certain sports supplements are therapeutic goods

December 2019

Consumers Health Forum of Australia (2019)
Submission to the Therapeutic Goods Administration Consultation: Proposed clarification sports supplements are therapeutic goods.
Canberra, Australia

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Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

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Introduction

Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

Robust regulatory systems are essential in ensuring the safety of consumers who use medicines, and in addressing any issues quickly when they arise. The Therapeutic Goods Administration (TGA) plays a pivotal role in ensuring the medicines available to consumers meet and uphold community expectations and Australian regulatory standards. CHF supports the role of TGA as the regulator; we believe overall it does an excellent job of ensuring Australians have access to safe and high-quality medicines.

CHF appreciates the opportunity to provide feedback to the proposed clarification certain sports supplements are therapeutic goods (proposed clarification). Our response to the relevant consultation questions are below.

Key Considerations

Do you support the proposal for certain sports supplements to be declared to be therapeutic goods? What are the reasons for your answer?

CHF support the proposed clarification for the following reasons:

- Concerns have been raised by consumers that the current Australian and New Zealand Food Standards Code does not appropriately deal with some sports supplements (classified as food) and the health claims they are making.
- CHF recognise there are emerging issues with sports supplements putting consumers at serious risk of harm.
- The current regulatory status and food-medicine interface creates much uncertainty and confusion around how some sports supplements are regulated. CHF find it very concerning that as a result, some products may be available to consumers 'without being subject to appropriate controls or that there may be delays in regulatory authorities taking action where significant health and safety risks are detected[1]'.

Would the proposed declaration have an impact on the availability and choice of sports supplements of consumers? What are your reasons for your answer?

CHF recognises that the proposal may have a long-term impact in reducing the availability and choice of sports supplements where unsafe/dangerous sports supplements are taken off market. However we believe that this would be an appropriate and acceptable result.

CHF believes that the level of short-term impact on the availability and choice of sports supplements will depend on what transitional arrangements the TGA implements. We would suggest a standard transitional scheme where after a set date, for example 1 March 2020, all new supplements will be assessed under the proposed declaration before becoming available on the market. While all existing

[1] Therapeutic Goods Administration 2019, 'Consultation: Sports supplements Proposed clarification that certain sports supplements are therapeutic goods', Department of Health , available at: https://www.tga.gov.au/sites/default/files/consultation-proposed-clarification-certain-sports-supplements-are-therapeutic-goods_0.pdf

supplements have two years to be assessed after which they will be removed from the market if they have not appropriately complied with therapeutic good regulations.

Are you aware of products on the market that would not be captured by the proposed declaration but should be? What are the reasons for your answer? Please provide specific details and rationale for why these products should be therapeutic goods.

Overall, the CHF supports the proposed clarification that sports supplements which are or may be presented, advertised or used as therapeutic goods will be classified and regulated as therapeutic goods. We believe it is important all three of these factors are considered as any product a consumer may reasonably believe will have a therapeutic effect on their performance should be required to provide evidence not only for that effect but also the safety and quality of the product. Even if that product is chemically identical to, for example, a diet or weight loss product that doesn't present or advertise a therapeutic effect and is regulated as a food product not a therapeutic good.

We believe that the decision tree on page 14 of the consultation paper is robust and should capture all of the sport supplements that need to be considered as therapeutic goods rather than food products. Our only concern is in the final criteria "Is the dosage form of the good a pill tablet or capsule?" Our interpretation of the intent of this criterion is that if a sport supplement takes a physical form that is similar to a therapeutic good, then a consumer could reasonably believe it to be a therapeutic good and as such it should be regulated as a therapeutic good. We support this idea. However we are aware that some therapeutic goods come in different forms than listed in the decision trees, such as in liquid concentrate. As such we would suggest that the criteria in the decision tree should be amended to be "Is the dosage form of the good a pill, tablet, capsule, liquid or other form that is similar to what a therapeutic good may have?" Having this broader wording will not only cover the dosage forms of current sport supplements and therapeutic goods but also future ones that may be developed.

CHF would also like to see an articulation of what ingredients are proposed to or expected to fall under the "specified in the order" criterion in the decision tree on page 14 of the consultation paper. We could see no ingredients listed in the consultation that necessitated the inclusion of such a criterion.

Additional Feedback

An additional question we have on the potential regulation of sports supplements is whether the TGA expects supplements will be regulated as Aust L, Aust L(A) or Aust R products. Or how different supplements might be put into different regulatory classifications. In particular in relation to the criteria of a supplement containing an ingredient "expressly identified in the WADA Prohibited List" or those which contain substances that exceed the limits in the permissible Ingredients Determination and/or Food Standards Schedule 29. Given many sport supplements are widely available at supermarkets and gyms, what classifications of therapeutic good sport supplements will continue to be available at those locations and what will be restricted to locations such as pharmacies? Corollary, how will online stores and personal importation of sports supplements from overseas be affected by the proposed clarifications?

The CHF would like to know if the TGA be seeking appropriate extra resources to appropriate regulate these products, in particular the advertising compliance area which is already under-resourced for the volume of therapeutic good advertising complaints it currently receives?