Submission to the Therapeutic Goods Administration consultation relating to ‘sports supplements’ - proposed clarification that certain sports supplements are ‘therapeutic goods’

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Preamble

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public’s health in Australia.

The PHAA works to ensure that the public’s health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people’s health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.
The public health case for TGA scrutiny of ‘sports supplements’

PHAA welcomes the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) consultation on sports supplements.

Regulatory provisions allowing health claims on food are at odds with the public health nutrition principles including:

- Dietary disease risk reduction requires a total diet and dietary pattern approach, not one based on an individual food.
- All major chronic diseases where diet plays a causative or protective role, and for which labelling and advertising claims could be anticipated, are multi-factorial in nature.
- Discretionary (ultra-processed) food industries and global food manufacturers drive the Nutrition Content and Health Claims regulatory framework, contributing to public health nutrition risks resulting from biological (dietary imbalances), social equity (more expensive foods displaying claims) and environmental sustainability (use of resources in processing) dimensions. (1, 2)

Unless managed with strong regulation, monitoring and enforcement, Nutrition Content and Health Claims may be counterproductive to public health in Australia. PHAA supports strengthening of the systematic review and pre-approval processes for products carrying general level health claims and rigorous and timely monitoring of the regulation implementation and evaluation of impacts and outcomes on population health in Australia and New Zealand.

PHAA has previously highlighted concerns about foods making therapeutic claims and a trend of sponsors of therapeutic goods reformulating products as foods to avoid the provisions of the Therapeutic Goods Advertising Code. (PHAA submission Jan 2018) Concerns include challenges in using the Food-Medicine Interface Guidance Tool of the TGA and complaints passing between the TGA and state food agencies without being resolved. (3) As well, state food agencies may not be well equipped to deal with misleading therapeutic claims, given that the bulk of their regulatory remit is in other areas.

PHAA supports the proposal to clarify certain sports supplements as therapeutic goods to ensure they are regulated appropriately to protect consumers. The safety of consumers should be of prime consideration. The reported findings of illegal prescription medicines, novel substances with unknown safety profile and toxic substances in sports supplements is unacceptable and must be rectified. As well, if products are classified as food consumers may not take appropriate care with the amount they consume compared to their response to a medicine. This has concerning consequences if the consumer is influenced by a performance claim into thinking ‘more is better’.

Recommendations

PHAA supports the proposal that products in the form of pills, tablets and capsules be classified as therapeutic goods as such products are not foods and would be providing little nutritive value.

PHAA remains concerned about foods carrying therapeutic claims. We recommend all sports supplements that sit within the Food Standard be permitted to carry only pre-approved claims, to prevent claims based on poor quality evidence appearing on pack and in advertising. Goods carrying claims on labelling or in
advertising of a therapeutic nature should be classified as therapeutic goods. This should be clarified in the flow chart. Also, further clarity should be added to the flow chart to ensure that products containing substances in a form not permitted in food are classified automatically as therapeutic goods.

Processes for the regulatory requirements for medicines are not as robust as indicated in the proposal (page 15). To ensure claims are supported by good quality evidence and that advertising does not mislead consumers about appropriate benefits, PHAA recommends pre-approval of claims of therapeutic benefits for listed medications and proactive monitoring of labelling and advertising. Self-substantiation without pre-approval relies on a sponsor’s understanding of levels of evidence and systematic literature review capability without checks in place to protect consumers from misleading advertising.

Finally, the TGA must act quickly and decisively on breaches of the regulation, including forcing retractions and imposing significant fines. Failure to enforce the law undermines the authority of the TGA and fails to deter breaches by others.

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3 December 2019
References

Public Health Association of Australia submission on Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 and related bill 12 January 2018


