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

Contact for recipient:
Additional Committee Support
Senate Community Affairs Legislation Committee
A: PO Box 6100, Parliament House, Canberra ACT 2600
E: committee.sen@aph.gov.au
T: (02) 6277 3585

Contact for PHAA:
Michael Moore – Chief Executive Officer
A: 20 Napier Close, Deakin ACT 2600
E: phaa@phaa.net.au T: (02) 6285 2373
# Contents

- **Introduction** ........................................................................................................... 3
- **The Public Health Association of Australia** ............................................................. 3
- **Vision for a healthy population** ............................................................................... 3
- **Mission for the Public Health Association of Australia** ........................................ 3
- **Preamble** .................................................................................................................. 3
- **Details of the Bill** ...................................................................................................... 4
  - **Purpose of the bill** .................................................................................................. 4
  - **PHAA response to the Bill** ................................................................................... 4
    - **Foods making therapeutic claims** .................................................................... 4
    - **Pre-approval of advertisements** ...................................................................... 5
    - **Advertising complaints processes** .................................................................. 5
    - **Traditional medicine claims** .......................................................................... 6
- **Conclusion** ............................................................................................................... 7
- **References** ............................................................................................................... 8
Introduction

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.

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.

Preamble

PHAA welcomes the opportunity to provide input to the Inquiry into the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 and related bill. 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. The Australian Government, in collaboration with the States/Territories, should outline a comprehensive national cross-government framework on promoting a healthy ecosystem and reducing social and health inequities. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.
Details of the Bill

Purpose of the bill

The Bill makes amendments to the *Therapeutic Goods Act 1989* to:

- Support the implementation of a number of important recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review);
- Provide clarity regarding issues raised in relation to the processing of applications by the Department of Health, through the Therapeutic Goods Administration (TGA), by the Federal Court’s decision in *Nicovations Australia Pty Ltd vs Secretary of the Department of Health* [2016] FCA 394 (*Nicovations*); and
- Make a number of miscellaneous amendments to the Act, principally aimed at ensuring greater consistency across the regulation of different kinds of therapeutic goods.

The Review was undertaken to identify unnecessary or ineffective regulation and propose opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods. The Bill supports the implementation of key Review recommendations, including in particular the introduction of a scheme for the granting of provisional marketing approval of medicines, reforms to the advertising of therapeutic goods, changes to the regulation of complementary medicines, and streamlined sanctions and penalties under the Act. Further amendments in the Bill align the provisions in the Act relating to biologicals with Review-related changes for medicines and medical devices.

PHAA response to the Bill

PHAA has provided general support for the recommendations of the Review in previous submissions. Several of the measures will redress long-standing concerns with the advertising of therapeutic goods to consumers, particularly around complementary medicines. PHAA is generally supportive of this Bill being passed. However, the PHAA has four remaining areas of concern that we believe require additional consideration. These issues would ideally be addressed through the legislation, but could also be achieved through regulatory changes. We note though, that regulations are not subject to the same level of Parliamentary scrutiny as legislation.

Foods making therapeutic claims

Foods making therapeutic claims should be subject to the same accountability measures as any other therapeutic good. The PHAA is concerned that there appears to be a trend of sponsors of therapeutic goods reformulating products as foods to avoid the provisions of the Therapeutic Goods Advertising Code. Such products can be difficult to classify using the Food-Medicine Interface Guidance Tool of the Therapeutic Goods Administration (TGA), and jurisdictional confusion can mean that complaints can bounce back and forth between the TGA and State Food Authorities without being resolved. Moreover, State Food Authorities may not be well equipped to deal with misleading therapeutic claims, given that the bulk of their regulatory remit is in other areas.

In addition, sponsors of foods are adding ingredients – which may be considered therapeutic goods in other settings – about which they are making therapeutic claims. For example, the routine addition of plant sterols to breakfast cereals recently approved by FSANZ has resulted in therapeutic claims that would be unlikely to be allowable for a dietary supplement under the Therapeutic Goods Advertising Code 2015. However, there is not a similar Code against which to judge therapeutic claims made for food. Self-
PHAA submission on Therapeutic Goods Amendment (2017 Measures No. 1) Bill

regulatory measures do exist, but these lack the detailed provisions of the Therapeutic Goods Advertising Code as they relate to health and medical claims. Ironically, the shortcomings in the complaint system for dealing with therapeutic claims about food has the same problems that led the government to streamline and improve the complaint system for advertising therapeutic goods.

We therefore ask you to consider broadening the focus of the new Code and complaint system, and the legislative changes required, to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

Pre-approval of advertisements

Pre-approval of advertisements should remain until the associated reform package has been reviewed for effectiveness. The government has accepted a recommendation that the current pre-approval of advertisements in print, radio and television media would cease. This recommendation is conditional on related reforms also being introduced – commencing from 1 July 2018 – including: increased post-marketing surveillance; a more effective complaint system; increased penalties and sanctions for regulatory violations, and an industry education program.

The PHAA is concerned about abandoning pre-approval of advertisements without a formal review of the effectiveness of the proposed reform package. We note that the majority of published submissions to the TGA consultation on advertising reforms did not support removal of pre-approval in favour of self-regulation; with all those supporting the changes coming from industry or media organisations.

Although there is room for improvement, the current pre-approval process is largely efficient and effective. It reviews over 2,000 advertisements per year with an average turnaround time of 7 days, and identifies changes required in most advertisements it reviews to bring them in alignment with the Code. Prevention is better than cure, and the current Bill replaces a co-regulatory scheme of known effectiveness with a self-regulatory scheme of unknown effectiveness. This is particularly important for media advertisements, which may persist even once found to be in breach of the Code (for example, remaining in print media indefinitely).

We therefore ask you to recommend that the government consider a transitional period until a formal review and assessment of the reform package has been completed.

Advertising complaints processes

The TGA should ensure that appropriate stakeholders remain involved in advertising complaints processes and that decisions will be transparent. The PHAA supports the TGA taking over the advertising complaints system. However, there has been little detail on how the TGA expects to ensure continued stakeholder involvement (as currently provided by the soon to be abolished Complaint Resolution Panel and Code Council) and how the TGA will ensure transparency around the complaints process, including publication of complaints received, the outcome achieved, and the parties involved.

The PHAA would also like to take this opportunity to note that to adequately discharge their regulatory role, the TGA needs to be adequately resourced. Currently the TGA is run primarily on a cost-recovery model, with industry fees funding the TGA. The additional regulatory roles being undertaken by the TGA (e.g. the complaints processes mentioned above) will only be effective if appropriately enforced. However, the economic costs of enforcement have previously stopped important regulatory actions by the TGA that would have been of undoubted public benefit. In theory, the TGA has the power to refer matters of advertising non-compliance to the Commonwealth Director of Public Prosecutions for non-compliance with the Advertising Code. However, in practice this has never been done as the penalty of 60 penalty units (a maximum fine of $6600 for individuals and $33,000 for corporations) means that it is “not cost-effective for the TGA to initiate a formal investigation of an advertising breach with a view to preparing a brief of
evidence for consideration of prosecution by the Director of Prosecutions”, nor has it ever been so. It is therefore seen by the TGA as not to be in the public interest to proceed with such actions, even though the TGA acknowledges that “prosecution is currently the only option available where administrative requests fail to achieve compliance”.4 We would argue that although initially financially disadvantageous to the government (as maximum fines are unlikely to recoup legal costs), referral of such action and the subsequent fines may serve as a sufficient deterrent to future non-compliance, resulting in significant public health benefit that would outweigh potential economic costs.

The TGA should be given adequate resources to fully enforce the regulatory role that falls under its jurisdiction. Even the strongest regulations cannot survive a lack of regulatory will (or in this case ability due to inadequate resourcing).

We therefore ask you to examine in detail the measures the TGA have devised to continue stakeholder involvement and ensure transparency of decisions under the new system. We also ask you to examine whether the TGA will have appropriate resources for their expanded regulatory roles and will not be disproportionately reliant on industry funds.

Traditional medicine claims

There needs to be adequate controls on the use of traditional medicine claims. The government has accepted a package of recommendations designed to reduce non-evidence-based claims and stimulate innovation in the complementary medicines sector. This package consists of three major components: limiting product claims that can be made without pre-approval by the TGA (the permitted indication list); a new assessment pathway whereby sponsors who have clinical trial evidence to justify an intermediate-level claim can submit this to the TGA to get their claim approved, and a period of data protection for sponsors who provide data for an approved evidence-based claim or a new ingredient.

The PHAA supports these changes in principle, though we do have some concerns about the extent of the TGA’s proposed permitted indication list. The current list contains 1,345 draft permitted indications submitted by industry, many of which may not be entirely appropriate for inclusion based on scientific evidence to back them or their history of use for traditional claims. For example, adrenal health is likely to relate to the adrenal fatigue hypothesis, which has neither a compelling scientific evidence base to support it5 nor a sufficient history of use for traditional claims – it would fail the “three generation rule” as it was first popularised by chiropractor James Wilson in 1998. We would suggest that the proposed list of permitted indications should be tightened significantly and focused on modest indications (e.g. “may be helpful...”, “may assist...”, etc).

The TGA’s proposed list of indications also includes many traditional indications. The PHAA believes it is appropriate to respect and acknowledge other medical traditions – some of which have provided conventional medicine with efficacious medicines – but believes that this needs to be done in an appropriate way. International developments, such as the development of a traditional medicine chapter in the update of the International Classification of Diseases, necessitate that regulators begin to identify ways in which to ensure claims based on traditional knowledge do in fact have a legitimate basis to make those claims. However, some of the claims in the proposed list would be unlikely to be supported by established texts in those traditions (for example herbal monographs such as the British Herbal Pharmacopeia, or see the adrenal fatigue example mentioned previously). In some cases the product making traditional claims may not reflect the product that was traditionally used (for example, *Withania somnifera* was typically taken in the Ayurvedic tradition as a milk decoction, yet few modern herbal medicine products sold in Australia utilise this technique, even though they make traditional claims based on it). The PHAA suggests that traditional indications should be reviewed to ensure that they do align with the traditions from which
they are purported to come, so that the use of traditional indications is not used as a pathway to entrench inappropriate claims.

Whilst the PHAA supports greater regulation around traditional claims made for medicines, we note that traditional evidence of use does not abrogate the responsibility for the appropriate inclusion of scientific evidence around safety, such as evidence of adverse events, herb-nutrient-drug interactions or adulteration. Additionally, whilst traditional medicine claims are a valid form of knowledge, they are not scientific evidence. As such, any claims based on traditional evidence should make it unequivocally clear that the claim is one based on tradition, not on scientific evidence, to ensure that the consumer is appropriately informed.

As such, whilst PHAA supports in principle the proposed changes we ask you to require the TGA to significantly tighten the permitted use of approved indications for complementary medicines – both in regards those based on scientific evidence and those based on traditional evidence.

**Conclusion**

PHAA supports the broad directions of the Bill and generally supports the passing of the Bill. However, we are keen to ensure practical application and implementation of the Bill, in line with this submission. We are particularly keen that the following points are highlighted:

- Foods making therapeutic claims should be subject to the same accountability measures as any other therapeutic good
- Pre-approval of advertisements should remain until the associated reform package has been reviewed for effectiveness
- TGA should ensure that appropriate stakeholders remain involved in advertising complaints processes and that decisions will be transparent
- The TGA should be fully funded by Government, independent of Industry
- There needs to be adequate controls on the use of traditional medicine claims

The PHAA appreciates the opportunity to make this submission and to contribute to this Bill.

Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.

Michael Moore BA, Dip Ed, MPH
Chief Executive Officer
Public Health Association of Australia

Jon Adams
Convenor, Complementary Medicine
PHAA Special Interest Group

12 January 2018
References


