Submission No 21

THE PROMOTION OF FALSE OR MISLEADING HEALTH-RELATED INFORMATION OR PRACTICES

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Sub

Australian Government

Department of Health
Therapeutic Goods Administration

Mrs Leslie Williams MP
The Chair
Committee on the Health Care Complaints Commission
Parliament House, Macquarie Street
SYDNEY NSW 2000

Our Reference: R13/991823

Dear Mrs Williams MP

TGA Submission to the Inquiry into the promotion of false and misleading health related information practices

The Therapeutic Goods Administration (TGA) as a division of the Australian Government Department of Health is pleased to contribute towards the New South Wales Parliamentary Committee on the Health Care Complaints Commission (the Committee) inquiry into the promotion of false and misleading health related information or practices.

The TGA's overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied in or exported from Australia. The role of the TGA is to apply the therapeutic goods legislation, primarily the *Therapeutic Goods Act 1989* (the Act).

It is important to note that the TGA does not regulate the dissemination of health related information that is not related to a particular therapeutic good, nor does it regulate health care practitioners.

However, there are aspects of the TGA's regulatory remit which may be relevant to your inquiry, in particular, the TGA's regulation of listed complementary medicines and the advertising of therapeutic goods. In this regard, I **attach** an overview of what the TGA is responsible for as well as a summary of how the TGA regulates listed complementary medicines and the advertising of therapeutic goods.

The TGA is concerned where messages regarding public health and safety may not be accurate and balanced and may be misleading to patients and consumers.

Please contact me if you would like to discuss any of these matters further.

Yours sincerely,

[redacted]

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TGA Health Safety Regulation

What does the TGA do?

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health. The TGA's overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied either imported or manufactured, or exported from Australia. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable timeframe, to new therapeutic goods.

How does the TGA regulate?

The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries.

The TGA regulates therapeutic goods through:

- pre-market assessment;
- post-market monitoring and enforcement of standards; and
- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods must be listed, registered or included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia, unless specifically exempt under the Act.

What are 'therapeutic goods'?
In relation to the evaluation, assessment and monitoring done by the TGA, therapeutic goods are broadly defined as products for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling or preventing conception; and
- testing for pregnancy

This includes things that are:

- used as an ingredient or component in the manufacture of therapeutic goods; or
- used to replace or modify of parts of the anatomy

Risk based approach
The TGA approves and regulates products based on an assessment of risks against benefits.

All therapeutic goods carry potential risks, some of which are minor, some potentially serious. The TGA applies scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk.

The level of TGA regulatory control increases with the level of risk the medicine or device can pose. Risk information is used by the TGA when deciding how to approve a medication for supply. For example, a low-risk product may be safely sold through supermarkets, while higher-risk products may only be supplied with a prescription.

The TGA's approach to risk management involves:

- identifying, assessing and evaluating the risks posed by therapeutic products
- applying any measures necessary for treating the risks posed; and
- monitoring and reviewing risks over time.

The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs.

Listed and registered products
As mentioned, medicines must be included on the ARTG before they can be supplied in Australia.

Consistent with the TGA's risk based approach, high risk medicines, such as those requiring a prescription, are *registered* on the ARTG. Meanwhile, lower risk medicines are *listed* on the ARTG.

The TGA thoroughly evaluates the quality, safety and efficacy of registered medicines medicines before they may be supplied and used by Australians. In contrast, listed medicines are not individual evaluated for efficacy before being included in the ARTG.

The regulation of listed complementary medicines

Complementary medicines comprise medicinal products containing herbs, vitamins or minerals; nutritional supplements; traditional medicines, such as indigenous Australian medicines, Chinese medicines and Ayurvedic medicines from the Indian subcontinent; homoeopathic medicines, and some aromatherapy products.

Complementary medicines supplied in or exported from Australia are generally required to be included in the ARTG; however, some, such as very dilute homoeopathic preparations, are not required to be included.

The vast majority of complementary medicines are considered low risk and are therefore *listed* rather than *registered* on the ARTG.

Listed complementary medicines are not individually evaluated before they are released onto the market, but may be assessed to ensure they comply with legislative requirements after they have been listed. However, listed medicines must be manufactured in accordance with the principles of good manufacturing practice and may only make certain therapeutic claims.

Sponsors of listed medicines must certify to the TGA that they hold information or evidence to support any indication (specific therapeutic use) or claim made in relation to the listed medicine.

To maintain consumer confidence in the quality, safety and effectiveness of complementary medicines supplied in Australia, the TGA undertakes post-market regulatory activities including:

- random or targeted compliance reviews of listed medicines, where we assess information about the product against the legislative requirements
- information on adverse reactions to complementary medicines received by the TGA
- random and targeted laboratory testing of products and ingredients
- random and targeted surveillance in the marketplace, including audits of manufacturing sites and product recall if required; and
- monitoring the advertising of therapeutic goods with compliance reviews initiated where necessary.

Indications and claims for listed complementary medicines
Indications are the specific therapeutic uses of therapeutic goods. The terms 'indication', 'therapeutic goods' and 'therapeutic use' are defined in section 3 (interpretation) of the Act.

Listed medicines may only include indications and claims relating to health maintenance and health enhancement, and may generally not refer to a serious form of a disease, disorder or condition, or indicate they are for treatment or prevention of any condition.

In particular, to be eligible for listing a medicine cannot have indications that are for the treatment of certain diseases and conditions set out in Appendix 6 of the Therapeutic Goods Advertising Code (the Advertising code)[1].

It is an offence for a sponsor to advertise a listed medicine for an indication other than the indication accepted for the listing of the medicine on the ARTG.

It is also a condition of listing that the sponsor of a listed medicine will not, by any means, advertise the goods for an indication other than those accepted for the listing of the medicine on the ARTG.

Restricted representations and prohibited representations

In addition, sponsors cannot advertise an indication (including by putting it on the label of a medicine) that contains a prohibited representation[2] or a restricted representation[3] unless it has been approved or permitted by the TGA[4]. This aligns with the principle that medicines may only be listed (rather than registered) if they pose low risk to consumers.

Generally speaking a restricted representation is a reference, expressly or by implication, to serious forms of diseases, conditions, ailments or defects. 'Serious' means forms of diseases, conditions, ailments or defects that are:

- generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional; and/or
- generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

Thus indications that do not involve the treatment of the diseases and conditions set out in Appendix 6 but do contain a restricted or prohibited representation cannot lawfully be advertised for listed medicines without express TGA approval for their advertising.

An indication itself can pose a risk to consumers if, for example, when included in advertising, it may lead a consumer to attempt to self-treat a condition that cannot be diagnosed accurately or treated safely without the assistance of an appropriately qualified healthcare practitioner.

Regulating advertising of therapeutic goods

The advertising of therapeutic goods to consumers and health professionals is controlled by a combination of statutory measures administered by the TGA and self-regulation

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[1] These are Neoplastic Sexually Transmitted Diseases (STD), HIV AIDS and/or HCV, mental illness, cardiovascular diseases, dental and periodontal diseases, diseases of joint, bone, collagen, and rheumatic disease, diseases of the eye or ear likely to lead to blindness or deafness, diseases of the liver, biliary system or pancreas, endocrine diseases and conditions including diabetes and prostatic disease, gastrointestinal diseases or disorders, haematological diseases, infectious diseases, immunological diseases, mental disturbances, metabolic disorders, musculoskeletal diseases, nervous system diseases, poisoning, venomous bites and stings, renal diseases, respiratory diseases, skin diseases , substance dependence, urogenital diseases and conditions.

[2] 'Prohibited representations' are set out in Part 1 of Schedule 2 of the Therapeutic Goods Regulations 1990, a copy of which is at Appendix 1.

[3] 'Restricted representations' are set out in Part 2 of Appendix 6 of the Advertising Code, a copy of which is at Appendix 2.

[4] See sections 42DF and 42DK of the Act.

through Codes of Practice administered by the relevant therapeutic goods industry associations. Advertising directed to the general public is permitted for the majority of medicines available for over- the-counter sale, while advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited.

Legislation administered by the TGA in relation to advertising of therapeutic goods includes:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- Therapeutic Goods Advertising Code 2007 (TGAC); and
- the current *Poisons Standard 2012*.

Advertising to consumers is permitted for the majority of medicines available for over–the-counter sale, including listed complementary medicines. The regulatory requirements relating to the advertising of therapeutic goods to the general public are principally (but not exclusively)[5] set out in Part 5-1 (Advertising and generic information) of the Act, Parts 2 (Advertisements) and 6 (Committees) of the Regulations and in the Therapeutic Goods Advertising Code (which is made under section 42BAA of the Act). Apart from advertising that is exclusively directed at health professionals, the requirements in Part 5-1 do not apply to advertisements for goods that have been exported or are intended exclusively for export[6].

The purpose of these requirements is to protect public health by promoting the safe use of therapeutic goods, ensuring that they are honestly promoted as to their benefits, uses and effects.

Further information on Australia's co-regulatory system of advertising for therapeutic goods, including details of the Therapeutic Goods Advertising Code Council (TGACC), the Complaints Resolution Panel and the Complaints Register, may be obtained from the TGACC Internet site. The Therapeutic Goods Advertising Code Council makes recommendations about the advertising requirements and any changes to the Code.

Complaints about advertising

Complaints about advertisements directed to consumers in specific media (such as newspapers, magazines, the Internet, radio and television) are considered by the Complaints Resolution Panel.

[5] The prohibitions on advertising goods for indications/uses/purposes that have not been approved are not located in Part 5-1.

[6] Section 42AC of the Therapeutic Goods Act.