CMA Submission:
Enhancing Sanctions and Penalties in the Therapeutic Goods Act 1989

To:
MMDR Consultations
Enhancing sanctions and penalties
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

From:
Complementary Medicines Australia
PO Box 450
Mawson
ACT 2606
Telephone: 02 6260 4022
E-mail: carl.gibson@cmaustralia.org.au
Website: www.cmaustralia.org.au

May 31, 2017

Contents

Introduction

Complementary Medicines Australia (CMA) appreciates the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation paper "Enhancing Sanctions and Penalties in the *Therapeutic Goods Act 1989*", dated May 2017.

On 8 April 2015, CMA made a comprehensive submission to the Expert Panel Review of Medicines and Medical Devices Regulation, announced by the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash and chaired by Emeritus Professor Lloyd Sansom AO. The CMA submission addressed the Stage Two Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods (recommendations 33 to 58). On the 15 September 2016, following consultation with industry, consumers and healthcare professionals, the Government provided its response, which largely accepted the Medicines and Medical Devices Regulation (MMDR) suit of recommendations.

The acceptance of recommendations twenty-eight and fifty-seven relate to enhancing sanctions and penalties in the *Therapeutic Goods Act 1989*. Specifically, the approval of recommendation fifty-seven approves that the Australian Government give consideration to whether the current range of investigation and enforcement powers should be broadened.

CMA supports the main themes of the MMDR; that is to identify ways to improve access to therapeutic goods for consumers and ensure that the regulatory settings are appropriately aligned to risk and remove unnecessary regulatory and administrative burden, whilst maintaining the safety of therapeutic goods in Australia. The Act can be amended to better reflect public health and consumer protection outcomes that it is designed to achieve.

Executive Summary

Increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, one that will continue to generate an evidence base on which polices can be developed to improve health and strengthen Australia's economic fabric.

Over the last few decades the Australian complementary medicines sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports. Whilst manufacturing is essential to a diverse and resilient economy, and offers a disproportionally large contribution to exports and research, it is well recognised that Australia is a high-cost place to do business.

The implementation of the Medicines and Medical Devices Regulation (MMDR) recommendations fifty-five, fifty-seven and fifty-eight go hand in hand in changing the entire process of vetting and pre-approval of advertising on a basis of increased penalties and sanctions for compliance that will be underpinned by a sponsor education program.

The removal of pre -approval requirements will help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

The broadening of enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements and deter inappropriate and misleading advertising of products.

Importantly, the development of a sponsor education program will assist sponsors and advertisers in understanding their obligations and will be particularly vital once the reforms to the advertising regulatory framework are in place.

Stakeholder consultation

As part of stakeholder consultation, CMA provided a submission on the regulatory frameworks for advertising therapeutic goods, which closed on the 21 December 2016.

The CMA submission highlighted that both consumers and industry desire advertising that provides accurate and adequate information about complementary medicines. The advertising framework under which complementary medicines are regulated ought to reflect the lower risk profile of these products, and deliver a streamlined system that is easy to navigate for both business and consumers.

CMA supported the removal of the current mandatory pre-approval requirements for several reasons, including reducing unnecessary complexity for sponsors and advertisers and to minimise excessive regulatory and financial burden upon businesses.

CMA acknowledges that recommendations fifty-seven (enforcement powers) and fifty-eight (sponsor education) are critical for managing potential concerns of the reforms and is of the firm belief that the implementation of these recommendations will ensure responsible advertising of complementary medicines. The vast majority of the complementary medicines industry appreciate the importance of responsible advertising of therapeutic products. The complementary medicines industry strongly supported the retention of a therapeutic goods advertising code, the ability for the regulator to take swift action against blatant major non-compliance and repeat offenders, and a strong educational component within the advertising framework.

Layered approach to compliance and enforcement

It is important that the proposed amendments to the Act provides for an effective layered approach to compliance and enforcement. Vitally, the main objective should be to ensure regulatory actions are proportionate with the risk that the therapeutic goods pose.

Enhancing sanctions and penalties

Recommendation 57 - The Government accepts the need for stronger compliance powers against misleading advertising, noting that broadening enforcement powers will benefit consumers by ensuring appropriate compliance with regulatory requirements and deter inappropriate and misleading advertising of therapeutic goods.

The vast majority of industry seeks to comply with the regulations. Acknowledging that listed medicines pose a lower risk profile, the new regulatory framework should be effective in allowing for a scale of mechanisms to support compliance that reflect the severity of a breach, while also providing the regulator with the ability to swiftly and effectively deal with those who severely flout the rules or repeatedly fail to comply.

CMA supports that a gradation of sanctions and penalties for each prohibited action should be provided to effectively manage the level of risk for each offense. As part of the gradation approach, there may be a role for the proposed third party providers for advertising copy advice. For example, in the event that a breach is not a major breach, the TGA could direct an offending company to have their advertisements pre-approved by the third party provider for a specified period of time, or that an individual from the company must undergo compulsory advertising training. This coupled with enhancements and increases in post market monitoring activates and compliance reviews for complementary medicines, sets the stage for an effective deterrent regime.

Introduction of substantiation notices – advertising

The Government accepted the Expert Panel's recommendation that consideration be given to broadening the current range of enforcement and investigation powers. Consistent with the 2016 consultation, it was proposed that the Act be amended to allow the regulator to issue substantiation notices requiring a person to give information and or produce documentation that could substantiate or support a claim or representation made by the person in an advertisement of a therapeutic good.

The regulator proposes that the substantiation notices be similar to those used by the Australian Competition and Consumer Commission (ACCC). Consistent with this, a person served with a notice would be required to comply with the notice within 21 days; the person would not be required to prove that a claim or representation is true or not misleading; rather it would be used as a preliminary investigative tool that would be used to determine whether further investigation was warranted.

If a person does not respond to the substantiation notice or fails to do so within the compliance period, or provides false or misleading information or documents in response to the notice, the amendments proposes various actions being available, including:

- commence criminal proceedings;
- commencing litigation; and
- issuing infringement notices as an alternative to formal court action.

Significant penalties for non-compliance and/or the provision of misleading information are also proposed, ranging from 12 penalty units to 250 penalty units.

CMA requests that additional information be provided in relation to the detailed circumstances in which the regulator would issue substantiation notices and provide examples of such circumstances.

CMA also proposes that, consistent with the ACCC 21 day time frame, the period in which to provide documentation allows for circumstances where an extension can be granted. CMA believes that a legitimate attempt to provide information which could (rather than would) substantiate a claim would be adequate to comply with a notice.

Introduction of public warning notices – advertising

Consistent with the 2016 consultation, it was proposed that the Act be amended to allow the regulator to issue public warning notices similar to the ACCC. It is proposed that the Act be amended to allow the issue of a public warning notice where the regulator:

- has reasonable grounds to suspect that an advertisement for therapeutic goods may constitute a contravention of a provision in the Act;
- are satisfied that one or more other persons may have suffered, or is likely to suffer, detriment as a result of the advertisement; and
- are satisfied that it is in the public interest to do so.

CMA agrees that the key consideration in the issuing of a public notice would be whether there is an **imminent** need to inform consumers.

CMA requests further information about how the regulator intends to set up its public warning notice register and the extent of the detail of information that would be provided to the public in such notices.

Introduction of injunctions

The RPSPA provides for a framework of standard regulatory powers to be exercised by government agencies across the Commonwealth. Its key features include investigative powers and enforcement powers such as civil penalties, infringement notices, enforceable undertakings and injunctions. The Act currently allows for all of these regulatory tools **except for injunctions** and the regulator anticipates that by enlivening the ability to seek an injunction, the reforms will allow serious advertising non-compliance to be addressed in a timely manner.

CMA believes it is in the best interests of industry and consumers for the TGA to have the ability to apply to a court for an interim or permanent injunction to immediately restrain a person from advertising when such advertising poses **serious** risks to public health and safety.

Consistent with the 2016 stakeholder consultation on advertising reforms, the TGA propose that the power to apply for an injunction by introduced by adoption of the powers in the *Regulatory Powers (Standard Provisions) Act 2014* (RPSPA), which would be consistent with other Commonwealth legislation.

The powers allow investigation of suspected contraventions of offences and civil penalty provisions. The investigation powers include powers to search for and seize evidence as well as inspect, examine, measure and test anything on a premises.

In addition, the RPSPA provides for the use of civil penalty provisions, infringement notices and injunctions to enforce regulatory provisions, and the acceptance and enforcement of undertakings relating to non-compliance with provisions.

The proposed amendments to the Act to adopt the provisions of the *Regulatory Powers (Standard Provisions) Act 2014*, will include:

- Monitoring;
- Investigation;
- Infringement Notices; and
- Injunctions (new tool, not currently provided for in the Act)

Strict liability offences in the Act

The Government has endorsed the Expert Panel's recommendation to provide for graduated penalties that would allow the regulator to respond to a range of non-compliance – from repeated minor breaches through to serious non-compliance.

As outlined in the consultation document, the current Act requirement for many strict liability offences that the relevant goods, if used, would likely result in harm or injury to a person requires an [unnecessary] complex assessment of the circumstances where the underlying action is so serious that it is not appropriate to include this additional requirement. Therefore, the TGA propose removing the requirement of the "likelihood of harm or injury to any person" from each strict liability criminal offence in the Act so as to align all strict liability offences with the proposed amendments for strict liability offences in relation to advertising.

That is, the proposed new strict liability offences relating to advertising will not have an element of culpability (likely to result in harm or injury) and as a consequence the proposed amendments will also result in a **substantial reduction** in penalties from 2,000 to 100 penalty units, aligning strict liability offences with many other strict liability offences available to comparable Commonwealth regulators.

CMA supports the intent for reforms to the advertising framework provide for graduated penalties that allow the regulator to respond appropriately to the full range of non-compliance issues - from repeated minor breaches through to serious non-compliance. However, given the breadth of this

change to the Act and the potential implications of the removal of the parameter to prove culpability, we respectfully reserve the right to see further detail of the drafted legislation before commenting further on the impact this may have on our sector.

In addition, CMA suggests that there may be a role for repeat/minor non-compliance breaches of the advertising code to be dealt with more efficiently through a centralised third party organisation, as proposed and accepted by recommendation fifty-six, as described below.

Education Program

Recommendation fifty-eight - The Government accepts that the TGA should develop a formal education program to provide sponsors and advertisers with appropriate information and tools to assist them in understanding their obligations and achieving compliance with advertising requirements. This will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of Recommendation Fifty-Five).

In supporting a strong education component (rec 55 refers), CMA proposes that a third party provider of voluntary advertising copy advice (referred to as AUS-TAPS/ASB in our 2016 submission) be recognised by the TGA. That is, such services would be available on a voluntary fee-for-service basis and where identified through TGA non-compliance activity, industry members would be required to seek the services of copy advice at their own expense to address any deficiencies for a required period of time.

The Advertising Standards Bureau (ASB) is responsible for the administration of the complaint resolution component of the advertising self-regulation system in Australia. The Bureau supports the work of the Advertising Standards Board (Standards Board) and Advertising Claims Board (Claims Board), the bodies established to consider public and competitor complaints respectively

about advertising and marketing communications against provisions set out in the relevant advertising codes.

As described in stakeholder responses to the 2016 consultation, CMA believe the ASB would be an appropriate body for the handling of complaints under the design of a new centralised advertising complaints management process. There is an opportunity for the TGA and an organisation such as the ASB to work collaboratively in the handling of complaints related to advertising of therapeutic products and to develop a formal education/accreditation program, with ongoing management the responsibility of the ASB.

It is considered that the Bureau's independent, well-recognised and proven complaint resolution process offers a practical and cost-effective solution to the problems with the current complaints process highlighted over successive reviews, including the recent findings of the Expert Review. Bringing complaints about advertising of therapeutic products within the complaint resolution process managed by the Bureau achieves the goal of a single, central point for complaints (MMDR rec 56 refers) about advertising of therapeutic products, with the advantage that efficient processes and procedures for complaint handling are already in place. A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers.

CMA supports that the Bureau is best placed to develop and maintain a robust and effective advertising complaints management process for therapeutic product advertising, one that provides confidence for consumers and industry and leverages off the existing model and extensive experience the ASB have in advertising complaint management.

Industry education

Listed complementary medicines are included in the Australian Register of Therapeutic Goods (ARTG) via an electronic application process that is designed for efficient access to market. At the time of listing, the product sponsor must certify that they hold the evidence to support any indications or claims made about their medicine, and that the indications and claims are true, valid and not misleading. However, to become a sponsor one does not necessarily require specialist knowledge about one's legal or regulatory responsibilities.

CMA supports the implementation of an accreditation/licensing scheme for medicine sponsors, as an efficient solution to ensuring that before a sponsor is able to list products on the ARTG they have undertaken a reasonable level of compliance training and will be subject to compliance monitoring. This would further engage industry and assist in the removal of regulatory burden arising from a lack of understanding, whilst providing an additional level of assurance for the protection of consumers.

It is envisioned that such a program would cover and assess a learner's ability to:

- submit product listings on the ARTG;
- source suitable evidence to support indications and prepare it in a manner appropriate for TGA submission;
- determine appropriate indications and claims for a product;
- prepare and review advertising/marketing for a product; and
- provide required label information for a product.

The program could be set up so that at least one company-nominated individual would need to complete the associated assessments to receive a statement of attainment or certificate.

Once training was completed, the individual would be given an 'Authority ID' which could be issued

by a body such as ASB, an ID number would then be required in order to list a therapeutic product on the ARTG. This requirement for an 'Authority ID' allows the ability for the TGA to rescind the license of repeat minor non-compliance offenders and also goes some way to replacing the need for a mandatory pre-approvals system for advertising.

Ideally, sponsors would also be required to nominate to abide by an industry association code of practice. This would not mean that the sponsor must become a financial member of said association, nor would it restrict their ability to join alternate associations. This concept was proposed by the Working Group for the Promotion of Therapeutic Products in 2011, as a recommendation to strengthen and standardise industry self-regulation and to provide a mechanism to ensure compliance by both members and non-members of industry associations. This had a very high level of support across multiple stakeholders at the time, and would help to provide the ability for an effective sanctions and penalties framework to deter non-compliance.

Summary

A responsive and effective regulatory framework for complementary medicines should balance safety and market access priorities to the benefit of consumers and industry and align with the government's commitment to increase productivity and competitiveness. With the set of MMDR reforms and a combination of co-regulatory mechanisms described in this submission, the TGA will continue to operate effectively and efficiently, while also maintaining appropriate public health and safety protections.

Overall, the proposed modifications to the RPSPA will update the suit of regulatory tools of the TGA and provide alignment with other comparable regulators and current Government policy.