Complementary Medicines Australia submission to the Therapeutic Goods Administration Consultation:

The Regulatory Framework for Advertising Therapeutic Goods

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Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment with regard to the TGA's consultation on the regulatory framework for advertising therapeutic goods. CMA is exclusively committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. CMA supports appropriate industry regulation to ensure consumers have access to complementary medicines of the highest quality.

The increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, both economically and as an employer. 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.[1]

CMA has acknowledged the Government's focus on reducing unnecessary red tape to enable Australian businesses to be competitive on the global stage, and welcomed the recent announcement that the Government accepts the recommendations of the Review of Medicines and Medical Devices Regulation (MMDR), led by Professor Lloyd Sansom AO. The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the lower level of risk these products represent. For our industry, as for other Australian industries, putting the right regulatory environment in place will enable, promote and encourage innovation and competitiveness.

Both consumers and industry want advertising that provides accurate and adequate information about complementary medicines. The advertising framework under which complementary medicines are regulated needs to reflect the lower risk profile of the products, and deliver a streamlined system that is easy to navigate for both business and consumers. CMA provides the following comments for consideration.

[1] Australian Workforce & Productivity Agency. (2014). Manufacturing Workforce Study

Pre-approval of Advertisements

Recommendation 55: The Government accepts that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public should be stopped in favour of a more self-regulatory regime. The implementation of Recommendations 57 (enforcement powers) and Fifty-Eight (sponsor education) are critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

The Australian Government has accepted the Expert Panel's recommendation that the process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime. CMA supports the removal of 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. In addition, the system is no longer efficient or capturing all media; most notably the rapidly growing area of internet advertising is not covered. With the rapid pace of technological development, it is highly likely that firms will be communicating with consumers via a range of channels, some of which we may not be even be aware of yet. Ideally, the new advertising framework needs to be simple, rational and effective.

CMA notes and acknowledges that recommendations 57 (enforcement powers) and 58 (sponsor education) are critical for managing potential concerns and is of the firm belief that the implementation of these recommendations will ensure responsible advertising of listed complementary medicines. The vast majority of the complementary medicines industry do not want to deliberately mislead or offend current or potential customers, and 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.

Self-regulation encourages an industry to take greater responsibility to ensure advertising to consumers is legal, decent and honest and prepared with a sense of social responsibility to the consumer, and with due respect to the rules of fair competition. Many of our members are very supportive of the concept of a voluntary pre-approvals framework. CMA envisages that this system could be administered by a not-for-profit third party organisation, similar to the Therapeutic Advertising Pre-vetting Service (TAPS) in NZ or the Council of Better Business Bureaus in Canada and the US, where experienced independent consultants act as advisors/adjudicators.

The third party organisation (named AUS-TAPS for ease of this discussion) would be in a position to provide a number of services relating to the advertising of listed therapeutic goods and as a not-for-profit organisation, AUS-TAPS would derive its income largely by voluntary subscription from member companies.

Services could include:

- voluntary copy advice as a service to industry that meets established best practice;
- establish the policies and procedures (guidance) for the voluntary pre approvals of advertising direct to the public;
- develop and make available checklists, tools and guidance to assist in avoiding misleading, non-substantiated or deceptive advertising claims;
- co-delivery with the body responsible for complaints handling functions, to deliver education and training initiatives to industry participants on requirements of the Code, decision trends and complaint process; and
- an online archive, available by subscription, that could include case reports as well as refer to a searchable system of advertising determination reports (by NRA or external organization by tender as rec 56 refers).

AUS-TAPS as a third party provider, would be in a position to administer a repository of industry advertising whereby a responsible individual(s) would be able to sign off on their company's new advertising material and upload a proof of concept to the repository. This would allow AUS-TAPS to monitor trends in communications with consumers and develop guidance targeted to assist industry in avoiding non-compliant advertising. It would also serve to encourage an in-house responsible person to be accountable for their actions in the appropriate advertising to consumers.

See appendix 1 for a flow chart design of how this system could operate in the self-regulatory environment.

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. Given the low risk nature of listed medicines, the new advertising 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.

It is seen as in the best interests of both the 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.

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 and believes that there is also a potential role for AUS-TAPS in the scale of sanctions. For example, in the event that the breach is not a major breach, the TGA could direct that an offending company must have their advertisements pre-approved by AUS-TAPS 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, sets the stage for an effective deterrent regime.

By supporting a strong education component (rec 55 refers), CMA proposes that AUS-TAPS be recognised by the TGA in providing the above services to industry. That is, the services of AUS-TAPS 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 AUS-TAPs at their own expense to address any deficiencies.

Support for this mechanism utilises a mix of self-regulatory and co-regulatory arrangements which are already supported under the Act and Regulations[2] and would, we believe, best achieve the aims of the MMDR in delivering an advertising framework that for business is simplified in its approach and for consumers, robust in its sanctions and penalties.

[2] Advertisements for complementary medicines are regulated by both co-regulatory and self-regulatory arrangements under the Act and Regulations

Complaints Handling

Recommendation 56 - The Government accepts that current mechanisms for managing complaints should be disbanded and a new mechanism established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, thereby benefiting consumers.

The Australian Government has accepted the Expert Panel's recommendation that the current mechanisms for managing complaints should be disbanded and that a single agency should be responsible for receiving and managing complaints about the advertising of therapeutic products to the public. It was also agreed by the Government that complaints will be managed and resolved in line with best practice principles such as those set out in the Commonwealth Ombudsman's: Better Practice Guide to Complaints Handling.

Criticism that has often been levelled at the current complaints handling mechanism includes that the framework is disjointed and confusing, is inefficient and costly, and lacks an appeals process. A current criticism of the CRP is that the panel invests too much time in consideration of issues of efficacy, which not only slows the process down but can be more appropriately dealt with by the regulator or by a separate external organisation.

CMA believes that the new complaints mechanism should handle complaints quickly, efficiently and prioritised according to potential safety impact on the consumer. Advertising complaints that lead to consideration of quality and safety matters should be prioritised in terms of consumer safety over and above other matters in this self-selected category of goods.

The current regulatory framework does not require listed medicines to be evaluated for clinical effectiveness prior to marketing. However, it is a requirement under the *Therapeutic Goods Act 1989* and the sponsor signs a statutory declaration stating that the information submitted is true, the final product contains only permitted ingredients, the label complies with all regulatory requirements and the company has the necessary evidence to support the claims being made, including therapeutic claims. This is balanced with a risk based pre and post market approach to compliance. For example, the TGA undertakes a number of random and targeted reviews of therapeutic claims made by listed medicines and assesses the evidence that companies are required to hold to support these claims. If, as a result of these reviews, it is found that the company listing the medicine does not have the necessary evidence, then the approval to supply the medicine (the listing) can be cancelled off the ARTG and from supply.

Under recommendation 49, the NRA will develop a more comprehensive post-market monitoring scheme that has seen the TGA double (and will double again) its post market listing and compliance reviews on listed products. Further, CMA proposes that if a product is

withdrawn or cancelled from the ARTG because of an identified major compliance issue, and the sponsor subsequently chooses to re-list the product, then the product should be flagged for priority targeted review so as to assess compliance status.

The Electronic Listing Facility (ELF) provides a list of 'coded permitted indications' that sponsors may choose from when self-listing their medicine on the ARTG. Under the proposed new regulatory framework, there will be a refined list of permitted indications, from which sponsors must exclusively draw for listed medicinal products in the ARTG (rec 38 refers). In addition, there will be a third option for listing medicines onto the ARTG where the sponsor can elect for their product, that contains ingredients already permitted in listed medicines, to undergo pre market assessment of efficacy indications and claims (rec 39 refers).

While the Government endorsed a single point of contact for advertising complaints, the Panel was of the view that, with appropriate resourcing, the function of receiving and managing complaints could be established within the TGA, another Commonwealth agency, or could be outsourced. CMA supports a call for tenders for external organisations to undertake the complaints handling function.

Option1:

CMA has established a self-regulatory mechanism for the complementary healthcare industry. Its focal point is its Marketing & Supply Code of Practice which seeks to self-regulate the marketplace by encouraging compliance with relevant Commonwealth and State legislation. The major objective of CMA's complaint handling mechanism is to resolve advertising problems identified in the marketplace in relation to complementary healthcare products; both therapeutic goods and others such as foods. The CMA's self-regulatory mechanism is supported by the Therapeutic Goods Administration (TGA).

By CMA continuing to manage complaints involving advertising directed to healthcare professionals, the existing mechanism of referring complaints to the NRA or food authority, where identified as relating to public safety, would continue.

Option 2:

CMA supports a call for tenders for external organisations to undertake the complaints resolution process for all therapeutic product advertising to the public.

The Advertising Standards Bureau (ASB) is an independent self-regulation body that manages the national advertising complaints resolution process. The Bureau functions as secretariat for the Advertising Standards Board and the Advertising Claims Board – the two independent bodies are established to determine consumer and competitive complaints against the advertising self- regulatory Codes.

The ASB has a commitment to international best practice in advertising self-regulation and measures its performance in administering Australia's advertising self-regulation system against international standards. An independent review process provides the community and advertisers a channel through which they can appeal decisions made by the Advertising

Standards Board.

CMA notes that in the ASB submission to this consultation, public complaints about particular advertisements, in relation to issues such as public safety, are considered cost-free to the community, while competitor claims between advertisers in relation to truth, accuracy and legality of particular advertisements are considered on a user- pays basis by the Advertising Claims Board.

It is envisaged that the ASB would work closely with the Code Administration Committee (based within TGA or elsewhere), AUS-TAPs and industry associations on complaint statistics, trends and consumer/industry concerns. It is also envisaged that the ASB, in setting up an advertising standards board to undertake determinations relating to complementary medicine advertising issues, would recruit and engage a number of relevant independent experts. These experts would be called upon as required and ideally have expertise in the field of public health and complementary medicine practitioner background. The panel of experts would provide a qualified opinion on technical material and substantiation of claims made in advertising to be presented together with complaint and advertiser materials to the Standards Board for determination.

Future of the Therapeutic Goods Advertising Code, Advertising Code Council, CRP

Recommendation 52: The Government accepts that advertising of therapeutic products to the public should continue to be regulated by the TGA under a legislative framework which includes an advertising code, noting that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.

Therapeutic Goods Advertising Code

The regulatory framework requires that advertisements of therapeutic products to the public are subject to the requirements of the *Therapeutic Goods Act 1989 (the Act)* and *Regulations*, the *Competition and Consumer Act 2010* and other relevant laws. Additionally, advertisements for therapeutic goods directed to consumers must comply with the *Therapeutic Goods Advertising Code* (the Code). The Government accepts that the legislative framework, which includes an advertising code, continues to be regulated by the TGA.

The broad based principles of the Code are appropriate and any oversight of the revised Code should be broadly-based and representative of its constituent industries. It is important to note that revision or redevelopment of the Code is likely to occur at the same time as a number of other reforms that will impact upon the industry's ability to advertise and communicate clearly with consumers.

These reforms include the Permitted Indications project that aims, with the removal of the free text field, to eliminate the use of inappropriate indications and claims being entered on the ARTG. In turn, this will affect the clarity to industry as to what is allowable in advertising, but also risks inappropriately limiting the claims that can be made.

The Advertising guidance document "*Guidance on the Assessment of Potentially Restricted Representations Included in Advertising Claims Based on Indications for Listed Medicines* (TGA R14/684839)", should be finalised, published and made available on the TGA website for industry and consumers to refer to.

An increase in sanctions and penalties will address the need for the Code to be more explicit and will require clear, transparent guidance to industry to ensure the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of the goods, is socially responsible and does not mislead or deceive the consumer.

Advertising Code Council

Consistent with the Smaller Government Agenda[3], the Government has agreed to the abolition of the Therapeutic Goods Advertising Code Council. The abolition of the Code Council and the CRP has implications for the future provision of expert advice on advertising to the TGA.

Future Provision of Expert Advice

CMA notes that the discussion paper states: "With the Government's decision to abolish both bodies, both the TGACC and the CRP will be replaced by alternative mechanisms for providing advice to the TGA on matters relating to advertising."

Currently, the Therapeutic Goods Advertising Code Council is responsible for the currency of the Code while the Therapeutic Goods Administration administers the Code. CMA suggests that a Code Administration Committee (based in TGA or elsewhere) and made up of key industry participants should take on the function of "Code owner" in that it would be responsible for code development, regular review and maintenance. A not-for-profit third party provider such as an Australian Therapeutic Advertising Pre- vetting Service (AUS-TAPS) and the ASB, as detailed in this submission, would be well suited to provide a number of services relating to the advertising of listed therapeutic goods, and provide expert advice to the TGA.

CMA supports that the representation of membership on the relevant committees and expert panels will need to include a diverse range of expertise relating to the advertising of a diverse range of therapeutic goods, including specific expertise representative of the complementary medicines industry.

[3] *Smaller Government agenda; Budget Review 2015–16 Index; Parliament of Australia http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/BudgetReview201516/Gov*

Industry Education

Recommendation 58 - The Government accepts that the TGA should develop a formal education programme 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).

There is an opportunity for the TGA and organisations such as AUS-TAPS and ASB to work collaboratively to develop a formal education/accreditation programme, with ongoing management the responsibility of AUS-TAPS.

Listed complementary medicines are included in the ARTG via an electronic application process that is designed to allow simple and fast access to market for low risk complementary medicines. 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 any knowledge about one's legal, regulatory and ethical responsibilities.

CMA supports the implementation of an accreditation/licensing scheme for 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 lack of understanding, whilst providing an additional level of assurance for the protection of consumers.

It is envisioned that such a programme would cover and assess a learner's ability to, for example:

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

The programme 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 AUS-TAPS, 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 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 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.

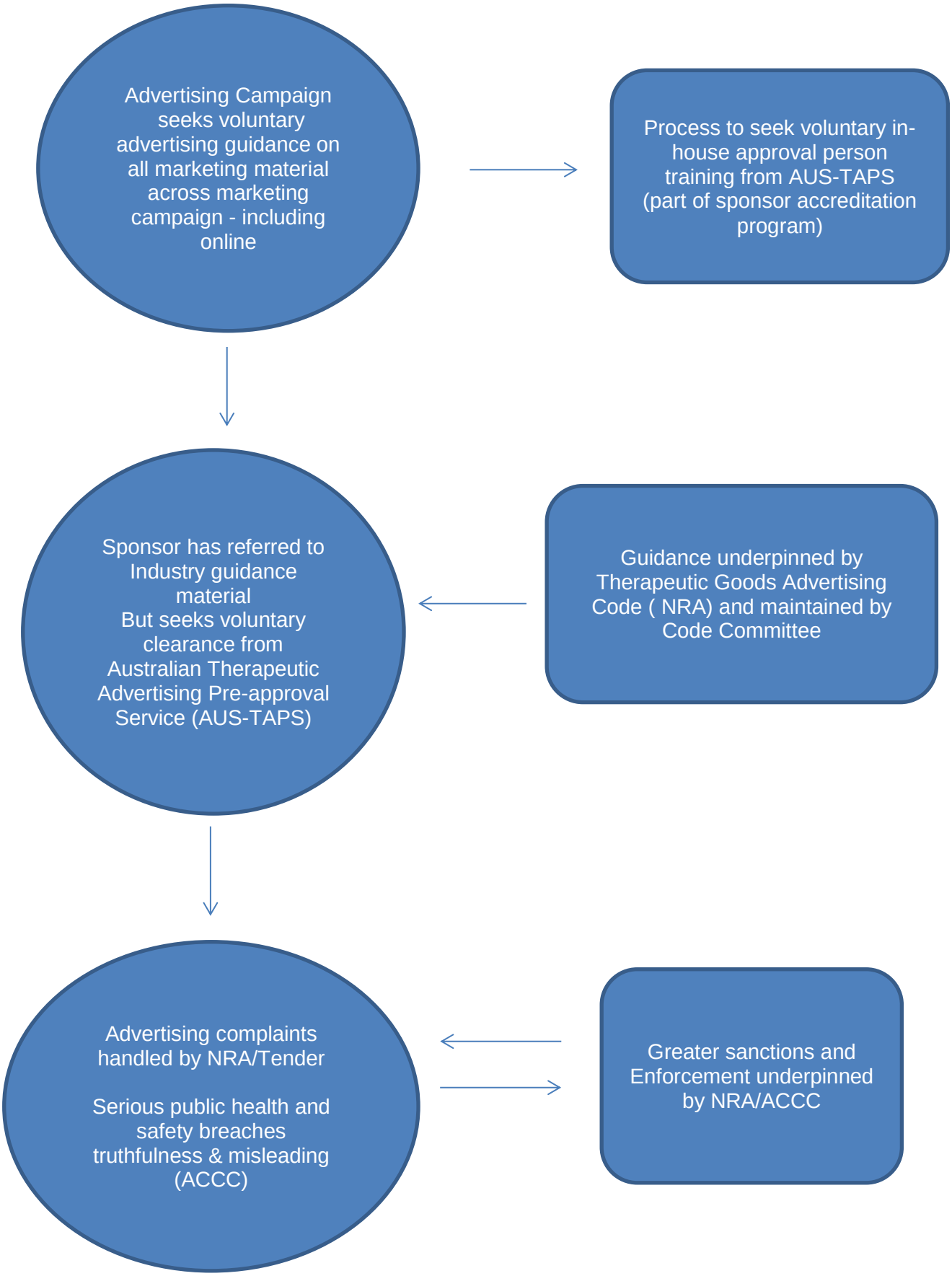
Summary

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 these reforms and a combination of self/ co-regulatory mechanisms described above, the TGA will continue to operate effectively and efficiently in respect of regulatory imposts such as timeframes and costs to industry, while also maintaining appropriate public health and safety protections.

Appendix 1 - Pre-approvals framework for direct to consumer advertising

Building blocks for a better framework:

- An administrative body (AUS-TAPS) to establish policies and procedures (guidance) for the voluntary pre approvals of advertising direct to the public. The system would be administered by a third party (not for profit) organisation (similar to TAPS in NZ or Council of Better Business Bureaus in Canada and the US) where experienced independent consultants act as advisors/adjudicators).
- Industry service arm to include checklists/tools/guidance to assists CM companies in avoiding misleading, non-substantiated or deceptive advertising claims and an online archive (available by subscription) that could include case reports, as well as refer to a searchable system of advertising determination reports (by NRA or third party).
- Industry campaign would support self-regulation and that industry "police the market place itself".
- A single agency to deal with complaints management – monitor, review and challenge CM advertisements to ensure that ads are truthful and non-misleading (Rx 56 accepted by Government). Tender process for external organisations will be an option.


Advertising Campaign seeks voluntary advertising guidance on all marketing material across marketing campaign - including online
Process to seek voluntary in-house approval person training from AUS-TAPS (part of sponsor accreditation program)
Sponsor has referred to Industry guidance material
But seeks voluntary clearance from Australian Therapeutic Advertising Pre-approval Service (AUS-TAPS)
Guidance underpinned by Therapeutic Goods Advertising Code (NRA) and maintained by Code Committee
Advertising complaints handled by NRA/Tender
Serious public health and safety breaches truthfulness & misleading (ACCC)
Greater sanctions and Enforcement underpinned by NRA/ACCC