Complementary Medicines Australia *submission to the Therapeutic Goods Administration consultation:*

Complaints handling - Advertising of therapeutic goods to the public

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Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the TGA's consultation on the draft Therapeutic Goods Advertising Code and associated guidance material.

CMA is committed to a vital and sustainable complementary medicines sector and represents stakeholders across the value chain, including sponsors, manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. The demand for supportive, low-risk complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare. The sector has evolved into an industry with a world class reputation that supports Australian skilled jobs, research innovation, domestic manufacturing and international exports.

Advertising forms the primary capability of the lower risk complementary medicine industry to reliably, responsibly, and accurately communicate information about products that are available for self-selection by consumers. CMA has supported the reforms to the advertising framework that were recommended by the Expert Panel Review of Medicines and Medical Devices, which were largely introduced in March 2018 by the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*. The new framework, supported to date by CMA, incorporates the following three pillars:

1. Phase-out of the system of advertising pre-approvals and a move to a more self-regulatory advertising scheme.
2. Removal of the Complaints Resolution Panel, with the TGA as the single body responsible for the handling of complaints about the advertising of therapeutic goods to the public, from 1 July 2018.
3. Broader enforcement powers and revised sanctions to ensure appropriate compliance with advertising regulatory requirements under the improved advertising scheme.

As per our submission to the consultation on the revised Advertising Code, with the exception of some technical refinements and practical considerations, CMA is largely supportive of the intent of the new Code. The current consultation addresses the complaints handling process where breaches of the Code take place, in respect of the new scheme as described in brief above. To fairly apply the Code and other advertising provisions, we have previously expressed support for Advertising Code requirements that were appropriate in scope, minimally subjective, have clarity of interpretation, and that are able to be applied fairly and consistently. Objective and reliable application of the Code through the TGA complaints

handling process is critical to the success of a self-regulatory advertising scheme where advertisers may understand and apply the advertising framework.

CMA acknowledges and supports the intent of the complaints process to resolve advertising matters swiftly, to emphasise education of advertisers regarding compliance. We support the consideration that has gone into creating a structure and process for dealing advertising complaints with a practical risk-based approach. Our response provides input into several areas described for the consultation, and seeks further details regarding right of appeal, trend analysis, governance, vexatious complaints, and reporting in order to provide a whole response to the advertising complaints handling mechanisms.

General comments on the complaints handling process

CMA notes the new powers and sanctions provided by *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*, to address advertising non-compliance; along with the triage and prioritisation for the management of complaints outlined in the consultation document which link the degree of non-compliance with anticipated actions.

TGA Approach

CMA supports the approach discussed in the paper of consistency, transparency, an ethical approach, and the risk-based prioritisation of cases to use limited resources most effectively. In particular, we applaud the front-line approach of supporting, advising, and providing the tools for education and correction of advertisements where necessary, with the last line of action being enforcement tools reserved but available when required for serious, blatant, and higher-risk cases.

Vulnerable populations

The introduction to the consultation paper places an emphasis on complaints handling in relation to vulnerable populations:

> "Promotion of therapeutic goods by their very nature may target specific sections of the population that are potentially vulnerable due to age, illness or disability for example. … the Therapeutic Goods Advertising Code 2015 focuses on requirements that relate to advertising to the public and the special requirements that must be met when advertising to vulnerable populations."

The draft 2018 Code contains similar provisions, in respect of restricted representations.

The purpose of emphasising vulnerable populations for advertising generally is somewhat unclear for practical application by advertisers. It is a true statement that therapeutic goods, by their nature (of providing relief to ailments), causes their audience to be those who need these therapeutic agents

including reasons of age and illness. The distinction between *appropriately* targeting the appropriate population (for example, glucosamine products for an older population with mild osteoarthritis) and *inappropriately* targeting the relevant population through perceived vulnerability has not been made clear through the framework. It is important for advertisers and enforcement officers to have a grasp of the intent between compliant and non-compliant in this area, as advertisers must advertise to relevant populations, particularly those that are only substantiated by clinical evidence for a certain age- or illness-related population – however these are also the populations that may be perceived as vulnerable populations. CMA agrees that all consumers, including vulnerable populations, must not be subject to inappropriate or predatory advertising. It is also true that the information conveyed to consumers must be able to include sufficient information as to be accurate and transparent enough to ensure proper use, that is, restriction of advertising must not occur to the extent that the intended purpose and proper application of the goods is inappropriately vague or obscured, decreasing the quality use of medicines.

Triaging and investigation

The consultation proposes categorising breaches of the Advertising Code into 4 categories ranging from low to critical with differing modes of communication from the TGA and expected responses from the advertiser based on the level of risk posed. It appears that following triage complaints will enter an "investigation phase" which allows for the entity responsible to respond to complaints levied against them, and where this complaint is upheld, the opportunity to take appropriate corrective actions.

It is unclear from the structure and expression of the process described, whether the investigation phase precedes the prioritisation of the complaint, or whether the matter is prioritised and the actions described (such as correspondence between the TGA and the advertiser) is considered to be the investigation phase. Presumably once an entity receives a request for information of action from the TGA under the Act, that the process has been formalised and the timeframes for consideration have commenced. However the order of events is not explicitly clear, and we recommends that the guidance be altered to reflect which stages are informal and formal, with the specific actions to be undertaken by the TGA in these phases.

Right of appeal and regulatory action

Details around specific penalties and sanction in the different categories did not form part of the consultation. Further, the structure of the new notices (such as infringement notices, substantiations notices, and directions notices) that are introduced under the *Regulatory Powers (Standard Provisions) Act 2014* are a new framework and not familiar to industry. Without the detail of how these tools work in practice, we are unable to provide a whole response to this consultation.

Clarification of the process, the nature of the forms, and the in particular, the details regarding the right of reply and appeal mechanisms are required to form a view of the complaints handling mechanisms and details. How are infringement notices, for example, laid out and what are the options for response? At

what stage in the described processes for each category, would an advertiser have a right to dispute the validity of an alleged breach? An appeal process must be described and published in the guidance for the complaints process, along with types of supporting information required.

Additionally, there needs to be clarification regarding how an appeal to a decision or accusation will impact the timeframes described in the document, if and where there are stop clocks, etc.

This query leads to a possible subsequent process that where, should the TGA elect to enforce further powers and sanctions including infringements, injunctions and cancellations from the ARTG. A guidance document would benefit from examples of situations where this might take place, eg the offence is critical or where the entity does not demonstrate a willingness to take corrective action, or where the TGA and entity are opposed in their views of the matter, and the likely penalty to be imposed in those instances. While such situations are likely to be assessed on a case by case basis, however it would be useful for advertisers to be aware of probable consequences. In such circumstances, how is this legal action taken? For example, should a breach be determined and is considered to be a criminal offense, will the matter be referred to the Director of Public Prosecutions for further investigation and action, and in this case, what are the likely steps of this process?

Vexatious complaints

CMA supports the section of the consultation document that described that the TGA has a process for dealing with vexatious complaints. Vexatious complaints are often those based upon a complainant's perceived view of how a consumer may be misled by an advertisement, rather than a genuine likelihood of such an occurrence based upon the widely applicable legal notion of a reasonable consumer.

The consultation discusses much transparency around the review and outcomes of advertising investigations, but it does not take into account these large numbers of vexatious complaints arising from the same sources. Transparency is deserved both ways. Both consumers and the industry have the right to some information about the sources of complainants, even though it is recognised that individual names cannot be published.

We strongly recommend and request, along with other advertising data, the publication of categories of complaints that provide insights and transparency as to the nature of complaints that the regulator must process. Such categories could include:

- Number of complaints deemed valid and invalid and in or out of jurisdiction;
- Percentage or number of complainant categories for each sector (complementary medicines, OTC medicines; devices), including:
    - Genuine (average) consumers;
    - Industry complainants;
    - Complainants representative of a special interest group or affiliated with organisations (complainants who are the general public but are not considered average consumers).

Priority based complaints handling model

CMA supports the triaging and prioritisation of advertising complaints based on the degree of risk posed as well as the frequency of non-compliance, and the emphasis placed by the TGA on education regarding corrective actions.

Low priority cases

CMA supports the general approach of a low level approach to low level or cases that may not be considered an overt or definite breach, which conserves resources for more serious cases. The consultation notes that the TGA reserves the right to review closed low priority cases, monitoring for compliance. This has not necessarily taken into account that the advertiser has not had a right of reply through the initial low priority process (a TGA letter is sent and then the case is closed). There may be reasons why the advertiser believes the advertising is not in breach, as alleged. Any re-opening of a case must take into consideration what reply rights have been given at the initial review, and reply rights must be included at the re-opening of any review to account for this scenario.

An advertiser should not be marked as trending as an ongoing or deliberate non-compliant advertiser, or provided with penalties/sanctions, where allegations have been produced without reply provisions.

Medium priority cases

CMA notes that regarding these matters that sponsors have only been granted 14 calendar days to respond and action changes due to correspondence from the TGA. This is a short timeframe for sponsors to respond to the warning letter, particularly given that postal communication can take up to 7 calendar days, and that changes to advertising campaigns in motion are quite complicated, involving chains of approval and changes to contracts and other business processes and agreements. Some changes might be performed relatively promptly, other forms of advertising can take longer depending on processes involved. The tightness of the timeframe indicates a level of urgency that seems inconsistent with the level of risk posed by the non-serious breaches described in this category. The timeframes for anticipated responses should be reviewed to ensure achievable timeframes and natural justice provisions are in place.

High priority cases

CMA supports the categorisation outlined in the consultation document. The action (immediate direct contact), appears to match the category where the breach is serious and risk-based, but not when the category is reached due to escalation by ongoing low-risk breaches.

Critical priority cases

CMA supports the categorisation outlined in the consultation document. There is the need for some caution around how 'undermining' of public health campaigns is interpreted. For example, messaging that directly contradicted a campaign or directly encouraged inappropriate or dangerous health behaviours should fall into this category. However care should also be taken not to "over-interpret" this statement in the context of usual behaviour of reasonable consumers. The wording of this part could be considered to ensure it captures only captures messaging that captures real risk rather than perceived risk. The Department of Prime Minister and Cabinet's Office of Best Practice Regulation website has some clear documents with principles and questions that could be used as a basis for interpreting when matters do and do not pose a genuine risk that requires regulatory action.

CMA supports the need to protect consumers with swift action where a genuinely high level of safety risk is posed. It is necessary that there are mechanisms, including checks and balances and appropriate internal documentation procedures available to balance the power of an individual to require swift actions to prevent this kind of power from being used beyond its meaning and intent. This category is also challenging because the question of the right of reply naturally comes up in this category due to immediate action being required by the regulator through direct means.

TGA Business Areas – Process for conducting reviews of information submitted during investigations

Whilst the process for complaints handling and reporting is noted, any process for internal referrals to different business areas is not described. The label is explicitly included in the definition of an advertisement. Labels have previously been primarily reviewed by the regulatory area. Similarly, evidence for claims has most often been considered the jurisdiction of the regulatory area, although also sometimes reviewed as part of advertising. The key considerations that arise out of this for industry is as follows:

- Consistency
- Cost

Consistency is a primary regulatory objective. Companies need to make regular and ongoing decisions about advertising, printing labels, which are lengthy decision-making processes involving numerous staff members and stages of clearance, including costly changes to labels and advertising campaigns across many platforms. Reviews of advertising claims in respect of labels and evidence must be harmonised between the areas to reduce costly regulatory impacts occurring if there is a regulatory inconsistency between TGA business areas. There must be a 'single-phase' approach where labels, evidence reviews, and restricted representation considerations are reviewed (where required) once and not separately, to ensure consistency and prevent multiple changes required at different times by different areas.

Cost efficiencies are also relevant in a single-phase regulatory approach. The industry is regulated by a cost-recovery model, and it is inefficient for different areas to be reviewing the same information at the same time or different times (unless specifically justifiable). For the upcoming business year, the listed medicines sector is already facing a 10% increase in fees to account for increased regulatory compliance regime. Costs should not continue to rise for sponsors and advertisers. Streamlined and efficient mechanisms must be implemented. Eventually, all costs recovered by the regulator must in turn be recovered by industry from consumers; an efficient system is better for all stakeholders.

Trend analysis and reporting outcomes

The consultation indicates that the complaints will be linked to the responsible entities and that trends in non-compliance will be analysed and documented. This section could benefit from additional guidance as to the types of matters that will be considered a trend. For example, will the same product be tracked for the same matter; or same matter for different products, or the same matter with different interpretation.

Reporting outcomes can have a severe outcome upon advertisers and businesses. Any reporting must have an abundance of fairness and legal caution applied. We would also ask what self-measuring mechanisms or audit procedures will be built in to ensure that 'regulatory creep' and inconsistent outcomes or unreasonable decision making does not start forming part of the complaints handling, in either the near or far future.

It is also difficult to envision that the TGA is able to publish an attitude to compliance, something that is described as part of the decision-making process in this consultation, but is subjective and consequently difficult to measure and report with reliability or lack of bias.

It will also be a necessary consideration, as per the discussion above regarding the single-phase evaluation and not doubling or repeating work across TGA business areas, that the same compliance issues are not reported twice (once in the regulatory branch and again in the advertising report). This would skew figures and not represent a balanced picture of industry outcomes, noting that these are often chosen to be picked up and portrayed in other public and media forums.

As described under vexatious complaints above, we seek equal transparency about the nature of the type of complaints and complainants as that for complaints and outcomes reporting.

Governance

The composition of the proposed new TGA Therapeutic Goods Advertising Committee must contain members that have balanced views and interests. In the representation of industry, CMA and industry representatives of CMA strive to represent a fair and balanced and responsible approach to consumer and industry needs. We note that there has previously been conflicts of interest and other difficulties from other groups previously. Members from other stakeholder bodies should be similarly selected to enter such a forum with a balanced and constructive viewpoint rather than a rigid approach that expresses views in opposition to Government and World Health Organization objectives and agreements.

Education, Guidance and Advertising Hub

CMA fully supports the emphasis on education, recognising that greater understanding of the regulatory framework will ideally and ultimately reduce the amount of regulatory action. The resources and channels identified represent a current and broad cross section of educational platforms.

We particularly support the centralised hub for education, training, inquiries and applications for real-time training of new and ongoing regulatory and marketing staff, and predict that a centralised area will confer consistency in decision making and enhance communication between the TGA and stakeholders.

Conclusion

Thank you for the opportunity to comment on this consultation. CMA supports in principle the triaging, categorisation and prioritisation of complaints as well as transparent reporting of non-compliance.

We withhold further comment on the details until a more complete description of the full regulatory process including sanctions and penalties, regulatory tools and right of reply mechanisms are described. Advertiser guidance will also benefit from these additions.

Further detail about the handling of vexatious complaints is desirable, with a need for transparency regarding complainant categories as well as transparency on complaints and advertising reviews.

CMA looks forward to working further with the TGA to further refine the advertising complaints handling process.