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12 June 2018

Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted by email to: advertising.consultation@health.gov.au

Dear Sir / Madam,

Consultation: Complaints handling - Advertising therapeutic goods to the public

We refer to your call for submissions re the above.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

This submission has been prepared with input from the ASMI membership and reflects their combined views.

Summary

In addition to the detailed commentary below, we have also attached a "tracked" copy of the consultation document (as Attachment 1) in order to illustrate and clarify the principal points made on the following pages as well as to identify further concerns that were more practical to describe by way of the "tracked" copy.

This submission and the "tracked" copy of the consultation document need to be read in conjunction with each other.

In our view:

- The consultation document has the appearance of having been rushed, it contains a number of errors and questionable proposals and it omits a number of key considerations.
- Many of the necessary details have been omitted from the consultation document.
- Despite the Government directive, the TGA has not proposed a single-agency approach
- Despite the Government directive, the TGA has not proposed a best-practice system.
- The proposed reforms will produce a complaints system that is in many ways inferior to the current system, and will still leave some of the current issues unresolved.
- The proposed system will be unnecessarily complex, unfair and biased.
- The proposed system will encourage non-compliance in those areas which are specifically being ignored by the TGA.
- The proposed reforms will not produce a body of useful decision documents (and may instead produce a large body of defective decisions – open to challenge).
- The TGA will be focussing too much on conducting education and producing guidelines and not spending enough time making and publishing robust decisions.
- Much more work needs to be done by the TGA (in collaboration with stakeholders) to achieve the desired aims of a single-agency, best-practice, complaints system.

The only apparent improvement is that the TGA will take on responsibility for all consumer –facing media (as opposed to the CRP's jurisdiction which was limited to specified media only).

Recommendations

Recommendation 1: A senior TGA staff member should put their name to each and every consultation document to certify two things: (1) that the document has been reviewed in its entirety and is complete and error free, (2) that the proposals described in the document are clearly articulated and accurately reflect the TGA's intent and policy.

Recommendation 2: The TGA must act as the single agency for all therapeutic product complaints receipt and management and must adopt a best-practice approach to those complaints.

Recommendation 3: The TGA must not simply focus on those complaints with a direct safety impact, the TGA has an obligation to investigate and determine all the complaints received and to investigate and determine all alleged breaches of the TGAC, irrespective of whether there is a direct safety impact or not.

Recommendation 4: The TGA should acknowledge and adopt (so far as is possible) the Commonwealth Ombudsman's *Better Practice Guide to Complaint Handling*.

Recommendation 5: The TGA must revise the proposed processes to eliminate actual and perceived bias.

Recommendation 6: The TGA must revise the proposed processes to permit a fair hearing.

Recommendation 7: The TGA should be adopting best-practice processes that address the acknowledged issues with the current system (without introducing new issues).

Recommendation 8: The TGA should abandon their flawed approach to prioritising and instead simply screen and prioritise complaints into the following four paths: Vexatious or misconceived complaints, Obvious (objective) breaches, Serious breaches involving consumer safety, the Remainder.

Recommendation 9: The TGA should be adopting a decision making process that ensures that the interests of all stakeholders are served and that will lead to robust determinations that are capable of withstanding challenge.

Recommendation 10: The TGA must introduce strict policies and processes to address the conflict of interest inherent in the TGA acting as both complainant and decision maker.

Recommendation 11: The TGA must be clearer about how they will identify the organisations and the persons apparently responsible for advertising.

Recommendation 12: The TGA must publish detailed outcomes promptly and accurately for all complaints.

Recommendation 13: The TGA must adopt a system that at least retains the current positive elements, addresses the current issues and that does not introduce new issues.

Recommendation 14: The TGA should not be dedicating resources to training interested stakeholders and preparing complex guidance documents, instead the TGA should rely on the timely publication of sufficiently detailed outcomes to form the basis of all their educational activities.

Recommendation 15: The TGA should be transparent about the TGA resources and the organisational structure that will be applied to the complaints handling system.

Consultation Document Quality

The consultation document has the appearance of having been rushed, it contains a number of errors and questionable proposals and it omits a number of key considerations.

By way of illustration we note that Table 2 (on page 8) is missing information that appears to have been lost in some sort of "cutting-and-pasting" exercise from the same table that appears on the TGA's website[1]. There are also problems with the range of terms used (either inconsistently or inappropriately or without proper definition). These are obvious errors that should have been picked up during the final screening prior to publication.

In terms of the content itself, there are a number of unusual aspects to the proposals (e.g. the complete absence of any reference to best-practice design) (e.g. the apparent absence of any opportunity for advertisers to respond) (e.g. the apparent focus on consumer safety and apparent disregard of the other sections of the Code) (e.g. the closure of a matter when a notice is sent, without any effort to ensure that the notice was even received, much less that the notice was understood or even justified). When stakeholders see such proposals, they are faced with three possibilities:

- These are genuine reflections of the TGA's proposals, or
- These are errors or omissions by the TGA, or
- These are misinterpretations by stakeholders of what the TGA really meant

Unfortunately, we have no choice (given the short time frames and limited consultation) but to assume that the first possibility applies and to then address our response to the TGA's proposals as they are described. So, in this instance we have had to assume that the TGA will offer no opportunity for advertisers to respond, that the TGA has not considered best-practice to be a desirable attribute, that the TGA will indeed only focus on breaches that involve consumer harm, that the TGA will send a notice and not follow up – because this is what the consultation document actually says.

The same scenario unfolded with the recent TGAC 2018 consultation, where an extraordinary amount of mandatory text was apparently required by the draft Code.

It would save stakeholders a lot of time and would facilitate better consultation responses if the quality and content of the consultation documents were improved. Towards this end, we suggest that a senior TGA staff member should put their name to each and every consultation document when it is published so as to certify two things: (1) that the document has been reviewed in its entirety and is complete and error free, (2) that the proposals described in the document are clearly articulated and accurately reflect the TGA's intent and policy.

Recommendation 1: A senior TGA staff member should put their name to each and every consultation document to certify two things: (1) that the document has been reviewed in its entirety and is complete and error free, (2) that the proposals described in the document are clearly articulated and accurately reflect the TGA's intent and policy.

[1] https://www.tga.gov.au/regulatory-compliance-framework

Background - Australian Government Response to the MMDR Review

In September 2016, the Department of Health published the "Australian Government Response to the Review of Medicines and Medical Devices Regulation"[2]. Of relevance to this consultation was recommendations 56, as follows:

> *"The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is 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."* [emphasis added]

This recommendation was accepted by the Government, noting that:

> *"A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers."* [emphasis added]

As far as complaints in relation to therapeutic goods advertising is concerned, the TGA has been given two clear tasks:

1. To act as the single agency for complaints receipt and management
2. To adopt a best-practice approach in relation to those complaints.

In our view, the TGA proposals in the consultation document will not achieve either of these outcomes.

In relation to the single agency approach, the TGA appears to be concentrating only on the parts of the TGAC that impact on consumer safety (instead of accepting responsibility for enforcement of the entire Code) and appears to contemplate referral to other agencies such as the ACCC (instead of assuming full responsibility for enforcing the Code). Recommendation 56, and the Government's response to it, do not confine the single agency's remit just to safety related complaints.

In relation to the best-practice approach, the TGA appears to ignore the principles of procedural fairness as well as avoiding robust decision making and transparency of processes and outcomes. On this point, we note that the consultation document does not contain a single reference to the term "best-practice", it does not describe what a best-practice system might look like, it does not identify resources that would assist in designing a best-practice system and it certainly does not describe how the TGA's proposals reflect any best-practice principles.

Recommendation 2: The TGA must act as the single agency for all therapeutic product complaints receipt and management and must adopt a best-practice approach to those complaints.

[2] http://www.health.gov.au/internet/main/publishing.nsf/content/MMD-govresp

Background – the Objects of the Therapeutic Goods Act

The Objects of the Therapeutic Goods Act[3] (per section 4(1)(a)) are as follows:

> *"... to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods ...."* [emphasis added]

Despite there being four clear objects in the Act, the TGA appear to be focussing solely on safety, with many sections of the consultation document seemingly ignoring (or de-prioritising) complaints without a direct safety impact. Indeed the consultation document incorrectly states that safety is the "primary regulatory focus" of the *Therapeutic Goods Act* (at page 4 of 23) and that addressing health and safety issues is the "ultimate objective" of the TGA (at page 6 of 23). This is not accurate and not acceptable. The TGA must consider all four objects of the Act as they relate to advertising complaints and must consider all aspects of the TGAC as part of the complaints system.

Recommendation 3: The TGA must not simply focus on those complaints with a direct safety impact, the TGA has an obligation to investigate and determine all the complaints received and to investigate and determine all alleged breaches of the TGAC, irrespective of whether there is a direct safety impact or not.

Background – Best Practice Guidelines

The Commonwealth Ombudsman[4] has published a *Better Practice Guide to Complaint Handling*.

While the TGA's 2016 consultation on "The regulatory framework for advertising therapeutic goods"[5] made reference to the Guide, it is interesting that the present consultation document makes no reference to the Guide at all and appears to be inconsistent with the Guide on a number of points.

Because the Ombudsman's Guide concerns organisational responses to complaints being made by individuals about the organisation itself, it is not entirely relevant here (notably it does not properly cover off transparency of outcomes for the benefit of other parties). Nevertheless, the Guide contains much which should be relevant to therapeutic goods advertising.

For example, we note that the Guide (see pages 9 - 16) includes the following essential principles, which appear to have been overlooked or minimised in the consultation document:

- Fairness (including impartiality and transparency),
- Accessibility,
- Responsiveness, and
- Efficiency

[3] http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/tga1989191/s4.html
[4] http://www.ombudsman.gov.au/publications/better-practice-guides
[5] https://www.tga.gov.au/consultation/consultation-regulatory-framework-advertising-therapeutic-goods-november-2016

We also note that the Guide (see pages 21 – 26) includes the following process elements, which appear to be absent or diminished in the consultation document:

- A fair and independent review of the issues
- Impartiality
- Transparency
- Relying on evidence rather than preconceptions
- Allowing natural justice
- Responses which include the particulars of the investigation, the findings and the decision
- Follow up
- External review

By contrast with the TGA proposals, all of these principles and process elements were part of the now disbanded CRP system.

Recommendation 4: The TGA should acknowledge and adopt (so far as is possible) the Commonwealth Ombudsman's *Better Practice Guide to Complaint Handling*.

Background – Procedural Fairness

The Australian Law Reform Commission (the ALRC) has published information in relation to procedural fairness[6], we are concerned that procedural fairness appears to be entirely absent from the proposed TGA complaints handling processes.

The ALRC publication describes procedural fairness as "*a reasonable opportunity for parties to present their cases*" [14.18] and indicates that procedural fairness "*traditionally involves two requirements: the fair hearing rule and the rule against bias*" [14.20].

Disturbingly, the TGA consultation document includes no plans for a fair hearing and instead appears to actively incorporate bias.

In relation to the rule against bias, the ALRC indicates that:

> *"The rule against bias ensures that the decision maker can be objectively considered to be impartial and not to have pre-judged a decision."* [14.20]
>
> *"The content of the rule against bias is flexible, and determined by reference to the standards of the hypothetical observer who is fair minded and informed of the circumstances."* [14.21]

And yet, the consultation document requires the TGA decision maker to form preconceived views about advertisers based (for example) on the advertiser's "record", on whether the advertiser is "willing to comply", whether the advertiser has acted "deliberately" or "blatantly", whether there is an "ongoing pattern" of conduct or whether the advertiser is "aware" of their obligations. An advertiser's past behaviour and their assumed opinion regarding compliance should have no bearing on the TGA's assessment of whether a breach has occurred (past behaviour may be

[6] https://www.alrc.gov.au/publications/procedural-fairness-duty-and-its-content

relevant in terms of sanctions, but must not be taken into account in assessing the compliance of a particular advertisement with the TGAC).

The TGA decision maker forms these views prior to contacting the advertiser (based only on the complaint), without the benefit of any response from the advertiser and solely for the purpose of assigning the complaint to a priority category. In our view, this is a clear demonstration of bias.

Recommendation 5: The TGA must revise the proposed processes to eliminate actual and perceived bias.

In relation to the fair hearing rule, the ALRC indicates that:

> *"The hearing rule requires a decision maker to afford a person an opportunity to be heard before making a decision affecting their interests"* [14.20]
>
> *"...a fair hearing will generally require the following ... prior notice ... disclosure of the 'critical issues' to be addressed ... a substantive hearing ... with a reasonable opportunity to present a case."* [14.22]

In our view, the consultation document provides no fair hearing to any advertiser.

In section 8.1 of the consultation document (the "Investigation phase"), the TGA indicates that:

> "The investigation phase allows the responsible entity an opportunity to respond to assertions of non-compliant advertising and, where there has been non-compliance, to demonstrate a willingness to rectify, and actually rectify, the non-compliance in a timely manner." [emphasis added]

There are two main objections to this passage, firstly nowhere else in the document does this "opportunity" appear, and secondly the passage contemplates the apparently common situation where there is already an established non-compliance *before* the investigation even commences.

In relation to the "opportunity to respond", we note that:

- The description of low priority cases (section 8.2 of the consultation document) contains no such step and proceeds straight to the notice.
- The description of medium priority cases (section 8.3 of the consultation document) contains no such step and proceeds straight to a formal warning seeking information only on what steps the advertiser will be taking to remedy the non-compliance.
- The description of high priority cases (section 8.4 of the consultation document) contains no such step and proceeds straight to a warning (or phone call) where the advertiser will be asked to address the non-compliance.
- The description of critical priority cases (section 8.5 of the consultation document) contains no such step and proceeds straight to an immediate contact by email or phone where the advertiser will be required to address the non-compliance.

The TGA, must revise their processes so as to afford advertisers a fair hearing (by giving them notice, by outlining the allegations made, by allowing an opportunity to respond to the allegations and by allowing an opportunity to have the TGA's determination reviewed).

Recommendation 6: The TGA must revise the proposed processes to permit a fair hearing.

Expected Components of an Acceptable Complaints Handling System

In our 21 December 2016 response to the TGA's consultation on "The regulatory framework for advertising therapeutic goods" (see Attachment 2), we described the attributes necessary for an *acceptable* complaints handling system and we continue to hold the same view.

In relation to non-prescription therapeutic goods, there needs to be one advertising code, one complaints body and one process.

Based on the above background elements, in our view the preferred system for handling complaints about non-prescription therapeutic goods must:

- Have a single body to receive and *determine* all complaints, regardless of:
  - The advertising medium,
  - The advertiser's membership of an industry association, or,
  - The audience targeted (i.e. consumers and healthcare professionals, noting that while the Therapeutic Goods Act and the TGAC distinguish between the audiences, the Australian Consumer Law makes no such distinction)
- Have a single Advertising Code which applies to all advertisements
- Have published processes which include mandatory timeframes
  - Timeframes to be in weeks rather than months (so as to allow a proper balance between principles of fairness and efficiency)
  - Parties to complaints need to know at what stage proceedings are at and what the next steps are
- Publish all outcomes quickly and in sufficient detail to be educative
- Be designed with efficiency in mind
- Include an administrative step to screen and prioritise into:
  - Vexatious or misconceived complaints (to be rejected promptly)
  - Obvious, objective, breaches (e.g. missing mandatory statements) (to be handled simply)
  - Serious breaches involving consumer safety (e.g. cancer treatments) (to be determined as a priority)
  - The remainder (to be determined in the order received)
- Only determine those issues raised by the complainant
- Include an option to combine multiple, separate, complaints about an advertisement or campaign where it is practical and efficient to do so
- Consider the seasonality of some campaigns (e.g. cold and flu products)(e.g. sunscreens) and the rapid turnover of "fad" ingredients and provide timely responses accordingly
- Include effective sanctions, which:
  - Are enforceable
  - Are selected appropriately from a range of options
  - Include financial penalties which are of the appropriate size

- Be appropriately resourced
- Incorporate a multi-stakeholder Panel (which must include technical expertise, industry expertise, advertising/communications expertise, consumer representation and healthcare professional representation)
- Include an appeals process (with mandatory timeframes)

Such a system would adequately address the recognised manifold problems inherent in with the current complaints arrangements (see below).

In our view, the processes proposed by the TGA do not even amount to an *acceptable* approach to complaints handling (much less the *best-practice* approach directed by the Government). The TGA proposals do not address the existing issues and (for the reasons outlined above) appear to introduce even more problems (e.g. intrinsic bias and the absence of a fair hearing).

Recommendation 7: The TGA should be adopting best-practice processes that address the acknowledged issues with the current system (without introducing new issues).

Priority Categories

The four priority categories introduced by the TGA are overly complex, unnecessary and inherently likely to introduce bias. It is unclear how these four categories were arrived at or why they are even necessary. It is also unclear how the TGA will categorise the complaints, who will conduct the classification and what decision making criteria those persons will use.

In effect, the TGA are taking what should be a simple, administrative task (i.e. to screen and prioritise) and turning it into a mini-investigation.

The proposed process is complex and will require an assessment of a great range of materials before an investigation even takes place (and certainly before any response from the advertiser or publisher has even been asked for). For example, in order to just prioritise a complaint, the TGA decision maker will need to assess[7] the:

- Likelihood of an actual breach having occurred
- Potential impact of any likely breach on consumers (but not on competitors?)
- The "seriousness" of the alleged breaches and the "seriousness" of the likely breaches
- Similarities between the alleged breach and other complaints previously received either about the advertiser, the product or other element warranting "grouping"
- Past behaviour of any of the parties apparently or likely to have been involved
- The motive(s) of the parties, their level of awareness of advertising requirements and their level of disregard for compliance
- Use of "mass" advertising
- "Potential to influence others" in the industry
- Extent or targeting of the advertising
- Exposure to vulnerable populations
- Relevant public health messages

[7] Based on the text of the consultation paper itself and on the pyramid included on page 11 of the paper.

- Evidence likely to be put forward by the parties in support of the advertisement and in answer to the alleged breaches

All of this information needs to be collated and analysed simply to work out which category the complaint rightly belongs to.

It is difficult to imagine someone at the TGA having to go through this process for each and every complaint (even assuming that this information can or will be available).

It is also difficult to imagine that someone at the TGA having gone through that exercise will bring an impartial mind to the subsequent investigation (and as mentioned above a fair hearing must be a part of any best-practice system).

The TGA should instead leave all of this information gathering and analysis for the investigation itself and simply prioritise complaints along the following four paths:

- Vexatious or misconceived complaints (to be rejected promptly)
- Obvious, objective, breaches (e.g. missing mandatory statements) (to be handled simply)
- Serious breaches involving consumer safety (e.g. cancer treatments) (to be determined as a priority)
- The remainder (to be determined in the order received)

In this way, screening and prioritising would remain an efficient administrative function, rather than a time consuming, improbable, bias producing and unnecessarily complicated process.

Recommendation 8: The TGA should abandon their flawed approach to prioritising and instead simply screen and prioritise complaints into the following four paths: Vexatious or misconceived complaints, Obvious (objective) breaches, Serious breaches involving consumer safety, the Remainder.

Necessary Minimum Steps in Determining a Complaint

With all of the above in mind, and with regard to the interests of complainants, advertisers, consumers and industry, we suggest that a best-practice complaints process should include the following necessary steps to determine each complaint (as a minimum):

1. Receipt of the complaint
2. Acknowledgement of the complaint
3. Triaging as a simple administrative process (see above re screening and prioritising)
4. Contacting the advertiser (describing the complaint and seeking a response)
5. Reviewing all the materials and making a determination
6. Advising the advertiser and the complainant of the outcome and publishing the determination
7. Providing a mechanism for appeal/review

Such an approach will lead to robust determinations that are capable of withstanding challenge.

Recommendation 9: The TGA should be adopting a decision making process that ensures that the interests of all stakeholders are served and that will lead to robust determinations that are capable of withstanding challenge.

Complaint Sources and Conflict of Interest

It is clear that the TGA will receive complaints from third parties in a similar fashion to the way the CRP did. In addition (and unlike the CRP) the TGA will have a surveillance power and will (in effect) therefore be generating its own complaints and then conducting the investigations into those complaints.

No details about this aspect of the reform have been included in the consultation paper. It is not clear who will be generating these TGA complaints, on what basis, against what criteria or whether they will be random or targeted (or both). It is also unclear how (or whether) the TGA will keep the generation and investigation of complaints entirely separate.

In any event, the TGA acting as both complainant and decision maker is a clear conflict of interest and the TGA will need to introduce mechanisms to ensure that the TGA complainant(s) and the TGA decision maker(s) are entirely separate groups, have no contact with each other (apart from forwarding on the complaints) and have no opportunity to influence either the targeting of the complaints by the one group or the outcomes of the investigations by the other group. Anything less than this would introduce an unacceptable level of conflict of interest, which would have to cast doubt on the validity of the subsequent TGA decision(s).

Recommendation 10: The TGA must introduce strict policies and processes to address the conflict of interest inherent in the TGA acting as both complainant and decision maker.

Complaint Recipients

One of the big questions for the TGA to decide is who is responsible for the advertisement. Under the current system (where past behaviour is not a necessary factor in screening and prioritising complaints) this is less problematic. Under the proposed system, identifying exactly who is responsible will be critical (since the TGA will need to assess – among other things - the motive(s) of the parties, their level of awareness of advertising requirements and their level of disregard for compliance). How will the TGA determine this? Given the penalties and sanctions available (and the apparent impact of past behaviour) this will be critical and yet it is not mentioned at all in the consultation document. Under the proposed reforms it would seem to be necessary for the TGA to determine both the responsible *organisation* and the responsible *person*.

In terms of the responsible organisation, this may not be just the sponsor or even the sponsor. For example, the responsible organisation could be:

- The sponsor (e.g. where the sponsor and the advertiser are the same), and/or
- The advertiser (e.g. where product is licensed from the sponsor by the advertiser), and/or
- The publisher (e.g. of a catalogue for a retailer, without sponsor knowledge), and/or

- The broadcaster, and/or even
- The distributor of point-of-sale materials

In terms of the responsible person, this could be:

- The CEO
- The Director(s)
- The Regulatory Affairs person who authorised the material
- The Marketing person who authorised the material

This will be especially difficult where there is a large corporation with different management teams for different portfolios. Say for example, there was a previous breach found in relation to one team's materials in relation to their vitamin product and now the TGA have received a complaint in relation to the corporation's analgesic advertising. Will the whole organisation be imputed with knowledge of the earlier breach? Will the TGA treat the different business units as different entities for the purposes of determining whether there are "ongoing breaches"? Will the TGA treat the individual persons as different entities, with different levels of regard for compliance? None of this is made clear in the consultation document.

Recommendation 11: The TGA must be clearer about how they will identify the organisations and the persons apparently responsible for advertising.

Transparency and Accuracy of TGA Reporting

In our 21 December response to the TGA's consultation on "The regulatory framework for advertising therapeutic goods" (see Attachment 2), we outlined our concerns with the transparency of TGA reporting (given the very limited number of outcomes actually published by the TGA) and with the accuracy of the reports that the TGA did publish (citing the 2013 AAT decision in relation to restricted representations[8]).

Along with other stakeholders, we continue to hold these concerns.

In our view, the TGA must publish outcomes in at least as much detail as the CRP has done.

The TGA cannot decide only to publish some outcomes, partial outcomes or aggregate outcomes.

In order for stakeholders to have confidence in the TGA and its complaints processes (and in order for advertisers to be as informed as possible), the TGA must publish detailed outcomes promptly and accurately. Publication of detailed outcomes will assist:

- Advertisers (to comply with their obligations)
- All parties (to understand the processes and have confidence in them)
- Complainants (to prepare effective complaints)
- Trainers (to use the determinations to educate others)
- The TGA (by reducing the need for specific training and education)

[8] http://www.austlii.edu.au/au/cases/cth/aat/2013/388.html

Transparent and accurate reporting is also a necessary part of any best-practice complaints system and, in our view, should be the major element of the TGA's education activities.

Recommendation 12: The TGA must publish detailed outcomes promptly and accurately for all complaints.

The Current System (Issues and Positives)

Stakeholders (including ASMI) agree that there are a range of problems inherent in the current complaints system and these issues include:

- The myriad interconnected processes.
- Complaints options being dictated by the advertising medium, the audience to whom the advertising was directed and the advertiser's industry association membership.
- The complaints processes being complex and not effectively covering all media, all advertisers or all audiences.
- The CRP only making recommendations and not being able to impose sanctions.
- There being no formal appeal mechanism in relation to CRP determinations.
- TGA actions being neither timely nor transparent.

In our view, the processes proposed by the TGA will not address these existing issues and (for the reasons outlined above) appear to introduce even more problems (e.g. complexity, bias, the absence of a fair hearing, conflicts of interest where the complainant and the decision maker are the same person).

Of concern, the proposed system will not be transparent and will not be fair.

Also of concern, the acknowledged positive elements of the current complaint system will be lost:

- There will no longer be multi-stakeholder decision making
- There will no longer be fair hearings, on the evidence, and free from bias
- There will no longer be routine (and detailed) publication of all determinations

The only apparent improvement is that the TGA will take on responsibility for all consumer –facing media (as opposed to the CRP's jurisdiction which was limited to specified media only).

Recommendation 13: The TGA must adopt a system that at least retains the current positive elements, addresses the current issues and that does not introduce new issues.

Governance

For the reasons outlined in Attachment 1, the new Committee will be a poor substitute for the multi-stakeholder, co-regulatory, statutory committees that it will replace (i.e. the TGACC and the CRP). Without legislative underpinning it is hard to see how the new Committee can have any proper "governance" role. The new Committee's terms of reference and its precise role remain

unclear. The consultation document indicates that the new Committee will "provide advice" to the TGA on a range of issues, but without legislative underpinning the TGA will be completely free to ignore that advice.

Proposing that the new Committee has the same acronym as the Code, is one more example of the poor quality of the consultation document.

Nevertheless, ASMI has been an active member of both the TGACC and the CRP and would expect to be invited to participate on this new Committee.

Education and Guidance

For the reasons outlined in Attachment 1, we have serious concerns about the appropriateness of the TGA staff being engaged in running a training organisation for poorly prepared advertisers.

Further to those comments, in our view, while the objects of the Act may permit the TGA a limited role in educating sponsors, the objects of the Act do not permit the TGA any role in educating consumers or other stakeholders.

In relation to cost-recovery, the TGA's website[9] indicates that:

> *The TGA is required to recover its costs through fees and charges for all activities that fall within the scope of the Therapeutic Goods Act 1989, including the TGA's public health responsibilities.*

In addition, the Australian Government Charging Framework[10], includes the following Charging Policy Statement:

> *Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the government has decided to fund that activity.*

Taken together, this means that:

- If the TGA want to educate poorly prepared advertisers, then those advertisers should be charged for that education, and
- If the TGA want to educate other stakeholders (e.g. consumers) then the government should fund that activity.

Under no circumstances should sponsor's fees and charges be used to educate consumers, interested stakeholders or poorly prepared advertisers.

Furthermore, in the recent past, the TGA recognised that the TGACC/CRP secretariat could not cope with the level of complaints being received and organise TGAC training seminars at the same time. As a result, the TGACC ceased to run the seminars and industry were left to make their own arrangements for the seminars to continue. Given that the number of complaints likely to be

[9] https://www.tga.gov.au/fees-and-payments
[10] https://www.finance.gov.au/resource-management/charging-framework/

received by the TGA will be greater than the number previously received by the CRP (see below), it is hard to imagine the TGA finding the time and the resources to determine all those complaints and operate as a training organisation at the same time.

For the reasons outlined in Attachment 1 (and in previous submissions), we have serious concerns about the TGA's proposed widespread use guidance documents in relation to advertising compliance.

In our view, the TGA's actual decisions on compliance will be far more relevant and instructive and for this reason the TGA determinations need to be published in full, promptly and accurately. For this reason also, the timely publication of sufficiently detailed outcomes should form the basis of all the TGA's educational activities.

Recommendation 14: The TGA should not be dedicating resources to training interested stakeholders and preparing complex guidance documents, instead the TGA should rely on the timely publication of sufficiently detailed outcomes to form the basis of all their educational activities.

TGA Resources Need to be Adequate and Focussed

For the TGA to perform acceptably as the single complaints agency, appropriate resourcing will be required.

The CRP determined hundreds of complaints per a year (in addition to the hundreds that were forwarded on to the TGA to determine). It is reasonable to expect that the TGA (as the single agency) will receive at least the same amount of complaints.

Additionally, the TGA will be generating complaints themselves.

Further, the CRP had a limited jurisdiction in terms of the media that could be reviewed. The TGA will have no such limit on its jurisdiction and will be able to determine complaints in relation to every type of consumer-facing media.

A substantial increase in complaint numbers should therefore be anticipated.

Stakeholders need to be confident that the TGA is adequately resourced and that those resources will be focussed appropriately on determining complaints.

The consultation document contains no information about TGA resourcing, or TGA structure.

Recommendation 15: The TGA should be transparent about the TGA resources and the organisational structure that will be applied to the complaints handling system.

Other Potential Outcomes of the TGA's Proposals

In addition to the concerns raised above, the TGA's flawed proposals are likely to have a number of unintended adverse impacts, some of which are as follows:

- Lack of a fair hearing and incorporation of bias will lead to poor decision making and will therefore expose the TGA to routine and unnecessary challenges of those decisions by affected parties.
- Referral to other agencies will lead to complexity, lack of certainty and lack of accountability.
- The TGA's focus on safety will encourage intentional non-compliance with the other parts of the TGAC.
- Lack of transparency will undermine confidence in the TGA and its processes.
- Failure to publish detailed outcomes promptly and accurately will deprive stakeholders of valuable insights and will increase the TGA's educative burden.
- Complex screening processes will lead to unnecessary delays.

Tracked Copy

Further to the comments provided above in relation to our principal concerns we have included a "tracked" copy of the consultation document (see Attachment 1) to illustrate these and other concerns not addressed above (since it was more practical to describe them by way of the "tracked" copy). The comments above and the "tracked" copy of the consultation document need to be read in conjunction with each other.

We remain available to meet with you to discuss any of the above should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

List of Attachments

Attachment 1 A "tracked" copy of the consultation document with ASMI comments

Attachment 2 ASMI's 21 December 2016 response to the TGA's consultation on "The regulatory framework for advertising therapeutic goods" (see pages 8 – 10 in relation to the transparency and accuracy of TGA reporting)

Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Complaints handling - Advertising of therapeutic goods to the public

Version 1.0, May 2018

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

1. Introduction

Effective risk-based regulation, compliance and enforcement of the therapeutic goods advertising regulatory scheme form part of our contribution to the Department of Health's vision of better health and wellbeing for all Australians, now and for future generations.

The *Competition and Consumer Act 2010* and associated state and territory laws provide consumer protections from false or misleading advertising of products and services. The *Therapeutic Goods Act 1989* (the Act) provides a primary regulatory focus on public health and safety.

While consumer protection laws also apply to the advertising of most therapeutic goods, many therapeutic goods are not ordinary items of commerce.[1] 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 legislation governing therapeutic goods regulation sets out the regulatory framework and obligations when advertising therapeutic goods.[2] However, the *Therapeutic Goods Advertising Code 2015* (the code)[3] focuses on requirements that relate to advertising to the public and the special requirements that must be met when advertising to vulnerable populations.

The provisions in the legislation and regulation around advertising use broad definitions that can apply to any person (and not only sponsors who have goods included in the Australian Register of Therapeutic Goods (ARTG)). Therefore any person who advertises a product with therapeutic claims (such as the effectiveness of the product to treat an illness), can be subject to the advertising requirements for therapeutic goods.

Therapeutic claims can include where goods are represented in any way to be, or for any other reason likely to be taken to be used in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury or influencing, inhibiting or modifying a physiological process in persons.

The legislation governing therapeutic goods regulation restricts when and how therapeutic goods can be advertised and provides for compliance and enforcement provisions to achieve compliance with the TGA advertising scheme. Substantial sanctions, including heavy fines and or terms of imprisonment can apply in cases of ongoing or serious non-compliance with the advertising scheme.

Comment [A1]: While this is correct. The TGAC also clearly covers false, misleading, unsubstantiated and exaggerated claims.

This appears to suggest that the TGA will be leaving false and misleading advertising to the ACCC and the States and Territories. There is no reason for the TGA to exclusively focus on only some parts of the Code.

Comment [A2]: Not true.

The Objects of the *Therapeutic Goods Act* (see section 4(1)(a)) are as follows:

"... to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods ...."

Safety is just one of the four objects of the Act.

Comment [A3]: What does this mean? Will the TGA only be protecting vulnerable consumers?

Comment [A4]: Therapeutic claims are just one particular type of claim.

All advertising and all claims are subject the Act, the Regulations and the Code.

The TGA should not just be focusing on therapeutic claims.

Comment [A5]: As above.

2. Government's response to the expert panel's recommendations

The Australian Government's response to the Expert Panel's Review[4] of the regulation of medicines and medical devices was released on 15 September 2016. Specific recommendations were made about broadening enforcement powers to benefit consumers through appropriate compliance with advertising regulatory requirements, and to deter inappropriate and misleading advertising of therapeutic goods. These broadened powers and revised sanctions

Comment [A6]: Not strictly correct. Recommendation 57 merely suggested that consideration be given as to whether the powers should be broadened – not that they necessarily had to be broadened.

[1] Not all therapeutic goods are considered consumer goods - e.g. X-ray machines in hospitals.
[2] *Therapeutic Goods Act 1989* (Cth), Therapeutic Goods Regulations 1990, Therapeutic Goods (Medical Devices) Regulations 2002, the Therapeutic Goods Advertising Code 2015.
[3] Therapeutic Goods Administration, Therapeutic Goods Advertising Code (2015), https://www.legislation.gov.au/Details/F2015L01787.
[4] Australian Government's response to the Expert Panel's Review, https://www.tga.gov.au/australian-government-response-review-medicines-and-medical-devices-regulation

were included in the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* which was enacted on 5 March 2018.

The Australian Government agreed to a single body approach to the management of complaints about advertising of therapeutic goods to the general public, reducing complexity and encouraging greater consistency in decision-making, thereby benefiting consumers. The Government has decided to make the TGA the single body responsible for the handling of complaints about the advertising of therapeutic goods to the public from 1 July 2018.

To progress implementation we are now consulting with stakeholders on the design of the new complaints-management process.

3. Requirements for the advertising of therapeutic goods to the public

Advertisements for therapeutic goods to the public in Australia are subject to the requirements of the *Therapeutic Goods Act 1989* (the Act). The Act defines *advertise* to mean:

> ***advertise***, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:
>
> (a) is on the label of the goods; or
>
> (b) is on the package in which the goods are contained; or
>
> (c) is on any material included with the package in which the goods are contained.

Advertising of therapeutic goods to the public must also comply with the code. The code is under final review and is the subject of a separate public consultation. The object of the advertising code is to ensure that marketing and advertising of therapeutic goods to consumers is conducted in a manner that:

- promotes the safe and proper use of therapeutic goods by minimising misuse, overuse or underuse of the goods; and
- is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and
- supports informed health choices; and
- is consistent with current public health campaigns.

Whether conduct falls within the scope of 'advertise' is considered according to the standard of a reasonable consumer to whom the advertisement is directed rather than by the actual intention of the person responsible for the advertising material. In other words, it is the anticipated impact on a reasonable audience, rather than the subjective intention of the advertiser, that defines whether or not conduct is 'to advertise' or complies with the code.

Comment [A7]: Recommendation 56 also called for a new mechanism "consistent with the best practice principles for complaint handling".

This consultation document falls short of best practice in a number of ways (see below and see our accompanying response).

The Government has directed the establishment of a "single agency approach" to complaints handling. On this basis the TGA must take responsibility for determining all alleged breaches of the entire Code. The TGA should not be tempted to focus only on parts of the Code or be tempted to forward matters on to other agencies (such as the ACCC).

The Government also directed the TGA to establish a system that was consistent with best-practice principles and yet the consultation document does not contain a single reference to the term "best-practice", it does not describe what a best-practice system might look like and it certainly does not describe how the TGA's proposals reflect any best-practice principles.

Comment [A8]: This appears to conflict with the definition of "advertise" above which is based on an *intent* to promote. While the impact on the notional "reasonable consumer" will be relevant in assessing compliance with the Code, it is hard to see how it is relevant to whether an activity amounts to advertising or not.

How will the TGA define this "reasonable consumer" and assess the impact of advertising activities on them?

Comment [A9]: This is a new concept. What is the purpose of introducing this new term? Previously, and as above, the focus has been on the reasonable *consumer*. How will the TGA define this "reasonable audience" and assess the impact of advertising activities on them? What is the purpose of introducing this new term? What are the practical differences between a reasonable consumer and a reasonable audience?

4. New powers and sanctions

As earlier noted, the range of sanctions available to the TGA to use individually or in combination to address non-compliance including advertising non-compliance was supplemented by the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*; they include:

Substantiation Notices

- Powers to issue directions about advertisements or generic information
- Cancellation or suspension of therapeutic goods from the ARTG
- Public Warning Notices
- Injunctions
- Infringement Notices
- Enforceable Undertakings
- Preparation of a brief of evidence for criminal prosecution
- Civil action.

5. Purpose of this consultation

The purpose of this consultation is to seek stakeholder's views on the proposed complaints handling model as it relates to advertisements for therapeutic goods directed to the Australian public.

Our expanded suite of regulatory tools is sufficiently flexible to allow a choice of the most appropriate regulatory response; it facilitates an effective layered approach to compliance and enforcement. As a responsive regulator we use a risk-based framework where the level of regulatory intervention is appropriate and proportionate with the risk associated with the advertising of therapeutic goods. Our risk assessment has a particular emphasis on whether reliance on advertising claims by consumers could pose a health and safety risk to the public.

The TGA has published detailed educational and guidance information online for health professionals, consumers and the industry about advertising therapeutic goods to the public. This includes information regarding the various restrictions and exemptions to the advertising regulatory scheme. Where compliance cannot be achieved through assistance and education, more coercive enforcement actions will be undertaken.

The ultimate objective is to ensure that our regulatory actions are appropriate and proportionate with the risk that the advertising of therapeutic goods to the public poses, and to address any potential health and safety issues to the Australian public.

We are seeking your views on the TGA's proposed new complaints handling model and graduated responses to advertising non-compliance.

Comment [A10]: The TGA should not just focus on risk/harm/detriment to consumers.

For alleged breaches that are not objectively or obviously justified (e.g. missing mandatories) then the level of investigation should be consistent. While the level of intervention (penalty?) should be proportionate to the level of the established breach.

If the TGA ignores significant breaches of the Code simply because no consumer harm was evident, then the reputation of the new system and stakeholders' confidence in it will be damaged.

If the TGA only intend to focus on the parts of the Code with a bearing on health and safety, then why does the Code even have other requirements?

Comment [A11]: As above

Comment [A12]: As above.

Comment [A13]: The TGA needs to concern itself with the entire Code and not just those aspects which have a bearing on safety. The "ultimate objective" for the TGA is described in section 4(1)(a) of the *Therapeutic Goods Act* as follows:

"... to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods ...."

6. Our approach

TGA works with the public to understand needs and be responsive to expectations. We work with the regulated industry and advertisers to support better advertising outcomes.

We carefully consider how to respond to all potential breaches of the advertising requirements. While we determine the substance of each individual complaint formal compliance action will not be necessary in every matter that comes to our attention. Some matters are better dealt with using education and/or guidance.

To ensure that our finite resources are managed appropriately we consider a range of factors when deciding whether to investigate and take compliance or enforcement action. It is the substance and severity of a complaint that dictates the level of resources dedicated to it.

In the first instance, where minor non-compliance issues are identified we will often work with the advertiser using an educative approach in order to achieve compliance. However, escalation of regulatory action will be considered if the advertiser is not willing to comply or the breaches of the advertising requirements are such that there is an impact on the ability of the consumer to use the therapeutic goods safely or appropriately in line with the goods' intended therapeutic purpose.

We are less likely to investigate matters that are one-off events, unless non-compliance is a deliberate and blatant breach of the legal requirements, it is part of an ongoing pattern of non-compliance, and/or there are public health consequences from the non-compliant behavior.

Our complaints process is supported by the following principles:

- We will work ethically within our legislative framework for regulating therapeutic goods advertising
- Our approach to handling and determining complaints will be consistent
- We will be transparent in our dealings and will report on details of our performance in managing complaints
- We will expend resources appropriately by focusing on risk and addressing the most serious non-compliance, and
- We take all complaints seriously and will action them within set time frames

Figure 1: Compliance approach

Table1: Our Approach to Compliance

Help and Support	Inform and Advise	Correct Behaviour	Enforce
Make compliance easy	Help to become and stay compliant	Deter by detection	Administrative, civil or criminal action

Comment [A14]: As noted above, and below, the TGA's focus on safety only may mean that complaints about advertising that have a commercial impact could be disregarded or de-prioritised. The substance and severity of the complaint should be assessed in terms of the extent of the apparent non-compliance and not simply the extent to which a consumer might be harmed by the advertising.

Comment [A15]: The TGA should be acting on the substance of the breach, not the substance of the complaint (since every complainant will be certain that their concerns are justified). At this point it is still only an alleged breach in the form of a complaint – no determination will have been made (and the complaint may well be unfounded, misconceived or even vexatious).

Comment [A16]: The TGA should be investigating all the matters that are brought to their attention. How else can there be a reasonable assessment of the level of non-compliance?

Comment [A17]: How can the TGA determine if something is deliberate or blatant? Especially if they will forming this view *before* contacting the advertiser?

Comment [A18]: How can it be both a "one-off event" and a part of an "ongoing pattern"?

Comment [A19]: How will stakeholders know this, unless all determinations are published?

Comment [A20]: This appears to contradict the statement above (i.e. " ... we consider a range of factors when deciding whether to investigate.."). According to this bullet point, the TGA will action every complaint and yet according to the material above, the TGA will only investigate some complaints. Clarity is required.

Comment [A21]: It is unclear why the consultation document includes such obvious statements? Stakeholders should be entitled to assume that the TGA will work ethically and within the law.

Comment [A22]: Who will the civil action be taken against?

Table 2: Regulated Entity - Attitude to compliance

Voluntary Compliance	Accidental Non Compliance	Opportunistic Non Compliance	Intentional Non Compliance
• Effective compliance systems • Management is compliance	• Ineffective and/or developing compliance systems • Management is	• Resistance to compliance • Limited or poor compliance systems • Management not compliance orientated	• Deliberate non compliance • No compliance systems • Criminal intent
"Committed to doing the right thing"	**"Trying to do the right thing"**	**"Don't want to comply but will if made to"**	**"Decision to be non-compliant"**

Comment [A23]: Not sure what this means?

Comment [A24]: Not sure what this means?

7. The complaints process

Although we prefer complaints to be made on our online advertising complaint form, complaints can also be submitted by email, telephone or posted to the TGA. Where we cannot action a complaint within the advertising framework we will endeavour to refer the complaint to the appropriate area of another agency with the appropriate jurisdiction to action it.

Comment [A25]: Advertising framework is much broader than what the TGA complaints process is planning to address.

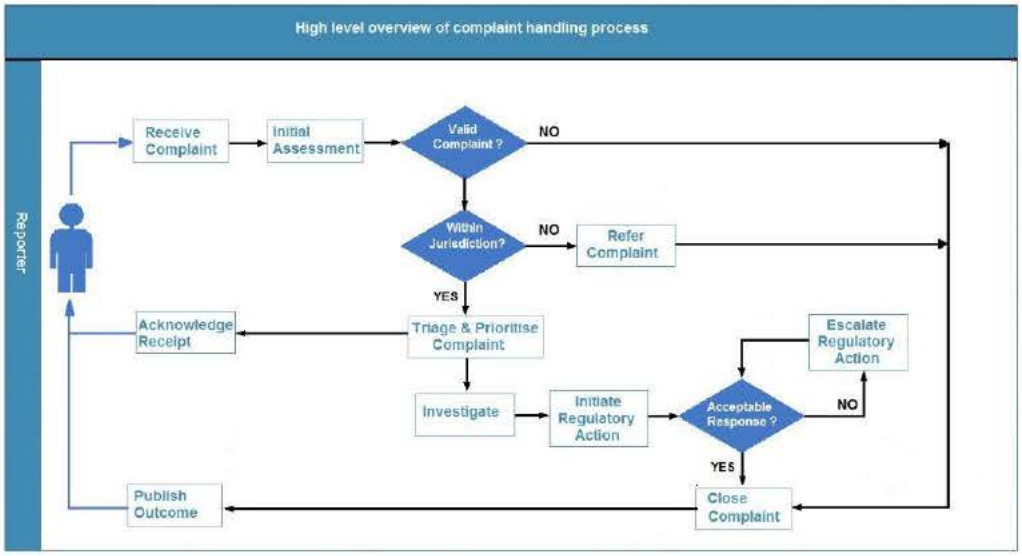
The online complaint form, that will be available on the advertising hub of the TGA website, will ask the complainant for specific information and allow them to upload digital attachments so that we have all of the information necessary about the advertisement and the advertiser to properly assess and investigate the complaint. Online complainants will receive a unique identification number visible on the form at the time of submission.

If a complaint is received outside of the online hub, and the complainant can be identified, the acknowledgement process will be manual and the complainant will, within 10 working days, be given a unique identification number for reference.

Not only do we accept anonymous complaints but we will treat the identity of a complainant who chooses to be identified in confidence.

Regardless of the way the complaint is received, it will be entered into our Complaints Handling System where the complaint will be actioned and tracked as a complaint *lead*.

At a high level, our complaints process is as follows



7.1 Accepting your complaint lead

Leads will be assessed for validity as we can only legally action complaints about advertisements for therapeutic goods; we cannot action complaints about foods, cosmetics, general consumer goods, chemicals, veterinary medicines, and health insurance or healthcare professionals. We do not have any legislative power to seek compensation on behalf of consumers, as this falls within various consumer protection schemes and is beyond the remit of the *Therapeutic Goods Act 1989*.

There are some complaints we cannot action as they are outside the jurisdiction of the legislation we administer. We often cannot action a complaint about advertising that is conducted or that originated offshore. There are some constitutional constraints on dealing with individuals who advertise solely within their own state or territory and are otherwise not engaged in interstate trade. These matters may be referred to state or territory authorities with appropriate jurisdiction.

In these cases the complainant will be advised that their complaint has been closed and they will be consulted as to whether they want us to refer the case to a more appropriate authority.

If a complaint is assessed as a valid complaint, within our jurisdiction, the *lead* will be moved to a *complaint* case and the complainant will receive an email or letter confirming this with the case identification number

If a number of *leads* are received that may relate to different advertisements and different *responsible entities*, but relate to similar classes of therapeutic goods (for example cosmetic injections), we will consider grouping these *leads* into one *case* so they may be dealt with in one action – say by way of a targeted educational campaign and/or by notifying the responsible entities involved and making them aware of their regulatory obligations. We will report on the number of complaints as well as the case outcome.

Comment [A26]: According to this diagram every valid complaint will result in a published outcome. In the interests of TGA transparency and advertiser education this must happen.

However, the sections below indicate a different approach, with some outcomes not published at all and other outcomes only published in aggregate.

Like the CRP before it, the TGA must publish every single determination in sufficient detail to assist advertisers.

Comment [A27]: What about complaints about these products making therapeutic claims in advertising?

Comment [A28]: This part of the process should have target timeframes assigned.

Comment [A29]: How long will the TGA hold each lead for in order to see if more similar leads arrive?

Will this delay leads? Or will the TGA review each lead against those cases already on foot so as to advance the later leads?

7.2 Triaging of complaints

Staff within the TGA will assess and triage complaint cases about advertisements taking into consideration attributes of the complaint including but not limited to the frequency of advertising, the likelihood of consumer harm and the intent of the advertiser. Like other regulators we will have a process to deal with vexatious complaints. Following assessment, complaints will be triaged into one of four priority categories; low, medium, high and critical.

Comment [A30]: This part of the process should have target timeframes assigned.

Comment [A31]: The TGA needs to focus on more than just consumer harm. The TGA must also consider:

-The potential for a complaint to be vexatious or unjustified.
-The possible extent of the non-compliance (e.g. absence of evidence),
- The obviousness of the non-compliance (e.g. presence of prohibited representations or the absence of mandatory statements),
-The commercial impact (even in the absence of consumer safety implications),
-Etc.

Comment [A32]: How will the TGA determine the intent of the advertiser? Especially since they will forming this view *before* contacting the advertiser? On the basis of the complaint alone? On the basis of the individual's pre-conceived notions about the advertiser?

Comment [A33]: Triaging should be an administrative task and not some mini-investigation.

As described in our written submission, triaging should be a simple process of placing each complaint into one of four easily determined categories as follows:

1.Vexatious or misconceived complaints (to be rejected promptly)

2.Obvious, objective, breaches (e.g. missing mandatory statements) (to be handled simply)

3.Serious breaches involving consumer safety (e.g. cancer treatments) (to be determined as a priority)

4.The remainder (to be determined in the order received)

8. Priority based complaints handling model

We will assess and triage complaints about advertisements for therapeutic goods into one of the four priority categories after taking into consideration:

- whether the claims made or reliance on the claims made in the advertisement is likely to cause public harm
- the likely impact of the advertising on the ability of consumers to safely and appropriately use the goods for their intended purpose
- the frequency and likely impact of the non-compliant advertising and its influence on other advertisers to the detriment of consumers
- the advertisers' awareness of their advertising obligations.

The priority level assigned to each case will determine how quickly we commence investigation, notify the person responsible for the advertising, and ultimately the regulatory tools used to achieve compliance, and dictate our key performance indicators.

Comment [A34]: The TGA needs to consider the compliance or non-compliance with all the elements of the Code and not just these factors.

For example, highly misleading claims about an otherwise very safe product in relation to a self-limiting condition would be apparently ignored and yet could generate significant profit for the advertiser, significant economic loss to consumers, significant commercial detriment to competitors and significant reputational damage to the TGA if allowed to continue.

For example, unsubstantiated claims misleadingly describing the superiority of one brand of a particular active against another brand of the same active (in the context of the approved indications) may not pose any risk of harm, but will have significant commercial impact and would clearly be in breach of the Code. Such a breach would apparently not be a priority for the TGA.

Comment [A35]: What does this "public harm" mean? Physical harm? Economic harm? Undermining public confidence in therapeutic goods? Undermining public confidence in the TGA? How will the TGA assess this?

Comment [A36]: What does "detriment of consumers" mean? Physical detriment? Economic detriment? How will the TGA assess this? Is there a difference between "harm" and "detriment"?

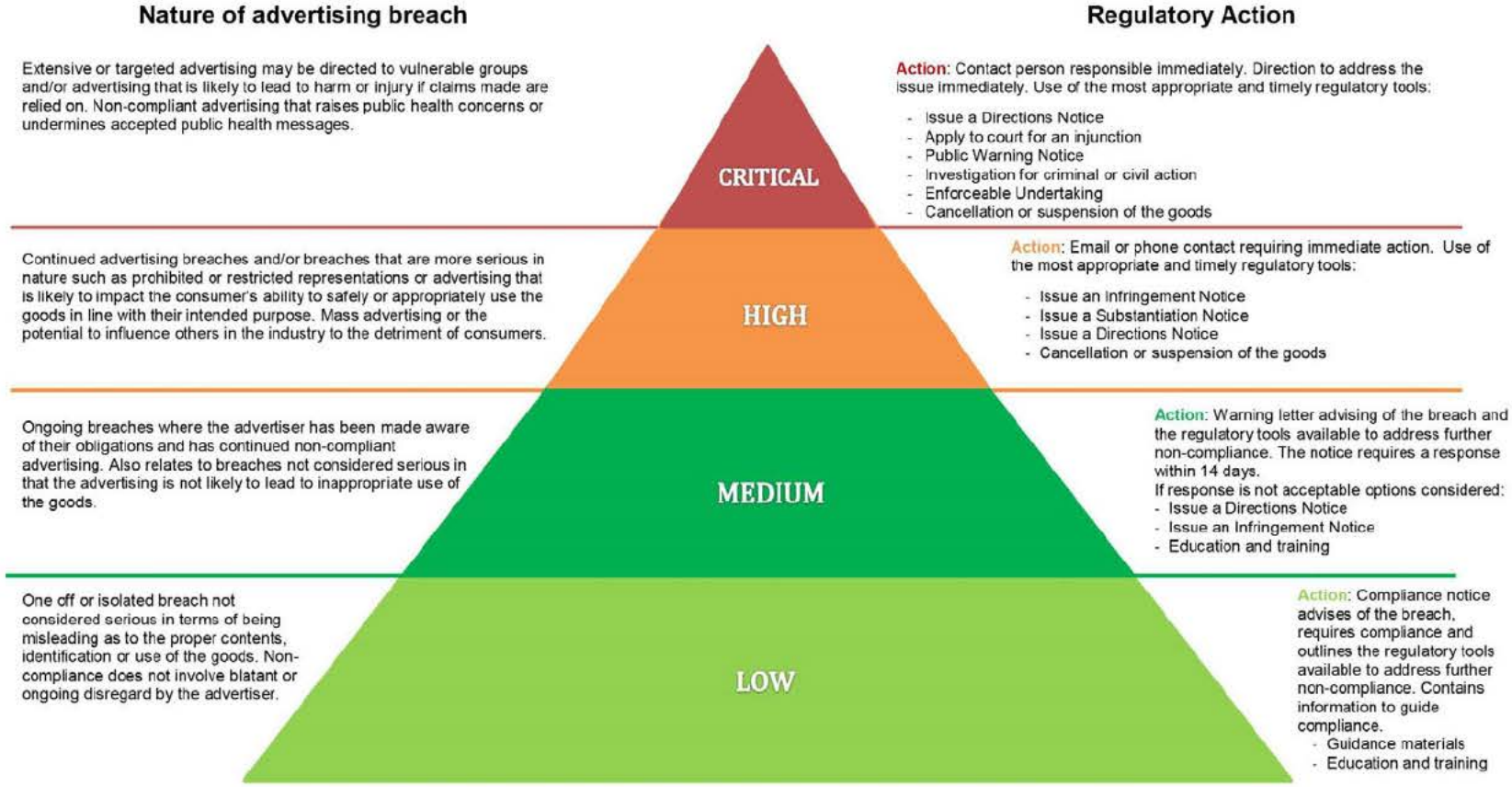
Comment [A37]: How will the TGA determine the "awareness" of a particular advertiser? They won't have contacted the advertiser yet and they won't even know who actually approved the advertisement within the organisation. Also at this stage the organisation that is being targeted is only apparently responsible for the advertisement.

It looks like the TGA will be assuming that a series of previous "notices" (about older advertisements) that were sent from them to someone who is now apparently responsible for a new advertisement – notices which did not even require acknowledgment (see below) - will amount to evidence that ...

Comment [A38]: This classification system appears to involve the TGA forming a view about the merits of the complaint, the presence of a breach and the seriousness of that breach without giving the advertiser the opportunity to answer the complaint and without any TGA investigation actually having occurred yet.

This approach is completely inconsistent with the principles of procedural fairness (i.e. a fair hearing and the absence of bias). ...

Overview of proposed complaints handling model once a breach is established



Comment [A39]: Target timeframes required

LOW (Nature)
- How will the TGA know if something is a "one off" or whether it reflects a "blatant or ongoing disregard"?
- Is there a difference between "one off" and "isolated"?
- What is "not seriously misleading"?

LOW (Action)
- No publication? No follow up?
- What does guidance and training entail? Who will do it? Will the TGA be issuing regulatory/advertising advice?

MEDIUM (Nature)
- Ongoing breaches of what?
- How will the TGA determine that inappropriate use is unlikely?

MEDIUM (Action)
- What sort of breach? Not much detail under "nature".
- Breaches without a safety impact (regardless of the commercial or economic impact?) will never reach higher than a "Medium".
- This is an inadequate level of response for an advertiser who has already been "educated"
- Does acceptable mean complete agreement?

HIGH (Nature)
- Aside from the references to prohibited or restricted representations, these criteria are very ambiguous and subjective.
- Mass advertising? What has frequency got to do with whether a breach has occurred? How will this even be measured?

HIGH (Action) ...

8.1 Investigation phase

Following assessment and triage, complaints will undergo investigation to examine the advertising material subject of the complaint, to establish the person responsible for the advertisement (responsible entity) and to consider whether the alleged breach has been committed. The investigation phase allows the responsible entity an opportunity to respond to assertions of non-compliant advertising and, where there has been non-compliance, to demonstrate a willingness to rectify, and actually rectify, the non-compliance in a timely manner. Using this response and the priority assigned to the complaint case, we determine the most appropriate regulatory tools to address the non-compliant advertising.

Comment [A40]: No details are provided about the investigation process.

Who will conduct the investigation? How will the investigation be conducted? What sources of information will be considered relevant? What qualifications will the decision maker possess? Etc.

There is no description of any appeal process.

Comment [A41]: Not clear when this "opportunity" actually arises.

The description of low priority cases (8.2 below) contains no such step and proceeds straight to the notice.

The description of medium priority cases (8.3 below) contains no such step and proceeds straight to a formal warning seeking information only on what steps the advertiser will be taking to remedy the non-compliance.

The description of high priority cases (8.4 below) contains no such step and proceeds straight to a warning (or phone call) where the advertiser will be asked to address the non-compliance.

The description of critical priority cases (8.5 below) contains no such step and proceeds straight to an immediate contact by email or phone where the advertiser will be required to address the non-compliance.

Comment [A42]: How will the TGA determine that there "has been non-compliance" at this point, when the investigation is yet to take place?

Comment [A43]: Needs defining

Comment [A44]: What happens if the advertising is found to be compliant?

8.2 Low priority cases

These are cases of one-off or isolated advertising breaches that are not considered serious in terms of being misleading or confusing as to the content or proper use or identification of the therapeutic goods and do not involve ongoing or blatant non-compliance by the advertiser.

- Advertisers identified as the responsible entity for the alleged breach of the advertising scheme will be sent a regulatory obligations notice by email or letter.
- The regulatory obligations notice will advise the entity of the alleged breach and will have accompanying information to guide compliance.
- The responsible entity will be asked to review their advertising material for compliance and will be advised of the regulatory tools available to the TGA to address any further non-compliance.
- The matter will be closed when the notice is sent.
- Closed matters may be subject to a later review to ensure compliance has been met and is ongoing.

Regulatory obligations notices will not seek a written response from the responsible advertiser; however any response received will be addressed.

All low priority matters will be recorded in our Complaints Handling System and reported on. Recorded information may form part of a later review and/or how we address further or more serious non-compliance by the advertiser.

Comment [A45]: The TGA cannot just focus on these two elements. Firstly because the TGA must administer the entire Code, secondly because there is no Code section that prohibits "confusion".

Comment [A46]: No opportunity for the advertiser to answer the complaint prior to the TGA making a determination.

Comment [A47]: No opportunity for the advertiser to respond to the TGA's determination.

Comment [A48]: No follow up by the TGA to confirm either receipt of the notice or remedy of the purported breach.

No mechanism to have the TGA's determination reviewed or tested.

No sanction or penalty applied?

Comment [A49]: How can the TGA be confident that their determination is sound if they do not allow the advertiser to answer the alleged breach?

How can the TGA be confident that their notice has been received, understood or acted upon if they do not require a response

Comment [A50]: What does this mean? The chart on page 9 indicates that all valid complaints will be published, but this suggests that something less will be published.

Comment [A51]: Each alleged non-compliance ought to be examined on the basis of the particular advertisement and its compliance with the Code. How is past behaviour relevant?

8.3 Medium priority cases

These are cases of ongoing advertising breaches where the advertiser has been made aware of their advertising obligations and continues to advertise the therapeutic goods in a non-compliant manner. This category relates to advertising breaches that are not considered serious in nature as they are unlikely to result in unsafe or inappropriate use of the therapeutic goods.

- Advertisers identified as the responsible entity will be sent a formal warning by email or letter as soon as possible.
- The warning letter will advise the entity of the alleged advertising breach and will have accompanying information and guidance on the advertising scheme.
- The responsible entity will be advised of the regulatory tools available to the TGA to address non-compliance.
- The warning letter will request a written response within 14 days seeking information on what action the entity intends to remedy the non-compliance.

An acceptable response will move the matter to closed status. If no response is received within 14 days or the response is not sufficient to warrant closing the matter, we will pursue this with the responsible entity and it may require escalation of our regulatory response.

The information from this case will form part of our considerations in cases of further or more serious non-compliance by the responsible entity.

Comment [A52]: The TGA cannot just focus on some elements of the Code.

The TGA must administer the entire Code.

Comment [A53]: No opportunity for the advertiser to answer the complaint prior to the TGA making a determination.

No opportunity for the advertiser to respond to the TGA's determination.

No mechanism to have the TGA's determination reviewed or tested.

Comment [A54]: Not clear where the transformation from complaint to actual non-compliance takes place.

Comment [A55]: Not defined.

From the context, we have to assume that there is only one acceptable response – complete agreement with the TGA determination.

Comment [A56]: No sanction or penalty applied?

Comment [A57]: Each alleged non-compliance ought to be examined on the basis of the particular advertisement and its compliance with the Code. How is past behaviour relevant?

8.4 High priority cases

These are cases of continued advertising in breach of requirements despite evidence the advertiser is aware of their obligations and has previously been provided education and or guidance material by the TGA. This would also involve advertising breaches:

- that are considered more serious in nature such as advertisements containing prohibited or restricted representations
- claims that will likely lead to inappropriate use
- advertising that is likely to have an impact on the ability of consumers to use the therapeutic goods safely or appropriately in line with their intended therapeutic purpose.

A higher priority may also be given to mass advertising campaigns because of the potential to influence other advertisers in the industry to the detriment of consumers.

- Advertisers identified as the responsible entity will be sent a warning by email or contacted by telephone as soon as possible and asked to address the non-compliance issue immediately.
- A determination will be made as to the most appropriate regulatory tools to be used.

The information from this case will form part of our considerations in cases of further or more serious non-compliance by the responsible entity.

Comment [A58]: The TGA cannot just focus on some elements of the Code.

The TGA must administer the entire Code.

Comment [A59]: Not clear where the transformation from complaint to actual non-compliance takes place.

No opportunity for the advertiser to answer the complaint prior to the TGA making a determination.

No opportunity for the advertiser to respond to the TGA's determination.

No mechanism to have the TGA's determination reviewed or tested.

Comment [A60]: On what basis will this second determination be made, how will it be made and by whom?

Comment [A61]: Each alleged non-compliance ought to be examined on the basis of the particular advertisement and its compliance with the Code. How is past behaviour relevant?

8.5 Critical priority cases

These are cases where the advertising claims made, or reliance on them, may result in or is likely to result in harm or injury to consumers. Critical priority may also be given to advertising which is directed to the most vulnerable consumers or that undermines public health campaigns, raises significant public issues or has the potential to undermine public confidence in government, industry or the TGA.

- We will seek to identify the person responsible for the offending advertising either through direct contact or using open or closed source information.
- An advertiser identified as the responsible entity for breaches of a critical priority will be contacted by email or telephone immediately and required to address any non-compliance issues immediately.
- Subject to the responsible entity's action and the seriousness of the breach the TGA will determine what regulatory tools it uses for regulatory compliance and enforcement.
- It is unlikely that a matter assessed as critical would be closed simply by receipt of a response from the responsible entity.

If an acceptable response and action is not immediately forthcoming by the responsible entity of an advertising matter of critical priority, we will escalate our response and employ regulatory tools to enforce compliance, which may include civil or criminal litigation.

8.6 Monitoring and trend analysis

The TGA will link incoming complaints to a responsible entity involved in previous compliance cases. Closed compliance cases may be selected for monitoring and review.

Information on complaint trends will be published in bi-annual reports. This information will inform the identification and prioritisation of compliance risks, and the targeting of our education and compliance work.

9. Reporting outcomes and measuring performance

The proposed use of a case identification number will allow monitoring of individual complaints throughout the process. When matters are finalised and closed, outcomes will be published.

Some sections of the therapeutic goods legislation require us to publish information such as when we issue directions. Other sections of the legislation allow us to publish information such as Public Warning Notices.

We will publish the outcomes of complaint cases and information on enforcement outcomes, including those that are administrative actions such as cancellation or suspension of therapeutic goods from the ARTG.

Like other regulators, we will publish information on our website on specific actions:

- enforceable undertakings that we enter into

Comment [A62]: The TGA cannot just focus on some elements of the Code.

The TGA must administer the entire Code.

Comment [A63]: What does this mean?

Comment [A64]: Not clear where the transformation from complaint to actual non-compliance takes place.

No opportunity for the advertiser to answer the complaint prior to the TGA making a determination.

No opportunity for the advertiser to respond to the TGA's determination.

No mechanism to have the TGA's determination reviewed or tested.

Comment [A65]: On what basis will this second determination be made, how will it be made and by whom?

Comment [A66]: Not defined.

From the context, we have to assume that there is only one acceptable response – complete agreement with the TGA determination.

Comment [A67]: Which parties will be pursued? The Head of the business, the Directors, the Senior staff, or the person(s) actually responsible for approving the materials? The sponsor? The advertiser? The publisher? The broadcaster? The distributor of the material?

Comment [A68]: There should be publication of all complaints received and outcomes, with detailed determinations (including reasoning) as per the current CRP database. This will allow advertisers to understand how the TGA is interpreting the advertising legislation and will act as an educational tool.

This would also be consistent with the best-practice approach that the TGA has been instructed to adopt.

- information about infringement notices
- court outcomes
- directions notices
- public warning notices.

Publishing information about such matters is central to the requirement for the TGA to be transparent in its advertising complaints handling process. Our new regulatory tools mean that persons who publically advertise in contravention of the therapeutic goods advertising scheme can potentially face both a financial penalty and reputational damage from having their name reported on the TGA's website.

- **Low priority outcomes**, we will not disclose the identity of those persons who have been sent a regulatory obligations notice, however the case identification number, date received, date completed and the outcome will be published.
- **Medium priority outcomes**, where an acceptable response is received to a warning letter, the details of the responsible entity along with the case identification number, date received, date completed, the therapeutic goods involved, compliance action/s taken and the outcome will be published.
- **High priority outcomes**, where these matters are resolved, the details of the responsible entity, the case identification number, date received, date completed, the therapeutic goods involved, the compliance action/s taken and the outcome will be published.
- **Critical priority outcomes**, where these matters are resolved, the details of the responsible entity, the case identification number, date received, date completed, the therapeutic goods involved, the compliance action/s taken and the outcome will be published.

New key performance indicators (KPIs) will be reported in bi-annual reports. We will use two metrics for reporting time to action complaints and time to close complaints.

Time to action complaints means the time from when the complaint was received, assessed and triaged to when we have made our initial engagement with the person responsible for the advertising. These times depend on the priority given to each accepted complaint and include:

Low Priority	Medium Priority	High Priority	Critical Priority
95% in 14 days	95% in 40 days	95% in 20 days	100% in 10 days

Time taken to close complaints means the time from when the complaint was received, assessed and triaged to when we assess that no further action is required. These times are our intended timeframes in which to close out matters and depend on the priority given to each accepted case:

Low Priority	Medium Priority	High Priority	Critical Priority
90% in 20 days	90% in 90 days	90% in 90 days	90% in 60 days

Comment [A69]: While the "time to action" and the "time to close" are described below, there is no indication of how long it will take to publish the outcomes. This is necessary in order to assess whether the TGA proposed times are appropriate.

Comment [A70]: This will be of no educative value to advertisers.

This will be of limited value in assessing TGA performance.

Comment [A71]: Not defined (see above).

What happens if the response is not acceptable?

Comment [A72]: Details of the complaint and the TGA reasoning behind the determination will be of value and must also be published – not just the outcome.

Comment [A73]: Not defined. What does "resolved" mean in this context? What happens if the matter is not resolved?

Comment [A74]: Details of the complaint and the TGA reasoning behind the determination will be of value and must also be published – not just the outcome.

Comment [A75]: Not defined. What does "resolved" mean in this context? What happens if the matter is not resolved?

Comment [A76]: Details of the complaint and the TGA reasoning behind the determination will be of value and must also be published – not just the outcome.

Comment [A77]: Not clear when the clock will start. At receipt? When triaging is complete? Clarity is required in order to assess whether the TGA proposed times are appropriate.

Comment [A78]: "Initial engagement" is not a term that is used in the preceding sections. Does this mean the warning notice, letter, email or phone call? Or does this mean the purported "opportunity to respond" identified in section 8.1? Clarity is required in order to assess whether the TGA proposed times are appropriate.

Comment [A79]: Not clear when the clock will start. At receipt? When triaging is complete? Clarity is required in order to assess whether the TGA proposed times are appropriate.

9.1 Exceptions to the metrics

Some complaints may be referred internally within the TGA such as where the complaint triggers an efficacy or safety review which may also, in more complex matters, require external advice or a submission to an advisory committee. In these cases we will monitor progress and report on outcomes when the matter is finalised.

Matters that require court action can take some time to properly investigate and assemble, for example for criminal prosecutions. Outcomes that are dependent on court decisions either civil or criminal can, according to available court resources, take longer to resolve and close. In these cases we will report on outcomes when the matter is finalised.

If we have referred the matter for action to an external agency such as another Commonwealth or State regulator we will report the time taken from receipt of the complaint to referral to that agency.

We seek the views of stakeholders on our proposed complaints handling model.

10 Governance

A new non-statutory committee, the Therapeutic Goods Advertising Committee, will be formed. The TGAC would meet three or four times per year, most likely in association with some meetings of the TGA Consultative Committee (TCC) who meet twice a year.

This committee will have wide representation across stakeholders involved in therapeutic goods advertising and will include representation from:

- patient and health consumer representative bodies
- therapeutic goods industry
- publishers and broadcasters (including social media and internet)
- healthcare practitioners, and
- advertising and other parts of the media industry.

The committee will act as a forum for engagement on advertising issues and will provide advice on thematic issues in advertising complaints, compliance priorities and education plans.

The committee will review the TGA's KPIs in managing complaints and provide advice on the bi-annual report.

The committee will also advise on the policy settings for therapeutic goods advertising, including for products such as medical devices that were formerly not completely included within the advertising regulatory framework.

Comment [A80]: This Committee will be a poor substitute for the multi-stakeholder, co-regulatory, statutory committees that it will replace (i.e. the TGACC and the CRP).

While not perfect, the TGACC and the CRP were exemplars of co-regulation. The reforms proposed in this consultation document do not represent improvements or progress over the current system (indeed in many instances the reforms are retrograde steps).

This Committee can have no proper "governance" role. Without legislative underpinning the Committee will have no power and no authority. The administration of the Committee, its meetings, its process, its transparency will depend entirely on the goodwill of the TGA. The TGA will be free to ignore the Committee, to reconstitute the Committee, or disband the Committee at will.

Nevertheless, ASMI has been an active member of both the TGACC and the CRP and would expect to be invited to participate on this new Committee.

Comment [A81]: We already have TGAC (the Therapeutic Goods Advertising Code). To avoid unnecessary confusion a new name and acronym should be selected.

11 Education and guidance

Education and guidance are a key strategy in support of compliance, and will inform the public about the appropriate advertising of therapeutic goods and in how to make a complaint.

To assist advertisers to understand their obligations we will provide an e-learning program on our website, along with guidance and information materials. The program is expected to be available mid-2018, and modules may be added over time.

We will develop a number of guidance documents and will work with key stakeholders to discuss specific needs. We will raise awareness about the new advertising complaints handling process and the role of the TGA in the regulation of advertising for therapeutic goods.

A number of resources and channels will be engaged:

- TGA website advertising hub
- Stakeholder workshops and roadshows
- Twitter
- YouTube
- Printed and online fact sheets, and material for industry publications
- E-learning program and other training materials
- SME Assist seminars.

12 The TGA website advertising hub

The TGA website advertising hub will have a selection of ways to access information about the advertising of therapeutic goods to the public, and to make contact with the TGA on advertising matters. You will be able to:

1. **View our education and guidance material**
2. **Make an enquiry about therapeutic goods advertising**

   Enquiries received through the hub will be automatically acknowledged and given an identification number. While it is not the role of the TGA to act as a regulatory consultant, we will strive to assist and will respond to enquiries with relevant information by email.
3. **Make an application to advertise therapeutic goods with a restricted representation**

   Please note that this facility will not become available until later in 2018 as a minor legislative amendment is required to allow for online submissions.

   Until the online submission option becomes available the current application form will continue to be used. The form can be downloaded from the TGA website as a PDF or Word document and when completed should be emailed back to the TGA. The form can be accessed at Application for approval to use a restricted representation in advertising.

Comment [A82]: TGA staff should not be engaged in running a training organisation for poorly prepared advertisers. Nor should they be engaged in mocking-up examples of compliant and non-compliant advertising. Instead, the TGA should focus on investigating complaints and publishing determinations. The TGA's actual decisions on compliance will be far more relevant and instructive.

Is there a potential conflict of interest here when the personnel responsible for enforcing compliance are also the personnel instructing advertisers on how to comply? For example, will the educators be tempted to make their compliance roles easier by taking an extremely conservative view of what is permitted in advertising and advising advertisers accordingly?

Comment [A83]: Instead of relying on guidance documents, the TGA should publish detailed determinations of the complaints it receives and generates. As with the current CRP determinations, the publication of these outcomes - on their own - will be of far greater value than any TGA guideline.

Comment [A84]: As detailed in our 4 May 2018 response to the TGAC2018 consultation, ASMI is not supportive of the TGA's intended widespread use guidance documents in relation to advertising compliance, for the following reasons:

1. The existence of such guidelines will lead to lazy drafting of the Legislative Instruments. In such a situation the drafters would be tempted leave any complex matter "to be explained in the guideline" (as proposed for TGAC 2018 and as is currently happening with the Labelling Order TGO92).
2. . TGA staff will treat the guideline as law and advertisers will be prevented from some activities simply because the guidelines did not appear to allow them (as is also currently happening with the Labelling Order TGO92).
3. The TGA could change the guidelines "at will" and would not even be subject to the (limited) oversight attendant on changes to a Legislative Instrument (as has recently happened with the ARGCM).
4. . The TGA may be slow to update the guidelines leaving stakeholders uncertain as to the requirements or the TGA position (as is currently happening with the guidelines supporting TGO92)
5. TGA staff should not be engaged in mocking-up examples of compliant and non-compliant advertising, since the TGA's actual decisions on compliance will be far more relevant and instructive. ...

Comment [A85]: The hub should also include all the complaint determinations (those made under these new arrangements as well as a database of the prior CRP determinations)

Advertisements for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in the code as restricted representations, unless prior approval is given under the Act.

By selecting the *"make an application to advertise therapeutic goods with a restricted representation"* option on the TGA advertising hub you will be able to make an application to advertise therapeutic goods with a restricted representation. When available, online applications will be acknowledged automatically by return email with an identification number.

In considering an application for approval to include a restricted representation in an advertisement, the decision-maker must be satisfied that the representation is accurate and balanced and is not misleading or likely to mislead. The decision-maker can seek advice and will also ensure that public interest criteria are applied. Further information on restricted representations can be found at Restricted representations.

4. Make a complaint about an advertisement

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Advertising Compliance Unit	May 2018

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21 December2016

Advertising Consultation
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Dear Sir/Madam,

Submission to the Consultation on the Regulatory Framework for Advertising Therapeutic Goods

We refer to your call for submissions re the above.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

Our recommendations in response are summarised on the next page (with our rationale on the following pages).

ASMI Recommendations

For the reasons detailed below, ASMI makes the following recommendations:

1. Removing pre-approvals takes away a valuable consumer protection, and the transition to the new compliance measures needs to be carefully managed.

2. The TGA needs to demonstrate proficiency with the new compliance measure before pre-approvals are removed.

3. There must be tangible benefits to obtaining pre-approval, for a self-regulatory approach to be successful.

4. The TGA are underutilising the mechanisms currently available. Effective use of the substantial existing powers needs to be the objective, rather than the introduction of additional burden and red tape.

5. If sanctions and penalties do need to be increased they must be set transparently and according to existing Commonwealth Government principles.

6. The design elements of an appropriate complaints system are more important than the identity of the managing body. We want - one advertising code, one complaints panel and one process.

7. In order for stakeholders to have confidence in the processes, the TGA needs to improve transparency.

8. When the TGA does report outcomes of compliance activities, the reporting should be accurate.

9. The Therapeutic Goods Advertising Code needs to be updated and expanded.

10. Measures need to be put in place to ensure that the valuable input from the CRP and the TGACC continues to be available to the TGA.

11. If the TGA provides clear regulatory guidelines and timely publication of regulatory decisions, then the need for a formal education program will be reduced.

Pre-approval of advertisements

Removing pre-approvals takes away a valuable consumer protection, and the transition to the new compliance measures needs to be carefully managed.

For the reasons described in our previous submissions, advertising pre-approvals has worked well to protect consumers in Australia (and in comparable markets such as the UK and New Zealand). Removing pre-approvals will take away this protection and has the potential to damage the reputation of the industry.

Despite this, the Government decision to abolish pre-approvals has now been made and so transition will be the key.

In order to minimise the risks to consumers and to maintain the reputation of the industry, pre-approvals must not be abolished until the TGA has demonstrated proficiency with their new compliance measures.

If this transition is not handled strategically then we will have a system which lacks both pre-publication advertising control and post-publication compliance. The reputations of the TGA and the industry will be damaged and consumers will not be properly protected.

Proposed Transition Arrangements

The TGA needs to demonstrate proficiency with the new compliance measure before pre-approvals are removed.

With the preceding points in mind, we suggest the following transition steps be adopted:

1. Advertising pre-approvals continue as they currently stand.
2. The TGA's new compliance measures are introduced.
3. The TGA develops proficiency with the new compliance measures in relation to all media not subject to pre-approval.
4. Once the TGA has demonstrated that the new measures are working, then pre-approvals can be removed and the TGA can apply the new compliance measures to all media.

This is the most logical way to maintain consumer protection as well as the reputations of the industry and the TGA.

A More Self-regulatory Approach?

There must be tangible benefits to obtaining pre-approval, for a self-regulatory approach to be successful.

Both the Expert Review Panel and the Government have called for a more self-regulatory approach to advertising pre-approvals.

The TGA can assist with this outcome by including design elements that encourage and promote pre-approvals.

For example, the new compliance measures could identify pre-approval as a mitigating factor when determining sanctions and penalties. Sponsors may then consider pre-approvals to be of value if they know that (should they subsequently be found in breach) they will be subject to reduced penalties.

For example, sponsors repeatedly found in breach of the advertising requirements could be compelled to have their advertising pre-approved for a specified period of time.

The TGA consultation paper suggests (at page 9) that any third party could establish a self-regulatory pre-approvals framework. However, it is difficult to imagine that advertisers would pay for a non-mandatory pre-approvals system that offered no benefits beyond "*a level of confidence in the advertisement's compliance with the regulatory framework*".

Sanctions and Penalties

The TGA are underutilising the mechanisms currently available. Effective use of the substantial existing powers needs to be the objective, rather than the introduction of additional burden and red tape.

In this consultation paper, the TGA repeats the assertions from the 2013 consultation that the issues surrounding advertising compliance will be fixed simply by increasing the range of available sanctions and by increasing the size of the available penalties.

The TGA provides no evidence that this is a likely outcome.

In this consultation paper, the TGA also assert that their call for more powers has widespread support. On page 11 of the consultation paper the TGA states that:

> *"Approximately 85% of respondents supported enhanced investigation and enforcement powers, rather than the status quo."*

This contradicts the TGA's own archive on the 2013 consultation, which states:

> *"Consultation on proposals aimed at amending the regulatory framework for advertising of therapeutic goods to the general public closed on 19 July 2013. A total of 1276 submissions were received by the TGA in response to the Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public. The vast majority were from complementary-therapy practitioners in response to proposal 6 of the consultation RIS. Most of these submissions supported the status quo in relation to this proposal."*[1] [emphasis added]

ASMI understands that this "vast majority" of 2013 submissions comprised over 1,000 responses solely addressing the issue of whether or not Naturopaths and Herbalists should continue to be considered to be healthcare professionals (i.e. proposal 6 from that consultation). It is therefore not mathematically possible for "approximately 85%" of respondents to have supported enhanced investigation and enforcement powers.

It is also worth noting that the ASMI submission of 19 July 2013 (on behalf of more than 50 ASMI members) only provided conditional support for increased sanctions and penalties.

[1] https://www.tga.gov.au/submissions-received-consultation-regulation-impact-statement-regulating-advertising-therapeutic-goods-general-public

The TGA does not have widespread support to increase investigation and enforcement powers.

Furthermore, the TGA already has a comprehensive suite of investigation and enforcement powers described in the *Therapeutic Goods Act* including the following:

- The Secretary may request information in relation to *advertising* and there are civil penalties for failing to comply (s8)
- There are civil penalties for *advertising* outside the ARTG indications (s22(5))
- It is a standard condition of registration that *advertising* has to be consistent with the indication(s) in the ARTG (s28(5))
- The Secretary may suspend the registration or listing of a product (s29D)
- The Secretary may cancel the registration or listing of a product for (among other things) its presentation, its *advertising* or a failure by the sponsor to provide information or documents (s30)
- There are criminal penalties for non-compliance with requirements (s30EC)
- There are civil penalties for non-compliance with requirements (s30ECA)
- The Secretary can compel a sponsor to provide information relating to (among other things) the safety, efficacy or *advertising* of any product (s31)
- There are fines and potential custodial sentences where a sponsor either fails to comply with a request, or provides false or misleading information in response to a TGA request for information (s31)
- There are civil penalties where a sponsor provides false or misleading information in response to a TGA request for information (s31AAA)
- There are fines for publishing non-approved or non-compliant *advertisements* (s42C)
- There are fines for a range of *advertising* offences (s42DL)
- There are fines for *advertising* that is not compliant with the TGAC (s42DM)
- There are fines for generic information that is not compliant with the TGAC (s42DP)
- The Regulations can make provisions for infringement notices (s 42YJ and s 42YK)
- Secretary can accept court-enforceable undertakings (s 42YL)

However, it is not enough to have the powers available; the TGA must have the expertise and the appetite to enforce those powers. Despite the range of existing powers, and despite the TGA's stated concerns about the advertising of therapeutic goods, there is a real absence of published TGA activity in this area, for example:

- The most recent compliance action relating to advertising was in December 2014[2].
- There have only been two enforceable undertakings published[3].
- The court actions undertaken by the TGA all relate to unapproved or counterfeit goods[4].

In any event, should the TGA's powers actually prove insufficient, the ACCC can always take carriage of the matter as they have recently done in relation to:

- Amber teething necklaces
- Sensaslim
- Homeopathic vaccinations
- Holographic wrist bands

[2] https://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date
[3] https://www.tga.gov.au/compliance-undertaking
[4] https://www.tga.gov.au/court-action

Sanction and Penalties – as Proposed

If sanctions and penalties do need to be increased they must be set transparently and according to existing Commonwealth Government principles.

It is unclear how the TGA arrived at the proposed penalties and it is unclear why those penalties are disproportionality large and inconsistent with relevant Commonwealth guidelines.

ASMI is concerned that the proposals appear to be based on an assumption that the problems with the current system can be fixed by simply increasing the size of the penalties. The TGA has provided no evidence to support such a course of action.

ASMI notes that the Commonwealth Attorney General has published "A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers"[5] and it is disappointing to see that the TGA consultation paper has made no reference at all to this guide.

While we have not made a comprehensive review of the Commonwealth Attorney General's guide, we do note the following obvious departure from recommended practice. While the Attorney General's guide indicates that "*The maximum penalty that can be imposed on a body corporate is 5 times higher than the penalty that can be imposed on a natural person*" [The "body corporate multiplier rule"], the TGA has applied a multiplier of 10 so that that the proposed penalties for body corporates are 10 times those proposed for individuals.

It is also worth noting that the proposed penalties are substantially greater than those already specified in the Australian Consumer Law (the ACL). Under the ACL, the maximum penalty for false or misleading conduct is $1,100,000 for corporations and $220,000 for individuals[6], whereas the TGA are proposing maximum penalties of $9,000,000 and $900,000 respectively (these for breaches of the advertising code under section 42DM).

We have no way of knowing how the TGA arrived at these figures, why they are so large or why the TGA chose to disregard relevant Commonwealth guides on the topic.

There should be no change to the sanctions and penalties until the TGA clearly articulates the reasoning behind the proposals.

<u>Complaints Handling</u>

The design elements of an appropriate complaints system are more important than the identity of the managing body. We want - one advertising code, one complaints panel and one process.

The consultation paper makes reference to the Commonwealth Ombudsman's "Better Practice Guide to Complaint Handling"[7]. This guide contains much which could be relevant to therapeutic goods advertising. However, because it chiefly concerns individual's complaints about government agencies, it does not properly cover off transparency of outcomes for the benefit of other parties. Care therefore needs to be taken to prevent too much reliance on this guide.

[5] https://www.ag.gov.au/Publications/Pages/GuidetoFramingCommonwealthOffencesInfringementNoticesandEnforcementPowers.aspx
[6] https://www.accc.gov.au/business/business-rights-protections/fines-penalties
[7] http://www.ombudsman.gov.au/__data/assets/pdf_file/0020/35615/Better-practice-guide-to-complaint-handling.pdf

As described previously by ASMI (and by other stakeholders) the manifold problems with the current complaints system include:

- Myriad interconnected processes.
- Complaints options are dictated by the advertising medium, the audience to whom the advertising was directed and the advertiser's industry association membership.
- The complaints processes are complex and do not effectively cover all media, all advertisers or all audiences.
- The CRP only makes recommendations and cannot impose sanctions.
- There is no formal appeal mechanism in relation to CRP determinations.
- TGA actions are neither timely nor transparent.

In our view, the design elements of an appropriate complaints system are more important than the identity of the managing body. In relation to non-prescription medicines, we want - one advertising code, one complaints panel and one process.

At this stage of the reforms, rather than focus on who should handle the complaints about therapeutic goods advertising, we have chosen to describe the attributes of our preferred system. In our view the preferred system for handling complaints about non-prescription therapeutic goods should:

- Have a single body to receive and *determine* all complaints, regardless of:
    - The advertising medium,
    - The advertiser's membership of an industry association, or,
    - The audience targeted (i.e. consumers and healthcare professionals, noting that while the Therapeutic Goods Act and the TGAC distinguish between the audiences, the ACL makes no such distinction)
- Have a single Advertising Code which applies to all advertisements
- Have published processes which include mandatory timeframes
    - Timeframes to be in weeks rather than months (so as to allow a proper balance between principles of fairness and efficiency)
    - Parties to complaints need to know at what stage proceedings are at and what the next steps are
- Publish all outcomes quickly and in sufficient detail to be educative
- Be designed with efficiency in mind
- Include screening and prioritising into:
    - Vexatious complaints (to be rejected promptly)
    - Obvious, objective, breaches (e.g. missing mandatory statements) (to be handled simply)
    - Serious breaches involving consumer safety (e.g. cancer treatments) (to be determined as a priority)
    - The remainder (to be determined in the order received)
- Only determine those issues raised by the complainant
- Include an option to combine multiple, separate, complaints about an advertisement or campaign where practical to do so
- Consider seasonality of campaigns (e.g. cold and flu products)(e.g. sunscreens) and provide timely responses accordingly
- Include effective sanctions, which:
    - Are enforceable
    - Are selected appropriately from a range of options
    - Include financial penalties which are of the appropriate size

- Be appropriately resourced
- Incorporate a multi-stakeholder Panel (which must include technical expertise, industry expertise, advertising/communications expertise, consumer representation and healthcare professional representation)
- Include an appeals process (with mandatory timeframes)
- Be funded by the TGA (with penalties being used to offset costs and to educate advertisers – provided measures can be put in place to prevent revenue raising)

If the body eventually selected to handle complaints can meet these requirements, then ASMI would support that body.

In order to illustrate the complexity of the current systems we have included the following attachments:

- Attachment 1 is a list of the current complaint options available in relation to therapeutic goods advertising. This list demonstrates the wide range of options available together with some of the key aspects (and limitations) of each option.
- Attachment 2 is a flow chart (prepared by ASMI in 2014) of some of the current complaint options. This chart demonstrates the complexity of the current arrangements.
- Attachment 3 is a draft flow chart (prepared by the TGA in 2014) of the CRP processes. This chart demonstrates the complexities of just one of the complaint options available.

Transparency

In order for stakeholders to have confidence in the processes, the TGA needs to improve transparency.

On page 20 of the consultation paper, the TGA notes that:

> *"At present, there is little transparency in how cases brought to the Complaints Resolution Panel progress through review."*

This is not true. The transparency of the CRP has not been called into question. It is common ground amongst stakeholders that it is the TGA who lack transparency. Whereas the CRP publish its procedures, acknowledge all complaints, keep the parties informed of progress and publish every determination on their website, the TGA are not anywhere near so transparent.

By way of Illustration, we note that:

- Since 2010, the TGA has claimed to have a process for handling complaints which fall outside the CRP's jurisdiction. Despite frequent requests to do so, the TGA has not provided or published details of the process.

- The 2014-2015 CRP annual report[8] shows that, during the report period, the CRP referred 185 complaints to the TGA without the Panel making a determination (since the TGA were better suited to deal with the complaint). During the same period, the CRP referred 39 defiant advertisers to the TGA (by way of a Recommendation to the Secretary). As far as we can tell, none of the resulting outcomes have been published by the TGA.

[8] http://www.tgacrp.com.au/wp-content/uploads/files/ComplaintsSummaryFor2014-2015.pdf

- The 2015-2016 CRP annual report[9] shows that, during the report period, the CRP referred 86 complaints to the TGA without the Panel making a determination (since the TGA were better suited to deal with the complaint). During the same period, the CRP referred 57 defiant advertisers to the TGA (by way of a Recommendation to the Secretary). As far as ASMI can tell, none of the resulting outcomes have been published by the TGA.

- So, in the past 2 years, the CRP referred 328 complaints to the TGA, and none of the outcomes have been published.

- In November 2015, the TGA caused to be published a Legislative Instrument (the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2015*[10]) the sole and specific purpose of which was to permit the TGA to publish outcomes of advertising complaints where the CRP had made a Recommendation to the Secretary. Despite 12 months elapsing since this publication was made, and despite the substantial number of complaints referred by the CRP, the TGA has not been able to publish a single outcome.

- The power to publish under the November 2015 Legislative Instrument was in addition to the pre-existing TGA power to publish determinations made by the TGA under Regulation 9 (i.e. Regulation 9 Orders). It is worth noting that the last Regulation 9 Order was published in December 2014.

- These powers are in addition to the power under s61(5A) of the *Therapeutic Goods Ac*t, which provides that the Secretary may release to the public therapeutic goods information relating to any decision or action taken under the Act or the regulations[11].

So, even with a range of powers and even with a substantial quantity of complaints materials referred from the CRP, the TGA has not seen fit to publish a single outcome in more than 24 months!

Accuracy of TGA Reporting?

When the TGA does report outcomes of compliance activities, the reporting should be accurate.

In 2013, there was an illuminating decision from the AAT on the nature of restricted representations (*Health World Limited and Minister for Health and Ageing* [2013] AATA 388[12]). While the advertisement was ultimately found to be in breach because of the absence of a qualifier regarding traditional Chinese use, the references to "cystitis" were found not to be in breach (since they were not restricted representations).

While the advertisement was found to have breached 4(1)(b) of the TGAC, there was no breach of 42DL(1)(c) of the *Therapeutic Goods Act* and there were no breaches of paragraphs 4(2)(a), 4(2)(b), 4(2)(c) or 5(2) of the TGAC.

So the advertisement was found to be largely compliant and the determination provides a detailed examination of what amounts to a restricted representation.

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[9] http://www.tgacrp.com.au/wp-content/uploads/files/CRP_complaints_summary_1-Jul-2015_to_30-Jun-2016.pdf
[10] https://www.legislation.gov.au/Details/F2015L01900.
[11] https://www.tga.gov.au/court-action
[12] http://www.austlii.edu.au/au/cases/cth/aat/2013/388.html

Despite this outcome (and despite the clear educative value of the determination), the TGA website coverage of the decision[13] simply states that:

> *"While the AAT found that the advertisement breached the Code (but not the Act) (see paragraph 83 of the decision), for the reasons set out in paragraphs 84 to 92 of the decision, the AAT decided not to order that the advertisement or relevant claims be withdrawn or to order a retraction of the advertisement. In those circumstances, the AAT decided to revoke the TGA's 27 April 2012 decision."*

It is open to speculation as to why the TGA have reported the outcome in such cursory manner.

Future of the TGAC, the TGACC and the CRP

The Therapeutic Goods Advertising Code needs to be updated and expanded.
Measures need to be put in place to ensure that the valuable input from the CRP and the TGACC continues to be available to the TGA.

The Therapeutic Goods Advertising Code:

- Needs to be updated to address the deficiencies already identified by stakeholders (such as ASMI and the TGACC)
- Needs to cover all non-prescription advertising (to both consumers and healthcare professionals)
- Should include a sunsetting clause so as to ensure that it is kept up to date.

The Complaints Resolution Panel can be disbanded only if the multi-stakeholder complaints handling body (described above) is in place.

The Therapeutic Goods Advertising Code Council currently provides useful advice to the TGA in relation to general advertising issues, amendments to the TGAC, applications for restricted representations and applications for review of advertising pre-approval decisions. With the removal of pre-approvals the role of the TGACC will be diminished, however the TGA would continue to benefit from receiving multi-stakeholder advice in relation to advertising matters and there should be a formal mechanism for the TGA to obtain that advice.

Industry Education

If the TGA provides clear regulatory guidelines and timely publication of regulatory decisions, then the need for a formal education program will be reduced.

The TGA already has an obligation to provide clear and unambiguous regulatory guidelines and this is especially important given the proposed increase in penalties.

Timely publication of sufficiently detailed regulatory decisions will be of great educative value to advertisers.

[13] https://www.tga.gov.au/advert-complaint/urinary-tract-support-health-world-limited-complaint-no-201012013-update-0

ASMI would support the TGA running an education program only so long as it was a "user-pays" system and not funded out of the TGA's revenue from sponsors. In a similar way to the current training sessions on the TGAC that are conducted by ASMI.

However, as discussed above, ASMI could also support the TGA using money from advertising fines and penalties to educate advertisers.

We are concerned to note that on page 23 of the consultation paper, the TGA states that:

> *"The simplest way to achieve this would be to align the requirements for advertising with the information contained within the ARTG for a particular product. This will require greater clarity within the Advertising Code and a disciplined approach to what claims are allowed to be included on the ARTG"*

It is well established that inclusion in the ARTG is a process concerned with product *indications* (i.e. the specific therapeutic uses of the product) and that advertising is a process concerned with product *claims* (i.e. what the advertiser says about the product). These two processes (i.e. inclusion in the ARTG and advertising) are separate and have separate requirements. The TGA's conflation of these terms is of concern for the following reasons:

- It suggests a misunderstanding of the terms on the part of the authors of the consultation paper, or,
- It signals an intention by the TGA to restrict advertising to indications only.

We would therefore request further explanation from the TGA on this point.

We note that sections 22 and 28 of the *Therapeutic Goods Act* already require an alignment between advertising and the indications included in the ARTG, so it is unclear what additional "clarity" and "discipline" the TGA are seeking to achieve.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

Attachment 1 – List of Current Advertising Complaint Options

For a complainant wishing to lodge a complaint about therapeutic goods advertising the following options are currently available:

Option	**Comments**
Formal request to cease publication	• Quick • Applies to all advertisers and all media
CRP	• Can only make recommendations • TGA and Panel Members bear the costs • Applies to some media
ASMI Complaints Panel	• Only applies to members • Unsuccessful party pays the costs • Applies to all media
Advertising Standards Bureau Process	• Decisions are complied with voluntarily but supported by publishers and broadcasters • Complainant pays the costs (where the complaint relates to claim substantiation) • Applies to all advertisers and all media
Approach TGA directly	• No published process • Unclear scope
Complaint under another industry Code	• Requires membership of another association • Scope would depend on the Code
Alternative Dispute Resolution (e.g. mediation)	• Confidential outcomes • Applies to all advertisers and all media
Interlocutory Injunction	• Costly • Applies to all advertisers and all media

Attachment 2 – ASMI Flow Chart of some of the Current Complaint Options

Attachment 3 – TGA DRAFT Flow Chart of the CRP Process