4 October 2018

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

Submitted online and by email to: advertising.consultation@tga.gov.au

Dear Sir / Madam,

Consultation: Proposed therapeutic goods advertising code guidance

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

The ASM position can be summarised as follows:

- The Guidelines are a premature distraction, the TGA must fix the new Code before working on the Guidelines.
- The new Code is not an improvement. It is not clear. It is not easy to follow. Complexity and ambiguity are recurring problems with the new Code and find no better incarnation than working out exactly which mandatories are required for an advertisement under sections 12(4)(d) to 12(4)(i).
- The new requirements for “Health Warnings” and “Prominence” must be removed.
- The TGA must adopt a reasonable, pragmatic, approach to transition (as they have with every other recent reform).

Disappointingly, many of the issues articulated in our previous submissions on the Draft Code (4 May 2018\(^1\)) and the Proposed Complaints processes (12 June 2018\(^2\)) remain unresolved.

In our view, the TGA’s priorities should be:

1. Correcting the issues with the new Code (i.e. fixing the errors, removing the unacceptable new requirements and using clear, objective, unambiguous language)
2. Implementing appropriate transition arrangements for advertising
3. Determining and publishing complaints outcomes in a timely and detailed fashion

Then, and only then, should the TGA look to develop Guidelines.

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\(^1\) ASMI notes that no submissions have been published in relation this consultation.
\(^2\) ASMI notes that no submissions have been published in relation this consultation.
Recommendations

The recommendations bolded below are considered to be critical and should be addressed as a matter of urgent priority.

**Recommendation 1:** The TGA’s first priority should be addressing the issues with TGAC 2018 (by correcting the errors, increasing clarity and removing the new (and unacceptable) requirements.

**Recommendation 2:** The TGA should acknowledge that new advertising requirements have been introduced (and that these new requirements were not as a result of the MMDR).

**Recommendation 3:** The TGA should identify those sections of the current TGAC that require clarification and removal of subjectivity.

**Recommendation 4:** The TGA should acknowledge that new advertising requirements have been introduced over and above the purported enhancements in relation to clarity and objectivity.

**Recommendation 5:** The TGA should explain why the new Regulatory Guidelines (ARGATG) were introduced without consultation.

**Recommendation 6:** The TGA should articulate exactly how the new Code is an improvement over the current Code (especially since a huge volume of new attendant material is now required to support the Code).

**Recommendation 7:** The numerous subjective and ambiguous terms in the new Code should be removed, replaced, revised or at the very least properly defined in the Code.

**Recommendation 8:** The TGA should correct the errors and omissions identified in the new Code.

**Recommendation 9:** The TGA should conduct a Regulation Impact Statement (RIS) so as to properly articulate the purported regulatory failure(s), to properly identify the parts of the current Code that required revision and to properly assess the regulatory solutions incorporated into the new Code (and their costs).

**Recommendation 10:** The TGA should have conducted adequate consultation on all the documents associated with advertising reform and should have taken special care to ensure that the Legislative Instruments were consulted upon in full prior to publication of the final versions.
Recommendation 11: The TGA should adopt a 2 year transition period consistent with a reasonable and pragmatic approach (with the clock to re-start with the publication of a clear Code).

Recommendation 12: The TGA should properly consider the impacts on industry (and other stakeholders) before finalising the transition arrangements.

Recommendation 13: The TGA should publicly acknowledge that new requirements have been introduced. The TGA should consult on the new requirements openly, conduct a Regulation Impact Statement and then identify any new requirements in the Guidelines (so as to assist experienced stakeholders in preparing materials compliant with the new Code).

Recommendation 14: The new requirements in relation to Health Warnings and Prominence should be removed. The new mandatory statement “THIS MEDICINE MAY NOT BE RIGHT FOR YOU” should be removed and replaced with a single mandatory statement (see Recommendation 16).

Recommendation 15: The impractical treatment of digital/social/emerging media in the new Code should be replaced with the following:

- Where the mandatory requirements can be presented prominently in the primary advertisement they should be included.
- When limited by physical space, duration or character count, it should be acceptable to place the mandatory requirements one click away from the primary advertisement (with the link prominently displayed).

Recommendation 16: There should only be three mandatory requirements for an advertisement:

1. A reference to the product name
2. A reference to the product use
3. A single mandatory statement (one for S3 medicines and a separate one for S2 and unscheduled medicines) (together with any category specific statement included in the Code)

Recommendation 17: The TGA should delay publishing the Guidelines until the issues with the new Code have been addressed and then continue to work with all stakeholders to develop, implement and maintain a useful set of Guidelines (together with processes for updating and maintaining them).
Recommendation 18: The new Code needs to be capable of standing on its own as the single most important document relating to advertising. Guidelines should only be used to describe the legal underpinning of the Code, the complaints procedures in place and the TGA’s processes for determining and publishing compliance outcomes. Guidelines should not be used to explain the requirements of the Code or the interpretation of the Code or to show examples of compliant or non-compliant behaviour.

Recommendation 19: The TGA must publish detailed outcomes promptly and accurately for all complaints.

Recommendation 20: 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 21: The Guidelines are a nice-to-have (non-essential) accompaniment to the essential Code and the complaint determinations.

Recommendation 22: The TGA should have prepared mocked-up advertisements to clarify and demonstrate the new requirements in the new Code. This would have been of some assistance in understanding the TGA’s view of the more ambiguous new requirements such as Health Warnings, Prominence, Scientific Representations, Public Health Campaigns, On-line Purchasing and Testimonials.
Priorities

In our view, the TGA should adopt the following priorities for addressing the current issues with the revised TGAC:

First, the TGA needs to get the new Code right:

- This is a legislative instrument, it has legal force, it has a formal change process
- The language is not clear, certain or objective (when that has been the stated intention of the reforms)
- There are new (and unacceptable) requirements (some of which were not been consulted on)
- The transition arrangements cannot work (and need to be redesigned and reset)

Second, the TGA needs to get the complaints system right:

- As per the Government response to the MMDR, the new system needs to represent “best-practice”
- The system needs to embody procedural fairness
- The system needs to include an appeals mechanism
- The system needs to include transparent, timely and detailed reporting of determinations so that all stakeholders can see how the TGA are interpreting the new Code

Then, the TGA can prepare the Guidelines, noting that:

- The Guidelines have no legal force
- The Guidelines can be updated “at will” by the TGA
- The Guidelines will need to be a “living document” and will be expected to change over time as the TGA and other stakeholders gain experience with the new Code

As the draft Guidelines properly state on page 9 of 76:

“In the event of any inconsistency between the Act, the Therapeutic Goods Regulations 1990 (the Regulations) or the Code and this guidance or other published policies, the Act, the Regulations and the Code prevail.”

Getting the Code right must therefore be the TGA’s first priority.

Recommendation 1: The TGA’s first priority should be addressing the issues with TGAC 2018 (by correcting the errors, increasing clarity and removing the new (and unacceptable) requirements.

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”3.

None of the recommendations are relevant to the TGAC.

There was nothing in any of the 58 MMDR recommendations about deficiencies with the TGAC (or necessary changes/additions to the TGAC) and there was nothing additional in the Government’s response to the MMDR recommendations.

There was a recommendation that advertising requirements be made consistent for medicines and medical devices (recommendation #54).

There was a recommendation that the TGA should adopt a single, best-practice, complaints process (recommendation #56).

There was a recommendation that “consideration be given” as to whether the TGA’s investigation and enforcement powers should be broadened (recommendation #57). The TGA took this to mean that investigation and enforcement powers should be increased. Then, in response those increased penalties and sanctions, the TGA felt obliged to re-write the TGAC to make it “clearer”.

Apart from the inconsistencies between medicines and devices, the Expert Panel made no specific observations about any shortcomings of the TGAC and there was no mandate for the TGA to re-write the TGAC or to introduce new advertising requirements.

ASMI is concerned that the changes embodied in TGAC 2018 have been introduced without justification, without scrutiny and without notice.

It is unclear why the TGA has made substantial changes to the TGAC.

It is unclear how the TGA has made these changes without conducting a Regulation Impact Statement (RIS).

It is unclear why the TGA has played down the changes and sought to disguise them as merely “clarification” of existing requirements when there are actually substantial increases in mandatory requirements.

**Recommendation 2: The TGA should acknowledge that new advertising requirements have been introduced (and that these new requirements were not as a result of the MMDR).**

### Background – Stated Objectives

Throughout the various consultations, the narrative has been about more detail, increasing objectivity, reducing subjectivity, increased clarity and specifying details.

It is worth noting that in all the various consultations, the TGA has not articulated which parts of the previous Code were in need of clarification or why they needed to be clarified.

It is reasonable to assume that many stakeholders would have taken the TGA at their word, assumed that no changes were being implemented, and decided not to participate in the consultation process. The quantity and quality of the submissions received by the TGA would thereby have been diminished.

In all the TGA consultation documents the narrative has been about clarity, objectivity, certainty, coping with emerging media etc., for example:
The 2017 TGAC consultation (Aug – Oct) identified the following elements:

- Remaining “relevant in a highly dynamic environment”
- “more detailed objective requirements”
- “minimising subjectivity”
- “clearer and more specific details”

The 2018 TGAC consultation (Mar – Apr) identified:

- “increased clarity and objectivity in order to support the new enforcement compliance powers”

Furthermore, the Explanatory Statement⁴ which accompanied the TGAC 2018 contains no mention of substantial changes, fails to identify any specific changes and indicates (on page 2) that:

[Remaking the TGAC supports MMDR recommendations 57 and 54 by] ... “providing increased clarity and objectivity”... and “improving consistency between the requirements for medicines and medical devices.”

[The 2018 TGAC includes amendments that] ... “Enhance and clarify previous provisions”, “address inconsistencies and previously identified regulatory issues” or “are of a minor and/or technical nature.”

However, the new Code is not clearer or more objective (see below) and does far more that clarify existing requirements (new requirements have been introduced – see below).

Despite the published statements to the contrary the new TGAC introduces a number of new requirements (some of which were never consulted on) as well as a huge increase in prominence of the new/existing mandatory requirements.

A list of all the new requirements in TGAC 2018 has been included in Attachment 1.

Recommendation 3: The TGA should identify those sections of the current TGAC that require clarification and removal of subjectivity.

Recommendation 4: The TGA should acknowledge that new advertising requirements have been introduced over and above the purported enhancements in relation to clarity and objectivity.

Compliance with the Stated Objectives

The stated objectives of increasing clarity and objectivity have not been achieved.

The language used in the new Code is subjective, confusing and ambiguous (see below).

The necessity for 76 pages of Guideline on the Code together the “Explanatory Statement” (page 7 of 76) and the numerous foreshadowed “fact sheets” (see page 7 of 76), the “information sheets” (page 14 of 76), the “further guidance” (page 17 of 76), the “further information” (page 72 of 76) plus the new Regulatory Guidelines⁵ (the ARGATG described on page 6 of 76) plus the

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foreshadowed online education modules all tend to suggest that the new Code is not clear, is not objective and definitely cannot “stand on its own”. Instead, the new Code requires an inordinate amount of explanation and clarification in order to work.

The sheer volume of the attendant materials to the 2018 TGAC is a certain indication that the new Code is not clear.

It is also worth noting that there has been no public consultation on the new Regulatory Guidelines (the ARGATG).

Recommendation 5: The TGA should explain why the new Regulatory Guidelines (ARGATG) were introduced without consultation.

Recommendation 6: The TGA should articulate exactly how the new Code is an improvement over the current Code (especially since a huge volume of new attendant material is now required to support the Code).

Subjective vs. Objective

As we have stated in our previous submissions, the new Code needs to be a sophisticated blend of principles and specific requirements. As we have said in the past, with the TGA’s “new enforcement and compliance powers” (i.e. increased sanctions and penalties) the draft Code needs to provide crystal clarity for stakeholders (with the TGA’s increased penalties and sanctions comes an obligation on the TGA to make it clear what is expected).

Stakeholders should expect the requirements to be clear, certain, objective and the structure of the Code to be logical and easy to follow. They should also expect the principles described in the new Code to provide sufficient flexibility and certainty so as to apply to any advertising situation and to be able to adapt to the rapidly changing media environment.

It is arguable that none of these expectations have been met.

The new Code is not easy to follow\(^6\), it includes numerous subjective terms, it is short on actual objective requirements, it consists of a re-arrangement of existing terms from the current Code, it includes complex - almost incomprehensible - definitions such as the one for “health warnings” and it does not even properly address existing digital and social media (as well as completely ignoring the possibility that new media might emerge).

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\(^6\) For example, the requirements in section 12 are especially difficult to determine. Section 12(4)(d) requires an advertisement to contain “the indications” (as opposed to a reference to the indications). Section 12(4)(e) requires a list of the ingredients (as opposed to just the active ingredients - or even the active/excipient ingredients declared on the label). Then sections 12(4)(g) and 12(4)(h) refer to the required statements in sections 13(3) and 13(2), however section 13(1) indicates that section 13 does not apply to advertisements covered under section 12. Also, the choice of options provided in section 12(4)(f) – in relation to health warnings - is made redundant by the requirement in section 12(4)(i) to include "any other mandatory warnings...". There are many other examples in the new Code which are difficult to follow, are not set out in a logical fashion and appear to duplicate and/or contradict other sections – this is just one. We look forward to seeing a TGA mock-up of an advertisement which complies with section 12 of the new Code.
By way of illustration, we note the following subjective/ambiguous/uncertain terms in the new Code. As we have said before, the problem is not so much working out what the dictionary definitions of the words are, the problem is that stakeholders need to know what interpretation or emphasis the TGA or the courts will apply to the terms when it comes to assessing compliance. For instance while the term “likely to mislead” is the subject of a large body of Australian case law, what are “unrealistic expectations about product performance” in the context of an advertisement for therapeutic goods? (This is why detailed publication of complaints outcomes is so important – see below)

Because of subjectivity or ambiguity, the following terms (at least) should be removed, replaced, revised or at the very least properly defined in the Code:

- **Page 2**
  - Easily read
  - Reasonable viewing distance
  - Clearly heard and understood
  - “Health Warning”

- **Page 3**
  - The same prominence as the most noticeable representation(s)
  - Easily read, reasonable viewing distance, clearly heard and understood
  - A visual advertisement not designed to be viewed all at once
  - As often as necessary to ensure that it is likely to be seen by a viewer
  - Public health campaign
  - Conducted, approved or funded

- **Page 4**
  - Ethical
  - Mislead or deceive (as opposed to being *likely* to mislead or deceive)
  - Unrealistic expectations about product performance
  - Supports informed health care choices
  - Likely impact
  - Reasonable person
  - Total presentation and context
  - Genuine news

- **Page 5**
  - Legible
  - Valid
  - Accurate
  - Substantiated
  - Truthful
  - Balanced
  - Not misleading or likely to mislead
  - Harmful
  - Ineffectual

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7 The definition provided is very difficult to work with and senior TGA staff have provided conflicting advice as to which RASML warnings (for example) meet the definition of a “Health Warning”
8 Confusingly, clauses (b) and (c) of the definition for “prominently displayed or communicated” are the same as clauses (a) and (b) of the definition for “displayed or communicated”
9 Although useful guidance will presumably be available from the case law relating to section 18 of the *Australian Consumer Law* (regarding “likely to mislead or deceive”)

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- Page 6
  - Support the safe and proper use
  - Presenting the goods in accordance with the directions ... for use
  - Exaggerating product efficacy or performance
  - Delaying necessary medical attention
  - Inappropriate or excessive use
  - Safe
  - Harmful consequences

- Page 7
  - Accurate description (repeated on pages 8, 10 and 11)
  - Trade name (repeated on pages 8, 10 and 11)

- Page 9
  - Written advertisements that consist of 300 characters or less\(^{10}\) (and on page 12)
  - Close proximity

- Page 13
  - Scientific or clinical claim
  - Scientific terminology
  - Appropriate
  - Clearly communicated
  - Readily understood
  - Scientific representation
  - Consistent with the body of scientific evidence
  - Citation to scientific literature (explicit or implied)
  - Research results
  - Researcher
  - Financial sponsor

- Page 14
  - Verified
  - Typical
  - Involved with the production, sale or supply
  - Relative
  - Associate

- Page 15
  - Relevant (and current) public health campaign

- Page 16
  - Medically accepted
  - Requires diagnosis or treatment or supervision
  - Suitably qualified
  - Medically diagnosed
  - Medically accepted
  - Suitable for self-treatment and management
  - Requires medical interpretation or follow up

\(^{10}\) Especially if that limit is self-imposed.
• Page 17
  • Likely to take advantage
  • Vulnerability of consumers
  • Likely to result
  • Timely professional medical advice
  • Negative health consequences
  • Likely (alone, through repetition or together with other references)
  • Negative impact on public health

We would oppose these essential terms being defined in the Guidelines. Our concerns about the utility of a Guideline document are described in detail below. Of relevance here, the TGA could change the Guideline definitions “at will” (and so create non-compliance), the TGA could delay updating the definitions (and so create ambiguity and uncertainty for stakeholders), the TGA staff could rigidly apply the definitions (or choose not to apply them at all) as they liked and still be compliant with the Code. The Code is the legislative instrument and so needs to be the “single source of truth” when it comes to defining key concepts and essential terms.

Apart from the wording of the mandatory statements themselves, there is very little in the way of clear, unambiguous, objective requirements in the new Code.

Recommendation 7: The numerous subjective and ambiguous terms in the new Code should be removed, replaced, revised or at the very least properly defined in the Code.

Errors and omissions from the new Code

A list of all the new requirements in TGAC 2018 has been included in Attachment 1.

While many of the new requirements appear to be deliberate, the following appear to be inadvertent errors or omissions that have been introduced during re-drafting:

• Section 11(1)(c) – the use of “or” in place of the previous “and/or” renders the section meaningless
• Section 12(4)(d) – the requirement to include “the indications” as opposed to “a reference to the indications” adds unnecessary complexity and adds material that will not be available to in-person purchasers
• Section 12(4)(e) – the requirement to include “a list of the ingredients” as opposed to “the active ingredients” adds unnecessary complexity and adds material that will not be available to in-person purchasers
• Section 13(1)(c) – the use of “or” in place of the previous “and/or” renders the section meaningless
• Section 14(1)(c) – the use of “or” in place of the previous “and/or” renders the section meaningless
• Section 28 - required warnings which contain restricted representations are still not covered by a blanket TGA approval (this is especially problematic given the new requirements in relation to Health Warnings)
• It is no longer a requirement to comply with the laws of the Commonwealth, States and Territories (previously required under section 4(1)(a)), this creates a potential limitation on pre-approvals under Regulation 5G(1)(a) and may create other compliance issues.
Recommendation 8: The TGA should correct the errors and omissions identified in the new Code.

Background – Absence of a Regulation Impact Statement (RIS)

We understand that the MMDR reforms have not required Regulation Impact Statements because they are based on the outcomes of an Expert Review.

However, as noted above, there was no specific MMDR recommendation to update the TGAC and, as noted below, there are numerous new requirements being introduced in the new Code under the guise of increased detail and clarity.

In our view, the new Code (and especially the new requirements) should have been subject to a RIS. This would have meant that the purported regulatory failure(s) would have been identified, and the merits of the regulatory solution(s) would have been subjected to scrutiny.

It is worth noting that there will be increased costs associated with:

- Developing and distributing materials that comply with TGAC 2018.
- Collecting and destroying materials that comply with TGAC 2015 and which cannot comply with TGAC 2018 (because it is not possible to construct advertising materials which simultaneously complies with both Codes) (and because there is effectively no transition period from one Code to the other)
- Re-designing advertisements to accommodate the increased space taken up by all the new mandatory requirements. Meaning that greater advertising space will have to be booked and paid for. While it was possible to prepare a small print ad (e.g. quarter page) under TGAC 2015, small print ads appear to be a thing of the past with all the new mandatory requirements necessary (see, for example, the draft print copy included in Attachment 3).
- The training of staff (and agents) on the new Code and the new requirements.

Recommendation 9: The TGA should conduct a Regulation Impact Statement (RIS) so as to properly articulate the purported regulatory failure(s), to properly identify the parts of the current Code that required revision and to properly assess the regulatory solutions incorporated into the new Code (and their costs).

Consultation processes and timings

Earlier this year (between 29 March and 27 April) the TGA conducted a public consultation on a draft TGAC. This four week period included school holidays and Easter (and so limited the time that stakeholders had to review the draft and provide comment). As outlined above, the TGAC is a Legislative Instrument. Because the TGAC has legal force and a formal change process, ASMI considers that an abridged four week consultation period was inadequate.

In contrast, stakeholders have been given eight weeks (between 9 August and 4 October) to comment on the Guidelines which will accompany the new TGAC. As outlined above, these Guidelines are essentially a TGA internal document that has no legal force and can be updated “at will”. ASMI considers that if the TGA can permit eight weeks to consult on a “living document” like the Guidelines then at least that amount of time should be permitted in relation to the Code.
This is especially troubling when the new Code introduced on 1 July included new requirements not previously consulted on (see below).

To add further to our concerns about appropriate consultation periods, we note that the new Regulatory Guidelines (ARGATG) were introduced in full on 1 July 2018 with no prior consultation.

Recommendation 10: The TGA should have conducted adequate consultation on all the documents associated with advertising reform and should have taken special care to ensure that the Legislative Instruments were consulted upon in full prior to publication of the final versions.

Transition Arrangements - Generally

The proposed “transition” arrangements are not practical and not reasonable.

They are also not accurately described on page 9 of 76 of the draft Guidelines.

There is effectively no transition period between the current Code and the new Code.

The current Code will remain in force until the new Code takes effect on 1 January 2019.

So what this means is that between now and midnight on 31 December advertisers, broadcasters, publishers and sponsors can only produce and use materials which must comply with the current Code.

Immediately after midnight on 31 December all advertising will have to comply with the new Code and at this time all previous advertising will be in breach (because even ignoring the various new requirements in the new Code, the mandatory statements will be different – and the new Code does not contain a “words to the effect of” clause like the current Code).

Prior to midnight on 31 December, advertisers, broadcasters, publishers and sponsors cannot produce or use new advertising in anticipation of the new Code, because:

- The new requirements are still unclear (1 January is now just over 3 months away and the wording of the new Code is still uncertain, the TGA still have not responded to calls for clarity – especially in relation to “Health Warnings” and “Prominence” - and the TGA’s proposed solution – these Guidelines – are still in draft form)
- Even if they do know, any new materials they produce won’t comply with the current Code.

After midnight on 31 December, advertisers, broadcasters, publishers and sponsors cannot use advertising that complied with the current Code, because:

- The current Code will no longer be in force, and
- The new Code will have new requirements.

Overnight all advertising will have to change. Sponsors will have to review their entire advertising portfolio and revise every current piece to ensure compliance with the new Code. Every piece of point-of-sale material will have to be recalled, destroyed and replaced. Every web-page will have to be updated. Every billboard, bus siding, taxi back and train advertisement will have to be
reviewed. Every print advertisement will have to be reviewed and the lead times for every publication will have to be factored into the preparation of materials variously complying with the current and the new Code. Industry cannot be expected to fund and manage such a monumental task!

Adding complexity to this is the 2 year approval period granted to advertisements which are subject to mandatory pre-approval. As with advertisers, broadcasters, publishers and sponsors, the Advertising Services Managers (ASMs) must apply the current Code up until midnight on 31 December and must apply the new Code immediately after. We understand that the 2 year approval period will be honoured by the TGA, however this will lead to discrepancies between advertising based on the medium employed (with multi-media campaigns being disjointed with the pre-approved advertising including the current mandatory statements and the self-assessed materials including the new mandatory statements. This will increase costs if the pre-approved materials need to be updated and approved all over again. This is a very challenging scenario for the internal compliance requirements of our members and represents a high degree of risk.

In many other areas of TGA reform (and even for ongoing periodic updates), there are reasonable transition periods in place. This is necessary to provide certainty for the regulator, the regulated industry and affected stakeholders. This is necessary to minimise the financial and business impact of regulatory change. By way of example, reasonable, pragmatic, transition arrangements are already in place for:

- The revised labelling requirements under TGO92 (4 years) *(affecting large numbers of products)*
- Updates to TGA fees and charges (12 months plus a signalling period beforehand)
- Scheduling (with a minimum 10 month period between the public notice of the proposed change and the effective date of any resulting change) *(affecting only a small number of products at a time)*
- Revised warning statements per RASML (18 months) *(affecting only a small number of products at a time)*

It is worth noting that changes to the Permitted Ingredients list (which is a Legislative Instrument similar to the draft Code) were initially imposed without a transition period and that a range of practical problems have thereby resulted (with the TGA now proposing to introduce a range of transition periods up to 18 months) *(affecting only a small number of products at a time)*.

By way of contrast, the TGA has proposed a zero period of transition for advertising, even though *every single non-prescription medicine and device will be affected*!

As we have noted in previous submissions, the issues surrounding therapeutic goods advertising are long-standing, with some issues remaining unresolved after more than 10 years¹¹. We also note the TGA’s stated intent to simply improve the clarity and certainty of the Code consequent to their new investigation and enforcement powers. In this context, the TGA’s rush to introduce the new Code with a “hard” transition of 1 January 2019 is difficult to understand or justify.

The TGA’s approach to transition is not acceptable and we repeat our call for the TGA to adopt a 2 year transition period consistent with a reasonable and pragmatic approach.

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¹¹ For example, ASMI is aware of correspondence going back as far as 2007 to the TGA from the Therapeutic Gods Advertising Code Council on the specific shortcomings of the Code.
Recommendation 11: The TGA should adopt a 2 year transition period consistent with a reasonable and pragmatic approach (with the clock to re-start with the publication of a clear Code).

Transition Arrangements – Specifically

For above-the-line materials the 2 year approval period will align with the typical usage of the advertisement. Transition issues should not arise – providing that the advertisement can be approved this year and providing that the advertisement does not need revision early in 2019.

For below-the-line materials (i.e. those not subject to mandatory pre-approval) the proposed transition arrangements are unacceptable.

With the assistance of the ASMI membership we have been able to compile the following specific information in relation to the development and potential replacement of various different types of advertising. Noting that there will be variability between members depending on the size of the organisation, its internal compliance processes and the resources available.

We strongly recommend that the TGA take the following information into account when finalising the transition arrangements.

In approaching the transition from one Code to another, members will need do the following:

1. Await finalisation of the new Code and clarification of all the new and ambiguous requirements
2. Review and become familiar with the new Code requirements
3. Train all staff (marketing and regulatory) on the new Code
4. Train external agencies
5. Review and update all advertising materials
6. Produce new advertising materials
7. Identify, locate, collect and destroy old advertising materials
8. Replace with new advertising materials
9. Budget accordingly
10. Allocate resources accordingly

Production steps

Development of new materials either from scratch or as an update typically requires:

- Work 6 -12 months ahead with planning/ execution
- Internal planning and alignment (for existing items this would involve an audit of all the pieces to be updated and the changes required)
- Briefing external creative agency
- Internal review of concepts from agency (this could take 2 to 3 rounds of back and forth with the agency for changes and feedback)
- Development of final advertising materials by agency (this could take from 2 weeks to 2 months depending on the medium)
- Internal review and sign off (marketing & regulatory) (this could take 2 -3 rounds of back and forth with the agency for changes and feedback)
• Printing (or production) of items
• Delivery and storage at storage facility
• Despatch to sales field team or merchandise team storage sheds, or
  o [Despatch to media (some partners work months in advance)]
• Sales / merchandise field team to execute in stores (they work to an 8 week call cycle and
could be responsible for servicing up to 2500 pharmacies), or
  o [Advertising in publication]

**Production Timings**

For below-the-line materials (e.g. POS, Catalogues, websites, digital, etc)

Some estimated total lead times from brief to in-store / in-use include:
  * 26 – 52 weeks for brand new websites
  * 20 - 26 weeks for completely new creatives
  * 18 weeks for a simple localisation of a global piece
  * 12 weeks for new digital assets
  * 10 - 12 weeks for e-commerce / digital
  * 8 -12 weeks for complex website changes
  * 8 -12 weeks for small POS (e.g. wobblers, display units etc.)
  * 4 – 10 weeks for changes to existing websites
  * 4 – 6 weeks for existing digital assets
  * 3 – 4 weeks for simple website changes

Some estimated production times (once copy is signed off) include:
  * Up to 26 weeks to come in from overseas
  * 7 - 12 weeks from sign-off to availability in Pack Centre (local production)
  * 12 weeks for catalogues
  * 11 weeks from sign-off to availability in Pack Centre (overseas production)
  * 3 – 4 weeks for locally produced, simple, items

Some typical times in the market include:
  * Up to 2 years for plastic units
  * 12 months for cardboard POS
  * The length of a season or up to 12 months for seasonal products
  * 3 weeks to a year for general pieces
  * 2 – 4 months for POS
  * As long as the SKU is listed (for e-commerce / digital)
  * Websites reviewed at least annually
  * Websites get updated every 6 to 12 months
Added complications

- If a video advertisement is intended for free-to-air TV and is approved in 2018 it will be assessed for compliance against the current Code throughout the full 2 year approval period (i.e. up until 2020). The same advertisement may also be placed by the advertiser on their website in 2018 or aired on pay TV in 2018. However, it is unclear what Code should apply to these latter placings on 1 January 2019. On the one hand they are advertisements that are identical to an already approved one. On the other hand would they be expected to comply with the new Code as of 1 January 2009 since they are not appearing in specified media?
- Key aspects of the new Code remain unclear (e.g. Health Warnings) (e.g. the new “prominence” requirements) and compliant advertising cannot be produced until clarity is achieved
- Merchandisers / temp field force don’t usually work over December and January
- Retailers don’t usually allow advertising material changeovers during December and January
- Advertisers are generally working 6 months ahead
- There will be added complexity for retailers as they help (or permit) replacing the materials
- There will be wastage & disposal of materials
- There will be impacts on retailers, distributors and advertisers
• Print and video can’t be recalled – but new creatives can be provided for future bookings
• Digital own channels can be removed and updated with new materials. Influencer or those items picked up by third parties and republished or shared by others are often untraceable and therefore can’t be recalled.

Some quotes from affected members:
New Requirements in the TGAC

Despite TGA comments to the contrary (see above), the new Code includes a great number of new requirements. These new requirements are described in Attachment 1.

These new requirements should have been the subject of public consultation and should have been assessed through a Regulation Impact Statement (RIS).

Some of these new requirements were not present in the draft Code and appeared for the first time when TGAC 2018 was published in its final form.

The TAG admitting that there have been changes and identifying the changes in the Guidelines will actually help advertisers comply with the new requirements.

Because of their substantial impact on advertising the following new requirements need to be removed pending an open and transparent consultation on their need and their impact:

- The definition of “Health Warnings” and the requirement to reproduce them in advertising
- The Statement “THIS MEDICINE MAY NOT BE RIGHT FOR YOU” and its likely interpretation by consumers that OTC medicines are not safe
- The new definition of “prominently displayed”
- The required compliance with “Public Health Campaigns”
- The new requirements in relation to “Scientific Representations”
- The new requirements in relation to “Endorsements”
- The new requirements in relation to “Testimonials”
- The new definition of “Restricted Representations”

We are especially concerned because the following new requirements were not included in the draft TGAC consulted upon (and appeared, fully formed, for the first time in the TGAC 2018 Legislative Instrument). These requirements were not consulted upon:

- Health Warnings
- The Statement “THIS MEDICINE MAY NOT BE RIGHT FOR YOU”
- The requirement for “prominent” elements to be the “most noticeable” representations

Recommendation 13: The TGA should publicly acknowledge that new requirements have been introduced. The TGA should consult on the new requirements openly, conduct a Regulation Impact Statement and then identify any new requirements in the Guidelines (so as to assist experienced stakeholders in preparing materials compliant with the new Code)
Health Warnings

ASMI objects to this new requirement for a number of reasons, principally that:

- It was not consulted upon.
- There has been no regulatory failure identified which would justify such a radical change to advertising requirements.
- It confuses the different roles of labelling and advertising.
- The new requirement will result in information in advertisements being different to the information on product labels since the Health Warnings will be some sub-set of the various statements from RASML, the Poisons Standard, 26BB, the permitted indications list, etc. that are already required to appear on the label (i.e. there will be more warnings on the label than appear in the advertisement)
- Different sponsors will make different decisions based on the ambiguous and subjective definition of a Health Warning and this will result in different advertisements for similar products having different warnings (i.e. consumers may incorrectly assume that the products with fewer warnings may be “safer” even though they pose the same risk)

In addition the definition of a “Health Warning” itself is complex, ambiguous, subjective and almost incomprehensible. By way of illustration:

- On 17 July ASMI wrote to the TGA seeking advice as to the interpretation of the definition (given its wording) and seeking advice as to which of the various RASML statements for Dextromethorphan, Ibuprofen, Paracetamol and Phenylephrine (some common OTC ingredients) met the definition of a Health Warning (so as to better understand the TGA’s interpretation of the requirement)
- On 6 August ASMI received written advice from the TGA that nine of the eleven RASML warnings for Ibuprofen met the definition (and would therefore have to be included in advertising)
- On 21 September ASMI received verbal advice from the TGA that the earlier advice regarding Ibuprofen was not correct and that far fewer than the nine RASML warnings actually met the definition (although no specific advice at to which ones did meet the definition was provided)
- As at the time of drafting this response ASMI has still not received any further clarification about the Ibuprofen statements from the TGA
- As at the time of drafting this response ASMI has still not received any advice at all regarding the RASML warnings for Dextromethorphan, Paracetamol or Phenylephrine from the TGA

If the TGA cannot identify what a Health Warning is, how are advertisers meant to do so?

In our view, it is unreasonable to expect advertisers to have to obtain this sort of detailed regulatory advice from the TGA prior to advertising.

It is worth noting that the Guidelines include the actual definition from the new Code (see page 61 of 76) as well as the following bland statement on pages 24 and 29 (which arguably applies to every therapeutic good):

*Some therapeutic goods, particularly certain medicines, may cause unintended side effects or adverse events even when taken or used according to the directions or instructions for use.*
At no point in the Guidelines is there any examination of the definition or any attempt to explain or illustrate it.

**The Statement “THIS MEDICINE MAY NOT BE RIGHT FOR YOU”**

ASMI objects to this new requirement for a number of reasons, principally that:

- It was not consulted upon
- It has arisen from an unknown source
- It has not been tested with consumers
- It has the potential to create fear and distress in consumers
- It has the potential to undermine confidence in registered medicines
- It has the potential to contradict the advertisement itself
- For the great majority of consumers in the target audience(s) the medicine may, in fact, be right for them

**The requirement for “prominent” elements to be the “most noticeable” representations**

ASMI objects to this new requirement for a number of reasons, principally that:

- The definition itself is ambiguous, unclear, and subjective
- There has been no regulatory failure identified which would justify such a radical change to advertising requirements
- The effect will be for the warning statements and mandatory inclusions to be the most prominent elements in the advertisement (i.e. more prominent than the name of the product or what it does)

**Recommendation 14:** The new requirements in relation to Health Warnings and Prominence should be removed. The new mandatory statement “THIS MEDICINE MAY NOT BE RIGHT FOR YOU” should be removed and replaced with a single mandatory statement (see Recommendation 16).

**Digital, Social and emerging media**

The current Code has remained essentially unchanged since 2007 and does not properly accommodate the wide range of media currently in use.

Even if the new Code were to accommodate all current media, it would quickly become obsolete if it fails to accommodate emerging media.

It is essential that the new Code acknowledges the wide range of media currently available and provides a pragmatic way of dealing with compliance (especially in relation to mandatory requirements).

As the TGA noted at page 7 of their 2017 consultation document on the TGAC:
“... the methods and media used for promotion have expanded beyond the traditional mainstream media ... The updated Code ... will need to remain relevant in this highly dynamic environment (in particular evolving online media platforms) ...”

Instead of providing a useful examination of current media, the new Code includes an extremely specific and hence problematic proposal to exclude only some mandatory requirements for “written advertisements” consisting of 300 characters or less in sections 11(5) and 13(4) (this is up from the 256 character limit that was included in the draft Code).

In summary, the TGA position appears to be that all advertisements must include an unreasonable amount of mandatory information in the same place regardless of the medium employed and if that doesn’t fit, then you cannot use that medium!

Interestingly, the loose drafting of sections 11(5) and 13(4) appears to mean that if a sponsor chose to limit their print advertisement to 299 characters they could take advantage of the exclusion offered in the two sections.

We would like to propose the following alternative:

- The current Code allows the modification of the mandatory statements where the medium requires it (e.g. the truncated requirements for 15 second radio advertisements in section 6(3)(c) and section 7(1)(c)).
- It is therefore reasonable to assume that the TGAC is not intended to prohibit the use of any specific media (rather to ensure responsible and appropriate advertising).
- Modification of the mandatory requirements to suit the limitations of the medium should be retained in the new Code.
- Consistent with this approach, where an advertisement consists of 2 (or more) parts with a call to action linking them (as many digital/social pieces do), then it is reasonable to treat the parts together as a single ad for the purposes of compliance.
- Where the mandatory requirements can be presented prominently in the primary advertisement they should be included.
- When limited by physical space, duration or character count, it should be acceptable to place the mandatory requirements one click away from the primary advertisement (with the link prominently displayed).

In this way many of the more complicated aspects of current digital and social media compliance would be addressed, for example:

- Paid search engine advertising
- Organic search engine outputs
- Character limits in Twitter
- Instagram promotions

In this way, also consumers would have access to the information they need and the adaptability of the Code would be increased.
Recommendation 15: The impractical treatment of digital/social/emerging media in the new Code should be replaced with the following:

- Where the mandatory requirements can be presented prominently in the primary advertisement they should be included.
- When limited by physical space, duration or character count, it should be acceptable to place the mandatory requirements one click away from the primary advertisement (with the link prominently displayed).

Role of advertising

In the same way that there is a single, undiluted, message regarding S3 medicines (e.g. the pharmacist must decide) there should be a single, undiluted, message regarding other non-prescription medicines (e.g. the label is the most important source of information, read it before purchase and read it before use).

The new Code misunderstands the interplay between advertising and labelling. The excessive amount of mandatory information included in the new Code is an attempt to use advertising to do more than it can reasonably be expected to do (e.g. to provide Quality Use of Medicines education, to arbitrarily list warnings and precautions, to arbitrarily include ingredient advice, to include unnecessary details about references, testimonials and endorsements, etc.).

Based on our (current) understanding of the new Code, we have prepared a mocked-up print advertisement for a fictional ibuprofen product and included it as Attachment 3.

This is too much information to include in every advertisement.

This is too much to reasonably expect a consumer to be able to retain (or act upon).

Some of these requirements (particularly those to do with Health Warnings and ingredient disclosures) could result in information in the advertisement that is different to the information on the product label. This will create confusion and will not assist consumers to appropriately select and use their non-prescription therapeutic goods.

Advertising plays a different role to labelling. Advertising will vary depending on the audience, the medium and the product type. Advertising creates awareness but is ephemeral (it will only be noticed or paid attention to if it is relevant). Labelling assists product selection and product use.

ASMI supports the need for consumers to have the relevant information about non-prescription therapeutic goods available to them at the appropriate time to enable them to make the right (informed) decision:

- For advertising, this is the name of the product and what it does.
- At the point of purchase, this is information about ingredients, warnings, dosing, where to go for further information etc. (i.e. the product label)
- At the point of use, this is information about ingredients, warnings, dosing. Where to go for further information etc. (i.e. the product label)
Advertisements are time/space limited and the key take out message(s) need to be imparted/received/retained – not diluted or obscured due to too much information (and no matter how much information you squeeze into an advertisement, it will always be less information than is already on the label).

In our view, the interplay between advertising and labelling can be summarised as follows:

- There are three main touch points that need to be considered
  - Firstly, awareness about the product (this is what advertising is for)
    - If relevant to the consumer, they will notice the ad
    - If not relevant, the ad will not resonate and will not be noticed
    - The ad is a call to action for those to whom it is relevant
    - Realistically you can only expect an ad to impart a small number of key messages
    - Realistically you can only expect a consumer to retain a small number of key messages
  - Secondly, product selection (this is what the label is for – together with professional advice if needed)
    - For S3 medicines the pharmacist has to be involved
    - For S2 medicines advice is available if necessary
    - For unscheduled medicines the TGA has already decided that the product can be safely sold in the absence of professional advice
    - There has been a lot of work done with the new labelling order so that all the important and relevant information is already on the label
  - Thirdly, product use (this is what the label is for)
    - At the time of use all the relevant information needs to be available on the label

With all of this in mind, we therefore repeat our previous proposal that advertisements should only have to include:

- A reference to the product name
- A reference to the product use
- A single mandatory statement, either:
  - For S3 medicines ("Ask your pharmacist – they must decide if this product is right for you" – or words to the same effect), or
  - For S2 and unscheduled medicines ("Read the label – to decide if this product is right for you" – or words to the same effect) (together with any category specific statement included in the Code)

In the same way that that there is a single, undiluted, message regarding S3 medicines (e.g. the pharmacist must decide) there should be a single, undiluted, message regarding other non-prescription medicines (e.g. the label is the most important source of information, read it before purchase and read it before use).

Obviously a different approach will be necessary where the label is not available (e.g. for on-line purchases) and in that case we suggest that advertisers be required to reproduce all the label information on the website (or other medium).

To illustrate the benefits of a single, undiluted, message over the excessive use of mandatory statements we have included the following two attachments (which were both previously provided to the TGA):
• Attachment 4 is a mocked-up print advertisement for a fictitious product (Coughlex Cold & Flu Relief + Cough) prepared to the March 2018\textsuperscript{12} draft Code.

• Attachment 5 is an ASMI proposal for the same print ad and the same fictitious product.

<table>
<thead>
<tr>
<th>Recommendation 16: There should only be three mandatory requirements for an advertisement:</th>
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<tbody>
<tr>
<td>4. A reference to the product name</td>
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<tr>
<td>5. A reference to the product use</td>
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<tr>
<td>6. A single mandatory statement (one for S3 medicines and a separate one for S2 and unscheduled medicines) (together with any category specific statement included in the Code)</td>
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**Role of the Guidelines**

The Guidelines should help stakeholders to navigate the Code (e.g. through checklists) (e.g. through stepwise approaches to ensuring compliance) (e.g. through a logical layout) (e.g. with the inclusion of an index).

The Guidelines should help experienced stakeholders identify what is new (so as to make transition easier).

ASMI will not support any Guideline that purports to explain the requirements of the Code or the interpretation of the Code or that purports to show examples of compliant and non-compliant behaviour.

As described above, as described in previous ASMI submissions, as acknowledged on the TGA website and as acknowledged in the draft Guidelines, the new Code will be the single most important document in terms of therapeutic goods advertising. The increase in sanctions and penalties underscores the document's importance. As indicated above (and in previous submissions), the interpretation of the new terms and new requirements in the new Code should be defined in the Code itself and not in the Guidelines.

There are numerous concerns with the draft Guidelines themselves. These concerns are described in the “tracked” copy included as Attachment 2, some are also discussed below.

Despite this, ASMI remains committed to working with the TGA and other stakeholders to develop, implement and maintain an up-to-date and useful set of guidelines.

To assist with this, the TGA needs to develop, publish and adopt processes for regular updates to the guidelines and for updates necessary to correct errors.

| Recommendation 17: The TGA should delay publishing the Guidelines until the issues with the new Code have been addressed and then continue to work with all stakeholders to develop, implement and maintain a useful set of Guidelines (together with processes for updating and maintaining them). |

\textsuperscript{12}We have kept this earlier mock-up because it was too difficult to construct one with the new Code.
As we have stated in previous submissions, ASMI would support guidelines only to the extent that they described the legal underpinning of the Code, the complaints procedures in place and the TGA’s processes for determining and publishing compliance outcomes.

ASMI would not support any guidelines that purport to explain the requirements of the Code or the interpretation of the Code or that purport to show examples of compliant and non-compliant behaviour, for the following reasons:

1. The existence of such a guideline has led to lazy drafting of the Code. The drafters have been tempted leave the complex matters “to be explained in the guideline” (as has happened with the Labelling Order TGO92).
2. TGA staff will treat the guidelines as law and advertisers would be prevented from some activities simply because the guidelines did not appear to allow them (as has also happened 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. Or the TGA may be slow to update the guidelines leaving stakeholders uncertain as to the requirements or the TGA position (as has happened 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.
6. Lastly, it is difficult to see how useful guidelines could be drafted when the TGA’s own “customer service standards” place so many limits on the advice that can be given.

For example, the TGA’s customer service standards indicate that the TGA cannot:

- “give definitive advice on specific issues relating to your particular circumstance”
- “offer interpretation of the legislation and its applicability to your circumstance”
- “provide detailed responses”
- “provide advice regarding your business decisions”
- “confirm that a business decision is appropriate and compliant with requirements”

In addition, the TGA’s customer service standards also advises that the TGA’s responses contain “general information” given “without prejudice” and are “not binding on the TGA”.

Recommendation 18: The new Code needs to be capable of standing on its own as the single most important document relating to advertising. Guidelines should only be used to describe the legal underpinning of the Code, the complaints procedures in place and the TGA’s processes for determining and publishing compliance outcomes. Guidelines should not be used to explain the requirements of the Code or the interpretation of the Code or to show examples of compliant or non-compliant behaviour.

Role of Published Determinations

As we have stated previously (and as other stakeholders have publicly agreed) the published complaints determinations provide an essential role in understanding and complying with the requirements of the TGAC. The actual complaint determinations will be of more value in assisting advertisers than the TGA’s Guidelines, the TGA’s Regulatory Guidelines, the TGA’s fact sheets or the TGA’s education modules.

The TGA must commit to publishing complaints determinations accurately, promptly and in sufficient detail to fulfil this essential role.

It is worth noting that the only reason the Guidelines can reference previous CRP determinations is because the CRP actually published them and published them in detail. The only reason that stakeholders have been able to rely on previous CRP determinations is because the CRP actually published them and published them in detail.

The TGA’s new complaints processes were launched in 1 July 2018. It is disappointing to see that although the TGA has so far determined 286 complaints only 7 have included “outcomes” (as at 28 September 2018). None of the 7 outcomes include a copy of the offending advertisement, none include the TGA’s reasoning and none include any link between the advertisement’s elements and the (purported) breaches.

It is also concerning to note that most of the complaints appear to have been determined in only a week to ten days (although the only way to be sure is to access each complaint individually to obtain the “date received” – for some reason the public register includes both the “outcome date” and the “date closed” which in most instances appears to be the same date).

It is hard to imagine that the TGA could assess the jurisdictional issues, obtain a copy of the advertisement, verify the complaint, contact the advertiser, receive a response from the advertiser, consider the response and the complaint in full, draft up and finalise a response and then publish the outcome in such a short time (and still ensure a robust, “best-practice”, system embodying the principles of procedural fairness). It may be so, but there is insufficient published detail to know for sure.

The TGA’s published “outcomes” are of no value to advertisers at large, no value to the specific advertiser in question and of no value to complainants or other stakeholders.

The only value of the published outcomes appears to be a demonstration of the TGA’s workload.

In our view, the TGA must publish outcomes in at least as much detail as the CRP had 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)

• Consultants (to assist their clients to understand the requirements)
• Trainers (to use the determinations to educate others)
• The TGA (by reducing the need for specific training and education)

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

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 20: 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.

Some Specific Comments about the Draft Guidelines

For all of the reasons outlined above, we are not convinced that the new Code is an improvement, nor are we convinced that the draft Guidelines will be useful.

Nevertheless we offer the following comments in addition to the specific comments included in the tracked copy of the Guidelines included as Attachment 2.

The Guidelines are not well laid out, they are not generally helpful and in some instances they are not internally consistent or consistent with the new Code. Some of the concerns with the draft Guidelines include:

• There are still outstanding issues with the new Code itself (which therefore makes the Guidelines redundant and premature).
• The structure, layout and readability of the Guidelines are not ideal
• There is no attempt to explain the definition of “Health Warnings”
• There is duplication of materials found elsewhere (e.g. the definitions on pages 58 – 68)
• The Inaccurate descriptions of the “key differences” (page 7)
• The introduction of requirements in excess of those in the new Code (e.g. “vulnerability” on page 11)
• Inconsistency of language used to describe the same issue in various places (e.g. the requirements in relation to “consistency” between the ARTG entry and the claims)
• Irrelevant examples (e.g. 10(a)(i) on page 20)
• Ambiguous explanations (e.g. use of the term “powerful” on page 21)
• Incomplete and potentially misleading advice (e.g. regarding “discounts” on page 22)
• Inaccurate advice (e.g. regarding “guarantees” on page 23)
• Simply cutting-and-pasting the words of the new Code (e.g. 11(2)(c) on page 26)
• Contradictory descriptions of the requirements (e.g. 12(4)(d) on page 31)
• Failure to explain what new terms actually mean (e.g. “medically accepted” on page 45)
• Confusing explanation of a non-existent issue (e.g. “unbranded advertising” on page 72)
• Content which does not provide guidance (e.g. “puffery” on page 75)

There are also a number of elements missing from the Guidelines, such as:

• Given the complex drafting and ambiguous language used in the new Code, the Guidelines should include tools to help stakeholders navigate the new Code (e.g. checklists) (e.g. stepwise approaches to ensuring compliance) (e.g. a flow chart for identifying which mandatory requirements apply to which advertisements), (e.g. through a logical layout) (e.g. with the inclusion of an index), etc.
• Given that there are new requirements in the new Code, the Guidelines should identify “what is new” and “what is the same” so that experienced advertisers (and complainants, consultants and trainers) can quickly assess what new requirements they need to come to terms with (and what existing requirements remain relevant).

As we have stated above (and previously) the Guidelines should be treated as a “living document” with processes in place to identify issues and correct them as they emerge and with processes for routine review and consultation.

Recommendation 21: The Guidelines are a nice-to-have (non-essential) accompaniment to the essential Code and the complaint determinations.

Mocked-up ads

In order to illustrate the complexity of the new Code and the impact of the new requirements on advertising, we have prepared a mocked-up list of requirements for a print advertisement for a fictional ibuprofen product and included it as Attachment 3.

The difficulties with applying the new Code will be evident from the number of “Assumptions”, “Notes”, citations and cross-references we have had to include in the document.

A print advertisement represents the simplest application of the new Code, the difficulties we experienced will be magnified where the advertisement is in video form (since there will need to be an assessment of the relative “prominence”/“noticeability” of the various audio, video and print representations) or if it is an advertisement to which section 12 of the new Code applies (given the tangled and laborious wording used in that section – see for example our comments in footnote 6 on page 9 above).

There are no TGA mock-ups in the Guidelines. From this we can only conclude that the TGA experienced the same difficulties we did in applying the new requirements.
Recommendation 22: The TGA should have prepared mocked-up advertisements to clarify and demonstrate the new requirements in the new Code. This would have been of some assistance in understanding the TGA’s view of the more ambiguous new requirements such as Health Warnings, Prominence, Scientific Representations, Public Health Campaigns, On-line Purchasing and Testimonials.

Tracked copy of the Guidelines

Further to the comments provided above, we have included a “tracked” copy of the Guidelines (see Attachment 2) 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 Guidelines 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

<table>
<thead>
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<th>Attachment</th>
<th>Description</th>
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<tr>
<td><strong>Attachment 1</strong></td>
<td>ASMI’s tabulation of the new requirements in TGAC 2018</td>
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<td><strong>Attachment 2</strong></td>
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<td><strong>Attachment 4</strong></td>
<td>A “mocked-up” print advertisement for a fictitious product (Coughlex Cold &amp; Flu Relief + Cough) per the March 2018 draft Code</td>
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<tr>
<td><strong>Attachment 5</strong></td>
<td>A “mocked-up” print advertisement for a fictitious product (Coughlex Cold &amp; Flu Relief + Cough) per the ASMI proposal</td>
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