Australian Self-Medication Industry Ltd.
ACN 607 233 116
ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Direct Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

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

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

Dear Sir/Madam,

Submission to the Consultation on the Therapeutic Goods Advertising Code (proposed improvements including proposed framework for Schedule 3 medicine advertising)

We refer to your call for submissions re the above.

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

Contents

Executive Summary

There is no doubt that reform is needed, however the TGA has provided a poor quality consultation document that misses the opportunity of obtaining useful feedback on a draft Code.

We would summarise the key elements of our response as follows:

1. ASMI supports reforms aimed at improving the TGAC ("the Code").

2. The Code is no longer fit-for-purpose and needs to be revised.

3. The revised Code must cover all therapeutic goods, must apply to all audiences (i.e. both consumers and healthcare professionals), must apply to all current media and must be able to accommodate a "highly dynamic environment" (without having to be updated every time a new advertising technique emerges).

4. The revised Code needs to be a sophisticated blend of principles and specific requirements.

5. It is disappointing to see that much of the consultation document is essentially just a re-organisation of the exiting Code principles presented in a series of groupings that do not always make sense and in a way that does not foster debate.

6. It is also disappointing to see the way certain issues are conflated (e.g. the confused presentation in relation to "specific demographic groups of patients") and other issues are presented incorrectly (e.g. the distinction between *indications* and *claims*).

7. It is unclear why the TGA has introduced or retained a range of very subjective terms (e.g. "unduly glamorise", "be likely to") when the stated aim has been to make the requirements more objective and more certain.

8. The consultation document (and the process itself) would have been much more effective had the TGA acted on all the previous stakeholder feedback and provided a draft Code for discussion. There are many sections of the current Code which are outdated, ambiguous, circulatory, redundant and poorly worded. The TGA should have acted on previous feedback to produce a draft Code for consultation this time.

9. ASMI will not support "American style" disclaimers that would require all RASML labelling statements and all possible adverse events to be included in advertising.

10. It should be possible for the principles based requirements to apply to **all** therapeutic goods (both medicines and devices), and for these to be complemented with specific requirements relating each type of goods.

11. The revised Code should be clearly structured so that sponsors and advertisers can quickly and accurately locate relevant information.

12. 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.

13. It is disappointing to see that despite a significant level of support for S3 advertising reform, the TGA has not put forward recommendations to match.

14. ASMI supports a default regulatory position which allows S3 advertising, together with a mechanism to prevent advertising of specific substances based on public interest and safety criteria.

We have attached a "marked up" copy of the consultation document (as Attachment 1) in order to illustrate the points made on the following pages.

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.

3.1 The Advertising Code

In our view, the revised advertising code must cover all therapeutic goods, must apply to all audiences (i.e. both consumers and healthcare professionals), must apply to all current media and must be able to accommodate a "highly dynamic environment" (without having to be updated every time a new advertising technique emerges).

Healthcare Professional Advertising

Importantly, the revised Code should include a section on advertising directed to healthcare professionals.

This is a significant regulatory gap that is not being addressed.

The failure to close this regulatory gap means that healthcare professionals will continue to be exposed to non-compliant and potentially misleading materials which can negatively impact the quality of information passed on to consumers.

The current system effectively means that the only oversight of advertising directed to healthcare professionals is that provided by industry associations over their own members. For non-association members there are no relevant codes or guidelines and there are no pathways for assessing compliance or imposing sanctions.

Given the wide range of professionals covered by the current regulatory definition (with herbalists, homeopaths and naturopaths included alongside doctors, nurses and pharmacists), the potential impact (on consumers) of non-compliant materials directed to professionals should not be under-estimated.

Further information on this topic is included in our correspondence to the TGA (dated 26 July 2017) which is included as Attachment 2 to this submission.

Objective vs subjective

It is interesting to note that while the consultation document states (on page 7) that:

> *The updated Code proposed for consultation subsequent to our receipt of feedback on this paper will need to remain relevant in this highly dynamic environment (in particular evolving online media platforms), while at the same time holding all types of therapeutic goods advertising to the public to the same standards.*

The TGA's solution (on page 9) is to remove subjectivity and create objectivity (presumably through a long list of prohibited and permitted activities). As the TGA will know from the 1999 review of a code with a long list of prohibitions (a trigger for the review) and the work that has been done in relation to "permitted indications" for listed medicines, having a long list is not conducive to flexibility or responsiveness.

Emerging media and techniques

In order for a revised TGAC to be responsive to a "highly dynamic environment", the Code will need to anticipate changes in:

- Media
- Promotional techniques
- Communication technology
- The interface between devices and medicines
- The interface between therapeutic goods and other types of products
- Etc.

An objective list of prohibitions will not permit such responsiveness.

3.2 Schedule 3 Advertising guidelines

In summarising the feedback from the Consultation, the TGA indicates that, in relation to the advertising of pharmacist-only medicines (Schedule 3 substances):

> "… there was support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of these substances."

Despite this significant level of support, the TGA has not put forward recommendations to match.

Instead, the proposed changes are minimal and not reflective of this broad level of support. Effectively, there are no changes proposed to the regulatory framework and guidelines; there is only an increased discretion being proposed for the Delegate.

A discussion of the ASMI position in relation to S3 advertising is included later (in sections 6.1 to 6.4) and our detailed position, the rationale, the evidence and our proposals for reform are comprehensively explored in our submission on the topic dated 5 May 2017 (which has been included as Attachment 3 to this submission).

4.1 Changes to support effective sanctions and enforcement of advertising requirements

There needs to be a balance between certainty and flexibility. This is why the current Code reflects a principles-based approach. It is too difficult to articulate a comprehensive list in the first place, let alone a list that will accommodate unforeseen advances in advertising media and techniques.

ASMI understands that prior to the 1999 review of the Code and regulations much of the Code consisted of a long list of prohibitions. ASMI also understands that this "black-and-white" approach was abandoned because it failed to anticipate changes in advertising techniques.

By way of illustration, even the flexibility inherent in the current principles-based Code fails to properly accommodate:

- Social media (e.g. Twitter and Facebook)
- Digital media accessed on hand-held devices
- Online "deals" websites
- Brand name reminders
- Range ads
- Advertisements that contain some foreign language text
- Etc.

A principles based approach would also be consistent with the approaches taken in other areas of regulation (e.g. the Australian Consumer Law). The ACCC applies substantial penalties and sanctions without abandoning the principles-based approach in the ACL.

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

ASMI believes that minimising subjectivity and enabling clear and consistent interpretation of the provisions of the new Code is useful for advertisers and sponsors. Minimising subjectivity and providing prescriptive requirements is useful, however these clear interpretations and definitions can be difficult to apply across all forms of advertising and all media.

For some provisions proposed for the new Code, minimising subjectivity will be difficult to achieve and ASMI believes that it is also necessary for the Code to have a set of principles-based objectives that can be applied across all forms of advertising and can take context into account.

There will be advertisers who will try to circumvent prescriptive requirements in creative ways, and advertising principles can address this type of behaviour.

Inclusion of some principles based provisions in the Code will also allow an interpretive approach to be taken with claims directed to specific target audiences, the potential impact of these claims on vulnerable populations, and will make it easier to apply the Australian common law principle of the "reasonable consumer's" view of the advertising.

Should the Code include only very objective, prescriptive requirements, and not some additional principles-based overarching provisions, it could also affect the regulator's ability to deal with matters that should be interpreted or are implied in advertising.

4.2 Core objectives for the new Code

It is disappointing to see that these four core objectives are essentially just a re-organisation of the exiting Code principles presented in a series of groupings that does not always make sense and in a way that does not foster debate. For example, it is difficult to imagine that a stakeholder will argue that advertising should be permitted to be unbalanced and misleading!

The consultation document (and the process itself) would have been much more effective had the TGA acted on all the previous feedback and provided a draft Code for discussion.

> We wish to obtain feedback to support the development of a proposed new Code that contains clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.
>
> The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.
>
> Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).
>
> Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

<u>Clearer and more specific requirements of what is and isn't permitted</u>

ASMI supports the development of a new Code that contains clearer and more specific details of what is and is not permitted in respect of "advertisements".

A useful first step for the introduction of clarity is consistency in terminology used in relation to advertising, and advertisements and other definitions contained in the Code. We note that the proposed amendments to the Act refer to "advertising" not "Advertisement", however the consultation paper refers to "advertisements(s)". The two terms are different and clarity and consistency on these definitions is needed.

In the past, and as reflected in many CRP determinations, there is often discussion on what constitutes advertising and advertisements, for example:

- What is "bona fide news"?
- Is a "news" clip that makes claims about the results of research into a particular substance considered to be advertising?
- Are posts on social media "advertising"?
- Are internet search outputs "advertising"?
- Are patient leaflets "advertising"?
- What is the proper distinction between labelling and advertising
- Etc.

Advertisers are using innovative technology in different ways and are creative in how to represent products and substances and it is important for the Code to be able to capture all new and emerging advertising techniques.

There is also confusion among sponsors in relation to the publication of articles that refer to substances; sometimes these "articles" have been used by advertisers in ways that seemingly circumvent the Code. The new Code must be flexible enough to cover these articles and advertorials. While "generic information" is referenced in the legislation, this communication form is not referenced or included in the Code and so problems are rarely addressed.

Often, sponsors will refer to substance names as opposed to brand names; the Code should be clear that advertising and claims made for substances, being therapeutic goods, are covered by the Code.

The few illustrative examples above show how difficult it is to be prescriptive, clear, objective and specific in relation to what is and is not permitted in relation to advertising and what constitutes an advertisement.

Any proposed new Code must include some requirements that are clear and specific, however it must also be based on principles that can be interpreted in relation to the many different and creative forms of advertising and advertisements.

Views on the proposed requirements

ASMI supports the proposed requirements in principal, noting that some of these are essentially the same as the provisions of the existing Code, with some re-wording and re-ordering.

Each of the four main points is followed by some "discussion" and it is not clear to the reader what parts of this discussion are proposed as part of the new Code.

Some parts of the discussion that appears below each of the four principal requirements include additional sections from the existing Code. It is not clear whether or how these requirements will be translated or re-worded to form part of the new Code.

ASMI has reviewed the four key points described in the consultation paper and wishes to provide comment in relation to each of these:

1. Advertisements (Advertising) must comply with the Therapeutic Goods Act 1989, regulations made under this Act, and the Therapeutic Goods Advertising Code

ASMI agrees with this provision and notes that it is the same as that in the existing Code. We note that the proposed amendments to the Therapeutic Goods Act 1989 refer to "advertising"; Key definitions of these important terms must be considered as part of this requirement, noting the many forms of advertising and new, emerging advertising techniques.

2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG

ASMI agrees with the principle that advertisements should be truthful, balanced and not misleading, noting that similarly worded requirements are included in the current Code.

Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG

The second part of this statement, that "claims about therapeutic goods must be consistent with the entry of the goods in the ARTG" requires some further discussion.

Medicines and indications

The ARTG entry contains the *indications* for products, such as "temporary relief of cold and flu symptoms" or similar. Advertising *claims* can be different to indications and may be therapeutic claims or non-therapeutic claims. Therapeutic claims may include a listing of symptoms that form part of an indication (e.g. runny nose, sore throat, dry cough, muscle pain, joint pain etc. as appropriate for the product), or other product or formulation related claims such as "fast acting", "fast absorption", "long acting", "24 hour-allergy relief", "convenient once a day formula" etc. Non-therapeutic claims can include "pleasant tasting", "number 1 selling", or similar. The ARTG entries do not include all possible product claims, nor do the ARTG entries always include a complete list of claims.

Confusion regarding indications and claims has led to the proliferation of claims entered in the custom indications field for some listed medicines. Long lists that include many non-therapeutic claims are common so as to allow these to be included in advertising – this is a big part of the current problem with interpreting "advertising claims" as being the same as "indications" and the requirement that claims used in advertising must be consistent with the ARTG entry.

ASMI suspects that the intended wording may have been for advertised "*product indications*" to be consistent with the ARTG entry, which is an entirely appropriate requirement. A requirement for all *claims* (both therapeutic and non-therapeutic) to be consistent with the relevant ARTG entry is unworkable and constrains advertisers.

Medical devices and intended purpose

ASMI agrees that the advertising of medical devices should be truthful, balanced and not misleading. Given that the intended purpose of medical devices can be broad, any therapeutic claims relating to use of a medical device should be consistent with the intended purpose, however there ought to be flexibility to allow appropriately worded and positioned advertising claims. For example, the intended purpose of a group of support bandages may be "compression and support" – however it should be acceptable for a wrist support product within that group to advertise for "support and relief of wrist pain".

The wording of the proposed Code requirements relating to consistency of advertising with ARTG indications or intended purpose must be carefully worded to ensure that there is no impact on the ability to make therapeutic and non-therapeutic claims (provided they comply with the Code) and that there is sufficient flexibility for differences in wording between ARTG indications and intended purpose with the wording of therapeutic claims in advertising.

Advertising must not contain any matter that is likely to lead to a person to believe that they are suffering from a serious ailment or that harmful consequences may result from the product not being used

ASMI agrees with the above provision for the proposed Code, noting also that there are some products that are indicated for the prevention of harmful conditions, such as sunscreens, folic acid for prevention of neural tube defects, and nicotine replacement therapy to prevent smoking related disease.

For the above types of products these claims are not misleading, are reflective of public health initiatives and advertising of these indications and claims ought to be allowed without fear of advertising breaches being found. The wording of the proposed Code should be refined to enable advertising of these or any other products, the use of which can be prevent or minimise harms to health.

Advertising (including a product label) must not contain any claim, statement or implication that……..it is effective for specific demographic groups of patient (particularly where this may be a vulnerable group)……

ASMI finds this wording rather unclear and some further explanation of "specific demographic groups of patients" is needed.

Specific products for children, claims about the elderly, and claims such as "suitable for use in pregnancy" or "suitable for use by asthmatics" are legitimate and useful claims that provide useful information about the product to consumers. There are some products that claim a use for specific conditions – for example antifungals labelled for tinea, or for vaginal thrush.

This type of wording is not clear about what the requirement aims to achieve.

Advertising must contain all mandatory and applicable information

ASMI questions why the requirements for mandatory statements and mandatory information has been included in the section that describes the requirements for advertisements to be truthful, balanced and not misleading. The Code should be drafted so that sponsors and advertisers can quickly and intuitively find the different requirements.

We also request further clarity as the requirement implies that all mandatory warning statements (e.g. RASML statements, Poison Standard statements) will be required in all advertising. This is impractical and requires a more tailored approach. What is a requirement for labelling (e.g. RASML) cannot be assumed to be practical for inclusion in all forms of advertising.

While we appreciate that the statement "Always read the label and use only as directed" may be ignored by some consumers and some more consumer focussed information may be desirable especially for certain types of medicines, the complete RASML statements and Poisons Standard statements include lengthy warning statements and information that may not be necessary or desirable (or even possible) for inclusion in all forms of advertising. For example, for paracetamol labelling RASML requires the overdose statement and Poisons Information Centre Freecall number for both Australia and New Zealand to be included on the label; we suggest that this is not appropriate for advertising. RASML requires interaction warning statements; it may also be impractical to include the full list of warning statements and precautions in radio and TV advertisements or in advertisements that include little but the product name / picture / price and a tagline.

On the other hand, this information may be useful and desirable in advertisements that allow a consumer to purchase the product at the same time – as these consumers have no access to important labelling information prior to purchase.

Further thought and consultation are needed in relation to this requirement, with a view to differentiating the extent of information required for different types of products and the different types of advertising media, and whether or not a purchase is possible (e.g. from a website).

ASMI also requests further clarity on the meaning of the last paragraph in point 2, regarding "specific warning information" for various classes of therapeutic goods. The point about specific warning information appears to conflate labelling requirements and advertising requirements. ASMI suggests that while it is understood that label claims must comply with the provisions of the Code, product labels are regulated by TGO 92, RASML and the Permitted Ingredients List. This paragraph implies that mandatory statements designed for the new Advertising Code will also be applied to labelling, which is separately regulated. It should not be a requirement for labelling to state "Always read the label…use as directed, (etc.)".

3. All claims used in advertisements for therapeutic goods must be substantiated

ASMI supports the requirement for claims to **have been** substantiated (prior to publication) – as sponsors and advertisers should hold substantiating evidence for all claims, whether therapeutic or non-therapeutic. ASMI also agrees that advertisements that provide scientific information should present this information in a manner that is accurate and can be understood by the audience to whom it is directed, and that the claims should be reflective of the body of evidence, i.e. information and claims in advertisements should not be "cherry picked" from scientific studies or scientific literature.

The terms "scientific information" should be clearly defined in relation to advertising; there is often confusion among advertisers as to what constitutes scientific information in an advertisement.

While it is desirable for advertisers to accurately provide the relevant citations and to identify the sponsor of the study, sometimes this is not known and subject to change over the years as company mergers and acquisitions take place. It should be sufficient to provide accurate citations as per the study or data (authors, title, journal dates, volumes, page number etc.) enabling the reader to search for the cited information.

Sometimes sponsors cite "data on file" when unpublished study information is used to support claims. ASMI believes that the use of "data on file" should continue to be allowed, as in the case of registered medicines it is often part of the data package that supported the regulatory submission for product approval. It should not be necessary for advertisements to rely only on published information for substantiation. Data on file is usually commercial in confidence clinical or market research and its publication can be disadvantageous and result in misuse of the information by competitors. Sponsors should, however, be willing to respond to queries from healthcare professionals and consumers if requested, and provide relevant summaries or excerpts from the data on file as appropriate to those who request it.

In relation to use of testimonials, ASMI supports the proposal that testimonials should have been authenticated, should be genuine, typical, and current (although there will be differences in how "current" is interpreted); there should also be acknowledgement of valuable consideration and whether testimonials are made by persons who are related to the sponsor or advertiser. We question whether the persons included in testimonial advertising should be identified – and whether the consultation paper implies that the name of these people should form part of the advertisement.

ASMI notes the provision about endorsement and questions how this fits in with the section on substantiation of claims; we believe that endorsements should be a separate section. It appears that this requirement is similar to that of section 4(2)(c) of the current Code. The experience of the CRP has shown that there can be difficulties in interpreting this requirement – what types of

endorsements are to be allowed, considering that some products (for example) use designs such as the Pharmacy Guild Gold Cross on product labels and hence, advertising.

4. Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help

Mandatory information

ASMI supports the need for balance and accuracy in advertising, and for consumers to have the relevant information about the products that they purchase and use to self-manage various medical conditions.

As already stated in this submission, ASMI does not support "American style" disclaimers that would require all RASML labelling statements and all possible adverse events to be included in the advertising requirements. There is no evidence that including these extensive disclaimers in advertising results in more appropriate or safer use of medicines.

In relation to providing adequate information to consumers about risks, cautions and side effects, ASMI believes that certain mandatory statements ought to be included in advertising and that these should be tailored to be appropriate for certain products (e.g. analgesics, vitamins/minerals, sunscreens, medical devices) and to be flexible enough to accommodate different types of advertising (e.g. short duration television and radio commercials vs. website advertisements from which purchases can be made). Consultation on any revised mandatory requirements should take place. The current problem of some mandatory statements being restricted representations also needs careful consideration in this review, i.e. context etc.

The experience of sponsors and advertisers has been that there is wide variability in interpreting how mandatory statements should be applied. While added guidance is desirable, the requirements should not be prescriptive as it is impossible to be specific to the entire range of media and viewing platforms and the size and duration of advertisements appearing in these media.

Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use of the goods

ASMI supports the principles of quality use of medicines (QUM) and that it is important for advertising to not encourage or be likely to encourage inappropriate or excessive use of medicines.

This requirement is consistent with that included in section 4(2)(f) of the current Code.

ASMI believes that there is a need for more clarity in the wording of this provision, and there has been confusion on how this provision can be interpreted in relation to discounting and other "value" offers. Consumers buy medicines in various ways, including to have on hand for conditions that are familiar and recurring (e.g. headache, allergies, gastrointestinal symptoms such as reflux). In this scenario there is no evidence that purchase of "value" offers or discount offers results in inappropriate or excessive use.

Certain products are also used long term, e.g. minoxidil, nicotine replacement therapy, emollients for skin conditions, sunscreens – and there should be no implication that purchase of multiple packs of these products will result in inappropriate or excessive use.

Advertisers require better guidance on this provision, and at least some form of assurance that discounting and value offers do not, on their own, constitute encouragement of excessive or inappropriate use. The wording of this requirement has often been a source of debate at the CRP, noting that there have been very few breaches of this provision over the years. Where breaches have been found, these are often the result of a combination of factors in the wording and representations of the advertisement, e.g. the use of wording or language that directly encourages inappropriate use by trivialising the conditions to be treated, together with lack of mandatory statements and offers of bundled quantities directly to consumers that greatly exceeded scheduling limits.[1]

Advertisements should not unduly glamorise or prey on vulnerability

ASMI seeks some clarification on the term "unduly glamorise"; it is subjective and open to interpretation. Does this provision cover celebrity endorsement, or does it mean that sponsors cannot use an attractive presenter in an "advertorial style" advertisement?

Similarly, some explanation or context for the statement "prey on vulnerability" should be provided as it is not only unclear but also assumes intentional non-compliance or unethical behaviour by sponsors or advertisers.

If the proposed Code is to be clear and objective, terms such as "unduly glamorise" are difficult to interpret.

Public interest criteria

ASMI notes the proposed public interest criteria and has concerns that some of these are unclear and repetitive. We note the following points:

- *the advertisement must not impair the ability of a member of its audience to choose an appropriate therapeutic product to treat, manage or avoid a disease, condition, ailment or defect because of the vulnerability of the member of the audience;*

ASMI would like some further clarity on this statement, especially the part "because of the vulnerability of the member of the audience". We question why this provision is directed solely towards a single, vulnerable audience member. If a principle is important (i.e. that of choosing an appropriate product), then it ought to apply to the entire audience. Also, it is more appropriate and consistent with the Australian Consumer Law for the requirements of the Code to be assessed in terms of probable impact upon the reasonable person to whom the advertisement is directed (as per section 3 of the current Code).

Prominent inclusion of a statement such as "if symptoms persist see your healthcare professional" work towards ensuring that if a medicine has not resulted in the desired therapeutic effect, consumers should seek advice.

Sometimes a medicine may be chosen on the basis of symptoms indicated. Should the medicine not deliver the relief desired, this may not only mean that the choice was inappropriate; it may mean that further investigations are needed.

[1] CRP Determination Complaint 2016-01-008. Link: http://www.tgacrp.com.au/complaint-register/?_year=2015&_search=Guild&_id=2913

- *the advertisement is not likely to create a false expectation in its likely audience that the product will deliver health benefits or improvements to their quality of life;*

ASMI believes that the (current) wording "unrealistic and unwarranted expectations of product effectiveness" is clearer. We request clarification of the term "false expectation", given that no medicine can reasonably be expected to be 100% effective.

The wording around "false expectation" is also related to health benefits or quality of life improvements.

The provisions of the current Code are clearer.

- *the advertisement is not likely (alone or through repetition or together with other references) to have a negative impact on public health or on persons to whom the advertisement is not directed);*

ASMI questions the inclusion of "alone or through repetition". Many advertisements are used on multiple occasions, and internet advertising can be viewed as frequently as desired.

We are concerned at what is meant by "through repetition" and how repetition can result in a breach of the Code.

ASMI is also concerned with the reference to "negative impact on public health" and how this can be measured.

Each advertisement should be viewed as an individual piece and viewed in terms of its probable effect on the reasonable consumer rather than a vague reference to its repetition having an impact on public health.

Medical devices

ASMI suggests that the Code should have some principles based requirements that apply to all therapeutic goods, and some specific requirements relating to medicines and to medical devices – perhaps in the form of an Appendix. This could cover issues such as mandatories, and perhaps devices for which "prior approval" provisions should apply.

The CRP has viewed many advertisements for medical devices, including devices such as joint replacements, devices used as part of intraocular lens surgery, lasers, DEXA devices. Some advertisements are concerning in that they also channel consumers through certain pre-determined referral pathways.

ASMI believes that there is scope for clarifying advertising arrangements relating to device advertisements and ensuring that consistent principles apply across all therapeutic goods.

Advertisements must also not discourage consumers from taking medicines prescribed by a healthcare professional. Subject to the media of publication or broadcast of the advertisement, mandatory statements, contraindications and warning statements must be included in advertisements such as "if symptoms persist consult your healthcare professional" or the warnings included in legislative instruments made under the Act for this purpose. (e.g. in the Medicines Advisory Statements Specification 2016). The nature of such statements, and their duration (for broadcast media), font size (in print media) or relative prominence (e.g. in outdoor marketing) may also be specified.

This paragraph is repetitive – covering again the issue of mandatory statements. ASMI suggests a separate section on mandatories, containing clear requirements.

We reiterate that ASMI does not support "US style" disclosure of a long list of precautions, contraindications and adverse events and there is no evidence that this provides any benefits to consumers.

ASMI believes that RASML statements are specific to labelling, and a more nuanced approach to mandatory statements should apply to advertising. While consumers should have access to all relevant contraindications and precautions contained in labelling information if they wish to purchase online, ASMI does not support any requirement for short radio and television advertising to include all of the RASML warning statements, and tailored mandatories are required for different classes of products.

Sponsorship advertisements

Further clarity is required on what constitutes a "sponsorship advertisement".

We assume, based on the bullet points, that this pertains to events that are sponsored by companies or brands, examples of which could be "fun runs", charity functions or other events which a medicine or medical device sponsor has supported.

Further explanation and consultation is needed.

Disease Awareness Campaigns

The discussion that follows also refers to disease awareness campaigns by sponsors of therapeutic goods, and a statement that these must **not** identify a therapeutic good or sponsor either expressly or by implication.

Disease Awareness Campaigns are often conducted by the prescription medicines sector, either with or without the involvement of patient support groups. The proposed requirements would have an impact on sponsors of prescription medicines, and are inconsistent with the requirements of the Medicines Australia Code of Conduct which requires identification of the sponsor of the campaign for reasons of transparency to both consumers and to healthcare professionals, attributing the advertising to a pharmaceutical company.

ASMI requests further broad-based consultation on the proposed provisions relating to disease awareness campaigns looking specifically at unintended impact on prescription medicines, as well as transparency implications.

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.

The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).

Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

ASMI has provided feedback throughout the process of the Medicines and Medical Devices Review (MMDR), as well as previous consultations on advertising and the Scheduling Policy Framework in relation to S3 advertising.

There is a need for revision of the Therapeutic Goods Advertising Code and the principles based requirements that apply to all therapeutic goods, together with some clear requirements tailored to different types of advertising. The media landscape is constantly evolving and the new Code must be able to be applicable and relevant to all forms of advertising.

The document should be clearly structured so that sponsors and advertisers can quickly and accurately locate relevant information.

ASMI acknowledges that some stakeholders have requested guidelines to be available for advertisers. While this may be useful, it can also be a concern as it can encourage "regulatory creep" and the routine application of guidelines instead of examining and interpreting the Code. Guidelines can also be changed without consultation, introducing stricter interpretation. A lack of version control of Guidelines can also be concerning as the contents may change over time.

In determining complaints, the TGA should rely on the wording of the Code and not change interpretations over time by the use of Guidelines.

4.3 The Council recommendations

Testimonials

The current requirements in relation to testimonials are clear.

Samples

As the TGA will know, the Code was amended to remove references to "free" samples because of the complexities introduced when advertisers offered products for sale at extremely low prices. The current Code therefore refers only to "samples" and it is disappointing to see the TGA re-introduce such a problematic term.

In ASMI's view this section of the Code should be removed. The sampling of therapeutic goods is a legal activity which is controlled by the States and Territories. Advertisers wishing to sample therapeutic goods seek permission from the Department of Health in the State or Territory where the proposed activity is to take place. Once that approval is given, the Commonwealth has no place preventing advertisers from telling consumers about that approved sampling exercise.

Restricted Representations

ASMI agrees that reform is needed in relation to restricted representations, however the reforms need to carefully balance a number of factors:

- The current, and proposed, permitted indications for listed medicines which contain restricted representations.
- The medicines which legitimately and rightly refer to restricted representations (e.g. sunscreens and skin cancer, folic acid and neural tube defects, nicotine replacement therapy and smoking related disease, calcium and vitamin D and osteoporosis).
- The devices such as condoms which legitimately and rightly refer to serious conditions (e.g. "may help reduce the risk of transmission of sexually transmissible disease (STD)").
- The warning statements (for medicines and devices – whether in RASML or not) that appropriately refer to serious diseases in the context of instructing consumers not to use the product (e.g. "Please SEEK ADVICE before using this product if you have diabetes as your foot condition may require treatment by a healthcare professional")
- The yet-to-be-finalised distinction between listed medicines and the proposed "third pathway" for "assessed listed" medicines.
- The disbanding of the TGACC and the uncertainty surrounding future approvals of restricted representations.
- Etc.

The cursory manner in which this subject is addressed and the confusing way it has been conflated with "scientific information" in the consultation document does not assist meaningful discussion of the reforms.

Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?

Over the last several years, the Council (and other stakeholders such as ASMI) have all provided a substantial body of advice to the TGA as to the revision of the Code.

ASMI is a member of the Council, and this author is aware of correspondence going back as far as 2007 to the TGA from the Council on the specific shortcomings of the Code.

Unfortunately, most of this advice has been ignored by the TGA and it is disappointing to see the advice from the Council given such a cursory examination in the consultation document.

As recently as August 2016, the Council provided the TGA with a list of "micro" and "macro" suggestions for reform of the Code. None of which are covered here.

In August 2017, members of the Complaints Resolution Panel provided the TGA with a list of general and specific recommendations for reform of the Code. None of which are covered here.

On the basis of this previous advice, the TGA could have produced a revised Code for consultation. Instead we have a confused re-hash of the existing principles.

This is a lost opportunity and this current consultation is an unnecessary pre-cursor to the revised Code which will (inevitably) be the subject of further consultation.

The feedback from the Council (and other stakeholders) has been clear. There are many sections of the current Code which are outdated, ambiguous, circulatory, redundant and poorly worded. The TGA should have acted on that feedback to produce a draft Code for consultation this time.

4.4 Consultation comments

Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?

Removing subjectivity from the Code
Clearly and unambiguously communicate requirements
Include specific examples of compliant and non-compliant advertising

For the reasons outlined earlier in this response, ASMI does not support this sort of approach to the Code. In order to provide the most versatile set of requirements, the Code should be a principles based document first and contain some objective requirements second. In order to provide detailed instruction to advertisers, the TGA should efficiently and transparently publish all its determinations.

Accompanying guidelines to assist with understanding

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 guideline that purported to explain the requirements of the Code or the interpretation of the Code or that purported to show examples of compliant and non-compliant behaviour, for the following reasons:

1. The existence of such a guideline would lead to lazy drafting of the Code. In such a situation the drafters would be tempted leave any complex matter "to be explained in the guideline" (as is currently happening with the Labelling Order TGO92).
2. TGA staff would treat the guideline as law and advertisers would be prevented from some activities simply because the guidelines did not appear to allow them.
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.
4. 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.
5. Lastly, it is difficult to see how a useful guideline could be drafted when the TGA's own "customer service standards"[2] 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"

[2] https://www.tga.gov.au/tga-customer-service-standards

- "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".

5 Price Information Code of Practice (PICOP)

This proposal is outside the normal area of interest of ASMI and its members.

ASMI therefore makes no comment in relation to this element of the consultation paper.

6 An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines

6.1 Overview

ASMI supports the advertising of Pharmacist Only (S3) medicines to consumers.

Our detailed position, the rationale, the evidence and our proposals for reform are comprehensively explored in our submission on the topic dated 5 May 2017 (which has been included as Attachment 3 to this submission).

Consistent with our 5 May 2017 submission, our evidence-based position can be summarised as follows:

- S3 medicines should be able to be advertised to consumers (with certain exceptions).
- The default regulatory position should allow advertising, with a mechanism available to prevent advertising of specific substances based on public interest and safety criteria.
- Advertisements for S3 medicines should have separate mandatory requirements.
- There is no evidence that advertising of S3 medicines leads to inappropriate use.
- In fact, research conducted on behalf of ASMI demonstrates a range of positive outcomes from S3 advertising:
    - It increases consumer awareness of the available therapeutic options,
    - It drives more 'health conversations' between pharmacists and consumers,
    - It does not drive inappropriate demand by consumers, and
    - Pharmacists do not feel pressure to supply a particular brand or a particular product.
- The advertising restrictions disempower consumers because "they are not allowed to know" about S3 medicines. Consumers continue to consult GPs for conditions which could be safely managed by pharmacists.

Once a decision in favour of a more liberal approach to S3 advertising is made, the transition will need to be carefully designed and managed with input from all affected stakeholders and following consideration and possible amendment of related legislation. ASMI remains committed to working with all stakeholders to ensure that this takes place, and suggests that the following take place:

- There should be initial agreement on criteria for which S3 substances should not be advertisable (via transparent consultation process).
- The Therapeutic Goods Advertising Code should be updated to reflect new S3 requirements.

- Following commencement of the changes, there should be a review of substances which are not currently permitted to be advertised against the criteria mentioned above. There should be an ordered process by which the advertisable status of these substances is reviewed (initiated for each substance either by the Delegate or by a sponsor).
- There should be no further examination of those substances which can currently be advertised to consumers (since they have already been reviewed).

The consultation paper states that there was support from a significant majority of stakeholders for broadening the direct-to-consumer advertising of Schedule 3 medicines. The approach described in this consultation paper does not reflect the majority view of stakeholders as it in effect describes no change from the status quo approach – other than the Delegate having the discretionary power to decide whether or not to refer an application for S3 advertising to the ACMS.

The list of factors in the current Scheduling Policy Framework, currently described in the November 2000 NCCTG S3 Advertising Guidelines[3] , has been included in the consultation and it is not proposed that these statements will be altered. This is disappointing, and is a lost opportunity to update the guidelines to enable these to be more consistent with the stated view supporting more a broader scope for the advertising of Schedule 3 medicines.

By not updating these guidelines, it is implied that sponsors will still be required to demonstrate the potential public health benefit of advertising, placing continuing unclear expectations on sponsors to produce evidence of difficult to define public health benefit. Historically this has been one of the most difficult requirements for sponsors to address, as it is difficult to interpret the highly subjective data requirements to meet this factor.

6.2 Product advertising requirements

ASMI supports mandatory requirements for S3 advertising that reinforce the professional role of the pharmacist and clarify that a product request will not automatically result in the supply of a product.

This could be in the form of mandatory statements or it could be in the form of a message conveyed by other words to the same effect. In either case the final requirements should be based on the outcomes of research and should be reflective of acknowledged communication principles.

For example, research conducted on behalf of ASMI (see Attachment 3) used a mock S3 advertisement that conveyed the role of the pharmacist through a combination of visuals, spoken word and printed word rather than simply relying on specific mandatory statements in specific locations.

The two statements proposed in the consultation paper differ from those currently in the Code and there is no indication as to how they were arrived at, nor is there any evidence to show that they convey the desired message, that they are any better or that they offer any improvement at all over the current statements. ASMI cannot support the proposed statements.

ASMI does not support the mandatory placement of the statements as proposed in the consultation document. Firstly there is no evidence put forward to support the proposal. Secondly the proposal will not be flexible enough to accommodate all existing media and techniques (e.g. point of sale and social/digital media). Thirdly there is no scope to accommodate emerging media and techniques.

[3] https://www.tga.gov.au/publication/schedule-3-advertising-guidelines

6.3 Substances unsuitable for inclusion in Appendix H

As outlined above, ASMI supports a default regulatory position which allows S3 advertising, together with a mechanism to prevent advertising of specific substances based on public interest and safety criteria.

There should be agreement on the criteria for S3 substances not to be advertised and there should be a review of substances which are not currently permitted to be advertised against this criteria. ASMI suggests that the following S3 medicines should not be advertised to consumers:

- Medicines that have documented potential for abuse or diversion, e.g. pseudoephedrine
- Medicines that are for chronic medical conditions and are recommended by a doctor as part of a treatment protocol, e.g. nitrates for angina
- Injectables used for emergency situations, such as adrenaline, naloxone, glucagon, noting that there may be a public safety benefit in being able to provide support materials on appropriate use to carers (this is not possible under the current restrictions).
- Medicines used as part of a medical or surgical procedure, e.g. bowel preparations prior to surgical or diagnostic procedures

6.4 Process for adding a substance to Appendix H

As outlined above, ASMI supports a default regulatory position which allows S3 advertising, together with a mechanism to prevent advertising of specific substances based on public interest and safety criteria.

However, the approach preferred by ASMI involves a reversal of Appendix H from a "positive" list (i.e. substances that are permitted to be advertised), to a "negative" list (i.e. to include substances not permitted for advertising, on the basis that they meet certain criteria or factors).

Under the approach preferred by ASMI, advertising of Schedule 3 substances ought to be the default position, with a decision to be made on substances that should not be advertised.

This automatic inclusion in Appendix H should occur without the need for a separate justification over and above the rescheduling application itself.

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H. In particular, we would appreciate feedback on

- the specific requirements for advertisements containing Schedule 3 substances
- factors to be considered by the delegate
- restrictions on inclusion in Appendix H
- the proposed process

The ASMI position in relation to each of these points is described in Attachment 3.

Summary

There is no doubt that reform is needed, however the TGA has provided a poor quality consultation document that misses the opportunity of obtaining useful feedback on a draft Code.

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

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

List of Attachments

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

Attachment 2 Correspondence from ASMI to the TGA (dated 26 July 2017) on the issue of "Therapeutic Goods Advertising Directed to Healthcare Professionals"

Attachment 3 ASMI submission (dated 5 May 2017) in relation to "The Scheduling Policy Framework and Advertising of Pharmacist-Only Medicines (Schedule 3 Substances)"

Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Therapeutic Goods Advertising Code

Proposed improvements including proposed framework for Schedule 3 medicine advertising

August 2017

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

The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. It does not regulate healthcare practitioners, their services or practices. These activities are regulated for certain practitioners through the National Registration and Accreditation Scheme, which is implemented by the Australian Health Practitioner Regulation Agency in partnership with 14 National Health Practitioner Boards.

The regulatory requirements for the advertising of therapeutic goods to the public are set out in the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations) and the *Therapeutic Goods Advertising Code 2015* (the Code). These requirements also apply to advertisements for health services directed to the public that also promote a therapeutic good associated with that service.

The Act defines *advertisement*, in relation to therapeutic goods, as including;

> *any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods*.

This definition is very broad and captures therapeutic good advertisements that are published or broadcast in a number of media, including newspapers, magazines, television (including pay TV), radio, the Internet (including Facebook, Twitter and other social media) catalogues and point of sale material. It also captures the product label if it includes a statement, pictorial representation or design that is intended to promote the use or supply of a therapeutic good.

The Code is a legislative instrument made under section 42BAA of the Act by the Minister or their delegate. It is the core compliance standard underpinning the legislative framework regulating the advertising of therapeutic goods to the public. A person commits an offence under the Act if they publish or broadcast an advertisement or generic information about therapeutic goods that does not comply with the Code.

The object of the Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

Direct-to-consumer advertising of medicines which require a prescription from a registered healthcare practitioner (Schedules 4 and 8 of the *Poisons Standard*) is banned as is the advertising to the public of certain pharmacist-only (Schedule 3) medicines. Only non-prescription medicines (over-the-counter and complementary medicines) and medical devices can be advertised directly to the public. These advertisements must comply with the Code and other advertising requirements set out in the Act and Regulations.

As foreshadowed in the 2016 advertising consultation (*Consultation: The Regulatory Framework for Advertising Therapeutic Goods - November 2016*), the Code will be redrafted to:

- provide for more objective tests to determine breaches of the Code, given the anticipated introduction of strict liability offences (Recommendation 58 of the Expert Panel Review of Medicines and Medical Devices Regulation)
- address the inconsistencies between medicines and medical devices (where appropriate) in accordance with Review Recommendation 54; and
- incorporate other amendments that have been discussed with stakeholders in recent years but have been on hold while the advertising framework was under review.

The Code also contains provisions for the advertising of medicines containing Schedule 3 substances, when included in Appendix H of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). Following public consultation in April 2017 on the *Scheduling Policy Framework and Advertising of Pharmacist-only medicines (Schedule 3 substances)*, there was strong support for permitting the direct to consumer advertising of a wider range of Schedule 3 substances, provided there were certain additional controls. A proposed framework, including specific provisions proposed to be included in the Code to underpin advertising of S3 medicines to the public, is included in this paper.

2. Review recommendations and the Government's response

The Review advertising recommendations and the Government's response are relevant to the redrafting of the Code:

1. Recommendation Fifty Two

The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the [TGA] under a legislative framework which includes an advertising code.

The Australian Government, in accepting Review Recommendation Fifty-Two, noted that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.

2. Recommendation Fifty Four

The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.

The Australian Government, in accepting Review Recommendation Fifty-Four, noted that increasing the consistency of approach could help reduce complexity for advertisers. It also noted that the difference between medicines and medical devices means that consistency may not be appropriate in particular circumstances

Commented [A1]: The same overarching principles should apply for both medicines and medical devices

3. Recommendation Fifty-Five

The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

Commented [A2]:

Commented [A3]: The advertising framework can be either co-regulatory or self-regulatory. Presently, a co-regulatory framework applies. Some clarity is required on what is meant by "a more self-regulatory" framework, and what additional incentives (other than enhanced sanctions & penalties) will be put in place for industry to self-regulate, given that it will be impossible for the TGA to act upon each and every breach of the advertising framework and some in the industry will try to test the limits of any new framework.

The Australian Government, in accepting Review Recommendation Fifty-Five, noted that the acceptance of Recommendations Fifty-Seven (enforcement powers) and Fifty-Eight (sponsor education) is critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

Commented [A4]: This will come at the cost of overall compliance and there should be some incentives for sponsors to comply

4. Recommendation Fifty-Six

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. The Government should consider the following options:

A. establishing the function within the NRA [.e. the Therapeutic Goods Administration]or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or

B. calling for tenders from external organisations to undertake the function.

The Australian Government, in accepting Review Recommendation Fifty-Six, noted that a single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers. To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process.

Commented [A5]: ASMI looks forwards to participating in stakeholder consultations

Following the 2016 advertising consultation, the Government decided to make the TGA the single body responsible for handling of complaints about the advertising of therapeutic goods to the public.

5. Recommendation Fifty Seven

The Panel recommends that, further to Recommendation Twenty Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

The Australian Government, in accepting Review Recommendation Fifty-Seven, noted that broadening enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements, and deter inappropriate and misleading advertising of products.

Commented [A6]: (i) Enhanced sanctions and penalties will improve compliance only if there is a will to apply them. If the probability of regulatory action to enforce compliance is seen to be low, risk taking behaviour will continue (maybe even increase with the removal of pre-approvals) and compliance will be difficult to achieve. (ii) The process of applying sanctions and penalties must be fair and transparent. Confidence in the application of sanctions and penalties will not be achieved if, for example, a particular advertiser is found to be in breach of the Code and has sanctions applied, whereas other advertisers are making similar or stronger claims with no regulatory action. (iii) The framework for achieving compliance must not be based solely on sanctions and penalties. The existence of sanctions and penalties does not on its own lead to compliance. (iv) ASMI questions whether the TGA will have the resources and ability to apply sanctions and penalties for continued "low level" breaches - ones that may not necessarily be considered serious enough to attract sanctions and penalties, however these continued misrepresentations will have an impact on consumers and competitors. There must be an environment created where advertisers voluntarily comply and develop a culture of compliance.

6. Recommendation Fifty Eight

The Panel recommends that the National Regulatory Authority facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.

The Australian Government, in accepting Recommendation Fifty-Eight, noted that developing sponsor education programmes to assist sponsors and advertisers in understanding their obligations will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of Recommendation Fifty-Five).

In addition the Review made two recommendations regarding the advertising of Schedule 3 substances (Pharmacist-only medicines).

7. Recommendation Twelve

The Panel recommends that the Schedule 3 Advertising Guidelines be reviewed, in consultation with State and Territory Governments, and in concert with the review of the Scheduling Policy Framework, to:

1. Provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substances for inclusion on Appendix H of the Poisons Standard; and
2. Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance on Appendix H, so as to streamline these processes and reduce duplication.

The Australian Government, in accepting Recommendations Eleven and Twelve, noted that the Australian Health Ministers Advisory Council (AHMAC) has overall policy responsibility for the *Scheduling Policy Framework*, and therefore would need to consider any proposed changes.

8. Recommendation Fifty Three

The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the Poisons Standard continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

The Australian Government, in accepting Recommendation Fifty-Three, noted that the issue of advertising of Schedule 3 (Pharmacist only) medicinal substances will be considered as part of a review of the *Scheduling Policy Framework* (Recommendations Eleven and Twelve).

See the complete Review recommendations and the Government response for further details.

Commented [A7]: Should there also be some similar restrictions on advertising of particular devices i.e. a particular class of device or those requiring medical or surgical intervention? The concern applies particularly for device advertisements that channel people directly to medical practitioners that will use them, thereby by-passing the standard GP to specialist referral pathway.

3. Background

3.1. The Advertising Code

The last major update of the Code was completed in 2007. The Code was last remade and registered in the Federal Register of Legislation on 13 November 2015, to ensure its continued operation while the Review was ongoing[1]. For this reason, the Code was remade with minimal changes necessary to correct inaccuracies and/or out of date information as well as ensuring consistency of the Code with the Act and Regulations at that time.

Since 2007 there has been significant **broadening of the types of therapeutic goods** being promoted and sold directly to the public. These have included:

- genetic tests for diseases and for prediction of patient metabolism of /responses to medicines,
- the range and presentation of complementary medicines,
- point of sale in-vitro diagnostic devices (IVDs), and
- certain types of surgically implantable devices for a range of uses.

Similarly, the **methods and media used for promotion have expanded** beyond the traditional mainstream media to include:

- social media;
- embedded advertising in a variety of entertainment streaming media and platforms;
- product and sponsor websites;
- mobile platforms that can deliver personalised advertising; and
- "viewer aware" electronic bill boards and in store advertising.

The updated Code proposed for consultation subsequent to our receipt of feedback on this paper will need to remain relevant in this highly dynamic environment (in particular evolving online media platforms), while at the same time holding all types of therapeutic goods advertising to the public to the same standards

Commented [A8]: Consider also some treatments that are marketed for various serious medical conditions e.g. stem cell treatments for serious medical conditions, some life-threatening

Commented [A9]: TGA must also give some consideration to HCP advertising, which for OTCs and CMs is directed to pharmacists, naturopaths etc. Not all sponsors are members of industry associations and for sponsors who are not, there is no complaints mechanism in place – and this is a significant gap in coverage. We question why advertising to doctors is covered through universal application of the MA code but advertising to pharmacists, naturopaths, GPs, allied health professionals is not covered for OTCs and CMs.

[1] The Therapeutic Goods Advertising Code 2007 would have stopped operating (sunset under the *Legislative Instruments Act 2003*) on 1 April 2017 if no action was taken.

Changes to the Code are also required to improve clarity and objectivity of provisions due to **proposed changes to the advertising sanctions and penalties regime** (Review Recommendation 57), and in relation to Review Recommendation 54 to improve consistency between medicines and medical devices. Subject to the Government decision on its preferred option, a range of potential changes to the Code will be considered in relation to the advertising of pharmacist-only (Schedule 3) medicines to the public.

The Code will also be required to be **consistent with the proposed complementary medicine reforms that may impact on advertising** such as the permitted indications list (Review recommendation 38) and the new "Assessed Listed Medicine" pathway (Review recommendation 39) for sponsors of Listed medicines who can substantiate higher level product claims than those on the permitted indications list, and provide such evidence of product efficacy to the TGA for pre-market review. Required revisions to the Code may also include changes consequent to allowing certain complementary (and potentially OTC) medicine products to include a "claimer" of efficacy on their labels and promotional materials, consistent with the Government's acceptance of recommendation 45 of the MMDR.

Commented [A10]: ASMI has concerns about the possible introduction of a "claimer". This strongly implies TGA endorsement, a breach of the current advertising code. If introduced, there must be a level playing field and it should be able to be applied to all registered non-prescription medicines.

Further, the Therapeutic Goods Advertising Code Council (the Council)[2] has reviewed various aspects of the Therapeutic Goods Advertising Code 2007 and made a number of recommendations to enhance and clarify several provisions. These proposed changes were kept on hold until the Government's responses to the Review recommendations became available. We have also become aware of other inconsistencies and regulatory issues with the Code over this same period.

Commented [A11]: ASMI is disappointed that since the introduction of the Therapeutic Goods Advertising Code, there have been no significant updates to the Code despite these inconsistencies and regulatory issues having been brought to the attention of the TGA.

3.2. Schedule 3 Advertising guidelines

The *Guidelines for brand advertising of substances included in Schedule 3 of the Poisons Standard* were written in 2000 and have not been updated since that time. For example, the document includes references to multiple committees and processes that no longer exist.

Furthermore, the consideration of substances for inclusion in Appendix H of the Poisons Standard appears to build on a default view that Schedule 3 substances should not be advertised unless there are exceptional public health benefits in doing so. In their discussion in the MMDR Report, the Expert Panel referred to the advertising of pharmacist-only medicines as [effectively] being banned in Australia, and that this was out of step with other comparable countries.

Feedback from the *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)*, showed that there was **support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of these substances**. In most cases, this support was conditional on the expectation that there would be specific requirements for these advertisements to ensure that consumers were aware that pharmacist advice and instructions on use of the medicine were required, and that certain Schedule 3 substances would not be appropriate for DTC advertising.

Commented [A12]: If that is the case, the proposed changes are minimal and not reflective of this broad level of support. Effectively, there are no changes proposed to the regulatory framework and guidelines; there is only increased discretion given to the Delegate.

One proposed approach for consultation (see Section 6) captures these expectations, while utilising a mechanism that currently exists for Schedule 3 substances to allow for a smooth reform transition. It is anticipated that the general advertising requirements as set out in the Code will continue to apply to advertisements for Schedule 3 medicines, but with additional specific requirements to inform consumers, to manage the higher risks around these substances,

[2] A statutory committee established under Regulation 42A to advise the Minister on matters relating to the advertising of therapeutic goods (See Regulation 42B).

but at the same time to recognise that they have been determined suitable for access without a prescription.

4. Proposed Code changes

4.1. Changes to support effective sanctions and enforcement of advertising requirements

It would be of mutual benefit to advertisers and regulatory decision makers to have clearer and more detailed objective requirements applying to advertisements about therapeutic goods directed to the public at large. The proposed enhanced enforcement and sanctions regime applying to advertising will provide a foundation to encourage compliance. This will only be effective if the provisions that set out requirements and details regarding non-compliance under the Code are clear and that any subjectivity in their interpretation is minimised. It is therefore proposed that changes be made to the Code include removing, or minimising subjectivity in the interpretation and implementation of the specific advertising provisions set out in the Code

Commented [A13]: The Code must be able to be applied to continually evolving media. A principles-based Code has the advantage of being able to be applied to all forms of creative advertising that may be designed to exploit gaps in any "detailed objective requirements".

The proposed Code changes are of particular importance given the Government's acceptance of Review recommendations:

- Fifty-Five - "the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime"; and
- Fifty-Eight – "...developing sponsor education programmes to assist sponsors and advertisers in understanding their obligations...".

Commented [A14]: Is a "more self-regulatory regime" the same as complete self-regulation that will occur following removal of pre-approvals.

Introduction of enhanced compliance and enforcement powers for non- compliant advertising in conjunction with a more objective Code and centralisation of the management of advertising complaints with the TGA are part of a wider system measures being rolled out to improve compliance with the therapeutic goods advertising legislation. These measures also include a formal advertising compliance education program for sponsors and advertisers to provide them with a range of information and tools to assist them to remain compliant with the advertising requirements.

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

Commented [A15]: A Principles based code can apply to all advertising and takes context into account. In minimising subjectivity and becoming more prescriptive, advertisers may be able to circumvent any prescriptive requirements.
Having principles based provisions in the Code also takes into account the target audience, impact on vulnerable populations, as well as the Australian common law principle of the "reasonable consumer" view of the advertising.
By not including some principles based provision in the code, it could affect the regulator's ability to deal with matters that should be interpreted or are implied in advertising.

4.2. Core objectives for the new Code

A new Code would be required to satisfy four core objectives:

1. **Advertisements must comply with the *Therapeutic Goods Act 1989*, regulations made under this Act, and the *Therapeutic Goods Advertising Code***

Commented [A16]: The proposed amendments to the Act uses the term "advertising" rather than "advertisement". The terminology used in the Code should be consistent with that of the Act.

Part 5.1 of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* specify requirements and prohibitions applying to advertisements to the public about therapeutic goods that must be complied with by advertisers and sponsors of therapeutic goods. Other sections in the Act also **prohibit particular promotional behaviours** by any person (e.g. use of indications

or purposes for products not included on the ARTG). Similarly, the Code specifies requirements in relation to the content, statements, claims and representations about therapeutic goods.

2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG

Any representation (any written, pictorial or other descriptive matter) or claim (whether therapeutic or not) in the advertisement about therapeutic goods must be **truthful, balanced, valid and must be consistent with the indications (medicine) or intended purpose** (medical device) accepted in relation to the ARTG.

The intended purpose in a medical device inclusion can be very broad, as it may cover a range of medical devices in a grouped inclusion ('kind of medical device'). However, any representation made for a medical device must still be consistent with the intended purpose accepted in relation to the particular medical device's inclusion in the ARTG, and as detailed in its labelling and instructions for use. The Code may need to differentiate between medicines and medical devices in setting out these requirements.

Specifically advertisements **must not** directly or by implication, omission, ambiguity, exaggerated claim or comparison, **mislead or deceive, or be likely to mislead or deceive,** or abuse the trust or exploit the lack of knowledge, or exploit the superstitious or, without justifiable reason, play on fear or cause distress.

Advertisements must not contain any matter that is likely to **lead a person to believe that they are suffering from a serious ailment or that harmful consequences** may result from a therapeutic good **not** being used.

In addition, an advertisement (including a product label) **must not contain any claim, statement or implication that:**

- the therapeutic good is safe or that its use cannot cause harm; or
- that it has no side effect/s or risks associated with its use; or
- that the good is effective in all cases or conditions; or
- the product is infallible, unfailing, magical or miraculous, or that it is a certain, guaranteed or sure cure; or
- it is effective for specific demographic groups of patient (particularly where this may be a vulnerable group) without detailing the supporting evidence.

Advertisements **must contain all mandatory and applicable information** to provide consumers relevant information that encourages responsible use and promotes safe use of the therapeutic good. Mandatory information, (e.g. requirements to include contraindications and warning statements) will be listed in the new Code. In addition, some advertisements for medicines must contain additional statements based on the scheduling classification of the substance/s in the medicine under the current Poisons Standard

As provided for under the current (2015) Code, certain categories of therapeutic goods such as analgesics, vitamins and weight loss or management products will be subject to **specific warning information** and other requirements that need to be prominently displayed or communicated in the advertisement including the product label. Depending of the decision of government around possible changes to the advertising of Schedule 3 medicines, these provisions may need to be extended to include certain categories of Schedule 3 medicines.

3. All claims used in advertisements for therapeutic goods must be substantiated

Commented [A17]: ASMI questions the proposed requirement for non-therapeutic claims to be consistent with the ARTG indications. Non-therapeutic claims are not assessed by the TGA and can include statements such as "number 1 selling" "pleasant flavour" etc which are unrelated to the ARTG indications.
ASMI believes that all advertising must be truthful, balanced and not misleading and that the advertised indications must be consistent with the ARTG entry.

Commented [A18]: This is confusing. All advertisements should be truthful & not misleading and consistent with the ARTG entry – how should this be different for devices? The same principles should apply.

Commented [A19]: Sunscreens, folic acid for NTDs?

Commented [A20]: Further clarity is required. Does this mean that a "suitable in pregnancy" or a children's product claim cannot be made without detailing the supportive evidence? Not sure what this means, and what these demographic groups are.

Commented [A21]: Does this mean that all advertisements (e.g. for analgesics) will require all RASML statements to be included? How can this be done e.g. in a TVC or radio ad – there are many warning statements for some products. Should this apply only when a product can be purchased online? Or does this mean US style information with each advertisement?

Commented [A22]: This should read "must have been substantiated" – as advertisers must have substantiated the claims prior to these being advertised.

Scientific information referred to in advertisements **must be presented accurately, be educationally appropriate** and written in language that can be readily understood by the audience to whom it is directed. Details of the scientific information relied upon must be publicly accessible.

The advertisement must **identify the sponsor of the scientific study** and must also detail if the sponsor of that study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement.

This requirement also covers comparative advertising of therapeutic goods. The advertising of therapeutic goods must not be disparaging must be factual, fair, and already substantiated. It must refer to the source of any scientific information and must be reflective of the body of available scientific evidence.

In relation to **testimonials**, the advertisement must be authenticated, genuine, current and typical and acknowledge any valuable consideration provided for the testimonial. The person providing the testimonial must be accurately identified and must not be an employee or related to the sponsor or the advertiser.

Certain **endorsements by health related bodies or organisations** would still be allowed, but subject to requirements to ensure they are not misleading and clearly disclose the relationship with the advertiser and basis for the endorsement.

4. **Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help**

Promotion of therapeutic goods must be consistent with current social expectations for public media and presentation of claims and content in advertisements must also be consistent with any relevant public health or safety campaigns of the Commonwealth, State or Territory governments.

An advertisement about therapeutic goods **must not encourage, or be likely to encourage inappropriate or excessive use of the goods.** An advertisement must also not unduly glamorise products or prey on the vulnerability of particular consumers.

In assessing compliance of an advertisement under this particular requirement, the following public interest criteria are to be applied:

- the advertisement must not impair the ability of a member of its audience to choose an appropriate therapeutic product to treat, manage or avoid a disease, condition, ailment or defect because of the vulnerability of the member of the audience
- an advertisement for a medicine must be consistent with Quality use of Medicines (QUM) objectives and in relation to non-prescription medicines, that the advertisement must be for a condition that is suitable for self-diagnosis or self-management and must not impair the ability of a member of its likely audience to self-diagnose and/or self-manage that condition;
- the advertisement should not encourage or result in consumers or members of the public refraining from seeking timely and appropriate professional advice about the disease or the condition as it is important to prevent negative health consequences, deterioration or progression of disease;
- the advertisement is not likely to create a false expectation in its likely audience that the product will deliver health benefits or improvements to their quality of life;

Commented [A23]: What is "scientific information"? This is an important definition.

Commented [A24]: What does "educationally appropriate" mean? Does it mean "able to be understood by the target audience"? or does it mean something more?

Commented [A25]: Does this mean a citation or a link? Does this mean that a statement such as "data on file" is not allowed? Details required of what is meant.

Commented [A26]: Where possible, because the sponsor is not always known / details not always available or there may have been changes over time. Also should state "the sponsor of any scientific study".

Commented [A27]: All aspects of the Code should apply to comparative advertising as well.

Commented [A28]: This is often contentious and difficult to define, as any sponsor of a product used in comparative advertising of another product will interpret the comparison as disparaging.

Commented [A29]: "must have been authenticated" – advertisers should have ensured that testimonials are authentic before publication.

Commented [A30]: Define "current". More than a year? More than 5 years?

Commented [A31]: Does this mean accurately identified in the advertisement? Or in the substantiating documentation held?

Commented [A32]: It's hard to understand what is allowed here. Is this referring to 4(6)(c)? Does this include HCP bodies?

Commented [A33]: Does this mean that all advertisements will now require a full declaration of side effects? As well as RASML warning statements? This is unclear

Commented [A34]: Is this a high level principle? If so, it ought to be explained and included in that section. Also, social expectations are debatable and depends on the audience, and the type of media used.

Commented [A35]: How should this section be interpreted? Does "unduly glamorise" mean no celebrity endorsements? This is a subjective requirement, open to interpretation. Advertisers will always try to present the product in the best possible light.

Commented [A36]: Why is this clause needed? This principle should apply to all consumers, irrespective of vulnerability. N.B audience vulnerability was already referred to in page 10 previously)

Commented [A37]: The current Code uses the term "unwarranted expectation" which is fairly clear

- the advertisement is not likely (alone or through repetition or together with other references) to have a negative impact on public health ~~or on persons to whom the advertisement is not directed~~); and
- in relation to medical devices:
  - the content of the advertisement is balanced and adequately sets out warnings, precautions and risks that make a particular treatment or procedure inadvisable;
  - the advertisement clearly identifies the important role of an appropriate healthcare professional and the advice that he or she provides; and
  - that the advertisement could not be construed to claim or imply that the use of the device or procedure is suitable in all cases.

Subject to the Government's final position on the advertising of pharmacist-only medicines to the public, consideration will need to be given to strengthening this section of the Code.

Advertisements must also **not discourage consumers** from taking medicines prescribed by a healthcare professional. Subject to the media of publication or broadcast of the advertisement, mandatory statements, contraindications and warning statements must be included in advertisements such as "if symptoms persist consult your healthcare professional" or the warnings included in legislative instruments made under the Act for this purpose. (e.g. in the *Medicines Advisory Statements Specification 2016*). The nature of such statements, and their duration (for broadcast media), font size (in print media) or relative prominence (e.g. in outdoor marketing) may also be specified.

In relation to **sponsorship advertisements**, it is proposed that a sponsorship advertisement must:

- clearly and primarily promote the team, individual, competition, event or activity being sponsored; and
- not contain a direct or implied claim or a sales message including any brand tag-line for a therapeutic product, other than product name, or in the case of a medical device, a purpose for use; and
- not imitate or use any part of a therapeutic product advertisement from any medium, or refer or link the advertisement from any medium.

It is also proposed that any disease awareness campaigns by sponsors of therapeutic goods, healthcare professionals, associations and other groups (e.g. Heart Foundation, Cancer Council) require that the campaign must be factual and balanced and support consumers in making informed health choices. Such campaigns must not identify a specific therapeutic good or sponsor either expressly or by implication.

Advertisements **must not offer any personal incentives** including product based contests, to pharmacy assistants, or other sales personnel employed by healthcare practitioners to recommend or supply therapeutic goods.

Similarly, any sponsorship advertisements promoting a team, individual, competition, event or activity will be subject to the advertising requirements.

The requirements proposed above are not exhaustive, and will be further specified in a draft of the Code legislative instrument that will be consulted upon publicly in the coming months.

Further, the assessment of conformity of an advertisement under the new Code should remain in terms of the probable impact upon a reasonable person to whom the advertisement is directed.

Commented [A38]: Not sure what this means. Is there a point at which repetition has a negative impact on public health?

Commented [A39]: This is difficult to demonstrate – how to measure a negative impact on public health?

Commented [A40]: Perhaps for devices, ASMI believes that there is scope for specifying certain devices that may not be suitable for advertising directly to consumers, especially since some of these products provide links to particular doctors and procedures, thus circumventing the GP referral process

Commented [A41]: The three points below are generic and apply to mall therapeutic goods, not only devices

Commented [A42]: This should state "treatment" – as not all treatments involve taking medicines

Commented [A43]: This looks as though inclusion of RASML statements will now be a requirement. Confirmation / clarity required on what these requirements will be

Commented [A44]: Assume this means that the Code will now specify prominence, but how will this capture all media?

Commented [A45]: Some clarity required on what a "sponsorship advertisement" is

Commented [A46]: i.e. the recipient

Commented [A47]: This seems to be an inconsistency between medicines and medical devices

Commented [A48]: A list is unnecessary and becomes quickly out of date.

Commented [A49]: This new requirement on disease awareness campaigns may affect prescription medicines as well. Also, "directly or by implication" – is this overly strict?

Commented [A50]: Sponsorship requirements already are covered in the section above; all advertisements are subject to the requirements of the Code

There are no proposed changes to the requirements in relation to professional recommendations.

Commented [A51]: Assume that this means HCP endorsement

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.

The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).

Commented [A52]: While this may appear useful, this may become "regulatory creep" as the non-mandated guidelines will be enforced as law

Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

4.3. The Council recommendations

As identified in the 2016 advertising consultation, the Council has made a number of recommendations to improve the operation of the Code.

These proposed changes include:

New definitions of prohibited and restricted representation

Commented [A53]: There can be other sorts of restricted representations not covered here. For example – as has been previously raised – repeatedly used misleading claims by a particular sponsor could be deemed "restricted representations"

- The current definitions of "prohibited" and "restricted" representation, particularly in the light of new diagnostic techniques (such as those involving direct-to-consumer genetic testing), the advertising of diagnostic tests and the plan to allow enhanced efficacy claims for certain complementary medicines (Recommendation 39 of the Review refers) may be inadequate. The current restriction of prohibited claims to "treatment, cure and prevention" should be broadened to include all references to prohibited claims unless otherwise allowed in the Code.

New restricted representations

- Reference in an advertisement for a therapeutic good to any procedure (or product requiring such a procedure for its intended purpose), that can only be performed by a suitably qualified healthcare professional to become a restricted representation

Commented [A54]: Does this mean that certain procedures e.g. stem cell therapy, gastric banding devices, injectable fillers, etc. could become restricted representations?

- Reference to "obesity" either directly or indirectly to become a restricted representation within the meaning of the *Therapeutic Goods Act 1989* (the Act).
- Clarifying that the representation "prevention of skin cancer" in respect of certain sunscreens is permitted as a restricted representation.
- Clarifying that the representations "devices that are used in contraception" or "in the prevention of disease transmission" are restricted representations.
- Amending the provisions dealing with "scientific information" to ensure that:

Commented [A55]: This should have been a separate sub-heading

  - references to a specific research study in an advertisement must sufficiently identify the study as to allow consumers to access it;
  - it is educationally appropriate in language which is readily understood by the audience to whom it is directed; and

Commented [A56]: Assume that this means using language that can be easily understood by a reasonable consumer?

- it continues to identify funding source, commissioning body for the study and any relationship to the sponsor or advertiser.

Testimonials and free samples

- Testimonials in advertisements to be subject to clearer more objective conditions.
- Prohibiting offers of free samples of therapeutic goods as part of an advertisement. Exceptions would be sunscreens and class I medical devices (including for example condoms and dressings where the intended purpose does not require intervention by an appropriately qualified healthcare professional) but excluding IVDs.

While an option would be to make changes to the Code to address all of the Council's recommendations, this would also need to take into consideration comments received from stakeholders in response to the 2016 advertising consultation and the current consultation regarding proposals to redraft the Code.

4.4. Consultation comments

A number of comments were received in response to the 2016 advertising consultation regarding the proposal to redraft the Code. These comments included:

1. Support for the **development of a new Code** to remove subjectivity by revising the interpretative provisions, particularly in light of the proposed enhanced sanctions and penalties, and consideration that it is important that any 'simplification' of the process for advertising regulation is not compromised by increased uncertainty around the implementation of the Code itself;
2. The Code should **clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising** and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis; and
3. There should be accompanying **guidelines** to assist with understanding of the requirements to enable compliance to the Code

Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?

Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?

5. Price Information Code of Practice (PICOP)

Pricing is a key element of a consumer's decision to purchase. The TGA recognises the need for a mechanism to permit the price of therapeutic goods to be communicated to consumers even where the goods themselves cannot lawfully be promoted directly to consumers.

The current Code supports the communication of "price information" to consumers where that information is consistent with the "*Price Information Code of Practice - September 2006*" (PICOP). This is permitted as set out in the PICOP even where the therapeutic good cannot otherwise be promoted directly to the public (e.g. for prescription medicines). **Better underpinning of the PICOP** is proposed in developing the new Code.

Commented [A57]: These should probably be regarded separately; they are different issues that have different requirements. We query why they are described together

Commented [A58]: However some interpretive requirements are useful, to address the evolving advertising techniques and media

Commented [A59]: This is more suited to training and educational material rather than inclusion in guidelines. Will the TGA be mocking up advertisements?

Commented [A60]: Guidelines can be subsequently applied in the same way as the legislative instrument – creating "creep"

The current arrangements set out in the PICOP apply to a limited range of goods and may only be accessed by particular specified practitioners. We will be considering the mechanism for assisting with price communication and whether the PICOP is appropriate for this purpose and the detailed requirements currently set out in the PICOP.

Do you consider that the PICOP should:

- remain in the new Code, or
- be established as a separate legislative instrument under the *Therapeutic Goods Act* 1989, or
- are there other mechanisms for managing compliance with the PICOP?

Commented [A61]: An Appendix to the Code may be a suitable way of achieving this

6. An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines

6.1. Overview

As outlined in Section 3.2 above, feedback from the *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)*, showed that there was support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of medicines containing these substances. In most cases, this support was conditional on the expectation that there would be specific requirements for these advertisements to ensure that consumers were aware that pharmacist advice and instructions on use of the medicine were required, and that certain Schedule 3 substances would not be appropriate for DTC advertising.

Based on feedback from this consultation, a proposed approach could be that Schedule 3 medicines can be advertised directly to consumers unless the Delegate determines that advertising is not appropriate for medicines containing a particular substance (or class of substances).

Existing Schedule 3 substances could be considered by a working group of jurisdictions, medical practitioners, pharmacists, consumer and industry representatives on a case-by-case basis, and advice sought as required from the Advisory Committee on Medicines Scheduling. The substances would then be included (or not included) in Appendix H following a decision by a delegate of the Secretary.

Commented [A62]: In effect, the only change is discretionary referral to the ACMS. This looks like status quo; there is no acknowledgement that S3 advertising should be the default position unless the product/substance is unsuitable as per the criteria listed below.

To ensure enforceability for substances that are permitted to be advertised, it is proposed to retain the current Appendix H mechanism of the Poisons Standard to specify those substances that *may* be advertised to the public (i.e., remains a "positive" list).

It would remain an offence to advertise any Schedule 3 medicine that is not included in Appendix H. directly to consumers.

The current Scheduling Policy Framework specifies that in making a decision on whether or not a substance should be included in Schedule 3 of the Poisons Standard, the Delegate may consider the following matters:

- The potential public health benefit;

- The likelihood of advertising of the substance leading to inappropriate patterns of medication use;
- The provisions of the Code and any prohibited and restricted representations relevant to the substance;
- Whether the application may result in advertising of goods for an indication other than those included in the Australian Register of Therapeutic Goods;
- The responsibility of pharmacists to be actively involved in the supply of [these] substance(s);
- Available Consumer Medicine Information;
- Available Risk Management Plan and application to the substance in an S3 environment;
- The level of patient education necessary to ensure safe and effective use;
- The desire of consumers to manage their own medication;
- Any other information that is relevant to the decision making.

It is not proposed that these requirements be altered

Commented [A63]: The requirement to demonstrate "public health benefit" has been difficult to interpret with respect to data requirements. There may be benefits to an individual, but is this synonymous with "public health"? This has historically been one of the most difficult factors to address because different people interpret this differently and have different ideas on what level of data are required to address this.

6.2. Product advertising requirements

Advertisements for Schedule 3 substances included in Appendix H will be subject to all general requirements as set out in the Code and the Act.

The following additional requirements are proposed for advertisements for medicines containing Schedule 3 substances:

> **"Your pharmacist *must decide* if this product is suitable for you."**

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the top of the advertisement, for broadcast media this should be the leading statement.

Commented [A64]: Does this mean the first thing that is said? i.e. before introducing the product name or health benefit/disease state?

> **"Ask your pharmacist about side effects relevant to you"**

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the bottom of the advertisement, for broadcast media this should be the ending statement.

It is proposed that a single standard phrase is to be included at the top/beginning and bottom/end of an advertisement to facilitate consumer education and standardisation of messaging. More specific requirements around statements will be consulted upon at the time of public consultation on the draft advertising code.

6.3. Substances unsuitable for inclusion in Appendix H

For some substances, it is acknowledged that direct-to-consumer (DTC) advertising would not be appropriate. It is a proposed that a working group, inclusive of a wide range of stakeholders would assess the existing list of substances included in Schedule 3. As a guide, the following categories may not be appropriate for DTC advertising:

- Injectable
- Substance for use in emergency situations

- Where safer analogues or therapeutically equivalent medicines are available
- Where there is potential for inappropriate use, abuse or diversion
- Where the substances form part of surgical procedure
- Medicine for treatment of chronic condition that requires a doctor as part of the treatment

Commented [A65]: Does this mean that a "me too" (e.g. the 2nd or third PPIs) would not be considered suitable? Or should the dot point state "safer analogues of therapeutically equivalent medicines"? (e.g. loperamide vs diphenoxylate)

6.4. Process for adding a substance to Appendix H

It is proposed that a similar process to re-scheduling, including public consultation, will be followed for consideration of Appendix H inclusion, and in parallel with the scheduling consideration

Commented [A66]: This represents no change at all

This process is consistent with the Scheduling Policy Framework, as an addition to Appendix H is an amendment to the Poisons Standard, however referral to the ACMS would be at the Delegate's discretion. Public consultation supports natural justice for applicants and also provides a mechanism to identify any potential diversion, misuse, or broader public concerns.

It is also anticipated, consistent with scheduling decisions, there will be an implementation date set so as to allow pharmacists time to undertake education and preparedness activities.

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

In particular, we would appreciate feedback on

- the specific requirements for advertisements containing Schedule 3 substances
- factors to be considered by the delegate
- restrictions on inclusion in Appendix H
- the proposed process

7. Next steps

Following review of submissions received in response to this consultation and as foreshadowed in the 2016 advertising consultation, revision of the Code will proceed in consultation with the current Council.

A further round of public consultation on the new draft Code is planned for late 2017/ early 2018. The new Code is expected to be in force before (or at the same time as) other proposed changes to the advertising framework come into effect.

The TGA proposes that further revisions to the Code will be consulted publically in accordance with the established processes for developing and amending legislative instruments.

Commented [A67]: But what processes or requirements would apply to revising the accompanying guideline?

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising Compliance Unit/RPECB	29/8/2017

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 1605
https://www.tga.gov.au

Reference/Publication #

Australian Self-Medication Industry Ltd.
ACN 607 233 116 ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Direct Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

26 July 2017

Pio Cesarin
Therapeutic Goods Administration
Department of Health
PO Box 100,
WODEN ACT 2606

By email to: [redacted]

CC: Professor John Skerritt, Deputy Secretary Health Products Regulation Group, Department of Health

Dear Pio,

Therapeutic Goods Advertising Directed to Healthcare Professionals

We refer to your advice of 6 July re the above and the TGA's recent publication on their website of information regarding advertising reforms under the heading "Simplified and improved arrangements for handling therapeutic goods advertising complaints".

As you know, ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

On 6 July, at the TGA/ASMI Liaison Meeting, you advised those present that the TGA's proposed revisions to handling therapeutic goods advertising complaints would not cover advertising directed to healthcare professionals. We note that this advice is consistent with the materials subsequently published on the TGA's website.

We wish to register with you our great disappointment that this known regulatory gap will not be remedied as part of the TGA's reforms. The failure to close this regulatory gap means that healthcare professionals will continue to be exposed to non-compliant and potentially misleading materials and that the current un-level playing field between association members and non-members will be perpetuated.

We urge you to take immediate action to address this regulatory gap.

As you would know from our previous submissions on the topic, and from submissions by other stakeholders, the current system effectively means that the only oversight of advertising directed to healthcare professionals is that provided by industry associations over their own members. For non-association members there are no relevant codes or guidelines and there are no pathways for assessing compliance or imposing sanctions.

As you would also know, a wide range of professionals are covered by the current regulatory definition (with herbalists, homeopaths and naturopaths included alongside doctors, nurses and pharmacists). Non-compliant materials directed to professionals have the potential to mislead these professionals and thereby negatively impact the quality of information passed on to consumers.

We would also like to draw to your attention the fact that comparable markets such as Canada[1], New Zealand[2,3] and the United Kingdom[4] all have regulatory systems with combined oversight of therapeutic goods advertising directed to healthcare professionals and directed to consumers.

We therefore recommend to you the following three alternatives for remedying this issue (presented in our order of preference):

1. The TGA should adopt the Working Group on Promotion of Therapeutic Products 2011 recommendation[5] that all sponsors (regardless of association membership) be required to subscribe to a nominated industry code of practice as a condition of registration or listing. This would remove what is effectively a two-tiered system where members of the industry associations are held accountable to their codes of Practice and non-members are free to promote their products without oversight or sanction. Such an arrangement is already in place for prescription medicines and there is no reason why a similar approach should not be taken for non-prescription medicines.

2. The TGA should include all advertising directed to healthcare professionals in the new complaints handling arrangements. As we identified in our 21 December 2016 response to the consultation on the Regulatory Framework for Advertising Therapeutic Goods, there needs to be a single body to receive and determine all complaints, regardless of the advertising medium, regardless of the advertiser's membership of an industry association, and regardless of the audience to whom the material is directed.

3. Should the TGA be unwilling (or unable) to assume oversight of advertising directed to healthcare professionals, this regulatory gap would need to be closed by the Australian Competition and Consumer Commission (ACCC). While this is our least preferred option, oversight provided by a generalist regulator would still be better than no oversight at all.

We remain available to discuss this matter in more detail and look forward to hearing from you as soon as possible.

We understand that a second bill to amend the *Therapeutic Goods Act* is being drafted together with the revised *Therapeutic Goods Regulations*, we would very much like to see this regulatory gap closed as part of these changes to the legislation.

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

Yours sincerely,

[redacted]

Steven Scarff
Regulatory and Legal Director

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[1] https://www.canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/policies-guidance-documents/advertising-preclearance-agencies-health-product.html [Refer to Part 3.5.1]

[2] http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part7_Advertising_of_therapeutic_products.pdf [Refer to part 5.5]

[3] http://www.asa.co.nz/complaints/our-jurisdiction/ [The ASA "will consider complaints about any advertisement in any medium."]

[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376398/Blue_Guide.pdf [Refer to section 2.1]

[5] Working Group on Promotion of Therapeutic Products, *Report to Parliamentary Secretary Catherine King* 18 March 2011.

Australian Self-Medication Industry Ltd.
ACN 607 233 116 ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Direct Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

5th May 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

(Sent via electronic submission)

Dear Sir/Madam,

Re: Consultation: The Scheduling Policy Framework and Advertising of Pharmacist-Only Medicines (Schedule 3 Substances)

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. ASMI members make up 85 per cent of the $4 billion consumer healthcare products market and employ approximately 18,000 people, with exports estimated at $1.2 billion annually.

Further information about ASMI and ASMI members is available on our website (www.asmi.com.au).

Thank you for the opportunity to provide feedback to this consultation on the Scheduling Policy Framework (SPF) and advertising of Pharmacist-Only Medicines.

ASMI has consulted with its members and the material below provides principles-based feedback from an industry perspective, on questions raised in the consultation paper that relate to the MMDR recommendations 11 and 12.

We have the following observations on the consultation and forthcoming reform process:

- Although the consultation paper sought feedback on many options for reform, there was insufficient detail and clarity on some of these proposals.
- We understand that the TGA will be collating feedback and there will be discussion on scheduling and the SPF at the AHMAC meeting. No information was provided on whether a draft SPF will be provided to stakeholders for comment following the meeting.
- ASMI believes that any updates to the SPF document should be properly consulted. The detail and implementation of any reforms is critical.
- No information has been provided on whether other information included in the SPF, such as scheduling factors, application processes & pathways, and fees will be considered for amendment – there are many elements of the SPF that have not been covered in this consultation.
- There is overlap with State & Territory legislation and other TGA legislation such as advertising. Further details on regulatory implications may require separate consideration.

ASMI welcomes further discussion on options for reform, noting that this consultation paper appears to be a first step to align on principles – with detail to follow. As key stakeholders in scheduling, noting that ASMI members submit the bulk of S4 to S3 and S2 to exempt (GSL) rescheduling applications, we believe that our members have relevant experience to share.

In order to assist the reader, this response provides a brief summary addressing the proposed policy recommendations, followed by a detailed point-by-point discussion on the policy recommendations, business improvements and ongoing improvements.

We trust that this submission is helpful and welcome the opportunity to provide further input.

Yours sincerely,

[redacted]
Quality Use of Medicines Manager

Summary

ASMI is pleased to provide comments on proposed reforms to the Scheduling Policy Framework and approaches to the regulation of advertising of Schedule 3 medicines. The comments provided are based on consultation with ASMI members, many of whom have experience with rescheduling of medicines, in particular S4 to S3 down-scheduling or "switch", as well as rescheduling from S3 or S2 to lower schedules or to exempt from scheduling.

It should be recognised that consumers benefit in several ways from "switch". The down-scheduling of medicines is a key enabler for consumers to better manage their health in consultation with pharmacists and includes faster access to medicines that provide symptom relief, assist with treatment of minor ailments or allow access to time-critical emergency products, such as emergency contraceptives and asthma relievers.

OTC medicines also provide high value to the Australian health system. Consumer research from the Macquarie University Centre for the Health Economy (MUCHE)[1] estimates that if the eight largest categories of OTC medicines were not available, there would be an estimated 58 million additional GP visits for people to obtain their medication. The cost of this would be approximately $3.86 billion per year – of which $2.5 billion would be borne by Medicare, $1.04 billion by consumers and $360 million by health insurers. This cost increases to over $10 billion per annum if the *indirect* costs of visiting a doctor (e.g. productivity losses) are taken into account.

The SPF should recognise the key healthcare and health economic benefits to rescheduling, and the scheduling framework should:

- acknowledge not only risk, but benefit;
- streamline and integrate the processes for registration and variation with scheduling decisions;
- include a mechanism for reviewing scheduling decisions;
- incentivise re-scheduling applications;
- remove the complexities introduced through the various State requirements;
- have a transparent mechanism for policy oversight;

Given the importance of switch, ASMI supports the development of a co-ordinated approach that can:

- identify target candidates for future switches;
- encourage a collaborative effort with consumers, pharmacists, GPs, and the medicines industry that enables a progressive and best-practice approach to scheduling;
- limit unnecessary red tape by introducing a streamlined end-to-end process for rescheduling and product registration;
- reduce restrictions on S3 direct-to-consumer advertising & communications to increase consumer awareness of this category, which will encourage medicines sponsors to engage in switch;

The key points of the ASMI submission are listed below, following the order of the consultation paper:

Governance

Policy Recommendation 1: Split the SPF into a policy document and guidance; and
Policy Recommendation 2: Establish an informal working group to provide advice

ASMI has the following comments:

- Further clarity is needed on mechanisms for policy oversight of the SPF.
- Application data requirements and application formatting requirements should be reviewed as part of the exercise of separating policy from guidance. Clearer data requirements are needed, as well as consideration of a mechanism for pre-submission meetings to provide support and direction to companies interested in submitting innovative rescheduling applications.

[1] Macquarie University Centre for the Health Economy: *The Value of OTC Medicines in Australia*, March 2014.

- The role and membership of the proposed Working Group should be clarified; it is unclear from the consultation paper whether the role of the group will be to advise on policy matters or whether the group will provide advice on amendments to the SUSMP or the SPF.
- Will the role of the Working Group extend to proactive consideration of candidate substances for rescheduling – as suggested elsewhere in the consultation?
- Further detail and consultation is needed on the terms of reference, membership, role and functions of the Working Group and whether it should be a formal advisory body rather than an informal group. *(For details, see page 8)*

Decision-making principles

Ongoing Improvements 1: Applicants presenting to the advisory committees

ASMI supports this initiative, however further detail should be provided on implementation and procedures; Further consultation with stakeholders is required. Presentations should be organised in a way that does not interfere with the efficient running of meetings or the number of agenda items that can be considered at each meeting.

Business Improvement Measures 1: Structure and content of the committees' advice

ASMI supports a clearer explanation of the cascading principle and how it is applied, to be included in the SPF.

ASMI also supports improvements to the structure and content of the advisory committee's advice. No detail has been provided on any proposals to change the wording of the scheduling factors as part of this consultation. The wording of these factors should be the subject of public consultation prior to any update of the SPF. ASMI believes that this should be considered as there is scope for improvement – there is currently undue emphasis on risk, insufficient attention to risk mitigation and ambiguity in the wording. *(For details, see page 10)*

Transparency

Business Improvement Measures 2: Public summary of the scheduling submission and other communication processes

ASMI supports the proposed requirement for inclusion of a brief summary of scheduling applications for public dissemination. The default information should be a brief tabulation, as published for the invitations for public comment for the March 2017 meetings of the ACMS, and joint ACMS-ACCS.

ASMI does not agree that the entire application should be published; this is unnecessary and inefficient. The recent changes to the invitation for public comment provide an appropriate level of detail for interested stakeholders.

ASMI supports the development of improved communication and tracking but input from stakeholders who have experience in lodging applications is needed to ensure it meets its intended purpose.

The TGA should be transparent about whether any of the proposed reforms will have cost implications for applicants. *(For details, see page 11)*

Risk-benefit value tree

Business Improvement Measures 3: Greater emphasis on benefits as well as risks

ASMI supports the inclusion of the Brass model of the benefit/risk value tree as part of the guidelines for re-scheduling. The use of the Brass value tree provides a structured and transparent methodology for evaluating the relevant benefits and risks, thereby enabling the regulator to make a more fully informed judgement of the various domains.

The provision of a benefit/risk value tree as part of an application for rescheduling should be optional; it should be developed by the applicant. If applicants prefer to provide assessment of benefit vs risk in other formats, this ought to be an acceptable option as well.

ASMI believes that this approach is in line with the MMDR recommendations 11 and 12.

Ongoing Improvements 2: Improved guidance on risk and benefit
Although improved guidance is welcome, there should be no expectation that the regulator performs a separate value-tree assessment. The regulator's role should be to evaluate each individual application taking into account risks vs benefits and the relevant scheduling factors as presented by the applicant. Regarding evidence of benefits, it should be acknowledged that evidence of benefit can be based on data of different types. (*For details, see page 13)*

Interim decisions

Policy Recommendation 3: Public consultation on interim decisions
ASMI supports amendments to the public consultation on interim decisions that would allow stakeholders to make comments regardless of whether initial comments were made on the scheduling proposal invitation for public comment (initial round).

ASMI supports provision of a plain language summary with the interim decision, conditional on it being included in addition to the comprehensive reasons for decision. Scheduling has significant commercial impact and ASMI does not support any changes that result in less detailed information being provided.

ASMI has concerns around the proposal for extending the timeframes for submission, noting that this should be done only on a case by case basis for scheduling proposals that are highly contentious, impact many sponsors and are likely to result in a large number of submissions. Routinely extending timeframes could be counter-productive, delaying implementation of scheduling changes.

Business Improvement Measure 4: Guidance on legal nature of scheduling and scheduling decisions
ASMI supports amendments to the Therapeutic Goods Act to allow decisions made under Part 6-3 to be reviewable. *(For details, see page 15)*

Timing of scheduling decisions

Business Improvement Measures 5 - Decision transparency and information sharing.
The TGA should address more clearly the available options for timing of scheduling decisions in relation to medicines, to provide certainty of timeframes and assist sponsors in meeting switch effective dates. *(For details, see page 16)*

Proactive consideration of candidate substances for rescheduling

Ongoing Improvements 3 – Proactive identification of substances for rescheduling
ASMI supports the establishment of a working party (WP) that can periodically undertake a proactive review of substances to identify potential candidates for rescheduling. The WP should have a collaborative approach and have clear and transparent terms of reference, procedures and processes. Stakeholders and potential applicants should have confidence in the WP recommendations.

The WP should also be structured so that it can periodically provide advice on the broader Scheduling Policy Framework, to help ensure a progressive and best practice scheduling policy. *(For details, see page 17)*

Tools for better 'management' of rescheduled medicinal substances

Policy Recommendation 5: New controls for certain medicines that have been down-scheduled to pharmacist only classification (S3)
ASMI believes that the above proposal has merit and could help formalise controls for newly rescheduled medicines – such as pharmacists' protocols, record keeping or other activities. However, issues around possible duplication or interface with existing pharmacist professional practice activities, and processes for

updates or modifications to the proposed Appendix require further consideration. Any proposals should be fully consulted with the relevant stakeholders, including industry, healthcare professionals and the State and Territory jurisdictions. *(For details, see page 18*)

Parallel processes and other incentives (medicines)

Ongoing improvements 4 – Down-scheduling - alignment with OTC product submission and incentives.
ASMI strongly supports the development and implementation of an integrated, concurrent, streamlined end-to-end process for rescheduling and product registration. The current sequential system is lengthy and results in duplication of resources and inefficiency.

An integrated, concurrent rescheduling and product registration application process could accommodate the provision of mechanisms that support applicants – such as pre-submission meetings and advice.

Incentives for rescheduling - ASMI strongly supports the inclusion of incentives for rescheduling in the SPF. This is not inconsistent with health policy and provides fairness and recognition for the investment of the innovator company. This may be done in a similar way to the UK or the US, providing a period of exclusivity (preferably 3 years as per the US model) for innovative switches where specific clinical data was generated to support the switch application. Alternative means of market exclusivity could also be explored. Additional consultation is needed. *(For details, see page 19)*

Improving the clarity of the SPF

Business Improvement Measures 6 - Improving the clarity of the SPF
ASMI advises that there is insufficient detail provided on the proposed improvement measures in the consultation paper. While some of the proposals appear to have merit, further detail is needed on how the proposals will be implemented.

For some measures, such as rescheduling of second (and subsequent) in class, there are significant concerns. This proposal should only be considered when adequate provisions for the protection of the "first in class" or innovator are in operation otherwise this will prove to be a significant disincentive for sponsors to submit, knowing that the second and subsequent in class will be rescheduled with little or no effort on the part of these subsequent entrants. Subsequent entrants will receive a "free ride" on the basis of the investment of the first. *(For details, see page 21)*

Advertising of Schedule 3 medicines

ASMI proposes that the current restrictions on advertising and communication on Schedule 3 medicines should be lifted, in the interests of raising consumer awareness of well-established efficacious products which are available with pharmacists' advice. The current arrangements disempower consumers because they are "not allowed to know" about certain S3 medicines. There is a fundamental difference between level of access (scheduling) and communication (advertising) and the considerations for each are different.

With respect to these advertising restrictions, Australia is out of step with countries that have a similar regulatory framework, such as the UK and New Zealand and Canada.

ASMI supports a default regulatory position permitting Schedule 3 Medicines to be advertised, together with the following protections that are elements of the ASMI proposed communication model for S3 medicines:

- Provision for exceptions, on a case-by-case basis, where there is a strong case that that direct-to-consumer advertising would not be in the public interest.
- A structured communication format containing the following 3 components:
    - Information about the condition:
    - Mandatory intervention by a pharmacist: this component of the communication aims to promote and reinforce the professional role of the pharmacist.

    - Allowing branded product information: the brand awareness component is a critical element to make the model commercially viable, but it takes a secondary role to the more important educational aspects of the communication.
    - To ensure legal underpinning and universal compliance it is proposed that these three components be mandated in a new section in the Therapeutic Goods Advertising Code (TGAC).
- As included in the ASMI model, support for pharmacists and pharmacy staff is necessary to ensure that staff are fully prepared prior to the commencement of direct-to-consumer communications of S3 medicines. As a minimum this should include:
    - Comprehensive protocols, algorithms or guidelines and product information.
    - Counselling skills development to address the issue of consumers demanding a product and/or resisting pharmacist counselling (noting that this exists regardless of advertising).

ASMI looks forward to further discussions on advertising of S3 medicines. We would appreciate the opportunity to be involved in further discussions on the details that are yet to be consulted, such as possible legislative and regulatory changes, processes and pathways. *(For details, see page 23)*

Issues for Stakeholder Comment

Governance

Policy Recommendation 1 - Split the SPF into a policy document and a guidance handbook. These documents would also incorporate changes to the current SPF that are agreed following the current consultation.
Policy Recommendation 2 - Establish an informal working group to provide advice on possible amendments to the SUSMP

ASMI agrees that since the SPF was released in July 2010, there has been a lack of policy oversight. The SPF has undergone minimal review and amendment, other than to reflect the outcomes of the recently completed *Poisons Control Project*[2]. This has contributed to what is referred to in the consultation document as a "policy void" and Australia's lagging behind comparable overseas regulators such as New Zealand and the UK in the area of "switch" or re-scheduling from prescription to OTC.

In terms of policy, there is scope to make the operation of scheduling arrangements more efficient and effective, and this can be done by addressing the following key issues as part of Australia's scheduling policy. These include:

- A clear and transparent mechanism for ongoing policy oversight
- A multi-stakeholder working party that can provide advice to AHMAC on scheduling policy and propose amendments to the SPF so that it remains relevant, up-to-date and consistent with overall health policy
- The SPF should be consistent with the overall health policy and the National Medicines Policy. The notion of access to medicines is a central plank of Australia's National Medicines Policy which emphasises the need for "timely access to the medicines that Australians need, at a cost individuals and the community can afford".
- Recognition that pharmacists are a vastly under-utilised resource and that they are well placed to play a greater part in the delivery of primary healthcare
- A clear articulation of the benefits of switch – as part of the benefits and risk assessment
- Streamlined business processes that link TGA processes and scheduling processes
- Appropriate intellectual property protection provisions for regulatory data required to support switch applications

<u>Policy Recommendation 1</u>

ASMI supports the proposed policy recommendation to split the SPF into a policy section and a guidance handbook for applicants, separating out application requirements and supplementary guidance from scheduling policy. Separation of guidance from policy may allow greater flexibility for periodic review and update.

In separating out policy from application requirements, an opportunity is presented to closely examine the application format and data requirements themselves.

In comparison with the application requirements of New Zealand and the UK, the Australian requirements are more complex and repetitive, due to the need for an overview, the body of evidence data, as well as a summary and an additional summary of supporting data.

[2] The Poisons Control Project was undertaken as a result of recommendation 5.2 from the 2010 Product Commission Report on Chemicals and Plastics. Amendments to the SPF reflected one of the projects agreed outcomes which resulted in the transfer of all substances contained in Appendix C of the SUSMP to a new Schedule 10.

ASMI questions whether all of the data described above ought to be required for a decision on the appropriate level of access for a medicine. ASMI recommends that consideration be given to examining the appropriate level of data that can be reasonably expected to enable provision of sound advice and decision-making by the Advisory Committees and the decision-maker respectively, using simpler and more streamlined guidance that eliminates duplication.

As discussed in the section on parallel processes, consideration should be given to developing a mechanism for face to face pre-submission meetings to provide non-binding advice on requirements for innovative rescheduling applications. The PBAC and TGA prescription medicines evaluation processes allow face to face meetings and these enhance dialogue and understanding and will facilitate preparation of higher quality applications.

Policy Recommendation 2

Policy Recommendation 2 refers to the establishment of "*an informal working group to provide advice on possible amendments to the SUSMP".*

ASMI notes that amendments to the SUSMP are made usually made by the Delegate following advice from the ACMS and ACCS.

The consultation paper refers elsewhere to this proposed group being responsible for proactive consideration of candidate substances for rescheduling (see Ongoing Improvements 3, page 18). ASMI is supportive of this role, however we feel that the group that is established should have a broader role that includes:

- Policy development, with the involvement of all key stakeholders – government, consumers, healthcare professionals, industry and educators
- Development of a list of health priorities or disease categories to target and medicines to manage these
- Reviewing regulatory processes that facilitate the rescheduling of medicines without compromising public health and safety
- Making recommendations for providing community pharmacists with the skills and tools to manage various acute and chronic conditions in collaboration with GPs

Further clarity on this proposal is needed. ASMI queries whether the Working Group referred to as part of this recommendation ought to be formalised, what its membership should be to provide a broad range of views, whether it should provide advice on possible amendments to the SPF as well as candidate substances for rescheduling, and whether it addresses the issue of ongoing policy oversight. There is ambiguity in the wording of this policy recommendation.

We also note the policy void left after the NCCTG was disbanded is the lack of clarity of responsibility for maintaining the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*[3].

Further consultation is needed.

Policy oversight

There is a need for a suitable mechanism for scheduling policy oversight to ensure the ongoing development and maintenance of the SPF and other relevant guidelines. Lack of policy oversight has been a recurring theme from past consultations.

ASMI is concerned that neither Policy Recommendation 1 nor Policy Recommendation 2 refer expressly to any ongoing formal mechanism that could deliver a suitable mechanism for ongoing policy oversight.

[3] https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8

In Recommendation 2, the informal Working Group is referred to as a group that can "periodically advise on updates to the SUSMP", conflating its purpose with that of the Delegate. It does not refer to policy oversight of the SPF. The ambiguity is continued when referring to "Ongoing Improvements 3 – Proactive identification of substances for rescheduling" where one of the functions of this informal group is to make non-binding recommendations on substances that ought to be re-scheduled.

Other than that, while the consultation paper refers to improvement in governance as a general principle it does not provide sufficient detail on the mechanism for improved governance and the purpose and frame of reference for the proposed informal working group(s). While the consultation refers to the need for policy oversight of the SPF, the policy recommendations outlined above refer to the working group providing advice on possible amendments to the SUSMP. The SUSMP is regularly updated following scheduling decisions and decisions arising from AHMAC, however a critical point is that the consultation document makes no recommendations for policy oversight of the SPF, which is not considered regularly at AHMAC meetings.

Decision-making principles

Ongoing Improvements 1 - Applicants presenting to the advisory committees
A pilot exercise to assess the value of applicants presenting directly to the advisory committees should be undertaken.

ASMI supports the proposal to allow applicants to present directly to the advisory committees, in a similar way that is currently allowed at the Medicines Classification Committee meetings in New Zealand.

The ability to present at the advisory committee meetings provides an improvement in transparency and gives applicants confidence that the most important aspects of a scheduling application have been presented to their satisfaction.

ASMI believes that this should be able to be achieved in a manner that does not interfere with the efficiency of the meetings. It would be counter-productive if presentations caused delays and reduced the number of applications that could be considered at each meeting. It should be done in a way that does not impose additional burden or resource constraints on the Scheduling Secretariat, the sponsors or the advisory committees. The following guidelines could be considered as a way of streamlining the process:

- Optional, not mandatory
- Should only be used for more complex, S4 to S3 rescheduling applications
- Applicants should nominate whether they will present at the time of application, in order to assist the secretariat in planning meetings
- Reasonable time limitations should apply, and possible limits on number of presenters (e.g. no more than 2)
- Applicants should advise beforehand the type of information that can be presented and should be prepared to answer questions if needed

A pilot exercise to assess the value of presentations seems like a reasonable approach. ASMI is of the view that the details of any pilot exercise, policy around meeting presentations and procedures that should be followed by further consultation.

Guidelines on presentations to the committee should be incorporated into the application guidelines to provide clear direction to applicants.

Business Improvement Measures 1 - Structure and content of the committee's advice
a. A clearer explanation of the cascading principle and how it is applied should be included in the SPF.
b. The structure and the content of the Committee's advice, and the delegate's reasons should be revised to ensure they are meeting the needs of stakeholders. Particular consideration should be given to explaining how the advice and reasons relate to the scheduling factors, and how the information that applicants have submitted has been reflected in the decision-making process.

ASMI supports the use of the cascading principle in determining the appropriateness of schedules however it is not always clear how it is applied. To applicants, decisions can sometimes appear to be arbitrary rather than based on specific criteria.

In addition, the wording of the scheduling factors is equally if not more important as it is the scheduling factors that ultimately determine the scheduling of a substance. No mention has been made in the consultation around revision of the scheduling factors, even though it was industry's understanding that the wording of these factors would be the subject of consultation prior to any update of the SPF. ASMI believes that this should be considered as there is scope for improvement – there is currently undue emphasis on risk, insufficient attention to risk mitigation and ambiguity in the wording. Possible amendments to the wording of the scheduling factors was raised during the stakeholder consultations held in November 2016, however this issue has not been addressed as part of this consultation paper.

ASMI supports the proposed measure of including a clearer explanation of the cascading principle in the SPF. This will be beneficial to applicants as well as other stakeholders. Any revision to the scheduling factors should be transparent and discussed with stakeholders.

ASMI agrees that the information provided in the Interim Decisions and the Final Decisions should clearly relate to the scheduling factors, how the cascading principle was applied and the factors that the Advisory Committees and Delegate have taken into consideration – i.e. the risks and benefits as required in section 52E. This will provide a clearer understanding and confidence in the decisions made.

Transparency

Business Improvement Measures 2 – Public summary of the scheduling submission and other communication processes
a. A summary for public dissemination should be provided by scheduling applicants, and this would be published as part of the public consultation process. This could be included in the application template. If an appropriate summary is not provided by the applicant, the default option could be that the entire (de-identified) application would be published for public consultation.
b. A mechanism should be developed to alert stakeholders of items

ASMI agrees with the consultation's statement that the extent of information available on scheduling applications as part of the public comment process is generally inadequate for stakeholders to make meaningful input. Insufficient clarity on the agenda items can lead stakeholders to misinterpret a scheduling proposal and can cause time and resources to be tied up in responding to scheduling proposals that may in actual fact be irrelevant for them. An example of this is the agenda item for the October 2012 meeting of the joint ACMS/ACCS which referred to a proposal to include thymol in schedule 6.[4] If the agenda had specified that the proposal pertained to use by beekeepers, it would have been very useful for stakeholders and would have saved time and effort preparing irrelevant submissions on use of thymol in mouthwashes.

[4] https://www.tga.gov.au/consultation-invitation/invitation-public-comment-acms-and-accs-meetings-october-2012

ASMI acknowledges that the TGA has already made some changes to the format of the invitation for public comment notices for the March 2017 meetings of the ACMS and joint ACMS-ACCS[5], where a brief summary of the scheduling proposal for each application was provided, together with the CAS number for chemicals, a summary of the scheduling proposal and potential uses of the substances provided in tabular format. ASMI supports this initiative and members generally have found it useful.

ASMI does not object to the proposal for applicants to provide an appropriate summary of their application for publication purposes and would support this being included in the requirements. However, the default position should be publication of a summary such as the one provided in the invitations for public comment to the March 2017 advisory committee meetings, rather than the entire de-identified submission. The summary format is a good balance of brevity and information needed for meaningful public comment.

ASMI is opposed to publication of the entire de-identified application. Applications usually contain commercial in confidence material that can include information such as:

- formulations, clinical studies, post-marketing studies and safety data, excerpts from the CTD
- market research, consumer research, sales and marketing statistics, marketing strategies
- specific operational tools and materials such as pharmacist screening and supply tools
- training materials intended for pharmacists and pharmacy assistants

Sponsors could be disadvantaged should this material be published.

The purpose of the public comment process is for stakeholders to provide the Delegate and advisory committees with comments and indicate support or otherwise for a scheduling proposal, rather than to evaluate an entire application – and to this end we question whether the public or stakeholders require the entire application, often hundreds or (occasionally) thousands of pages long, in order to make meaningful and informed comment. ASMI does not believe that stakeholders require disclosure of commercially sensitive material in order to make informed and effective public comment and publication of the entire submission may send the message that those who wish to comment should review the entire submission.

The TGA states that submissions would be "de-identified". It is relevant to note that even if de-identified, it may be quite easy for members of the public to surmise the identity of the applicant by use of the ARTG and other methods, e.g. familiar letterhead designs. Industry lacks confidence that submissions would be adequately "de-identified" given that there have been instances where there has been insufficient or inaccurate redacting of public submissions during public consultations on scheduling and other TGA consultations. ASMI believes that public availability of the entire application, even if de-identified will have a substantial impact on the readiness of sponsors to submit rescheduling applications and does little to protect the intellectual property of applicants.

Although in New Zealand applications are currently published, the local industry strongly opposes this practice as it gives competitors access to a body of work prepared by an applicant for a particular proposal. It should be noted that the therapeutic goods framework in New Zealand is being re-written.

ASMI's view is that the publication of entire submissions, even if de-identified, would be a significant disincentive for rescheduling, would reduce innovation and sponsors would be reluctant to invest the significant financial and other resources needed to prepare applications only for these to be made public.

In relation to Business Improvement Measure 2(b), ASMI agrees that the Secretariat should have the option of alerting relevant stakeholders and contact them directly, as this may make the consultation process

[5] https://www.tga.gov.au/consultation-invitation/consultation-further-proposed-amendments-poisons-standard-joint-accs-and-acms-meeting-and-accs-meeting-march-2017

more efficient and effective. This is particularly an issue with chemicals scheduling where some chemicals can have varied uses – e.g. in industrial, domestic, workplace situations and where affected stakeholders may not proactively engage with the TGA website publications inviting public comment.

In relation to Business Improvement Measure 2(c), ASMI agrees in principle with communication milestones and tracking to improve communication between the Secretariat and applicants – although more work and consultation will be needed during the design and implementation of these business processes. It is important to ensure that the systems developed will meet the intended purpose, work smoothly and are clear and efficient. ASMI also would like to raise the issue of cost and question – to what extent will development of new communications systems introduce additional costs for applicants, as this is not mentioned in the consultation paper.

An important issue that falls under the category of business improvement measures is that of better communication between applicants and sponsors with the Scheduling Secretariat. It should be possible for applicants to better understand the structure of the Secretariat, understand its function and know who to contact within the Secretariat for questions on application requirements or formatting, or even data requirements. The Secretariat should be adequately resourced to perform this supportive function.

Risk-Benefit Value Tree

Business Improvement Measures 3: Greater emphasis on benefits as well as risks
When updating the SPF guidance for submissions, consider how greater emphasis can be placed on potential benefits as well as risks of proposed rescheduling of substances.

ASMI believes that scheduling policy should include a greater and broader emphasis on potential benefits from rescheduling, a view that has been articulated in parts of the consultation document.

Down-scheduling or "switch" should not be viewed principally as a risk to the community. There should be recognition that improving consumer access to medicines can provide benefits for self-care, for example more immediate symptom relief, enhanced choice for consumers, avoidance of treatment delay, or better involvement by consumers their health care. There are also associated economic benefits through reduction of health care costs and more efficient use of healthcare resources.

Down-scheduling from prescription to Schedule 3 can help drive consumer-centred care, with partnerships between pharmacists, medical practitioners and consumers if managed appropriately. Risk-mitigation measures can be applied to newly down-scheduled medicines; new S3 medicines can be properly managed by pharmacist intervention, and consumer resources and communications can help provide consumers with information to assist with understanding their condition and how to use the medicines safely.

The UK and New Zealand have a more progressive attitude to rescheduling and there is no evidence that this more progressive approach has resulted in any adverse consumer outcomes or widespread misuse or abuse of medicines. The Australian consumer does not markedly differ to the New Zealand or UK consumer in terms of health indicators, health literacy and health related behaviours.

The UK and New Zealand guidelines for reclassification include reference to the Brass value tree, a model developed by Brass et al[6] for assessing risk vs benefit contribution due to reclassification / rescheduling that allows applicants to evaluate all potential additional risks and benefits resulting from down-scheduling, assign values for frequency and severity and examine options for risk mitigation – thereby providing the potential for a structured and transparent way of considering all of the relevant attributes of down-

[6] Brass E.P, Lofstedt R, Renn O. Improving the decision making process for non-prescription drugs: A framework for benefit-risk assessment. Clinical Pharmacology & Therapeutics 2011: 90(6) 791-803

scheduling a particular medicine. In New Zealand and the UK, applicants may provide a benefit vs risk assessment using the value-tree model together with other required data as part of the re-scheduling application.

ASMI believes that the TGA ought to adopt a similar approach to that of the UK and New Zealand and that the SPF and associated guidelines for rescheduling applications should be updated to provide the option for applicants to submit a Brass value tree benefit/risk analysis as part of their submission. This should be optional not mandatory, and the guidelines should be sufficiently flexible to allow applicants to address benefit / risk in other ways should they wish to use alternative or novel approaches. In general, a more flexible approach should be taken, as opposed to prescriptive requirements.

In support of demonstrating or providing evidence for potential benefits (such as compliance, reduced time to treatment, benefits of improved access, patient preferences), applicants should have the option of providing a broad range of relevant data of various types that includes consumer or market research, simulations or "in-use" studies from other markets. This evidence should be acceptable in establishing self-care benefits.

ASMI does not support the suggestion that the Brass value tree benefit/risk assessment should be conducted by the regulator (TGA, ACMS) as part of the evaluation and decision making process. The applicant should have the option of providing the Brass, or any other type of assessment, as part of the application and the regulator's role should be to evaluate the information provided and to consider whether all applicable benefits and risks have been included as part of the submission, rather than do a post-hoc value tree benefit/risk assessment.

ASMI notes some of the concerns that have been expressed in this section of the consultation and in relation to these concerns, wishes to raise the following (as per the order of the bullet points, page 15 of the consultation paper):

- We acknowledge that there is variation in the type of applications provided for rescheduling. The Brass paper describes the use of the value tree methodology in relation to non-prescription medicine assessments and ASMI sees its relevance particularly for down-scheduling from prescription to OTC or from OTC to general sale. The objective of allowing use of benefit / risk methodology should not be to create a schema that must be used in <u>all</u> situations. It should be optional, enabling use by applicants who consider that it is suited to their particular application. Allowing its use as an optional tool would be consistent with the UK and New Zealand approach and would provide flexibility for applicants to structure their application in their preferred way.

- We question the comment that "*not all scheduling considerations require equal consideration of both risk and benefit*". Section 52E requires the Delegate to consider risks and benefits as part of every scheduling decision. We acknowledge that for some substances, the risks of down-scheduling may outweigh the benefits – hence the reason for the regulatory framework providing different schedules, i.e. so that the most appropriate schedule can be used based on benefits and risks that must be considered before each and every scheduling decision is made. ASMI does not consider the above comment to be a valid reason for not allowing the option to use benefit / risk methodology as part of any scheduling application.

- There is concern that this could create additional burden for applicants in addition to the current data requirements. ASMI believes that making the use of the value tree methodology optional rather than mandatory should allay any concerns around burdensome and over-prescriptive requirements.

- The 4th point (page 15 of the consultation) states that *"Scheduling applications are considered on the grounds of public health and there was limited support by those consulted for a significant change to scheduling policy to enable formal consideration of economic benefit. Rather, specific benefits to patients or chemical users of wider public access could be considered"*. ASMI's view is that individual scheduling applications are currently and should continue to be considered on the grounds of risk vs benefit relating to the proposed level of access. This is the primary consideration, as required under section 52E. However, in broad policy terms, the economic benefits of wider public access is an important benefit in the context of pressures on health budgets and allocation of healthcare budgets and resources. Scheduling policy and enhanced access to medicines that are appropriate for self-care can result in a reduced burden on government health and welfare services.

Ongoing Improvements 2: Improved guidance on risk and benefit
Prepare worked examples of the risk: benefit tree for recent scheduling considerations and assess the utility of this approach for scheduling applications.

ASMI supports the proposal for the TGA to provide some worked examples of the risk/benefit value tree, to assist applicants who may be unfamiliar with the model and its utility.

As part of the development of any new requirements and new guidance, information and education should be provided for industry as well as for evaluators of these applications.

Interim Decisions

Policy Recommendation 3: Public consultation on interim decisions
Amend the Therapeutic Goods Regulations to allow general public consultation and receipt of submissions from any interested parties on the interim decision and remove the prescriptive requirements on time available for submissions.

ASMI agrees with the proposal to allow general public consultation and receipt of submissions from interested parties on the interim decision. This would reduce pressure on interested parties to always comment on the agenda items, as a placeholder just in case there is a need to subsequently comment on the interim decisions.

ASMI has concerns and only cautiously supports the proposal to remove the prescriptive requirements on time available for submissions. This could possibly be beneficial if confined to contentious, far reaching rescheduling proposals and interim decisions such as the recent deliberations on codeine, however we are concerned that if not used judiciously it could result in longer timeframes for applications. ASMI recommends that the existing timeframes should be the default and any extension be reserved for submissions that have widespread impact involving a large number of sponsors and healthcare professionals and be likely to generate a large number of public submissions.

Just as there are possibilities for increasing timeframes for some complex applications, there may be scope in decreasing timeframes for some straightforward applications – and if flexible timeframes are being considered then this should be part of the discussion.

The consultation paper states that some stakeholders would like the interim decision to be in "plain English" to better explain the intent of the scheduling proposal. We question what exactly this means. It should be noted that the interim decision serves many purposes – and for some applicants it is the only explanation given for a decision that has significant commercial impact. Interim decisions should therefore provide sufficient detail to enable the applicant to properly understand the reasons why an application was successful or unsuccessful and to provide guidance for applicants wishing to make similar submissions in

the future. ASMI therefore does not agree with any proposal to provide less detailed information in the interim decision; the interim decision should provide comprehensive reasons for the decision.

In order to assist other stakeholders who do not require a high level of detail, ASMI acknowledges that some stakeholders may find it useful to have a simple summary of the scheduling proposal and decision and recommends that a summary should be provided in addition to the comprehensive reasons for the interim decision. There should be no overall reduction in the quantity or detail of information provided to the applicant and other interested parties via the interim decisions publication process.

Business Improvement Measure 4: Guidance on legal nature of scheduling and scheduling decisions
Include an explanation of the legislative nature of scheduling decisions and why they are not appealable in the SPF.

As a matter of principle, ASMI believes that sponsors or other persons who are affected by a scheduling decision ought to have access to a full range of review processes (including both merits review and judicial review).

We therefore suggest that section 60 of the Therapeutic Goods Act should be amended so that decisions under Part 6-3 can be reconsidered by the Minister and, if necessary, reviewed in the Administrative Appeals Tribunal. Judicial review in the Courts ought also to be available.

In order to give full effect to such review, Part 6-3 of the Therapeutic Goods Act may also need to be revised.

Importantly, the revision of the Act needs to allow review of decisions to amend the Poisons Standard [per section 52D (2)] as well as decisions not to amend the Poisons Standard.

ASMI understands that the scheduling decisions are part of a joint State/Territory framework, however States and Territories adopt the decision of the Delegate, and ASMI believes that the Delegate's final decision should be reviewable and legislative changes can be made to enable review.

Timing of Scheduling Decisions

Policy Recommendation 4 – consider a chemicals scheduling delegate within APVMA
In consultation with the Agriculture and Water Resources portfolio, explore options to establish a delegate in the APVMA to streamline scheduling applications for relevant (agricultural and veterinary) chemicals, with due consideration to the management of the process and ensuring that the specific roles and responsibilities of each delegate are clearly defined.

Business Improvement Measures 5- Decision transparency and information sharing.
Include an explanation in the SPF of jurisdictional requirements for decisions to enhance stakeholder understanding. Identify an early alert mechanism to ensure the initial applicant, the jurisdictions, and stakeholder groups have the maximum time available for activities associated with a decision. Develop a mechanism to allow early information sharing between the APVMA and the Secretariat to better screen and manage agricultural and veterinary chemicals applications.

ASMI has no specific comment on policy recommendations and business improvement measures for streamlining scheduling applications for agricultural and veterinary chemicals.

For ASMI members and industry in general, certainty of time frames to enable products to meet switch effective dates and be ready for market is crucial. Policy Recommendation 4 relates to enabling streamlined processes for agricultural and veterinary chemicals. ASMI has been advocating for adoption of streamlined processes for medicines, and parallel processes are addressed elsewhere in the consultation (see ASMI comments on "Parallel processes and other incentives (medicines)", below).

The information in the section titled "Timing of Scheduling Decisions" confusingly refers to medicines as well as chemicals, however Policy Recommendation 4 refers only to the APVMA and chemicals. The statement in the business improvements section also confusingly refers to an early alert mechanism but appears to confine it to agricultural and veterinary chemicals.

ASMI requests more detail on what the policy recommendation and business improvements mean for medicines, where time is needed for professional education and training activities and labelling amendments. Extending the switch effective date and making the entire process longer is not a solution to the problem and the consultation paper provides to options on how these existing problems can be addressed.

Proactive consideration of candidate substances for rescheduling

Ongoing Improvements 3 – Proactive identification of substances for rescheduling
Implement a system for proactively identifying substances for rescheduling, similar to schemes in place in some comparable international jurisdictions.

ASMI supports the establishment of a committee or Working (WP) Party that includes the regulator, medical practitioners, pharmacists, industry and consumers to proactively consider substances or groups of substances that could be considered for rescheduling. As per the comments in the consultation paper, this approach seems to be working well in other jurisdictions. It would be a useful exercise for an Australian Working Party to periodically conduct some international benchmarking to assess whether Australian consumers have access to medicines in a similar way to comparable overseas markets.

The role of the WP should be to provide non-binding recommendations. The usual scheduling process – i.e. submission of an application should follow.

In establishing a WP to proactively consider candidate substances for rescheduling, ASMI supports transparent and efficient processes, including publication of meeting minutes or deliberations. Although it is understood that any WP recommendations would be dependent on an application being made, applicants should have confidence in the WP recommendations – and there is an expectation that the Advisory Committee and Delegate would be aligned with any WP recommendations. This is important, so as to ensure that time and resources are not wasted in making applications based on WP recommendations, only for them to be unsuccessful if the Advisory Committee and Delegate subsequently have a differing view.

It is unclear from the consultation paper whether the WP proposed for proactive consideration of candidate substances is intended to be the same or a sub-group of a WP that will be periodically reviewing the SPF and providing advice on possible amendments to the SPF and the SUSMP (mentioned in the section titled "Policy Recommendations 2). ASMI believes that there should be further discussion on the proposed WP and its terms of reference and procedures.

Tools for better "management" of rescheduled medicinal substances

Policy Recommendation 5: New controls for certain medicines that have been down-scheduled to pharmacist only classification (S 3)
Create a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for certain Schedule 3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4 (prescription only). This new appendix will function in a similar manner to Appendix D, which specifies additional controls for particular Schedule 4 or 8 substances.

ASMI supports the above recommendation in principle but would like further detail and consultation on how the above proposal is proposed to be implemented.

Additional controls as per the above proposal could potentially provide a mechanism for innovative switches in Australia – e.g. oral contraceptives, erectile dysfunction drugs, antibiotics for acute urinary tract infections and other acute conditions. The additional controls via a new Appendix in the SUSMP can provide an opportunity for enhanced risk management that could include record-keeping by pharmacists, training and use of supply protocols.

Although not specifically discussed the consultation paper, advances in technology are enabling development of new platforms that can enhance diagnosis, monitoring and compliance, and digital technologies could be included as "tools" that enable enhanced management of rescheduled medicines.

It could also provide a framework enabling pharmacists to provide patient centred, continuing care models of practice and limited prescribing of certain medicines such as cholesterol lowering agents, diabetes medicines, repeats of antihypertensive for stable patients, asthma preventers, and other medicines used for chronic conditions that can be diagnosed by a doctor and subsequently managed by the pharmacist.

Pharmacists already have a legal responsibility and professional obligation to ensure appropriate supply of Schedule 3 medicines. The PSA prepares guidance documents on provision of Pharmacist Only Medicines, which describes a series of recommended steps for pharmacists to follow when supplying S3 medicines. With S4 to S3 rescheduling applications, the applicant generally seeks input and advice from the relevant professional bodies such as medical practitioners and pharmacists, with the aim of developing pharmacist guidance documents for provision of the rescheduled medicine. Pharmacist training is also conducted on any new switches. It appears from the consultation, that the proposed tools for management of rescheduled substances may be a way of formalising these professional practice responsibilities through the Poisons Standard.

While the proposal has its merits, there is potential for interface with other bodies and regulations, including regulation of individual practitioners through State and Territory Poisons legislation, AHPRA, Pharmacy Board regulation of pharmacy premises, arrangements for pharmacist remuneration through various CPA agreements, and interaction with privacy legislation. These areas of commonality or interface must be considered.

An important issue is to what extent a new Appendix will duplicate the already existing controls on supply of medicines and replicate professional practice requirements already in existence. Duplication should be avoided.

Therefore, while generally supporting the proposal described in policy recommendation 5, ASMI requests that any amendments to the SUSMP that may involve additional controls on S3 medicines should be further

consulted and developed in collaboration with pharmacists, healthcare professionals and industry to ensure that they are practical and can be easily adopted within the community pharmacy environment.

We would also note the following issues that should be thought through:

- Once incorporated in an Appendix to the SUSMP, the specific additional controls are part of a Commonwealth legislative instrument as well as State and Territory controls. Consideration should be given to how future amendments or modifications will occur. At some point, questionnaires may need to be changed, material in training courses may change, or with continuing experience in the community the additional controls could be removed or loosened. State and Territory input is essential as the jurisdictions will be required to adopt the proposed Appendix.
- What the process will be for changing or removing the "additional controls" in the Appendix? It seems unreasonable to expect changes to the "additional controls" should go through the entire scheduling application requirements process, which can take a year from lodgment to implementation.
- Will there be a process in place to ensure regular update of these requirements?

Parallel processes and other incentives (medicines)

Ongoing improvements 4 – Down-scheduling - alignment with OTC product submission and incentives?
a. Develop a mechanism to better align applications to reschedule an active substance from Schedule 4 to Schedule 3 with the marketing authorisation applications for newly rescheduled Schedule 3 medicines.
b. Consider options for market incentives for down-scheduling, for example similar to the UK system, and whether development of a similar mechanism for the Australian context would be in the interests of public health

Alignment of rescheduling & product applications

A major source of frustration to some sponsors has been the way that TGA registration processes do not integrate well with the scheduling processes. It is often very difficult to meet the "switch effective date" (currently approximately 3 months after the final decision) due to the lack of concurrent processes for scheduling and TGA applications for registration and decisions on warning statements. This requires management of exemptions from the States and Territories for continuing to supply mislabelled stock and communication with wholesalers and pharmacists.

Currently, for S4 to S3 rescheduling / product applications, a sponsor must apply for rescheduling first, wait for the rescheduling process to be completed and for the new entry to be included in the Poisons Standard, then apply for registration of new product with the TGA – essentially a sequential process often taking more than 2 years end-to-end.

This problem of lack of alignment of rescheduling and product applications also applies to S2 to general sale rescheduling applications, where the TGA cannot evaluate labelling changes associated with the rescheduling until the new entry in the Poisons Standard takes effect. Additional difficulty is incurred with subsequent RASML consultation on labelling, where the RASML consultation can result in amendments to labelling warning statements resulting in the need to design new labels after the rescheduling and product application processes have been completed.

Flowchart 3 of the Scheduling Policy Framework[7] suggests that a concurrent application and scheduling process exists. This is inaccurate, because under the TGA Business Processes (BPR), the TGA cannot evaluate an application until the scheduling has been finalised.

The delays caused by the current sequential scheduling and registration process are disadvantageous to innovators and there have been instances where "me too" products have been first to market a rescheduled medicine despite not having had any input into the rescheduling process that enabled the switch. This has also occurred with S2 to general sale switches, where a competitor product has been able to amend signal headings and launch without going through the labelling amendments that were imposed on the innovator[8].

The TGA OTC Medicines evaluation section now "flags" any "me-too" products such that any new labelling requirements resulting from rescheduling are captured, however this does not provide an adequate solution for the lack of efficient, streamlined and integrated product scheduling and registration process. There is duplication and impact on costs and resources in needing to prepare and submit two separate applications, in different formats, which have some commonalities.

Alignment with States and Territories is also a key issue. There should be clear and consistent information for sponsors on how to manage stock in trade within pharmacies that has incorrect signal headers following rescheduling (i.e. "mislabelled" stock). There are currently no published guidelines on how to obtain State and Territory exemptions for "mislabelled" stock other than the contact details on the TGA website; ASMI suggests publication of a process to be followed, information needed and timeframes for issuing exemptions.

To further support applicants, particularly those who are considering submitting innovative rescheduling applications, consideration should be given to developing a mechanism for face to face pre-submission meetings to provide non-binding advice on requirements for innovative rescheduling applications, covering aspects of data requirements and risk mitigation approaches. As an example, the PBAC offers a similar process for PBS listing applications.

In summary, ASMI supports the proposal to develop a mechanism to better align applications for rescheduling. Scheduling processes require better integration with TGA registration processes. Sponsors should have the opportunity to submit concurrent applications and for the process to work effectively and in a streamlined manner. Sponsors also should have the option of nominating a switch effective date that suits their commercial plans.

Further consultation with industry is needed for any reforms in this area, and ARGOM should also be updated accordingly.

Incentives for down-scheduling

Mechanisms such as data and market exclusivity provide incentives for companies to invest in research to generate the regulatory data supporting rescheduling applications for prescription to OTC switch. Innovation in "switch" is critical for the ongoing provision of high quality and accessible medicines. ASMI strongly supports incentives for down-scheduling that will encourage investment in R&D and enable greater capacity for return on that investment.

As discussed earlier in the consultation, there have been examples where the innovator submitting the rescheduling application has faced more barriers than subsequent entrants to the market, who have

[7] Scheduling Policy Framework Feb 2015. https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals

[8] Personal communication. ASMI can provide details on request

received a “free ride” and sometimes launched before the innovator. These are significant concerns with the current system.

Insufficient data protection or exclusivity for the switch initiator can be detrimental, discouraging sponsors from initiating first-in-class rescheduling applications if the expectation is that subsequent substances in the therapeutic class will be rescheduled with little to no effort on the part of subsequent entrants a short time afterwards.

ASMI notes that different terminology has been used throughout the consultation process when referring to the possibility of incentives for applicants. At times the term “data protection” has been used, sometimes “market exclusivity” is used as well as the term “incentives”. Despite the different terminology the principle is the same, i.e. that there should be some form of incentive to recognise and encourage investment and innovation.

ASMI believes that incentives should be commensurate with the degree of investment and there should be further exploration of options in that regard.

As global benchmarks in comparable markets, the UK, the US and Japanese models should be considered. The UK model allows one year’s data protection following the change of classification of a medicinal product, if the submission was based on clinical trials or pre-clinical tests. Experience with this model shows that this period is too short in the context of the OTC environment. The US model is preferable, as it allows for three years exclusivity for submissions requiring clinical trials; similar arrangements to the US exist in Japan.

Whether the incentives are provided through a period of market exclusivity (such as flagging a new scheduling entry for a set period) or through data protection mechanisms (such as those used in the UK) – the most appropriate mechanism for the Australian context can be examined further and should be subject to more detailed consultation.

ASMI’s view is that adequate incentives are needed, commensurate with the degree of investment, to provide fairness to sponsors who initiate innovative rescheduling applications. There should be recognition of the considerable financial resources allocated - by investing in the research, providing post-market studies and data, performing consumer research, working with healthcare professionals and pharmacists to develop training and resources for the rescheduling of a medicine.

ASMI believes that providing incentives for rescheduling is not inconsistent with the scheduling principles and the SPF. It will encourage innovation and development of the sector, provide benefits of improved access to medicines and economic benefits by wider utilisation of pharmacist skills.

Improving the clarity of the SPF

Business Improvement Measures 6 - Improving the clarity of the SPF

1. Amend section 3.2 to provide the delegate with greater discretion when deciding to refer (or to not refer) particular substances to the relevant advisory committee(s) for advice, particularly for:
   a. rescheduling considerations of “second in class” medicinal substances (where the committee has already considered and the delegate already determined that a substance in the same pharmacological / medicinal class be rescheduled, based on similar considerations);
   b. a number of Schedule 5 and Schedule 6 chemicals scheduling applications;
   c. straightforward considerations of scheduling of a particular substance used in an agrochemical or veterinary medicine that has been subject to a recent evaluation by the Australian Pesticides and Veterinary Medicines Authority (APVMA);
   d. and consideration of Appendix E, F and K entries of the SUSMP.

2. Clarification that Appendix E and F requirements do not apply to workplace chemicals where they are subject to the requirements of the Globally Harmonised System for the classification and labelling of chemicals (GHS, discussed further below).[5]
3. Decisions to include a substance in Appendix K can be a delegate-only decision and not require referral to the Advisory Committee for Medicines Scheduling.
4. Amendment to the description of the Cascading Principle and the details for inclusion in Appendix B.

ASMI supports proposals to improve the clarity and usability of the SPF and to improve the efficiency of the scheduling process.

ASMI agrees in principle with the proposal for the SPF to be amended, to allow the Delegate to make certain decisions on scheduling matters without necessarily referring to the relevant Advisory Committee for advice. These may include:

- Applications relating to reclassification of a second (or subsequent) human therapeutic substance in a class where the safety and use profile does not differ significantly from a substance of that class that has already completed a rescheduling process.
- A number of Schedule 5 and Schedule 6 chemicals
- new or amended entries in Appendix E, F or K

For applications relating to reclassification of a second or subsequent human therapeutic substance in a class, ASMI's support is conditional – in that:

- It should be accompanied by measures to protect the initiator of the "first-in-class" rescheduling application – as discussed under "incentives" in the previous section.
- Adequate experience should have been gained with the first- in-class product, for example using the pharmacist supply protocols. It should be noted that the applicant for the "first in class" will have developed pharmacist training materials and S3 supply protocols and it would be expected that the supply protocols will need to be amended to include information on the "second in class", and address matters such as dosage differences and differences in contraindications, precautions and interactions.
- Any applications relating to "second or subsequent in class" substances and Appendix entries should be referred to the Advisory Committees and be included in the public consultation process.

ASMI will not be commenting on APVMA applications and workplace chemicals requirements.

Regarding the 4th point of the Business Improvement Measures described above, namely the amendment to the description of the cascading principle and details for inclusion in Appendix B – ASMI believes that this point is unclear and no detail has been provided in the consultation on how the description to the cascading principle will be amended.

This applies also to any amendments to details for inclusion in Appendix B, which refer to substances considered not to require control by scheduling. The consultation paper has not detailed exactly what these amendments are and how the scope of Appendix B will be changed.

We look forward to providing further input on future amendments to the SPF.

Globally harmonised system and scheduling

ASMI has no comment on this section.

Advertising of Schedule 3 (pharmacist only) medicines

Advertising of Schedule 3 (Pharmacist only) medicines
We wish to obtain stakeholder feedback to support the development of options for government to consider around the reform of advertising requirements for pharmacist-only (Schedule 3) medicines. Some considerations include:
• Criteria for allowing advertising of medicines containing Schedule 3 substances under the TGA Advertising Framework.
• Possible retention of some form of "list" similar to Appendix H. We seek feedback on the alternatives of whether this would be a positive list (substances considered and permitted to be advertised, status quo) or a negative list (list of substances not permitted to be advertised to consumers, with anything off the list authorised to be advertised by default) from this public consultation.
• Any restrictions or requirements that should be applied to advertisements or other form of information provided for medicines containing these substances, e.g. mandatory and repeated mention that the product should be selected with the advice of a pharmacist, requirement to describe possible adverse events, requirement to emphasise that the particular OTC products containing the substance in question are only for short-term use.
• An exploration of what regulatory enforcement/compliance powers would be required in the event that restrictions for the advertising of S3 substances were changed, noting that the Government has agreed that advertising pre-approval processes should be removed once appropriate compliance and enforcement powers are in place (MMDR Recommendation 55).
• Relationship with possible additional requirements for pharmacist education and provision of information by patients (e.g. to declare that they do not have certain pre-existing conditions for which the OTC medicine would be contra-indicated) at the point of sale, for particular medicines that have been down scheduled from S4 to S3.
• Consideration of a potential mechanism to allow sponsors to seek approval to advertise to the public products containing Schedule 3 substances as part of a market authorisation application for the medicine(s) in question.

ASMI's comments on S3 advertising are in two parts – a general discussion of the ASMI S3 advertising model and associated observations on how it could be implemented in the Australian context, followed by responses to the specific questions raised in the consultation paper.

General comments on S3 advertising and the ASMI model

ASMI supports reforms to the current restrictions on advertising of Schedule 3 medicines and proposes that Schedule 3 Medicines – which must all be supplied only on a pharmacist's advice – should all be able to be advertised to consumers, with certain exceptions.

In many countries with similar demographics to ours, this is allowed. There is no evidence from these countries of inappropriate consumption because of that advertising.

There is, as well, also no evidence of inappropriate consumption, attributable to the advertising, of those few S3 products that can be advertised here.

The present restriction on advertising of S3 medicines:

- is not supported by any published evidence
- is based on outdated and restrictive guidelines (pre-widespread use of the internet) with unclear criteria that have not been updated for more than 15 years[9]
- is inconsistent with the National Medicines Policy

The advertising restrictions disempower consumers because "they are not allowed to know" about S3 medicines. Consumers continue to consult GPs for conditions which could be safely managed by

[9] NCCTG Schedule 3 advertising guidelines, November 2000. https://www.tga.gov.au/publication/schedule-3-advertising-guidelines

pharmacists. The restrictions constrain the ability to make consumers aware of medicines which are available without a prescription and without requiring a GP visit.

Benefits resulting from advertising of S3 medicines

Raising public awareness of Schedule 3 Medicines has the potential to deliver benefits for all stakeholders. Among these benefits are:

- consumers will be aware of a broader range of therapeutic options
- consumers will therefore be able to better treat a condition for which they had been using a less effective medicine
- in some cases, where professional advice would not otherwise be sought, consumers will be encouraged to discuss symptoms with their pharmacist and be appropriately referred to the doctor, or treated if necessary with a medicine or lifestyle advice
- earlier knowledge of treatment possibilities will, in some cases, ease anxiety about disease
- medicines will be used to treat conditions earlier
- the professional role of community pharmacists will be highlighted – both in managing certain conditions, and increasing understanding of the role of the pharmacist as an information source
- the pharmacist – consumer relationship will, in some cases, be strengthened
- for government by encouraging better use of available healthcare resources
- for industry by encouraging the investment for research to generate the regulatory data to support applications for rescheduling of appropriate medicines from Prescription Only (Schedule 4) to Schedule 3.

ASMI Proposal

ASMI proposes an alternative model for direct-to-consumer advertising and communication of Schedule 3 Medicines, whereby:

- the default regulatory position would allow advertising of these medicines, with certain exceptions, i.e. a risk-based approach to S3 advertising
- provision would be made for these exceptions based on public interest and safety criteria
- a structured information-based communication template would apply to all advertisers through underpinning in the Therapeutic Goods Advertising Code, to ensure that the advertising delivers the stated information provision objectives
- regulatory controls would ensure compliance

The proposed ASMI model is described in further detail below, in the section titled "Issues raised by the consultation". Importantly, it is supported by research on consumers and pharmacists (see below), showing that the model is aligned with relevant quality use of medicines indicators.

Evidence in support of the ASMI model

CHERE (UTS) conducted research on behalf of ASMI, to determine the impact on quality use of medicines (QUM) of this proposed S3 advertising model on consumers, pharmacy assistants and pharmacists[10]. The research involved 1300 consumers, 500 pharmacists and 500 pharmacy assistants in a randomised study to assess the impact of a "mock" S3 product TV advertisement. Participants were engaged in a series of surveys and discrete choice experiments (DCEs) in a policy-relevant case study of advertising of a S3 pharmacist only medicine (oral famciclovir), using a realistic hypothetical information style advertisement.

The DCEs were designed to investigate the impact of advertising on the behaviour and preferences of consumers, pharmacists as well as pharmacy assistants through a controlled stated-preference experiment.

[10] CHERE Estimating the impact of schedule 3 consumer advertising. Final report, November 2016. https://www.uts.edu.au/sites/default/files/CHERE_report_S3_final.pdf

This approach has been demonstrated to be particularly useful to examine the likely effects of policies that have not been put into place, thereby providing important information to guide the design of such policies.

The context of the experiment was the treatment of a cold sore, a minor ailment that can be managed by self-medication. A mock TV-style advertisement was produced by the ASMI for the proposed S3 communication model with a hypothetical brand (Brand FAM) in a real S3 category (cold sore treatment). The mock advertisement was 30 seconds long and contained three components: disease state information, importance of pharmacist, and product information and brand awareness. The choice experiments were designed to reflect realistically the exchange of information and the choices that are likely to be made in a typical health care seeking or health service provision scenario. Respondents were asked to consider a series of hypothetical scenarios and choose their preferred medicine to purchase (for the consumer DCE) or recommend (for the pharmacist or pharmacy assistant DCEs).

The key findings of this research were:

- Advertising activates consumers to seek advice from pharmacists
- Advertising resulted in an increase in consultations with pharmacists
- Pharmacists continue to triage consumers appropriately and provide advice based on professional practice standards, i.e. not supplying a product, supplying an alternative product or referral to a GP
- Consumers were happy to accept pharmacist recommendations (did not insist on advertised product).
- Advertising does not drive inappropriate use.

Importantly, the research debunks certain assumptions about advertising of S3 medicines. It clearly showed that S3 Advertising increases consumer awareness of the available therapeutic options, it drives more 'health conversations' between pharmacists and consumers; it does not drive inappropriate demand by consumers and pharmacists do not feel pressure to supply a particular brand or a particular product.

<u>Transition</u>
Once a decision in favour of a more liberal approach to S3 advertising is made, the transition from a "positive" Appendix H list to a "negative" list will need to be carefully designed and managed with input from all affected stakeholders and following consideration and possible amendment of related legislation.

ASMI remains committed to working with all stakeholders to ensure that this takes place. We envisage that the transition could take place as follows:

- Initial agreement on criteria for which S3 substances should not be advertisable (via transparent consultation process) is a necessary prelude to transition
- The Therapeutic Goods Advertising Code and other necessary regulations should be drafted and in place (prior to transition)
- The substances currently in the "positive" Appendix H are replaced with all other substances in Schedule 3. This means that on "Day 1" there will be no change to which substances can or cannot be advertised
- Following commencement of the changes, there should be a review of substances which are not permitted to be advertised against the criteria mentioned above. There should be an ordered process by which the advertisable status of substances is reviewed.
- Any subsequent rescheduling application will proceed according to the revised processes developed prior to implementation of these new requirements

Response to specific matters raised in the consultation

ASMI would like to provide the following comments in response to the specific questions in the consultation:

Criteria for allowing advertising of Schedule 3 medicines

The current restrictions on advertising of S3 medicines are unjustified and they deliver no net public health benefit. In fact, the restrictions may have a negative impact. They constrain the ability to make consumers aware of treatments available without a prescription; consequently consumers continue to consult GPs for conditions that can be safely managed by pharmacists.

ASMI proposes that advertising of S3 medicines should be permitted by default, with specific exceptions, on a case-by-case basis where there is a strong case that direct-to-consumer advertising would not be in the public interest. Examples of exceptions, i.e. S3 medicines that should not be brand advertised include:

- medicines that have documented potential for abuse or diversion, e.g. pseudoephedrine
- medicines that are for chronic medical conditions and are recommended by a doctor as part of a treatment protocol, e.g. nitrates for angina
- injectables used for emergency situations, such as adrenaline, naloxone, glucagon, noting that there may be a public safety benefit in being able to provide support materials on appropriate use to carers (this is not possible under the current restrictions).
- medicines used as part of a medical or surgical procedure, e.g. bowel preparations prior to surgical or diagnostic procedures

Possible retention of some form of "list" similar to Appendix H

ASMI advocates for Appendix H to be a "negative list", i.e. it should include substances that should not be advertised.

The list of exceptions should be based on transparent public interest criteria such as those mentioned above.

A clear separation between scheduling and advertising controls is long overdue. The primary aim of scheduling is to determine the appropriate level of access consumers should have to medicines. This regulatory decision is based on the degree of risk and the level of healthcare professional intervention required to protect consumers. The main risk factors are the inherent toxicity of a substance and the seriousness of the condition for which the substance is indicated, or of potential misdiagnosis or delayed diagnosis. Once the appropriate level of access has been determined through a scheduling decision advertising does not alter the level of access.

As a result of the inclusion of Schedule 3 advertising controls in the Scheduling Policy Framework (SPF) and SUSMP (Appendix H) consideration of advertising controls and access controls have become conflated and the distinction between access to S3 medicines and consumer advertising and communication has become progressively blurred.

Restrictions on advertising impose restrictions on communication. With the widespread acceptance of digital technology, this is an outdated approach. Consumers can access medical information online, however under the Australian regulatory framework they are not allowed to know about certain S3 medicines available through a pharmacist. This consultation provides a pathway for some of these inconsistencies to be addressed and a more reasonable approach be taken with respect to communication about S3 medicines.

Restrictions or requirements that should be applied to advertisements – the ASMI model

ASMI is proposing an alternative regulatory model for direct-to-consumer communication of Schedule 3 Medicines. The proposed model is distinct from "conventional" advertising where the main emphasis is on brand awareness in a genericised and crowded market environment.

The main objectives of the proposed model are to:

- create consumer awareness of therapeutic options in Schedule 3 in a structured, balanced and responsible way, and
- encourage consumers to seek information from pharmacists.

Key aspects of the model

- A default regulatory position permitting Schedule 3 Medicines to be advertised;
- Provision for exceptions, on a case-by-case basis, where there is a strong case that that direct-to-consumer advertising would not be in the public interest.
- A structured communication format containing the following 3 components:
    - Information about the condition: this aims to inform consumers about the symptoms and/or condition for which the product is indicated;
    - Mandatory intervention by a pharmacist: this component of the communication aims to promote and reinforce the professional role of the pharmacist. It should emphasise the need for counselling to determine whether the product is appropriate for a particular condition and/or consumer and should aim to clarify that a product request does not automatically result in the supply of that product; and
    - Branded product information: the brand awareness component is a critical element to make the model commercially viable, but it takes a secondary role to the more important educational aspects of the communication.
    - To ensure legal underpinning and universal compliance it is proposed that these three components be mandated in a new section in the Therapeutic Goods Advertising Code (TGAC).
- Support for pharmacists and pharmacy staff to ensure that staff are fully prepared prior to the commencement of direct-to-consumer communications of S3 medicines. As a minimum this should include:
    - Comprehensive protocols, algorithms or guidelines and product information.
    - Counselling skills development to address the issue of consumers demanding a product and/or resisting pharmacist counselling (noting that this exists regardless of advertising).

Advertising is an awareness tool that provides information on the condition, the medicine as well as a recommendation to talk to the pharmacist. Given the format of advertising it cannot and should not replace professional advice, the label and the CMI.

S3 medicines are available only from the pharmacist, who has a responsibility to assess whether a medicine is suitable for the consumer. All S3 medicines have CMIs which can be provided to consumers – the CMI contains all of the necessary information to ensure safe use. The label also contains information on contraindications, warnings and precautions. ASMI does not therefore support inclusion of adverse events, directions for use etc. as part of advertising; this information should be provided by the pharmacist and the CMI. There is an existing regulatory framework on advertising which provides suitable advertising controls and mandatory statements for advertising of certain product categories, e.g. analgesics.

Exploration of regulatory enforcement / compliance

Advertisements for therapeutic goods are subject to the requirements of the *Therapeutic Goods Act 1989* and Regulations, the *Competition and Consumer Act 2010* and other relevant laws. Advertisements for

therapeutic goods directed to consumers must also comply with the Therapeutic Goods Advertising Code (TGAC).

The TGAC is underpinned in the Therapeutic Goods Legislation and all advertisements (above-the-line and below-the-line advertisements) directed to consumers must comply with the TGAC. This applies to all sponsors and advertisers, regardless of membership of any industry or professional body.

The TGA reserves the right to intervene or investigate in matters where the breaches in advertising are of a serious nature, especially where consumer safety is a concern.

Currently, there are also additional controls in the form of pre-approvals. All advertisements in the following media require mandatory pre-approval prior to publication or broadcast:

- Broadcast media - TV and radio
- Print media - newspapers & magazines (including inserts)
- Outdoors - including billboards, bus shelters, sides & interiors of buses, taxi displays
- Cinema films

These advertisements are referred to as “above-the-line” or advertisements in “mainstream media”.

ASMI sees value in the pre-approval process and notes that separate consultations on advertising are taking place. Lack of pre-approvals should not be put forward as a reason for not reducing the existing controls on advertising of S3 medicines. In any event, and noting that discussion of advertising controls is ongoing, any decisions that are made in relation to updating the TGAC and the co-regulatory arrangements should ensure that the resulting legislative framework is suitable for regulation of all OTC medicines including S3 medicines. The TGAC requirements should ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive the consumer.

The Therapeutic Goods Advertising Code should also be updated to ensure legal underpinning and universal compliance for the proposed specific requirements for advertising of S3 medicines – i.e. equal prominence of the three required components: (i) information on the product, including brand name and description (ii) information on the condition, (ii) the requirement for information on the role of the pharmacist in determining whether the medicine is suitable.

ASMI looks forward to further consultation on the regulatory framework for advertising and compliance mechanisms for S3 medicines.

<u>Relationship with possible additional requirements for pharmacist education</u>
ASMI advocates that sponsors of newly down-scheduled S3 medicines should develop (in consultation with pharmacist and healthcare professional bodies) comprehensive guidelines, product information and support materials for pharmacists and pharmacy staff to ensure that staff are fully prepared prior to the commencement of direct-to-consumer communications of an S3 medicine.

In addition, pharmacy professional bodies should continue to provide education and training for pharmacists and pharmacy staff that includes counselling skills and communication skills to assist them in their interactions with consumers and address the issue of consumers demanding a product and/or resisting pharmacist counselling (noting that this applies regardless of advertising and irrespective of scheduling).

<u>Consideration of a potential mechanism to allow sponsors to seek approval to advertise an S3 medicine as part of a marketing authorisation application</u>
ASMI supports separation of advertising from scheduling, and for S3 advertising to be the default position, with exceptions as described above. ASMI believes that while the ACMS and the Delegate make

recommendations and decisions on the level of access (scheduling), decisions on advertising of an S3 medicine may be better dealt with within the TGA.

While the consultation paper seeks feedback on whether "*Consideration of a potential mechanism to allow sponsors to seek approval to advertise an S3 medicine as part of a marketing authorisation application"* we note that the meaning of the term "approval to advertise" in this question is unclear. Does this refer to approval to allow a particular substance in S3 to be advertised (i.e. whether it refers to a decision on *whether* a particular S3 substance should be advertised), or whether it is referring to a mechanism by which sponsors of a new S3 medicine should obtain TGA approval of a specific advertisement (comparable to the UK MHRA consideration of the communications plans).

ASMI's view is that advertising of S3 medicines should be the default. The decision that should to be made is not *whether a particular S3 medicine should be advertised*, but to consider *whether it meets the criteria for medicines that should not be advertised*.

The TGA can draw upon the experiences of the TGA Advertising Unit which regularly considers advertising issues and applications for restricted representations, together with the resources available within the Complementary & OTC Medicines Section. Any TGA decisions regarding whether an S3 substance should not be advertised must also be accompanied by the relevant appeal provisions. There are advantages for certain decisions on advertising to be made within the TGA. This could include permissions for certain types of information to be allowed to be made available to certain audiences, with strict conditions, much in the way that permissions for use of "restricted representations" are made.

Currently, the advertising pre-approvals process provides clearance for advertising in mainstream media, for all medicines including S3 medicines – a point that is acknowledged in the consultation. ASMI believes that pre-approvals serve a very important purpose in preventing inappropriate advertising and pre-approvals should be retained.

ASMI looks forward to further discussions on advertising of S3 medicines. We would appreciate the opportunity to be involved in further discussions on the details that are yet to be consulted, such as possible legislative and regulatory changes, processes and pathways.