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

The 2018 Therapeutic Goods Advertising Code & associated guidance

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Introduction

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

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain – including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. The consumer demand for complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare. Over the last few decades the Australian complementary medicines sector has evolved into a world class industry supporting domestic skilled jobs, research, manufacturing and exports.

Advertising is a central pillar of the capability of the lower risk complementary medicine industry to communicate information about products that are available for self-selection by consumers. CMA supports the introduction of the new Code in response to the advertising recommendations of the Review of the Medicines and Medical Devices Regulation. We support the further alignment of the Code with World Health Organization policy objectives and the Australian Government's Quality Use of Medicines framework.

In our response to the Advertising consultation in October 2017, CMA expressed support for Advertising Code requirements that were appropriate in scope, minimally subjective, have clarity of interpretation, and that are able to be applied fairly, reliably and consistently. The draft Code presented, as a whole, presents a balanced advertising environment which allows the ability to appropriately advertise a product to the public while maintaining proper consumer protection. *However*, there are areas of regulatory overlap and refinements that are required on technical issues to make the Code practical in application and that will prevent implementation difficulties.

Our assessment primarily considers the effect upon the advertising of complementary medicines and has raised some items that would assist in harmonizing the advertising requirement with those of the complementary medicines regulatory branch. We have also raised areas we believe would create significant red-tape for little benefit to ensure that best practice regulation is in effect.

We acknowledge the vast amount of work and careful consideration that has gone into producing these documents, and appreciate our views being heard through consultation.

General Considerations

Guidance

Much of the guidance that affecting the practical implementation of the Guide is under development. We appreciate ongoing dialogue for those part of the guidance that are currently undeveloped or being re-developed.

Transition Arrangements

The new Code contains a number changes from the 2015 Code including many new or changed mandatory requirements. In this respect, we acknowledge the TGA's commitment for any pre-approved advertisement under the 2015 Code to be used for the full 2 year approval period.

There must also be a specified transition period provided for those advertisements produced under the 2015 Code that are not required to be pre-approved. This period should also be 2 years to allow any coordinated advertising campaigns to be finalised in unison.

Implementation

The draft Code is significantly different to the existing. While recognising the new advertising framework requires change to meet modern considerations, there are many concerns about the implementation challenges of new and changed requirements. In particular – how additional mandatory information will fit into various advertising mediums that are fundamentally limited by time and financial resources, particularly for complementary medicines that are lower volume turnover than other consumer medicines.

The many changes to mandatory statements and other new requirements that are as yet untested. The Code will require flexibility in application and a method for industry and TGA to record the areas that are not able to function reasonably for further assessment.

CMA support the proposed education mechanisms for sponsors and advertisers, in particular the online training portal.

The vast majority of sponsors are well aware of advertising obligations, however there are many other advertisers who are not aware that they are or will be bound by an Advertising Code. There will need to be education and awareness raised around this for these advertisers.

Finally, we strongly advocate that all mechanisms through legislation, guidance, and compliance officer training are explored to ensure that application of the Code is objective, fair, and creates a level playing field for industry.

Response to individual requirements

Sections 1 to 9

- CMA supports Sections 1 to 9 of the Code in the proposed form.
- Technical issues relating to guidance is included in Attachment 1.

Section 10 – Effect

- CMA supports the intent of Section 10.
- Section 10 requires minor amendment for clarification to reduce confusion in application. Technical discussion is included in Attachment 1.

Section 11 – What must advertisements contain

- CMA supports the intent of Section 11.
- Section 11 requires minor amendment for correct application to listed medicines. Technical discussion is included in Attachment 1.

Section 12 – What must advertisements contain – direct marketing and internet marketing

- CMA supports the required availability of the information within Section 12, for digital and other direct marketing sources where the consumer is able to directly purchase within that advertisement. As per the guidance, it appears that this is the intention.
- The terms 'direct marketing' and 'internet marketing' need definition within Section 4 of the Code, rather than the guidance. Technical discussion is included in Attachment 1.

Section 13 – Required Statements

- CMA supports the intent of Section 13.
- There are several areas that require minor amendment and clarification. Technical discussion is included in Attachment 1.

Section 14 – required statement for pharmacist only medicines

- CMA supports the proposed statement.

Section 15 – Required statements

- CMA supports the intent of Section 15.
- Section 15 requires minor amendment for clarification to reduce confusion in application. Technical information is included in Attachment 1.

Section 16 – Endorsements

- CMA supports the intent of Section 16 and the currently drafted guidance.
- We request consideration of the additional guidance under development.

Section 17 – Testimonials

- CMA supports the intent of this Section.
- We recognise that this area is particularly challenging to manage. We support the TGA in developing ways to sensibly and appropriately manage testimonials.
- We are unable to fully respond to this part without the full meaning and effect of the guidance that is under development. We appreciate an ongoing conversation in relation to this part.
- We note and support the exclusion provided in the guidance for testimonials and recommendations that are freely made on social media and which are outside the control of the advertiser.
- To capture the intent but avoid difficulties in implementation, we propose a minor amendment for clarification. Technical discussion is included in Attachment 1.

Section 18 – Incentives

- CMA supports Section 18 and the associated guidance.

Section 19 – Advertising to children

- CMA supports that advertisements should not be directed at children. Discussion on requirement for clarification is included in Attachment 1.

Section 20 of the Code – Allergens

- CMA supports appropriate regulatory mechanisms to protect consumers from inadvertently consuming products that represent a risk of allergy.
- Section 20 needs attention and amendment to harmonise with recent changes to allergy disclosure by other regulatory requirements. Technical discussion in Attachment 1.

Section 21 – Consistency with public health campaigns

- CMA supports the intent of this Section. Technical discussion is included in Attachment 1.

Sections 22, 24

- CMA supports these Sections.

Section 23 – Complementary Medicines

- CMA supports Section 23. We do not support any expansion of this Section. We note Australia's commitment to the World Health's Organisation's strategy on traditional medicines. Technical discussion is included in Attachment 1.

Section 26 – Weight Management

- CMA supports Section 26 and the intent of managing weight loss claim advertisements responsibly. Technical discussion is included in Attachment 1.

Section 28 – Restricted representations

- In the main, CMA supports the proposed wording of the restricted representations.
- CMA proposes an amendment to allow **alignment with permitted indications**. Technical discussion is included in Attachment 1.

Section 29 – Prohibited representations

- CMA supports Section 29.

Attachment 1.

Section 3

Guidance (p11) – 'Prominently displayed or communicated' – clarifications

1. **Visual/spoken statements**.

   For the paragraphs 'For visual statements' and 'For spoken statements', it is not evident whether they stand alone as a descriptor of the interpretation of "prominently displayed and communicated" for *all* advertisements, or only applied to advertisements directed to people with eyesight difficulties as per the example provided in the preceding paragraph. The intended target of the visual/spoken statement paragraphs should be clarified to avoid confusion by advertisers.

2. **Scrolling**

   The part about not being able to scroll to view the information should be removed. Advertisements used on electronic media (pictures or words) are auto-formatted by the platforms that they used on and the presentation varies widely depending on the viewing hardware and individual settings of the user. Hundreds of hardware variations exist – different desktop computers, laptops, tablets, and various kinds of phones – which can be set to numerous different settings including enlarged accessibility views and texts. It is technologically impossible for advertisers to account for all devices and user settings in order to prevent the requirement to scroll.

3. **Pop-ups**

   Similarly, the ability to prevent ('disable') pop-ups is frequently provided within software (as a check-box within software settings), or by third-party software, which is only controlled by end users on various hardware devices. Advertisers and content providers have no influence over this process and consequently it is confusing within the guidance to state that the use of pop-ups is dependent upon the inability for it to be disabled.

   In addition, the term 'disabled' may not be understood by all stakeholders, and might be taken to mean pop-ups that can be closed after opening (which is acceptable/necessary), rather than the intended meaning of pop-ups that can be prevented from appearing.

Section 6

Guidance – Reasonable person

The proposed guidance around a 'reasonable person' discusses an advertisement being appropriate for the targeted audience. While it is a useful discussion the guidance document generally, it does not fit with this part, and doesn't capture the meaning and intent of a 'reasonable person'.

The idea of a 'reasonable person' is one of the key pillars underlying the interpretations of compliance with the Code. It is critical that those being guided by the document including advertisers, other external stakeholders, and TGA compliance officials all have the same understanding in the new enforcement regime of sanctions and penalties.

In relation to therapeutic goods and precedent case law, it would be best drafted by a legal officer.

Various example definitions of 'reasonable person' are available online:

*"A phrase frequently used in tort and Criminal Law to denote a hypothetical person in society who exercises **average care, skill, and judgment in conduct** and who serves as a comparative standard for determining liability."*[1]

*"Someone who uses such qualities as **attention, knowledge, intelligence and judgment** which a society requires of its members to protect their own interests and the interests of others."*[2]

Guidance – health professionals

The guidance for herbalists, etc, is confusing due to the words "provided they are…". The wording should reflect that which is in 42AA of the Act: "*herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a State or Territory; or*"; **and** the following part about Schedule 1 of the Regulations needs to note that this Schedule also includes the aforementioned professions – herbalists, etc.

Section 7

Clarity is needed in the guidance on including pack shots in price advertisements. Currently, clean skin shots can be required for approval, which is not representative of the product for sale.

[1] https://legal-dictionary.thefreedictionary.com/Reasonable+Person
[2] http://www.thewernerlawfirm.com/faq/what-does-the-legal-term-reasonable-person-mean/

Section 8

Guidance (p18) – Approved Advertisements – substantiation for listed medicines

The bottom of page 18 contains clarifications regarding substantiation of therapeutic claims through the pre-approval process. It has been recognised that there should be increased harmonisation between the regulatory branch and the advertising branch to reduce unnecessary red-tape for both industry and the regulator, to prevent the substantiation for claims of Listed medicines being provided and assessed twice. Where:

- The **evidence** for the therapeutic indications included in the advertisement have been **assessed** as part of a post-market **listing compliance review**; and
- The proposed **indication/claim** for the advertisement is **consistent** with the meaning and intent of the **assessed indication**; and
- the sponsor is able to provide a **record of the assessment** where the indication has been reviewed for evidence and the review acceptably **concluded** with the indication on the ARTG, with a **copy of the ARTG record** dated to the time when the assessment of acceptable substantiation was made;

then, in the majority of circumstances the sponsor should be able to use the above information as an available option for substantiating the claim within the advertisement. Exceptions to this are circumstances within an advertisement where the meaning has changed, such as a picture changing the meaning and intent of the advertised claim.

Section 8

Guidance – Approved Advertisements - timeframes for

The guidance on approved advertisements would benefit from a discussion of advertisement approval timeframes as described by the Therapeutic Goods Regulations. This is an area that has presented ongoing confusion and administrative difficulties for advertisers.

Section 9

Guidance – Consistency with Register entry – clarifying for listed medicines

CMA supports the intention of this paragraph – that advertising must be consistent with the entry for the therapeutic goods on the ARTG. However, we note that the term 'consistent' has been variably interpreted in the past. In particular, there have been concerns about whether indications should be used exactly as they are presented on the ARTG.

With the introduction of permitted indications for complementary medicines, sponsors do not have the flexibility to word indications on the ARTG more specifically for their products to enable normal market differentiation and appropriateness to the individual medicine. The regulatory branch are aiming to keep the permitted indication list minimal, reducing repetition. With this view, guidance for permitted indications was created to reflect that within the same meaning and intent (providing that there is not a broader or more specific therapeutic target), indications and claims could be re-worded flexibly to accurately convey the individual medicine use.

To avoid confusion in compliance assessments of advertisements, the guidance needs to describe what consistent means, including describing the kind of variability that *is* acceptable and reference to the other TGA guidance that reflects this.

Guidance – Non-therapeutic claims

The required evidence to substantiate non-therapeutic or promotional claims has not been clear and has created many difficulties in the advertising pre-approval process, and will continue to cause difficulties in a self-regulated environment. Clear guidance on the substantiation of non-therapeutic claims is needed, including examples obtained from the TGA's knowledge in this area.

Section 10

Paragraph 10(a)(i) – clarifying

The guidance clarifies that the intent of this paragraph is to prevent advertising representations which are inconsistent with any of the directions for use. The wording of paragraph 10(a)(i) has the potential to read as if all advertisements must be presented in a way that demonstrates accordance with the directions or instructions for use.

This would cause unnecessary complaints where advertisements are non-specific as to the directions for use (e.g. name and price only) or only cover limited aspects of the instructions for use (e.g., a fish oil medicine that is advertised for joint health, but the directions also contain a use for heart health and dermatitis).

To clarify and reduce potential problems in application, item 10(a)(i) could be worded to the effect:

"***presenting the goods in a manner that is not different to the directions or instructions for use***".

Section 11

Paragraph 11(2)(d) – minor amendment for correct application to listed medicines

Lower risk listed and listed assessed complementary medicines include the information stated in item 11(2)(d) on the visible product label. There is no requirement for a PI or CMI insert, or other alternate repository of information for consumers.

Therefore, the provision of paragraph (2)(c)(i) 'ALWAYS READ THE LABEL' meets the requirements for paragraph 2(d) for listed medicine types and an exclusion should be present when 'ALWAYS READ THE LABEL' has been used in the advertisement.

Section 12

Direct marketing and internet marketing

CMA supports the required availability information in Section 12 at the final purchasing location (such as a company website), recognising that it is the digital or direct marketing equivalent to the consumer accessing the necessary information on physical product label in a store.

The large volume of information required by Section 12 is not appropriate to general advertisements that are limited in scope.

Lack of definition of these terms within the Code creates confusion and a level of risk in the application of the Code. There is some confusion by industry stakeholders as to whether these requirements would require inclusion on general digital or print advertisements (where the product is not available for direct purchase). This confusion could extend to other stakeholders resulting in advertising complaints.

To avoid these difficulties, definitions of direct marketing and internet marketing should be included in the Code and reserved to the locations where the product can be directly purchased.

In particular, there needs to be an awareness raised to online retailers of products such as online chemists, who will be subject to the requirements of Section 12.

Section 13

Paragraph 13(4) – Refining the symptoms statement

CMA supports the intent to seek professional healthcare advice if symptoms persist, worsen, or change unexpectedly. However, the warning is a long and wordy message in an advertising environment that is increasingly filled with more information, distractions, and decreasing attention spans. Longer and unnecessarily wordy statements increase the likelihood of an audience 'tuning out' or ignoring a message. Succinct messages with critical information have a better chance of being absorbed and acted on.

The proposed statement does not gain effect by use of the term 'worsen'. Worsening symptoms are symptoms that are persisting. Worsening symptoms are changing symptoms. There is increasing consumer backlash against increasingly over-protective governmental mechanisms. Any reasonable person with deteriorating symptoms understands they should be assessed by a healthcare professional. A more succinct statement will be a more effective strategy for delivering a critical health message.

Paragraph 13(4) – Clarifying applicable circumstances

The term '**named'** need to be inserted before 'disease, condition, ailment, or defect'.

There have been ongoing difficulties in the application of the Code as to whether a named condition is required to be attached to a low risk symptom indication. The guidance for Permitted Indications (p19, including footnote 8) has clarified this by stating that low risk permitted indications for symptoms does not require linkage to a named disease, condition, ailment or defect. An example of an indication that can be used as a stand-alone symptom is 'relieve nasal congestion'.

This guidance is appropriate, particularly for medicines based upon the traditional relief from common low risk symptoms. Where a claim can be substantiated by evidence to relieve a symptom, but is not specifically studied for an associated condition, the artificial linking of the two creates regulatory red-tape that prevents acceptable advertisements from being approved.

If it is the intention of the Code is to capture any reference to symptoms, the reference to "disease, condition, ailment or defect" should be removed from the Section to avoid confusion between the advertising regulations and the guidance for permitted indications.

Paragraph 13(2) & (3)

Although we agree that the above statements conform to the legislation for medicines and devices respectively, we do not agree that changing the advisory statement is required. We support the retention of the existing 'Use only as directed' for the following reasons:

- The term is succinct and can be applied to both categories. There are many advertisements that have both medicines and devices, which will require both statements, becoming cumbersome to the advertiser and consumer.
- We do not agree that the term, to consumers, implies reference only to direction by healthcare professionals. 'Directed' is a common and broad term, for which it is understood it can mean label and/or the healthcare professional including pharmacists.
- Use of the terms "Directions for Use" and "Instructions for Use" are not requisite on medicine labels, or on all device labels. Therefore the terms do not create extra clarity for consumers.
- The lengthier mandatory statements increases advertising real estate, which creates extra burden particularly for radio and television advertisments.
- The existing term is familiar and well understood by consumers.

Section 15

Paragraph 15(b) – Clarification of '<u>any</u> research results'

The 2015 Code requirement of: '***Publication*** *of research results must identify the researcher and financial sponsor of the research*', has been amended in the proposed 2018 Code to:

'*Where an advertisement makes a scientific or clinical claim:* ***Any research results*** *….*'

The change of the wording may be interpreted to mean that use of any scientific product claim is captured by the meaning and intent of 'any research results', in which case the researcher and financial sponsor of every indication based on scientific information would require declaration. This will be not be possible where there is a wide variety of scientific materials that support an indication. Further, it is the intellectual work of the sponsor that could be easily reproduced by competitors.

The Section must be worded to reflect that it is only intended for circumstances where specific research results a particular study is being quoted. A clarification of the wording will avoid misunderstandings, such as:

> "**Stated results of a particular research trial must…**"

Paragraph 15(c) – Consumer access to research studies that are unpublished

This paragraph requires that if a research study is cited, the study must be sufficiently identified to enable consumers to access it. This implies that all research studies have reached the stage of publication prior to medicine approval. Advertisements for medicines based on unpublished studies would not be able to comply with this paragraph.

The process of publication is an independent process from the assessment and approval of Listed Assessed and Registered medicines, which may occur before or after medicine approval. The current data protection mechanism being examined by the complementary medicines branch for listed assessed medicines is based upon protection of a study prior to publication.

It is appropriate to use unpublished studies in medicine applications, which is reflected in corresponding application guidance by the TGA. The Section could to modified to add the term 'published'.

For unpublished studies, it is possible that a trial summary that provides sufficient information to consumers, while sufficiently protecting intellectual trial data, could be made available on the sponsor website. The clinical trial database reference number could be made available as confirmation of the trial.

Section 17

Paragraph 17(1)(a)(c) – typical results.

The necessity of preventing unlikely or misleading testimonials is recognised.

There is concern how this Section might be applied, and whether an individual person's statements would have to be significantly altered to meet the 'typical results' Section, noting that where goods are taken for a purpose not all users will experience an average result, nor is it straightforward for the advertiser or regulator to determine what the typical or average result would or should be. How is 'typical' measured and applied fairly so that genuine results can be meaningfully communicated?

Possibilities to capture the intent of this Section while remaining applicable could be altering the wording to, for example, '**results that would not be unexpected or unusual from the use of the goods in accordance with the directions for use, or purpose, of the goods'**.

Guidance (p28) – verifiable details

Currently, the guidance for item (1)(a)(i) requires that the term 'verifiable' includes name, age and address. It is not reasonable for a person making a testimonial to have their personal address published in an advertisement. It should be noted in the guidance if the verifiable details are only for use by the TGA and not to be published.

Section 19

The guidance would benefit from clarifying that therapeutic goods intended for children can be advertised if the advertisement is directed to the adult parent caregiver.

The draft guidance notes this part of the guidance is still currently under development. When finalised, it will provide significant direction over what can and can't be included in advertising, but most significantly, on labels for child medicines. Sponsors to use different imagery or graphics to differentiate child products from adult products to parents when they are selecting medicines from a wide range of products available on product shelves. This includes the differentiation of medicines within brands as well as umbrella branded medicines. There must be regulation careful consideration in drawing the line over what is acceptable to denote child products and for companies to create recognizable and appropriate branding, as opposed to what might be considered to be advertising directed specifically to children. We would appreciate continued consultation to determine the practicality of the line that is drawn for this Section as the guidance continues development.

Section 20 – Allergen statements

This Section requires further attention for the reasons outlined below.

This Section is one of most significant concern in terms of the ability to clearly interpret and have significant difficulties in practically applying. While it may be clear for a small subset of medicines that have a clear risk in some populations (for example, products where an ingredient of the medicine is bee pollen, peanuts, or shellfish), there is a great deal of products where it would not be clear whether a statement warrants inclusion on the advertisement or not. This is amplified by updated requirements of the TGO 92 and associated guidance. The TGO 92 requires a widely expanded range of allergen substance declarations, including common substances such as dairy, soy, etc. The proposed TGO 92 guidance requires that any medicine that contains, or is **likely to contain** a substance, is required to make a declaration. While we recognise the requirements of TGO 92 and the Advertising Code are not the same, in organisations allergen declaration requirements contain a significant amount of work through risk assessment. It will create additional regulatory red-tape to apply different risk assessments in different circumstances.

Section 20 appears to only require the most serious or significant sources of allergy risk, whereas the TGO 92 requires declaration of any risk due to trace amounts of allergy materials in a substance as per the TGO 92 guidance. It would not be clear to sponsors where declarations must be included on a medicine **label** but would not need to declared in an **advertisement**. This would result in inconsistent application by sponsors in advertisements, creating an inconsistent advertising landscape for consumers. It is especially important that consumers have consistency in allergen declarations so that they do not come to rely on the advertisement as the sources of information instead of the label, or develop unrealistic expectations that **no advertising disclosure** will mean **no risk of allergens**.

If under TGO 92 guidance in combination with Section 20 of the Code resulted in a significant number of required allergen statements (particularly relevant to complex natural substances in complementary medicines), this in combination with the 'prominently displayed or communicated' requirement would make some therapeutic goods impractical to advertise altogether, or would eliminate advertising mediums that are limited by time and space.

A medicine containing mainly glucosamine that is derived from crustacea is a simple and easily understandable and appropriate application of Section 20. However, there are less clear circumstances where risk of allergy is still theoretically present, if a medicine included, for example the type of statement suggested by guidance to TGO 92: "*Contains kelp, which is sourced from the ocean and may contain traces of crustacea*" or, "*Contains trace amounts of sulphites from the gelatin capsule*", or "*May contain traces of dairy due to being grown on a dairy media*", or "*Contains herb flowerheads that can contain traces of bee pollen*". It does not appear that these types of statements are necessary or reasonable to be prominently displayed upon a medicine advertisement. It would create a lot of information in an advertisement that is overwhelming when

it is being presented via general advertisements. However, inconsistent information (selective serious allergen information communicated by advertisements, and then additional allergen information communicated by medicine labels) will create a confusing and inconsistent messaging medium for consumers.

A simpler solution to a complex scenario could be where a medicine contains a label statement advising of allergens, there could be a prominently displayed statement such as, "**Allergen information**" prior to the statement "Always read the label" within general advertisements for those products that include allergens on their product labels. For this statement, there must be a prescribed list of allergens as some items create confusion as to their status (for example, sulfites).

In addition to this we support an allergen statement that is consistent with the label declarations at the purchasing interface (direct marketing or internet marketing – where the product is available for purchase without viewing the label).

This proposal alerts a consumer to the presence of allergens within the medicine (prompting examination of the label declarations in full), avoids duplication of the allergen risk assessment red-tape by sponsors, and avoids potentially dangerous inconsistent messaging for consumers.

Section 21

This is a new requirement. Caution and reasoning must be carefully applied in application of this Section. It must be appropriately balanced and not result in regulatory over-reach or interpretations that are overly broad. An example might be an advertisement that refers to reducing the risk of the common cold or flu or reducing the severity, must not be interpreted as an advertisement inconsistent with the public health messaging to obtain preventative flu vaccinations. Reference to and examples of a balanced interpretation must be included in the guidance to prevent future complaints and implementation difficulties.

Section 23

Requirements around disclosing the tradition of use. We support disclosure of the tradition of use in the advertisement, where:

- It is only required if related to the advertised therapeutic claim.
- It must not require more information than what is required by the permitted indication determination.
- Where the claim is supported by evidence from multiple paradigms, only the main paradigm requires stating. Otherwise the length becomes overly burdensome.

We do not support the expansion of the requirements, in particular:

- Meeting “prominently displayed or communicated”; requirements that are reserved for critical safety information.
- Extra clarifications around evidence are not required for an advertisement.
- The addition of warning statements about traditional medicines.

Section 26

We have concerns over how typical results can be measured and determined by sponsors and the regulator, and how they could be applied to an interpretation of whether images or visual representations are appropriately representative of typical results.

Section 28 – Restricted Representations

To allow harmonisation of advertising with permitted indications, and to prevent misinterpretation of the requirements of advertising medicines for medically diagnosed but self-manageable conditions which are appropriate for permitted indications, there needs to be an additional paragraph, to the effect:

'However, a form of disease, condition, ailment or defect is not a serious form if:

(d) **It is medically accepted that after initial diagnosis and patient advice, the form is suitable for self-management between medical assessment.'**

The purpose of this proposal is to allow the advertising of permitted indications that are appropriate for **low risk** listed medicines including permitted indications. Clearly the above exception is **only** suitable in combination with the symptoms persisting/changing unexpectedly statement, which will be legislatively required by the Code and also harmonised into the 26BF permitted indication determination which currently includes the symptoms persist statement.

Examples of the permitted indications that this part would harmonise without requiring individual restricted representation approvals are:

- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Decrease/reduce/relieve mild rheumatic aches and pains
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps decrease/reduce/relieve burning sensation upon urination associated with medically diagnosed cystitis
- Helps reduce occurrence of medically diagnosed cystitis
- Helps decrease/reduce/relieve symptoms of medically diagnosed cystitis
- Decrease/reduce symptoms of medically diagnosed cystitis by reducing urinary PH
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
- Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome
- Helps decrease/reduce/relieve symptoms of medically diagnosed fibromyalgia/fibrositis
- Helps decrease/reduce/relieve symptoms of mild medically diagnosed tenosynovitis
- Decrease/reduce/relieve symptoms of medically diagnosed shingles

It will also harmonise future indications that are approved for addition to the permitted indication list.

Perhaps more significantly, it will prevent the number of complaints that will be stating that other permitted indications are breaching Section 28 by implication. For example, permitted indications such as "*Decrease/reduce/relieve mild joint inflammation/swelling*" or "*Helps enhance/promote bone mineralization*" or "*Decrease/reduce/relieve cough*" or hundreds of other indications that could be complained about as implying any myriad number of conditions that are restricted representation by the proposed new definition, risking a large flood of complaints to the TGA Advertising branch. We are aware that stakeholders have deliberately employed such strategies before, that they are willing to continue pursuing such strategies, and that it could present significant and unreasonable difficulties for industry and the regulator if the legislation allows for any subjectivity of this interpretation. The addition of the above proposed statement (or similar) would clearly be able to differentiate what is acceptable and which complaints can be marked as unjustified.