



The Pharmacy
Guild of Australia

THERAPEUTIC GOODS ADMINISTRATION

Consultation: Therapeutic Goods Advertising Code – Proposed improvements including proposed framework for Schedule 3 medicine advertising

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National Secretariat

Level 2, 15 National Circuit, Barton ACT 2600

PO Box 310, Fyshwick ACT 2609

P: +61 2 6270 1888 • F: +61 2 6270 1800 • E: guild.nat@guild.org.au

www.guild.org.au

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INTRODUCTION

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to comment on the Therapeutic Goods Advertising Code.

The Guild supports *The National Strategy for Quality Use of Medicines (QUM)* and believes that QUM is best supported by the supply of medicines through community pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants, within a quality-assured framework.

The Guild believes the current principles-based Therapeutic Goods Advertising Code is largely appropriate and therefore does not support any major changes to the Code's requirements governing the advertising of therapeutic goods.

However, the Guild believes targeted improvements can be made into how and when the Code and the associated restrictions apply. The most significant challenge to the Code's role of protecting the Australian community from inappropriate advertising has been difficulty in effectively enforcing the Code. The Guild is strongly of the view that substantial resourcing as well as more appropriate sanctions are the only way to effectively manage and discourage advertising breaches.

Subject to the observations contained in the body of its submission the Guild supports reforms to the Pharmacist Only Medicine (Schedule 3) advertising regulations. The Guild sees the promotion of Schedule 3 medicines in this context as communicating to consumers the availability of medicines suitable for their health condition without the need for a prescription, subject to the mandatory assessment and confirmation by a pharmacist and is thus in the public interest.

SUMMARY OF COMMENTS

1. The Guild cautions against incorporating rigid objective parameters in the therapeutic goods advertising guidelines that restrict the ability of the regulator to make a decision that is appropriate in individual circumstances. The rules and guidelines must acknowledge the subtleties that exist between different advertisements and the impact these changes may have on a consumer's overall perception.
2. The Guild considers there needs to be a clearer and more consistent approach to the regulation of endorsements, in particular non-health professionals such as celebrities/athletes.
3. The Guild does not support the proposed changes to the sponsorship advertisement requirements. These proposals could restrict the promotion of public health information by medicine sponsors and public health organisations. This is clearly not in the interest of health professionals or consumers.
4. The proposal to broaden prohibited claims to all references relating to diseases such neoplastic and mental illness should be approached with caution. Many advertisements that are currently compliant with the advertising code, would no longer be permitted if the proposed amendments were adopted.
5. The Guild does not consider the current Restricted Representations approval process to be fit for its intended purpose in ensuring advertising meets the public interest.

6. While the Guild has no objection to the development of specific examples of compliant and non-compliant advertising, such examples should not be incorporated into the Code itself. Incorporating examples into the Code could create rigid objective parameters that could have legal implications particularly if an advertiser were to challenge a ruling in court.
7. The Guild offers in-principle support to establishing the Price Information Code of Practice (PICOP) as a separate legislative instrument under the Therapeutic Goods Act. If this option is adopted, it would be essential stakeholders are consulted during its development.
8. The Guild cautions against completely excluding broad categories of medicines from consideration for advertising on the basis of a single attribute that may or not be relevant in a particular circumstance. Many of these categories run the risk of arbitrarily excluding a large range of medicines from even being considered for advertising.
9. The Guild offers in-principle support for the proposed process for determining whether a down-scheduled prescription medicine is suitable for advertising. Determining suitability for advertising should continue to be considered via the current scheduling determination process (Advisory Committee on Medicines Scheduling and the Scheduling Delegate with public consultation on proposals).
10. The Guild recommends that pharmacy assistants should also be included under Sections 42AA of the *Therapeutic Goods Act* to enable sponsors and professional organisations to communicate important information to pharmacy assistants in order for them to perform their role. Pharmacy assistants should not be impaired in doing their job effectively due to restrictions in advertising therapeutic goods.

PROPOSED CODE CHANGES

4.1 Changes to support effective sanctions and enforcement of advertising requirements

While the Guild recognises that minimising subjectivity in the interpretation of the new Code is a worthwhile goal, it will be difficult to completely eliminate subjectivity given the nature of advertising and variation of opinion that often arise between interested parties, such as health professionals, consumers, medicine sponsors, government or retailers.

An average consumer's perception of an advertisement and likely reactions and actions in response to it are critical considerations in determining an advertisement's risk to public health.

The Guild would also caution against incorporating rigid objective parameters that restrict the ability of the regulator to make a decision that is appropriate in individual circumstances. Context and associated factors are a critical consideration. While a particular statement or message in isolation may not breach the guidelines, if it is accompanied with other messages and/or branding, the impact and message conveyed to a consumer can change dramatically.

The rules and guidelines must acknowledge the subtleties that exist between different advertisements and the impact these changes may have on a consumer's overall perception.

The Guild supports formal advertising compliance programs that highlight specific case studies to inform stakeholders regarding what is and what is not acceptable in regards to advertising of therapeutic goods.

The Guild also sees increasing the online accessibility and searchability of complaint outcomes as a key step in supporting industry education. It may also be of benefit if industry is able to seek guidance on the development of promotional material in some instances prior to distribution. In the absence of any guidance, some sponsors and organisations may be hesitant to publish all together which may not be in the public interest.

As mentioned in our response to previous consultations, the Guild supports enhanced investigation and enforcement powers as well as sanctions and penalties for breaches of the advertising regulations. The Guild also supports non-financial enforcement powers such as “take-down” orders or correction notices which would help with maintaining advertising compliance in the public interest.

In addition, there needs to be a stronger focus on advertisers who are ‘repeat offenders’, including product sponsors who may have multiple products on the ARTG. There also needs to be a greater consideration of precedent and the history of non-compliance of the advertiser. While we understand that intentional non-compliance is not common, we would support targeted surveillance by the TGA to manage problematic categories such as weight-loss products, as well as repeat offenders.

4.2 Core objectives for the new Code

The Guild offers in-principle support for the core objectives for the new Code subject to the more detailed comments made below.

The Code in its current form is comprehensive and prohibits all of the key elements that are necessary to protect the public from harm.

The Guild believes it remains appropriate for peak health bodies and organisations representing health professionals to endorse products, provided the nature of the endorsement is disclosed. We note the discussion paper mentions certain endorsements by health related bodies or organisations would still be permitted subject to the conditions outlined.

4.2.1 Endorsements

The Guild considers there needs to be a clearer and more consistent approach to the regulation of endorsements.

The *Therapeutic Goods Advertising Code* currently does not allow health professionals to endorse a therapeutic good. However endorsements in the form of testimonials provided by non-health professionals (e.g. celebrities or athletes) are permitted.

Given such individuals are often seen by the general public as ‘genuine’ and ‘trustworthy’, an endorsement for a therapeutic good by a non-health professionals could have the same or greater influence on a consumer to purchase the product. As celebrities, including athletes, are not bound by the professional obligations of health professionals, consideration should be given to greater restriction of endorsements by celebrities than consumers and general actors.

4.2.2 Sponsorship Advertisements

The Guild does not support the proposed changes in their current form.

Sponsors provide funds for education and training to a number of different audiences as well as more general public health awareness campaigns.

It is unlikely that a commercial entity would provide this support if they cannot even identify themselves as a sponsor.

Indeed, the Guild works to support public health organisations such as Diabetes Australia, the Heart Foundation and the Lung Foundation in various disease awareness campaigns. Under these proposals, the Guild may be precluded from promoting public health information through community pharmacy under this proposed change. This is not in the public interest.

Potential campaigns that could be impacted by this proposal include:

- Smoking cessation campaigns run by non-for-profit organisations such as the Cancer Council
- Community wellness events, such as sponsorship of a fun-run, local sporting team, or
- Websites that provide general information on a condition and provide links to supports services such as www.turntohelp.com.au

This is clearly not in the interest of health professionals or consumers. It would also mean that Governments may need to fill this void by dedicating significant funds into the development and dissemination of public health promotion and awareness campaigns.

The Guild notes the proposals in this area are not exhaustive and that further consultations will be undertaken when a draft legislative instrument is published. The Guild looks forward to further consultation opportunity to ensure that the contents of the instrument are in the public interest.

4.3 The Therapeutic Goods Advertising Code Council (TGACC) recommendations

4.3.1 New definition of Prohibited Representations

The proposal to broaden prohibited claims to **all references** relating to diseases such neoplastic and mental illness should be approached with caution.

If the proposed amendments were adopted, many advertisements that are currently compliant, would no longer be permitted. This is particularly pertinent given the very broad definition of advertisement and the fact the term *representation* is not defined in the code. Specific examples of advertisements that may be prohibited include:

- Products that are indicated and promote general mental health and wellbeing
- Bowel Cancer screening test kits
- HIV Test Kits
- Skin Cancer spot checks

These representations are already restricted by Section 5(2) of the Code, which require the TGA to provide an advertising exemption for the representation to be made. No case has been made for this proposed change to Prohibited Representations, which would remove the discretion of the TGA to allow these representations if it were demonstrated they were in the public interest.

It appears counterintuitive that a package of reforms intended to provide the regulator with more enforcement power and scope to consider the public interest would include measures that remove this function. Indeed, it could be argued that where Restricted Representations were only granted where there was a clear public interest that there would be no need for Prohibited Representations.

Prohibited Representations also limit the ability of health providers to include relevant warning statements in material falling within the broad definition of 'advertisement'. For example, the following statement would be prohibited in consumer educational material which met the definition of 'advertisement':

- Example 1

"Product X is intended for management of self-limiting mouth ulcers. If you have other health conditions which affect the immune system, such as HIV or cancer, talk to our pharmacist about appropriate management options".

For this example, the claim may not be appropriate as a subtitled disclaimer in broadcast TV advertising, but may be quite appropriate on an online-pharmacy website describing a product available for sale. Under the Prohibited Representation regulations, the TGA is not in a position to allow such representations in any circumstances.

Such broad restrictions are likely to affect not just medicine sponsors but also:

- Community pharmacies
- Peak health organisations providing consumers with information on their websites about how their health condition is managed
- Health professionals describing the nature of services they provide.

The Guild does not support measures that place an undue regulatory burden on small business such as community pharmacies and prevent the promotion of products that are in the public interest.

4.3.2 New definition of 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.

The Guild cautions against amendments that make any procedure that can only be performed by a suitability qualified healthcare professional a Restricted Representation.

Such broad restrictions are likely to affect not just medicine sponsors but also small businesses that supply therapeutic goods such as community pharmacies. The Guild restates its opposition to measures that place an undue regulatory burden on pharmacies and prevent the promotion of products that are in the public interest.

This proposed measure could prevent the promotion of public health messages. Such examples include:

- Services offering inhaler techniques for patients suffering asthma or COPD
- Smoking cessation products
- Breastfeeding mothers and advice for mothers with newborns and/or young children
- Wound management and first aid
- Asthma support and advice (including thunderstorm asthma)
- Travel advice and support
- Information on men's and woman's Health
- Diabetes Screening

Restricted Representations: Evolving health environment

There has been a long standing provision that the ‘threshold’ for Restricted Representations relates to a condition requiring health professional diagnosis or management. With the rapid rise in consumer self-management and the evolving professional scope in many health professions, this is increasingly unclear.

The Guild sees challenges in the application of the proposed changes for the following reasons:

- *Inability for consensus*
Groups representing health professionals often take contrasting views on whether a particular health professional is ‘suitably qualified’. If such an amendment were to be adopted, there needs to be clear reference that explicitly outlines the sorts of circumstances where **only** a health professional is suitably qualified to perform the service.
- *Distinction between self-care and primary health care*
The distinction between self-care and primary health care is increasingly blurred. This is a result of greater consumer engagement with management of their health and accessibility of health information. In the example highlighted in the discussion paper (direct-to-consumer genetic testing) a health professional may simply be the point of contact for the consumer and the actual testing is performed offsite by a private contractor. This raises the question of whether both parties must be suitably qualified and how this would be determined. This also applies to other tests such as bowel cancer screening and HIV tests.
- *Inconsistent application*
There are many advertisements which have been long accepted to be included in consumer advertising which appear to conflict with this provision as, following diagnosis, it is accepted there is an element of self-care. Examples predominately relate to AUST L products and include:
 - Medically diagnosed irritable bowel syndrome (IBS) and probiotics
 - Representations of ‘antibiotics’ in relation to probiotics (as antibiotics are only available on a prescription from an authorised health care professional).
 - Health maintenance claims, such as ‘maintain healthy sugar levels’ or ‘maintain healthy blood pressure’ where the likely takeout message for the average consumer is an indirect reference to managing conditions such as diabetes or hypertension.

Effectiveness of proposed change

The Guild also questions that if such products were instead advertised as a service (e.g. ‘testing services available here’ or ‘ask about how we can help you prevent <health condition>’) whether these changes to the Code would actually have any practical effect.

Reference to “obesity” either directly or indirectly to become a restricted representation within the meaning of the Therapeutic Goods Act 1989 (the Act).

The Guild supports this proposal.

Clarifying that the representation “prevention of skin cancer” in respect of certain sunscreens is permitted as a restricted representation.

The Guild supports this proposal. We note there would need to be specific exclusion of these representations from the Prohibited Representations, as currently exists in the Code.

Clarifying that the representations “devices that are used in contraception” or “in the prevention of disease transmission” are restricted representations.

The Guild believes this specific proposal requires refinement because the intent of this clause is unclear.

Currently, there is a specific exemption for contraceptive devices in regards to the Prohibited and Restricted Representation provisions. The Guild believes this is appropriate.

The Guild does not support any requirement for products such as condoms to require TGA approval to make these claims. These products have a strong evidence base to substantiate claims and is clearly in the public interest to promote the availability and intended purpose of these products to consumers in a timely manner.

We also note the broad definition of ‘advertisement’ would also capture a significant proportion of public health ‘safe sex’ campaigns and inadvertently place these campaigns in breach of Restricted Representations provision within the Code and relevant sections of the *Therapeutic Goods Act*. This is clearly not in the public interest.

Amending the provisions dealing with “scientific information” to ensure that:

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

The Guild offers in-principle support to this recommendation, consistent with the previous recommendations to Government by the TGACC. It would be beneficial if further clarification was provided in the code as to what is defined as ‘scientific information’. The interface between ‘health information’ such as description of physiological processes, pathophysiology etc. and ‘scientific information’ should be clearly defined.

The Guild encourages such studies supporting scientific information to be made readily available to health professionals such as pharmacists so they are able to assess and communicate the findings to consumers as required. It is difficult to describe to consumers the limitations of scientific information used in advertising where the research is not readily accessible.

4.3.3 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 IUDs.

The Guild seeks clarification on the definition of a ‘free sample’ under this proposed change. An example would be whether offering a gift or additional product with the purchase of a particular product would be considered in the same manner as a handout of a sample with no conditions.

The Guild reserves its position on the proposed changes to testimonials until the proposed objective conditions have been developed and published for further consultation.

4.4 Consultation comments

4.4.1 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

As mentioned above, while the Guild recognises that minimising subjectivity in the interpretation of provisions in the new Code is a worthwhile goal, it will be difficult to completely eliminate subjectivity given the nature of advertising and differences of opinion that often arise between a complainant and a respondent.

For example; the likely consumer take-out from a medicine claim “works 40% faster than other brands” will vary depending on its context. This could include:

- Visual representation – such as fonts, size, emphasising features, analogies with other activities (e.g. racing cars)
- Whether the claim is used in isolation, or includes other explanatory information relevant for context (e.g. limitations of the claim)
- Audience to which the claim is targeted at, including whether the claim is easy to understand or relevant in terms of therapeutic benefit for that audience;
- The person or organisation making the statement
- The timing of the claim (e.g. seasonal factors).

Such factors can have a significant impact upon an average consumer’s perception of an advertisement and their likely reactions and response to it. Consequently, determining whether an advertisement complies with the Code is sometimes complex and require careful judgement. Nonetheless these are essential considerations in determining whether an advertisements is a risk to public health.

The Guild cautions against incorporating rigid objective parameters that restrict the ability of the regulator to make a decision that is appropriate for individual circumstances. As described above, while a particular statement or message made in isolation may not breach the guidelines, if it is accompanied with other messages and/or branding, the impact and message conveyed to a consumer can change dramatically. Examples can be seen throughout the Complaint Resolutions Panel (CRP) determinations in recent years, including the following examples:

- Complaint 2012-08-010 and 2012-10-024 Nurofen and ‘source of pain’ – context related to include visual representations of pain depicted on human body
http://www.tgacrp.com.au/complaint-register/?_search=nurofen&_id=2181
- Complaint 2014-07-022: Sambucol and contextual representation of ‘flu’
http://www.tgacrp.com.au/complaint-register/?_search=TVC&_id=2589
- Complaint 2016-03-002: Zyrtec and context/emphasis in comparative claims “starts to work faster”
http://www.tgacrp.com.au/complaint-register/?_year=2016&_paged=4&_id=2983

The rules and guidelines must acknowledge the subtleties that exist between different advertisements and the impact these changes may have on a consumer’s perception.

4.4.2 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

While the Guild has no objection to the development of specific examples of compliant and non-compliant advertising, such examples should not be incorporated into the Code itself. Incorporating examples into the Code could create rigid objective parameters that could have legal implications particularly if an advertiser were to challenge a ruling in court. It may also give advertisers a false sense of security that a particular advertisement is compliant when in fact it is in breach due to other important factors such as the context or placement of an advertisement. Such examples are more suitable for inclusion in formal education material for stakeholders to provide a general indication of acceptable advertising.

Given the nature of advertising therapeutic goods, it is difficult to completely remove ambiguity from the Code. If advertisers are uncertain of an advertisement's compliance with the Code, the advertisement should not be published until they are satisfied it meets its regulatory obligations.

The Guild supports consistent interpretation and application of the advertising requirements. If there is regular updating of the requirements, consistency needs to be considered in the context of the requirements that existed at the time of each determination. Additionally, the body of evidence regarding health and medicine information is constantly evolving and claims which were previously considered reasonable may become obsolete as more significant research becomes available.

5 Price Information Code of Practice (PICOP)

The Guild offers in-principle support to establishing the PICOP as a separate legislative instrument under the Therapeutic Goods Act. If this option is adopted, it is essential stakeholders are consulted during its development. Support would also need to be provided to professional organisations to provide training to health professionals such as pharmacists about the legislative requirements and their responsibilities.

The Guild is also willing to work with the TGA to identify and resolve any 'gaps' or inconsistencies in the current framework.

The Guild would like to see clearer penalties for breaches and the outcomes of complaints to be published on the TGA website. The Guild considers the current process to be inadequate with regulators at times not able to provide timely responses and resolutions. There is little point in having a code of practice if its provisions are not effectively enforced.

It would also be of educational value if the TGA were to publish an indicative format or presentation of a price list which could be used by advertisers as a guide to this code of practice.

AN OPTION FOR AN ADVERTISING FRAMEWORK FOR SCHEDULE 3 (PHARMACIST ONLY) MEDICINES

6.1 Overview

The Guild restates its support for reforms to the Pharmacist Only Medicine advertising regulations, so as to enable these products to be advertised under the following conditions:

- Sufficient time is allocated for pharmacists to become familiar with the increased availability, demand and associated professional responsibilities when products are rescheduled from Schedule 4 to Schedule 3.

- Industry assists the profession through both consultation and funding to develop relevant professional support materials for the supply of Schedule 3 medicines.
- Pharmacists are provided with relevant training to support the professional supply of Schedule 3 medicines.
- All advertisements inform consumers that Schedule 3 products are only available in consultation with a pharmacist.
- All advertisements include a direction to 'Ask Your Pharmacist'.
- The last two requirements are incorporated into appropriate legislation/ regulation (*Therapeutic Goods Act, Therapeutic Goods Advertising Code*).
- Adequate enforcement and sanctions are applied in circumstances where an advertisement is found not to have complied with the relevant regulations.

The Guild supports a responsible approach to advertising for Schedule 3 medicines which would encompass the following requirements:

1. Information about the condition
2. Discussion with a pharmacist on whether the product is appropriate (ASMI template)
3. Relevant information about the product

The Guild is comfortable with the Appendix H mechanism remaining as a list of substances that may be advertised to the public.

6.1.1 Establishment of Schedule 3 Advertising working group

The Guild also offers in-principle support to the establishment of a working group to consider the suitability of existing Schedule 3 medicines for inclusion on Appendix H on a case-by-case basis. Community pharmacy representation and involvement in such a working group is essential.

6.2 Product Advertising Requirements

6.2.1 Additional requirements for advertisements for Schedule 3 medicines

While the Guild supports the intent of the proposed statement "*Your pharmacist must decide if this product is suitable for you*" a more appropriate statement would be:

*"Your pharmacist **will decide** if this product is suitable for you"*

The Guild considers the revised proposed statement more clearly communicates to consumers the regulatory requirements attached to the supply of products.

Similarly instead of the statement "*Ask your pharmacist about side effects relevant to you*", the Guild proposes:

*"Ask your pharmacist **about the safe and effective use of this medicine**"*

The Guild consider the revised proposed statement has a more positive tone and is a broader statement that captures other elements relating to the Quality Use of Medicines.

6.3 Substances unsuitable for inclusion in Appendix H

6.3.1 Categories that are not appropriate for advertising

The Guild cautions against completely excluding broad categories of medicines from consideration for advertising on the basis of a single attribute that may or not be relevant in a particular circumstance. Many of these categories run the risk of arbitrarily excluding a large range of medicines from even being considered for advertising. The Guild considers the factors currently outlined in the Scheduling Policy Framework provide sufficient guidance to decision makers regarding an individual substance's suitability for advertising.

It is worth noting that many advertisements for these types of products would be considered Restricted Representations, hence would still be subject to TGA approval following consideration against public interest criteria. The Guild considers this a more appropriate mechanism to consider manage the appropriate advertising of Therapeutic Goods, rather than via the list below.

Injectable

The Guild does not believe a medicine should be excluded from advertising consideration purely on the basis that it is injectable. For example, there may be merit in allowing adrenaline for the treatment of an allergic reaction as a responsible public health message. The Guild challenges the consistency of this approach given there are injectable medicines (such as injections for B-12 deficiency) that are currently exempt from scheduling and can therefore can be advertised to consumers, subject to other requirements of the *Code*.

Substance for use in emergency situations

While at first glance this appears reasonable, the Guild notes its application and reality is less straightforward. In the context of OTC products, there needs to be clear guidelines as to what constitutes an 'emergency situation'. Consumer awareness of availability of a product for use in emergency situations does not necessarily promote inappropriate or indiscriminate use. This is demonstrated through extensive literature in relation to sexual health and access to contraceptive products. We therefore question the broad exclusion of Schedule 3 medicines used in 'emergency situations' from being advertised. A recent example is ulipristal (which is indicated for emergency contraception), which was recently added to Appendix H and considered as appropriate by the scheduling expert advisory committee to be advertised to consumers. The proposed criterion would preclude this product from be advertised.

Where safer analogues or therapeutically equivalent medicines are available

The Guild does not consider this is a valid criterion for excluding Schedule 3 medicines from listing on Appendix H. The suitability of a Schedule 3 medicine to be included on Appendix H should be considered solely on the individual therapeutic properties of the medicine and the likelihood of compliant advertising to adversely impact on the safe and effective use of medicine, or treatment options for the health condition. We believe appropriate application of comparative advertising principles within the *Code* adequately manages this issue.

A Schedule 3 medicine may ultimately be more suitable than other medicines due to other factors such as reduced dosing (e.g. modified release tablets) or ease of administration (e.g. an oral tablet compared to a topical cream) and it may be in the public interest to promote the availability of these medicines.

Where is there is potential for inappropriate use, abuse or diversion

The Guild agrees with this proposed exclusion in regards to medicines that may be subject to abuse and personal misuse or diversion.

Where the substances form part of surgical procedure

The Guild agrees with the proposal and we do not consider substances indicated for surgical procedures are suitable for advertising. However, we also note these are captured through Restricted Representation and may not require duplicative regulation.

Medicine for treatment of chronic condition that requires a doctor as part of the treatment

The Guild questions the need for such a criterion as such substances are unlikely to be listed in Schedule 3, hence advertising is not a relevant consideration.

6.4 Process for adding a substance to Appendix H

The Guild offers in-principle support for the proposed process for determining whether a down-scheduled prescription medicine is suitable for advertising. Determining suitability for advertising should continue to be considered via the current scheduling determination process (Advisory Committee on Medicines Scheduling and the Scheduling Delegate with public consultation on proposals).

In general policy terms, the Guild believes Schedule 3 medicines should be included on Appendix H (subject to the outlined in the overview section) unless it is clearly **not** in the public interest to do so. This should be the guiding principle when considering whether a medicine should be included in Appendix H.

ADDITIONAL COMMENTS

RESTRICTED REPRESENTATIONS APPROVAL PROCESS

The Guild does not consider the current Restricted Representations approval process to be fit for purpose.

Applying to advertise a Restricted Representation is a time consuming process and deliberation is lengthy. The experience of advertisers is that requests are regularly rejected; including reasonable requests to include warning statements referencing serious conditions on product packaging.

The system is not fit for its intended purpose in ensuring advertising meets the public interest.

The Guild does support streamlined systems for timely approval of Restricted Representations, where regulation is proportional to the risk. The Guild contends factors relevant to risk include:

- Audience reach
- The type of audience to which the advertisement is directed
- Whether the advertising is in relation to a regulated health service (e.g. pharmacy services) which would be subject to professional obligations

EXEMPTIONS FROM ADVERTISING RESTRICTIONS FOR PHARMACY ASSISTANTS

Community Pharmacy employ pharmacy assistants and their regular duties require them to order, handle and supply therapeutic goods. Moreover, patients can and do ask pharmacy assistants about therapeutic goods available through pharmacy. It is therefore appropriate for them to receive training about the therapeutic goods they supply as well as training in other pharmacy/ health issues of the day.

As pharmacy assistants are not registered health professionals, for the purposes of advertising of therapeutic goods they are considered consumers. Therefore, any content directed at pharmacy assistants must adhere to the same protocols and restrictions as if the content were directed at general consumers.

This creates a number of problems when attempting to provide important and relevant information to pharmacy assistants. These include:

- Not being able to communicate contraindications of complementary medicines, unscheduled medicines, *Pharmacy Medicines* or *Pharmacist Only Medicines* (which are permitted to be advertised) in training materials which are caught within the broad definition of 'advertisement'.

For example:

- References to diabetes, cardiovascular disease or cancer constitutes a restricted representation or prohibited representation under the *Therapeutic Goods Advertising Code*. They cannot therefore be included in warning statements in training materials describing how to appropriately supply products.
- References to cancer, immunocompromised persons (e.g. people living with cancer, HIV, organ transplants etc.) as important referral points to the pharmacist when responding to a product request.
- Training on supply of diabetes consumables through government subsidy schemes such as the NDSS may be inadvertently caught within the definition of 'advertisement' and be Restricted Representations.
- Inability of product sponsors to inform pharmacy assistants of medicine interactions, particularly between prescription and complementary medicines. For example, advertising of St John's Wort containing a reference to interactions with tramadol, prescription-antidepressants or cyclosporin may breach provisions in the *Therapeutic Goods Act* regarding prescription medicine advertising
- Inability of product sponsors to convey medicine-nutrient interactions –noting that many vitamin and mineral supplements are considered therapeutic goods.

The Guild notes that Section 42AA of the *Therapeutic Goods Act* disapplies the part to 'advertisements' directed exclusively to a number of classes of people including health professionals as well as others who are involved in the sale and supply of therapeutic goods. This list includes health practitioners that are not regulated under the Health Practitioner Regulation National Law such as:

- Nutritionists
- Homeopathic practitioners
- Naturopaths

The Guild recommends that pharmacy assistants also be included on this list to enable sponsors and professional organisations to communicate important information to pharmacy assistants in order for them to perform their role. Pharmacy assistants should not be impaired in doing their job effectively due to restrictions in advertising therapeutic goods. It is essential they receive appropriate training and advice that mentions scheduled substances or health conditions so they can provide this service or know when to refer the patient to a pharmacist.

It is also important to note that pharmacy assistants work under the direct supervision of a pharmacist at all times. Pharmacy assistants are trained to, and in many cases obligated to refer a consumer to the pharmacist for further information and advice and will ultimately make a determination regarding the suitability of an appropriate medicine.