The Pharmacy Guild of Australia

THERAPEUTIC GOODS ADMINISTRATION

Complaints handling – advertising of therapeutic goods to the public

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INTRODUCTION

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to comment on the Therapeutic Goods Administrations' (TGA) Consultation on complaints handling – advertising therapeutic goods to the public.

The Guild is the peak pharmacy organisation representing community pharmacy. The Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

The Guild has restricted its comments only to those sections of the Consultation paper that we believe require further consideration or clarification.

Summary of Submission

The Guild acknowledges the TGA's commitment to significantly improvem the timeliness of considering advertising complaints outlined in the submission, and provides in-principle support to the risk-based sanction model described in the consultation document. However, we are concerned at the proposed approach to triage of complaints, particularly in relation to how 'low' priority complaints will be handled.

In response to the consultation document, the Guild urges the TGA to undertake further work in the following areas.

Resources

The Guild considers the Complaints Resolution Panel consistently made sound decisions in applying the *Therapeutic Goods Advertising Code* (the *Code*) and the *Therapeutic Goods Act* (the *Act*). Unfortunately, the resources allocated to the Panel meant complaints were unable to be considered in a timely manner.

The Guild is concerned that the consultation documents do not address the significant increase in personnel resourcing which will be required within the TGA to adequately support an effective complaints system for the advertising of therapeutic goods.

Transparency

A strength of the Complaints Resolution Panel (CRP) has been publically available determinations for each complaint considered in the complaints register. The provision of full text determinations on the register has served as a valuable deterrent to non-compliance with advertising regulation, as well as helped educate advertisers and the Australian public on how the code is applied.

In contrast, the consideration and outcome of complaints which had been referred by the CRP to the TGA (e.g. for non-compliance with sanctions or being out-of-scope) did not have the same level of transparency, with the outcome of many complaints not being publically available.

The proposed risk-matrix for considering complaints erodes the transparency of the existing complaints register, and results in a significant reduction in transparency for communicating complaint outcomes to advertisers, complainants and the Australian community. It may also result in increased non-conformance of 'low' and 'moderate' risk issues as the regulator's application of many aspects of the *Code* will not be made public. The Guild considers this unsatisfactory.

Risk categorisation

The Guild provides is in-principle support to a risk-matrix which helps categorise the severity of and priority to respond to advertising breaches, particularly where there is a risk of consumer harm through advertising of therapeutic goods. However, we do not support a risk-matrix being used to make a decision on whether or not the regulator properly considers the complaint and makes a decision on whether the alleged breaches have occurred.

Risk criteria

The risk-matrix described in the consultation document uses vague descriptions for level of risk which cannot be applied consistently. The Guild is also concerned that relevant factors for an advertisement's risk do not appear to have been considered in the risk framework:

- consumer financial loss through being misled as to product effectiveness;
- size of the advertisement audience; and,
- extent of commercial advantage achieved through non-conformance.

Determining breaches for 'low priority' complaints

We are concerned the approach appears to make a determination on whether a breach is serious before deciding whether the breach needs to be determined or not. It is concerning that 'low priority' complaints will not be formally determined. This will encourage non-compliance for minor breaches of the *Code* and *Act*. While the safety risk to consumers of an individual advertisement may be triaged as minor, this approach creates a competitive disadvantage to advertisers who strive to fully comply with the regulations and encourages a casual approach to 'minor' breaches from advertisers, undermining the intent of the regulation. The Guild considers this unsatisfactory.

The Guild provides the following comments on specific sections of the consultation document.

6 OUR APPROACH

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

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

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

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

Our complaints process is supported by the following principles:

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

Guild Comments

The Guild has some reservations about the underlying attitude described in the TGA's approach. We believe that all non-compliance issues notified to the TGA should be dealt with in an equal manner, and that not addressing 'non-serious non-compliance' sends a poor signal to advertisers who wish to flout aspects of the regulation. We would also expect that all Government Departments would work ethically within their legislative frameworks and do not see the point in highlighting this as a principle – it should be a "given".

The approach implies through omission that few resources will be devoted to the majority of complaints which do not fall in the 'most-serious non-compliance' category. We believe it is therefore inconsistent to claim *"Our approach to handling and determining complaints will be consistent"* where the majority of complaints will not result in a determination.

We would also ask what the TGA would consider a "one off". Is this a "one-off by the advertiser, or one off based on a specific matter? If the same advertiser has a number of low level priority offences or breaches, but on separate matters - are these singularly considered one off' or would they be considered in a context of a pattern of behaviour?

7 THE COMPLAINTS PROCESS

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

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

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

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

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

Guild Comments

In addition to pre-approval of advertisements in specified media, complaints are the primary compliance mechanism for breaches of advertising regulation. It is therefore imperative that possible complaints about non-compliant advertising and determination are made as easy as possible. It is particularly important that it is easy for complainants who are not familiar with 'the system' to make a complaint about advertising content which concerns them. We therefore strongly support a 'no wrong door' approach to complaints submission.

We recommend resources be made available to small businesses and consumers to help them navigate the complaint submission process. This includes the availability of telephone support during business hours, and an email address which will be responded to within one business day.

The design of the online complaints form should focus on ease of experience for the complainant primarily, and for efficiency of the regulator's internal processes as a secondary priority to this.

We recommend the unique identification number provided to complainants (and presumably advertiser(s)) which will be able to be used to search online for the current status of the complaint. It should also be able to be used to find the determination for every complaint. This is important for transparency for all parties subject to a complaint and public transparency.

There are times where a complainant may not wish for their identity to be treated privately. Confidentiality of the complainant should only be maintained during the process where it is requested by the complainant. The Guild supports as much transparency as possible in complaints handling, and recommends the category of complainant (e.g. consumer, pharmaceutical industry, non-government organisation etc.), where known, be included on the complaint register.

7.1 ACCEPTING YOUR COMPLAINT LEAD

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

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

In these cases the complainant will be advised that their complaint has been closed and they will be consulted as to whether they want us to refer the case to a more appropriate authority.
If a complaint is assessed as a valid complaint, within our jurisdiction, the lead will be moved to a complaint case and the complainant will receive an email or letter confirming this with the case identification number.

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

Guild Comments

Out-of-scope complaints

The Guild questions the approach taken to complaints outside of the jurisdiction of the TGA. Where a complaint is assessed as outside of the TGA's jurisdiction, where legally permissible, this should be provided by the TGA to the appropriate body as the default approach, rather than asking the complainant for permissions. This could be communicated on the complaint submission form, with an opt-out option if they did not wish this to occur.

Identification of themes

We do question why a number of complaints received on the same topic would be targeted by an educational campaign and not stronger enforcement action. We note it is incongruent with the TGA's risk profile described in the consultation paper for complaints graded higher than 'low priority' to be managed primarily via education activities.

7.2 TRIAGING OF COMPLAINTS

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

Guild Comments

Triage process

The triaging of a complaint in practice represents a preliminary determination of the complaint. As such, it is essential the person or persons making this decision possesses the appropriate skill, experience and understanding to make these judgements. As therapeutic goods are not normal items of commerce, and the substantive advertising requirements are principles-based, we consider it essential an experienced health professional, such as a medical practitioner or pharmacist, be involved in this decision process.

Vexatious complaints

It is unclear from the consultation document what criteria will be used to determine whether complaints are vexatious. The categorisation of a complaint as vexatious is highly subjective as it needs to be demonstrated it is without basis and its intent is to cause annoyance or unwarranted embarrassment. This is not something which an individual officer within the TGA is likely to be able to effectively demonstrate.

For clarity, the Guild does not believe the following, in isolation, would qualify as vexatious:

- Repeated complaints against a non-compliant advertisement where the advertiser does not take appropriate corrective action.
- A large number of complaints against a single advertiser in which the majority of alleged breaches are found justified.
- Large number of complaints about similar advertising claims from multiple retailers (e.g. for a specific product) which are justified.
- A revised complaint following a determination by the TGA which provides further information.

The Guild would be interested in what the process will be to deal with vexatious complaints and who will decide whether a complaint is vexatious or not.

8 PRIORITY BASED COMPAINTS HANDLING MODEL

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

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

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

Guild Comments

Timeliness

The Guild supports the principle that the speed at which complaints should be processed should be prioritised on risk –however the implementation of this is challenging. We support service timeframes which commit the TGA to swifter regulatory action where a substantial threat to public safety is identified at triage.

It is important to distinguish that priority and service timeframes are not confused with different processes which stratify how to consider a complaint. We do not support a prioritisation approach where a decision is never made on whether a 'low priority' complaint is substantiated.

Priority criteria – likelihood of harm

The likelihood of an advertisement to cause harm or being misleading is a key part of the complaint determination process. It is something difficult to quantify in a triaging process, and requires expertise and collaboration of health professionals and consumers. We have concerns that this role may be undertaken by administrative personnel within the TGA who do not have the expertise of a pharmacist, medical practitioner or similarly qualified health professional.

Priority criteria – transparency and integrity

The criteria above are not-specific and are not further articulated in the categories discussed below. The Guild believe further work by the TGA is required to provide clarity through:

- Specific qualification of the above criteria for each level of priority
- Examples in guidance documents on how this will be applied
- Timeframes for each level of priority
- Specific examples of enforcement action which will occur at each level

The application of these should be audited frequently by an independent third-party to provide public confidence in the application and categorisation of complaints and the data supporting the KPIs. The Guild believes further public consultation should occur once this work is done to ensure the criteria is robust and appropriate.

8.1 INVESTIGATION PHASE

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

Guild Comments

Specific aspects of the proposed priority levels are provided below. However, we emphasise that the substance of all complaints should be considered on its merits. Specifically:

- All complaints should be considered and determined whether or not they are in breach of specific advertising regulations. For example, if a complaint alleges five breaches of the *Code* in an advertisement, the regulator has a responsibility to make a determination on which of these provision in the *Code* have been breached.

- The TGA should require and consider a response from the advertiser for ALL alleged breaches of advertising regulation. The exception may possibly be in regards to vexatious complaints. We contend a case should never be closed at the point of issuing an education or compliance letter.

- All complaints should be available for review on a publically accessible register, although we recognise for lower level complaints it may be reasonable to mask the name of the advertiser and complainant.

- Where an advertiser has worked to rectify non-compliance quickly, this should be recognised on the complaint register.

- Sanctions reasonably should escalate for repeat offences and where there are unreasonable delays in rectification, as we have argued in previous submissions to advertising consultations.

The ‘most appropriate regulatory tools to address non-compliant advertising’ should be publically described on the TGA website, with clear criteria as to when they are used also described. This is essential for transparency and to support ongoing public confidence in the regulator.

8.2 LOW PRIORITY CASES

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

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

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

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

Guild Comments

The proposed approach above lacks transparency. The Guild does not believe that once an obligations notice has been sent that the matter should be closed as there is no evidence that this action resolves the issue which is the substance of the complaint. We believe that the matter should only be closed when the responsible entity has replied to the TGA to accept that it has taken steps to ensure that the breach has been rectified and that steps have been taken to ensure that the entity does not breach the advertising rules in the future.

If the TGA adopts the proposed system against this advice, we suggest that where an advertiser disputes that a breach has occurred, it should be escalated to a ‘medium priority’ case and fully determined.

At a minimum, the following should be publically available on a complaints register for each complaint deemed ‘low priority’:

- Advertiser(s) category (e.g. pharmaceutical company, supermarket, media outlet etc.)
- Category of complainant (if confidentiality requested)
- Description of advertisement (or theme)
- Alleged breaches of Code/Act and found breaches
- Why the case was categorised as ‘low priority’

8.2 MEDIUM PRIORITY CASES

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

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

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

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

Guild Comments

Ongoing advertising breaches

The criteria for what is considered 'ongoing advertising breaches' is unclear in the consultation document. For example, does this include:

- Single case of failure to rectify advertising non-conformance from a 'low priority case';
- Complaints about multiple advertisements from the same advertiser within a specific time frame (e.g. 12 months); and/or
- Multiple advertisements with similar breaches which are the responsibility of the same advertiser not rectified following a 'low priority case'.

A key improvement in the complaints handling reform package was the ability for more effective enforcement action against repeat offenders. The Guild considers the criteria for this needs to be clearly defined and triggered relatively quickly following even a small number of substantiated complaints (e.g. a 'three strikes' policy).

TGA enforcement action

The TGA's approach to considering the complaint is unclear in this category. It is unclear whether the TGA will make a determination on whether the alleged breaches of the code are justified. The Guild reiterates it is essential the TGA make a determination on whether alleged regulatory breaches are justified for all complaints. It is also important natural justice that advertisers have the opportunity to respond to an alleged breach before a determination is made.

At a minimum, complaints in this category should be required to:

- Demonstrate corrections have occurred (removal of non-compliant advertising) and that corrective action has been taken (systems amended to prevent recurrence).
- Request retailers who have been provided with the non-compliant advertising for reproduction withdraw relevant claims and cover the reasonable costs.

Advertiser response

It is unclear what constitutes “an acceptable response” from the responsible entity. We believe that the TGA needs to have this defined before it embarks on this new complaints handling system. The Guild would welcome the opportunity to comment on this prior to implementation.

Public complaints register

At a minimum, the following should be publically available on a complaints register for each complaint deemed ‘medium priority’:

- Advertiser(s) name(s) and category of advertisers
- Complainant name or category of complainant (if confidentiality requested)
- Description of advertisement
- Reproduction of advertisement
- Alleged breaches of Code/Act
- Confirmed breaches of the Code/Act, and alleged breaches not found to be in breach
- Why the case was categorised as ‘medium priority’
- What the response of the advertiser was to the obligations notice and whether further action was required.

8.4 HIGH PRIORITY CASES

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

This would also involve advertising breaches:

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

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

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

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

Guild Comments

Similar to the 'medium priority' category above, the criteria for 'continued advertising in breach' is not qualified. As above, 'high priority' complaints upheld must be included on a public register.

Criteria for 'high priority'

In addition to the criteria for this category above, we believe it should also include;

- Repeated non-compliant advertising likely to lead to commercial advantage as a result of non-compliance.

TGA enforcement action

The TGA's approach to considering the complaint is unclear in this category. It is unclear whether the TGA will make a determination on whether the alleged breaches of the code are justified. The Guild reiterates it is essential the TGA make a determination on whether alleged regulatory breaches are justified for all complaints. It is also important natural justice that advertisers have the opportunity to respond to an alleged breach before a determination is made.

We do not consider a warning letter alone would be an appropriate sanction for complaints categorised as 'high-priority' which have been found to breach the regulations. At a minimum, complaints in this category should be required to:

- demonstrate corrections have occurred (removal of non-compliant advertising) and that corrective action has been taken (systems amended to prevent recurrence);
- provide appropriate corrective messaging to consumers who have been subject to the advertising; and
- request retailers provided with the non-compliant advertising for reproduction withdraw non-conformant material and cover the retailers reasonable costs to do so.

Corrective messages should also be provided to health professionals to assist them in supporting their patients who may have been misled by the material.

8.5 CRITICAL PRIORITY CASES

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

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

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

Guild Comments

As outlined in the criteria above, only the most egregious breaches of advertising regulations would fall within this category. The Guild is therefore concerned that mandatory sanctions and prosecution to do not appear to form a mandatory part of 'critical priority cases'. Where advertising is '*likely to result in harm or injury to consumers'*, at a minimum, enforcement powers should:

- Require corrective notices to be distributed to the audience who have been exposed to the advertisement, at the cost of the advertiser. Corrective messages should also be provided to health professionals to assist them in supporting their patients. Should an advertiser cease to exist (e.g. insolvency) prior to a determination being made, the TGA should assume responsibility for providing corrective messaging to protect public health.

- Initiate financial penalties and other punitive actions.

- Be prominently included in the complaint register, with the advertiser clearly disclosed.

Criminal or civil prosecution may be appropriate in some cases even where an advertiser has complied with a request to remedy from the TGA. This is not apparent in the discussion above.

Part of the criteria includes a risk to the reputation of the TGA, industry and government. We recommend the inclusion of health professionals and providers of health care in this criterion. For example, advertising which undermines public trust in pharmacists or hospitals would likely be of a very serious nature.

We have some concerns at the terminology above, such as:

- *Immediately* – this is not quantified. We understand the TGA can issue 'take down' orders, which should be referenced here.

- '*Open or closed source information'* – it is unclear what is meant by this; we take it to mean through publically accessible or government-privileged channels. We consider this should apply equally to all levels of complaint and is assumed. We recommend removal of these terms.

8.6 MONITORING AND TREND ANALYSIS

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

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

Guild Comments

Monitoring and trend analysis should be able to be conducted by interested parties, such as researchers and industry organisations by examining a publically available complaints register. This register should be available, on request, in a format which can be used for data analysis (e.g. Spreadsheet or database extract).

Reporting should provide analysis or insight beyond basic statistics which could be gleaned from reviewing an online complaints register. Reporting should occur frequently enough to provide insight into whether the complaints system is achieving its purpose of protecting the public from non-compliant advertising. We note some other complaints bodies report monthly on the status and outcome of complaints.

9 REPORTING OUTCOMES AND MEASURING PERFORMANCE

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

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

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

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

- *enforceable undertakings that we enter into*
- *information about infringement notices*
- *court outcomes*
- *directions notices*
- *public warning notices.*

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

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

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

Guild Comments

We have provided comments on complaints disclosure throughout our response.

In summary:

- ***Low priority cases***: We do not accept it is appropriate not to make a determination on a 'low priority' complaint and therefore outcomes of these complaints should be reported. It is also important to disclose why the complaint was considered as 'low priority'.

- ***Medium priority cases***: In addition to the above, we consider these complaints should include a full text copy of a determination. This would include disclosure of the:
    - advertisement which was the subject of the complaint,
    - the advertiser(s) responsible,
    - the complainant, or where anonymity requested, the category of complainant;
    - the breaches which were confirmed; and,
    - why the complaint was categorised as 'medium priority'

- ***High priority outcomes***: For clarity, these should contain at least the information we have described above, including a copy of the advertisement and a copy of any corrective information the advertiser(s) has been required to make.

- ***Critical priority outcomes***: For clarity, these should at least contain the information we have described above, including a copy of the advertisement and any corrective information the advertiser(s) has been required to make. The TGA should routinely consider whether a press release to mainstream media is required to protect public safety in these instances. It may also be necessary for interim decisions to be published before a final determination if needed to protect public health.

9.1 EXCEPTIONS TO THE METRICS

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

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

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

Guild Comments

Transparency of referred complaints is essential to achieve public confidence in the regulator. Where the TGA initiates other internal investigations as a result of an advertising complaint, such as those described above:

- The advertising aspect of the complaint should be considered independent of other investigations and an outcome publically available in accordance with standard time frames.
- It should be clear on the complaint register that additional compliance activities are being undertaken.
- The outcome of those investigations should be able to be identified via the complaint on the complaints register.
- A link should be provided to the complaints register for the external entity the complaint is referred to. If a complaints register does not exist, this link should be to the complaints page on the website so the complaint can be followed up.

We note the title of this section is confusing and revision of language should be considered in describing exceptions to standard complaints handling on the TGA website.

10 GOVERNANCE

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

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

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

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

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

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

Guild Comments

The Guild strongly supports the maintenance of an advisory body to provide expert advice to the TGA on matters concerning the advertising of Therapeutic Goods. The Guild recognises the vital work previously undertaken by the Therapeutic Goods Advertising Code Council and is pleased a similar body will exist in the new complaints handling system to support its integrity.

It is essential the advisory body have a strong Terms of Reference which clearly describes its role and function. The Terms of Reference must include a responsibility for the TGA to accept and act on its advice. The Guild consider the committee is able to provide valuable advice and direction in relation to:

- Future advertising reforms
- Functioning of the complaints process
- Emerging trends and issues
- Channels to communicate effectively with stakeholders on advertising issues.
- Review of guidance documentation

The committee should possess legislative responsibility to make recommendations to the Minister in matters of public interest. As an oversight body, it should possess the ability to act independently of the TGA in situations where it is needed to fulfil its responsibilities.

The Guild highlights that such a committee must be adequately resourced. We contend at least health professional and consumer representatives should have expenses and sitting fees fully funded by the TGA. Failure to do this risks the committee possessing inadequate expertise to perform its intended function, as was seen with the current Complaints Resolution Panel.

The Guild looks forward to nominating a representative for this Committee so that it may continue to contribute to this important work and represent community pharmacy.

11 EDUCATION AND GUIDANCE

Education and guidance are a key strategy in support of compliance, and will inform the public about the appropriate advertising of therapeutic goods and in how to make a complaint.
To assist advertisers to understand their obligations we will provide an e-learning program on our website, along with guidance and information materials. The program is expected to be available mid-2018, and modules may be added over time.
We will develop a number of guidance documents and will work with key stakeholders to discuss specific needs. We will raise awareness about the new advertising complaints handling process and the role of the TGA in the regulation of advertising for therapeutic goods.

Guild Comments

The Guild has commented throughout this submission small businesses, such as community pharmacies, require additional support to understand their advertising obligations. The education and guidance strategies which are appropriate and effective for small business differ from those effective for the pharmaceutical and medical device industry.

Key differences which should be considered in small-business education strategies include:

- Education should be shorter, reflecting the time-poor nature and wide scope of compliance obligations small business owners and managers need to be cognisant of.

- Education needs to be available in a geographically diverse area, as small businesses such as pharmacies are dispersed throughout Australia. For example, 30% of community pharmacies are in regional, rural or remote locations, and often are responsible for their own advertising material.

- Education needs to be pitched at a level relevant for suppliers and retailers, rather than sponsors of therapeutic goods.

The Guild's Learning and Development team have previously partnered with government and industry to produce and host a series of high quality online learning modules on a wide range of topics of interest to the industry. The team is highly skilled at developing activities which engage pharmacists in content and effectively develop skills in a variety of educational topics.

Similarly, the Guild's annual Australian Pharmacy Professional (APP) on the Gold Coast provides an ideal opportunity to deliver education on advertising compliance obligation to community pharmacy's decision makers.

The Guild would welcome the opportunity to discuss both these engaging and cost-effective opportunities to support community pharmacy in meeting their regulatory obligations for the advertising of Therapeutic Goods.