TGA CONSULTATION: COMPLAINTS HANDLING

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TGA CONSULTATION: COMPLAINTS HANDLING

There are a number of concerns with this TGA proposal:

1. **Triaging**

   Key terms are not defined but the process appears to prioritise physical harm over economic harm and other forms of consumer detriment.

2. **Complaint priorities**

   Complainants apparently will not be informed as to the priority TGA officers assign their complaint: low, medium, high and critical.

3. **Transparency**

   Even if a complainant submits a detailed complaint alleging specific breaches of the Therapeutic Goods Advertising Code 2018, it is unclear if these specific allegations will be forwarded to the advertiser responsible.

   In addition, if the TGA finds additional breaches of the Code when assessing the complaint, it is unclear if these will also be communicated to the advertiser, let alone the complainant.

   Regardless of priority, there apparently will be no information published on what alleged Code breaches were determined by the TGA to be justified or not justified.

   For low priority cases, no details of who is responsible for the advertisement will be disclosed.

   For low and medium priority cases, it appears up to the complainant to check if a "regulatory obligation notice" or an "acceptable response" achieved compliance.

   For high and critical priority cases, no information will be provided to the complainant and the public until a final outcome is achieved; if this involves Court action, this may take years.

   It is important for educating complainants, advertisers and the industry that details of specific Code breaches upheld or rejected by the TGA be published, as has been the practice of the CRP. This is also crucial for monitoring the performance of the TGA.

4. **Time taken to close complaints**

   These statistics will be meaningless because compliance is not routinely checked.

5. **Monitoring and trend analysis**

   Post-marketing compliance data must be broken down into targeted and random reviews, categories of products, and the most non-compliant companies named.

6. **The TGA website advertising hub**

   This site is a work-in-progress. Although it shows promise, we have provided feedback on many concerns.

7. **Conclusion**

   We reiterate the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.

Background

The concept of the TGA taking over the Therapeutic Goods Advertising Complaint System to provide a single, more efficient, complaint body with powers to apply timely and meaningful sanctions for regulatory violations is excellent.[1] However, the TGA's proposed implementation leaves a lot to be desired.

Issues

1. Triaging

This process is said to depend on an assessment by TGA officers as to whether the advertisement is likely to (my emphasis):

- Cause **public harm**;
- 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**, and
- the advertisers' awareness of their advertising obligations (**previous upheld complaints?**).

Our concern about these triaging criteria is that the key terms used are not defined and the process appears to prioritise physical harm over economic harm and other forms of consumer detriment.

For example, does consumer detriment include consumers being misled by advertising into:

- Purchasing a more expensive product when more cost-effective alternatives are available (the ACCC Nurofen case)[2]?
- Purchasing an ineffective product, for example Brauer[3] or Owen homeopathics[4] hay fever products instead of an effective registered product available at pharmacies containing fexofenadine hydrochloride[5]?
- Forsaking evidence-based action because of misleading claims, for example neglecting a healthy diet and instead consuming heavily advertised multi-vitamin supplements[6]?

Senior TGA staff have said that their charter does not extend to protecting consumers from their own stupidity or gullibility. Yet apparently "stupid" choices can be rational decisions when vulnerable consumers are misinformed by misleading and deceptive advertising.

For example, how many people would be seduced by the promotion of black salve if there was full disclosure that it is not effective for treating cancer and it destroys normal tissue? How many parents would administer homeopathic (or other traditional) medicines to their children if there was full disclosure that there is no scientific evidence that these products work?

The purpose of the Therapeutic Goods Advertising Code[7] is to ensure that consumers are not misled or deceived by unethical advertising to allow them to make informed choices on the basis of accurate

[1] https://www.tga.gov.au/consultation/consultation-complaints-handling-advertising-therapeutic-goods-public
[2] https://www.accc.gov.au/media-release/accc-targets-alleged-false-and-misleading-nurofen-claims
[3] https://shop.brauer.com.au/collections/allergy-relief/products/brauer-hay-fever-o-s-20ml
[4] https://www.owenhomoeopathics.com.au/product/homeopathic-hay-fever-complex/
[5] https://telfast.com.au/antihistamines/telfast-120mg/
[6] https://swisse.com/en-au/products/vitamins-supplements/mens-health/swisse-mens-ultivite
[7] https://www.tga.gov.au/sites/default/files/draft-therapeutic-goods-advertising-code-guidance-2018.pdf

information about the quality, safety and efficacy of the product. The latter is also the object of the *Therapeutic Goods Act 1989,*[8] which the TGA is tasked with upholding.

We are concerned that some senior TGA staff apparently want to abdicate their responsibilities in this area. We have opposed the suggestion that the TGA should exclude so-called "low-risk" products, such as vitamins and homeopathic medicines, from the TGA's regulatory responsibility.[9] We are especially concerned that the TGA has yet to publish public submissions to this consultation, or its own conclusions, despite the consultation closing on 12 May 2017.

We agree with the submission the ACCC kindly provided us; it is the TGA's responsibility as a specialist regulator to be responsible for the regulation (including consumer protection) of all therapeutic goods. The ACCC does not have the expertise or resources to take over of the regulation of these areas (see appendix).

2. Complaint priorities

Following assessment, the TGA says complaints will be triaged into one of four priority categories; low, medium, high and critical. From the pyramid on page 11:

"Low priority advertising breaches (low priority cases)" are defined as:

- One-off breach not considered serious in terms of being misleading as to the contents, identification or use of the goods.

  Yet 88% of 109 complaints found justified by the Complaint Resolution Panel (CRP) in 2016-17[10] were found to breach s. 4(2)(c) of the 2015 Code, "Must not mislead or be likely to mislead".

"Medium priority advertising breaches (medium priority cases)" are defined as:

- On-going breaches despite the advertiser having been made aware of their obligations but not likely to lead to unsafe or inappropriate use of the goods.

  Yet 22% of 109 complaints found justified by the CRP in 2016-17 were found to breach s.4(2)(i) of the 2015 Code, "Must not claim that goods are completely safe, harmless, or free of side-effects" and 9% breached s.4(2)(f) of the 2015 Code. "Must not encourage excessive or inappropriate use of the advertised product".

"High priority advertising breaches (high priority cases)" are defined as:

- Continued advertising breaches (despite previous warning),

  Pharmacare Laboratories provides an ongoing example which the TGA has so-far failed to address.[11]

- Advertising prohibited or restricted representations likely to impact on consumers ability to safely or effectively use the product,

  60% of 109 complaints found justified by the CRP in 2016-17 were found to breach s.5 of the 2015 Code. "Prohibited or restricted representations".

[8] https://www.legislation.gov.au/Details/C2017C00226

[9] https://www.tga.gov.au/consultation/consultation-options-future-regulation-low-risk-products

[10] http://www.tgacrp.com.au/wp-content/uploads/CRP-complaints-summary-1-Jul-2016-to-30-Jun-2017-including-graphs.pdf

[11] http://www.tgacrp.com.au/complaint-register/?_search=Pharmacare

- Mass advertising, or the potential to influence others in the industry, to the detriment of consumers.

  What about 110,000 Chemist Warehouse sample packs containing Swisse Magnesium, etc., distributed to children and adults at the MCG and AFL Grand Final Footy Show at the Rod Laver Arena; complaint sent to the TGA in October 2017, still without an outcome?

"Critical advertising breaches (critical priority cases)" are defined as:

- "Extensive or targeted advertising directed to vulnerable groups"

  Kids' vitamin gummies are a continuing example about which the TGA has done nothing: these products are unhealthy, poorly regulated and exploitative.[12]

- "Advertising that is likely to lead to "harm or injury if the claims are relied upon", or

  Advertisements for Black salve are a nice example of physical harm and injury.

  However, does "harm" include economic harm from being "ripped off" by misleading and deceptive claims, or harm from consumers forsaking evidence-based treatments because they are attracted to more heavily, cleverly marketed products advertising false hope?

  Complementary medicines used for menopausal symptoms are a nice example.[13]

- "Advertising that undermines accepted public health messages".

  Advertisements for homeopathic immunisation are a nice example.

  But what about advertisements for multi-vitamins that undermine public health messages about the importance of eating a balanced diet containing fruit and vegetables?

It will be important that the resources noted on page 16 (11. Education and guidance) contain examples of complaints that the TGA has triaged into the above categories.

Our own view is that the majority of complaints likely to be submitted will be of "high" or "critical" priority if properly assessed by the TGA.

We are concerned that complainants apparently will not be informed as to the priority TGA officers assign their complaint.

3. Transparency

We have extensive concerns about this area.

First, even if a complainant submits a detailed complaint alleging specific breaches of various section of the Therapeutic Goods Advertising Code 2018, it is unclear if these specific allegations will be forwarded to the advertiser responsible.

In addition, if the TGA finds additional breaches of the Code when assessing the complaint, it is unclear if these will also be communicated to the advertiser, let alone the complainant.

Instead, for low and medium priority cases it appears that only a non-specific "regulatory obligation notice" or "warning letter" will be sent.

We reiterate that it is crucial for educating complainants, advertisers and the industry that details of specific Code breaches upheld or rejected by the TGA (determinations) be communicated and

[12] https://theconversation.com/kids-vitamin-gummies-unhealthy-poorly-regulated-and-exploitative-76466
[13] https://www.mja.com.au/journal/2015/203/3/use-complementary-and-alternative-medicines-menopausal-symptoms-australian-women

published, as has been the practice of the CRP. This is also crucial for monitoring the performance of the TGA.

Second, we comment on the different case priorities the TGA proposes to assign.

"Low priority cases"

Complainants who send a valid complaint will apparently receive an email with a case identification number. However, it appears that the complainant **will NOT be told the priority level their complaint has been assigned to.**

The complainant may find some information about their complaint in TGA bi-annually statistics: the case identification number, date received, date completed and the "outcome"; that is, a "regulatory obligation notice" was sent.

There apparently will be NO information published on:

- **The product involved;**
- **What alleged Code breaches were determined by the TGA to be justified or not justified?**
- **If the "notice" achieved compliance? Although the TGA says some targeted post-marketing reviews may be done on such cases.**

Why should the complainant have to follow up if compliance has been achieved; why not the TGA in all cases?

"Medium priority cases"

An acceptable response to a warning letter appears to be merely a statement from the sponsor that the alleged breach has been responded to.

Once again, NO information is provided on:

- **What alleged Code breaches were determined by the TGA to be justified or not justified?**
- **Whether the sponsor achieved actually compliance?**

For medium priority cases, the details published in bi-annually statistics appear to be the case identification number, the therapeutic good involved, the responsible entity, the date the complaint was received, date warning letter sent and the "outcome" (that is, the sponsor said problem fixed or, if no response was received, the complaint was escalated).

Experience with the current CRP shows that many sponsors will assert they will fix the problem, but then don't; alternatively, they may correct the breaches pointed out, but then create new ones!

In short, monitoring compliance is essential; trusting sponsors is naive!

High and critical priority cases

In these cases, the TGA state they will determine the most appropriate regulatory tools to be used.

Once again, NO information is provided on what alleged Code breaches were determined by the TGA to be justified or not justified.

The TGA notes that 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, the TGA will report on outcomes when the matter is finalised.

At this time, 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.

This means that it may be several years before a final outcome is achieved. In the interim, apparently the complainant and the public will not be informed that this advertising has been assigned a high or critical priority level, what the problems are, nor what action is in train.

The ACCC informs the public when it institutes Court proceedings;[14] why not the TGA?

In summary:

- No complainant will be told the priority level their complaint has been assigned to after triaging.
- Regardless of priority, there apparently will be NO information published on what alleged Code breaches were determined by the TGA to be justified or not.
- For low priority cases, there will be no disclosure of who is responsible for the advertisement.
- For low and medium priority cases, it appears to be up to the complainant to check if a "regulatory obligation notice" or an "acceptable response" actually achieved compliance.
- For high and critical priority cases no information will be provided to the complainant and the public until a final outcome is achieved and, if this involves Court action, this may take years.

In short, the proposed TGA complaint system provides much less transparency that the current CRP system. This is unacceptable.

We are also aware of hundreds of outstanding complaints, sent to the TGA by the CRP, which currently lack a public outcome. The TGA have stated that their current priority is getting up the new Code and complaint system, not dealing with old complaints.

Nevertheless, there is considerable cynicism, based on the above experience, about the TGA's ability (and will) to provide an efficient and transparent complaint system.

We understand that the TGA has prepared a legislative instrument that will facilitate publishing all complaint outcomes: *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018*.

We expect that when this latest legislative instrument is enacted, the TGA will at least report the outcome of all complaints forwarded to the TGA by the CRP from December 2017 as a result of the transition from the CRP to the TGA.

This would reassure complainants that the TGA is committed to transparent reporting of complaint outcomes and to community health, wellbeing and consumer protection.

4. Time to close complaints

Time taken to close complaints means the time from when the complaint was received, assessed and triaged to when we assess that no further action is required. These times are our intended timeframes in which to close out matters and depend on the priority given to each accepted case:

Low Priority	Medium Priority	High Priority	Critical Priority
90% in 20 days	90% in 90 days	90% in 90 days	90% in 60 days

[14] https://www.accc.gov.au/media-release/accc-targets-alleged-false-and-misleading-nurofen-claims

On average, the days taken for all complaints handled by the current CRP is 92 days. However, those involving detailed responses from the advertiser and determinations finalised by the Panel can take 6 months or more.[15]

In the new complaint system, the TGA states low priority cases are closed once a regulatory obligations notice to be sent (with no follow-up) while medium and high priority cases receive a warning letter or email / telephone call respectively and are closed on receipt of an "acceptable" response (with apparently no checking that compliance has actually been achieved).

Only in critical priority cases does the TGA state that it is unlikely that these cases would be closed simply by receipt of a response from the responsible entity.

In summary, it appears that in all, except perhaps critical cases, the TGA will close the case without actually checking if compliance has been achieved or not, and without publishing a determination of alleged Code breaches. While this will certainly result in shorter "time taken to close complaints" compared to those of the Panel, the new statistics will be of dubious value.

5. Monitoring and trend analysis

We are concerned about the TGA's ability to perform this task. For example, the TGA has been requested to break down its post-marketing compliance data into targeted and random reviews. This breakdown is NOT present in the TGA's annual performance statistics[16] and half yearly performance snapshots.[17]

Rather the TGA lumps data on compliance breaches for both targeted and random reviews together. This means that if the TGA targets a category of product (such as sunscreens) which have less compliance breaches than other categories (such as herbal or homeopathic products), then the overall compliance rate appears to improve as the latest TGA snapshot showed.[6] This was reported by the media as, "Complementary Medicine Compliance Improves (80% non-compliance drops to 56%)".[18] TGA targets need to be reported publicly, not merely made available for industry to selectively report.

The latest TGA data provided, "Listing Compliance Reviews FY2016-17"[19] has the following problems:

- It gives percentages but not absolute numbers. Good reporting practice means all percentages presented should be preceded by the numbers they represent.
- It has added a new column to the table, "Project" which is not present in the "Annual performance statistics report: July 2016 to June 2017 3.3.2 Compliance reviews".[20] What does this mean? If it's projects mentioned in the annual report that targeted oral probiotics indicated for vaginal conditions and listed medicines with blood glucose and cholesterol indications, what other investigations comprise the "targeted" column?

It is also important to break down the results for the main categories of products targeted by random reviews: e.g. Vitamins and minerals, Fish oil, Western Herbal Medicine, Chinese Traditional medicine,

[15] http://www.tgacrp.com.au/wp-content/uploads/CRP-complaints-summary-1-Jul-2016-to-30-Jun-2017-including-graphs.pdf
[16] https://www.tga.gov.au/annual-performance-statistics-reports
[17] https://www.tga.gov.au/half-yearly-performance-snapshot-july-december-2017
[18] https://pharmacydaily.com.au/news/cm-compliance-improves/72662
[19] http://www.medreach.com.au/wp-content/uploads/2018/05/TGA-Listing-Compliance-Review-Stats-by-Type-2015-17.pdf
[20] https://www.tga.gov.au/book/export/html/765127

Ayurveda (Indian) medicines, Homeopathic Medicines, Probiotics, Sunscreens and Aromatherapy products.

Finally, it's crucial to report to consumers and health professionals the most non-compliant companies. This will help consumers to select products and health professionals to give advice. It will also provide a stimulus for the named companies to improve.

In the second Civil Society Seminar on, "The Advertising of Therapeutic Goods and Services (and its regulation)"[21] held at Monash law Chambers on Sept 8, 2017, and attended by the TGA's now departed Ross Hawkins, we heard a presentation[22] by Suzanne Crowle, Director of Engagement and Complaints, of NSW Fair Trading.

The NSW Fair Trading Complaints Register provides information about businesses that are the subject of 10 or more complaints received by Fair Trading in a calendar month. It's updated monthly and only includes complaints considered by Fair Trading to have been made by a real person, relating to a real interaction with a business. It provides information about the name of the business; the number of complaints NSW Fair Trading has received about the business in the last month and the product groups complained about.

If NSW Fair Trading can do this monthly, why can't the TGA do it at least 6-monthly?

6. The TGA website advertising hub

We have been involved in user testing of this site for which we had to sign a confidentiality agreement.

The site is a work-in-progress. Although it shows promise, we provided feedback on many concerns.

7. Conclusion

Finally, we reiterate the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.

[21] http://www.medreach.com.au/?p=2223

[22] http://www.medreach.com.au/wp-content/uploads/2017/09/Crowle-NSW-Fair-Trading-Complaints-Register.pdf