



**TGA CONSULTATION: THE  
REGULATORY FRAMEWORK  
FOR ADVERTISING  
THERAPEUTIC GOODS**

**Submission by**

**Dr Ken Harvey**

**Adjunct Associate Professor**

**and**

**Sasha Hall and Tiana Moutafis**

**Summer Vacation Scholarship BMedSci/Law Students**

**School of Public Health and Preventative Medicine**

**Monash University**

**12 December 2016**

# TGA Consultation: The Regulatory Framework for Advertising Therapeutic Goods

## Summary

This consultation addresses the Government's response to seven recommendations made by the "Expert Review of Medicines and Medical Devices Regulation" (MMD Review) on the regulatory framework for advertising therapeutic goods.

Currently, Australia has an excellent Therapeutic Goods Advertising Code but an overloaded and under-resourced complaint system that provides no effective penalties for Code breaches. The result is a market flooded with products of doubtful value with claims that often go far beyond the limited (or absent) scientific evidence that sponsors are meant to hold to justify their claims. There is also little incentive for sponsors of complementary medicines to undertake the research required to prove that their products work. A better return on investment comes from spending money on promotional hype and celebrity endorsement.

This paper assesses whether three key recommendations proposed will redress this situation.

**Recommendation Fifty-Five:** Abandoning pre-approval of the advertising of therapeutic products in favour of a more self-regulatory regime.

The government has agreed that removal of pre-approval requirements is conditional on the implementation of other recommended consumer protections being introduced. These include advertising claims being consistent with Permitted or Approved Indications (r.38), strengthening of post-market monitoring (r.49), improving the complaint management process (r.56) and industry education (r.58).

The current pre-approval process is delegated to Industry Associations and limited to medicines advertised to the public in "specified media", mainly television, radio and print advertisements, not the Internet. In addition, advertisements for medical devices are not covered.

However, the pre-approval process does review around 2000 advertisements per year with an average turnaround time of 7 days. Most advertisements reviewed require changes to avoid Code breaches; sometimes wholesale revisions. Pre-approval is the only defence between a misleading advertisement on prime-time television and the unwitting consumer; complaints and post-marketing reviews take a long time to remove bad advertisements.

A better alternative to abandoning pre-approval is to extend the process to all advertisements, for both medicines and medical devices, in all media. Prevention is better than cure. In addition, the "self-regulatory" regime favoured by the Government is unlikely to be effective as the company currently responsible for the most upheld complaints is not a member of any industry self-regulatory association.

**Recommendation Fifty-Six:** Disbanding the current mechanism for managing complaints.

The controversy is about who should manage and be involved in the new system. The Therapeutic Goods Administration (TGA) appears to be positioning themselves to take over; acquiring similar powers to the Australian Competition and Consumer Commission (ACCC) and abolishing the current Code Council and Complaint Panel along the way. This is seen as the TGA taking over a role that was shared in the past with stakeholders (consumer, health professional, industry and media organisations). There is also concern that the TGA lacks a consumer protection culture, is perceived to be too close to industry, has failed to address long-standing problems and it is not transparent about the outcomes of complaints it currently handles.

There are vocal groups with their own agenda who advocate handing the complaint system to the ACCC, as that body is currently structured and resourced. The ACCC has a consumer protection culture, excellent investigative and compliance powers under Australian Consumer Law and the necessary legal expertise. They have also taken on several cases involving the advertising of therapeutic goods, for example Nurofen targeted pain relief and Homeopathy Plus.

However, the ACCC receives many thousands of complaints per year covering a wide range of areas. Given current resources they can only pursue a small number of illustrative cases through the courts.

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Moving the complaint system to the ACCC would mean that most complaints would not be dealt with; effectively providing NO controls. In addition, the ACCC has consistently argued that where there is a need for specialist regulators, they should not be rolled into the ACCC.

A more innovative suggestion is closer partnership between the ACCC and the TGA in the transition to, and in the initial phase of, a new complaint system. This would involve seconding a senior enforcement manager from the ACCC to the TGA to oversee the new system (and change the TGA's culture) while keeping the best of the current system (the Code Council and Complaint Panel) and fixing the flaws, such as the lack of power to enforce determinations. Strategic cases such as MyDNA (which involved a pharmacy chain) would still be dealt with by the ACCC. This is in accord with the multi-regulator model supported by a recent Productivity Commission draft report.

**Recommendation Fifty-Seven:** Stronger compliance powers against misleading advertising.

It is proposed that more effective sanctions and penalties are instituted for breaching advertising requirements, including civil penalties (substantial fines), injunctions (to restrain a person from contravening advertising requirements) and the power to order compliance, such as the withdrawal of an advertisement and the publication of a retraction.

Currently, there are no civil penalties available for a breach of advertising requirements and, to our knowledge, the TGA has never attempted to impose criminal penalties as the penalty levels were thought to be too low to be worth taking on a court case.

Sanctions and penalties must be sufficient to counter the commercial return that can be obtained by breaching the Therapeutic Goods Advertising Code and related regulations. In this regard, it is crucial that product de-listing, significant fines and retractions of claims are available for egregious conduct. The latter are needed to correct the misinformation promulgated, warn consumers about the company involved and name and shame. Retractions must be placed in all the media that the offending claim was published, in the same size and for the same time as the offending claim was promulgated.

The new sanctions and penalties suggested in Table 1 of the consultation document should be adequate if imposed.

**In conclusion:** Consumer protection must be the *raison d'être* of the new complaint handling system. Adequate resources must be provided to enable timely, efficient and effective functioning. The new system should act as a one-stop-shop for complaints, be accessible via the Internet, have the power to initiate complaints and be widely publicised.

Sanctions and penalties must be sufficient to counter the commercial return that can be obtained by breaching the Therapeutic Goods Advertising Code and related regulations. Key stakeholders (consumer, health professional, industry, media and the TGA) must be involved both in complaint handling, in updating the Therapeutic Goods Advertising Code from time to time and in monitoring the effectiveness of the system.

All complaints must be logged in a database, have an acknowledgment provided to the complainant, and sent to the person / company complained about for a response within a set time-frame. A determination should be made about the merits of each complaint, including appropriate sanctions and penalties, sent to the complainant and the person / company complained about, and then (if not appealed against) published on the complaint body website within a given time-frame. Natural justice principles must be incorporated. There must be an avenue for the person / company complained about to appeal a determination but, while that appeal is being determined, the advertisement under question must be withdrawn. If the appeal fails; the determination will be published.

Finally, performance reporting must enable the timeliness and effectiveness of the system to be monitored and identify problem areas that may require system improvements &/or new policy initiatives.

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## The Consultation

This consultation addresses the Government's response to seven recommendations made by the Expert Review of Medicines and Medical Devices Regulation (MMD Review) on the regulatory framework for advertising therapeutic goods.<sup>1</sup> It provides an opportunity for interested parties to give their views on the appropriate body or bodies for the handling of complaints under the design of a new centralised advertising complaints management-process and other recommended reforms to the advertising regulatory framework. Related recommendations on the regulatory framework for complementary medicines will be dealt with elsewhere.<sup>2</sup>

## Background

Since 2002, there have been 17 government consultations and reviews concerning the regulatory framework for advertising therapeutic goods and the regulation of complementary medicines (see appendix). A consistent theme has been the absurdity of a light-touch regulatory system for perceived low-risk products that involves no pre-market evaluation, trusts sponsors to obey the rules and has no timely or effective penalties for breaches of the regulations.

The result is a market flooded with products of doubtful value with claims that often go far beyond the limited (or absent) scientific evidence that sponsors are meant to hold to justify their claims. There is also little incentive for sponsors of complementary medicines to undertake the research required to prove that their products work. A better return on investment comes from spending money on promotional hype and celebrity endorsement.<sup>3</sup>

The Therapeutic Goods Administration (TGA) has recently published data concerning post-marketing reviews of listed medicines.<sup>4</sup> TGA compliance activity more than doubled from 212 (2014-15) to 473 (2015-16). Medicines with verified compliance breaches increased from 73% (2014-15) to 80% (2015-16). Labelling, advertising and evidence continued to be the major compliance breaches for listed medicines. More products were found to have safety related issues; zero in (2014-15) compared to 13 (2015-16). In addition, for 2015-16, the Therapeutic Goods Advertising Complaint Resolution Panel found 98% of 141 complaints justified (and a 40% non-compliance rate with Panel "requests" for redress).

These appalling statistics are a sad reflection on the failure of the TGA to bring this industry into check over many years. The result has been a loss of trust in the TGA and ongoing harm to consumers. Although complementary medicines are regarded as low-risk products, low-risk does not mean no risk. Direct harm can result from poorly disclosed adverse events, such as allergic reactions to Echinacea, and from the interaction of products such as St John's wort with many conventional medicines. Indirect harm results from consumers forgoing more evidence-based remedies (often to the detriment of their health) because they are taken in by misleading and deceptive promotion. This also wastes their money which could be better spent.

Reform has been stalled by consistent industry opposition, changing bureaucrats, changing ministers, changing government and changing policy, the latest of which was the Abbott government's "Cutting Red Tape" agenda.<sup>5</sup> Despite this, the July 2015, MMD Review recommended many measures which, if implemented, could substantially improve the situation.

These included a limited list of "permitted indications", sponsors to publish evidence supporting the claims made, a disclaimer on product labels and promotion that efficacy claims have not been

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<sup>1</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp>

<sup>2</sup> <https://www.tga.gov.au/implementation-reforms-public-consultation-forecast>

<sup>3</sup> <https://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be>

<sup>4</sup> <https://www.tga.gov.au/book-page/3-complementary-medicines-0#s34>

<sup>5</sup> <https://www.cuttingredtape.gov.au/>

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independently assessed, and a new Listing pathway for the industry whereby higher-level claims could be made if the TGA found the evidence acceptable.

In addition, increased and better targeted post-marketing surveillance was recommended, coupled with a better resourced and more effective complaint system. If this package was accepted, it was recommended that pre-approval of advertisements (currently limited to specified media) could be dropped in accord with the government's desire to reduce red tape.

In September 2016, the Government rejected or watered down several important recommendations, presumably due to industry lobbying. For example, the disclaimer was rejected and the need for the industry to publish evidence supporting their claims was made optional.

The TGA has now embarked on many consultations about implementing the MMD Review recommendations of which this is one. Recommendations relating to the regulatory framework for advertising therapeutic goods will now be discussed.

## Recommendations

### Recommendation Fifty-Two

The Government accepts that **advertising of therapeutic products to the public should continue to be regulated by the TGA under a legislative framework which includes an advertising code**, noting that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.

**Comment: uncontroversial, accepted.**

### Recommendation Fifty-Three

The Government accepts that **advertising to the public should continue to be prohibited for Schedule 4 and 8 prescription medicines**. The issue of **advertising of Schedule 3 medicinal substances will be considered as part of a review of the Scheduling Policy Framework<sup>6</sup>** (r.11 & r.12).

**Comment: prohibition of advertising of prescription medicines to the public is uncontroversial, accepted.**

**Advertising of Schedule 3 (pharmacy only) products is controversial and will be debated elsewhere.**

### Recommendation Fifty-Four

The Government accepts that the **future requirements for advertising therapeutic products to the public should be made consistent for all medicines and medical devices**, noting that increasing consistency of approach could help reduce complexity for advertisers. The Commonwealth also notes that the differences between medicines and medical devices means that consistency may not be appropriate in particular circumstances.

**Comment: controversial (relates to r.55& r.56 below).**

There is currently no pre-approval of low-risk medical devices which (as with Listed medicines) are included on the ARTG by the sponsor without TGA oversight. In 2015-2016 the Complaint Panel reported that complaints about medical devices accounted for 27% of all complaints handled by the

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<sup>6</sup> The review of the Scheduling Policy Framework will be addressed through separate consultations and is outside the scope of this paper.

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Panel. Pre-approval of such advertisements by an industry body such as the Medical Technology Association of Australia (MTAA)<sup>7</sup> should substantially reduce these complaints.

## Recommendation Fifty-Five

The Government accepts that **the whole process of vetting and pre-approval of the advertising of therapeutic products to the public should be stopped** in favour of a more self-regulatory regime. The implementation of *Recommendations Fifty-Seven* (enforcement powers) and *Fifty-Eight* (sponsor education) are critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

### Comment: controversial

This recommendation appears based on the ideology of "cutting red-tape" regardless of any appraisal of the evidence supporting the current system. The MMD Review did not seek any data about the effectiveness of the current pre-approval process. In addition, no outcome indicators have been suggested by the Government or the TGA to judge whether it will be appropriate to remove pre-approval; only process indicators:

"The requirements for pre-approval of certain advertisements for OTC and complementary medicines will not be removed until a stronger penalties and sanctions framework has been implemented, an efficient and effective complaints resolution process is in place and a formal industry education program has been established".

It will be important for the current delegated advertising approval officers to monitor the number of corrections in submitted material before, during and after r.57 and r.58 are introduced to objectively establish their impact.

#### Pros of pre-approval<sup>8</sup>

- Reviews over 2000 advertisements per year with an average turnaround time of 7 days.
- Most advertisements reviewed require changes to avoid Code breaches; sometimes wholesale revisions.
- Pre-approval is the only defence between a misleading advertisement on prime-time television and the unwitting consumer; complaints and post-marketing reviews take a long time to remove bad advertisements.
- Some of the worst offenders are not members of industry associations, so self-regulation is unlikely to impact.
- Prevention is better than cure.

#### Cons of pre-approval

- The pre-approval process is only directed at medicines advertised to the public in "specified media", mainly television, radio and print advertisements, not the Internet. Advertisements for medical devices are not covered.
- Delegated by TGA to two industry associations (ASMI & CMA); decisions are not always consistent.

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<sup>7</sup> <https://www.mtaa.org.au/>

<sup>8</sup> <http://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/>

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- Delegates do not have the time to review the evidence supporting the claims in detail; thus, some pre-approved advertisements may still be found to breach the Code by the Complaint Panel (albeit said to be a small number).

The government has agreed that removal of pre-approval requirements is conditional on the implementation of other recommended consumer protections:

- Advertising claims being consistent with Permitted or Approved Indications (r.38);
- Strengthening of post-market monitoring (r.49); and
- Improving the complaints management process (r.56).

However, it can be argued that pre-approval should be extended to all advertisements for both medicines and medical devices and the function delegated to a combined ASMI-CMA-MTAA pre-approval office.

Finally, the “self-regulatory” regime favoured by the Government is doomed to failure as the sponsor responsible for the most complaints upheld by the Complaint Panel is not a member of any industry association.

## Recommendation Fifty-Six

The Government accepts that current mechanisms for managing complaints should be disbanded and a **new mechanism established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public.** A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, thereby benefiting consumers.

To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process and consider whether to establish the function within the TGA or another existing Commonwealth agency; or to call for tenders from external organisations to undertake the function.

**Comment: uncontroversial, but the devil will be in the detail of who will take over, how the new body will function and what resources will be provided.**

Before considering the options put forward it is worth reviewing the pros and cons of the current system involving the Code Council, the Complaint Panel, the TGA and occasionally the Australian Consumer and Competition Commission (ACCC).

Pros:

- The Code Council advises on Code updates<sup>9</sup> and restricted representations<sup>10</sup> while the Complaint Panel makes determinations on complaints received. Both bodies are set up under the Therapeutic Goods Regulations 1990 and contain a broad mix of people representing stakeholder interests (industry, media, health professionals, consumers and TGA staff). The Code Council has 15 members;<sup>11</sup> the Complaint Panel has 9.<sup>12</sup> This allows a variety of stakeholder considerations to be brought to revising the Code and making complaint determinations. It also provides legitimacy of the process to the stakeholder organisations involved.
- The Complaint Panel provides a public account of all complaints dealt with. Those dealt with by the Panel have a determination published on their website about the outcome of the

<sup>9</sup> <https://www.tga.gov.au/publication/therapeutic-goods-advertising-code>

<sup>10</sup> <https://www.tga.gov.au/restricted-representations>

<sup>11</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_reg/tgr1990300/s42c.html](http://www.austlii.edu.au/au/legis/cth/consol_reg/tgr1990300/s42c.html)

<sup>12</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_reg/tgr1990300/s42t.html](http://www.austlii.edu.au/au/legis/cth/consol_reg/tgr1990300/s42t.html)

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complaint, including a request for claims found to breach the Code to be withdrawn or, for more egregious claims, a retraction to be published.<sup>13</sup> If the Panel feels that a complaint is better dealt with by another authority such as the TGA (for example, a complaint about a product that has not been registered, listed or included on the Australian Register of Therapeutic goods (ARTG)) then that decision is also published.<sup>14</sup> Complainants are also notified of the outcome of their complaint.

- Complaint Panel determinations are generally regarded as objective and evidence-based and have been upheld by the Courts when appealed against.<sup>15</sup>

## Cons:

- Of late, the Code Council has not been notified of all requests for restricted representations; these have been dealt with by the TGA in isolation which has led to controversial decisions.<sup>16</sup> Suggestions for Code updates by the Council have also not been progressed by the TGA.
- The Complaint Panel has no power to enforce its determinations. Cases of non-compliance (40% in 2015-16)<sup>17</sup> are sent to the TGA who may initiate a new investigation and may issue a "Regulation 9 order" for compliance. The latter can (and often are) appealed against to the Minister &/or the Administrative Appeals Tribunal resulting in further delays. The TGA also lacks the power to impose appropriate sanctions and penalties. As a final resort, the ACCC may be involved.<sup>18</sup> Meanwhile, promotion found in breach of the Code continues, often for years.
- The Complaint Panel is overloaded and under-resourced which results in unacceptable delays in finalising complaints. For example, the RACGP delegate has been unable to attend because the TGA has refused to provide sitting fees. Considerable work by Panel members is done pro bono in their own time. Referral of non-compliance to the TGA (and a separate investigation) results in further delays.
- Finally, there is confusion as to where to send complaints and the total numbers received. While the Complaint Panel offers a central complaints mailbox, the TGA and Industry Associations also accept complaints directly. Complaints sent directly to the TGA or dealt with by Industry Associations are not recorded on the Complaint Panel Summary of Complaints report.<sup>16</sup>

## Option 1: The TGA

Perceived problems with a TGA takeover:

- The TGA appears to lack a consumer protection culture.
- The TGA would need to acquire additional complaint handling, investigative and compliance powers.
- The TGA is seen to be taking over a role that was shared in the past with stakeholders.
- The TGA has made bad decisions in isolation: for example, approving an advertisement for the homeopathic product, "Restless Legs Relief", which contained restricted representations.<sup>14</sup>

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<sup>13</sup> <http://www.tgacrp.com.au/complaint-register/>

<sup>14</sup> <http://www.tgacrp.com.au/withdrawn-complaints/>

<sup>15</sup> <http://www.smh.com.au/national/swisse-ads-did-mislead-as-complaint-is-upheld-again-20130607-2nvok.html>

<sup>16</sup> <http://www.medreach.com.au/?p=1661>

<sup>17</sup> [http://www.tgacrp.com.au/wp-content/uploads/files/CRP\\_complaints\\_summary\\_1-Jul-2015\\_to\\_30-Jun-2016.pdf](http://www.tgacrp.com.au/wp-content/uploads/files/CRP_complaints_summary_1-Jul-2015_to_30-Jun-2016.pdf)

<sup>18</sup> <https://www.accc.gov.au/media-release/accc-appeals-17m-penalty-against-reckitt-benckiser-for-misleading-nurofen-representations>

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- The TGA appears to be too close to industry: for example, when sent advertisements whose sponsors declined compliance with Complaint Panel determinations, they sometimes negotiate softer outcomes that eliminate the retractions sought.
- The information the TGA provides to consumers about Listed medicines fails to point out that these products are not evaluated to see if they work.<sup>19</sup>
- The TGA has failed to target sponsors with post-marketing reviews whom the Complaint Panel has found to repeatedly breach the Code.
- The TGA has not addressed long-standing problems that have been the subject of papers (appended), correspondence (appended) and numerous upheld complaints. Examples include products targeting weight loss (“Fat Blaster”, “Fat Magnet”, “Reducta”), sexual enhancement (“Horny Goat Weed for Him” and “Horny Goat Weed for Her” and numerous homeopathic products, including homeopathic melatonin and homeopathic growth hormone. Indeed, despite previous TGA consultations on the latter problem,<sup>20</sup> the Government and TGA now appears to want to abdicate its responsibilities for these and some other therapeutic goods (r.48).
- The TGA rarely ask sponsors to correct misleading indications / claims on their ARTG Public Summary documents despite the same claims being found to breach the Code on advertisements by the Complaint Panel.
- The TGA has consistently lacked transparency, both in the outcomes of advertisements submitted directly, and in many referred to them by the Complaint Panel for non-compliance. They rarely provide a public determination about complaints dealt with.
- In short, the TGA has never fulfilled the principles outlined in the Commonwealth Ombudsman’s “Better Practice Guide to Complaint Handling”.<sup>21</sup>

## Option 2: An existing Commonwealth agency such as the ACCC

The ACCC has been suggested as a possibility:

### Pros

- The ACCC has a consumer protection culture, excellent investigative and compliance powers under the provisions of Australian Consumer Law and the necessary legal expertise.<sup>22</sup>
- They have taken on cases involving the advertising of therapeutic goods for their educative or strategic effect, for example Nurofen targeted pain relief,<sup>23</sup> Homeopathy Plus,<sup>24</sup> and myDNA.<sup>25</sup>

### Cons

- The ACCC has consistently argued that where there is a need for specialist regulators, they should not be rolled into the ACCC.
- The ACCC receives many thousands of complaints per year covering a wide range of areas. Given finite resources they only take on a small number of cases to pursue through the courts; around 20 – 25 per annum. As mentioned above, very few of these involve the advertising of therapeutic goods.

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<sup>19</sup> <https://www.tga.gov.au/registered-and-listed-medicines>

<sup>20</sup> <https://www.tga.gov.au/regulation-homoeopathic-and-anthroposophic-medicines-australia>

<sup>21</sup> <http://www.ombudsman.gov.au/publications/better-practice-guides>

<sup>22</sup> <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>

<sup>23</sup> <https://www.accc.gov.au/media-release/court-finds-nurofen-made-misleading-specific-pain-claims>

<sup>24</sup> <https://www.accc.gov.au/media-release/court-imposes-penalty-for-false-or-misleading-claims-by-homeopathy-plus-and-ms-frances-sheffield>

<sup>25</sup> <https://www.accc.gov.au/media-release/chemmart-agrees-to-improve-its-promotion-of-%E2%80%9Cmydna%E2%80%9D-tests>

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- The ACCC may investigate a complaint for 4-6 months before deciding that, although the complaint had merit, it is not a priority to proceed with. No information about the results of such investigations are provided to the complainant or the public.
- In addition, there are vocal groups with their own agenda who advocate handing the complaint system over to the ACCC, as that body is currently structured and resourced.
- If current Complaint Panel functions are transferred to the ACCC without additional resources most complaints about the advertising of therapeutic goods will disappear into a morass of complaints that cannot be dealt with and only the odd one will make it through the courts. That will in effect amount to NO controls.

## Option 3: An Independent Non-Government Authority

An alternative model for complaints handling would be to outsource the process to an independent (non-Commonwealth) authority. The independent authority would be conferred with statutory powers to receive, investigate and determine complaints. It would administer the entire complaints handling process from receipt and assessment of complaints through to enforcement of compliance for advertisers in breach of the advertising requirements.

An example of such an authority is the NSW Health Care Complaints Commission set up under the Health Care Complaints Act 1993 No 105.<sup>26</sup>

This option does not appear to be as cost-effective as options 1 and 2. An independent non-government body would need to acquire legal, investigative and compliance expertise, as well as the critical appraisal skills required to evaluate the evidence underlying complaints about therapeutic goods.

## Comment on options 1 & 2.

In their consultation document, the TGA questioned whether the handling of complaints that encompass questions of efficacy can be achieved within an organisation outside of the TGA. However, as pointed out above, there are many problems with the TGA's current handling of complaints unrelated to the lack of effective sanctions and penalties.

A more innovative suggestion is closer partnership between the ACCC and the TGA in the transition to, and in the initial phase of, a new complaint system. This would involve seconding a senior enforcement manager from the ACCC to the TGA to oversee the new system (and change the TGA's culture) while keeping the best of the current system (the Code Council and Complaint Panel) and fixing the flaws, such as the lack of power to enforce determinations. Strategic cases such as MyDNA (which involved a pharmacy chain) would still be dealt with by the ACCC.<sup>27</sup> This is in accord with the multi-regulator model supported by a recent Productivity Commission draft report.<sup>28</sup>

The 2016 Federal Budget outlined \$20.4 million over four years from 2016-17, including \$9.5 million in capital funding, to improve the regulation of therapeutic goods in Australia. Increased funds were initially to come from TGA reserves and subsequently from increased fees and charges.<sup>29</sup> An appropriate moiety of these funds should be allocated to setting up a best practice complaint system under ACCC supervision.

This will require all complaints to be logged in a database, have an acknowledgment provided to the complainant and sent to the person / company complained about for a response within a set time-frame. A determination will be made about the merits of each complaint, including appropriate sanctions and penalties, sent to the complainant and the person / company complained about, and

<sup>26</sup> <http://www.legislation.nsw.gov.au/#/view/act/1993/105/full>

<sup>27</sup> <https://www.accc.gov.au/media-release/chemmart-agrees-to-improve-its-promotion-of-%E2%80%9Cmydna%E2%80%9D-tests>

<sup>28</sup> <http://www.pc.gov.au/inquiries/current/consumer-law#draft>

<sup>29</sup> [http://www.budget.gov.au/2016-17/content/bp2/html/bp2\\_expense-15.htm](http://www.budget.gov.au/2016-17/content/bp2/html/bp2_expense-15.htm)

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then (if not appealed against) published on the complaint body website within a given time-frame. Natural justice principles must be incorporated. There must be an avenue for the person / company complained about to appeal a determination but, while that appeal is being determined, the advertisement under question must be withdrawn. If the appeal fails; the determination will be published. Finally, performance reporting must enable the timeliness and effectiveness of the system to be monitored and identify problem areas that may require system improvements &/or new policy initiatives.<sup>21</sup>

## Recommendation Fifty-Seven

The Government accepts the need for **stronger compliance powers against misleading advertising, noting that broadening enforcement powers will benefit consumers by ensuring appropriate compliance with regulatory requirements and deter inappropriate and misleading advertising of therapeutic goods.**

**Comment: uncontroversial, accepted.**

Sanctions and penalties must be sufficient to counter the commercial return that can be obtained by breaching the Therapeutic Goods Advertising Code and related regulations.<sup>30</sup> For egregious conduct, product de-listing, significant fines and retractions of claims are crucial. The latter are needed to correct the misinformation promulgated, warn consumers about the company involved and provide a name and shame penalty. Retractions must be placed in all the media where the offending claim was published, in the same size and for the same time as the offending claim was promulgated.

Currently, there are no civil penalties available for a breach of advertising requirements and to our knowledge the TGA has never attempted to impose criminal penalties, as the penalty levels were thought to be too low to be worth taking to court.

The new sanctions and penalties set out in Table 1 of the consultation document should be adequate if imposed.

For false or misleading advertising, the proposed amendments would increase the fine under criminal law to a maximum of 500 penalty points (\$90,000)<sup>31</sup> and introduce civil penalties of maximum 1000 or 1250 penalty points for an individual (\$180,000 or \$225,000) and 10,000 or 12,500 for a corporation (\$1.8M or \$2.25M). Civil penalties of the same amount may be available for advertisements that contain prohibited/restricted representations, contain a claim not present on their ARTG entry, or otherwise do not comply with the Advertising Code. Alternatively, advertisers offending these provisions may be prosecuted under the criminal law for a maximum fine of 1000 penalty points (\$180,000).<sup>32</sup>

The TGA will also retain its ability to order corrective action ('Regulation 9 Order'), such as requiring the body to withdraw the advertisement or publish a retraction.<sup>33</sup> However, while previously there was no sanction for non-compliance with such an order, the proposed amendments include a criminal offence

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<sup>30</sup> <http://www.pc.gov.au/inquiries/current/consumer-law/draft/consumer-law-draft-overview.pdf>

<sup>31</sup> If did not result in injury. If the conduct was culpable and resulted in injury, the maximum fine may be increased to \$720,000 (and/or 5 years imprisonment).

<sup>32</sup> If did not cause injury. If the conduct was culpable and resulted in injury, maximum fine is increased to \$720,000 (however, this is not available for "prohibited representation" provision).

<sup>33</sup> Regulation 9 under the *Therapeutic Goods Regulations 1990*.

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(maximum fine of \$90,000)<sup>34</sup> and civil penalties (maximum fine of \$900,000 for individual and \$9M for corporations).

There are also measures that do not require court involvement: failure to comply with an order may be sufficient grounds for cancellation of the product's ARTG entry, may give rise to an infringement notice to both sponsors and non-sponsors of the product<sup>35</sup>, and/or may result in the TGA publishing details of the non-compliance on its website. If advertising claims are likely to cause injury, the TGA may also publish a public warning notice.

As court proceedings may take many months or years, it is proposed that interim injunctions be available to restrain advertisers from making the offending claims. This option may be available where an advertisement poses a risk to public safety, or contains false and misleading representations.

## Recommendation Fifty-Eight

The Government accepts that the TGA should **develop a formal education programme to provide sponsors and advertisers** with appropriate information and tools to assist them in understanding their obligations and achieving compliance with advertising requirements. This will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of *Recommendation Fifty-Five*).

**Comment: uncontroversial, accepted; noting that the TGA has already started some innovative education.**<sup>36</sup>

The TGA notes that in the absence of an advertising pre-approval system, industry (including publishers and broadcasters), healthcare providers and consumers will need clarity as to what is acceptable advertising. This is an area where education on the detail of both necessary and prohibited statements will simplify the regulatory environment.

The simplest way to achieve this would be to align the requirements for advertising with the information contained within the ARTG for a product. This will require greater clarity within the Advertising Code and a disciplined approach as to what claims can be included on the ARTG (see Recommendation 38 of the Review). There is concern that many indications on the 2013 TGA List of Permitted Indications are not evidence-based.<sup>37</sup> It would also require a substantial clean-up of the voluminous "free-text" of indications and claims which sponsors have currently added to ARTG Public Summary Documents (without TGA oversight) to avoid breaches of s.22(5) of the Therapeutic Goods Advertising Code 2015.

## Future of the Code Council and Complaints Panel

The Government has agreed that the advertising of therapeutic products to the public will continue to be regulated by the TGA under a legislative framework which includes an advertising code. However, consistent with its Smaller Government Agenda, it has also agreed to the abolition of the Code Council and the Complaint Panel. This has implications for the future provision of expert advice on advertising to the TGA.

The Code Council is currently established under the Therapeutic Goods Regulations 1990 and its functions include consideration of advertising requirements and changes to the Code, and making recommendations to the Minister about advertising standards and the use of restricted

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<sup>34</sup> If did not result in injury. If the conduct was culpable and resulted in injury, the maximum fine may be increased to \$720,000 (and/or 5 years imprisonment)

<sup>35</sup> Infringement notices would be accompanied by a pecuniary penalty of up to 5% of the maximum civil penalty for that offence.

<sup>36</sup> <https://www.tga.gov.au/compliance-and-education-listed-medicines>

<sup>37</sup> <https://www.tga.gov.au/consultation/consultation-permitted-coded-indications-listed-medicines>

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representations in advertising.<sup>38</sup> The Complaint Panel is also established under the Therapeutic Goods Regulations 1990. The Chair of the Complaint Panel is nominated by the Code Council.

## **Comment: controversial**

Given the abolition of the Code Council, the TGA has proposed that, if expert advice on advertising matters is required in the future, the matter will be referred to the committee with the most relevant expertise (supplemented by expert advisers as required). There is concern that with the changes proposed by the TGA, the decision as to whether the Code should be updated in the future, and by whom, will be left entirely to the discretion of the TGA. There is also concern that abolishing the Complaint Panel will deprive the proposed complaint system of valuable considerations by stakeholder representatives as well as the legitimacy that their involvement provides.

## **Future of the Therapeutic Goods Advertising Code**

The Therapeutic Goods Advertising Code 2015 is a legislative instrument made by the Minister under the Act. Its objects are to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

The Code sets out principles and minimum requirements for the acceptable and unacceptable content and effects of advertisements for therapeutic goods directed to consumers. It is an offence under the Act if a person publishes or broadcasts an advertisement about therapeutic goods that does not comply with the Code.

Many amendments to the Code have been on hold until the outcomes of the Review were known. It is proposed that these amendments, including those designed to address the parity of the Code in relation to medicines and medical devices, will now proceed in consultation with the current Code Council. The new Code is expected to be in force before (or at the same time as) other proposed changes to the advertising framework and will be the subject of separate consultation.

In improving the Code, considerations will include:

- The adequacy of the current definitions of “prohibited” and “restricted” representation, particularly in the light of new diagnostic techniques (such as those involving direct-to-consumer genetic testing) and the plan to allow enhanced efficacy claims for certain complementary medicines (r.39).
- Referring to obesity a restricted representation.
- Referring to a “serious medical intervention” a restricted representation.
- Amending the section on “scientific information” including ensuring that any scientific information in an advertisement is identifiable and accessible to consumers.
- The use of testimonials in advertisements.
- The offering of free samples of therapeutic goods as part of an advertisement.
- In addition to these specific considerations, the code will be redrafted with a view to providing more objective tests for breaches of the code, particularly given the possible introduction of strict liability offences for breaches of the code (see r.57 above).

## **Comment: controversial**

It is noted that these matters will be the subject of a separate consultation. This is important because many other suggestions for improving the Code have been put forward by Choice and others.

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<sup>38</sup> The Secretary can under section 42DF of the Act approve the use by a person of a restricted representation in advertising. Under that section, he is required to take into consideration any recommendation of the Code Council.

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## Appendix: Government consultations and reviews on complementary medicines and advertising

| Date | Initiative   |
|------|--|
| 2002 | Report of a Review of Advertising Therapeutic Products in Australia and New Zealand  |
| 2003 | Report of Expert Committee on Complementary Medicines in the Health System   |
| 2005 | Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products  |
| 2006 | Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia  |
| 2007 | Consultation - draft (Trans-Tasman) advertising rule   |
| 2008 | Regulation of homoeopathic and anthroposophic medicines in Australia   |
| 2009 | Draft Guideline for Levels and Evidence for Listed Medicines with Indications & Claims for Weight Loss   |
| 2010 | TGA Consultation: Improving advertising arrangements for therapeutic goods   |
| 2011 | Consultation and Report of the Working Group on Promotion of Therapeutic Products<br>Report of the Review to improve the transparency of the Therapeutic Goods Administration<br>ANAO Report. Therapeutic Goods Regulation: Complementary Medicines<br>TGA reforms: A blueprint for TGA's future |
| 2012 | Delivering reforms - Implementation plan for TGA Reforms<br>TGA Advertising regulatory framework: Options for reform   |
| 2013 | TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the public  |
| 2014 | Expert Review of Medicines and Medical Devices Regulation (Government de-regulation agenda)<br>Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator  |
| 2015 | Expert Review of Medicines and Medical Devices Regulation: recommendations and public forum.   |

# Commercialism, choice and consumer protection: regulation of complementary medicines in Australia

Ken J Harvey, Viola S Korczak, Loretta J Marron and David B Newgreen

Complementary and alternative medicines (CAMs) are being used increasingly in Australia, often in conjunction with conventional medicines.<sup>1</sup> While the demand for CAMs is growing, the regulatory framework is weak. The electronic lodgement facility, introduced in 1996, has made it easier to place new CAMs on the Australian Register of Therapeutic Goods (ARTG). Concern about the regulation of CAMs has been growing among organisations such as CHOICE.<sup>2</sup>

Here, we review the regulatory requirements for CAMs, compare weight-loss products listed on the ARTG with registered pharmaceutical products, analyse complaint procedures and advocate policy change. We have focused on weight-loss products because of widespread concern about an obesity “epidemic”, extensive advertising of the products and the large number on the market.

## Regulation of therapeutic goods in Australia

In 1989, the federal Parliament passed the *Therapeutic Goods Act 1989* (Cwlth), which created the ARTG. The ARTG has two parts: one for “registered goods” and the other for “listed goods”. Some goods captured by the Act are classified as “exempt goods” and are not entered in the ARTG (ss. 9A, 18). Box 1 shows the differences between the various categories of therapeutic goods.

“Registered” medicines are considered to be of relatively higher risk and are individually evaluated by the Therapeutic Goods Administration (TGA) for quality, safety and efficacy before market entry. “Listed” medicines are considered to be of relatively lower risk (Box 2).<sup>3</sup>

Most, but not all, CAMs are listed medicines.<sup>4</sup> Initially, the TGA did not require sponsors to have evidence to support claims made about their products. In 1999, concern that improbable therapeutic claims were being made about CAMs led to the introduction of a requirement that sponsors hold substantiating evidence.<sup>5</sup> Further, since a report by the Expert Committee on Complementary Medicines in the Health System, a random sample of about 20% of new listings is said to be assessed each year for compliance with TGA requirements.<sup>6</sup> Both these measures have been introduced to increase monitoring of CAMs.

In 1991, the government introduced fees and charges to industry for services provided by the TGA, such as ARTG applications, good manufacturing practice inspections and annual licensing. The aim was to achieve 50% cost recovery. In 1998, the government determined that 100% of costs would be recovered.<sup>7</sup> Illustrative TGA fees (at 1 July 2007) were \$170 200 for registering and evaluating a new prescription medicine (a new chemical entity); \$990 for registering and evaluating an over-the-counter product or CAM (plus \$6570–\$46 000, depending on the number of pages of data submitted); and \$540 for listing a medicine. The annual charge for a registered (non-biological) prescription medicine was \$3030; for a registered over-the-counter product, conventional or CAM, \$920; and for a listed medicine, \$690.<sup>7</sup>

## ABSTRACT

- Controls on the supply and promotion of complementary medicines in Australia are weak.
- We used weight-loss products as an example to compare the regulation in Australia of listed complementary medicines and registered pharmaceutical products.
- Complementary medicines are listed without evaluation for efficacy, while conventional pharmaceutical products are registered after evaluation for quality, safety and efficacy.
- From 1996 to 2006, over 1000 “weight-loss” products were listed on the Australian Register of Therapeutic Goods; most contained multiple unevaluated ingredients (herbs, vitamins, minerals) of dubious efficacy. Over the same period, 10 conventional medicines were registered; each contained one evaluated ingredient of proven efficacy.
- The number of listed weight-loss products (and complaints about their promotion) is increasing. These appear to be a direct consequence of the decision not to evaluate listed products for efficacy and the lower fees for listing a product, compared with registration.
- Complaint procedures (now overloaded) are no substitute for adequate regulation at the time of market entry.
- Regulatory reform of listed and homoeopathic products is required.

MJA 2008; 188: 21–25

Sponsors self-assess their medicines as being listable using the web-based electronic listing facility (ELF) of the ARTG. The ELF system automatically checks that the ingredients entered are consistent with those allowed in listed medicines and asks the sponsors to certify that they hold evidence to support the indications (and thus claims) made. Sponsors may pick either a coded indication such as “May aid or assist weight loss . . .” or a custom indication entered as free text in a memo field. More than one entry into either field is allowed. After payment of a fee, the ELF system automatically generates an “AUST L” number and a certificate of listing.

Since the introduction of the ELF, the time taken to list a product has been reduced from around 5 months to 10 days or less for about 90% of applications.<sup>8</sup>

Complaints from the public about listed products need to be submitted to various authorities, as summarised in Box 3.<sup>9</sup>

In February 2007, the Australian Government reintroduced a provision of the Therapeutic Goods Advertising Code, which had existed before August 2005, prohibiting health care professionals from endorsing therapeutic goods in advertisements to consumers. This provision took effect from 8 March 2007, but allowed existing advertisements to continue for either 2 years after approval (eg, in print) or 1 year if approval had not been required (eg, Internet advertisements).<sup>10</sup>

**1 Contrasting requirements of the Therapeutic Goods Administration (TGA) for different categories of goods**

| Requirement   | Registered goods<br>(pharmaceutical products)   | Listed goods<br>(complementary medicines)  | Exempt goods   |
|---|---|--|--|
| Label designation                                   | AUST R  | AUST L   | na   |
| Compliance with Code of Good Manufacturing Practice | Yes   | Yes  | No   |
| Manufacturers licensed by TGA                       | Yes   | Yes  | No   |
| Efficacy evaluated by TGA                           | Yes   | No   | No   |
| Stability (shelf-life) evaluated by TGA             | Yes   | No   | No   |
| Individual ingredients evaluated for safety by TGA  | Yes   | Yes  | Some (eg, those in antiperspirants, fluoride toothpastes)  |
| Examples  | All medicines included in a poisons schedule, all PBS medicines, all other medicines not listed or not exempt goods | Most herbal preparations, vitamins, minerals, glucosamine, some homoeopathic medicines (if the sponsors so choose), export goods | Homoeopathic medicines, extemporaneously dispensed medicines, dandruff shampoos, antiperspirants, fluoride toothpastes |

na = not applicable. PBS = Pharmaceutical Benefits Scheme.

**2 Main criteria used by the Therapeutic Goods Administration for listed complementary medicines (with the exception of homoeopathic products)**

- They may contain only ingredients approved for use in listed medicines (those with well established quality and safety profiles);
- They must be labelled and advertised only for indications consistent with low risk (eg, symptomatic relief of non-serious diseases, disorders and conditions) and must not be indicated for the treatment of a serious form of a disease, condition, ailment or defect as specified in the Therapeutic Goods Advertising Code;
- There must be evidence (which can be either traditional or scientific), held by the sponsor of the product, to support any claim that the sponsor makes relating to the medicine; and
- They do not contain substances that are scheduled in the Standard for the Uniform Scheduling of Drugs and Poisons or otherwise restricted (eg, included in Part 4 of Schedule 4 of the Therapeutic Goods Regulations 1990).

**3 Bodies handling complaints about listed products and registered over-the-counter products**

| Complaint   | Regulation   |
|---|--|
| About product quality or claims made on the pack or pack insert   | Therapeutic Goods Administration's Office of Complementary Medicines   |
| About promotional claims made in specified media (television, radio, Internet, newspapers, magazines, outdoor signs and cinema) | Complaints Resolution Panel assesses concerns against the Therapeutic Goods Advertising Code   |
| About other advertising, such as pharmacy window displays, brochures, leaflets and catalogues                                   | Complaints Resolution Committee of the Complementary Healthcare Council of Australia or Australian Self-Medication Industry's Complaints Panel |

**An example: weight-loss products**

In Australia, both listed and registered weight-loss products are available. To determine the numbers of each and compare them, we asked the TGA to search the ARTG for registered or listed products with the indication “weight loss”, or similar, for the period 1996 to 2006. We then supplemented the list by searching the shelves of pharmacies and health food shops and Australian Internet sites. Because of problems encountered, the TGA made available a subset of the ARTG database so that we could refine their search for weight-loss products. For the registered and listed products found, we compared the therapeutic claims with the published evidence. The website of the Therapeutic Goods Advertising Code Council was used to identify complaints and select illustrative case studies.

**Products identified**

The initial search output received from the TGA failed to show some registered weight-loss products, such as orlistat (Xenical [Roche]) and sibutramine (Reductil [Abbott]). It also failed to show many listed CAMs that were being actively promoted for weight loss.

Some of these problems resulted because the ELF system allowed sponsors of listed products to enter information into the ARTG in free text without verification by TGA staff. Some non-standard indications had been used for weight-loss products (such as “thermogenic”, “body sculpting”, “reduce carb cravings”), which made a complete search for such products difficult, if not impossible.

Our own search found over 1000 new weight-loss products listed on the ARTG from 1996 to 2006. New listings generally increased over the period, from 45 in 1996 to 144 in 2006. Most contained multiple ingredients (herbs, vitamins, minerals). Homoeopathic products are not included on the ARTG. Over the same period, 10 conventional medicines for weight loss were registered with the ARTG, each containing one ingredient, (orlistat, diethylpropion, phentermine, sibutramine). All these substances are officially scheduled poisons, and products containing them are registered for the management of obesity, unless the

product is for export. Those containing orlistat and sibutramine have been fully evaluated. Phentermine-containing medicines were “grandfathered” on to the ARTG because they were already on the Australian market when the Act took effect in February 1991. Diethylpropion is no longer marketed. The safety and efficacy of these agents has been comprehensively reviewed.<sup>11</sup>

Thus, sponsors could decide not to market products they had placed on the ARTG or to take them off the market but leave them on the ARTG. Taking into account these limitations, we found about 100 times as many listed weight-loss products on the ARTG as registered products. It is not possible to be too specific about numbers because there were confounding factors, such as the inclusion in the listed goods part of the ARTG of prescription-only medicines that were destined for export.

In our opinion, the indications for weight-loss products listed on the ARTG (and thus their promotional claims) were often not in accord with the limited scientific evidence available. Furthermore, the number of such listed products is increasing each year at a much greater rate than registered products. It is possible that this has been influenced by the decision not to evaluate listed products for efficacy and also the lower fees for listing a product compared with registration.

#### A typical weight-loss product

An example of a publicly available, listed weight-loss product is shown in Box 4. We are unaware of publicly available evidence from clinical trials to support the therapeutic claims made for this product or for many other listed (and homoeopathic) weight-loss products. Several systematic reviews have evaluated the commonly included ingredients and have concluded that, at best, more definitive clinical trials are required before conclusions can be drawn.<sup>12,13</sup> While these products are of relatively low risk, some herbal ingredients can cause harm by themselves and also by interacting with conventional medicines; both kinds of event may be underreported.<sup>14,15</sup>

The Complaints Resolution Panel found that the claims made about the illustrated product, Xantrax (Hershel-Beck Laboratories), breached the Therapeutic Goods Advertising Code as they were misleading and likely to arouse unwarranted and unrealistic expectations of product effectiveness.<sup>16</sup> In our experience, it usually takes 3 to 4 months for submitted complaints to be adjudicated by the Complaints Resolution Panel and several more

#### 4 Xantrax (Hershel-Beck Laboratories), an example of a listed weight-loss product

##### Ingredients

Each Xantrax tablet contains:

- *Camellia sinensis* (green tea)
- *Citrus aurantium* fruit (bitter orange)
- *Paullinia cupana* (guarana)
- *Panax ginseng* (Korean ginseng)
- *Ilex paraguariensis* (yerba mate)
- 11 additional vitamins and minerals

##### Therapeutic claims

Xantrax helps by:

- delaying gastric emptying thus prolonging a sense of fullness
- suppressing appetite
- maintaining healthy energy levels
- improving exercise performance
- enhancing the body’s ability to cope with stress
- supporting healthy metabolism



Pharmacy poster for Xantrax.

months before the results are made public. Meanwhile, promotional campaigns continue. In addition, the sanctions imposed appear ineffectual, as shown by the fact that some companies repeatedly breach the Therapeutic Goods Advertising Code. For example, from March 2004 to November 2007, the sponsor of Xantrax, Cat Media Pty Ltd, has had at least 28 complaints about its products, 22 of which have been upheld.<sup>16,17</sup> In 2006, the Panel received over 350 complaints, more than twice the number received in 2005. Of these, 170 have been finalised and 100 are still being processed, 60 concerning homoeopathic products and which were referred to the TGA, and 22 referred to other bodies. The system is clearly overloaded and under-resourced. We submitted complaints over 6 months ago that have yet to be addressed. We submitted complaints over 12 months ago that have been referred to other jurisdictions, about which we have heard no more; meanwhile, promotion continues.

#### Implications

In 2003, the Expert Committee on Complementary Medicines in the Health System was established to reassure the public about the safety and quality of CAMs. The Committee said (Finding 4.1.1) that the “Government needs to take a more active role in ensuring that consumers have access to reliable information about complementary medicines, and the skills to interpret information and make informed decisions”.<sup>6</sup> In 2005, the government responded to the expert committee report by accepting, noting or supporting all but one of the 49 recommendations. The TGA established the Complementary Medicines Implementation Reference Group to oversee the implementation and has provided progress reports.<sup>18</sup>

Despite the widespread use of CAMs, many consumers are unaware that listed medicines do not undergo the same stringent evaluation process as registered medicines, or indeed, that there is a difference between the two. Consumers are not sufficiently protected by regulation in this case. It

is difficult to reconcile the therapeutic claims made for many CAMs with the objects of the Act: “to provide for ... a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods...” (s. 4, our italics).

In an attempt to explain the difference, the TGA produced a pamphlet in 1995 called *Buying medicines — what’s on the label for me?* It was available in pharmacies and health food shops and is now on the Internet.<sup>19</sup> While the content reflects the legal situation, the omission that AUST L listed medicines are not evaluated for efficacy diminishes the utility of the pamphlet for the

very people to whom it is directed. This has financial as well as health implications for consumers. Brian Grogan, national president of the Pharmaceutical Society of Australia, has noted:

While those products that lack evidence for effectiveness may not actively harm the physical health of those who take them, they may well be harming patients' financial health, some of whom may have to forgo other more beneficial evidence-based treatments or other necessities.<sup>20</sup>

In addition, any herb has many different chemical constituents, the presence and concentration of which vary, depending on the source of the herb, and the extraction and standardisation methods used. Marked variations of chemical constituents have been found in different commercial products that purported to contain the same amount of a particular herb.<sup>21</sup> Currently, the TGA accepts crude assays that do not necessarily confirm that one herbal product has the same chemical constituents as another that has been proven to be clinically effective. In addition, the TGA does not require stability data on listed products.

Finally, the large number of repeated breaches of the Advertising Code by certain companies, together with an increasing backlog of complaints, shows that complaint procedures are no substitute for adequate regulation at the time of market entry. Consumers (and health professionals) cannot exercise informed choice about CAMs if they are denied information about the quality and efficacy of these products.

### Solutions

How could the present situation be improved? We propose the following actions:

- AUST L medicines (and homoeopathic medicines) should include on their labels a statement, such as "This medicine has not been evaluated by Australian health authorities for efficacy".
- A campaign to educate the public about such matters is needed. This would best be done by the National Prescribing Service, which is currently conducting a survey of educational needs in relation to CAMs.
- Ethical codes of conduct and complaint procedures for CAMs, over-the-counter and prescription drugs should be streamlined, harmonised and brought under one adequately resourced authority. Consistent (and meaningful) sanctions should be imposed on companies that repeatedly breach codes (for example, corrective advertising orders and fines linked to company turnover, with the money used to support the complaint system).
- The ARTG database should be updated with respect to listed products. Sponsors should be required to add key evidence supporting each indication on the ARTG and entries should be checked by staff of the regulatory body and coded with respect to therapeutic indication. This information should be publicly available on the Internet.
- The TGA should check the analysis of herbal products more thoroughly and allow sponsors to use clinical trial evidence relating to other products only where their own product has been shown to have an identical herbal preparation, extraction and standardisation process.
- Finally, we believe that, in the longer term, the listing system should be scrapped, and CAMs (including homoeopathic medicines) should be assessed for efficacy and delisted if evidence is lacking. Public money should be used for this, not listing fees. There is a current perception that 100% cost-recovery by the TGA

(as with the Food and Drug Administration in the United States) has led to commercial considerations outweighing the need for consumer protection.<sup>22,23</sup>

Listed weight-loss products would be a good place to start the regulatory reform, given the increasing problem of obesity in Australia.

### Acknowledgements

We are most grateful for the information provided by officers of the Therapeutic Goods Administration and the Therapeutic Goods Advertising Code Council.

### Competing interests

None identified.

### Author details

Ken J Harvey, FRCPA, Adjunct Senior Research Fellow<sup>1</sup>

Viola S Korczak, BEc(SocSc), MIPH, Health Policy Officer<sup>2</sup>

Loretta J Marron, BSc, AssocDipBus<sup>3</sup>

David B Newgreen, BPharm, MBA<sup>4</sup>

<sup>1</sup> School of Public Health, La Trobe University, Melbourne, VIC.

<sup>2</sup> Choice (Australian Consumers' Association), Sydney, NSW.

<sup>3</sup> Brisbane, QLD

<sup>4</sup> Melbourne, VIC.

Correspondence: k.harvey@medreach.com.au

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(Received 3 May 2007, accepted 31 Oct 2007)

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21/12/2015

Adjunct Professor John Skerritt  
Deputy Secretary, Regulatory Services Group  
Department of Health  
Therapeutic Goods Administration  
PO Box 100  
Woden, ACT 2605

Dear Professor Skerritt,

**Re: Advertising & Regulation of Homeopathic Products, e.g. Brauer, Martin & Pleasance, etc.**

I am writing to urge the TGA and the MMD Review Taskforce to recommend that government takes definitive action to protect consumers from the false claims of benefits that continue to be made for homeopathic products. This is in accord with the clear statement from our NH&MRC<sup>1</sup> that there is no credible scientific evidence to support such claims.

I have discussed this issue with Friends of Science in Medicine, the Consumers Health Forum, Choice, Australian Skeptics and the Doctors Reform Society. All these organisations share my concern about the promotion of homeopathic products (especially those aimed at childhood conditions). All fully support this letter.

In 2012, an important determination was made by the Therapeutic Goods Advertising Complaint Resolution Panel (CRP) concerning the promotion of Nature's Way Kids Smart (Homeopathic) Products (**2012-10-027 attached**). These products were also awarded the 2012 CHOICE "Shonky" award.<sup>2</sup>

The CRP was concerned that the promotion of these products was directed to a vulnerable category of consumers, for ultimate use of the products by children and infants. The panel noted that the misleading and unverified representations in the advertisement could in some instances result in consumers not seeking medication of demonstrated efficacy, because they would be misled into believing that the advertised products would have the benefits described in the advertisements.

The Panel was satisfied that it was necessary and appropriate for corrective information to be placed before the public and requested that the company concerned (Pharmacare) publish a retraction.

The sponsor declined to comply, the matter was referred to the TGA and in mid-2013 the Delegate of the Secretary of the Department of Health ordered compliance under regulation 9 of the Therapeutic Goods Regulations 1990.

Pharmacare then asked for the Minister for Health for a review of the Delegate's decision. Following review of the initial decision, a delegate of the Minister for Health made a decision on 19 November 2013 that was similar in substance to the initial decision. While the delegate of the Minister found that the advertisement breached the Code, the delegate decided not to order a retraction of the advertisement. On 19 December 2013, PharmaCare Laboratories Pty Ltd confirmed it had stopped the advertising of, and had discontinued, the Nature's Way Kids Smart Natural Medicine Range of products.

In 2014 the CRP forwarded a complaint (**2014/04/009**) from me concerned the promotion of three Brauer homeopathic products directed at babies and children to the TGA. The complaint also noted that information on Brauer's web-site, "How homeopathy works"<sup>3</sup> contained a selective distortion of the scientific literature that appeared to breach the Therapeutic Goods Advertising Code.



Mr. Mick O’Conner subsequently responded (**2014/008822**) that the TGA was considering the matter. I have yet to hear the outcome of this complaint. Meanwhile, the promotion of these products (and the unbalanced scientific information about homeopathy) remains unchanged.

I emailed Mr O’Connor and Ms. Trisha Garrett on June 10, 2014 asking for an update on reforms to the regulation of homeopathic medicines. I noted that this matter was first raised in 2003 by the “Expert Committee on Complementary Medicines in the Health System” and again in 2008 in a consultation paper on the “Regulation of Homoeopathic and Anthroposophic Medicines in Australia”.

On June 19, 2014 Ms. Garrett informed me (via email) that proposed reforms to the regulation of homeopathic medicines had been put on hold from 2011 pending the outcome of the final report from the NHMRC review on homeopathy.

The final NHMRC report and statement on homeopathy was published in March, 2015. It concluded (as have others<sup>4,5</sup>) that there are no health conditions for which there is reliable evidence that homeopathy is effective.

We also have the TGA 2014 “Guidelines on the evidence required to support indications for listed complementary medicines” which state (page 26)<sup>6</sup>,

“If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labeling and advertising associated with the medicine, for example: ‘this traditional use is not supported by scientific evidence’. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading.”

Turning this around, in the light of the final NHMRC statement, I submit that if the promotion of a homeopathic product does not include the statement, “this traditional use is not supported by scientific evidence” (and cite the NHMRC statement) then it must be misleading and deceptive and thus in breach of a number of provisions of the Therapeutic Goods Advertising Code.

Given the above, I now bring this issue to the attention of the TGA once again, and also to the Review of Medicines and Medical Devices Regulation Taskforce.

The three products I complained about in (**2014/04/009**) are still being promoted - Brauer Baby & Child Calm (no ARTG number)<sup>7</sup>, Brauer Baby & Child Cold & Flu (ARTG 132569)<sup>8</sup> and Brauer Baby & Child Pain & Fever Relief (no ARTG number)<sup>9</sup>.

Both the promotion of these products, and the ARTG Public Summary documents (where available), state that these products contain ingredients traditionally used in homeopathic medicine (or contain homeopathic ingredients). They do not include the disclaimer, “this traditional use is not supported by scientific evidence”. The promotion also makes the following claims:

- **“Baby & Child Calm** includes Passionflower, which is traditionally used in homeopathic medicine to work with your child’s body, helping to soothe irritability, restlessness and sleeplessness. Baby & Child Calm may be used from 6 months: the natural blackcurrant flavour and included oral measuring dropper make it easy to give to your child.”
- **“Baby & Child Cold & Flu** contains ingredients which are traditionally used in homeopathic medicine to temporarily relieve cold and flu symptoms such as a runny nose, sore throat, pain and fever. Cold & Flu can be used in children from 2 years of age, and may be used in children under 2 years with advice from your healthcare professional.”
- **“Baby & Child Pain & Fever** includes ingredients traditionally used in homeopathic medicine to provide temporary relief from pain and mild fever. Baby & Child Pain & Fever may be used



in babies from 6 months of age: the natural blackcurrant flavour and included oral measuring dropper make it easy to give to your child.”

I reiterate that CRP determination (**2012-10-027**) found that similar claims breached a number of provisions of the Therapeutic Goods Advertising Code and required a retraction. Given this previous determination I ask why has the TGA not taken similar action with respect to complaint (**2014/04/009**)?

I also draw your attention to the promotion of homeopathic products by Martin & Pleasance.<sup>10</sup> Their promotion makes the following claims:

- “Homeopathic formulations stimulate the body’s own ability to assist in restoring natural equilibrium and health. Martin & Pleasance proudly prepare our natural remedies using traditional methods in our own laboratory”.
- “These lactose free sprays can be used by everyone, including pregnant and breastfeeding women, babies, children and people currently on other medications. Simply match the cost effective sprays with these common ailments: Allergy Relief, Bladder Relief, Cravings Relief, Headache Relief, Heartburn and Reflux Relief, IBS Relief, Nausea Relief, Restless Legs Relief and Sleep Relief”.

Neither the promotion nor Martin & Pleasance’s ARTG public summary documents contain the disclaimer that, “this traditional use is not supported by scientific evidence”.

I put to the TGA, and the Review of Medicines and Medical Devices Regulation Taskforce, that the “Guidelines on the evidence required to support indications for listed complementary medicines” and the “Therapeutic Goods Advertising Code” must be amended to make it completely clear that contemporary scientific evidence trumps a history of traditional use. Thus, the promotion (and public summary documents) of **all** homeopathic products must prominently state that, “this traditional use is not supported by scientific evidence” and cite the NHMRC statement.

I also believe (as did the CRP in determination (**2012-10-027**)) that the promotion of homeopathic products for childhood conditions should be prohibited and this should also be incorporated in the documents mentioned above.

Another recurring problem that has been the subject of previous upheld complaints is homeopathic products that abuse the homeopathic principle of ‘like cures like’. CRP determination (**2011-05-021**) regarding is a good example. Regardless of this determination both Pretorius Homeopathic Melatonin<sup>11</sup> and DHEA (Dehydroepiandrosterone)<sup>12</sup> continue to be promoted. We also have Bioglan® Melatonin being promoted as follows:<sup>13</sup>

- “a homeopathic solution to help relieve insomnia and nervous tension as well as provide stamina and endurance when taken in the morning”.

And Bioglan® Melatonin Sleep Spray being promoted as:<sup>14</sup>

- “a fast acting spray that helps relieve insomnia. The homeopathic spray solution is ideal for sleep as it is rapidly absorbed into the bloodstream, to start working quickly”.

These products are not formulated in accord with the homeopathic tradition and, regardless of the statement that, “the claims are based only on evidence of traditional use in homeopathy”, they prey on consumers lack of understanding that homeopathic preparations contain no or negligible amounts of the substance promoted. For example:<sup>15</sup>

- “Human Growth Hormone production begins to decline at age 30 and by age 60 has tapered off substantially. Pretorius Human Growth Hormone (7x) helps restore & maintain energy to



maintain your bounce and vitality as well as triggering well-being with active homeopathic response”.

I am deeply disappointed that the TGA has not applied previous CRP determinations to new complaints referred to it. It is also disappointing that the TGA has not targeted these known problems using its post-marketing surveillance program. Given this inaction, it is not surprising that some question whether the TGA is a suitable organisation to take over the running of complaints from the CRP.

In conclusion, I reiterate the need for the TGA “Guidelines on the evidence required to support indications for listed complementary medicines” and the “Therapeutic Goods Advertising Code” to be amended to make it clear that the promotion (and public summary documents) of all homeopathic products must prominently state that, “this traditional use is not supported by scientific evidence” and cite the NHMRC statement on homeopathy.

I should be most grateful for your response to the concerns expressed above.

Sincerely,

Dr Ken Harvey  
Adjunct Associate Professor  
Department of Epidemiology and Preventive Medicine  
School of Public Health and Preventive Medicine

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Mobile: +61 419181910

Email: [kenneth.harvey@monash.edu](mailto:kenneth.harvey@monash.edu)

[www.medreach.com.au](http://www.medreach.com.au)

Cc MMD Review Taskforce <[MMDReviewTaskforce@health.gov.au](mailto:MMDReviewTaskforce@health.gov.au)>

- <sup>1</sup> <https://www.nhmrc.gov.au/guidelines-publications/cam02>
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- <sup>3</sup> <http://www.brauer.com.au/how-homeopathy-works>
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- <sup>5</sup> <http://www.parliament.uk/business/committees/committees-archive/science-technology/s-t-homeopathy-inquiry/>
- <sup>6</sup> <https://www.tga.gov.au/publication/evidence-guidelines>
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- <sup>11</sup> <http://www.pretoriusvitamins.com.au/supplements/melatonin-90s>
- <sup>12</sup> <http://www.pretoriusvitamins.com.au/supplements/dhea-90s>
- <sup>13</sup> <http://www.bioglan.com.au/products/brain-memory-sleep/melatonin-90s/>
- <sup>14</sup> <http://www.bioglan.com.au/products/brain-memory-sleep/melatonin-spray-50ml/>
- <sup>15</sup> <http://www.theecoshop.com.au/cart/product.php?productid=437&cat=92&page=1>