An update on advertising and complementary medicine regulatory reform

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Talk outline

• The painful & protracted history of reform.
• Where are we now?
• What’s being considered?
• The current Senate inquiry
• What can we do?
### Background

http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be

### Rules under review?

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<td>Report of a Review of Advertising Therapeutic Products in Australia and New Zealand</td>
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<td>Report of Expert Committee on Complementary Medicines in the Health System</td>
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<td>Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products</td>
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<td>Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia</td>
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<td>Expert Review of Medicines and Medical Devices Regulation (Government de-regulation agenda) Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator</td>
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Past reports 2002

- A new Complaints Panel be established with powers derived from the regulator’s power to license, with a condition of the license being compliance with the single Code and acceptance of any orders of the Complaints Panel;
- The powers to order both withdrawal and corrective advertising;
- The powers backed by substantial accumulating fines for each individual breach if those orders are disobeyed.


Past reports 2003

- Consumers may not be aware that Listed medicines are not evaluated for efficacy before their supply.
- There is an ethical responsibility on government to ensure consumers are informed about this difference between Listed and Registered medicines.
- Sponsors of Listed medicines should submit to the TGA a summary of the evidence they hold to support the efficacy of their products.

• There should be increased auditing of sponsors of Listed medicines to ensure that evidence of efficacy is held.
• The current penalty for offences under Section 22(3) of the Act should be increased from 60 to at least 150 penalty units.
• Homoeopathic medicines that make therapeutic claims should be regulated to ensure they meet appropriate standards of safety, quality and efficacy.

Past reports 2003

Past reports 2005-2007

2005 - Australian New Zealand Therapeutic Products Authority (ANZTPA); Joint regulatory scheme for the advertising of therapeutic products.
• 2007 - Postponement of the ANZTPA Project; “The [New Zealand] Government does not have the numbers in Parliament”.

http://www.anztpa.org/
Past reports 2006-2008

Past reports 2010-2011
Past reports
2012-2014

Delivering reform – implementation plan for TGA Reforms: A blueprint for TGA’s future
July 2017

TGA Reforms: A blueprint for TGA’s future
Progress Report as at 31 October 2013
January 2014

TGA Reforms: A blueprint for TGA’s future
Progress Report as at 31 December 2014
February 2015

Past reports
2015-16

Review of Medicines and Medical Devices Regulation
Discussion Report

Australia Government Response to the
Review of Medicines and Medical Devices Regulation
Mar 2016

Cutting Red Tape
The Australian Government’s online resource for regulation reform
Meanwhile

TGA Listed medicine compliance reviews: 2015-16

- 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 TGACRP found 98% of 141 complaints justified (and a 40% non-compliance with TGACRP “requests” for redress).


In short:

- The failure of the TGA to bring the industry into check has resulted in:
  - Loss of trust in the TGA as a regulator
  - Ongoing harm to consumers:
    - Direct harm from poorly disclosed adverse events from complementary medicines and their interaction with conventional medicines.
    - Indirect harm, by consumers forgoing more evidence-based remedies (often to the detriment of their health) because they are sucked in by misleading and deceptive promotional hype. This also wastes their money which could be better spent.

- So, will the MMDR recommendations help?
MMD Recommendations: Government response
15 Sept 2016

• Rejected by government:
  – sponsors to include a prominent disclaimer that products have not been independently assessed (r.44); rejected for more “education”.
  – sponsors to publish evidence supporting their claims (r.43); made optional.
  – TGA given the power to refuse listing (r. 34).

• Accepted (but controversial)
  – mandatory pre-approval of certain advertisements to cease in favour of self-regulation (r.55).

Pros and cons of pre-approval

• Pros
  – Reviews over 2000 advertisements per year with an average turnaround time of 7 days.
  – The majority of new advertisements 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.

Pros and cons of pre-approval

- **Cons**
  - The pre-approval process is only applies to “specified media”, mainly television, radio and print advertisements for medicines, not the Internet and not advertisements for medical devices.
  - Delegated by TGA to two industry associations (ASMI & CMA); decisions are not always consistent.
  - Delegates do not have the time to review the evidence supporting the claims in detail; thus some pre-approved advertisements are still be found to breach the Code by the TGACRP (albeit said to be less than 0.5%).


Currently

- The government agreed that removal of pre-approval requirements is conditional on implementation of other recommended consumer protections:
  - advertising claims being consistent with Permitted or Approved Indications (r.38);
  - strengthening of post-market monitoring(r.49);
  - improving the complaints management process(r.56)
  - enhanced penalties and sanctions for regulatory violations (r.57).
- All the above are meant to be implemented by July 1, 2018.
- However, another view is that it would be better to extend pre-approval to all advertisements making therapeutic claims and delegate the function to a combined ASMI-CMA-MTAA pre-approval office.
- Prevention is better than cure.
Currently

- Of 46 published submissions to the TGA consultation on advertising reforms, only 13% supported removal of pre-approval in favour of self-regulation; all came from industry or media organisations.
- Many stakeholders argued that the current system of pre-approval of advertisements must not be terminated until the formal 3-year review of the reform package has been completed.
- This would enabling the data collected to be used as a performance indicator of the success of advertising reforms.
- **To-date, this argument has been ignored.**


- Accepted: but needs ongoing input on implementation
  - “Free text” on ARTG to be replaced by a limited list of Permitted Indications (r.38).
  - a new listing pathway (option 2) where the sponsor can provide evidence acceptable to the TGA to support the safety and efficacy of health claims that fall outside the list of Permitted Indications (r.39).
  - improvements to the complaint process, post-marketing surveillance and increased penalties for regulatory breaches (r.56, r.49, r.57).
The problem: Free text on the ARTG

Scientific studies have demonstrated that Sambucol reduces the severity of cold and flu symptoms and shortens the duration of a cold. In a clinical trial, patients given Sambucol recovered on average 3 days faster compared to those given a placebo.

The TGA list of Permitted Indications

- The current TGA’s list (submitted by industry) contains around 1000 indications for "traditional medicines" such as Homeopathic products, Traditional Chinese Medicines, Ayurveda and others.
- Scientific investigation has not substantiated many aspects of these traditions, such as the homeopathic principles of “like cures like” and traditional Chinese medicine concepts of meridians through which the life-energy known as “qi” flows.
The TGA list of Permitted Indications

- It includes such gems as:
  - Balance aggravated Vata (Traditional Ayurvedic medicine only),
  - Harmonise middle burner, Spleen and Stomach (Chinese medicine tradition of use),
  - Dispel/expel/extinguish/disperse/clear External Wind (Chinese medicine tradition of use) and
  - Helps enhance/promote uterine health (Tradition of use, unspecified)
  - and Galactogogue/lactogogue/improve breast milk production (Tradition of use, unspecified)
- Clearly the TGA has been captured by industry and has endorsed pseudoscience.

The TGA list of Permitted Indications

- Which then encourages the claims for this product:
  - Breaks up congestion and stagnation of qi at the centre, dispels wind-damp and wind,
  - resolves spleen damp, tonifies spleen qi.
  - A valuable medicine for poor digestion due to deficiency of spleen with phlegm-damp or food accumulation causing nausea, vertigo, headache, pasty or loose stools, and flatulence
  - Excellent for wind-damp invasion of the stomach (summer-damp-heat stomach flu).
  - Valuable in motion sickness and morning sickness.
  - Traditionally used in cholera.
The solution?

- For consumers to make an informed choice about these medicines consumer and health professional groups have argued that a claim based on “traditional use” must have a disclaimer along the lines of what the US Federal Trade Commission uses for homeopathic products.
  - “This product’s traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works”.
- However, the TGA has rejected these submissions without providing any justification.

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A new listing pathway: AUST L(A)

- Sponsors can apply for “intermediate-level” health claims falling outside the permitted list. An example might be,
  - “our formulation of cranberry reduces the frequency of recurrent urinary infections in women”.
- For this, the TGA would assess the evidence substantiating the claim for a particular product.
- If the evidence stacks up (and there’s a debate about the type of evidence needed), the sponsor could place a TGA “claimer” (stamp of approval) on the label and any promotional material and be given a period of data protection.

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Advertising consultation proposals

- **Increased sanctions:**
  - Civil penalties (fines),
  - infringement notices,
  - Warning notices, injunctions, and
  - enforceable undertakings as additional enforcement options: Crucial!

- **Complaint handling:**
  - The government has accepted the TGA’s proposal to take over the complaint system.

Perceived problems with the TGA takeover

- The TGA is seen to be taking over a role that was shared in the past with stakeholders:
  - The current Code Council and Complaint Panel have industry, media, health professional and consumer representation (in addition to TGA staff) which allows a variety of considerations to be brought to revising the Code and making complaint determinations.

- The TGA has made bad decisions in isolation:
  - for example, approving an advertising restricted representation for the homeopathic product, “Restless Legs Relief” and the “traditional use of Saw Palmetto for medically diagnosed benign prostatic hyperplasia”.

- The TGA appears to be too close to industry:
  - 100% funded by industry; US FDA only 25%.
  - Consistently supports industry submissions.
  - Rejects those from consumers and health professionals.
Perceived problems with the TGA takeover

- The TGA has failed to target sponsors with post-marketing reviews whom the Complaint Panel has found to repeatedly breach the Code.
- Nor have they addressed long-standing problems that are the subject of numerous upheld complaints such as weight loss and sexual enhancement products.
- 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.
- Finally, the TGA has consistently lacked transparency, both in the outcomes of advertisements submitted directly, and in many referred to them by the TGACRP for non-compliance.

So, what to do? Put in a submission to the Senate inquiry

- Mainly due to support from the Greens (Senator Di Natale), on 30 November 2017, the Senate referred the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 to the Senate Community Affairs Legislation Committee for inquiry and report.
- The closing date for submissions has not yet been set.
- A public hearing will be held, the date has yet to be determined.
- The reporting date is 2 February 2018.
- So please put in a submission, for ideas, see: http://www.medreach.com.au/?p=2353.