



**TGA CONSULTATION: REFORMS TO  
THE REGULATORY FRAMEWORK FOR  
COMPLEMENTARY MEDICINES -  
ASSESSMENT PATHWAYS**

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# TGA CONSULTATION: REFORMS TO THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES - ASSESSMENT PATHWAYS

## Summary

This consultation by the Therapeutic Goods Administration (TGA) seeks feedback on recommendations 38, 39, 45 and 50 of the “Expert Review of Medicines and Medical Devices Regulation” (MMDR review), each of which was supported by Government.

The aim is to encourage improved rates of regulatory compliance, provide incentives for industry to improve the evidence base for complementary medicines and increase health professional and consumer confidence in TGA regulatory processes. The proposals deal with:

**Recommendation Thirty-eight:** The establishment of a limited list of **permitted indications**; restricting companies to pre-approved, “low-level” indications and claims for an ingredient such as, “may relieve the pain of mild osteoarthritis”.

Currently, unsubstantiated “free-text” indications are often made by sponsors of complementary medicines on their TGA application. These are then used as the basis for advertising claims. We agree that this option should be eliminated.

Permitted indications must also comply with the Therapeutic Goods Advertising Code. Therefore, we advocate that each indication proposed must be accompanied by an example of an ingredient that has evidence to substantiate the claim. We are concerned that a permitted indication that may be appropriate for one ingredient, could be used for another for which it is not.

We also have difficulties with the uncritical acceptance of the traditional paradigm. For example, “Raspberry Leaf” is promoted as “traditionally used to prepare the uterus for labour”. Yet, due to the lack of evidence for safety and efficacy such recommendations are questionable. Indeed, we argue that herbs lacking scientific efficacy data and modern safety data should never be used in pregnancy to avoid potential foetal adverse effects. We suggest pregnancy be added to the list of non-permitted indications and the Therapeutic Goods Advertising Code 2015, Appendix 6, Part 2, restricted representation list. We also advocate that all ingredients or products using traditional paradigm claims should have a prominent disclaimer next to their claims; “traditional use does not imply efficacy or guarantee safety”. We argue that homeopathic medicines need a similar disclaimer to that recently promulgated by the US Federal Trade Commission.

**Recommendation Thirty-nine:** A **new pathway** by which sponsors can apply for “intermediate-level” health claims that fall outside the permitted list (above).

An example might be, “our formulation of cranberry reduces the frequency of recurrent urinary infections in women”. For this, the TGA would have to assess the evidence substantiating the claim for a specific product. If the evidence stacks up, the sponsor could then show that the claim has been assessed by the TGA for efficacy on the product label and promotional material (by use of a “claimer”).

The registration pathway will still be available for complementary medicines that have evidence to support higher-level claims and the use of a “claimer” may also be approved.

For complementary medicines to claim efficacy via the new pathway we believe that their benefit on specific and defined health outcomes needs to be established by at least one independently conducted, randomised, placebo controlled trial, with blinding of outcomes. The trial must have been registered on the Australian New Zealand Clinical Trials Registry. The findings should be published in peer reviewed journals. Replication of study findings by independent researchers is important. In addition, it is conventional scientific opinion that evidence from observational studies is insufficient to show evidence of benefit.

Furthermore, evidence changes with time, initial small studies, often funded by the sponsors, may be positive, but these findings can be contradicted by subsequent, larger, better conducted trials.

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Accordingly, assessment of evidence for the new pathway by the TGA must state the date, the body of evidence on which the evaluation was performed and be placed in the public domain.

**Recommendation Forty-five:** The publication of a “claimer” that the medicine has been assessed by the TGA for efficacy.

In preliminary TGA stakeholder consultations, consumer representatives supported a prominent visual “stamp of approval” (a logo or symbol) because of the failure of the existing Aust L and Aust R labelling to inform consumers. However, industry representatives were concerned a highly visible identifier for a small number of evidence-based complementary medicines might affect sales of the bulk of listed ingredient / products without one. We support a prominent visual “stamp of approval” (a logo or symbol) as a “claimer” and have provided an example.

**Recommendation Fifty:** Introduction of mechanisms to improve the competitiveness and innovation of the Australian complementary medicines industry.

It is proposed that a sponsor would be given a 2-year period of market exclusivity for working up a new ingredient approved for use in a listed medicine. In addition, a sponsor who provided data for an approved evidence-based claim would be awarded a 3-year period of data protection. Furthermore, registered complementary medicines would be given a 5-year period of data protection for new active ingredients. This should encourage competition and innovation and eliminate “copy-catting” or “free-loading” by competitors. We agree with this proposal.

**In conclusion:** The proposed changes do not yet address the need for greater transparency in the regulatory process. Currently the TGA produces Australian Public Assessment Reports (AusPARs) for prescription medicines that provide information about the considerations that led the TGA to approve or not approve an application. These reports are especially useful for bodies such as the National Prescribing Service to educate health practitioners and consumers about the role of a newly approved medicine. The same should be provided for TGA newly-assessed complementary medicines.

The TGA has recently announced they will begin publishing the outcomes of laboratory testing from mid-2017. They have also committed to increasing their post-marketing compliance program of listed ingredient / products. Confidence in the TGA will be greatly improved if they also publish the details of the companies and ingredient / products that fail post-marketing evaluation and have complaints upheld.

Related recommendations are also crucial, such as improving the advertising complaint system, and the imposition of sanctions and penalties for regulatory violations sufficient to counter the commercial return from their breach.

If the entire package of recommendations is implemented, we believe that Australia will be a world leader in complementary medicines regulation. Despite the substantial and increasing use of supplements, no other country has developed a system that helps consumers and health professionals separate the evidence-based wheat from the chaff, improves confidence in the industry and regulator, stimulates more evidence-based ingredient and products and has the potential to boost exports. In addition, the Australian approach will greatly assist developing countries who lack the capacity to regulate supplements.

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## 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 ingredient / 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 ingredient / 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. While there are a few evidence-based complementary medicines available (including some registered ingredient / products) the public has great difficulty in sorting out the wheat from the chaff. There is also little incentive for sponsors of complementary medicines to undertake the research required to prove that their ingredient / products work. A better return on investment comes from spending money on promotional hype and celebrity endorsement.<sup>1</sup>

The Therapeutic Goods Administration (TGA) has recently published data concerning post-marketing reviews of listed medicines.<sup>2</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 ingredient / 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 ingredient / 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 ingredient / 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. Strong regulation is healthy for complementary medicines.<sup>3</sup>

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>4</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 ingredient / product labels and promotion that efficacy claims have not been 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.

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<sup>1</sup> <https://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be>

<sup>2</sup> <https://www.tga.gov.au/book-page/3-complementary-medicines-0#s34>

<sup>3</sup> <http://www.smh.com.au/comment/smh-editorial/strong-regulation-is-healthy-for-complementary-medicines-20170321-gv2v7t.html>

<sup>4</sup> <https://www.cuttingredtape.gov.au/>

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The TGA has embarked on several consultations about implementing the MMD Review recommendations of which this is one. Recommendations relating to reforms to the regulatory framework for complementary medicines, assessment pathways, will now be discussed.

## This Consultation

But first, a pre-emptive comment on the information box on page 6 of the consultation document.



The Panel did not consider the regulation of all low risk products in making recommendations relating to complementary medicines regulation. A range of products, including sunscreens, are not complementary medicines, but are currently listed on the ARTG. They are not being considered directly in this consultation but will be addressed in a separate consultation along with homeopathic products and other complementary medicines such as low dose vitamins and minerals.

It is our view that if a good makes therapeutic claims then it should be treated as a therapeutic good and regulated under the Therapeutic Goods Act 1989 and the Therapeutic Goods Advertising Code 2015.

For example, “Band-aids” are currently making claims that are in dispute (illustrated below) and claims about multivitamin preparations<sup>5</sup> have also been found to have breached the Therapeutic Goods Advertising Code.



There is currently a push<sup>6</sup> by some sections of the therapeutic goods industry to replace the Therapeutic Goods Advertising Code with the general provisions of Australian Consumer Law, thus removing complaints from the jurisdiction of the Therapeutic Goods Advertising Complaints Resolution Panel (TGACRP) and the TGA and placing it under the jurisdiction of the Australian Competition and

<sup>5</sup> [http://www.tgacrp.com.au/complaint-register/?\\_search=Berocca&\\_id=1743](http://www.tgacrp.com.au/complaint-register/?_search=Berocca&_id=1743)

<sup>6</sup> <https://www.theguardian.com/australia-news/2017/mar/20/swisse-pushes-coalition-to-reduce-role-of-therapeutic-goods-administration>

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Consumer Commission (ACCC). As has been pointed out by several commentators, this would effectively amount to no oversight of advertising claims at all.<sup>7,8,9</sup>

Against that background, we now address the consultation recommendations and questions.

## Recommendations

**Recommendation Thirty-eight:** The Commonwealth accepts this recommendation noting that implementation of the list of **Permitted Indications** will require legislative change and will be subject to consultation with consumers, sponsors and health professionals.

**Comment: controversial; the devil is in the detail.**

The aim is to eliminate the often unsubstantiated “free-text” indications that manufacturers of complementary medicines currently make on their TGA application, which are then used as the basis for advertising claims. Instead, sponsors will be restricted to a limited list of pre-approved, “low-level” indications for an ingredient, such as, “may relieve the pain of mild osteoarthritis”.

The consultation document proposes that only “low-level” indications will be suitable for inclusion in the permitted indications list, based on the following proposed criteria:

- The indication must meet the definition of a therapeutic indication (i.e. must describe a therapeutic use for the goods).
- The indication must be a “low-level” indication (see section 3: Establishing a risk-based hierarchy for therapeutic indications).
- The indication complies with the Therapeutic Goods Advertising Code when included on the ingredient / product label or promotional materials. For example, the indication must not: mislead, or be likely to mislead consumers, contain any implication that the medicine is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure; or contain any claim, statement or implication that it is effective in all cases of the condition.
- The indication must be consistent with the relevant treatment paradigm (scientific or a tradition of use).

It is also proposed that “low-level” indications suitable for inclusion in the permitted indications list may refer to:

- health enhancement
- health maintenance
- prevention of dietary deficiency
- a disease, ailment, defect or injury other than a serious form of those diseases.

These criteria will ensure that indications accepted for inclusion in the permitted indications list are appropriate for low risk medicines that are not evaluated pre-market. The proposed criteria will not reduce the ability of sponsors to use indications which are currently appropriate for listed medicines. The indication must also be consistent with the relevant treatment paradigm (scientific or a tradition of use).

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<sup>7</sup> <http://www.theage.com.au/federal-politics/political-news/vitamin-company-swisse-calls-for-selfregulation-of-complementary-medicine-advertising-20170315-guz8l5.html>

<sup>8</sup> <http://www.smh.com.au/comment/smh-editorial/strong-regulation-is-healthy-for-complementary-medicines-20170321-gy2v7t.html>

<sup>9</sup> <https://theconversation.com/swisse-cheese-there-are-too-many-holes-in-complementary-medicine-regulations-already-74981>

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The consultation document notes that a “low-level” indication, and therefore a permitted indication, **must not**:

- refer to, or imply, the prevention, alleviation, or cure of any form of a disease, ailment, defect or injury;
- contain a prohibited representation;
- contain a restricted representation;
- have been specified in a non-permitted indications list.

It is also proposed that the TGA will also specify certain indications that will not be included in the permitted indications list through the making of a non-permitted indications list (see Table 6 for examples). This will allow TGA to exclude indications of concern from the permitted indications list that may otherwise meet the eligibility criteria.

The consultation document asks:



## Criteria for permitted indications

- 4.1 Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?
- 4.2 What other considerations should be taken into account in implementing the permitted indications list?

We respond:

### 4.1 Yes

### 4.2 We have several concerns about how the list of allowed indications will be established.

- All permitted indications must comply with the Therapeutic Goods Advertising Code. Thus, we advocate that each indication proposed must be accompanied by an example of an ingredient that has evidence to substantiate the claim. For example, in Table 5, page 22, it is suggested that an appropriate permitted indication might be, “helps reduce the severity of common cold symptoms”. We should like to see the evidence that justifies this indication for a specific ingredient / product.
- We are also concerned that there is no mechanism proposed to stop a permitted indication that may be appropriate for one ingredient, being used for another ingredient for which it is not. For example, the claim, “helps reduce the frequency of common cold sore outbreaks” is controversial for lysine but even more so for lemon balm (*Melissa officinalis*).
- We are also had difficulties with the uncritical acceptance of the traditional paradigm. For example, “Raspberry Leaf” is promoted as “traditionally used to prepare the uterus for labour”.<sup>10</sup> Yet, it has been pointed out that due to the lack of evidence for safety and efficacy such recommendations are questionable.<sup>11</sup> Indeed, we argue that herbs lacking scientific efficacy data and modern safety data should never be used in pregnancy to avoid potential foetal adverse effects. We suggest pregnancy be added to the list of non-permitted indications (Table 6) and the Therapeutic Goods Advertising Code 2015, Appendix 6, Part 2, restricted representation list (diseases or conditions for which prior approval to advertise should be sought from the Secretary, Department of Health). We also advocate that all ingredient /

<sup>10</sup> <http://www.herbsofgold.com.au/products/product/1587>

<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pubmed/19880082>



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products using traditional paradigm claims should have a prominent disclaimer next to such claims that “traditional use does not imply efficacy or guarantee safety”.

- We have similar concerns about homeopathic medicines. We note that the TGA approved a restricted representation for homeopathic ingredient / product “Restless Legs Relief”.<sup>12</sup> We agree with the consultation document that restricted representations are NOT appropriate for medicines that lack demonstrated evidence of efficacy. We also support the incorporation of recent US FTC disclaimer on all homeopathic ingredient / products.<sup>13</sup>

## Implementation of the permitted indications list



- 4.3 Is Option 2 for selecting indications for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications?
- 4.4 What other considerations should be taken into account in implementing the permitted indications list?

**4.3 Yes, but note our caveat under 4.2 above.**

**4.4 See 4.2 above.**

**Recommendation Thirty-nine:** The Commonwealth accepts this recommendation, noting that legislative amendments are required to implement Option Two (**new pathway**). Implementing this recommendation would increase transparency for consumers, provide additional flexibility for sponsors and support innovation.

**Comment: controversial; the devil is in the detail.**

The concept is for a new pathway (easier than the current registration pathway) by which sponsors can apply for “intermediate-level” health claims that fall outside the permitted list (above).

An example might be, “our formulation of cranberry reduces the frequency of recurrent urinary infections in women”. For this, the TGA would have to assess the evidence substantiating the claim for a particular product. If the evidence stacks up (and there’s considerable debate about the type of evidence needed, see below), the product could then show that the claim has been assessed by the TGA for efficacy by a “claimer” (see below). The registration pathway will still be available for complementary medicines that have evidence to support higher-level claims and the use of a “claimer” may also be approved.

## Establishing a risk-based hierarchy for therapeutic indications

Based on risk factors, it is proposed that indications would be categorised into three levels of risk: low, intermediate and high, corresponding to the listing pathway, the new pathway and the registration pathway respectively.



## A risk-based hierarchy for therapeutic indications

- 3.1 Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways?

<sup>12</sup> <https://www.tga.gov.au/advert-exempt/advertising-exemption-martin-and-pleasance-restless-legs-relief>

<sup>13</sup> <https://www.ftc.gov/news-events/press-releases/2016/11/ftc-issues-enforcement-policy-statement-regarding-marketing>



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- 3.2 Do you envisage any difficulties with criteria used to include or exclude products from the new pathway?
- 3.3 What other considerations may need to be taken into account in implementing the new pathway?

**3.1 Yes.**

**3.2 No.**

**3.3 See 4.2 above.**

## Approaches to establishing efficacy

Many listed complementary medicine ingredient / products have indications based on published studies on the separate ingredients in a formulation. Given their low risk nature, it is appropriate that efficacy of listed medicines can be established without product-specific evidence. However, the Panel proposed that the evidence for the indications assessed via the new pathway should relate to the finished product, and we propose that the pathway is to be applied to products rather than ingredients.



### Approaches to establishing efficacy

- 3.4 Do you agree with the proposed methods to establish efficacy for products included via the new pathway?
- 3.5 Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?

**3.4 Yes.**

**3.5 Yes.**

## Evidence requirements

To enhance public confidence in complementary medicines and the regulatory framework, the minimum standard of efficacy evidence for products assessed via the new pathway will be higher than the level required to be held by sponsors to support non-efficacy assessed medicines. See Table 2 & 3. Page 17-18.



### Evidence requirements

- 3.6 Are the evidence requirements appropriate for the new pathway?
- 3.7 Do the proposed levels of assessment align with the proposed risk-based hierarchy?
- 3.8 What other considerations may need to be taken into account in implementing the new pathway?

**3.6 Yes.**

**3.7 Largely, but we have some concerns:**

For complementary medicines to claim efficacy, their benefit on specific and defined health outcomes needs to be established in the context of an independently conducted, randomised, placebo controlled

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trial with blinding of outcomes. The trial must have been registered on the Australian New Zealand Clinical Trials Registry (ANZCTR). The findings should be published in peer reviewed journals. Studies funded by sponsors may be biased to produce favourable results.<sup>14</sup> Replication of study findings by independent researchers is important.<sup>15,16</sup> It is conventional scientific opinion that evidence from observational studies is insufficient to show evidence of benefit.

In addition, although the ingredients used in complementary medicines may have been around for a long time, that does not mean that they are without harm, the latter can only be established through long term follow up and surveillance, usually through a variety of study types. For example, it took many studies for the U.S. Preventive Services Task Force to conclude that beta-carotene was associated with an increased risk for cancer in smokers.<sup>17</sup>

### 3.8 See below.

Evidence changes with time, initial small studies, often funded by the sponsors, can be positive but these findings may be contradicted by subsequent, larger, better-conducted trials.<sup>18</sup> The registered complementary medicine, ARTHRO-AID Glucosamine hydrochloride (ARTG: 68083), evaluated in 1999 is a good example.<sup>19</sup> Subsequent studies have failed to provide convincing evidence that Glucosamine hydrochloride relieves the pain of mild osteoarthritis.<sup>20</sup> In addition, trial results can be gamed by P-hacking<sup>21</sup> and distorted by sponsors and their public relations companies.<sup>22</sup> Assessment of evidence for the new pathway by the TGA must state the date, the body of evidence on which the evaluation was performed, and be placed in the public domain (as with AusPARs).<sup>23</sup>

The Therapeutic Goods Advertising Complaint Resolution Panel has noted,<sup>24</sup>

The Panel is concerned at the growing use of the words “clinically proven” in advertisements for therapeutic goods, when these words are not supported by an adequate and appropriate body of evidence that relates to the specific product (and not merely to a similar product or ingredient).

Given the strength of this claim, and the clear potential for it to mislead and deceive consumers, the Panel considers that its use in advertising should not even be contemplated unless unequivocally supported by robustly designed, published, peer-reviewed clinical trials which have been conducted upon the actual product being advertised or an identical formulation (as a minimum). Even where such evidence is available, the claim must also reflect the weight of all available evidence and not just the specific research being relied upon.

<sup>14</sup> <http://www.smh.com.au/national/health/big-pharma-funding-biases-drug-trials-in-favour-of-a-sponsors-product-review-20170220-gugr0d.html>

<sup>15</sup> <https://theconversation.com/half-of-biomedical-research-studies-dont-stand-up-to-scrutiny-and-what-we-need-to-do-about-that-45149>

<sup>16</sup> <https://theconversation.com/science-is-in-a-reproducibility-crisis-how-do-we-resolve-it-16998>

<sup>17</sup> <http://annals.org/aim/article/1832965/vitamin-mineral-multivitamin-supplements-prevent-cardiovascular-disease-cancer-recommendations-from>

<sup>18</sup> <http://www.nps.org.au/medicines/complementary-medicines/for-individuals/fish-oil-supplements/for-individuals/for-heart-health/how-results-have-changed-over-time>

<sup>19</sup> <https://www.tga.gov.au/list-evaluated-registered-complementary-medicines>

<sup>20</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2686334/>

<sup>21</sup> <https://theconversation.com/how-we-edit-science-part-2-significance-testing-p-hacking-and-peer-review-74547>

<sup>22</sup> <https://croakey.org/a-current-affairs-adhd-breakthrough-bona-fide-news-or-unethical-advertising/>

<sup>23</sup> <https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars>

<sup>24</sup> <http://www.tgacrp.com.au/decision-highlights/>

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The Panel has also stated:

When advertisers of therapeutic goods make representations regarding the efficacy of those therapeutic goods, they must ensure that the strength of the evidence is reflected in the strength of the representations. To do otherwise is likely to mislead the public and breach sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code

**Recommendation Forty-five:** The Commonwealth accepts this recommendation, **in principle**, noting that the **design and use of the promotional statements (claimers)** will require careful consideration by the TGA and further consultation with stakeholders.

**Comment: controversial; the devil is in the detail.**

In preliminary TGA stakeholder consultations, consumer representatives supported a prominent visual “stamp of approval” (a logo or symbol) because of the failure of the existing Aust L and Aust R labelling to inform consumers. However, industry representatives were concerned a highly visible identifier for a small number of evidence-based complementary medicines might affect sales of the bulk of listed products without one.

We offer the following design as a ‘claimer’ for product labels and promotional materials that have fulfilled TGA requirements for the new pathway.<sup>25</sup>



**Recommendation Fifty:** Introduction of **mechanisms to improve the competitiveness and innovation of the Australian complementary medicines industry.**

The Commonwealth accepts this recommendation in-principle noting the cross-government responsibility for innovation policy. The Department of Health will collaborate with other Departments (such as the Department of Industry, Innovation and Science) and with relevant stakeholders to consider this issue further. This reform aligns with the Australian Government’s National Innovation and Science Agenda.

It is suggested that a sponsor be given a 2-year period of market exclusivity for working up a new ingredient approved for use in a listed medicine. In addition, a sponsor who provided data for an approved evidence-based claim would be awarded a 3-year period of data protection. Furthermore, registered complementary medicines would be given a 5-year period of data protection for new active ingredients. This should encourage competition and innovation and eliminate “copy-cattng” or “free-loading” by competitors.

**Comment: agreed.**

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<sup>25</sup> <https://theconversation.com/which-supplements-work-new-labels-may-help-separate-the-wheat-from-the-chaff-73189>

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## Conclusion

The proposed changes do not yet address the need for greater transparency in the regulatory process. Currently the TGA produces Australian Public Assessment Reports (AusPARs) for prescription medicines that provide information about the considerations that led the TGA to approve or not approve an application. These reports are especially useful for bodies such as the National Prescribing Service to educate health practitioners and consumers about the role of a newly approved medicine. The same should be provided for TGA newly-assessed complementary medicines (both via the new pathway and the registration pathway). In addition, the TGA should update their list of evaluated registered complementary medicines to eliminate grandfathered products, link the product to the TGA evaluation (AusPARs) and add a separate category of products evaluated via the new pathway.<sup>26</sup>

The TGA has recently announced that they will begin publishing the outcomes of laboratory testing from mid-2017. They have also committed to increasing their post-marketing compliance program of listed products. Confidence in the TGA will be greatly improved if they also publish the details of the companies and products that fail post-marketing evaluation and have complaints upheld.

Related recommendations are also crucial, such as improving the advertising complaint system, and being able to impose sanctions and penalties for regulatory violations sufficient to counter the commercial return from their breach.

If this entire package of recommendations is implemented, we believe Australia will be a world leader in the regulation of complementary medicines. Despite the substantial and increasing use of supplements, no other country has developed a system that helps consumers and health professionals separate the evidence-based wheat from the chaff, improves confidence in the industry and regulator, stimulates more evidence-based products, has the potential to boost exports. In addition, the Australian approach will greatly assist developing countries who lack the capacity to regulate supplements.

**Submission Endorsed by Friends of Science in Medicine**



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<sup>26</sup> <https://www.tga.gov.au/list-evaluated-registered-complementary-medicines>

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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 Report of the Review to improve the transparency of the Therapeutic Goods Administration ANAO Report. Therapeutic Goods Regulation: Complementary Medicines TGA reforms: A blueprint for TGA's future
2012	Delivering reforms - Implementation plan for TGA Reforms 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) 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.