Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017: Response by Civil Society Representatives to Minister Hunt's letter

Summary

The Minister's letter provided more information on several issues of concern to civil society: pre-approval of advertisements and the new advertising regulatory system (education, enforcement, performance indicators, improved stakeholder engagement and an independent review). However, the Minister failed to adequately address other important concerns, such as the permitted indications proposal.

After careful consideration of the Minister's letter our recommendation to the ALP remains, that Labor request the government to amend the bill by removing Schedule 6 (Advertising), or alternatively, that Labor moves an amendment to delete Schedule 6. This will enable the rest of the Bill to proceed while the issues outlined below are resolved.

Pre-approval of advertisements

A substitute self-regulatory pre-approval scheme is possible, however such a scheme, with the necessary levels of industry and civil society consultation, competition law authorisation by the ACCC and implementation is simply not achievable by July 1, 2018.

New Advertising Regulatory System

A revised Therapeutic Goods Advertising Code is the centrepiece of the new complaints and enforcement system code. However, the new Code has yet to be drafted, consulted upon, approved and implemented. There is no way this can be accomplished in time for an enforcement date of July 1, 2018. Even with modest amendments following consultation, approval, publication and implementation will require a further 6 to 9 months.

Sponsors of OTC medicines (including complementary medicines) are already finalising advertising campaigns for winter cold and flu. They need at least 6-months' notice to gear up to the new Code requirements, especially as non-compliance will now attract serious penalties. In addition, the TGA needs to be able to cope with what we guarantee will be a flood of complaints and legal challenges to test the new system. Furthermore, the Administrative Appeal Tribunals and the Courts will not countenance legal action by the TGA if sufficient notice has not been given of the new regime.

The prospect of rushed drafting of a complex document with serious consumer protection and legal consequences to meet an artificial online is courting disaster.

Education

The addition of consumer education is welcomed and there are good examples to emulate, for example, the FDA Tips for Dietary Supplement Users.[1] However, health professionals must be added to the target audience. We also suggest the proposed TGA "advertising education officers" act as Consumer Complaint Coordinators (see US FDA).[2] The workshops proposed need to include examples of upheld complaints about misleading and deceptive promotion. They should also actively encourage people to submit complaints. But, as emphasised above, education cannot take place until the new Code and enforcement provisions are in place.

Enforcement, performance indicators, stakeholder engagement and an independent review

We welcome the incorporation in the Bill of new enforcement powers and the Minister's assurance about performance indicators, stakeholder engagement and the independent review. However, the Minister's assertion that the passage of the bill would position TGA in a similar way to other regulators such as the ACCC needs more careful consideration.

[1] https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110567.htm
[2] https://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/

The almost certain consequence of a raw and inexperienced organisation attempting to implement and enforcement-based compliance model (as proposed in the bill) is regulatory failure. Courts will simply not grant injunctive relief or award pecuniary penalties (much less criminal sanctions) to an enforcement agency without sound litigation skills and processes.

It is strongly recommended that Labor insist that the government issue a direction to the ACCC to undertake enforcement and compliance work and transfer skills to the TGA for a period of three years, or until such times that the TGA can demonstrate capacity to enforce new laws

Permitted indications

The Minister's letter said, 'There will be a new mandatory requirement for listed medicine products to identify the evidence base on the product label, for example, traditionally used in Chinese medicine'. The letter also alleged that the Consumer Health Forum supported the TGA's list of permitted indications. This is incorrect. The CHF Senate submission (no 19) said:[3]

> 'We support the proposal in the submission to the Committee from Associate Professor Ken Harvey and Professor John Braithwaite that there should always be a disclaimer for claims based on 'traditional use' making it clear that it is based on alternative health practices and not based on modern scientific or medical practice.'

Others have pointed out that the TGA list of traditional indications (submitted by industry) contains items that endorse pseudoscience and are meaningless to most consumers and health professionals, for example:

> 'Disinhibit Water', 'Stimulate stagnant Qi', 'Harmonise middle burner (Spleen and Stomach)', 'Unblock/open/relax channels', 'Replenish Essence',' Subdue Yang', 'Pacifies Kapha'.

Assoc Professor Harvey's supplementary Senate submission (2.1) rebutted the Department of Health arguments against disclaimers or advisories. He noted there is an urgent need for appropriate independent research, in association with consumer organisations, into the best way of helping consumers make an informed choice about traditional and complementary medicines. He suggested NPS MedicineWise might be an appropriate partner in this endeavour. Until this has been conducted he argued that the illogical, inconsistent and ineffective measures suggested by the TGA should be put on hold.

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3 https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/TGA2017MeasuresNo1/Submissions

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More detailed notes on the Minister's letter follow:

Pre-approval

Para 3. The Expert Panel recommended that mandatory pre-approval of advertisements be abolished in favour of a self-regulatory scheme.

Australia is the only country I know of that has mandated pre-approval of advertisements for products such as over-the-counter and complementary medicines. Other countries such as the UK and Canada have successfully implemented voluntary pre-screening programs, delivered by industry peak bodies. In Australia, one peak body ASMI, the Australian Self-Medication Industry (which represent OTC and complementary medicines companies) has proposed that they will step up and offer a similar service after the passage of the Bill.

a. Installing a pre-screening service for all advertisements for 2 years.

I intend to develop a pre-screening service that was available to provide advice within a short time frame on whether the submitted advertisements are likely to have compliance issues and provide specific advice as to how the advertisement should be amended. It would not be mandated but I expect most advertisers would avail themselves of this service, particularly if it were provided for free or at a discounted rate. This service could be operated by ASMI (with support and advice provided by the TGA), or the TGA alone (or a hybrid of both)). I will work with these parties to develop a proposal to stand up these arrangements as an alternative to mandatory pre-approvals from 1 July 2018.

Recommendation 55 of the Expert Panel, upon which the Bill claims authority, was predicated on the substitution of the current preapproval scheme (which does not apply to Internet advertising, is administered by two separate bodies and lacks coverage of non-member organisations) with another regime.

As noted in many submissions to the Senate enquiry, the Bill is totally silent on the development and implementation of a substitute scheme.

The current preapproval scheme for advertising is split between two industry organisations only one which is included in this proposal. In addition, any agreement or understanding between competitors to have marketing material preapproved or pre-screened is highly likely to be in breach of the competition provisions of the Australian Competition Laws. If the agreement is so vague or unenforceable as to not require authorisation by the ACCC, then it is certain to fail.

ASMI has indicated a desire to develop a scheme, however it is inconceivable that adequate consultation, drafting and submission to the ACCC authorisation process could be achieved in less than nine months to a year. This suggestion shows that the government recognises the gap in the Bill. However, this is a poorly cobbled together proposal which will not meet the safety needs of consumers of the certainty requirements of industry.

Australian Self-Medication Industry (ASMI) note in their submission (Number 43) that:

- *The Bill makes provision for the abolition of the mandatory preapproval from 1 July 2018. And*
- *ASMI is concerned that the Bill deals only with the first element of the expert panel recommendation and provides no incentive or guidance to words a self-regulatory regime.*
- *Publishers and broadcasters also face considerable uncertainty and potential cost burdens with the abolition of preapprovals.*

ASMI helpfully provides three options to improve regulatory and consumer outcomes in relation to advertising controls. These comprise a due diligence provision, retaining current arrangements for a transition period and an entirely self-regulatory model.

ASMI recommends that consideration should be given to both the due diligence provision and the transitional safety net option.

In the absence of a statutory mandate for a preapprovals scheme capable of detecting and preventing advertisements in breach of laws and codes, any such industry scheme would require authorisation by the Australian Competition and Consumer Commission (ACCC). In fact, the existing scheme and its predecessor were both subject to review and authorisation by the competition authorities. Experience shows that the development, authorisation and implementation of such a scheme will take a minimum of 18 months. As the current scheme is due to cease in less than five months it is inconceivable that an adequate replacement scheme will be ready. Rushing such measures invites serious errors which will have a direct impact on the economic and physical well-being of consumers as well as doing considerable damage to smaller therapeutic goods industry participants.

The Minister's letter said, 'I am also aware that if mandatory pre-approvals were maintained there is little incentive for companies to become familiar with the requirements for producing compliant advertisements'. This is fallacious. Companies will still have to comply with the requirements of the Therapeutic Goods Advertising Code 2015 for non-specified media such as the Internet, as indeed they are meant to do now (albeit with poor compliance).

We also warn against the TGA being involved as it would place the TGA in an invidious position when valid complaints were received about advertisements they had-pre-approved. As we have pointed out elsewhere pre-approval assessment does not usually extend to a detailed evaluation of the evidence used to support claims of efficacy, because of lack of time.4 Thus, pre-approval of an advertisement by ASMI (or the TGA) cannot guarantee an advertisement is compliant with all the requirements of the advertising framework.

Take-Away Message in relation to pre-approval

A substitute self-regulatory pre-approval scheme is possible however, such a scheme with the necessary levels of industry and civil society consultation, competition law authorisation and implementation is simply not achievable by July 1, 2018.

It is strongly recommended that Labor consider either the due diligence or the transition option put forward by ASMI and not rely on ill-considered offers of a substitute scheme being available in less than 20 weeks from now.

[4] https://theconversation.com/scrapping-pre-approval-of-medicine-ads-will-put-consumers-at-risk-90625

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New advertising regulatory system and Code

2 Their reasoning was that the current system was outdated and deficient in numerous ways and no longer fit for purpose. In its place they recommended implementation of a package of other measures (which are included in this Bill) such as a new advertising Code which more clearly specified advertising requirements in a legally-binding fashion, introduction of a mandatory list of permitted indications for complementary medicines (which forbids non-permitted claims being made), simplification of advertising complaints to a single agency with much tougher enforcement provisions and more timely complaints handling including the powers to seek injunction against highly-damaging advertising provide more than sufficient safeguards to render a requirement for mandatory pre-approvals of advertising redundant.

The core of the new regulatory scheme, as proposed by the Expert Panel, is a new advertising Code specifying advertising requirements in a legally binding fashion. The current code, though introduced in 2017, is years out of date in any event was not intended to be used as a black letter enforceable document.

Many attempts to revise the code have been made over the past decade. Complexity of issues and lack of political will have seen modernising efforts fail. During 2017, consultations were held as a basis for the development of a new Code.

Current policy ownership of the code resides in the Therapeutic Goods Advertising Consultative Council (TGACC) a body chaired by the TGA and comprised of a broad range of industry, academic and civil society interests.

Even though a revised Code has been the centrepiece of the new complaints and enforcement system, the government has left consultation with the designated policy body (TGACC) on the revision process until Friday February 2nd, the same day that the Senate Committee issued its report.

While the content of TGACC consultations is confidential, numerous participants were highly critical of the submission to the Senate committee made by the Department of Health and expressed incredulity that the code could be drafted, consulted upon, approved and implemented in time for an enforcement date of July 1, 2018. To date there is not even a draft of the proposed new code available and there is not expected to be one until early April 2018. With even modest subsequent amendments, approval, publication and implementation will require a further 6 to 9 months. The prospect of rushed drafting of a complex document with direct consumer health and welfare consequences to meet an artificial online is almost certainly courting disaster.

Take-Away Message in relation to the New Advertising Code

A new regulatory code for advertising of therapeutic goods is both necessary and desirable. The process of drafting a new code is already underway. There have been many public consultations and numerous submissions have been lodged relating to the new code. However, to date there has only a discussion paper on areas for amendment. Text has currently been developed and as the code is intended to be the basis for future legal enforcement (including substantial civil and criminal penalties) it is inconceivable that drafting, checking, industry consultation and implementation can occur in anything less than nine months. The Bill provides for the enforceability of the yet unwritten code in less than 20 weeks from now. As with the premature or abolition of pre-approval, material risk to the health and welfare of consumers is inevitable.

It is strongly recommended that Labor insist on a transition period in the introduction of the new enforceable Code and not rely on totally unrealistic assertions of a revised code being available in less than 20 weeks from now.

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TGA as an enforcement agency like the ACCC

3 This would position TGA in a similar way to other regulators such as the ACCC.

Civil society organisations have welcomed the incorporation in the Bill of many new enforcement powers and penalties available to the TGA. However, the assertion that the passage of the bill would position TGA in a similar way to other regulators such as the ACCC needs to be considered more carefully.

The ACCC, ASIC and the DPP are all enforcement agencies who have developed their institutional structures, levels of staffing, resources and expertise over many years. Both ASIC and the ACCC have spent a decade on specialist training for investigative staff, providing industry compliance information and then honing their litigation and enforcement skills.

Civil society organisations look forward to the development by the TGA of similar skills and levels of enforcement competence consistent with other agencies, however, as with preapprovals and implementation of a new enforceable code, it is not attainable in the allotted time.

To date, the TGA has not produced any enforcement strategies or priority statements (even in draft form) on which to base its future activities. There is currently a widely acknowledged resource crisis, which even the government members of the Senate committee acknowledge.

Even if the TGA was able to develop an enforcement and compliance strategy, recruit and train suitable staff and provide necessary industry guidance, the absence of the new enforcement Code undermines this potential.

The almost certain consequence of a raw and inexperienced organisation attempting to implement and enforcement-based compliance model (as proposed in the bill) is regulatory failure. Courts will simply not grant injunctive relief or word pecuniary penalties (much less criminal sanctions) to an enforcement agency without sound litigation skills and processes.

A possible remedy for this deficiency in the Bill could be through a direction to the ACCC. The relevant Minister could direct the ACCC to establish an area of activity in support of TGA enforcement and compliance.

The Bill imposes additional costs on the industry of some $20million over four years. The government could specifically fund the ACCC to undertake enforcement, training TGA investigators and develop and implement industry compliance programs for say 3 years. During that time responsibilities could progressively shift to the TGA and the safety and welfare of consumers protected.

Take-away message in relation to enforcement capacity

Submissions to the Senate enquiry, include those from individuals and organisations with cumulatively decades of enforcement and compliance experience. Though welcome, the new enforcement and compliance powers to be conferred on the TGA will of necessity take years not months to mature.

It is strongly recommended that Labor insist that the government issue a direction to the ACCC to undertake enforcement and compliance work and transfer skills to the TGA for a period of three years or until such times that the TGA can demonstrate capacity to enforce new laws

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Education

b. A comprehensive industry and consumer education program on the new advertising regulatory scheme TGA would employ two "advertising education officers" who will directly provide assistance in educating sponsors and advertisers of their obligations under the advertising code. They would operate a phone advisory service to advertisers (and consumers) as well as conduct workshops with advertisers (and consumer groups) in all capital cities. Some workshops would be co-hosted with peak industry bodies and the Consumer Health Forum. 10 of these workshops could be held in the first year of the new scheme. I intend to develop a pre-screening service that was available to provide advice within a short time frame on whether the submitted advertisements are likely to have compliance issues and provide specific advice as to how the advertisement should be amended. It would not be mandated but I expect most advertisers would avail themselves of this service, particularly if it were provided for free or at a discounted rate. This service could be operated by ASMI (with support and advice provided by the TGA), or the TGA alone (or a hybrid of both)). I will work with these parties to develop a proposal to stand up these arrangements as an alternative to mandatory pre-approvals from 1 July 2018.

For many years, the TGACC conducted semi-annual, intensive training workshops for industry participants on the Interpretation of the Advertising Code. The training workshops were well attended and recovered of the costs from participants.

Without explanation, the TGA directed that such training workshops no longer be held several years ago and instead several industry associations undertook such activities. Whilst not opposing this suggestion, it should be noted that many years of experience and practical training have been provided by the staff of the TGACC in just these activities.

Take away message on education program

It is recommended that Labor support this proposal whilst recognising that it is not a substitute for proper compliance and enforcement programs. 10 workshops are suggested for the first year of operation of the scheme. In that criminal and civil liability for breaches of the New Advertising Enforcement Code come into effect on July 1, and that such workshops cannot even begin until there is a drafted, agreed and implemented code, regulatory chaos is guaranteed.

Advertising complaints management

c. Public performance measures for advertising complaints management. I can confirm that TGA will be adequately resourced and staffed to manage complaints from July 1. Triage processes and public (time and performance) Key Performance Indicators for managing advertising complaints will be developed and published by the TGA, following public consultation on the KPIs with consumer groups and healthcare professionals as well as industry.

These measures would be reported publicly on the TGA website and to Government as part of the formal annual Regulator Performance framework report, provide confidence to stakeholders of the management of the complaints handling system. For example, it is proposed that critical complaints will be actioned within 10 days and high and medium impact cases closed within 20 and 40 days. This is far faster than the current (outsourced) Complaints Resolution Panel resolutions which average over 130 days, also noting that because the current panel's decisions are not binding, 40 % of advertisers decline to comply and the matter is then referred to the TGA for the process to start again

It is abundantly evident to all industry participants (industry, academics and civil society organisations) that the TGA is seriously under resourced and understaffed.

In the government, members of the Senate committee also seemed to recognise this fact.

It is a profound misunderstanding of the proposed new law to assert that critical complaints will be actioned within 10 days and high and medium impact cases closed within 20 and 40 days. In most cases, the enforcement agency will first need to examine complaint and to write to sponsors seeking substantiation of claims and the submission of technical studies to support them.

An even cursory review of the determinations made by the Complaints Resolution Panel will disclose that sponsors often submit hundreds and sometime thousands of pages of technical and scientific information to support their claims.

Where fast track legal proceedings are contemplated, the enforcement agency will, as a matter of the government's own Model Litigant Policy, provide adequate opportunities for sponsors to consider claims against them and respond. That needs to be followed by a letter of demand which is reasonable and refused before an application for an injunction can be lodged.

It is both naive and deceptive for the Minister to put his name to such a proposal. The best enforcement agencies in Australia include the ACCC and ASIC. Average case completion times for these agencies is much closer to a year than a few weeks. It must be recognised that the Australian court system will simply not tolerate lack of due process and in any event refusals to do so will end up in the AAT.

Claims by the Minister relating to the Complaints Resolution Panel should be discounted.

The key reason 40% of upheld complains from the CRP are sent to the TGA for enforcement is it has no enforcement powers and sponsors know that they can get away with non-compliance while continuing to use misleading and deceptive advertisements. The simple option of empowering the Panel to enforce determinations has never been accepted. Meanwhile, the TGA is so short of resources that it has more than 400 outstanding matters to considered.

Takeaway message on advertising complaints management

Measures proposed are unrealistic and unattainable and are likely to be in breach of both the model litigant policy and administrative law. Claims made in this response demonstrate clearly the lack of thought which has gone into complaints and enforcement design and without an arrangement such as a direction to the ACCC, consumers will be badly exposed.

Permitted indications

> In 2008, the former Government committed Australia as a signatory to the WHO Traditional Medicine strategy, which includes implementation of regulatory systems that support the availability of traditional medicine products. The Consumer Health Forum also supports there being a list of permitted indications along the lines described in the Bill. To give consumers greater clarity about the evidence base for listed complementary medicines, there will be a new mandatory requirement for listed medicine products to identify the evidence base on the product label e.g. "Traditionally used in Chinese medicine".

The Minister's statement (above) alleges that the Consumer Health Forum supported the TGA's list of permitted indications. This is incorrect. Their Senate submission (no 19) said:[5]

> 'We support the proposal in the submission to the Committee from Associate Professor Ken Harvey and Professor John Braithwaite that there should always be a disclaimer for claims based on 'traditional use'

[5] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/TGA2017MeasuresNo1/Submissions

making it clear that it is based on alternative health practices and not based on modern scientific or medical practice.'

The Department of Health's response was not to add the advisory sought, but rather (for TCM and Ayurvedic only) to place a statement on their label with words to the effect of:

> 'Seek advice from a registered Chinese medicine practitioner or Ayurvedic medicine practitioner to ensure this medicine is right for you'.

These statements are also contained in the TGA's 'Draft Permitted indications for listed medicines guidance' These advisories are:

> **Illogical** – as they only apply to a subset (206) of 1019 permissible indications. All products containing one or more of the 1019 permissible indications can be advertised and sold to the public because the sponsor has certified they hold evidence (traditional or scientific) to support the claims made. Why recommend consulting a practitioner for a sub-set when all products with permissible indications will be readily available in retail outlets and via the Internet?
>
> **Inconsistent** – because they do not apply to medicines invoking other traditions such as homeopathy, Western herbalism, etc.
>
> Why not suggest consumers seek similar advice from homeopaths for medicines invoking the homeopathic tradition?
>
> Why not a similar advisory for medicines invoking scientific rather than traditional evidence. For example, 'Seek advice from a registered pharmacist or doctor to ensure this medicine is right for you'?
>
> **Ineffectual** – because they do not educate consumers that traditional indications lack a scientific evidence base as requested. In addition, how many consumers would act on such advice?'

Assoc Prof Harvey reiterated his concern (and that of others) that, for the TGA to accept an industry provided list of 879 traditional indications, they are encouraging the industry to evade the need to prove their products work. Why else would they provide such a lengthy list?

Others have pointed out that the TGA list of traditional indications (submitted by industry) contains items that endorse pseudoscience and are meaningless to most consumers and health professionals, for example:

> 'Disinhibit Water', 'Stimulate stagnant Qi', 'Harmonise middle burner (Spleen and Stomach)', 'Unblock/open/relax channels', 'Replenish Essence',' Subdue Yang', 'Pacifies Kapha'.

Assoc Professor Harvey's supplementary Senate submission (2.1) rebutted the Department of Health arguments against disclaimers or advisories. He noted there is an urgent need for appropriate independent research, in association with consumer organisations, into the best way of helping consumers make an informed choice about traditional and complementary medicines. He suggested NPS MedicineWise might be an appropriate partner in this endeavour. Until this has been conducted he argued that the illogical, inconsistent and ineffective measures suggested by the TGA should be put on hold.

The Therapeutic Goods Act and Australian Consumer Law

Finally, it has been proposed by some academics that the Bill be amended to enable the powers of Australian Consumer Law to be available. They are and will continue to be available. The Therapeutic Goods Act and the Australian Consumer Law act in concert and both can be used for different aspects of enforcement, as has been demonstrated recently with inappropriate promotion of Nurofen products, which was prosecuted by the ACCC.

With 20,000 complaints a year, the ACCC has made it abundantly clear on numerous occasions and in numerous submissions that it does not have the capacity to undertake enforcement action in any but the most egregious therapeutic goods cases. The referenced action on Nurofen was only brought by the ACCC following a referral from the Complaints Resolution Panel. The panel, with a wide range of industry, medical and civil society expertise referred its determination to both the TGA and to the ACCC. The ACCC action took well over a year and was one of only a few actions taken by the ACCC in this sector over the last five years.

That is not to denigrate the commitment or capacity of the ACCC. Please refer to the recommendation that the ACCC be given a specific direction and resources to fill the skills gap until the TGA is up to speed.

Takeaway message on consumer law

The Bill is deficient in that it does not provide either a consumer protection objective, nor does it confer private rights of action to enable affected consumers to act in their own interests.

Overall conclusion

It is strongly recommended that Labor request the government to amend the bill by removing Schedule 6, or alternatively, that Labor moves an amendment to delete Schedule 6.

Assoc Prof Ken Harvey,
After consultation with,
Prof John Braithwaite, ANU,
Prof John Dwyer, FSM,
Prof Jon Jureidini, University of Adelaide,
Ass Prof Bruce Arnold, University of Canberra,
Allan Asher, Access 2,
Tim Mendham, Australian Skeptics

Sunday, 4 February 2018