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14 May 2017

MMDR Consultations
Enhancing sanctions and penalties
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted by email: (info@tga.gov.au)

Dear Sir/Madam,

Submission to the Consultation on Sanctions and Penalties in the *Therapeutic Goods Act*

We refer to your call for submissions re the above.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

Contents

Executive Summary

ASMI supports the TGA's adoption of a standard set of compliance and enforcement powers as set out in the *Regulatory Powers (Standard Provisions) Act 2014* (the RPSPA) which are also consistent with the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI also supports the TGA's adoption of other powers such as substantiation notices and public warning notices only so long as the TGA's processes and penalties align with those already in place for the ACCC.

ASMI is prepared to support the TGA's retention of powers to enter premises of regulated entities (and to take samples) where those powers are shown to be necessary and are shown to be consistent with the powers held by other Commonwealth agencies entitled to enter premises for the purpose of investigation.

A standard set of compliance and enforcement powers provides benefits to all stakeholders. These benefits will be diluted every time there is a departure from the standard and so the TGA's proposals to part-adopt, to modify, to add to, and to delete from, the standards set in the RPSPA should be resisted and should only be permitted where there is clear evidence of need.

ASMI therefore does not support the TGA's access to additional powers beyond those in the RPSPA (or already given to the ACCC) unless it can be demonstrated that the benefit outweighs the resulting additional complexity and uncertainty.

ASMI does not support the departures from the Expert Panel's recommendations put forward in the consultation paper:

- The purpose of the legislative re-draft contemplated by Recommendation 28 was primarily to simplify the structure and language, to achieve a more user-friendly approach, to maximise transparency of both policies and processes and *then* to provide for graduated penalties that would allow an appropriate response to the full range of non-compliance. Instead the consultation paper effectively ignores these primary purposes by taking a standard set of compliance and enforcement powers (from the RPSPA) and re-purposing them in a way which increases complexity and uncertainty. ASMI does not support such an approach.

- Recommendation 57 stated only that consideration be given to *whether* the current range of powers should be broadened, there was no recommendation that the powers *needed* to be broadened. Instead of an analysis of whether broadening is actually required, the consultation paper immediately proceeds on the basis that the TGA's powers must be broadened. ASMI does not support such an approach.

Reform cannot proceed on the flawed (and simplistic) assumption that the TGA's access to more powers and higher penalties will resolve perceived problems.

The TGA are underutilising the mechanisms currently available and before any reforms to sanctions and penalties are implemented, there needs to be a thorough and transparent examination of the TGA's limited use of their available powers.

If sanctions and penalties do need to be increased they must be set transparently and according to existing Commonwealth Government principles.

If the TGA provides clear regulatory guidelines and timely publication of regulatory decisions, then the need for a formal education program will be reduced.

In order for stakeholders to have confidence in the compliance processes, the TGA needs to improve transparency.

When the TGA does report outcomes of compliance activities, the reporting should be timely and accurate.

Any reforms coming out of this consultation need to be costed and their full financial impact assessed as part of the suite of inter-related reforms resulting from the MMDR Review.

In terms of timings, it is problematic for the TGA to be consulting on sanctions and penalties now. Given the complex and inter-related set of concurrent reforms which are ongoing, significant changes to the therapeutic goods regulatory system are inevitable. The timing of this consultation means that the TGA is basing their need for increased powers on the current system (which is going to change) rather than in relation to the system as it will be. Further to this, the TGA are expecting stakeholders to provide final comment on sanctions and penalties when there is no detail of the final regulatory scheme that will be in place around those sanctions and penalties.

In terms of transition, changes to sanctions and penalties should only come into force once all the regulatory reforms are in place and operating with clear guidelines. Stakeholders need to know exactly what their obligations are before they can reasonably be exposed to a new set of compliance and enforcement powers.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

Context of this consultation within the full suite of reforms

ASMI welcomes the opportunity to provide input into this consultation along with the numerous other consultations arising from the Review of Medicines and Medical Devices Regulation (the MMDR).

ASMI is broadly supportive of the MMDR process where it can be shown to provide a quantifiable benefit and does not add complexity, reduce transparency or lead to unintended outcomes.

It should be noted that all of the comments in this consultation response are provided without visibility of the overarching plans for the entire regulatory framework. The complete MMDR reforms project has many intersections within the medicines framework, and the full outcome of

this current consultation can only be understood in the context of the whole. Changes to advertising, scheduling, complaints handling, regulation of low-risk products, complementary medicines pathways, post-market monitoring, disclaimers, claimers, permitted indications, minor variations etc. are all being considered separately and will all have an impact on the suitability of the proposals within this consultation.

While ASMI will respond to each consultation separately, we reserve our final position and support until a review of the intersection of the completed consultations is made available for stakeholder consideration and input prior to any legislative changes being put forward.

ASMI therefore requests that the TGA provide a clear overview of how they intend to address each of the Government responses to the Expert Review recommendations. The current approach is segmented and stakeholders do not have transparency of the projected final product. ASMI also notes that these changes, along with associated reforms that are not specifically within the sanctions and penalties space, are likely to have a marked impact on the entire regulatory framework and this will come with business impacts and costs. ASMI therefore requests that a comprehensive Regulation Impact Statement (RIS) is provided to address these concerns, particularly where any TGA proposal does not align precisely with the Expert Review recommendations and Government response.

Previous submissions

ASMI previously made submissions in relation to both the 2013 and 2016 consultations on advertising reform. In our 2016 submission (dated 21 December 2016), we made the following recommendations relevant to sanctions and penalties:

- The TGA are underutilising the investigation and enforcement mechanisms currently available. Effective use of the substantial existing powers needs to be the objective, rather than the introduction of additional burden and red tape.
- If sanctions and penalties do need to be increased they must be set transparently and according to existing Commonwealth Government principles.
- In order for stakeholders to have confidence in the processes, the TGA needs to improve transparency of processes and outcomes.
- When the TGA does report outcomes of compliance activities, the reporting should be accurate.
- If the TGA provides clear regulatory guidelines and timely publication of regulatory decisions, then the need for a formal education program will be reduced.

ASMI continues to support these recommendations.

Regulation Impact Statement (RIS)

ASMI notes that the consultation paper makes no reference to either the financial impact of the proposals or the preparation of a Regulation Impact Statement (RIS).

ASMI also notes that the MMDR recommendations that formed the basis for this consultation (i.e. Recommendations 28 and 57) were non-specific and simply recommended that the Australian Government “undertake a comprehensive review” (of the legislation) and give “consideration” to whether the current range of powers should be broadened.

Given that the recommendations are of a high-level, general, nature that require further consultation with stakeholders and that are contingent on reforms to other aspects of the regulatory framework, it would be impossible to quantify the financial impact of the recommendations at this stage.

At a minimum ASMI would expect that refining of outcomes and recommendations from this consultation with stakeholders would be necessary to confirm practicality prior to making recommendations to Government. This would be consistent with the approach taken for other major proposals after the MMDR Review Report was released. ASMI would be concerned by any rush to change the legislation based on the outcomes of this initial consultation and without a proper consideration of the full impact of the reforms.

Consistent with the Government's best practice regulation requirements, we look forward to seeing a detailed RIS accompanying each of the finalised TGA reform proposals so as to demonstrate that the reforms have been fully costed.

Expert panel recommendations to government

ASMI notes that Recommendation 28 from the Expert Panel involved (among other things):

> *"a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods … with a view to simplifying its structure and language to achieve a more user-friendly approach … In doing so … the Act should be re-drafted in such a way as to … maximise transparency of both policies and processes …. to provide for graduated penalties that allow the NRA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance"*

It is counter-productive to the MMDR process to see that none of the proposals in the consultation paper reflect these aspects of recommendation 28, instead the consultation paper perpetuates the (flawed) view that if only the TGA had access to more powers and could impose higher penalties, then the problems would disappear.

ASMI also notes that Recommendation 57 from the Expert Panel stated only that consideration be given as to *whether* the current range of powers should be broadened – there was no recommendation that the powers *needed* to be broadened.

It is therefore disappointing to the see the consultation paper immediately proceed on the basis that the TGA's powers must be broadened.

Government's response to the expert panel's recommendations

The Government accepted Recommendation 28 in principle, by endorsing the intent but deciding to apply the reforms one piece at a time (as opposed to a single comprehensive review and re-drafting of the legislation).

As outlined above, it is disappointing to see recommendation 28 and the Government's response being interpreted so narrowly in this consultation.

The Government accepted Recommendation 57 on the basis that consumers would be protected because inappropriate and misleading advertising would be deterred. Recommendation 57 was also part of a suite of related Recommendations as follows:

- #53 regarding advertising prohibitions based on scheduling
- #54 regarding consistency between medicines and devices
- #55 regarding advertising pre-approvals
- #56 regarding advertising complaints mechanisms
- #58 regarding education of sponsors and advertisers

It is disappointing to see that none of these related recommendations are being considered as part of this consultation. Once again illustrating the TGA's apparent view that the only reform that is needed is more powers and higher penalties.

Purpose of this consultation

ASMI notes the following statement of the "purpose" of the consultation paper (on page 6):

> *"All these measures will align the Act with regulatory provisions comparable to other Commonwealth regulators ensuring that we will have the right tools to effectively address non-compliance with appropriate and effective risk-based graduated responses in a timely manner."*

ASMI supports this purpose. In the interests of simplification and reduction of red-tape the TGA should adopt a standard suite of provisions that are comparable with other Commonwealth regulators. In ASMI's view this would allow the TGA to take a proportionate response to compliance activities. Further to this, the TGA should only be given unique powers where there is a demonstrated need for such powers.

Injunctions and stakeholder consultation

Part 7 of the *Regulatory Powers (Standard Provisions) Act 2014* (the RPSPA), creates a framework for using injunctions to enforce provisions. ASMI supports the TGA's triggering of the RPSPA and the TGA's access thereby to the powers to use injunctions.

ASMI does not support any modification or expansion of the powers beyond those granted under Part 7 of the RPSPA.

The consultation paper (at page 6) indicates that:

> *"Most of the advertising consultation comments and feedback supported the widening of powers and sanctions but also wanted the wider powers to be consistent with other Commonwealth legislation."*

We reiterate our view that the TGA's powers should only be widened where there is a demonstrated need to do so and where other complementary regulatory mechanisms (e.g. advertiser and sponsor training, clear guidelines, pre-market controls, etc.) are also put in place.

The Regulatory Powers (Standard Provisions) Act 2014

Adopting the Regulatory Powers (Standard Provisions) Act 2014

ASMI supports the TGA's adoption of the RPSPA and is pleased to see the TGA acknowledge the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI supports the TGA's adoption of a standard set of compliance and enforcement powers.

ASMI notes the following statements made on page 9 of the consultation paper:

> *"The provisions of the RPSPA represent best practice in relation to regulatory powers and include operational safeguards while maintaining Parliamentary scrutiny over application of that Act to specific regulatory regimes. Standardisation provides regulatory agencies with the opportunity to use more uniform powers, and increases legal certainty for businesses and individuals who are subject to those powers."* [Emphasis added]
>
> *"Adopting the investigation, monitoring and enforcement provisions from the RPSPA allows for any future amendments to these provisions in the RPSPA to automatically apply to the Act without the need for us to make any amendments."* [Emphasis added]

The standard set of compliance and enforcement powers therefore provides benefits to all stakeholders. These benefits will be diluted every time there is a departure from the standard and so the TGA's proposals to part-adopt, to modify, to add to, and to delete from, the standards set in the RPSPA should be resisted and should only be permitted where there is clear evidence of need established in co-operation with affected parties.

Modifying the RPSPA

The consultation paper proposes three specific modifications to the RPSPA:

- To maintain the existing "sampling" powers of authorised officers.
- To maintain existing monitoring powers of authorised officers in specific premises.
- To maintain the current power in the Act to allow authorised persons on reasonable grounds to enter any premises without warrant and seize therapeutic goods.

ASMI cannot support these modifications, without justification.

The TGA's triggering of the RPSPA will give the agency access to a standard suite of provisions that are comparable with other Commonwealth regulators. The uniform nature of these powers provides clarity and predictability to all stakeholders (including the regulator) and every departure from the standard suite will create complexity and uncertainty.

The standard RPSPA suite should be sufficient for the TGA, and the consultation paper provides no evidence to the contrary.

As noted below on page 12 under "Substantiation notices" and under "Public warning notices", ASMI supports additional TGA powers (beyond those of the RPSPA) where the processes and penalties align with those of the ACCC.

However, the TGA's automatic retention of their existing powers is inconsistent with the Recommendations 28 and 57 of the Expert Panel. Neither recommendation specifies that certain of the TGA's of the existing powers are to be exempt from review.

ASMI acknowledges that the TGA are not the only Commonwealth agency with oversight of advertising nor are they the only Commonwealth agency with powers to enter premises of regulated entities for the purpose of investigation. While it is probable that the TGA's modifications to the RPSPA are in alignment with the powers of these other agencies, there is no discussion or justification in the consultation paper to show that this is the case.

The TGA should only be given access to additional, or different, powers from those in the RPSPA where there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted). The consultation paper provides no such demonstration of need and no rationale beyond the TGA's current ability to do so.

In ASMI's view, the expansion of powers beyond those in the RPSPA, should only take place following a thorough and transparent examination of the TGA's available powers and processes together with an assessment of the TGA's use of those powers and processes. Expanded powers should only be granted if the benefit outweighs the resulting additional complexity and uncertainty.

Timing of the consultation and transition

As noted on page 4 under "Context of this consultation within the full suite of reforms" and on page 6 under "Government's response to the expert panel's recommendations" this particular consultation looks only at one aspect of a complex and inter-related set of concurrent reforms which together have the potential to impact all aspects of the therapeutic goods regulatory system.

These other reforms will likely result in changes to the regulatory requirements and to the compliance obligations of stakeholders. It is therefore problematic for the TGA to be consulting on sanctions and penalties now, for without seeing how the new regulatory requirements operate, the TGA is in no position to assess where the shortcomings are. The TGA is basing their need for increased powers on the current system (which is going to change) rather than in relation to the system as it will be.

It is also unreasonable to ask stakeholders to provide final comment on sanctions and penalties when there is no final regulatory scheme in place. Without knowing what the final regulatory scheme looks like, how can stakeholders know what compliance and enforcement powers are necessary, how can stakeholders assess whether proposed penalties are warranted, how can stakeholders assess whether the proposed business processes are fair, transparent or efficient?

The timing of this consultation is therefore problematic.

The TGA also needs to consider a proper transition process. In ASMI's view, changes to sanctions and penalties should only come into force once all the regulatory reforms are in place and operating with clear guidelines. The implementation of any revised compliance and enforcement powers should be the last piece of reform to be put in place. Stakeholders need to know exactly what their obligations are before they can reasonably be exposed to a new set of compliance and enforcement powers.

Existing compliance mechanisms

The TGA are underutilising the mechanisms currently available and before any reforms to sanctions and penalties are implemented, there needs to be a thorough and transparent examination of the TGA's limited use of their available powers.

In this consultation paper, the TGA repeats the assertions from the previous consultation papers that the issues surrounding advertising compliance will be fixed simply by increasing the range of available sanctions and by increasing the size of the available penalties.

The TGA provides no evidence that this is a likely outcome.

As outlined in our 2016 submission, the TGA already has a comprehensive suite of investigation and enforcement powers described in the *Therapeutic Goods Act* including the following:

- The Secretary may request information in relation to *advertising* and there are civil penalties for failing to comply (s8)
- There are civil penalties for *advertising* outside the ARTG indications (s22(5))
- It is a standard condition of registration that *advertising* has to be consistent with the indication(s) in the ARTG (s28(5))
- The Secretary may suspend the registration or listing of a product (s29D)
- The Secretary may cancel the registration or listing of a product for (among other things) its presentation, its *advertising* or a failure by the sponsor to provide information or documents (s30)
- There are criminal penalties for non-compliance with requirements (s30EC)
- There are civil penalties for non-compliance with requirements (s30ECA)
- The Secretary can compel a sponsor to provide information relating to (among other things) the safety, efficacy or *advertising* of any product (s31)
- There are fines and potential custodial sentences where a sponsor either fails to comply with a request, or provides false or misleading information in response to a TGA request for information (s31)
- There are civil penalties where a sponsor provides false or misleading information in response to a TGA request for information (s31AAA)
- There are fines for publishing non-approved or non-compliant *advertisements* (s42C)
- There are fines for a range of *advertising* offences (s42DL)
- There are fines for *advertising* that is not compliant with the TGAC (s42DM)
- There are fines for generic information that is not compliant with the TGAC (s42DP)
- The Regulations can make provisions for infringement notices (s 42YJ and s 42YK)
- Secretary can accept court-enforceable undertakings (s 42YL)

However, it is not enough to have the powers available; the TGA must have the expertise and the appetite to enforce those powers together with the commitment to publish all outcomes in a timely fashion.

Despite the range of existing powers, and despite the TGA's stated concerns about the advertising of therapeutic goods, there is a real absence of published TGA activity in this area, for example:

- The most recent compliance action relating to advertising was in December 2014[1].
- There have only been two enforceable undertakings published[2].

[1] https://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date

- The court actions undertaken by the TGA all relate to unapproved or counterfeit goods[3].

Before any reforms to sanctions and penalties are implemented, there needs to be a thorough and transparent examination of the TGA's limited use of their available powers. As a minimum, stakeholders are entitled to know:

- Which powers are being used.
- Which powers are not being used (and why).
- What processes the TGA has followed.
- What outcomes have occurred.
- What successes the TGA has had (and what failures).
- What actions the TGA has been prevented from taking.
- What other shortcomings have been identified.
- How modifying existing powers (or adopting new ones) will resolve the identified issues

MMDR recommendations - enhancing sanctions and penalties for advertising

If sanctions and penalties do need to be increased they must be set transparently and according to existing Commonwealth Government principles.

It is unclear how the TGA arrived at the proposed penalties and it is unclear why those penalties are disproportionality large and inconsistent with relevant Commonwealth guidelines.

ASMI is concerned that the proposals appear to be based on an assumption that the problems with the current system can be fixed by simply increasing the size of the penalties. The TGA has provided no evidence to support such a course of action.

ASMI is pleased to see the TGA acknowledge the Commonwealth Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* in the consultation paper.

ASMI notes that the RPSPA contains frameworks for each of the following:

- Part 4 - Civil Penalty Provisions
- Part 5 - Infringement Notices
- Part 6 – Enforceable Undertakings
- Part 7 – Injunctions

In ASMI's view the Attorney General's Guide and the RPSPA together should be sufficient.

It is also worth noting that, as with the previous TGA consultations, the proposed penalties are substantially greater than those already specified in the Australian Consumer Law (the ACL). Under the ACL, the maximum penalty for false or misleading conduct is $1,100,000 for corporations and $220,000 for individuals[4], whereas the TGA are proposing maximum penalties of $9,000,000 and $900,000 respectively (these being the proposed civil penalties for non-compliance with regulatory requirements described on page 10 of the consultation paper).

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[2] https://www.tga.gov.au/compliance-undertaking

[3] https://www.tga.gov.au/court-action

[4] https://www.accc.gov.au/business/business-rights-protections/fines-penalties

Once again, we have no way of knowing how the TGA arrived at these figures, why they are so large or why the TGA chose to disregard relevant Commonwealth guides on the topic.

There should be no change to the sanctions and penalties until the TGA clearly articulates the reasoning behind the proposals.

Substantiation notices

ASMI supports the broadening of the TGA's powers to include substantiation notices only so long as the TGA's processes and penalties align with those of the ACCC.

The TGA should only be given access to additional, or different, powers from the ACCC where there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted).

The ACCC currently has the power to seek substantiation notices in relation to therapeutic goods and it should make no difference to advertisers or sponsors if the TGA also has the *same* powers.

However, ASMI is concerned that the proposed penalties for non-compliance with a TGA substantiation notice described on page 11 of the consultation paper exceed those currently available in relation to non-compliance with an ACCC[5] substantiation notice.

There is no explanation as to how the TGA arrived at these penalties, why they are so large or why they are different to those available to the ACCC.

The TGA should be seeking to align their powers with other Commonwealth regulators.

Public warning notices

ASMI supports the broadening of the TGA's powers to include public warning notices only so long as the TGA's processes and penalties align with those of the ACCC.

The TGA should only be given access to additional, or different, powers from the ACCC where there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted).

Infringement notices and the RPSPA

Part 5 of the RPSPA contains a frameworks for Infringement Notices, which the TGA should adopt without modification.

[5] https://www.accc.gov.au/publications/country-of-origin-food-labelling-0/country-of-origin-claims-and-the-australian-consumer-law/substantiating-your-claims/substantiation-notices

Standardising strict liability offences in the Act

ASMI supports the TGA's adoption of the RPSPA and is pleased to see the TGA acknowledge the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI supports the TGA's adoption of a standardised approach consistent with the RPSPA, the Attorney General's guide and the existing ACCC powers.

ASMI does not support the TGA adopting additional, different or unique powers unless there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted).

Complementing existing offences in the Act

ASMI supports the TGA's adoption of the RPSPA and is pleased to see the TGA acknowledge the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI supports the TGA's adoption of a standardised approach consistent with the RPSPA, the Attorney General's guide and the existing ACCC powers.

ASMI does not support the TGA adopting additional, different or unique powers unless there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted).

Strengthening existing aggravated criminal offences

ASMI supports the TGA's adoption of the RPSPA and is pleased to see the TGA acknowledge the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI supports the TGA's adoption of a standardised approach consistent with the RPSPA, the Attorney General's guide and the existing ACCC powers.

ASMI does not support the TGA adopting additional, different or unique powers unless there is a demonstrated need to do so (and where the resulting additional complexity and uncertainty is warranted).

Industry and stakeholder education

If the TGA provides clear regulatory guidelines and timely publication of regulatory decisions, then the need for a formal education program will be reduced.

The TGA already has an obligation to provide clear and unambiguous regulatory guidelines and this is especially important given the proposed increase in penalties.

Timely publication of sufficiently detailed regulatory decisions will be of great educative value to advertisers and sponsors.

ASMI would support the TGA running education programs only so long as they were a "user-pays" system (in a similar way to the current training sessions on the TGAC that are conducted by ASMI) and not funded out of the TGA's revenue from sponsors. Topics covered should include all aspects of sponsor obligations, for example:

- Creating and maintaining an ARTG entry
- Quality, safety and efficacy requirements
- Ongoing compliance with standards
- Ensuring that manufactured product meets the details on the register
- Advertising
- Complaints
- Post-market monitoring responsibilities
- Pharmacovigilance
- Recalls
- Sanctions and penalties

However, as discussed previously, ASMI could also support the TGA using money from advertising fines and penalties to educate advertisers.

Other reforms necessary

As outlined in our 2016 submission, appropriate sanctions and penalties are only one aspect of a comprehensive advertising compliance system, and (for the reasons also outlined in our previous submissions) the following aspects must be reformed alongside any changes to sanctions and penalties:

- Advertising pre-approvals
- Transition arrangements
- Complaints handling
- Clarity of regulatory requirements
- Transparency of TGA processes and decisions (see below)
- Accuracy and timeliness of TGA reporting (see below)
- Stakeholder participation in the development, implementation and ongoing review of reforms
- The future of the CRP and the TGACC
- The currency and usability of the Therapeutic Goods Advertising Code
- Industry education

ASMI looks forward to participating in the consultation processes for these other aspects and looks forward to seeing the resulting reforms being introduced as a package.

Given their direct relevance to sanctions and penalties, two of these aspects (TGA transparency and TGA reporting) are discussed in more detail below.

TGA transparency

In order for stakeholders to have confidence in the compliance processes, the TGA needs to improve transparency.

As outlined in our 2016 submission, it is common ground amongst stakeholders that the TGA lack transparency when it comes to compliance processes and outcomes. Whereas the CRP publish its procedures, acknowledge all complaints, keep the parties informed of progress and publish every determination on their website, the TGA are not anywhere near so transparent.

By way of Illustration, we noted that:

- Since 2010, the TGA has claimed to have a process for handling complaints which fall outside the CRP's jurisdiction. Despite frequent requests to do so, the TGA has not provided or published details of the process.

- The 2014-2015 CRP annual report[6] shows that, during the report period, the CRP referred 185 complaints to the TGA without the Panel making a determination (since the TGA were better suited to deal with the complaint). During the same period, the CRP referred 39 defiant advertisers to the TGA (by way of a Recommendation to the Secretary). As far as we can tell, none of the resulting outcomes have been published by the TGA.

- The 2015-2016 CRP annual report[7] shows that, during the report period, the CRP referred 86 complaints to the TGA without the Panel making a determination (since the TGA were better suited to deal with the complaint). During the same period, the CRP referred 57 defiant advertisers to the TGA (by way of a Recommendation to the Secretary). As far as ASMI can tell, none of the resulting outcomes have been published by the TGA.

- So, in the past 2 years, the CRP referred 328 complaints to the TGA, and none of the outcomes have been published.

- In November 2015, the TGA caused to be published a Legislative Instrument (the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2015*[8]) the sole and specific purpose of which was to permit the TGA to publish outcomes of advertising complaints where the CRP had made a Recommendation to the Secretary. Despite 12 months elapsing since this publication was made, and despite the substantial number of complaints referred by the CRP, the TGA has not been able to publish a single outcome.

- The power to publish under the November 2015 Legislative Instrument was in addition to the pre-existing TGA power to publish determinations made by the TGA under Regulation 9 (i.e. Regulation 9 Orders). It is worth noting that the last Regulation 9 Order was published in December 2014.

- These powers are in addition to the power under s61(5A) of the *Therapeutic Goods Act*, which provides that the Secretary may release to the public therapeutic goods information relating to any decision or action taken under the Act or the regulations[9].

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[6] http://www.tgacrp.com.au/wp-content/uploads/files/ComplaintsSummaryFor2014-2015.pdf
[7] http://www.tgacrp.com.au/wp-content/uploads/files/CRP_complaints_summary_1-Jul-2015_to_30-Jun-2016.pdf
[8] https://www.legislation.gov.au/Details/F2015L01900.
[9] https://www.tga.gov.au/court-action

So, even with a range of powers and even with a substantial quantity of complaints materials referred from the CRP, the TGA has not seen fit to publish a single outcome in more than 30 months!

Accuracy and timeliness of TGA reporting

When the TGA does report outcomes of compliance activities, the reporting should be timely and accurate.

The timely and accurate reporting of compliance activities will be of educative value to sponsors and advertisers and will have a general deterrent effect.

In 2013, there was an illuminating decision from the AAT on the nature of restricted representations (*Health World Limited and Minister for Health and Ageing* [2013] AATA 388[10]). While the advertisement was ultimately found to be in breach because of the absence of a qualifier regarding traditional Chinese use, the references to "cystitis" were found not to be in breach (since they were not restricted representations).

While the advertisement was found to have breached 4(1)(b) of the TGAC, there was no breach of 42DL(1)(c) of the *Therapeutic Goods Act* and there were no breaches of paragraphs 4(2)(a), 4(2)(b), 4(2)(c) or 5(2) of the TGAC.

So the advertisement was found to be largely compliant and the determination provides a detailed examination of what amounts to a restricted representation.

Despite this outcome (and despite the clear educative value of the determination), the TGA website coverage of the decision[11] simply states that:

> *"While the AAT found that the advertisement breached the Code (but not the Act) (see paragraph 83 of the decision), for the reasons set out in paragraphs 84 to 92 of the decision, the AAT decided not to order that the advertisement or relevant claims be withdrawn or to order a retraction of the advertisement. In those circumstances, the AAT decided to revoke the TGA's 27 April 2012 decision."*

It is worth noting that although the AAT decision was published on 7 June 2013, the TGA website was not updated until 17 July.

Such inconsistency simply opens the door to speculation as to why the TGA have reported the outcome in such cursory manner when it was clearly of substantial educative value.

[10] http://www.austlii.edu.au/au/cases/cth/aat/2013/388.html

[11] https://www.tga.gov.au/advert-complaint/urinary-tract-support-health-world-limited-complaint-no-201012013-update-0

Summary

ASMI supports the TGA's adoption of a standard set of compliance and enforcement powers as set out in the *Regulatory Powers (Standard Provisions) Act 2014* (the RPSPA) which are also consistent with the Attorney General's *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.

ASMI also supports the TGA's adoption of other powers such as substantiation notices and public warning notices only so long as the TGA's processes and penalties align with those already in place for the ACCC.

ASMI is prepared to support the TGA's retention of powers to enter premises of regulated entities (and to take samples) where those powers are shown to be necessary and are shown to be consistent with the powers held by other Commonwealth agencies entitled to enter premises for the purpose of investigation.

A standard set of compliance and enforcement powers provides benefits to all stakeholders. These benefits will be diluted every time there is a departure from the standard and so the TGA's proposals to part-adopt, to modify, to add to, and to delete from, the standards set in the RPSPA should be resisted and should only be permitted where there is clear evidence of need.

ASMI therefore does not support the TGA's access to additional powers beyond those in the RPSPA (or already given to the ACCC) unless it can be demonstrated that the benefit outweighs the resulting additional complexity and uncertainty.

Reform cannot proceed on the flawed (and simplistic) assumption that the TGA's access to more powers and higher penalties will resolve perceived problems.

In terms of timings, it is problematic for the TGA to be consulting on sanctions and penalties now. Given the complex and inter-related set of concurrent reforms which are ongoing, significant changes to the therapeutic goods regulatory system are inevitable. The timing of this consultation means that the TGA is basing their need for increased powers on the current system (which is going to change) rather than in relation to the system as it will be. Further to this, the TGA are expecting stakeholders to provide final comment on sanctions and penalties when there is no detail of the final regulatory scheme that will be in place around those sanctions and penalties.

In terms of transition, changes to sanctions and penalties should only come into force once all the regulatory reforms are in place and operating with clear guidelines. Stakeholders need to know exactly what their obligations are before they can reasonably be exposed to a new set of compliance and enforcement powers.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director