Review of the Therapeutic Goods Advertising Framework

Final Report on the impact of advertising reforms from the Expert Panel Review of Medicines and Medical Devices Regulation, and other initiatives

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1. Executive Summary

1.1 Objective

In line with the Government's commitment made in 2018 to review the reforms to the therapeutic goods advertising framework within two years from implementation, the review examined the impact of the new advertising measures regarding the commencement of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*, with reference to the advertising reforms from the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR Review) and other initiatives announced by the Minister.

The Review was led by Ms Rosemary Sinclair AM, the newly appointed Chief Executive at auDA.

Protiviti provided support to the Review.

1.2 Terms of Reference

The Review assessed the impact of the:

A. new advertising measures as included in the *Therapeutic Goods Act 1989* (the Act), in particular, the effectiveness of:

   i. the amendments to the *Therapeutic Advertising Code (No. 2) 2018* i.e. whether they have increased clarity and objectivity to support the compliance and enforcement powers in the Act and improved consistency between the requirements for medicines and medical devices;

   ii. the TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods to the public; and

   iii. broadened sanctions and penalties to deter inappropriate and misleading advertising of therapeutic goods.

B. other initiatives announced by the Minister in February 2018, namely:

   iv. a comprehensive industry and consumer education program of the new advertising measures;

   v. public performance measures for advertising complaints management, i.e. an assessment of the suitability of the TGA's key performance indicators for managing advertising complaints; and

   vi. stakeholder engagement activities on therapeutic goods advertising with a particular focus on the effectiveness of the Therapeutic Goods Advertising Consultative Committee (TGACC).

1.3 Background

The Therapeutic Goods Administration (the TGA) is Australia's regulatory authority for therapeutic goods. The TGA is part of the Australian Government Department of Health (the Department).

On 24 October 2014, the Australian Government announced the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) ('the MMDR Review'). The objective of that Review was to make recommendations to assist the Government to enhance the regulatory framework for medicines and medical devices so that:

- Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods, and
- areas of unnecessary, duplicative or ineffective regulation are removed or streamlined without

undermining the safety or quality of therapeutic goods available in Australia.[1]

The Expert Panel reported in two stages and made a total of 58 recommendations, which reflected an overarching intention to remove unnecessary regulatory burden and support the regulator and industry transition towards a more self-regulatory regime, without compromising the safety or quality of therapeutic goods or diminishing protections for the Australian public.

The principles underpinning that Review[2] are relevant to the consideration of progress on the seven recommendations which related to the advertising of therapeutic goods:

1. The role of regulation is to manage risk in order to protect public health and safety;
2. The level of regulation should be commensurate with the risk posed by the regulated products;
3. A risk-benefit approach to the regulation of therapeutic goods is appropriate;
4. The regulation of therapeutic goods should take a whole-of-lifecycle approach; and
5. The ultimate responsibility for medicines and medical devices regulation should remain with the Commonwealth.

Of the 58 recommendations, seven related to the advertising of therapeutic goods. The recommendations reflected the Panel's view that "…controls on advertising provide an important assurance that consumers have access to accurate information in making health choices"[3].

The Australian Government Response to the Review ('Government Response') was released on 15 September 2016, following consultation with stakeholders including consumers, healthcare professionals and industry:

> *"This response presents a strategic and systems-based approach to achieve long-term sustainable reform to the regulation of therapeutic goods in Australia. It identifies ways to improve access to therapeutic goods for consumers and remove unnecessary red tape for industry whilst maintaining the safety of therapeutic goods in Australia."*[4]

Of the total 58 recommendations, 56 of the recommendations were supported by the Government. All the recommendations relating to the regulation of therapeutic goods advertising were accepted. This resulted in a suite of changes to the therapeutic goods advertising framework, with reforms led by the Department and more specifically, the TGA.

Current Review Scope

This Review of the Therapeutic Goods Advertising Framework ('the Review') was intended to examine the impact and effectiveness of key changes to the advertising framework catalysed by the MMDR Review.

The advertising framework components to be considered in this Review included the relevant changes to the *Therapeutic Goods Act 1989 (Cth)* ('the Act'), which establishes the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. Specifically, the Review considered amendments to:

- the Therapeutic Goods Advertising Code, as the instrument made under the Act that sets out the legislative requirements for therapeutic goods advertising;

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[1] Samson, L., Delaat, W. and Horvath, J., *Expert Panel Review of Medicines and Medical Devices Regulation – Stage 1 Report*, (2015) ('*MMDR Review – Stage 1 Report*'), 1.

[2] *MMDR Review – Stage 1 Report*, 5.

[3] Samson, L., Delaat, W. and Horvath, J., *Expert Panel Review of Medicines and Medical Devices Regulation – Stage 2 Report*, (2015) ('*MMDR Review – Stage 2 Report*'), 54.

[4] Commonwealth of Australia as represented by the Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, (May 2016), 2.

- disband the Complaints Resolution Panel and nominate a single-body to be responsible for the management of public complaints about the advertising of therapeutic goods; and
- broaden the sanctions and penalties available to respond to breaches of advertising requirements.

The Review also examined a number of other initiatives announced by the Minister for Health ('the Minister) that supported the intent of the MMDR recommendations and implementation of changes to the advertising framework. These initiatives are led by the TGA and included:

- a comprehensive industry and consumer education program regarding the new advertising framework;
- development of public performance measures for the reformed complaints management function; and
- engaging with stakeholders regarding therapeutic goods advertising, particularly through a forum of relevant stakeholder representatives in the Therapeutic Goods Advertising Consultative Committee (TGACC).

Most of the changes regarding the therapeutic goods advertising framework noted above, have occurred within the last 12-18 months, with the TGA taking an approach of continuous improvement to implementing the reforms.

1.4 Overall Assessment

The changes to the therapeutic goods advertising framework within scope of this Review have been implemented in the last 12-18 months. In this regard, the Review has taken place at a timely crossroads, to reflect on the early experiences of implementation of the reforms, and to inform further improvement to the effectiveness of the regulatory framework for therapeutic goods advertising and a strengthened strategic focus on implementation.

The Review involved extensive stakeholder consultation, both with key stakeholder groups represented on the TGACC, and with a selection of Departmental staff members and senior executives. In undertaking these consultations, the Review noted a high degree of openness and highly thoughtful responses, which reflected an invested stakeholder base and a commitment to continuous improvement by the TGA. All stakeholders understood the importance of consumers having accurate information in making health choices. This was reflected in stakeholder commitment to supporting effective regulation of advertising in the interest of public health and safety.

Conducting the Review in the COVID-19 environment posed some interesting challenges, leading to innovative and amended ways of completing the Review. As a result, most consultations were held via teleconference, and the work conducted by the review team mostly occurred online and offsite.

The COVID-19 crisis required the TGA to develop and execute new strategies and approaches to cope with a public health emergency and as a result, the Review was able to identify some pertinent and significant changes in the operation of the TGA. A number of observations regarding this response have been captured in this review report.

The COVID-19 environment provided an opportunity for the TGA to demonstrate the value to consumers of focusing on compliance priorities, taking a strategic approach to communication and education tasks, and adopting an agile approach to the use of its enhanced powers. The Review suggests there is much for the regulator and industry to learn from this recent experience.

The Review noted that across all reform elements examined, the TGA has implemented the changes with a clear understanding of its accountability for public health and safety. The TGA has also demonstrated a positive and open-minded approach to continuous improvement to the regulatory framework and associated processes, such as through seeking feedback from stakeholders and reflecting on its approach in an iterative way.

Overall, the changes that have been implemented by the TGA have moved in the right direction in giving effect to the intended outcomes and benefits noted in the MMDR Review and Government

Response.

In initiating and implementing the reforms to the therapeutic goods advertising framework, the TGA efforts to date have emphasised an approach of informing and assisting industry with regards to the advertising framework. This is a natural course given the shift to a self-regulatory landscape and the large suite of reforms to the rules and processes that regulate therapeutic goods advertising. In this way, the TGA has taken on a role of assisting industry to understand the new framework as the first step to enabling improved self-compliance. The Review notes that in some areas, such as with enforcement responses and developing educational materials, the TGA has gone to great lengths to support industry.

The Review suggests that the TGA, with the regulatory framework and supporting processes for therapeutic goods advertising in place, is now well-placed to shift its approach and focus to achieve the aims of the reform program.

For industry, the next phase will involve more responsibility, with industry further developing their practices for self-compliance, becoming responsible and accountable 'partners' in achieving the aims of the regulatory framework and the intended consumer protection outcomes. The Recommendations made as part of this Review are intended to facilitate this approach.

For the TGA, the next phase will involve a more strategic approach to its responsibilities as the regulator of therapeutic goods advertising. The TGA should focus more directly on the intended outcomes and priorities of its compliance functions. A clearer vision of the outcomes and priorities of compliance activities should guide the TGA in updating its processes, performance measures, and aligning resources. The Recommendations made as part of this Review are intended to facilitate a more strategic and outcomes-focused approach to the TGA's regulatory framework for therapeutic goods advertising.

1.5 Summary assessment against Terms of Reference items

The key observation to report is that while good progress has been made implementing the Government's response to the MMDR Report, the focus has necessarily been tactical given the timeframes for implementation. With the benefit of the experience now gained over the last 12-18 months, and the need for rapid response in the early days of the COVID-19 pandemic, this Review finds that there has been progress in achieving the aims of the framework. The next phase in achieving further effectiveness and impact from the Therapeutic Good Advertising Framework will depend on a more strategic approach to a number of the review scope items. It should be noted based on stakeholder consultations, that the Department's approach is already one of continuous improvement and that stakeholders are also committed to contribute to further improving the regulation advertising of therapeutic goods to the public.

1.5.1 The amendments to the *Therapeutic Advertising Code (No. 2) 2018* i.e. whether they have increased clarity and objectivity to support the compliance and enforcement powers in the Act and improved consistency between the requirements for medicines and medical devices

The Review finds that the changes to the Code have resulted in improvement, with the new Code being clearer and easier to understand. Compliance is more straightforward for industry and advertisers and supports progress to a more self-regulatory regime. Assessment of advertising breaches is more straightforward for the TGA. There are opportunities for further refinement which are identified in the recommendations.

1.5.2 The TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods to the public

The Review finds that the TGA is well-placed to be the single-body for managing complaints about the advertising of therapeutic goods. Stakeholders reported that TGA has the relevant scientific and regulatory knowledge to effectively regulate the quality and safety of therapeutic goods. The single

body has reduced complexity and potential confusion in making complaints about advertising of therapeutic goods. A complaints management process has been implemented. There are opportunities for a more strategic approach to using complaints within the regulatory framework which are identified in the recommendations.

1.5.3 Broadened sanctions and penalties to deter inappropriate and misleading advertising of therapeutic goods

The Review finds that the broadened sanctions and penalties provide an appropriate breadth of responses for the TGA in deterring misleading advertising and achieving compliance outcomes for consumer protection in a self-regulatory environment. There are opportunities for the TGA, having focused on its role to inform and educate industry, to build on its experience in using the full range of broadened sanctions and penalties.

1.5.4 A comprehensive industry and consumer education program of the new advertising measures

The Review finds the TGA has been effective in developing and distributing information about the advertising framework and Code requirements. The TGA has been very responsive to industry requests for further information. There are opportunities for the TGA to move to a more strategic approach to providing information and education for both industry and consumers including setting priorities based on key regulatory outcomes and working with industry as responsible and accountable partners in achieving better consumer outcomes.

1.5.5 Public performance measures for advertising complaints management, i.e. an assessment of the suitability of the TGA's key performance indicators for managing advertising complaints

The Review finds significant opportunity for the TGA to revise its performance measures and key performance indicators to include a focus on priorities and outcomes for consumers rather than the current emphasis on timeliness of processes. The Review notes that the TGA has already begun work in this area through a focused concurrent management initiated review into the complaints management function.

1.5.6 Stakeholder engagement activities on therapeutic goods advertising with a particular focus on the effectiveness of the TGACC

The Review found that the TGA applies considerable effort to stakeholder engagement with a very broad range of stakeholders. There is opportunity to engage more strategically with stakeholders, to provide focused opportunities for engagement and to shift from informing stakeholders to engaging them more effectively to build shared responsibility for achieving improved compliance outcomes.

1.6 Summary of Recommendations for Further Improvement

With respect to each scope item, the Review made the following recommendations:

1.6.1 Regarding amendments to the *Therapeutic Advertising Code (No. 2) 2018*

Recommendation 1: Case Studies

To further increase clarity and objectivity of the Code, the TGA should consider using emerging case experience and decisions to create examples of the application and interpretation of the Code, including cases where provisions are considered by stakeholders to be ambiguous. The selection of case studies to publish may also be informed by the TGA's compliance priorities (Recommendation 5) and education priorities (Recommendation 12).

Recommendation 2: Focus Issues

The TGA should maintain and share a log of Code issues that stakeholders confirm after discussions

in TGACC sub-groups (Recommendation 20) as being unclear, inconsistent, or difficult to work with. Where case examples and educational materials are not sufficient to improve clarity and objectivity, the TGA should consider publishing policy clarification.

1.6.2 Regarding the TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods

Recommendation 3: Maintain TGA as the single body

The Government should maintain the TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods to the public. The TGA should continue to build its complaints handling capability and systems as outlined in Recommendations 4 to 7.

Recommendation 4: Strategic Re-set

The TGA should use the recommendations made in the concurrent management initiated review to reset the complaints management system to focus on achieving improved compliance outcomes through intelligence gathering, strategic triaging and integrated response.

Recommendation 5: Compliance Priorities

The TGA should develop and publish Compliance Priorities which are reviewed annually. In setting these priorities the TGA should develop factors to be considered, consult with stakeholders, and focus on consumer benefit. The Compliance Priorities should inform key performance indicators (KPIs) and reporting (Recommendations 14 and 15).

Recommendation 6: Integrated Information - TGA

The TGA should work to further integrate the management of complaints about advertising of therapeutic goods with other relevant areas within the TGA. This could be achieved by developing information-sharing practices across the TGA, to support:

- the compliance priorities across the TGA's regulatory areas; and
- identification of trends identified across high-volume complaints regarding products, types of therapeutic claims made, manufacturers, or suppliers.

Recommendation 7: Integrated Information – other Regulators

The TGA should co-develop information-sharing protocols to facilitate active information-sharing with relevant regulators, including Food Standards Australia New Zealand (FSANZ) and the Australian Competition and Consumer Commission (ACCC) regarding complaints and trends on relevant cross-sector products or issues. This should be supported by focused engagement with regulators (Recommendation 21) to define information-sharing needs and priorities.

1.6.3 Regarding broadened sanctions and penalties to deter inappropriate and misleading advertising of therapeutic goods

Recommendation 8: Regulatory Posture

The TGA should develop and promote a clear regulatory position on its approach to the use of the broadened sanctions and penalties to protect public health and safety. This should include the balance of focus between educative and punitive responses, and the principles that guide the use of more punitive compliance tools. The position should be clearly communicated to Departmental staff involved in advertising compliance and other stakeholders.

Recommendation 9: Skill development

The TGA should provide focused skills development on compliance and enforcement practice to support the advertising compliance team in implementing the TGA's regulatory position. This may include developing an understanding of case management and enforcement response at other regulators, and sharing lessons learned.

Recommendation 10: COVID-19 Response

The TGA should reflect on the lessons learned from the COVID-19 experience in responding to non-compliant advertising with sanctions and penalties in a timely manner. The COVID-19 experience also has useful learnings regarding the use of media and publicising the compliance actions taken by the TGA to raise awareness of the negative consequences of using non-compliant advertising.

1.6.4 Regarding the industry and consumer education program of the new advertising measures

Recommendation 11: Education Strategy

The TGA should develop an Advertising Framework Education Strategy with clearly defined priorities that are aligned to Compliance Priorities and consumer outcomes.

Recommendation 12: Education Priorities

The TGA should develop Education Priorities to more effectively target educational activities. In setting these priorities the TGA should develop factors to be considered, consult with stakeholders and focus on consumer and industry benefit. The education priorities should be publicised and clearly communicated to stakeholders. The priorities should be reviewed annually.

Recommendation 13: COVID-19 Communications

The Review recommends that the TGA use the COVID-19 experience, particularly in priority-setting and developing activities and mobilising the media in support of agreed priorities, as part of developing a more strategic approach to its education program.

1.6.5 Regarding the public performance measures for advertising complaints management

Recommendation 14: Indicators for Outcomes

The TGA should redevelop a suite of advertising compliance performance measures and indicators which focus on priorities and outcomes rather than processes and deadlines.

In considering a new approach to measures and indicators, the TGA should use the recommendations made in the concurrent management initiated review of the complaints handling process.

Recommendation 15: Performance Reporting

Once the TGA has developed new performance indicators for advertising compliance and complaints management, the TGA should publicise the measures, and report performance against the measures using the TGA website and annual reporting and media channels.

1.6.6 Regarding stakeholder engagement activities on therapeutic goods advertising

Recommendation 16: Stakeholder Engagement Plan

The TGA should ensure its Stakeholder Engagement Plan includes a focus on supporting effective regulation of therapeutic goods advertising. The stakeholder engagement plan should consider the TGA's compliance priorities (in line with Recommendation 5) and education priorities (in line with Recommendation 12). The plan would define purpose and objectives, priorities, and engagement methods specific to TGA's advertising compliance role.

Recommendation 17: Communications Plan

The TGA should ensure its Communications Plan reflects a strategic approach to communications including use of external channels (particularly media) to support its advertising framework compliance priorities, education strategy goals and stakeholder engagement strategy goals. Use of media and external channels should focus on increasing both consumer and industry awareness of the TGA's regulatory position in regard to advertising compliance. Well-targeted consumer information and regular public reporting on regulatory decisions made and outcomes achieved would be elements of

effective communication.

Recommendation 18: TGACC Ways of Working

The TGACC should be refocused to enhance its effectiveness as a collaborative forum focused on better outcomes for consumers through effective advertising compliance by industry. This may be achieved by updating the Governance Arrangements or developing an accountability charter which details:

- the refreshed objectives of the TGACC;
- roles and responsibilities of the TGA and members, which may include more opportunity for members to share their experiences, concerns or recent activities such as member education activities; and
- expectations of both the TGA and members.

Recommendation 19: TGACC Work Plan

The TGA should develop a list of key tasks and associated timeframes that require the input of the TGACC to finalise. This would include:

- developing annual compliance priorities;
- developing annual education priorities; and
- identifying significant case studies for use in the education program or media.

Recommendation 20: TGACC Focus Sub-groups

The TGA should consider hosting focused sub-groups with representation from the most relevant sector members from the TGACC. These should be hosted on an as-needed basis. A summary of key considerations and outcomes from these focused roundtables should be reported back to the wider TGACC group.

Recommendation 21: Regulator Meetings

The TGA should continue to hold regular meetings with other regulators to develop approaches and actions to address regulatory interface issues. A summary of key considerations and outcomes from the regulator meetings should be reported back to the wider TGACC group.

Recommendation 22: Stakeholder Survey

The TGA should develop a periodic (e.g. every two years) stakeholder survey to evaluate stakeholder satisfaction with stakeholder engagement efforts. The survey may also be used to gauge perceptions of the effectiveness of the TGA's compliance framework, which may inform performance reporting.

The survey should include input from key stakeholders consulted with and other partnering regulators. Areas of weakness or opportunities for improvement identified from the survey should inform updates to the TGACC Ways of Working, stakeholder engagement plan and communications plan.

1.7 Acknowledgements

The Review would like to acknowledge the following people and organisations for their contribution throughout this process:

Therapeutic Goods Administration

The Review would like to thank Adjunct Professor John Skerritt and the staff of the TGA for their openness in engaging in the Review and for their effort and time in responding to the Review's many requests for information – particularly given the additional work and unusual working experience during the time of the Review due to the COVID-19 response.

Stakeholders

The Review would also like to thank the many stakeholders who participated in the “remote” stakeholder consultation sessions, provided additional reports and materials to the Review and further comments as the Review progressed.

A list of stakeholders consulted as part of the Review is at **Attachment A.**

Secretariat Services

The Review would like to thank the team at Protiviti for assistance in the management of the review and in the preparation of the Review Report. Again this contribution was made in the unusual working conditions that formed part of Australia’s response to COVID-19. The Secretariat provided excellent support to the Review.

2 Background, Objective, Scope and Approach

2.1 Background

2.1.1 The TGA

The Therapeutic Goods Administration (the TGA) is Australia's regulatory authority for therapeutic goods. The TGA is part of the Australian Government Department of Health (the Department), and operates to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods. In this way, a key purpose and outcome of the TGA is to protect public, or consumer, health and safety through regulation.

The TGA regulates products that make therapeutic claims, which covers a broad range of substances and devices including over-the-counter, prescription and complementary medicines, simple devices like bandages through to complex devices such as pacemakers. All goods of this type must be entered on the Australian Register of Therapeutic Goods (ARTG) which is also managed and regulated by the TGA. While focusing on public health outcomes, the TGA aims to balance public health with regulatory burden, to provide Australians with timely and efficient access to therapeutic goods and advances.

The TGA annual budget is approximately $165 million and operates predominantly on a cost recovery basis.[5] The TGA recovers its costs through fees and charges for activities that fall within the scope of the *Therapeutic Goods Act 1989* (Cth) ('the Act'), which sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia, including the TGA's public health responsibilities. Fees are charged for a service, such as for a product evaluation, and are prescribed in the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*. A charge is a form of tax imposed on the regulated industry and is applied every financial year. A list of charges can be found in the Therapeutic Goods (Charges) Regulations 1990. While some funding is provided by the Government for meeting the cost of medicines and chemicals scheduling activity and to contribute to a range of fee-free services, the majority of the TGA's funding is generated under cost recovery arrangements. This cost recovery arrangement was raised by a few stakeholders as an area of concern that the TGA may be influenced by industry which comprises a key source of funding. However, the Review found no evidence that the TGA's sources of funding are influencing the agency's decision-making or its compliance practices.

2.1.2 MMDR Review

On 24 October 2014, the Australian Government announced the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) ('the MMDR Review'). The MMDR Review examined Australia's medicines and medical devices regulatory framework and processes with a view to identifying:

- opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods; and
- areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia.[6]

Further, a key principle (Principle 1) underpinning the MMDR Review was that the "role of regulation is to manage risk in order to protect public health and safety". Therefore, protection of consumers from unsafe and low-quality or ineffective therapeutic goods was considered a key purpose of regulation.

[5] Department of Health, *Therapeutic Goods Administration Business Plan 2019-20,* 10.

[6] *MMDR Review – Stage 1 Report*, 1.

The MMDR Review made a total of 58 recommendations across two reports released in March and July of 2015. The final eight recommendations of the second report were directed towards enhancing and streamlining the advertising framework to facilitate and maximise compliance and the management of complaints.

2.1.2.1 Recommendations Regarding the Therapeutic Goods Advertising Framework

As a summary, the MMDR Review made the following recommendations related to the therapeutic goods advertising framework:

- Recommendation Fifty-Two: that advertising of therapeutic goods to the public continues to be regulated by the TGA under an advertising framework that includes a code.
- Recommendation Fifty-Three: advertising to the public continues to be prohibited for certain prescription medicines, and the advertising of certain medicines specified in the Poisons Standard continues to be prohibited.
- Recommendation Fifty-Four: that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.
- Recommendation Fifty-Five: that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.
- Recommendation Fifty-Six: disbanding current compliant handling mechanisms and establishing a new system in which a single agency is responsible to receive and manage complaints on the advertising of therapeutic products to the public.
- Recommendation Fifty-Seven: that consideration be given as to whether the current range of investigation and enforcement powers should be broadened.
- Recommendation Fifty-Eight: that the TGA facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.

As reflected by these recommendations, an overarching intention of the MMDR Review was to support the regulator and industry in a transition towards a more self-regulatory regime, and to remove any unnecessary regulatory burden created by the therapeutic goods advertising framework, while protecting consumers from misleading and inappropriate advertising.

2.1.2.2 Government Response to the Review

In the Government Response, the Commonwealth accepted all the recommendations related to the therapeutic goods advertising framework, noting an overarching intention to reduce complexity and move towards self-regulation of the industry, while improving consumer access and maintaining the safety of therapeutic goods in Australia.

Importantly, the Government accepted recommendation Fifty-Five (removal of pre-approvals), noting that the acceptance of Recommendations Fifty-Seven (broadening enforcement powers) and Fifty-Eight (developing sponsor education) would be critical for managing potential public health concerns raised by consumers and healthcare professionals.[7] In their response, the Government acknowledged that the removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and would be consistent with their commitment to minimising unnecessary regulatory burden for sponsors and advertisers across the industry.

[7] Commonwealth of Australia as represented by the Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation* (May 2016), 36.

2.1.3 Changes to the Advertising Framework

Following the Government Response accepting recommendations fifty-two through to fifty-eight, numerous changes were made to the therapeutic goods advertising regulatory framework. Importantly, the Government made amendments to the Act, which establishes the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The TGA led the design of amendments contained in the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*, which came into effect on 6 March 2018. This formalised the removal of pre-approvals for therapeutic good advertisements (to take place from 1 July 2020); disbanded the Complaints Resolution Panel (CRP) that used to oversee advertising complaints, and also put in place new broadened sanctions and penalties for the TGA to apply to breaches of the regulatory requirements. As part of the suite of legislative changes, the Therapeutic Goods Advertising Code was also amended, with the intention to improve clarity and objectivity of the provisions and make requirements for medicines and medical devices more consistent.

2.1.4 Other Initiatives Announced by the Minister

Other initiatives to improve the regulation of therapeutic goods advertising were announced in February of 2018 by the Minister for Health ('the Minister'). These initiatives supported the intent of the MMDR recommendations or the implementation of changes to the advertising framework catalysed by the MMDR Review. These initiatives included: a comprehensive consumer and industry education program to support awareness and compliance with the new regime; developing public performance measures for the new complaints handling process; and engaging with stakeholders in implementing the suite of reforms and continuing to regulate therapeutic goods advertising.

2.1.5 Review of the Therapeutic Goods Advertising Framework

This Review of the Therapeutic Goods Advertising Framework ('the Review') was intended to examine the impact and effectiveness of key changes to the advertising framework, as outlined above, that were catalysed by the MMDR Review. The Review comes at a timely crossroads, having started 12-18 months in from implementation of most of the reforms. In this way, the Review reflects on the early experiences of implementation of the reforms, with a view to informing future direction and maturation of the regulatory framework for therapeutic goods advertising.

2.1.5.1 The Review and the COVID-19 Environment

The Review commenced in February of 2020, meaning that some of the original intended approach was modified by the social distancing measures introduced to combat COVID-19 and the role of the TGA in responding to this crisis.

The COVID-19 crisis also provided the unique opportunity to observe the TGA develop and execute new strategies and approaches to cope with a public health emergency, and as a result the Review was able to identify some pertinent and significant changes in the operation of the TGA. A number of observations regarding this response have been captured in this report.

2.2 Review Objective

In line with the Government's commitment made in 2018 to review the reforms to the therapeutic goods advertising framework within two years from implementation, the review examined the impact of the new advertising measures regarding the commencement of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*, with reference to the advertising reforms from the MMDR Review and other initiatives announced by the Minister.

The Review was led by Ms Rosemary Sinclair AM, the newly appointed Chief Executive at auDA.

Protiviti provided support to the Review.

2.3 Review Terms of Reference

The Review assessed the impact of the:

A. new advertising measures as included in the *Therapeutic Goods Act 1989* (the Act), in particular, the effectiveness of:

   i. the amendments to the *Therapeutic Advertising Code (No. 2) 2018* i.e. whether they have increased clarity and objectivity to support the compliance and enforcement powers in the Act and improved consistency between the requirements for medicines and medical devices;

   ii. the TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods to the public; and

   iii. broadened sanctions and penalties to deter inappropriate and misleading advertising of therapeutic goods.

B. other initiatives announced by the Minister in February 2018, namely:

   iv. a comprehensive industry and consumer education program of the new advertising measures;

   v. public performance measures for advertising complaints management, i.e. an assessment of the suitability of the TGA's key performance indicators for managing advertising complaints; and

   vi. stakeholder engagement activities on therapeutic goods advertising with a particular focus on the effectiveness of the Therapeutic Goods Advertising Consultative Committee (TGACC).

2.4 Scope Limitations

The Review has not considered the Government's decision, implemented through legislative change in 2018, to remove pre-approval for advertisements of medicines that appear in specified media from 1 July 2020. The Review has also not considered the legislation other than in the context of its operational impact on the new advertising measures, and has not provided any legal advice or legal opinions.

The Review has not evaluated the assessments and recommendations made in the MMDR Review, or the decisions made by the Commonwealth to accept or defer the recommendations in the Government Response. The Review has also not assessed the impacts or implementation of all recommendations from the MMDR Review, but just reviewed those relevant to the terms of reference.

The Review has been conducted in an independent manner.

The Review has relied on the information, research, expertise and knowledge of the therapeutic goods advertising framework gathered from consultation with stakeholders, industry and consumer body submissions, Departmental staff and TGA documentation. The Review has relied on the information

being provided in the belief that such statements and opinions were not false or misleading.

The Review has made comments and assessments based on the information available at the time of fieldwork, and represents a point in time assessment.

While the Review considered all feedback provided, this report does not discuss every piece of feedback received during consultations, but has focused on the representations that were common amongst multiple stakeholders or that resonated as important areas for consideration in conducting the assessments of impact and effectiveness.

Conducting the Review in the COVID-19 environment posed some interesting challenges, leading to innovative and amended ways of completing the Review. As a result, most consultations were held via teleconference, and the work conducted by the review team mostly occurred online and offsite.

2.5 Review Approach

The approach taken for this Review has involved multiple steps of investigation, consultation and analysis for each of the six scope items. Some key aspects of the approach were as follows.

- Review of relevant publicly available documentation, such as the MMDR Review and the Australian Government Response, the TGA website, and legislation and associated explanatory materials.
- Review of internal TGA documentation, including plans, governance documentation, procedural documentation and Departmental guidelines.
- Consultation with focus groups of TGACC members, including teleconferences to discuss insights on each scope item and providing a period of opportunity to submit written comments.
- Consultation with Departmental staff, particularly with staff involved in therapeutic goods advertising, staff involved with other compliance arms of the TGA, and relevant senior executives.
- Assessment of arrangements against better practice. To aid objective assessments, detailed analysis was undertaken against several better practice guides including:
  - Office of the Queensland Parliamentary Counsel, *Principles of Good Legislation: OQPC Guide to FLPs – Clear Meaning*, (2014);
  - Canada's Department of Justice, *Clear Legislation*, (last modified 2015);
  - Office of Parliamentary Council, *Reducing Complexity in Legislation*, (2016);
  - Australian Government, Department of Prime Minister and Cabinet, *Policy Implementation Toolkit - 3 Engaging stakeholders*, (2013);
  - Australian National Audit Office (ANAO), *Auditor-General Report No.17 - 2018–19, Implementation of the Annual Performance Statements Requirements 2017-18*, (2018);
  - Commonwealth Ombudsman, *Better Practice Guide to Complaints Handling,* (2009); and
  - Productivity Commission, *Regulator Audit Framework,* (2014).
- Gaining a high-level understanding of how other similar regulators operate, including through TGACC consultations, drawing on previous experiences working with regulators, and using publicly available information.
- Reviewing the report of an external consultancy engaged to undertake a management initiated review of the complaints management processes

3 Detailed Assessments and Recommendations

3.1 Amendments to the Therapeutic Goods Advertising Code

3.1.1 Background

The *Therapeutic Goods Act 1989 (Cth)* ('the Act') sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The Act details the requirements for listing, registering, or including medicines, medical devices and biological products on the Australian Register of Therapeutic Goods (ARTG). The Act also deals with other aspects of the law regarding advertising, labelling and product appearance of therapeutic goods.

Depending on the product, a therapeutic good may be subject to additional legislation or regulation. For example therapeutic goods may also be, or contain: consumer products subject to Australian Consumer Law (ACL) and the Australian Competition and Consumer Commission (ACCC); food subject to the Food Standards Code; or substances that are in the Poisons Standard which is regulated by State and Territory governments.

Under section 42BAA of the Act, the Minister or a delegate may, by legislative instrument, make a code relating to advertisements about therapeutic goods. Therefore, the current Code made under section 42BAA of the Act (the *Therapeutic Goods Advertising Code (No. 2) 2018*), is the legislative instrument setting out the minimum requirements that advertisers must meet in their advertisements of therapeutic goods directed to the public. The Code serves as a control to protect the public from false, inappropriate, and misleading claims and the risks they pose to public health. The new Code updated the *Therapeutic Goods Advertising Code 2015* (the 2015 Code) based on several recommendations from the MMDR Review and relevant areas for improvement or amendment identified by the TGA.

In Recommendation Twenty-Eight of the MMDR Review, the Expert Panel suggested a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods. This included recommending a review of the Act and associated regulations in their entirety, 'to simplify their structure and language to achieve a more user-friendly approach'. In the Government Response to the MMDR Review, the Commonwealth accepted this recommendation in-principle, stating that it will 'propose amendments to Parliament as required to implement particular recommendations… [and] will implement the intent of this recommendation when implementing agreed changes to legislation and regulations'.

Recommendation Fifty-Two of the MMDR Review makes more specific reference to the Therapeutic Goods Advertising Code, in stating that the advertising of therapeutic goods should continue to be regulated by the TGA under a legislative framework which includes an advertising code.

3.1.2 Tranches of Changes to the Code

Amendments to the Code were developed through extensive public and stakeholder consultation. The main intention behind these changes was to increase clarity and objectivity of requirements to support recognition of breaches and application of the new and broadened enforcement provisions in the Act (discussed further in Section 3.3 of this report). A clearer and more objective Code was intended to support the transition to a more self-regulatory regime, wherein industry would be more readily able to interpret the Code and produce compliant advertising in the absence of pre-approvals, and the regulator could easily identify breaches and apply penalties. Alongside this, there was an intention to improve consistency between the requirements for medicines and medical devices in line with Recommendation Fifty-Four of the MMDR Review.

The amendments to the Code occurred in three tranches. The first was the introduction of the *Therapeutic Goods Advertising Code 2018* ('the 2018 Code'). This introduced significant changes to the 2015 Code – considerably increasing the length through the inclusion of many more definitions, specifying mandatory statements to apply in different situations, and including more detail about the application of provisions. These changes considered ambiguities or inconsistencies that had been

identified through public consultation or by the former Therapeutic Goods Advertising Code Council.

Following this, suggestions raised in consultations led to more significant changes and small revisions being made through the *Therapeutic Goods Advertising Code (No. 2) 2018* ('the 2018 (No.2) Code'). This included at a summary: clarifying the definitions of 'health warning' and 'prominently displayed and communicated'; and clarifying provisions regarding required information and statements, awareness of public health campaigns, scientific representations, and indications for medicines. These additions were made and the 2018 (No. 2) Code took effect from 1 January 2019, and the initial 2018 Code never came into effect.

Most recently, another small collection of changes containing minor corrections and clarifications were introduced in July 2019. These amendments were made following feedback from industry and the TGACC. Key updates made in the most recent amendments included:

- clarifications to the definition of 'health warnings' for medical devices and other therapeutic goods;
- clarification that the section 11 mandatory statement applies to advertising of any therapeutic good that includes a Schedule 3 substance when the advertising is permitted by inclusion of the substance in Appendix H of the Poisons Standard;
- provision for advertisers to vary the wording of the indications or intended purpose from that included on the good's label or instructions;
- clarification on the test for whether there is a health warning for the purpose of certain requirements;
- clarification that certain requirements do not apply if an advertisement for therapeutic goods contains only the name of the goods, a picture of the goods, the price of the goods or where the goods may be purchased, or any combination of these;
- clarification that references to pregnancy, other than complicated pregnancies, are not captured as restricted representations; and
- providing advertisers with the option to use a single mandatory statement when telling consumers to 'read the label' when advertising multiple medicines at once.

The Review's assessment of whether amendments to the Code have improved clarity, objectivity and consistency drew on comparisons between the 2015 Code, and the most current version of the 2018 (No.2) Code, which will be referred to throughout as the 'new Code', 'current Code' or 'the Code'.

3.1.3 Overview Assessment of Improved Clarity and Objectivity

3.1.3.1 Overall Clarity and Objectivity to Support Compliance and Enforcement Powers

Stakeholder and staff feedback generally indicated that the new Code is clearer and easier to understand than its predecessor. Most representatives considered the changes to the Code to be improvements, which would make compliance more straightforward for industry and advertisers; and make assessment of advertising breaches and regulation more straightforward for the TGA. There was particularly positive feedback regarding the inclusion of new schedules to the Code, as having added clarity to areas of the Code that were previously brief or vague.

However, a few areas of the Code were raised across multiple consultations as being 'pain points' that had caused issues in interpretation or application for some users of the Code. Particular 'pain points' for stakeholders included the revised definition of 'advertise', provisions regarding testimonials and endorsements, the use of 'reasonableness' or 'likelihood' and similar subjective terms, and the length of required health warnings. These areas were analysed during the review and are discussed in further detail below in Section 3.1.4 of this report.

In assessing the new Code, the Review made reference to guidance and resources published by the

Office of Parliamentary Counsel,[8] Office of the Queensland Parliamentary Counsel,[9] and Canada's Department of Justice[10]. Assessment of the Code amendments against the principles and considerations in the above guidance confirmed that clarity and objectivity had generally improved. The new Code demonstrated a more robust and readily interpretable document than the 2015 Code. Areas of the Code that were previously considered vague are now more easily understandable due to the significant addition of new and amended definitions, aiding clearer and more objective application of provisions. Further, the detail stating the intended operation and application of provisions has increased and improved, adding clarity and objectivity to the circumstances in which the provisions apply. The amended structure and titles have more clearly signposted the relevance of provisions, assisting with efficient navigation and interpretation. While the length of the Code has increased significantly, this is attributed to the inclusion of new definitions, schedules and examples, and more detail on application of provisions which have increased clarity and the capacity for objective application throughout the Code.

The improved clarity and objectivity of the Code supports the move to a more self-regulatory regime and establishes rules that industry should be able to interpret more readily and easily to produce compliant advertising. The improvements to the Code also support the regulator in more clearly identifying breaches and applying appropriate penalties to respond and enforce the regulatory framework.

3.1.4 Assessment of Clarity and Objectivity in 'Pain Point' Provisions

As mentioned above, there were various specific areas that were raised during consultation as lacking clarity and being difficult to interpret. These areas are discussed in more detail below.

3.1.4.1 Meaning of 'Advertise'

An area of concern for many industry and media representatives was the newly introduced definition of 'advertise'. This definition is, however, drawn from section 3 of the Act rather than the Code.

> ***advertise**, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:*
>
> *(a) is on the label of the goods; or*
>
> *(b) is on the package in which the goods are contained; or*
>
> *(c) is on any material included with the package in which the goods are contained.*

Some stakeholders considered this definition may allow ambiguous or subjective interpretation in what is considered as 'intending', whether directly or indirectly to promote the goods. The explanatory statement to the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2018*, describes the definition, in consistency with the common law, as an objective test. That is,

> *"the question is whether the material or format, on its face and without reference to the actual intentions of those concerned with its circulation, publication, transmission, or dissemination, appears to be designed or calculated to draw public attention to and to promote the supply, sale or use of the particular therapeutic good".*

In this way, the question of whether the material is an advertisement, is designed as an *objective* assessment on the facts that is uniformly applied, rather than an assessment looking at the subjective

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[8] Office of Parliamentary Council, *Reducing Complexity in Legislation* (2016), https://www.opc.gov.au/sites/default/files/reducingcomplexity_0.pdf

[9] Office of the Queensland Parliamentary Counsel, *Principles of Good Legislation: OQPC Guide to FLPs,* (2014), https://www.legislation.qld.gov.au/file/Leg_Info_publications_FLP_Clear_meaning.pdf

[10] Canada Department of Justice, *Canada's System of Justice: Clear Legislation*, Department of Justice website: https://www.justice.gc.ca/eng/rp-pr/csj-sjc/ilp-pji/cl-lc/index.html

intent or actual impact of the material in individual circumstances. Therefore, the intention of the definition is to add objectivity, and clarity on its interpretation will be cemented in emerging case experience, which is discussed further in Section 3.1.6 of this report.

Further, the revised definition of 'advertise' leaves flexibility for the TGA to effectively respond to new advertising forms as media and the industry innovate, allowing for a more robust application of the Code going forward.

3.1.4.2 Testimonials and Endorsements

Testimonials was another area raised as causing concern for those interpreting the Code. Generally, the relevant provision is clearer in the current Code than it had been in the 2015 Code, with much of its increased length dedicated to delineating to whom the provisions apply and in what circumstances. The language, clear structure and defining of relevant terms indicated that this provision and its requirements are quite clear, unambiguous, and able to be objectively applied.

The Review assessment of the endorsements provision was similar. This section is easy to understand, with relevant definitions and exceptions described in adequate detail. The section is also laid out in a logical structure, stating the application of the provision, general restrictions, and then permitted endorsements predicated on relevant required statements.

Considering the above observations, the assessment suggested that the Code provisions and requirements regarding testimonials and endorsements are clear, unambiguous and apply objectively. Therefore, it may be that stakeholder concerns with regards to the testimonials and endorsements provisions of the Code are not directly related to legal clarity, but to the broad application and onerous requirements in the provisions. This feedback may be an area the TGA considers on a rolling basis for future amendments or clarifications regarding the Code (see Recommendation 2).

3.1.4.3 Health Warnings

Another area of concern for some stakeholders was the length and variations in required statements for health warnings. However, our assessment found that what is required and in what circumstance is very clear and is applied objectively. The perceived issue regarding the length of warnings is an issue of application and practicability rather than interpretative clarity or ambiguity, which the TGA may consider in future amendments (see Recommendation 2). Section 3.1.5 below, also discusses feedback from stakeholders that the requirements for health warnings for medical devices are relatively unclear, which the TGA may also consider.

3.1.4.4 Subjective or Ambiguous Terms

One final point raised by some stakeholders was that there was a high instance of subjective terms such as different variations of 'reasonableness', 'implied' and 'likelihood', limiting the objectivity and clarity of the Code. An example is the definition of 'advertise' (discussed above), and reference to 'a reasonable viewing distance' in the definition of whether something is 'prominently displayed or communicated'. Stakeholders were concerned that such terms could be broadly construed, and that determinations would be made on subjective and inconsistent interpretations.

Firstly, it is important to recognise that in common law, legal questions incorporating requirements such as 'reasonableness' and 'likelihood' are designed as objective, not subjective tests. That is to say, assessments are made independent of the parties involved, rather than being dependent on individualistic or subjective circumstances. The explanatory statement for the *Therapeutic Goods Advertising Code (No. 2) 2018* elaborates on the example of 'likelihood', stating that

> *"the view of the likely impact of the advertisement is through the objective eyes of a person to whom an advertisement is directed; subjective reactions which may be peculiar to specific individual attitudes and sensitivities are put to one side."*

In this way, the Code requirements referring to variations of 'reasonableness', 'imply', and 'likelihood' are designed to be objective tests that are uniformly applied to all cases.

The Review acknowledges that what is or is not 'reasonable', 'implied' or 'likely' may be unclear in

borderline or more complex cases. However, references to these kinds of terms is unavoidable, otherwise the legislative instrument would need to predict and exhaustively set out examples of all circumstances, situations, and consequences that may occur to which specific rules should apply. The Review also notes that these terms are clearer to apply in situations where advertisers demonstrate a culture of commitment to effective self-compliance and act within the boundaries of the requirements, and become less clear when advertisers test the boundaries of the rules.

3.1.5 Consistency between Medicines and Medical Devices

The new Code contains specific and different requirements for advertising of medicines and medical devices related to: the use of health warnings (section 4 and Schedule 1 of the new Code); what advertisements must contain for therapeutic goods that are not available for physical examination before purchase (section 12 of the new Code); and what advertisements must contain generally (section 13).

With regards to health warnings, we received some feedback stating that the requirements for medical devices are not as clearly prescribed when compared to medicines. For medicines, Schedule 1 of the Code provides specified health warnings that must be used depending on the ingredients used and the circumstances the medicines are used. However, health warnings for medical devices are less prescriptive and provide options on the types of required statements that may apply and be used. The note to the section in the Code provides an example of how certain statements may be drafted. The inconsistency in the degree of prescriptiveness between health warnings for medicines and medical devices is largely attributable to the ability to exhaustively list ingredients and the circumstances for their use with regards to medicines. This allows more prescriptive direction for relevant health warnings (e.g. potential side effects). A similar regime of prescribing health warnings for all combinations of parts that can be used and circumstances for the breadth of medical devices may not be practicable to draft in legislation. However, the TGA should note the feedback that some stakeholders believe the requirements for health warnings for medical devices are unclear, and consider any clarification that may be provided (see Recommendation 2).

With regards to the statements that advertisements must contain (in sections 12 and 13), requirements are differentiated between medicines and medical devices. The requirements (and associated wording of the required statements) are very similar. In these sections, the requirements for medical devices follow directly after medicines. There was some feedback that the requirements for medicines and medical devices being nested under the same section was not clear and easily navigable. On this point, the TGA may consider the use of sub-headings throughout the legislation to signpost the requirements for medicines as compared to medical devices.

In most other provisions of the Code, the requirements apply to ‘therapeutic goods’. Therapeutic goods are defined in the Act broadly, which includes assessment of whether they are represented in a way to be for therapeutic use ‘and includes biologicals, medical devices and goods declared to be therapeutic goods’ by the Secretary. The Act also contains an expansive definition of ‘therapeutic use’, which states:

> ***therapeutic use*** *means use in or in connection with:*
>
> *(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or*
>
> *(b) influencing, inhibiting or modifying a physiological process in persons; or*
>
> *(c) testing the susceptibility of persons to a disease or ailment; or*
>
> *(d) influencing, controlling or preventing conception in persons; or*
>
> *(e) testing for pregnancy in persons; or*
>
> *(f) the replacement or modification of parts of the anatomy in persons.*

In this way, requirements in the Code that refer to ‘therapeutic goods’ apply to both medicines and medical devices. This reflects consistent and uniform requirements for medicines and medical devices

in the majority of the provisions which apply to 'therapeutic goods'.

3.1.6 Consolidating and Demonstrating Clarity and Objectivity

Continued application of the Code and emerging case experience will further develop clarity and cement objectivity about the advertising requirements and the specific provisions that are considered by stakeholders to be ambiguous. In terms of enforcing the new Code, the TGA is in a period of relative infancy, as the bulk of compliance activities still relate to advertisements of products not on the ARTG, rather than comprising more complex cases dealing with application of specific provisions of the Code.

As the case-handling experience of the TGA matures, a more robust case history and precedent-setting will cement the clarity and objectivity of the code for the TGA and industry. Examples of more nuanced application of Code provisions should be made available to the public and industry, as they become available. The publicising of these cases may be prioritised or distributed based on the compliance priorities (referred to in Recommendation 5) or education priorities (referred to in Recommendation 12) of the TGA.

Recommendation 1: Case Studies

To further increase clarity and objectivity of the Code, the TGA should consider using emerging case experience and decisions to create examples of the application and interpretation of the Code, including cases where provisions are considered by stakeholders to be ambiguous. The selection of case studies to publish may also be informed by the TGA's compliance priorities (Recommendation 5) and education priorities (Recommendation 12).

Recommendation 2: Focus Issues

The TGA should maintain and share a log of Code issues that stakeholders confirm after discussions in TGACC sub-groups (Recommendation 20) as being unclear, inconsistent, or difficult to work with. Where case examples and educational materials are not sufficient to improve clarity and objectivity, the TGA should consider publishing policy clarification.

3.2 Move to the TGA as the Single Body for Complaints Management

3.2.1 Background

As part of the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2018*, amendments to the advertising-related provisions of the Act were made to 'support the Department (through the TGA) as the single body responsible for implementing a more transparent and efficient complaints management process about the advertising of therapeutic goods to the public'[11]. Amendments included transferring those powers previously held by the Complaints Resolution Panel (CRP) to the Secretary of the Department, and conferring new powers to support an effective complaints management process.

In the MMDR Review, the recommendation to abolish the advertising pre-approval mechanism, was made on the condition that other recommended protections for consumers are implemented. These consumer protections included improving the complaints management process (Recommendation Fifty-Six of the MMDR Review) and strengthening sanctions and penalties available to the TGA (Recommendation Fifty-Seven of the MMDR Review, discussed in Section 3.3 of this report).

The MMDR Review raised concerns about the previous complaints handling system including:

- the lack of transparency about complaints outcomes;
- the long resolution timeframes;
- that different bodies are involved to resolve complaints depending on the type of advertisement, causing confusion about lodging a complaint;
- and weaknesses in consistency in decision-making.

In response to these concerns, the Panel considered that the TGA should provide a single entry point for all complaints about therapeutic products, for appropriate triaging. In Recommendation Fifty-Six of the MMDR Review, the Panel recommended that:

> *current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options:*
>
> *(a) establishing the function within the NRA [(National Regulatory Authority)] or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or*
>
> *(b) calling for tenders from external organisations to undertake the function.*

The Government accepted this recommendation and noted that moving to a single agency offered the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers.

From 1 July 2018, the TGA assumed responsibility for receiving and considering all complaints about therapeutic goods advertisements directed to the public under a simplified complaints system.

In assessing the effectiveness of the TGA as the single body responsible for managing complaints, the Review considered the suitability of the TGA as the agency responsible for complaints management, and then considered the effectiveness of the procedural system implemented to support complaints management.

[11] Explanatory memorandum to the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017*, 71.

3.2.2 The TGA as the Single-Body for Complaints Management

Key stakeholders that were asked about the appropriateness of the TGA to manage complaints about therapeutic goods advertising were generally of the view that the TGA was well-placed to be the single body overseeing this process. Stakeholders expressed that the TGA had the relevant scientific and regulatory knowledge about therapeutic goods and had a line of visibility to therapeutic goods and industry.

The management of complaints related to the advertising of therapeutic goods is compatible with the mandate of the TGA to regulate the quality and safety of therapeutic goods,[12] and to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods[13].

Further, as noted in the stakeholder feedback, Departmental staff have relevant knowledge of the regulatory regime for therapeutic goods and relevant medical or scientific expertise to allow more timely, nuanced and in-depth analysis of therapeutic claims. The breadth of other related regulatory areas overseen by the TGA also means that it is well-placed to review industry compliance and protect consumers of therapeutic goods in a more holistic way. Further, complaints about advertising of therapeutic goods may provide useful information to inform and influence other regulatory areas within the ambit of the TGA's responsibilities. This is an area where there is scope to further integrate complaints management into broader areas of regulatory compliance (see Recommendation 6).

With the above considerations in mind, the Review is of the view that the TGA is well-placed to be the single-body for managing public complaints about the advertising of therapeutic goods. The management of all advertising-related complaints by the TGA has reduced complexity and confusion for the public in creating a single authority to submit complaints through. This is supported by a breadth of online information for the public on how to submit complaints.

Recommendation 3: Maintain TGA as the single body

The Government should maintain the TGA as the single body responsible for implementing a complaints management process about the advertising of therapeutic goods to the public. The TGA should continue to build its complaints handling capability and systems as outlined in Recommendations 4 to 7.

3.2.3 The Complaints Management System that has been Established

The TGA has developed a range of procedures to manage public complaints about therapeutic goods advertisements. This includes a six-stage process for managing complaints, comprising: acknowledgement of the complaint; initial assessment for suitability of TGA management; triage into priority categories or referral of the complaint; investigation of the complaint based on priority; action in response to outcomes of investigations; and publishing the complaints outcome. In treating complaints, a risk analysis is conducted to triage into four priority categories. The risk analysis considers whether the advertiser has breached the advertising legislation before and the seriousness of the breach. Throughout the six-stage process, the complainant is provided with notifications on the categorisation, assessment and outcomes of their complaint.

At the time of this Review, the TGA, with the help of an external provider, was undertaking a comprehensive management initiated review (referred to throughout as 'the concurrent management initiated review') of the complaints management framework, particularly of the processes that support compliance outcomes using a risk-based approach. With this in mind, this Review did not focus on the granular detail of complaints management processes, but focused on the higher-level strategic

[12] Department of Health, *Annual Report 2018-19*, 7.

[13] *About the TGA, Who we are & what we do*, TGA Website: https://www.tga.gov.au/who-we-are-what-we-do

elements and design of the system of complaints management in achieving compliance outcomes.

Across all stakeholders, there was a view that there has been an unexpectedly high volume of complaints, far surpassing the volumes previously processed by the CRP. This has resulted in a large and growing backlog of complaints to be actioned and resolved. There is a common understanding that there is a gap between the current TGA resourcing for complaints resolution and the requirement to review and respond to all complaints individually.

The focus of the complaints handling team has been on designing and operationalising processes in line with better practice for complaints management. This is in line with the commentary in the MMDR Review Report which referenced the Commonwealth Ombudsman's *Better Practice Guide to Complaints Handling* as an example model with which to base procedures. The MMDR Review Report also highlighted that 'complaints management processes should include prompt acknowledgement of complaints; keeping complainants informed of progress; providing a remedy where appropriate; and advising on options for the review of decisions'.

However, this Review acknowledges that the complaints handling principles and associated processes described in the MMDR Review commentary and the Ombudsman's guide, are more suited to managing administrative complaints made about the internal affairs of the agency to which the complaint is made. In these sorts of complaints, agencies undertake a service-oriented approach to create and maintain relationships with the individual complainant, with all complaints fully investigated and responded to individually. This reflects a resource-intensive exercise, with a focus on individual resolutions rather than systemic industry or market compliance outcomes. The key performance indicators for advertising complaints management (discussed further in Section 3.5 of this report), which measure time taken to action and close complaints, also reflect a focus on the resolution and timeliness of handling individual complaints, rather than achievement of compliance outcomes.

3.2.4 The Need for More Strategic Approach to Compliance

It is more common for Commonwealth agencies with similar regulatory functions, to use public 'complaints' as 'tip-offs' that contribute to the combined intelligence of the agency to use for compliance activities. Using public intelligence to contribute to the pool of information available to the regulator to triage, analyse, and respond, allows for more holistic analysis of risks and priorities, and strategic treatment against trends of suspected non-compliance across industry or products. This method presents a more strategic use of finite resources.

In the online record of complaints reviewed in late April, the Review noted that out of a total 3068 records, there were 7 critical priority cases, 3 high priority cases, 117 medium priority cases, and 2941 low priority cases. This reflected a trend where individual cases categorised as 'critical' or 'high' make up a very small proportion of total complaints. This poses the risk that cases that are being categorised as 'low' or 'medium' on an individual level, could potentially be considered 'high' or 'critical' if analysed at a more aggregate level. A more cost-effective and efficient method of achieving compliance outcomes would be to consider all complaints that come into the TGA and amalgamate them into a pool of information available to the regulator. From there the TGA would be able to consider appropriate responses for managing impact to consumers and act accordingly.

Setting compliance priorities provides a useful base to guide strategic consideration and response to public complaints and other intelligence available to a regulator. Compliance priorities facilitate a strategic risk-based approach to delivering effective compliance and changing industry behaviour. Regulators typically select priorities on an annual basis with consideration of industry behaviour and the public interest or community impact. This is the case with regulators such as the Australian Communications and Media Authority (ACMA) and the ACCC that develop both annual priorities and 'enduring' priorities. These agencies also publish their compliance priorities in the interests of transparency and alerting the public and industry of activities to be targeted.

The concurrent management initiated review also considered these more strategic design elements of using complaints as tip-offs in a compliance framework and provided in-depth analysis and recommendations regarding the changes required to supporting processes, which have been

accepted by the TGA.

Recommendation 4: Strategic Re-set

The TGA should use the recommendations made in the concurrent management initiated review to reset the complaints management system to focus on achieving improved compliance outcomes through intelligence gathering, strategic triaging, and integrated response.

Recommendation 5: Compliance Priorities

The TGA should develop and publish Compliance Priorities which are reviewed annually. In setting these priorities the TGA should develop factors to be considered, consult with stakeholders, and focus on consumer benefit. The Compliance Priorities should inform key performance indicators (KPIs) and reporting (Recommendations 14 and 15).

3.2.5 Further Integration of Complaints with Other Regulatory Areas

Throughout the Review, stakeholders from other compliance arms of the TGA shared feedback that treatment of advertising complaints is not fully integrated with other compliance functions of the TGA. The complaints management function, as a central point of contact for the regulator with the public, can be particularly useful in producing powerful insights on areas that are of most concern or exposure for consumers.

As mentioned above, the direction forward for management of public complaints is to use them as sources of public intelligence that are analysed and responded to more strategically with consideration of other information available to the regulator. In support of this strategic approach, there is scope for further collaboration with other compliance investigations and enforcement areas, or educational efforts of the TGA. An advertising complaint may indicate associated import, supply, production, efficacy or commercial issues which have to be investigated, or may highlight areas for educational activity. Trends on complaints may also inform identification of education priorities (see Recommendation 12), or the performance of compliance and educational efforts (see Recommendations 14 and 15).

Recommendation 6: Integrated Information - TGA

The TGA should work to further integrate the management of complaints about advertising of therapeutic goods with other relevant areas within the TGA. This could be achieved by developing information-sharing practices across the TGA, to support:

- the compliance priorities across the TGA's regulatory areas; and
- identification of trends identified across high-volume complaints regarding products, types of therapeutic claims made, manufacturers, or suppliers.

Further, complaints about advertising of therapeutic goods can be of relevance to other regulators (for example, food products making potentially therapeutic claims may be relevant to Food Standards Australian New Zealand (FSANZ), or therapeutic goods that are also consumer goods may be relevant to the ACCC. Currently, the triaging process considers whether the TGA should refer complaints to other agencies where it is not within the TGA's jurisdiction. There are also informal arrangements and ad hoc communications with FSANZ and the ACCC to discuss compliance issues of common interest. However, there may be instances where the boundaries of jurisdiction between regulators are blurred, or where complaints will lie within the TGA's jurisdiction but will still have learnings or issues that are relevant to other regulators. In these circumstances, without formal arrangements for communication and information-sharing, there is a chance that complaints are handled with a siloed approach. This siloed approach to managing complaints with cross-regulatory

implications may present a missed opportunity to inform other regulators of issues or risks within their jurisdiction, and limit more holistic protection of consumers across regulated areas.

Recommendation 7: Integrated Information – Other Regulators

The TGA should co-develop information-sharing protocols to facilitate active information-sharing with relevant regulators, including FSANZ and the ACCC regarding complaints and trends on relevant cross-sector products or issues. This should be supported by focused engagement with regulators (Recommendation 21) to define information-sharing needs and priorities.

3.3 Broadened Sanctions and Penalties

3.3.1 Background

The shift to a more self-regulatory regime for advertising therapeutic goods has been presupposed on further protections for consumers, one of which was strengthening sanctions and penalties available to the regulator. In Recommendation Fifty-Seven of the MMDR Review, the Expert Panel recommended the broadening of the range of investigation and enforcement powers. In the relevant commentary, the Expert Panel noted that the need to update and increase the sanctions is particularly important in the context of a move to a more self-regulatory regime. In the Government Response to the MMDR Review, this recommendation was accepted, and it was noted that "broadening enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements, and deter inappropriate and misleading advertising of products".

Broadened sanctions and penalties were introduced as part of amendments to the Act through the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*. The amendments came into effect on 6 March 2018 and introduced:

- a new tiered offence regime for prohibited advertising, consisting of a high-level offence with an aggravating element (has resulted in, will result in, or is likely to result in harm or injury to any person), an ordinary offence, and a strict liability offence (where intent does not need to be demonstrated). This tiered regime has tailored penalties to match the risk they pose in causing harm or injury;
- inclusion of new civil penalty provisions for prohibited advertising; and
- new powers for the Secretary of the Department to issue public warning notices, directions, and make enforceable undertakings.

The explanatory memorandum for these amendments echoed the intended outcomes expressed in the MMDR Review and Government Response for broadened sanctions and penalties "to more effectively deter inappropriate and misleading advertising of therapeutic goods". Over time, deterrence should result in greater responsibility being with industry for effective self-compliance.

3.3.1.1 Compliance and Enforcement Tools that Support Broadened Sanctions and Penalties

To give effect to these broadened sanctions and penalties, the TGA has a range of compliance and enforcement tools, which reflect a sliding scale of graduated responses to breaches. At a summary, these tools comprise the following.

- Educational letter or educational visit: The TGA may send educational material, in the form of an 'obligations letter' to the advertiser. The advertiser will be asked to make appropriate changes to their advertisement in order to comply with relevant therapeutic goods advertising requirements and to implement procedures to avoid future non-compliance. In some situations, the TGA may visit the advertiser to provide educational information.
- Referral: The TGA may refer any practice concerns to state or territory health departments, the ACCC and/or the Australian Health Practitioner Regulatory Agency (AHPRA).
- Substantiation notice: Substantiation notices may be used to request information to establish the person responsible for an advertisement or to obtain information to substantiate claims made in an advertisement. If an advertiser fails to comply with a substantiation notice, the TGA may use other more onerous enforcement responses.
- Suspension or cancellation of therapeutic goods from the ARTG: The Secretary may suspend or cancel a therapeutic good from the ARTG on the basis of advertising non-compliance. Suspension or cancellation is limited to cases where the sponsor of the therapeutic good is responsible for the non-compliant advertising.
- Public warning notice: Where the TGA suspects that there has been a breach of the legislation

in relation to the advertising of the therapeutic goods, a written notice can be issued to the public containing a warning about the advertised goods, provided it is satisfied that it is in the public interest to do so. The TGA can also issue a public warning notice if an advertiser has failed to comply with a substantiation notice and it is in the public interest to do so.

- Enforceable undertaking: The TGA may accept the offer of an enforceable undertaking from an advertiser who believes they have, or are likely to have, breached an offence or civil penalty provision. If the TGA accepts the undertaking, the advertiser is bound by the terms agreed to in the undertaking. A breach of the terms can result in the matter being referred to the Federal Court.
- Direction notice: The advertiser may be directed by the Secretary of the Department to take steps to address non-compliant advertising and/or retract or correct the advertising. Failure to comply with a direction may result in criminal prosecution or civil proceedings.
- Infringement notice: Infringement notices will have a maximum 12 penalty units for an individual or 60 penalty units for an incorporated body for non-compliant advertising. This attracts fines of $2,520 for an individual and $12,600 for an incorporated body. Multiple infringement notices can be issued, depending on the number of non-compliances identified.
- Civil action: If a court finds that an advertiser has failed to comply with the relevant advertising requirements or directions, it can impose civil penalties up to a maximum of 5,000 penalty units for an individual; or 50,000 penalty units for a body corporate for each contravention.
- Criminal prosecution: If convicted by a court, it can impose penalties of: imprisonment for 5 years or 4,000 penalty units, or both for aggravated offences; imprisonment for 12 months or 1,000 penalty units, or both; and 100 penalty units for strict liability offences. Offences by corporations can also attract a 5x multiplier. Multiple advertising offences may be pursued, and there is also provision for continuing offences (i.e. increased penalties for each day of non-compliance following notification of compliance issues).

The TGA may take the above actions, or a combination of the above actions where advertising is deemed non-compliant. The TGA's overarching approach to compliance is described in their 'Regulatory Compliance Framework'[14]. This framework outlines an intention for the TGA to use enforcement actions proportional to the severity of the non-compliance and the advertiser's attitude towards compliance. The large breadth of possible actions allows the TGA to have an appropriately tailored response to any possible breach of the Code or Act.

The guidance on 'complaints handling for the advertising of therapeutic goods to the Australian public'[15] and associated Compliance Toolkit notes that there are three tiers for graduated use of the compliance and enforcement tools (shown in the diagram on the following page). At the lowest level there is 'voluntary compliance' which utilises educational materials to aid advertisers with voluntarily complying with the advertising requirements. Following this there is 'assisted compliance', where the TGA inform and / or provide warning of the consequences of failing to comply to advertisers who may be unaware of, or fail to understand how to comply with the advertising requirements. Finally, there is 'regulatory compliance' which includes the use of the powers outlined in the Act to enforce regulatory compliance. In this instance the TGA can issue a substantiation notice, cancel or suspend the relevant therapeutic goods from the ARTG, or use a public warning notice to draw attention to misleading advertising or information being disseminated to the public. At this level, the TGA may also seek an injunction, issue an infringement notice, enforceable undertaking, civil penalty and finally, pursue criminal prosecution.

[14] *Compliance Management*, TGA Website: https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management

[15] *Complaints Handling for the Advertising of Therapeutic Goods to the Australian Public*, TGA Website: https://www.tga.gov.au/publication/complaints-handling-advertising-therapeutic-goods-australian-public

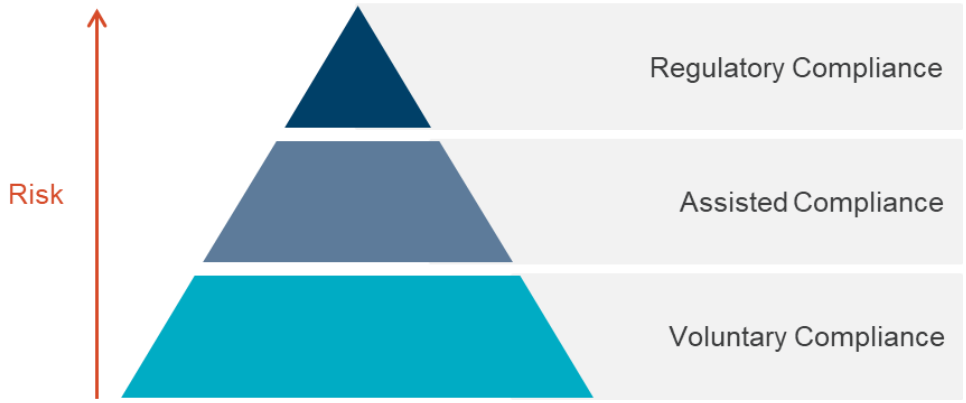

Figure 1: TGA's graduated responses to compliance risk

3.3.2 Effectiveness of the Amendments Broadening Sanctions and Penalties and Enforcement Tools

The feedback received during consultation with staff and stakeholders indicated widespread agreement that the broadened sanctions and penalties introduced are beneficial in achieving compliance outcomes, and are necessary to adequately protect consumers and deter inappropriate or misleading advertising. Departmental staff were also of the view that the broadened sanctions and updated enforcement tools provided the full suite of necessary mechanisms to support compliance and to deter prohibited advertising.

However, there was some opposition to the view that broadened sanctions and penalties were beneficial. Some stakeholders representing industry and media indicated that the broadened sanctions and penalties, combined with what they perceived as a broadened definition of 'advertise' in the Act, was negatively impacting industry. For example, industry peak body representatives suggested that some sponsors were removing all product information from their websites over fears that it may be perceived as non-compliant advertising. Stakeholders suggested that industry's risk-averse behaviour was limiting the genuine product information available to consumers to support informed decision-making.

The Review agreed with the comments made in the MMDR Review and Government Response and the representations of stakeholders that broadened sanctions and penalties are necessary for protecting consumers through deterring inappropriate and misleading advertising of therapeutic products. Without enhancements to sanctions and the powers to take action in response to breaches, there is a risk that the self-regulatory scheme may lead to greater non-compliance. In this way, the Review commends the amendments to the Act to broaden sanctions and penalties and the breadth of enforcement tools available to the TGA.

The Review notes the stakeholder concerns raised regarding the reaction from industry, but is of the view that any additional caution advertisers need to take in managing compliance with the Code requirements should be seen in the light of the need to provide protections to consumers. Rather, any change to industry behaviour that increases a cautionary attitude is in line with the intent of the amendments to deter non-compliant advertising. This is particularly the case with the move to a self-regulatory regime, wherein the onus shifts onto industry to act within the boundaries of the law and regulations. Further, the ongoing high number of complaints about misleading or inappropriate advertising that continues to be confirmed as valid, suggests that industry is not necessarily so risk-averse or fearful of the broadened sanctions and penalties that have been designed.

3.3.3 Effectiveness of the Use of the Broadened Sanctions and Penalties and

Enforcement Tools

In terms of using the broadened sanctions and associated enforcement tools, there was general consensus between Departmental staff and stakeholders that they were being underutilised. Consumer groups expressed that enforcement actions are not being used effectively to deter behaviour, with an overuse of educational obligations letters, and with a time-consuming process for enforcing harsher penalties.

The TGA feedback noted that while the regulator now had all the tools required to apply increased sanctions and penalties, historical case outcomes identified during this Review suggested limited uptake of these broadened measures by Departmental staff to the expected degree. Departmental staff indicated there may be a tendency to use an 'assisted compliance' approach, where compliance officers felt their duty was to help industry to self-comply, rather than enforcing compliance or punishing non-compliant advertisers outright. Further, staff also noted the potential to further use publicity and media regarding the compliance enforcement actions the TGA had taken to increase the reach of regulatory messaging and improve deterrence. Later discussions with staff noted this approach was changing in the COVID-19 environment (discussed further in Section 3.3.5 of this report).

Some industry stakeholders and Departmental staff were of the view that the broadened sanctions and penalties had changed industry behaviour. This was believed to be demonstrated in members of the regulated community showing awareness and knowledge of enhanced penalties and a genuine desire to comply during conversations between industry representatives and Departmental staff.

To assess the use of broadened sanctions and penalties, the Review considered the complaint actions and responses published on the TGA complaints database up until late April 2020. At the time of review, the database showed 3,068 records, of which 2,316 response actions were considered to fall within the 'voluntary compliance' or 'assisted compliance' tiers of graduated responses. These included:

- 60 cases with action "Initial contact with advertiser requiring action";
- 28 cases with action "Initial contact with advertiser requiring immediate action";
- 1684 cases with "Regulatory Obligations Letter"; and
- 544 cases with action "TGA requested removal of advertising from online platform".

Many other cases had no action undertaken as the advertisement was no longer active or had been referred internally or externally for review.

Overall, the Review observed that the TGA tended to adopt a 'light-touch' approach to using more onerous sanctions and penalties. Our review of the complaints outcomes database even found this to be the trend for critical priority cases. In all seven critical priority cases that were on file in late April 2020, the TGA had made contact with the advertiser in the first instance and provided the opportunity to self comply. In one case, three weeks after the initial contact advising the advertiser to comply, the TGA issued a directions notice directing the advertiser to cease making certain claims and to cease certain advertisements. In all the other six cases, the case was resolved with the advertiser removing the non-compliant advertising. According to the database, in some of these cases, the TGA took up to three months from the time of initial contact to confirm that the advertiser had removed the non-compliant advertising.

Review of high priority cases showed a similar trend. At the time of review of the complaints database, there were three high priority case records. In all cases the TGA had either made 'initial contact' or issued a 'warning letter' 'requiring immediate action'. In one of these cases, the TGA took additional graduated actions in response to continued non-compliance of the advertiser. The TGA issued a directions notice, and then commenced Federal Court civil penalty proceedings against Peptide Clinics Australia (Peptide Clinics Pty Ltd) in November 2018 for alleged breaches of the Act and the Advertising Code.

At the time of the Review, the Peptide Clinics case was the only case that had been taken to court

proceedings and closed. Federal Court proceedings were commenced by the Secretary for multiple suspected breaches of the Act and Code related to inappropriate or misleading advertising or advertising with reference to prohibited or restricted representations without approval or permission. During court proceedings, Peptide Clinics went into liquidation. However, the TGA continued to pursue the matter to obtain a court ruling on the case and utilise the precedent in future.

On 23 July 2019, the Federal Court found in the TGA's favour and applied a civil penalty to Peptide Clinics Australia Pty Ltd totalling $10 million. The significant financial penalties provide useful insight on the judiciary's position on the regulatory sanctions and penalties, give the TGA precedent to guide future cases, and provide the TGA with an example to use as a deterring reminder to industry that non-compliant advertising to the public can lead to significant consequences.

While the Peptide Clinics case provides a useful and powerful precedent for the TGA, the review of the complaints database at the time of analysis for this Review showed that in most cases, the TGA rarely used more serious penalties or enforcement responses, even when they would have been appropriate. Instead, compliance officers favoured an 'assisted compliance' approach, by giving the advertiser the opportunity to self-comply with regulations. In this way, the focus of compliance and enforcement actions at the TGA in response to advertising breaches tends to reflect an 'industry-service' approach. This approach is not aligned with the original intent of the amendments, which were designed to support the move to a more self-regulatory regime. The result has been significant resources applied to assist industry. The shift that is needed is to an industry putting more effort into the education of its members with the aim of achieving self-compliance and a regulator applying sanctions and penalties where these are warranted.

This 'industry service' or more 'light-touch' approach from the TGA may be undermining deterrence and may embolden risk-taking behaviour in industry with respect to compliance. Given that published data shows the TGA to be opting for 'assisted compliance' in the first instances for most cases, this approach creates the risk that advertisers may see the profit of misleading advertising as outweighing the risk of being detected or being punished in the event that it is. Such opportunism in industry could undermine the intended deterrent effect of the broadened sanctions and penalties.

3.3.4 Refocusing the Application of Sanctions and Penalties

The above analysis suggests that the enforcement activities of the TGA need to be refocused. As compared with the original intent of the MMDR Review and legislative amendments, there appears to have been a shift towards providing a service to industry, in aiding compliance and supporting self-regulation through educational activities and obligations reminders. Ideally, this should now be shifted towards a more direct focus on outcomes for public health and safety, and supporting industry compliance with effective and timely action directed to non-compliant advertisers.

This vision of the way forward was consistent with the views of the TGA's senior executives regarding use of broadened sanctions and penalties. In this regard, the appetite for stronger regulatory responses in the advertising compliance section needs to be clearly communicated to build internal confidence in more readily applying the full range of compliance and enforcement actions. Further skills development of staff in the regulatory and compliance arms, including developing an understanding of what is done by similar regulators, will assist in paving this way forward.

Recommendation 8: Regulatory Posture

The TGA should develop and promote a clear regulatory position on its approach to the use of the broadened sanctions and penalties to protect public health and safety. This should include the balance of focus between educative and punitive responses, and the principles that guide the use of more punitive compliance tools. The position should be clearly communicated to Departmental staff involved in advertising compliance and other stakeholders.

Recommendation 9: Skill Development

The TGA should provide focused skills development on compliance and enforcement practice to support the advertising compliance team in implementing the TGA's regulatory position. This may include developing an understanding of case management and enforcement response at other regulators, and sharing lessons learned.

3.3.5 Learnings from the COVID-19 Environment

As the testing and consultations completed as part of this review wrapped up during the COVID-19 pandemic, there was limited opportunity to conduct detailed analysis on the TGA's response in this environment. However, it is worth noting that the TGA has dealt with several high-profile enforcement actions for cases relating to misleading and inappropriate advertising in relation to COVID-19.

In consultations conducted towards the end of the review, Departmental staff indicated that there had been an internal shift in attitude, towards much more hardline enforcement in response to the more serious risk atmosphere presented by misleading advertising around COVID-19 claims. In recent times, there has also been increased media coverage of inappropriate and misleading COVID-19 related therapeutic goods advertising, and the fines that have been handed out. This has been supported by increased use of multiple public notices, particularly to warn consumers about illegal advertising about COVID-19. The Departmental staff comments, a high-level overview of information from the compliance database, and the media coverage of recent cases indicate that there has been an increase in the timely use of stronger enforcement responses, such as fines and public notices, with regard to COVID-related advertising.

The TGA is now well-placed to learn valuable lessons from this period regarding more quickly respond to misleading advertising with more serious penalties in order to protect public health and safety.

Recommendation 10: COVID-19 Response

The TGA should reflect on the lessons learned from the COVID-19 experience in responding to non-compliant advertising with sanctions and penalties in a timely manner. The COVID-19 experience also has useful learnings regarding the use of media and publicising the compliance actions taken by the TGA to raise awareness of the negative consequences of using non-compliant advertising.

3.4 Comprehensive Consumer and Industry Education Program

3.4.1 Background

As part of the MMDR Review, the Expert Panel considered that a formal sponsor education program was an essential method to encourage compliance, particularly with a move to a more self-regulatory regime without a pre-vetting process.

Recommendation Fifty-Eight of the MMDR Review, which was accepted by Government, compelled the TGA to facilitate *the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.*

Further, the explanatory memorandum to the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017* noted that the changes to the advertising framework will be accompanied by an education program to assist industry, sponsors and advertisers in understanding their obligations under the new regulatory framework so that they have the appropriate information to allow them to comply with the advertising requirements.

These statements highlight the intent for the TGA to design a program of guidance and education to provide an early, prevention-focused, and cost-effective way to inform stakeholders of regulatory advertising requirements and obligations, and to build the knowledge and skills to enable improved and self-managed compliance.

3.4.2 Informative and Reactive Educational Efforts to Date

Across all stakeholders consulted, there was a shared understanding that the TGA had been effective in developing and distributing baseline information about the advertising framework and Code requirements, and taking effort to respond to areas that had been identified needing further guidance. However, stakeholders provided mixed feedback of whether the educational material was appropriate to their needs.

Some stakeholders commented that there was inadequate specific educational material about the application of the Act and the Code and highlighted a need for more nuanced examples of advertising materials. Other stakeholders expressed the view that the TGA provides adequate support (and in some cases, over-invests) in responding to stakeholder requests for educational material. These stakeholders expressed the view that the current approach to education may be causing industry to be over-reliant on the TGA to provide guidance and advice on detailed areas of law or advertisements relevant to specific stakeholders, and that the expected role and responsibility on industry to move to increased industry based education and compliance had not yet evolved.

The documentation provided during the review indicated that there is a large amount of educational and guidance material released to industry. This included through online information disseminated through the Advertising Hub website, the development of legislative guides and ‘frequently asked questions’, and other workshops and presentations delivered to relevant groups. However, there was limited evidence of a strategic approach to providing education and guidance to industry and consumers, as a program of work. This included limited strategic planning around defining the priority topics for education for industry and consumers, including the rationale. Additionally, there was limited assessment of the most effective and efficient methods for reach and timing. To date, this has resulted in the primary focus on educational effort being targeted towards development of baseline guidance material, followed by a largely reactive approach to industry enquiries and requests. In this regard, the educational initiatives of the TGA are well-poised to move into a more strategic phase that also treats industry as responsible and accountable ‘partners’.

3.4.3 Moving to a More Strategic Approach to Education

While the education activities to date (Phase 1) have prioritised informing and consulting with industry, Phase 2 should emphasise a strategic approach to further involve, collaborate with, and empower

industry, and target consumer awareness. This approach of working with industry as responsible and accountable partners, and improving community awareness of the role and powers of the TGA will support further maturation of the education program.

A key component of implementing a strategic approach to the TGA education program is to discern educational priorities. The educational priorities for the advertising framework currently listed on the TGA website tend to be a list of activities delivered rather than priorities that are outcomes-focused or driven by objectives. Future priorities should be defined based on the TGA's analysis of particular areas of confusion or need with regards to clarity of the advertising framework. Additionally, these priorities should consider industry capability, and the protection of public health and safety.

The education priorities should also tie in with broader advertising and the TGA compliance priorities. An agreed set of priorities should guide a more strategic outlook for the use of the TGA's resources to deliver education to achieve goals for consumer awareness and industry compliance. These priorities should be reviewed on a periodic basis to maintain relevance and respond to changing needs and the regulatory environment. The information in the complaints handling database could also be analysed for trends to highlight gaps in knowledge and understanding within the industry. These identified gaps could also inform the educational priorities for the TGA. Clear communication of these priorities to industry should also help to manage industry expectations of the TGA's education program. This, in turn, should rebalance the responsibility between the regulator to provide guidance and the industry to learn and self-educate in order to achieve compliance.

Recommendation 11: Education Strategy

The TGA should develop an Advertising Framework Education Strategy with clearly defined priorities that are aligned to Compliance Priorities and consumer outcomes.

Recommendation 12: Education Priorities

The TGA should develop Education Priorities to more effectively target educational activities. In setting these priorities the TGA should develop factors to be considered, consult with stakeholders and focus on consumer and industry benefit. The education priorities should be publicised and clearly communicated to stakeholders. The priorities should be reviewed annually.

3.4.4 Agreeing and Developing Key Messaging

The Review also noted an opportunity for the TGA to consider working with expert groups such as the Behavioural Economics Team of the Australian Government (BETA) to effectively convey educational messages to advertisers that encourage compliance with the advertising framework. Effective communication and messaging through educational material will be useful in connecting the policy intent of the advertising framework to industry behaviour and may assist in rebalancing the responsibility for education, achieving a more collaborative and shared approach between the regulator and industry to effective consumer communications.

3.4.5 Strategic Use of External Channels

As noted above, a large portion of educational efforts following the development of baseline guidance has been used in response to industry requests and enquiries. Feedback from stakeholders and review of educational materials supported the view that until recently, educating industry has been the predominant focus of the guidance materials and activities, rather than having a targeted focus for each of industry and consumers. Both industry and consumer stakeholders noted that the Advertising Hub is a useful resource for finding information about the advertising framework. However, there had previously been feedback that the Advertising Hub was not easily navigable or searchable, and at the time of the Review, the TGA was in the process of redesigning the Advertising Hub.

Consultation with stakeholders indicated that an area for development and the TGA's future direction would be to focus on drawing consumer attention to the TGA's compliance work. Developing partnerships with media to pursue this direction will help broaden the reach of the TGA's advertising compliance messaging to the public. More recent educational materials and media coverage of the TGA advertising regulatory response during the COVID-19 pandemic reflect an increased focus on raising consumer awareness and education. In this regard, the Review noted an opportunity to use the COVID-19 experience in more extensively using the media and publicity to raise consumer awareness of the TGA and the regulation of advertising of therapeutic goods.

3.4.6 Lessons Learned from the COVID-19 Response

As noted above, during the response to the COVID-19 pandemic, there was increased media coverage to alert consumers about advertising of therapeutic goods claiming to prevent or cure the disease. The Review noted that the response to COVID-19 also demonstrated a more strategic and integrated approach to compliance and advertising framework education. This included a clear and shared understanding of priority – to protect consumers from misleading and inappropriate advertising and to support advertiser compliance with regards to advertising of COVID-19-related therapeutic goods. From this shared understanding of priority, targeted educational materials and media publicity about COVID-19 advertising were developed. The Review notes that these practices should be considered and reflected on in future development of the maturity of the education program in support of achieving compliant therapeutic goods advertising.

Recommendation 13: COVID-19 Communications

The Review recommends that the TGA use the COVID-19 experience, particularly in priority-setting and developing activities and mobilising the media in support of agreed priorities, as part of developing a more strategic approach to its education program.

3.5 Key Performance Indicators for Complaints Management

3.5.1 Background

Performance measures and associated indicators are a key component of tracking progress towards stated goals and evaluating performance in a transparent way, for all organisations. As a public entity with the objective to safeguard and enhance the health of the Australian community, performance measures and associated indicators are a particularly useful tool to demonstrate how resources have been applied to achieve the agency's purpose and public health outcomes.

The MMDR Review also made reference to developing performance measures for complaints management. In its commentary regarding establishing a new complaints management system, the Expert Panel stated that "[r]egular and ad hoc reporting should be publicly available including qualitative and quantitative measures of performance, and the system should be reviewed regularly to assess its effectiveness over time".

In the MMDR Review's commentary about complaints management, the timeframes for case resolution under the CRP were highlighted as lengthy, and the suggestion was made that triaging strategies could considerably reduce the timeframes for processing. The MMDR Review also drew attention to the timeliness information of the Australian Advertising Standards Bureau and the UK Medicines and Healthcare products Regulatory Agency (MHRA) Advertising Standards Unit. Furthermore, the MMDR Review indicated that the new complaints resolution body should adopt the best practice principles such as those set out in the Commonwealth Ombudsman's *Better Practice Guide to Complaints Handling*. This included consideration of 'efficiency', wherein complaints are resolved quickly and escalated appropriately.

In implementing the MMDR Review recommendation which emphasised timely resolution of complaints, it is understandable that the performance measures and associated key performance indicators (KPIs) developed by the TGA for the complaints management process are focussed on timeliness and milestones.

Target timeframes for complaint handling		
Category	**Time to action**	**Time to close**
Low	95% in 14 days	90% in 20 days
Medium	95% in 40 days	90% in 90 days
High	95% in 20 days	90% in 90 days
Critical	100% in 10 days	90% in 60 days

Figure 2: The TGA's current KPIs for complaints handling

The current KPIs for the complaints management system are a series of timeliness measures with targets to resolve cases in a set number of days. It uses a risk-triaging basis, wherein cases deemed to be of higher priority have shorter timeframes to 'action' and 'close' cases. In order to meet the milestones, the TGA has a series of required processes or assessments to make, and associated updates it must provide to the complainant for each case.

3.5.2 The Fitness for Purpose of the Current Performance Measures

Since these KPIs were implemented, the TGA has reported an unexpectedly high volume of complaints. The *Therapeutic Goods Advertising Compliance 2018-19 Annual Report* showed that the timeliness measures for complaints handling was only met for low-risk case closures and high-risk

case actions and closures. For the remaining five of the eight categories, the timeliness targets were not met. Even though the TGA has been processing thousands of complaints each year, the current design of the complaints handling system is not coping with the volume of complaints received given the obligation to respond to every complaint that is submitted.

The concurrent management initiated review on the TGA complaints handling processes conducted detailed analysis regarding the complaints caseload and trends on actioning and response. Noting this, the detailed data underpinning the TGA reporting against these performance measures will not be discussed here and was not within the scope of this Review. Rather, this Review focused on assessing whether these performance measures and KPIs are fit for purpose and effective in demonstrating achievement of outcomes or objectives.

The broad consensus from Departmental staff and stakeholders was that these performance measures are not fit for purpose as they do not show achievement of advertising compliance outcomes. Current performance measures may pose a risk for driving behaviours that are not consistent with the goals of the TGA's complaints management system. It was suggested that the current KPIs which focus on timeliness of progressing complaints through 'actioning' and 'closing' cases may lead to an increased risk that compliance officers prioritise deadlines over consideration of broader public health and compliance outcomes. This also poses the risk that compliance work focused on the lower-end of the risk priorities or lower-complexity cases that can be completed quickly within target timeframes. This may allow teams to keep up with performance measures in certain cases, but does not align with the desired outcomes of the function.

Analysis of the complaints management performance measures against the ANAO's criteria for implementing effective annual performance statements[16] showed there were gaps in the current benchmarks. The KPIs focus on quantitative measures of 'output' rather than providing qualitative assessments or indications on the achievement of compliance outcomes. The performance measures provide limited commentary on the compliance outcomes of cases, limited analysis or 'pulse check' on overall market compliance, or changes in advertising behaviours using the resolution of complaints or other information available through the complaints management function.

Additionally, the design of these KPIs, and the commentary in reporting against the measures could more clearly demonstrate alignment to the overall goals and priorities of the TGA and the Department. The performance measure, in the way it is currently designed and reported, tends to show a single process and its output rate, in isolation from its compliance function and wider regulatory mandate.

3.5.3 Redeveloping Performance Measures

For the way forward, the Review envisions a more outcomes-focused suite of performance measures and indicators and public reporting of results. The Review acknowledges that designing measures and indicators that reflect on compliance outcomes is an extremely difficult task, and is an area that regulators repeatedly struggle with. However, a useful starting point may be to consider the information available through the complaints database and the trends in complaints and industry behaviour that it may indicate. This may provide useful information with which to design a set of new performance indicators which looks at compliance outcomes more broadly across advertising regulation. This may include:

- comparing complaints information and identifying complaints trends over time (overall, and in priority or 'problem' areas);
- reviewing use of (or proportions of the use of) the full suite of enforcement responses;
- reviewing the rate of resolution of cases; and
- reviewing complaint trends against compliance and educational priorities (for example, to

[16] The Auditor-General – Australian National Audit Office (ANAO), *Auditor-General Report No.17 - 2018–19, Implementation of the Annual Performance Statements Requirements 2017-18* (2018)

gauge whether educational efforts have lowered complaints in that area, indicating changed industry behaviour).

Noting that timeliness was a key intended benefit of the reform to the complaints handling function, some reflection on the timeframes for resolving cases may still be useful.

The concurrent management initiated review of the complaints management process made similar observations to the commentary in this review regarding performance measures. That review has also made a range of recommendations and provided example indicators which the TGA may use in shaping the future direction of relevant performance measures and indicators.

Recommendation 14: Indicators for Outcomes

The TGA should redevelop a suite of advertising compliance performance measures and indicators which focus on priorities and outcomes rather than processes and deadlines.

In considering a new approach to measures and indicators, the TGA should use the recommendations made in the concurrent management initiated review of the complaints management process.

3.5.4 Transparency and Publicising

The TGA has publicised the current complaints management performance measures through its website and publishes an annual report on Therapeutic Goods Advertising Compliance. These publishing efforts demonstrate good transparency and accountability for performance. The TGA should continue publicly sharing measures and indicators of performance, and assessments of whether they were met.

Recommendation 15: Performance Reporting

Once the TGA has developed new performance indicators for advertising compliance management, the TGA should publicise the measures, and report performance against the measures using the TGA website and annual reporting and media channels.

3.6 Stakeholder Engagement Activities

3.6.1 Background

Stakeholder engagement is a key element of good governance and effective policy implementation. This is emphasised in relevant public sector better practice guides such as the ANAO's *Better Practice Guide: Public Sector Governance (2014)*, and the Department of Prime Minister and Cabinet's advice on effective 'Policy Implementation' and associated toolkits. Engaging with stakeholders and involving them in design and delivery of policy and projects allows agencies to gain insights into different and relevant perspectives, expertise and experiences, which can also help in the identification of opportunities and risks.

Engaging with stakeholders, including with those from areas to be regulated, is an important and powerful tool particularly in the context of making changes to a regulatory regime. Engagement helps the regulator to identify and reflect on relevant considerations in the design and implementation of changes, and to obtain buy-in for the updated regulatory regime. This is reflected, for example, in the Government Response to Recommendation Fifty-Six of the MMDR Review, which stated:

> *The Commonwealth accepts Recommendation Fifty-Six… To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints management process.*

3.6.2 Stakeholder Consultation Methods

Across the TGA, there is wide stakeholder consultation with industry. With regards to advertising regulation, the Review noted that additional engagement outside of the regular TGACC forums, for example on Code amendments or for educational activities, was taking place on an informal basis. The Review noted that there was opportunity for further planning and strategy in engaging with stakeholders outside of the TGACC.

Similar to our commentary regarding the education program, engagement activities to date have been operating in a largely reactive approach to industry enquiries and requests. So far there has been limited identification of the purpose and priorities or principles that guide which stakeholders to engage, for example, using risk-based analysis to form a view on who to engage with. There has also been limited identification of the timelines and methods for engagement with identified stakeholders. This means the TGA may not be identifying or engaging with the most relevant stakeholders outside of the TGACC (for example media channels to publicise the TGA's actions), or aligning resources to the most pressing areas or opportunities for stakeholder engagement. A strategic approach to engaging with stakeholders will support maturation of the regulation of therapeutic goods advertising and effective and efficient use of resources to support compliance.

Recommendation 16: Stakeholder Engagement Plan

The TGA should ensure its Stakeholder Engagement Plan includes a focus on supporting effective regulation of therapeutic goods advertising. The stakeholder engagement plan should consider the TGA's advertising compliance priorities (in line with Recommendation 5) and education priorities (in line with Recommendation 12). The plan would define purpose and objectives, priorities, and engagement methods specific to TGA's advertising compliance role.

Recommendation 17: Communications Plan

The TGA should ensure its Communications Plan reflects a strategic approach to communications including use of external channels (particularly media) to support its advertising framework compliance priorities, education strategy goals and stakeholder engagement strategy goals. Use of media and external channels should focus on increasing both consumer and industry awareness of the TGA's regulatory position in regard to advertising compliance. Well-targeted consumer information and regular public reporting on regulatory decisions made and outcomes achieved would be elements of effective communication.

3.6.3 The Therapeutic Goods Advertising Consultative Committee

The main forum for stakeholder engagement on therapeutic goods advertising is the TGACC. The TGACC, has representation from industry, health professionals, consumer groups, relevant regulators, and media bodies involved or with interest in the advertising of therapeutic goods to the public. According to the TGACC Governance Arrangements document, the purpose of the TGACC is to:

> *provide an opportunity for member organisations to share their views on policy, operational performance issues relating to therapeutic goods advertising regulation and the way it is administered. This consultation mechanism supports continuous improvement of regulatory practices as they apply to the advertising of therapeutic goods to the public.*

At a summary level, the terms of reference within the Governance Arrangements document elaborates that the TGACC will:

- provide input to policies relating to the TGA Advertising Code;
- provide a forum for engagement on emerging issues;
- assist with shaping the TGA's reporting activities with respect to advertising compliance;
- provide comment on issues relating to the handling of advertising complaints;
- provide input on the development of education and compliance priorities to address noncompliance of advertising for particular categories of therapeutic goods;
- disseminate information to representatives' stakeholders / constituents; and
- consider topics raised by members through the Chair.

The Governance Arrangements also stipulates that the scope of the TGACC is to 'act in a consultative capacity. The TGACC is not a decision making, advisory or approval body'.

Across all stakeholders consulted, there was a view that the TGA has been highly conscious of the importance of stakeholder input and committed to engage with stakeholders throughout implementation of reforms, including through the TGACC forum. This has been critical in shaping an informed and invested stakeholder base with regards to advertising of therapeutic goods. However, there was consistent feedback that the TGACC engagement to date has largely been the TGA informing or 'presenting' information to TGACC members, without sufficient emphasis on active discussion or exchange of ideas regarding the changes.

Feedback from many stakeholders, including Departmental staff, also noted that the TGA is a large forum, with 23 representatives. These members represent many different or disparate interests, meaning that constructive discussion can be inhibited in such a large forum, or that topics for discussion are not always relevant to everyone in the forum. Some TGACC members expressed interest in smaller, more focused discussions for topics that were most relevant to select members.

Review of the TGACC Governance Arrangements document and a sample of meeting documentation confirmed much of the feedback noted above. The agenda and meeting minutes for TGACC meetings to date have focused on the TGA informing the group of changes or reporting on the current state, and

taking questions from members. The documentation reflected limited opportunity or practice of sharing insights or workshopping ideas to leverage the expertise and experiences of TGACC members.

3.6.4 Move to Involvement and Collaboration with the Consultative Committee

In implementing government policy changes to advertising regulation, the focus of stakeholder consultation until now has naturally been on informing relevant stakeholders of the changes. In this regard, the next phase of stakeholder engagement should leverage involvement, collaboration, and the commitment of TGACC members with a focus on shared responsibility for achieving compliance outcomes. The TGACC membership provides great opportunity to tap into the insights and experiences of sectors regarding areas of concern for compliance or regarding what has worked to improve compliance among members or industry. The TGACC also provides a method to communicate directly or by proxy to the industry being regulated, and in this way, presents an opportunity to further encourage industry to act as responsible and accountable partners in achieving compliance.

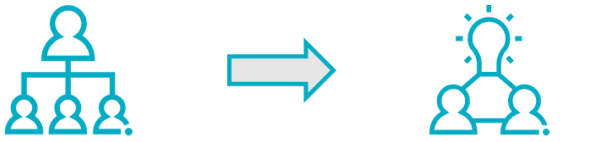

Figure 3: Illustration of future direction of stakeholder engagement

The TGACC documentation also confirmed feedback regarding the large membership, disparity of interests represented, and breadth of topics covered that did not require or encourage the involvement of all members. As compared to better practice principles for effective stakeholder engagement, there was scope to further define and agree the objectives of the TGACC and key outcomes that the group collectively work towards, which may facilitate more productive discussions. Further, Departmental staff noted engagement with the Consumers Health Regulators Group, which includes representation from ACCC, APRA and private health insurance agencies. This forum is an example of the TGA engaging with specific sectors to support compliance and consumer outcomes.

Recommendation 18: TGACC Ways of Working

The TGACC should be refocused to enhance its effectiveness as a collaborative forum focused on better outcomes for consumers through effective advertising compliance by industry. This may be achieved by updating the Governance Arrangements or developing an accountability charter which details:

- the refreshed objectives of the TGACC;
- roles and responsibilities of the TGA and members, which may include more opportunity for members to share their experiences, concerns or recent activities such as member education activities; and
- expectations of both the TGA and members.

Recommendation 19: TGACC Work Plan

The TGA should develop a list of key tasks and associated timeframes that require the input of the TGACC to finalise. This would include:

- developing annual compliance priorities;
- developing annual education priorities; and
- identifying significant case studies for use in the education program or media.

Recommendation 20: TGACC Focus Sub-groups

The TGA should consider hosting focused sub-groups with representation from the most relevant sector members from the TGACC. These should be hosted on an as-needed basis. A summary of key considerations and outcomes from these focused roundtables should be reported back to the wider TGACC group.

Recommendation 21: Regulator Meetings

The TGA should continue to hold regular meetings with other regulators to develop approaches and actions to address regulatory interface issues. A summary of key considerations and outcomes from the regulator meetings should be reported back to the wider TGACC group.

Recommendation 22: Stakeholder Survey

The TGA should include questions to evaluate stakeholder satisfaction with stakeholder engagement efforts regarding therapeutic goods advertising in its periodic stakeholder survey. The survey may also be used to gauge perceptions of the effectiveness of the TGA's compliance framework, which may inform performance reporting.

The survey should include input from key stakeholders consulted with. Areas of weakness or opportunities for improvement identified from the survey should inform updates to the TGACC Ways of Working, stakeholder engagement plan and communications plan.

Attachment A: Stakeholders Consulted

The table below summaries the external organisations and the Departmental staff consulted with, as part of the Review.

External Stakeholder Agencies:

- Accord Australasia
- Ad Standards
- Australian Chronic Disease Prevention Alliance
- Australian Competition and Consumer Commission
- Beiersdorf Australia
- CHOICE
- Commercial Radio Australia
- The Communications Council
- Complementary Medicines Australia
- Consumer Healthcare Products Australia
- Consumers Health Forum of Australia
- Country Women's Association of Australia
- Direct Selling Australia
- Food Standards Australia New Zealand
- Free TV Australia
- Medical Technology Association of Australia
- Medtronic Australasia
- National Rural Health Alliance
- NewsMediaWorks
- Pharmacy Guild of Australia

Departmental Staff:

- Deputy Secretary, Health Products Regulation Group (HPRG)
- First Assistant Secretary, Regulatory Practice & Support Division, HPRG
- First Assistant Secretary, Regulatory Legal Services Unit, HPRG
- Regulatory Education & Compliance Branch, Regulatory Practice & Support Division
- Advertising Compliance and Investigation Section, Regulatory Education & Compliance Branch, Regulatory Practice & Support Division
- Advertising Education and Assurance Section, Regulatory Education & Compliance Branch, Regulatory Practice & Support Division
- Regulatory Intelligence & Investigations Section, Regulatory Compliance Branch, Regulatory Practice & Support Division
- Regulatory Compliance Section, Regulatory Compliance Branch, Regulatory Practice & Support Division