



Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: TGA – enhancing sanctions and penalties in the *Therapeutic Goods Act 1989*

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TGA Health Safety
Regulation

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1. Introduction

In October 2014 the establishment of the Expert Review of Medicines and Medical Devices Regulation (the Review) was announced. The Expert Panel delivered two reports that assessed the regulatory framework for medicines and medical devices in Australia, and made [58 recommendations for reform](#)¹.

This consultation paper looks at two of those recommendations by the Expert Panel and the Governments response to those recommendations. The two recommendations and the responses are twenty-eight and fifty-seven, both of which specifically relate to enhancing of the sanctions and penalties in the *Therapeutic Goods Act 1989* (the Act).

The paper also outlines the proposed changes to the enforcement scheme for therapeutic goods in Australia, in response to the recommendations.

2. Expert panel recommendations to government

Expert Panel - Recommendation Twenty-Eight

The Expert Panel recommend that:

1. The Australian Government undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, including a review of the *Therapeutic Goods Act 1989* (the Act) and associated Regulations in their entirety, with a view to simplifying its structure and language to achieve a more user-friendly approach. In doing so:
 - A. the objects clause of the Act should be amended to better reflect the public health and consumer protection outcomes that the Act aims to achieve; and
 - B. the Act should be re-drafted in such a way as to:
 - I. maximise transparency of both policies and processes;
 - II. provide flexibility for the Australian NRA to appropriately modify processes to ensure a thorough analysis of safety, quality and efficacy, while avoiding unnecessary duplication;
 - III. recognise that medicines and medical devices are very different products and should be regulated accordingly;
 - IV. **provide for graduated penalties that allow the NRA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance;**
 - V. reflect contemporary practice standards for health professionals; and
 - VI. maximise the capacity of the Australian NRA to utilise electronic transactions and to collect information once to use for multiple purposes.
2. The Australian Government consider asking the Australian Law Reform Commission to undertake the proposed review and present a report to Government and to the Parliament.

¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation>

Expert Panel - Recommendation Fifty-Seven

The Expert Panel recommends that, further to Recommendation Twenty-Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

3. Government's response to the expert panel's recommendations

The [Australian Government's response to the Expert Panel's Review](#)² was released on 15 September 2016 and in relation to the specific recommendations on enhancing the sanctions and penalties in the Act, the Government has agreed the following:

Government response to Recommendation Twenty-Eight

The Commonwealth **accepts-in-principle** Recommendation Twenty-Eight but will propose amendments to Parliament as required to implement particular recommendations. It will implement the intent of this recommendation (which is to simplify the legislative framework and ensure it is more user-friendly) when implementing agreed changes to legislation and regulations.

Once legislative changes are implemented, an assessment will be made on the need for a more comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, and whether the benefits of redrafting and implementing new legislation would outweigh the costs of doing so.

Government response to Recommendation Fifty-Seven

The Commonwealth **accepts** Recommendation Fifty-Seven, and notes that broadening enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements, and deter inappropriate and misleading advertising of products.

4. Purpose of this consultation

To seek stakeholder's views on proposed legislative reforms to ensure the Act provides for an effective layered approach to compliance and enforcement.

The proposed amendments will provide us with an expanded suite of possible regulatory actions to address the severity of a compliance breach. The ultimate objective is to ensure that regulatory actions are proportionate with the risk that the therapeutic goods pose and to address any potential health and safety issues to the Australian public.

Some of the proposed amendments directly relate to the Government's response to the Expert Panel's Review such as the introduction of substantiation notices and public warnings in relation to advertising non-compliance. Other amendments from the Review will enhance sanctions and penalties and introduce the ability to seek an injunction to rapidly address serious cases of non-compliant advertising of therapeutic goods.

² <https://www.tga.gov.au/mmdr#austgovt>

Other proposed amendments intend to give further clarification to the 2006 amendments with changes to strict liability offences and the infringement notice regime that are consistent with contemporary Government policy.

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

5. Injunctions and stakeholder consultation

The Government response to the Expert Panel required the TGA (as a part of the Department of Health) to undertake stakeholder consultation on the implementation of the Review recommendations.

Stakeholder consultation on the [regulatory framework for advertising therapeutic goods](#)³ closed in December 2016. That consultation paper also referred to the 2013 [Consultation Regulation Impact Statement \(RIS\)](#)⁴ on the advertising regulatory framework to consider whether the range of investigation and enforcement powers should be broadened and enhanced.

Both consultation documents proposed measures to enhance current regulatory tools to address non-compliance with the advertising scheme for therapeutic goods. Most of the advertising consultation comments and feedback supported the widening of powers and sanctions but also wanted the wider powers to be consistent with other Commonwealth legislation.

Consistent with our 2016 stakeholder consultation, it is proposed that the power to apply for an injunction be introduced by adoption of the powers in the *Regulatory Powers (Standard Provisions) Act 2014*.

Enlivening the ability to use injunctions will allow us to rapidly address serious non-compliant advertising of therapeutic goods such as purported cancer cures or infant vaccines that may result in poor public health outcomes.

6. The Regulatory Powers (Standard Provisions) Act 2014

The *Regulatory Powers (Standard Provisions) Act 2014* (RPSPA) provides for a framework of standard regulatory powers to be exercised by agencies across the Commonwealth. The key features of the RPSPA include standard provisions in relation to monitoring and investigation powers, as well as enforcement provisions through the use of civil penalties, infringement notices, enforceable undertakings and injunctions. Implementation of the RPSPA supports the Government's regulatory reform agenda, as it simplifies and streamlines Commonwealth regulatory powers across the statute book.

The monitoring powers in the RPSPA are based on standard powers that can already be found in Commonwealth laws (including those currently in the Act) that provide for monitoring whether legislation is being complied with, or whether information given in compliance, or purported compliance with the Act is correct.

³ <https://www.tga.gov.au/consultation/consultation-regulatory-framework-advertising-therapeutic-goods-november-2016>

⁴ <https://www.tga.gov.au/consultation/consultation-regulation-impact-statement-regulating-advertising-therapeutic-goods-general-public>

The investigation powers in the RPSPA are found across the Commonwealth statute book (including those currently in the Act). The powers allow investigation of suspected contraventions of offences and civil penalty provisions. Investigation powers provided in the RPSPA include powers to search for and seize evidence as well as inspect, examine measure and test anything on the premises.

The RPSPA also provides for the use of civil penalty provisions, infringement notices and injunctions to enforce regulatory provisions, and the acceptance and enforcement of undertakings relating to non-compliance with provisions. The RPSPA conforms with the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*.⁵

As the purpose of the RPSPA is to provide Commonwealth regulatory agencies with a standard set of compliance and enforcement powers, new or amending Acts that require monitoring, investigation or enforcement powers of the kind available under the RPSPA have been, as a matter of Government policy, progressively drafted to trigger relevant provisions of those particular regulatory Acts.

The adoption of some RPSPA provisions, with the exception of civil penalties and enforceable undertakings, will bring our regulatory powers into line with comparable Commonwealth regulatory Acts including the *Biosecurity Act 2015*, the *Australian Sports Drug Agency Act 1990* and legislation administered within the Department of Health portfolios including by the National Industrial Chemicals Assessment Scheme, and the Office of Drug Control.

7. Adopting the Regulatory Powers (Standard Provisions) Act 2014

Reflecting the fact that the RPSPA only has effect where other Commonwealth Acts are drafted or amended to trigger the standard provisions in that Commonwealth Act, the Act will require amendment to adopt the powers from the RPSPA.

The Act currently provides for all of the same regulatory tools in the RPSPA, except for injunctions. Our 2016 stakeholder consultation on the [regulatory framework for advertising therapeutic goods](#) stated ‘it is proposed that the power to apply for an injunction be introduced, by adoption of the powers in the *Regulatory Powers (Standard Provisions) Act 2014*.’⁶

We propose to amend the Act to adopt the provisions of the *Regulatory Powers (Standard Provisions) Act 2014* (the RPSPA) in relation to:

- Monitoring;
- Investigation;
- Infringement Notices; and
- Injunctions.

If the investigation, monitoring and selected enforcement provisions are adopted from the RPSPA the existing provisions dealing with these matters including many provisions of Chapter

⁵ Criminal Justice Division of the Attorney-General’s Department, *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (2011).

⁶ <https://www.tga.gov.au/consultation/consultation-regulatory-framework-advertising-therapeutic-goods-november-2016> 5.3 Injunctions, p 14.

6, Part 6-2 and Chapter 5A of the Act and some provisions in the associated *Therapeutic Goods Regulations 1990* will be repealed.

In summary these proposed modifications to the RPSPA will update our regulatory tools, align them with those of other comparable regulators and conform to contemporary Government policy. This will also allow any amendments to the RPSPA to automatically flow to the Act.



We seek the views of stakeholders on our proposed adoption of the investigation, monitoring and enforcement provisions relating to infringement notices and injunctions from the *Regulatory Powers (Standard Provisions) Act 2014* (RPSPA).

8. Modifying the RPSPA

The current provisions in the Act for monitoring compliance and investigations contain powers of entry, search and seizure of evidence, whether by consent or with warrant.⁷ The current monitoring and investigation powers can apply whether or not the occupier of the premises subject to this activity is a sponsor of a therapeutic good or not.

The current provisions in the Act are similar to those in the RPSPA.⁸ There are however, certain differences which will require modification of the RPSPA. Specifically, the general powers provided by the RPSPA⁹ to *authorised persons* to monitor compliance are almost identical to those currently available to *authorised persons* in the Act.¹⁰

However, the RPSPA does not provide for authorised persons ‘to take samples of any therapeutic goods on the premises or any *thing*¹¹ on the premises that relates to any therapeutic goods’¹² currently provided for in the Act.

Accordingly we propose to modify the standard RPSPA monitoring powers to maintain the existing ‘sampling’ powers of authorised officers.

The Act also currently contains compliance monitoring powers specifically relating to premises occupied by regulated entities including those that have goods included in the ARTG, Australian manufacturers and persons granted conditional permits and authorities¹³ that are not provided for by the RPSPA.

Accordingly we propose to modify the standard RPSPA monitoring powers to maintain existing monitoring powers of authorised officers in specific premises.

These modifications are consistent with other legislation which involves compliance monitoring¹⁴ and reflects the nature of the things and activities regulated under the Act.

⁷ *Therapeutic Goods Act 1989* (Cth) Pt 6-2.

⁸ *Regulatory Powers (Standard Provisions) Act 2014* (Cth), Monitoring Pt 2, Investigation Pt 3.

⁹ *Regulatory Powers (Standard Provisions) Act 2014* (Cth) s 19.

¹⁰ *Therapeutic Goods Act 1989* (Cth) s 46A (regulated community), s 48 general powers.

¹¹ *Therapeutic Goods Act 1989* (Cth) s 45A (Definition of thing; *includes a substance, and a thing in electronic or magnetic form.*).

¹² *Therapeutic Goods Act 1989* (Cth) s 46A(b), 48(1)(b).

¹³ *Ibid* s 46A, *Therapeutic Goods Regulations 1990* (Cth) r 12AC.

¹⁴ *Narcotic Drugs Act 1967* (Cth) s 13L(b), *Gene Technology Act 2000* (Cth) s 153(1)(b).

For the protection of public health in the most serious circumstances it is also proposed to maintain the current power in the Act to allow authorised persons on reasonable grounds to enter any premises without warrant and seize therapeutic goods to avoid an imminent risk of death, serious illness or serious injury.¹⁵



We seek the views of stakeholders on our proposed modifications to the provisions from the *Regulatory Powers (Standard Provisions) Act 2014*.

9. Expected outcomes of adopting the RPSPA

Standardising regulatory powers across the Commonwealth, the RPSPA is intended to:

- significantly reduce the length of legislation in Commonwealth regulatory schemes
- provide greater clarity and consistency for agencies exercising powers with regulatory schemes
- make it easier for businesses that are subject to regulatory schemes to understand and comply with the law
- facilitate the development of a common body of law.

The provisions of the RPSPA represent best practice in relation to regulatory powers and include operational safeguards while maintaining Parliamentary scrutiny over application of that Act to specific regulatory regimes. Standardisation provides regulatory agencies with the opportunity to use more uniform powers, and increases legal certainty for businesses and individuals who are subject to those powers.

Adopting the investigation, monitoring and enforcement provisions from the RPSPA allows for any future amendments to these provisions in the RPSPA to automatically apply to the Act without the need for us to make any amendments. Specific amendments to the RPSPA such as those referred to in section 8 of this paper will be preserved.

10. MMDR recommendations - enhancing sanctions and penalties for advertising

MMDR recommendation 28 proposes that the legislation provide for graduated penalties that allow the regulator to respond appropriately to the full range of non-compliance, from repeated minor breaches through to serious non-compliance. Implementing the Government response to the MMDR requires amendments to the Act to secure better compliance with the Act so that public health and safety will be adequately protected.

The proposed MMDR amendments, consistent with the 2013 and 2016 stakeholder consultations, proposed supplementing existing criminal offences relating to advertising non-compliance currently in the Act. Both consultations included a proposal for a tiered offences regime, which included higher penalties for more culpable conduct resulting in harm or injury and the introduction of strict liability offences. Unlike tiered offences regimes elsewhere in the Act, the proposed new strict liability offences relating to advertising will not have an element of

¹⁵ *Therapeutic Goods Act 1989* (Cth) s 46B.

culpability (likely to result in harm or injury), resulting in much lower penalties than currently exist in the Act.

The proposed new tiered offences structure for advertising non-compliance would comprise the following alternative offences:

- a new fault-based offence with an aggravating element (conduct that has or will result in harm or injury, or conduct likely to result in harm or injury) attracting a maximum penalty of 4,000 penalty units and/or 5 years imprisonment; or
- a new strict liability offence with no aggravating element attracting a maximum penalty of 100 penalty units with no term of imprisonment; or
- the existing fault-based offence (with no aggravating element), which will be retained with the level of penalty increased, where appropriate, consistent with the level of penalties already in the Act applying to similar offences or to conduct that results or could result in similar consequences.

The proposed civil penalty provisions would allow Courts to impose either a maximum 5,000 penalty units for an individual or 50,000 penalty units for a corporation. It is anticipated that the level of civil penalties will act as an effective financial disincentive against non-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available. The availability of very high penalties aligns with other civil penalty provisions in the Act and gives courts the scope to penalise wrongdoers appropriately and to address ongoing or serious non-compliance, including in the most egregious of circumstances.

Infringement notices will play a crucial part in our risk-based graduated regulatory response to address non-compliant advertising of therapeutic goods in a timely manner. This enforcement option recognises that a lengthy prosecution process or civil proceedings may not be the optimal way of dealing with some breaches of advertising requirements.



These proposed amendments to the Act to include three tiered offence regimes with corresponding civil penalty provisions to address advertising non-compliance have been the subject of stakeholder consultations in [2013](#) and again in [2016](#) as part of the implementation of the Medicines and Medical Devices Review.

11. Substantiation notices – advertising

The Government accepted the Expert Panel's Recommendation that consideration be given to broadening the current range of enforcement and investigation powers, and noted that this would benefit consumers by enforcing appropriate compliance with advertising requirements.

In the MMDR 2016 stakeholder consultation, it was proposed the Act be amended to allow us to issue a substantiation notice requiring a person to give information and/or produce documents that could substantiate or support a claim or representation made by the person in an advertisement for therapeutic goods.

Our proposed substantiation notices would be similar to those available to the Australian Competition and Consumer Commission (ACCC)¹⁶. They would not require a person to prove

¹⁶ *Australian Competition and Consumer Act 2010* (Cth), sch 2 ch 5 pt 5-1 div 2 ss 219-222.

that a claim or representation is true or is not misleading; rather, they would be a preliminary investigative tool that will help us to determine whether further investigation is warranted.

Substantiation notices could be issued to people who have therapeutic goods included in the ARTG who place advertisements for their goods. Substantiation notices also apply to people who do not have goods in the ARTG, but place advertisements for therapeutic goods regardless of whether they distribute the goods by wholesale, retail or online.

Individuals are given statutory protections and are not required to provide information or documents if the information or documents may incriminate them or expose them to a penalty.

A person served with a substantiation notice would be required to comply with the notice within 21 days. Consistent with the scheme available to the ACCC, higher penalties can apply where false or misleading information is provided. The period for compliance with a notice may be extended where a person applies for the extension during the compliance period and where we consider it appropriate to grant the extension.

Various actions may be taken against persons who refuse to respond to a substantiation notice or fail to respond to a substantiation notice within the compliance period. For example, actions may include:

- commencing criminal proceedings
- commencing civil litigation
- issuing an infringement notice as an alternative to formal court action

Table 1 Proposed penalties for non-compliance with a substantiation notice

Entity	Maximum criminal penalty	Maximum civil penalty	Infringement notice penalty
Body corporate	150 penalty units = \$27,000	150 penalty units = \$27,000	60 penalty units = \$10,800
Individual	30 penalty units = \$5,400	30 penalty units = \$5,400	12 penalty units = \$2,160

Various actions can be taken against a person for providing false or misleading information or documents in response to the notice. For example, actions may include:

- commencing criminal proceedings
- commencing civil litigation
- issuing an infringement notice as an alternative to formal court action

Table 2 Proposed penalties providing false or misleading information in response to substantiation notices

Entity	Maximum criminal penalty	Maximum civil penalty	Infringement notice penalty
Body corporate	250 penalty units = \$45,000	250 penalty units = \$45,000	60 penalty units = \$10,800
Individual	50 penalty units = \$9,000	50 penalty units = \$9,000	12 penalty units = \$2,160

12. Public warning notices – advertising

Our MMDR 2016 stakeholder consultation proposed that the Act be amended to allow us to issue a public warning notice in a similar manner to other regulators such as the ACCC.¹⁷

It is proposed to amend the Act to allow the us to issue a public warning notice where we:

- have reasonable grounds to suspect that an advertisement for therapeutic goods may constitute a contravention of a provision of the Act
- are satisfied that one or more other persons has suffered, or is likely to suffer, detriment as a result of the advertisement, and
- are satisfied that it is in the public interest to do so.

A key consideration for us when evaluating if it is appropriate to issue a public warning notice would be whether there is an imminent need to inform consumers, so they can avoid detriment from advertisements about therapeutic goods.

For example, detriment may arise where there is an actual or a perceived risk to public health from advertising non-compliance, or attributable to persons who persistently or deliberately operate outside the regulatory scheme for advertising therapeutic goods.

We may also issue a public warning notice where a person refuses or fails to respond to a substantiation notice and we consider it to be in the public interest to issue the public warning notice.

These regulatory provisions and penalty levels are consistent with other comparable regulators¹⁸ such as the ACCC and ASIC and align with contemporary Government policy.



We are seeking our stakeholder's views on the proposal to amend the Act to include substantiation notices and public warning notices.

¹⁷ *Australian Competition and Consumer Act 2010* (Cth), sch 2 ch 5 pt 5-1 div 3 s 223.

¹⁸ *Ibid*, sch 2 ch 5 pt 5-1 divs 2-3, ss 205-206 and s 224 items 14 and 15.

13. Infringement notices and the RPSA

Infringement notices are currently available as an alternative to us pursuing litigation for breaches of strict liability criminal offences and contraventions of civil penalty provisions in the Act. The Act currently expressly provides for penalty unit amounts for infringement notices in relation to strict liability criminal offences which are one fifth of the maximum penalty amount for an individual¹⁹ and five times that amount for an incorporated body.²⁰

Because of the current 2,000 penalty units attached to many strict liability offences in the Act and the high penalty units applicable to contraventions of civil penalty provisions in the Act, the Act currently provides for substantial penalties for infringement notices far exceeding contemporary Government policy.

The Attorney-General's Department (AGD) policy²¹ is that generally, the amount payable under an infringement notice scheme should not exceed 12 penalty units for a natural person or 60 penalty units for a body corporate.

The proposed adoption of part 5 of the RPSA ensures that the penalty amounts consistent with AGD policy or lesser amounts will apply.

14. Standardising strict liability offences in the Act

The Government has endorsed the Expert Panel's recommendation to provide for graduated penalties that would allow the TGA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance.

The Act was amended in 2006 to enhance sanctions and penalties and included tiered offences regimes, civil penalties, enforceable undertakings and infringement notices. These provisions predated current Government policy on regulatory sanctions and penalties powers published in 2011.²²

Serious offences should be prosecuted in a court and should not be capable of being excused by an administrative assessment. The efficacy of an infringement notice scheme is a function of the application of straightforward and objective criteria providing for their issue rather than complex legal distinctions.²³ The current Act requirement for many strict liability offences that the relevant goods if used would likely result in harm or injury to a person requires an unnecessary and often complex assessment in circumstances where that underlying action is so serious that it is not appropriate to include this additional requirement.

Accordingly, it is proposed to remove the requirement of the *likelihood of harm or injury to any person* from each strict liability criminal offence in the Act. These amendments will align all strict liability offences with the proposed MMDR amendments for strict liability offences in relation to advertising. The advertising amendments and these proposed amendments will also result in a substantial reduction in penalties from 2,000 to 100 penalty units, aligning our strict liability

¹⁹ *Therapeutic Goods Act 1989* (Cth) s 42Y(2).

²⁰ *Ibid* 42Y(3).

²¹ Criminal Justice Division of the Attorney-General's Department, *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (2011), p58.

²² Criminal Justice Division of the Attorney-General's Department, *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (2011).

²³ *Ibid*, p58.

offences with many other strict liability offences available to comparable Commonwealth regulators.

These proposed amending measures will create consistency for all strict liability offences throughout the Act and will enliven an effective infringement notice scheme filling the current regulatory gap identified in the Review.

In summary, these proposed amendments together with adopting the infringement notice provisions from the *Regulatory Powers (Standard Provisions) Act 2014* will enable us to address many circumstances of non-compliance with infringement notices.

These amendments will fill the current regulatory gap identified in the Review and provide a viable alternative to litigation in the appropriate circumstances.



We seek the views of stakeholders on whether to amend the *Therapeutic Goods Act 1989* (the Act) to remove the current requirement that the prohibited action would be likely to result in harm or injury to any person from all strict liability offences coupled with a substantial reduction in penalty units.

15. Complementing existing offences in the Act

It is proposed to amend the Act to include strict liability offence provisions to complement, where appropriate, existing 'stand-alone' criminal offences throughout the Act for matters such as breaches of conditions, licences or permits.

These proposed amendments will provide scope for the issue of infringement notices to effectively address the current regulatory gap identified in the Expert Panel recommendations and create tools to address ongoing or less serious non-compliance consistent with our regulatory compliance framework.²⁴ Infringement notices will complement other regulatory tools such as education, guidance, warnings as a timely alternative to criminal prosecution or litigation of civil penalty proceedings in the Courts in the appropriate circumstances.

Consistent with other proposed amendments, there will be no requirement of likely harm or injury to any person, and a much lower penalty will apply.

These amendments coupled with adopting the infringement notice provisions from the *Regulatory Powers (Standard Provisions) Act 2014* will enable us to address many circumstances of non-compliance with infringement notices where appropriate.

These amendments will fill the current regulatory gap identified by the Expert Panel and will provide a viable alternative to litigation as part of an effective risk-based graduated response to regulatory non-compliance.



We seek the views of our stakeholders on whether we should amend the *Therapeutic Goods Act 1989* (the Act) to include strict liability offences to complement many existing 'stand-alone' criminal offences.

²⁴ Therapeutic Goods Administration, *Regulatory Compliance Framework* (2013), <https://www.tga.gov.au/regulatory-compliance-framework>

16. Strengthening existing aggravated criminal offences

The Government has endorsed the Expert Panel's recommendation to provide for graduated penalties that would allow for the TGA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance.

A number of offences in the Act follow a three tiered regime, where the most serious level top tier offence is fault based (requires intent or recklessness) and involves an aggravated element that the use of the goods has or will result in harm or injury to any person, or the use of the goods if used would result in harm or injury to any person. The other two tiers of the three tiered regime are a fault based offence with no aggravating element and a strict liability offence (no fault element) which currently has an aggravating element.

By way of example, the section 19B top tier offence relating to the import, export, manufacture or supply of medicines not included in the ARTG and not exempted or excluded from that requirement (physical elements)²⁵ requires the aggravating elements resulting in a maximum 5 years imprisonment or 4,000 penalty units of both.

It is proposed to include an additional circumstance of aggravation of *likelihood of harm or injury to any person* (removed from strict liability offences) to complement and strengthen current aggravating circumstances for top tier criminal offences throughout the Act to include this culpable activity or behaviour which has the potential to result in a public health risk.

The proposed amendments to all top tier offences would apply where:

- the use of the goods has resulted in, or will result in, or is likely to result in, harm or injury to any person; or
- the use of the goods, if the goods were used, would result in, or is likely to result in, harm or injury to any person; or

These proposed amendments will broaden the reach of aggravated criminal offences in the Act to include acts and omissions, or the use of therapeutic goods themselves which not only have or would cause harm but are likely to cause harm or injury to any person. These proposed amendments would enhance the protection of public health and allow courts to effectively punish the most culpable of activities or behaviour.



We seek the views of stakeholders on whether we should amend the Act to enhance existing aggravated criminal offences.

²⁵ *Therapeutic Goods Act 1989* (Cth) s 19B(1).

17. Summary of proposed amendments to current sanctions & penalties to provide consistency with MMDR advertising amendments and post market enhancements

Key amendments to the Act will strengthen sanctions and penalties and allow us to respond appropriately and in a timely manner to address non-compliance ranging from accidental minor breaches through to ongoing serious non-compliance. These amending measures include:

- adopting the monitoring, investigation and enforcement provisions relating to infringement notices and injunctions by adopting those provisions from the Regulatory Powers (Standard Provisions) Act 2014 (RPSPA)
- enlivening the ability to seek an injunction to address serious advertising non-compliance in a timely manner from the RPSPA
- reducing maximum penalties for infringement notices to a maximum of 12 penalty units for individuals and 60 penalty units for corporations through adoption of the provisions from the RPSPA
- modifying the RPSPA powers to maintain the power for authorised persons to sample therapeutic goods during compliance monitoring
- modifying the RPSPA powers to maintain the powers of authorised persons during compliance monitoring of premises of sponsors etc.
- modifying the RPSPA powers to maintain the powers for authorised persons to enter search and seize dangerous therapeutic goods on public health grounds
- enhancing sanctions and penalties for advertising non-compliance in accordance with the Review and subsequent consultations
- including civil penalties to apply to advertising non-compliance in accordance with the Review and subsequent consultations
- removing the requirement of likelihood of harm or injury to any person from all strict liability offences
- reducing the amount of penalty units to apply to strict liability offences commensurate with removal of the requirement of likelihood of harm or injury to any person
- the global inclusion of strict liability offences in the Act, where appropriate, to complement existing 'stand-alone' fault based criminal offences as an additional measure to ensure the integrity of the public health regulatory regime²⁶
- strengthening top tier aggravated criminal offences in the Act by including likelihood of harm or injury as a physical element to better address culpable behaviour provide for the issue substantiation notices in relation to advertisements for therapeutic goods
- publishing public warning notices where appropriate.

²⁶ Senate Standing Committee for the Scrutiny of Bills, Parliament of Australia, *Application of Absolute and Strict Liability Offences in Commonwealth Legislation* (2002), 283-286.

The proposed amendments to the Act will enhance our capacity to address non-compliance and complement our education and guidance material with a full suite of sanctions and penalties to fill current regulatory gaps. The proposed enhanced suite of sanctions and penalties will enable us to address non-compliance with risk-based graduated responses measured to meet each circumstance.

The proposed amendments to the Act will comply with contemporary government regulatory policy, and will align the sanctions and penalties available to us with other comparable Commonwealth regulators, maximising transparency of both policies and processes.

18. Industry and stakeholder education

Our compliance and enforcement decisions complement our regulatory compliance framework and take into account the nature of the non-compliance as well as any public health implications from the person's dealings with or use of the therapeutic goods.

Our first priority is to protect the health of consumers, particularly those who are not in a position to make informed judgements or effective decisions about the risks they may be exposed to.

In deciding how to deal with a non-compliance matter, we first consider education, guidance material or additional training for those who show a willingness to comply with the regulatory scheme. We do not regard actions of this nature as punitive or disciplinary in character.

The new provisions in the Act will also, however, enable us to take appropriate and effective compliance or enforcement action against people who persistently or deliberately operate outside the regulatory scheme for therapeutic goods that may result in a pecuniary penalty or a term of imprisonment especially in cases which involve:

- reckless, wilful or repetitive non-compliance
- dealings with therapeutic goods that threaten the health or safety of persons
- undermining the regulatory scheme, our reputation or the reputation of Australia's therapeutic goods industry.

Formal stakeholder education has the potential to improve compliance and promote greater quality and consistency of advice on the therapeutic goods regulatory scheme and to help manage the public health risks associated with inappropriate dealings with therapeutic goods.

An education program will be developed for sponsors and other stakeholders to provide information and tools to help them achieve compliance with our regulatory requirements. We will publish documents that will help sponsors and stakeholders to understand what their obligations are, what regulatory tools are available to us and how those tools will be used in a graduated risk-based response to regulatory non-compliance in appropriate circumstances.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Practice, Education and Compliance Branch	03/05/17

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