TGA Consultation – Enhancing sanctions and penalties in the TG Act 1989

MTAA Submission - May 2017

MTAA Medical Technology Association of Australia

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1 Executive Summary

On 3rd May 2017 the TGA opened the consultation *TGA – enhancing sanctions and penalties in the Therapeutic Goods Act 1989* which proposes a set of graduated penalties allowing the TGA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance.

The MTAA appreciates the opportunity to comment on this consultation. The MTAA supports the overarching intention to strengthen the post-market regulatory framework and deter inappropriate and misleading advertising of therapeutic goods, in line with recommendations 28 and 57 of the 2015 Medicines and Medical Devices Review (MMDR) by the independent expert panel lead by Emeritus Professor Lloyd Sansom AO.

In the next sections we provide detailed feedback to the proposed reforms.

2 Investigation, monitoring and enforcement provisions

The MTAA supports the adoption of investigation, monitoring and enforcement provisions relating to infringement notices and injunctions from the Regulatory Powers (Standard Provisions) Act 2014 (RPSPA), to enable the TGA 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.

3 Modifying the RPSPA

The MTAA supports the proposed modifications to the RPSPA to align the regulatory framework for therapeutic goods with regulations of other comparable regulators and conform to contemporary Government policy. The proposed changes to the RPSPA are:

- Modify the standard RPSPA monitoring powers to maintain the existing 'sampling' powers of authorised officers;
- Modify the standard RPSPA monitoring powers to maintain existing monitoring powers of authorised officers in specific premises;
- 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;

4 MMDR recommendations – enhancing sanctions and penalties for advertising

The MTAA supports the introduction of a three tiered offences regime with corresponding civil penalty provisions to address non-compliance with advertising rules for therapeutic goods;

- Fault-based offence with an aggravating element, i.e. conduct that has/ 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 (new);

- Strict liability offence with no aggravating element, attracting a maximum penalty of 100 penalty units with no term of imprisonment (new);
- 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 (existing).

We welcome the introduction of graduated penalties, specifically the proposed new strict liability offences relating to advertising that will not have an element of culpability (likely to result in harm or injury) and that will result in much lower penalties than currently existing in the Act.

We also agree that infringement notices represent a useful tool in a risk-based graduated regulatory enforcement framework that will allow a timely response to non-compliant advertising of therapeutic goods in situations where a lengthy prosecution process or civil proceedings may not be the optimal option.

5 Substantiation notices and public warning notices

The MTAA supports the introduction of substantiation notices and public warning notices to address false or misleading representations about therapeutic goods in situations as described in the consultation paper. This will enhance the post-market monitoring system and strengthen public confidence in the regulatory regime for therapeutic goods.

6 Standardising strict liability offences in the Act

The MTAA supports the removal of the requirement of the “likelihood of harm or injury to any person” from each strict liability criminal offence in the Act, and the related reduction in penalties, in order to align with other strict liability offences in comparable Commonwealth regulations.

7 Complementing existing offences in the Act

The MTAA supports amending the Therapeutic Goods Act 1989 (the Act) to include strict liability offences, which will complement existing stand-alone criminal offences. This will enable the implementation of an effective risk-based graduated response to regulatory non-compliance.

8 Strengthening existing aggravated criminal offences

The MTAA supports the proposed enhancement of existing aggravated criminal offences by including an additional circumstance of aggravation of ‘likelihood of harm or injury to any person’ (removed from strict liability offences). This has the potential to better differentiate aggravated criminal offences from strict liability offences, and to include acts and omissions, or the use of therapeutic goods which not only have or would cause harm but are likely to cause harm or injury.

9 Industry and stakeholder education

The MTAA strongly supports prioritising education, guidance and training for those who show a willingness to comply with the regulatory scheme. Compliance and enforcement actions should only be taken against people who persistently or deliberately operate outside the regulatory scheme.

The MTAA welcomes the opportunity to work collaboratively with the TGA in the development of an educational program for sponsors of therapeutic goods.