MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

MMDR consultation: Reforms and Operations
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

DUE DATE: 31st May 2017

Dear Sir/Madam

Medicines Australia welcomes the opportunity to provide comment on the proposals presented in the Therapeutic Goods Administration (TGA) consultation paper, *Consultation: TGA – enhancing sanctions and penalties in the Therapeutic Goods Act 1989).* These mainly relate to Recommendations 28 and 57 of the Medicines and Medical Devices Review report recommendations.

MA supports a strong and accountable penalties and sanctions approach to regulatory administration, with the TGA being provided sufficient powers to enforce these and therefore MA understands and does not oppose these proposals in general. Our feedback is contained in Attachment 1.

Our submission has been prepared with the input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members of RAWG are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector.

We would be happy to provide further comment on any aspect of our response and we appreciate learning of further developments as they are worked through from here.

Yours faithfully

Larissa Karpish
Manager, Industry & Regulatory Policy

Attachment 1. Consultation: TGA – Enhancing sanctions and penalties in the Therapeutic Goods Act 198

Legislative Area	Recommendations/Topic	Response/Comments
Adoption of Regulatory Powers		
Adoption of provisions contained in the **Regulatory Powers (Standard Provisions) Act 2014**	The views of stakeholders are sought on the proposal to adopt the investigation, monitoring and enforcement provisions relating to infringement notices and injunctions from the Regulatory Powers (Standard Provisions) Act 2014 (RPSPA)	MA support the proposal to adopt the specified provisions from Regulatory Powers (Standard Provisions) Act 2014 (RPSPA) as it supports the standardisation of regulatory powers across the Commonwealth Statute book.
Modification of provisions contained in the **Regulatory Powers (Standard Provisions) Act 2014**	Views of stakeholders are sought on proposed modification to the provisions from the Regulatory Powers (Standard Provisions) Act 2014 (RPSPA) specifically a) to maintain the existing 'sampling' powers of authorised officers b) maintain existing monitoring powers of authorised officers in specific premises and c) maintain the current power of the Act to allow authorised persons to enter on reasonable grounds any premises without warrant and seize therapeutic goods to avoid an imminent risk of death, serious illness or serious injury.	MA support the proposed modification to the Regulatory Powers (Standard Provisions) Act 2014 on the basis that the proposed modifications are intended to maintain the existing powers set out in the Therapeutic Goods Act.

Enhancing Sanctions and Penalties for Advertising		
A tiered offence structure for advertising non-compliance.	Proposal to introduce new tiered offences for advertising non-compliance	MA supports the introduction of a new tiered offence structure for advertising non-compliance including infringement notices.
Introduction of Substantiation notices consistent	The views of stakeholders are sought on the	MA agrees with the proposed approach to the

with the ACCC scheme.	proposal to amend the Act to introduce substantiation notices	introduction of substantiation notices recognising the consistency of the proposed approach with that of the ACCC in this area.
Introduction of Public warning notices in relation to advertising, consistent with ACCC.	The views of stakeholders are sought on the proposal to amend the Act to introduce public warning notices	MA supports the proposed approach to the introduction of public notices recognising the consistency of the proposed approach with that of the ACCC in this area.
Standardising strict liability offences in the Act	Views of Stakeholders are sought on whether to amend the Therapeutic Goods Act 1989 (the Act) to remove the current requirement that the prohibited action would likely result in harm or injury to any person from all strict liability offences coupled with a substantial reduction in penalty units.	MA supports the proposal to remove the requirement of the "likelihood of harm or injury to any person" from each strict liability criminal offence in the Act to achieve consistency with other areas of legislation within the Act and to align the penalties with other similar offences in other areas of legislation.
Complementing existing offences in the Act - Introduction of Strict Liability offences	Views of Stakeholders are sought on whether to amend the Therapeutic Goods Act 1989 (the Act) to include strict liability offences to complement many existing stand-alone criminal offences.	MA agree with the proposal to introduce strict liability provisions to other areas of the Therapeutic Goods Act to facilitate the broader use of infringement notices.
Strengthening existing aggravated criminal offences	Views of Stakeholders are sought on whether to amend the Act to enhance aggravated criminal offences by addition of an additional circumstance of *'likelihood of harm or injury to any person*'	MA agrees wit he proposal to amend the Act to include likelihood of harm or injury to the top tier criminal offences throughout the Act.