Australian Government

Department of Health and Aged Care

Therapeutic Goods Act 1989
Compliance Priorities 2023/24
Stakeholder Survey

The Therapeutic Goods Administration (TGA) in Australia administers the *Therapeutic Goods Act 1989*. The Act regulates the import, export, manufacture, supply and advertising of therapeutic goods in Australia. Each year, the TGA publishes compliance priorities that outline priority areas for its compliance activities for the import, supply and advertising of therapeutic goods.

To inform the development of compliance priorities for the 2023/24 financial year, the TGA is undertaking a review of its 2022/23 compliance priorities. To support the review, we are seeking information from the community including industry and other regulators about compliance and enforcement matters of concern or importance, particularly relating to the import, supply and advertising of therapeutic goods.

We value your expertise and advice and invite you to provide information to assist in the review. The more specific information you are able to provide, the more accurately we are able to assess the risk that certain issues present in the context of therapeutic goods regulation and community safety in Australia. For example, the number of allegations received in relation to a specific issue.

You are welcome to provide information in any format, however we have developed the following survey to provide guidance on the information we are seeking and to assist you in structuring your input.

Agency/organisation:

Contact details:

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1. What are the most concerning non-compliance trends or issues relating to therapeutic goods that have been observed in the course of your work throughout the 2022 calendar year? Please provide detail in the boxes below, including references to specific research or data where possible.

   Please duplicate the table for each issue.

Issue 1	Please provide details of the non-compliant behaviour/activity and any similarities you have observed within cohorts engaging in these behaviours.
	Please provide detail of actual and potential harms associated from this behaviour (e.g. human harms, financial harms, reputational harms, other).
	Please provide detail of the frequency with which this behaviour was observed in 2022 and whether this has increased or decreased in comparison with previous years.
	Please provide detail of any links between these behaviours and other criminal activity or criminal markets.
	Please list attachments or data files that you are providing, or insert links to relevant research, reports, articles or studies.

2. Please list any further concerns you have relating to:

Inappropriate advertising of therapeutic goods

Counterfeiting ***including intellectual property infringements, falsified, modified or substandard medicines or medical devices***

Import and/or export of unregistered therapeutic goods ***i.e. therapeutic goods that are not included on the Australian Register of Therapeutic Goods (ARTG)***

Supply and manufacture of unregistered therapeutic goods ***i.e. therapeutic goods that are not included on the Australian Register of Therapeutic Goods (ARTG)***

3. Please provide feedback on the TGA's 2022/23 compliance priorities (provided below) and their relative importance to the issues you've raised and whether they continue to be an issue for you or for the TGA (in your opinion)?

Priority	**Feedback**
Deter and address the unlawful import, advertising and supply of unapproved therapeutic goods associated with COVID-19	
Disrupt and address the unlawful import, advertising and supply of nicotine vaping products	
Ensure compliance with the requirements of the *Therapeutic Goods Act 1989* across the medicinal cannabis industry	
Disrupt and address the unlawful import, manufacture, advertising and supply	

of unapproved performance and image enhancing therapeutic goods, including sports supplements, with a focus on products containing schedule 4 (prescription only medicines) and schedule 8 (controlled drugs) poisons	
Address the unlawful use of restricted and prohibited representations in advertisements that have not been approved or permitted, particularly those that target especially vulnerable consumers	
Deter and address the unlawful advertising of unapproved therapeutic goods on digital platforms**,** including for pregnancy and prenatal goods, weight loss products and hangover cures	

4. Please provide any recommendations for how the TGA may partner with your organisation to better address the issues raised above?

This information is collected to inform the ongoing assessment of key issues impacting the compliance work of the TGA. Where lawful and appropriate this information may be shared with domestic and international government agencies and International Government Organisations to support this process.

Responses should contain information classified up to OFFICIAL and will be treated in accordance with the Protective Security Policy Framework (PSPF) for information at this classification.

Please contact the Regulatory Compliance Branch to provide information at a higher classification or with specific handling instructions. Any other questions about the survey or the way information will be handled can be directed to the Regulatory Compliance Branch: rcbcompliancegovernance@health.gov.au