

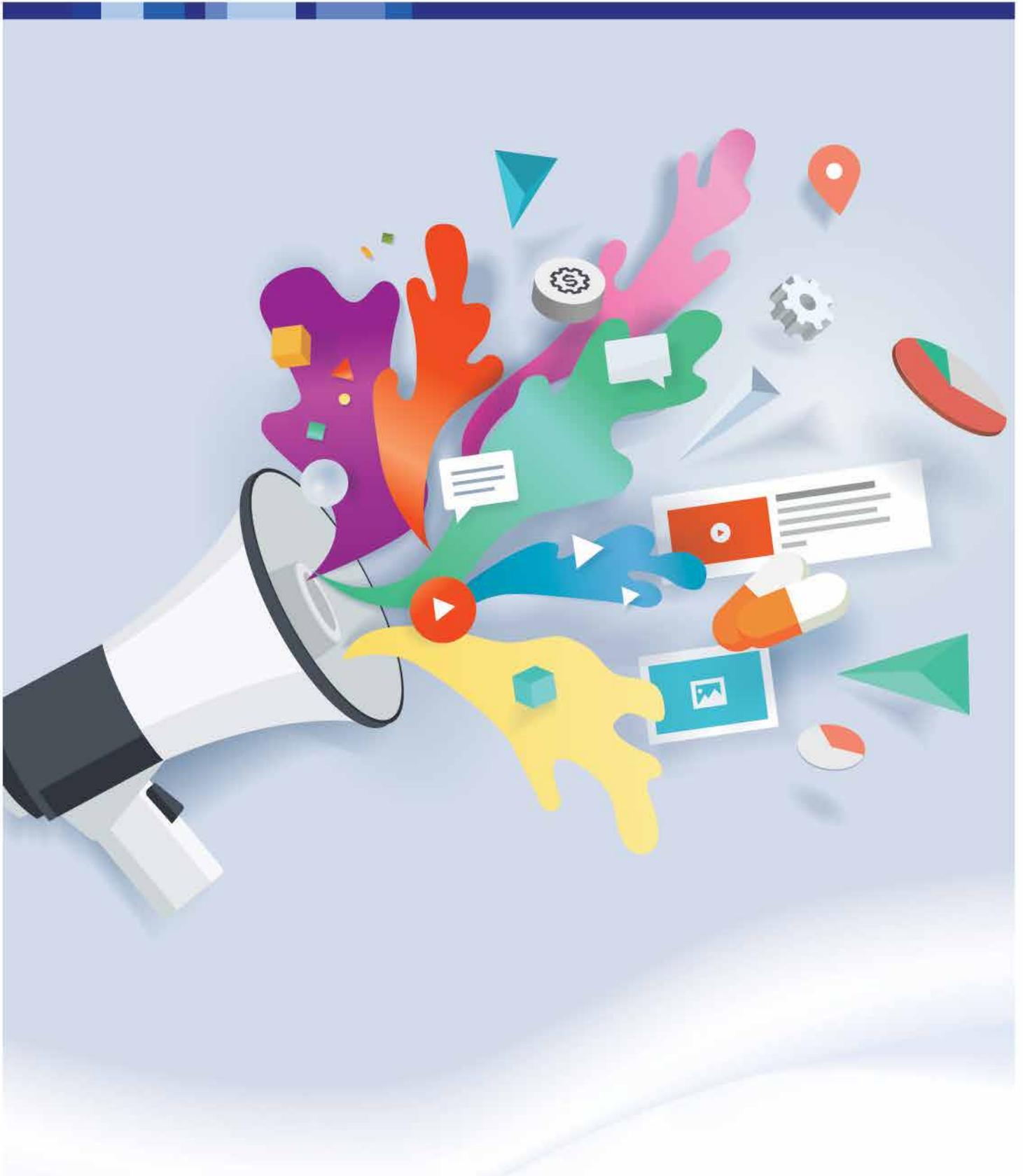


Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Advertising Compliance

Annual Report 2022–23



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Executive summary

The Therapeutic Goods Administration (TGA), within the Australian Government Department of Health and Aged Care, regulates therapeutic goods advertising through the administration of the [Therapeutic Goods Act 1989](#) (the Act) and associated legislation.

We safeguard and enhance the health of Australians by ensuring that advertising of therapeutic goods is socially responsible and supports informed consumer choice. Our enforcement activities are informed not only by our compliance priorities but also through observing high-risk behaviour or trends that present risk to consumer safety or the integrity of the regulatory framework. Our targeting of advertising promoting the 'off-label' use of the prescription medicine [Ozempic](#) is one such example.

This report covers the 2022-23 financial year. It is our fifth annual report on advertising compliance. Reporting on our enforcement and educational activities fosters transparency and accountability. This report outlines:

- our focussed regulatory efforts to curb non-compliant advertising in line with our compliance priorities and high risk to consumer health and safety
- compliance and enforcement actions we have taken against entities responsible for alleged unlawful advertising
- case studies that demonstrate interpretation and application of the legislative requirements
- our stakeholder engagement and education activities undertaken throughout 2022-23 to assist both regulated and unregulated entities to interpret and comply with the regulatory requirements.

2022-23 Highlights

We are committed to ensuring the safety of Australians through effective regulation of therapeutic goods advertising. Highlights of this report include:



About the advertising framework

In Australia, advertising for consumer goods (including therapeutic goods) must comply with the *Competition and Consumer Act 2010* (which incorporates the Australian Consumer Law). Additional legal safeguards are in place for therapeutic goods (such as medicines and medical devices) because they pose greater risks to consumers beyond those of ordinary consumer goods.

The legal requirements for advertising therapeutic goods are specified in the Act and the [Therapeutic Goods Advertising Code 2021](#) (the Advertising Code). Their purpose is to support consumers to make rational and informed decisions when self-selecting or using therapeutic goods.

The Advertising Code requires advertising to consumers to be ethical and not misleading or deceptive and only promote the safe and proper use of therapeutic goods. [Comprehensive guidance](#) has been published on our website to support advertisers to comply with these requirements.

Our compliance and enforcement approach

We undertake advertising compliance and enforcement activities using a risk-based, intelligence-led approach. We focus on non-compliance assessed to be of greatest concern or risk to consumer health and safety.

The Department of Health and Aged Care's [Corporate Plan](#) and the [TGA Business Plan](#) set out the Department's (including the TGA's) strategic priorities and intended outcomes. Our [compliance priorities](#) are determined in alignment with these plans. For the first time, we expanded our compliance priorities to include [Import, Advertising and Supply](#) to better reflect the breadth of our enforcement work.

During 2022-23 investigations into alleged non-compliance were undertaken because:

- a matter was related to a compliance priority (see Table 2 below), or
- a matter was deemed to pose a high level of risk to consumers or the integrity of the regulatory framework and was therefore selected for investigation, either individually or as part of a compliance project.

Changes to the Therapeutic Goods Act 1989

Changes to certain advertising, compliance and enforcement provisions in the Act commenced on 22 March 2023. These changes were included in the [Therapeutic Goods Amendment \(2022 Measures No. 1\) Act 2023](#). The changes were made to reduce administrative burden making a more efficient and effective regulatory scheme and included:

- Changes to allow the Secretary of the Department of Health and Aged Care to extend the period for payment of an infringement notice without the need for an application by the recipient of the notice.

- Clarifying and extending the types of people to whom advertising of therapeutic goods may be directed to (such as certain health professionals) without the material needing to comply with the requirements for advertising to the public (Part 5-1 of the Act).
- Expanding our information gathering powers to permit obtaining information from any person, including third parties, when part of the investigation is of an alleged contravention of the Act.

Changes to the Therapeutic Goods Regulations 1990

Changes made to the [Therapeutic Goods Regulations 1990](#) commencing 20 December 2022 clarified that extemporaneously compounded medicines that contain Schedule 3 (pharmacist only), Schedule 4 (prescription only) or Schedule 8 (Controlled Drugs) ingredients are prohibited from being advertised to the public.

Changes to other legislation

The [Therapeutic Goods \(Declared Goods\) Amendment](#) (Prohibited List) Order 2023 took effect on 1 March 2023.

The amendment was made to ensure currency of the definition of the [World Anti-Doping Code Prohibited Ingredient List](#) (Prohibited List) in the [Therapeutic Goods \(Declared Goods\) Order 2019](#) (Declared Goods Order). The definition had not been updated since 2020, during which time the Prohibited List had been updated three times, with 31 new ingredients added.

Information about the amendment was [communicated via the TGA website](#) and social media to ensure industry was made aware of the change and its limited impact on them.

Working with others

We have continued our cooperative work with other Australian Government authorities throughout 2022-23, including with the Australian Competition and Consumer Commission, the Australian Border Force, and the Australian Federal Police in areas where our regulatory remit overlaps or aligns. These activities have covered a range of issues to help ensure a consistent and cohesive approach.

The Therapeutic Goods Advertising Consultative Committee

Since 2018, the [Therapeutic Goods Advertising Consultative Committee](#) (TGACC) has consistently represented a diverse range of stakeholders from consumer, health professional, media, industry and other government bodies. It is a key forum for engagement on advertising policies and emerging issues. The TGACC met two times during 2022-23 and a communique was published on the [TGA website](#) following each meeting.

In its fifth year of operation, the TGACC provided valuable input on issues, including:

- the review of new [educational guidance](#) to ensure that it is fit for purpose and reflects the needs of stakeholders
- the [Do you check your medicine labels every time?](#) campaign to workshop the content, creative materials and delivery methods.

INTERPOL – Operation Pangea

Throughout July 2022 we led Australia's participation in INTERPOL's Operation Pangea to tackle illicit and counterfeit therapeutic goods worldwide. More than \$2 million of illegal imported products were prevented from reaching their destination within Australia's borders. Globally, more than US\$11 million of product were detected and seized.

Over 4,000 websites and web links that advertised and sold illicit or counterfeit products were shut down or removed. Dozens of organised crime groups were impacted. The media release about this action can be viewed at [TGA participates in global operation tackling illicit and counterfeit therapeutic goods](#).

In June 2023, we participated in Operation Pangea-ED specifically tackling illicit and counterfeit erectile dysfunction medication in the Asia Pacific Region. By engaging with online shopping platforms, we removed over 200 unlawful advertisements in Australia alone. We tested several suspected counterfeit erectile dysfunction products in TGA laboratories. We published 4 safety alert warnings about counterfeit products with undeclared sildenafil which can be viewed at [Australia tablets](#), [Big Penis USA tablets](#), [Germany Niubian tablets](#), and [USA Black Gold tablets](#).

This operation serves as a reminder that [purchasing medicines online can be dangerous](#).

Advertising compliance data and information

Detecting non-compliance

The TGA collects information about the import, export, supply, manufacture and advertising of therapeutic goods in Australia to identify non-compliance. We also receive valuable insights from the community, therapeutic goods industry and the media which, combined with our own monitoring activities, informs our work.

We assess all allegations of non-compliance received to determine whether it sits within our jurisdiction before risk assessing and prioritising cases in accordance with our compliance and enforcement policy.

Volume and source of reports of alleged non-compliance

The following table sets out the number of reports of non-compliance received in relation to alleged advertising breaches in 2022-23 compared with 2021-22. Reports received relates to all information referred to us, not all of which will result in a case, and some reports may result in multiple cases. As such the number of reports received will rarely equate to the number of cases created.

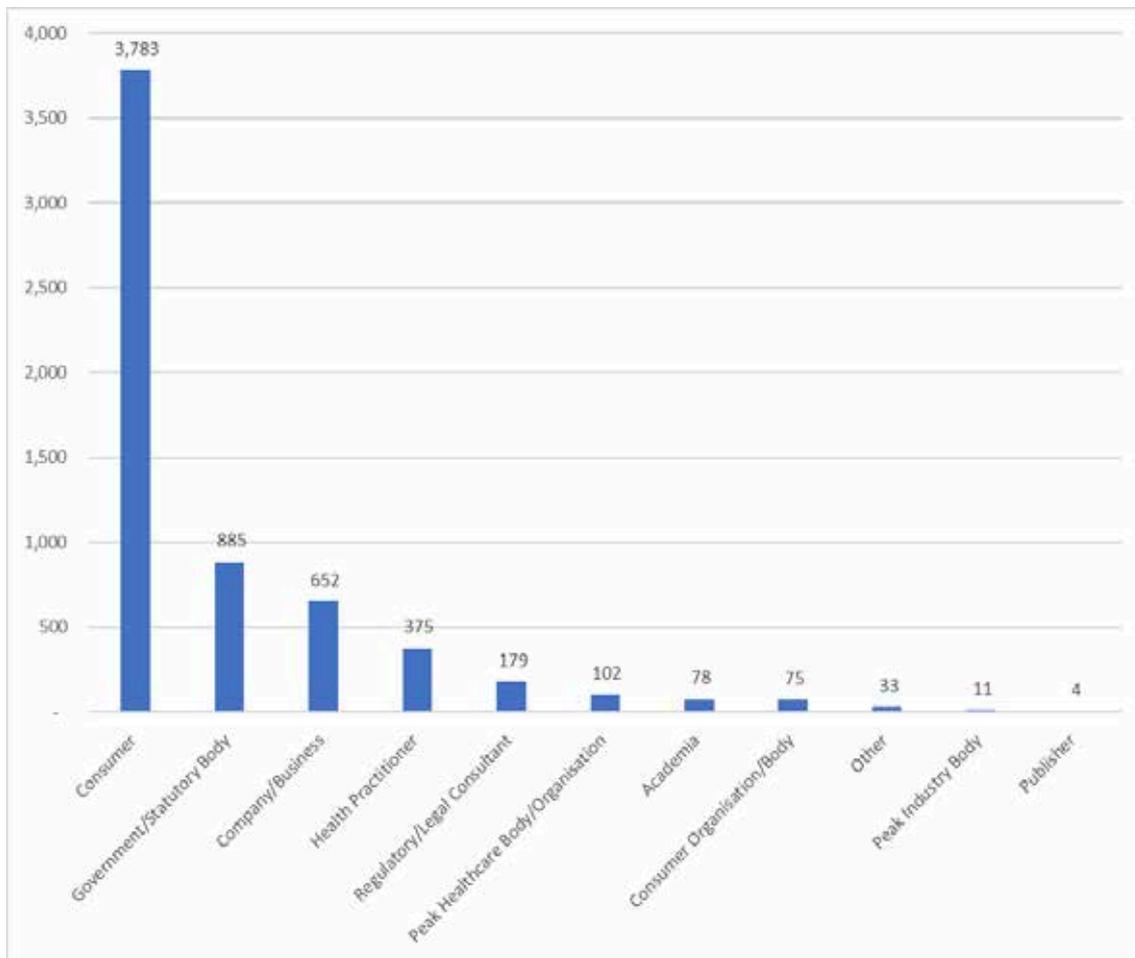
Table 1 – Alleged advertising contraventions report volumes

	2021-22	2022-23
Reports received	3,113	3,064
Cases created	3,061	3,273
Cases closed in the reporting period	2,348 ^a	3,450

^a Data migration and data cleansing activities have impacted the way this number is reported. In this report, cases closed for 2021-22 reflects all cases finalised between 1 July 2021 and 30 June 2022 except those that were impacted by data migration in October 2021. These have been excluded where the most recent outcome is recorded outside of the financial year.

In 2022-23, reports were received from the following sources.

Figure 1 – Sources of reports of non-compliance



Advertiser compliance following TGA action (compliance rate)

The advertising compliance assurance function is a systematic process of assessing whether advertisers who come to the TGA's attention have addressed their advertising compliance issues and maintained compliance.

Assurance review involves re-checking the advertising that was highlighted in a sample of closed cases. Where the TGA requested the removal of advertising, we confirm that the material was removed and not readvertised.

During 2022-23, we assessed 133 closed advertising cases and noted a 77% compliance rate compared to a 96% compliance rate in 2021-22. The increased rate of non-compliance is attributed to more comprehensive reviews as part of the assurance process. Where continued non-compliance was identified, the cases were escalated for additional investigation.

Allegations in relation to compliance priorities

The following table outlines the numbers of allegations received in 2022-23 in relation to the published compliance priorities.

Table 2 – Allegations and cases by compliance priority

Priority	Allegations received	Cases created *	Cases closed
Unapproved therapeutic goods associated with COVID-19	156	201	340
Nicotine vaping products	280	297	292
Medicinal cannabis products	362	384	357
Advertising of unapproved goods on digital platforms	382	382	297
Unapproved performance and image enhancing therapeutics goods including sport supplements	161	179	232
Unapproved therapeutics goods used in the beauty and cosmetic dental industry	118	128	163
Unapproved use of restricted and prohibited representations	141	143	132
IV drip therapy products @	22	22	-
Other #	1,442	1,537	1,637

* Note: Multiple reports may relate to the same case. Reports are triaged through the Advertising Compliance Risk Rating Tool and may be recorded for information only rather than progressing to cases for action.

@ While the category 'IV drip therapy' does fit into 'Other', it is an example of an individual high-risk topic we acted on outside of the published compliance priorities. It is covered in more detail below at [Individual high-risk cases](#).

The category type 'Other' relates to allegations and cases that are not part of one of the published compliance priorities.

Compliance assessment and outcomes

All signals of non-compliance are recorded and considered. We cannot pursue all matters that come to our attention. We will focus on those matters that concern public safety, allege serious breaches of the Act and regulations, and involve repeated or wilful non-compliance.

A range of [compliance and enforcement tools](#) are employed to address alleged non-compliance, either individually or in combination, and to encourage compliance with the Act. Table 3 provides a summary of the assessment of allegations and subsequent actions taken in 2022-23.

Table 3 – Compliance actions recorded

Action taken	Total
Assessed - no further action ^a	1,589
TGA requested removal of advertising ^b	16,328
Warning letter sent	256
Infringement notice issued	228
Value of infringement notices issued	\$2,152,512
Civil cases commenced	1
Civil cases finalised	0
Criminal cases commenced	1
Criminal cases finalised	1
Referred to another internal or external party for action	78
Direction notice issued	4
Enforceable undertaking entered	1

^a The term "no further action" refers to instances where we identified no appropriate avenues of action to take (e.g. no breach identified).

^b The term "TGA requested removal of advertising" refers to the number of advertisements requested for removal from a digital platform.

Unapproved therapeutic goods associated with COVID-19

Over the course of the 2022-23 financial year, the COVID-19 pandemic and related therapeutic goods compliance issues has slowly abated and has now ceased to be treated as an area of priority for the compliance section of the TGA. (This does not mean that individual compliance cases associated with COVID-19 are not actioned as appropriate.)

Details of non-compliance

It remains important that therapeutic goods associated with the prevention, diagnosis and treatment of COVID-19 infections are appropriately approved for supply in Australia. We addressed the illicit import, advertising and supply of unapproved therapeutic goods associated with COVID-19 pursuant to our [Regulatory Compliance Framework](#).

Key outcomes

Compliance outcomes in relation to therapeutic goods associated with COVID-19 for the 2022-23 financial year included the issue of 12 warning letters.

Unlawful import, advertising and supply of nicotine vaping products

Since October 2021, nicotine vaping products such as nicotine e-cigarettes, nicotine pods and liquid nicotine have been regulated as prescription only medicines. The advertising of prescription medicines, including nicotine vaping products, is generally prohibited.

These laws intend to balance the need to both:

- prevent adolescents and young adults from taking-up nicotine vaping (and potentially smoking)
- enable current smokers to access these products for smoking cessation with appropriate medical advice or supervision.

Details of non-compliance

Nicotine vaping products may be lawfully prescribed for smoking cessation however they are also being imported, advertised, and supplied unlawfully in Australia leading to inappropriate access to these products.

In administering and enforcing these laws, we sought to disrupt and address the unlawful import, advertising and supply of nicotine vaping products by:

- gathering and using intelligence to identify non-compliance

- collaborating with other health and law enforcement agencies to target and address unlawful imports and supply
- targeting and taking enforcement action in relation to unlawful advertising of nicotine vaping products to Australians.

Key Outcomes

In 2022-23:

- 48 [infringement notices](#) totalling \$202,464 were issued to 27 entities in relation to allegations of unlawful advertising of nicotine vaping products.
- 1 [enforceable undertaking](#) was entered into
- 4 [direction notices](#) were issued
- 1,006 advertisements were removed from digital platforms.

Additionally, two Federal Court proceedings were commenced against two companies and their sole directors in relation to alleged unlawful advertising. These proceedings remain ongoing.

Proposed reforms

On 2 May 2023, following public consultation on potential reforms, the Australian Government proposed strengthening regulation of vaping products by introducing new controls on their importation, contents, and packaging, while facilitating greater accessibility to vaping products for therapeutic purposes.

See [Taking action on smoking and vaping | Health Portfolio Ministers and Aged Care](#) for more information.

Compliance across the medicinal cannabis industry

Advertising of medicinal cannabis products to the public is prohibited in Australia. These products are regulated as prescription medicines and can only be accessed through TGA pathways for unapproved medicines following a doctor's prescription.

A multipronged strategy has been adopted to address identified non-compliant advertising across the medicinal cannabis industry (this includes individual suppliers, health practitioners, clinics, and the licensed industry). We increased enforcement efforts where entities received prior education or warnings.

Details of non-compliance

We observed, and are addressing, an increase in the following trends:

- the use of third-party platforms (such as media outlets and online business profiles), websites and social media platforms (e.g. Instagram and Twitter) to unlawfully promote the supply and use of medicinal cannabis products

- the promotion of therapeutic goods in conjunction with the promotion of health services (e.g. telehealth services relating to the prescription of medicinal cannabis products).

Key outcomes

The compliance and enforcement activities we took to address unlawful advertising of medicinal cannabis products resulted in significant outcomes that sent a strong deterrence message. In 2022-23:

- We issued 101 infringement notices (totalling \$1,292,040) to 7 entities across different sectors of the medicinal cannabis industry, including licenced medicinal cannabis companies, medicinal cannabis clinics and an individual. These were all in relation to alleged unlawful advertising of medicinal cannabis on online platforms, including websites and social media.

Advertising issues included referring to a company's own named products, use of unapproved references to serious diseases or conditions, such as cancer and epilepsy, and suggested or implied statements that particular medicinal cannabis products were recommended or approved by a government authority.

- We engaged with the event organisers of the Hemp, Health and Innovation Expo in Brisbane as part of our proactive disruption and deterrence strategy.

We issued 14 warning letters to entities intending to be exhibitors at the expo.

A number of exhibitors decided to withdraw from the expo, immediately remedied potential non-compliant advertising on their online platforms or made changes to their sale practices to comply with the advertising requirements.

- We removed 351 alleged unlawful advertisements for medicinal cannabis from digital platforms.
- We engaged with industry bodies regarding our planned education activities including updated guidance for businesses in the medicinal cannabis sector to encourage higher levels of voluntary compliance.
- We escalated enforcement action where entities received prior education about their advertising obligations. This may result in the commencement of civil penalty proceedings or the issue of infringement notices.

Case study – Advertising of medicinal cannabis products

Background

We have warned a number of medicinal cannabis entities about their advertising in-store, online, and on social media and third-party platforms.

For the past two years, we have provided extensive guidance to businesses on how to comply with the advertising requirements, including how to ensure that an advertisement for a health service is not also considered an advertisement for therapeutic goods.

Details of non-compliance

We considered that a medicinal cannabis manufacturer unlawfully advertised medicinal cannabis products on its website and social media pages. While not all information released to the public about therapeutic goods is advertising, in this case, we considered that the information published by the manufacturer was advertising because:

- the website contained testimonials from patients promoting the use of medicinal cannabis products to treat serious medical conditions
- the social media posts were promoted using hashtags that referred to medicinal cannabis products
- the website and social media posts made unauthorised claims about the efficacy of medicinal cannabis.

Actions taken

We issued 23 infringement notices totalling \$306,360 to the manufacturer for alleged unlawful advertising of medicinal cannabis, because the advertisements:

- referred to prescription-only medicines, including the company's own unapproved products
- contained unapproved references to the treatment of serious diseases or conditions, including cancer and epilepsy
- suggested that medicinal cannabis products were recommended or approved by a government authority.

This case is a reminder to all business involved with medicinal cannabis products that they must be aware of and comply with the regulations surrounding the advertising of therapeutic goods, which are in place for consumer protection.

Unapproved performance and image enhancing products and sport supplements

Australians seeking to enhance their physical performance and body shape are vulnerable and being taken advantage of. Unlawful advertising and supply of performance and image enhancing products direct them to health harming products containing scheduled and/or prohibited ingredients.

Products in this compliance priority, which are often sold together, include:

- sport supplement products, including fat burners, pre-workouts, nootropics, and ancillary products that claim to increase testosterone or lower oestrogen
- Selective Androgen Receptor Modulators (SARMs).

Details of non-compliance

Australian manufacturers and retailers of sport supplement products generally have a good awareness of banned stimulants, such as DMAA and DMHA, and have removed these ingredients from product formulations. However, we observe that some retailers continue to import products that contain these ingredients and advertise and supply them to Australians including:

- sport supplement products that:
 - contain substances included in Schedule 4 of the Poisons Standard, such as Levodopa and Synephrine
 - are sold widely via online marketplaces, online stores, and in bricks and mortar retail outlets.
- SARMs:
 - that predominantly include Schedule 4 or Schedule 10 substances in the Poisons Standard, such as the potentially carcinogenic ingredient Cardarine
 - where individuals involved in their sale employ obfuscation tactics to avoid detection and prosecution.

Through significant investigative efforts and the use of our coercive powers, we have been able to unveil numerous entities involved in unlawful SARMs advertising. We are progressing these matters for enforcement action.

Key outcomes

- On 17 March 2023, the Director of AusLabs, Smart Labs and iSARMs, was [sentenced](#) at Downing Centre Local Court to 2 years imprisonment and fined \$300,000 for their role in the manufacture, supply and advertising of illegal SARMs and nootropic products.

The sentence will be served by way of an intensive corrections order. The Director was also ordered to complete 750 hours of community service and received an additional \$1,100 fine for possession of a tablet press, which will be destroyed.

This court outcome follows a complex investigation which led to the seizure under warrant of manufacturing materials for illegal SARMs and nootropics.

- We issued 50 infringement notices totalling \$399,600 for alleged unlawful advertising of unapproved sport supplements.

Advertising of therapeutic goods used in the cosmetic and beauty industry

Some beauty and cosmetic dental products contain substances that are regulated as prescription medicines (such as botulinum toxin A (Botox) and hyaluronic acid fillers). These cannot be advertised to the public. The advertising of prescription medicines to the public is generally prohibited.

Details of non-compliance

Alleged unlawful behaviour in this industry related to advertising of:

- products containing prescription only ingredients (listed in Schedule 4 in the current [Poisons Standard](#))
- unapproved therapeutic goods.

Our concerns include the following trends among advertisers:

- misrepresenting products as being safe, such as anti-wrinkle injections and dermal fillers that contain prescription only ingredients
- widespread use of social media to promote cosmetic procedures and products containing prescription medicines, largely targeting young people
- using acronyms, nicknames, abbreviations, and hashtags on social media posts in a way that promotes the use and supply of unapproved therapeutic devices or medicines used in the industry.

Key outcomes

In addressing non-compliance, we have:

- collaborated with several regulatory agencies such as Ahpra to address non-compliance in relation to the advertising of therapeutic goods (TGA) and professional conduct (Ahpra)
- worked closely with social media platforms, such as TikTok, to remove over 10,000 advertisements unlawfully advertising unapproved beauty and cosmetic dental products directly to the public

- issued 18 warning letters to businesses or individuals alleged to contravene the Act, most of which came into compliance following receipt of TGA warnings
- sent educational and warning letters to a further 36 clinics and health practitioners identified as potentially parallel importing medicines and medical devices, some with alleged unlawful advertising. This was to educate them about their obligations relating to lawfully procuring and advertising therapeutic goods.
- issued a \$2,664 infringement notice to an individual for allegedly advertising unapproved therapeutic goods.

Case Study – Advertising of unapproved therapeutic goods in the beauty and cosmetic industry

About the advertising

Most cosmetic injections, such as anti-wrinkle and dermal fillers, are regulated as prescription medicines. While we do not regulate health services, advertisements for health services that refer (either directly or indirectly) to any therapeutic goods used in delivering those services fall within our remit.

Details of non-compliance

A beauty clinic built a significant social media presence on Instagram and Facebook, targeting vulnerable young consumers seeking to enhance their image using cosmetic injectables, notably Botox and hyaluronic acid fillers.

The advertising used appealing hashtags (#botox) and compelling before-and-after visuals of the proposed therapeutic benefits.

Action taken

We sent a warning letter to the clinic detailing the alleged contraventions of the Act and offering it an opportunity to correct its advertising activities. The alleged contraventions included the promotion of prescription medicines that were not included in the ARTG.

The letter contained educational material to help the company understand their advertising obligations under the Act.

The company acted promptly and removed all non-compliant advertising.

Advertising of unapproved goods on digital platforms

Digital platforms, including social media platforms, allow third-party advertisers to post content regarding therapeutic goods that can reach wide audiences. Unless exempt from this requirement, therapeutic goods must be entered in the ARTG before they can lawfully be advertised for supply in Australia.

Details of non-compliance

We targeted unapproved therapeutic goods being advertised on digital platforms, particularly in relation to products claiming to be for use in weight loss, hangover and pregnancy.

While addressing this issue, we became aware of other potentially unlawful advertising on digital commerce and social media platforms, such as:

- advertising of prescription-only medicines such as [Melanotan](#)
- advertising of products for unapproved indications such as of [Ozempic](#) for weight loss.

Key outcomes

- Our monitoring of digital platforms included increased engagement with online platforms. Following our requests throughout 2022-23, a total of 16,328 non-compliant advertisements were removed from 10 sites.

This is a 14-fold increase to the number removed during 2021-22 (1,147).

- Our increased monitoring of digital platforms allowed for greater flexibility to respond to new issues as they arose.

When social media influencers' role in the [Ozempic medicine shortage](#) became apparent, we shifted focus and engaged with platforms to remove at least 2,283 unlawful advertisements for Ozempic and related products.

- We developed a regular framework for engagement with individual digital platforms. This collaboration has led to the platforms taking steps, such as banning specific hashtags, to prevent some unlawful advertisements being published at all.
- The tools we developed to address this compliance priority are now able to be used more broadly to address emerging issues and compliance priorities into the future.

Individual high-risk cases

We investigate individual cases of unlawful advertising that present a risk to consumer safety or the integrity of our regulatory framework.

Intravenous vitamin and related therapies ('IV drips')

There is a growing market in Australia for intravenous vitamin and related therapies or 'IV drips'.

The market includes cosmetic surgeries, medical practitioners, compounding pharmacies and pharmaceutical manufacturers, nurses, beauty clinics, social media advertisers and businesses solely focused on providing these goods to Australians.

Details of non-compliance

IV drips are being marketed as a quick, safe, and effective way of staying healthy and treating and preventing several (serious) medical conditions such as cancer, mental illness and chronic fatigue. The marketing strategies appear designed to target vulnerable consumer groups and present a public health risk by promoting unapproved therapeutic goods that are not included in the ARTG, a contravention of the Act's advertising requirements.

Unlawful advertising in this way carries the risk of diverting Australians from seeking appropriate medical assistance. Limited studies support effectiveness of vitamin infusions in mainstream use.

Key outcomes

We undertook targeted compliance and enforcement activities to ensure that intravenous vitamin and related therapies are being lawfully manufactured, advertised, and supplied in Australia by:

- educating the industry on the regulatory requirements. We are planning to publish customised guidance material relating to the advertising requirements in 2023-24
- taking appropriate and proportionate enforcement actions in relation to repeat offenders.

In January 2023, we issued 20 infringement notices totalling \$159,840 for unlawful advertising of IV drips in alleged contravention of the advertising requirements in the Act.

We are progressing a number of investigations into serious, wilful and repeated non-compliance with the advertising requirements in this area.

Case study – Advertising of IV drips

About the advertising

Advertising of IV drips must comply with the advertising laws because IV drip products are therapeutic goods.

We have warned several providers of IV drips about their advertising online and on social media platforms. We continue to see unlawful advertising of IV drips especially to vulnerable populations, such as those undergoing treatment for cancer.

Details of non-compliance

A market leader was previously contacted by us regarding its unlawful advertising of IV drips. In contravention of the Act and the Advertising Code the entity's advertisements allegedly contained:

- prohibited and restricted representations
- unapproved government endorsements
- references to prescription only substances (including glutathione for parenteral use)
- statements that the goods were miraculous.

These advertisements were made on the entity's website and social media pages.

Action taken

We escalated our enforcement action to issue 20 infringement notices totalling \$159,840 to the entities.

The entity came into compliance with the advertising requirements.

Melanotan

Melanotan-II is an unapproved prescription medicine and is prohibited from being advertised to the public. It is commonly used as a tanning agent and can be supplied as a pill, cream, injectables and nasal or misting spray.

Details of non-compliance

Despite not being on the ARTG and therefore not evaluated for quality, safety, or efficacy by the TGA, Melanotan-II continues to be promoted as a tanning product. It has also been described as the 'Barbie Drug'.

We saw a concerning trend of advertisers marketing Melanotan-II as a safe and effective tanning agent, particularly targeting young people on social media.

Key outcomes

We strengthened our compliance strategy to curb the illegal import, supply, and advertising of Melanotan-II in Australia by:

- publishing a [media release](#) to:
 - urge consumers to only use products containing Melanotan on advice from a medical professional
 - warn of the potential dangers of consuming the prescription medicine
- partnering with social media platforms, such as TikTok, who in March 2023 banned all advertisements of Melanotan-II directed at Australian consumers
- requesting digital platforms to remove unlawful advertising of Melanotan. This resulted in 513 advertisements being removed from 3 platforms.

Ozempic

Ozempic is a prescription medicine that is included in the ARTG for the treatment of type 2 diabetes. It is also widely used 'off-label' for other conditions such as weight loss. Both Ozempic and other similar medicines were subject to high profile shortages worldwide, spurred on by illegal advertising and celebrity endorsements.

Details of non-compliance

We identified several Australian advertisers allegedly unlawfully advertising Ozempic for weight loss. We also identified several scams targeting consumers seeking the medicine.

The advertising to the public of Ozempic (semaglutide), and other type 2 diabetes medications such as Mounjaro (tirzapeptide) and Trulicity (dulaglutide), for a weight loss indication is unlawful because:

- they are prescription medicines
- weight loss is not an indication that is included in ARTG for these products.

Key outcomes

- We issued 8 warning letters to identified advertisers and provided guidance to assist them to understand their regulatory obligations. They subsequently removed their advertising.
- When we identified advertising of these products on digital or social media platforms, we requested the platforms remove it. This resulted in 2,283 advertisements for Ozempic and related medicines being removed from 3 platforms.
- We wrote to media broadcasters about their obligations concerning the promotion and representations of the use or supply of therapeutic goods when publishing news stories, including Ozempic.
- We published a media release to warn advertisers [that advertising Ozempic \(semaglutide\) is prohibited](#).

- We identified a number of [Counterfeit semaglutide vials](#) and published a [warning to consumers](#) and a series of social media posts about the risks of purchasing these medicines online and what to look out for when attempting to obtain supply.

Compliance education

Our [compliance education strategy](#) provides an overview of the activities we undertake to maximise compliance and minimise inadvertent non-compliance with the advertising requirements.

Our [Advertising and Compliance Education Plan 2023](#) sets out our planned activities based on:

- the [Import, Advertising and Supply Compliance Priorities 2022-23](#)
- stakeholder input and needs
- intelligence about emerging trends and issues.

In response to emerging trends in advertising non-compliance, we have published a series of guidance materials, safety alerts, and consumer awareness materials.

Safety alerts or warnings:

- [Advertising prescription medicine Ozempic \(semaglutide\) is prohibited](#)
- [A warning that advertising Ozempic \(semaglutide\) is prohibited](#)
- [Australia tablets](#)
- [Big Penis USA tablets](#)
- [Counterfeit semaglutide vials](#)
- [EVE Allylisopropylacetylurea tablets](#)
- [Germany Niubian tablets](#)
- [Multani Kaminividravana Rasa \(Kamini\) tablets](#)
- [Penisole capsules \(ayurvedic medicine\)](#)
- [TGA targets unlawful importation of prescription medicines](#)
- [USA Black Gold tablets](#)

Consumer awareness material:

- [Consumers warned about Ozempic scams](#)
- [Do you read the label every time?](#)
- Have you spotted a dodgy ad? Report it to TGA
- Beware of buying medicines and medical devices online

Guidance materials:

- [Advertising COVID-19 rapid antigen point-of-care tests and self-tests \(home use tests\)](#)
- [Complying with advertising requirements](#)
- [Guidance on applying the Advertising Code rules](#)
- [Guidance on mushroom products](#)
- [Therapeutic goods advertising and ASX announcements](#)
- [Using scientific or clinical claims \(representations\) in therapeutic goods advertising](#)
- [Weight loss products.](#)

Campaign – Do you check your medicine labels every time?

As part of developing the current Advertising Code, the TGA commissioned research as part of a review of the mandatory statements required to appear in advertising. The Advertising Code requires mandatory statements in advertising to direct the audience to read the label and directions for use (or consult their pharmacist) for information about the product's suitability. The research demonstrated that there is a lack of awareness of the mandatory statements and the associated 'safe use' behaviours they attempt to achieve, in particular among younger audiences.

As a result of this research we conducted a public education campaign to raise awareness of the 'safe use' behaviours when self-selecting over the counter (OTC) medicines, complementary medicines and medical devices.

The target audiences for this campaign were the Australian public, including young Australians aged 16-34 and Australians with low health literacy. It was promoted on Meta (Facebook and Instagram), digital display ads and pharmacy panels.

Campaign – do you check the label every time?

The [Do you read the label every time?](#) blog was published in support of the campaign. A range of social media posts and graphics on pharmacy boards have also been published. The following image is an example of the material included in that campaign.



Prior to the launch of the campaign, research showed that knowledge of statements on medicine labels and expected behaviours from reading them was low especially amongst younger consumers. This campaign reached over 2.4 million people on Meta, was displayed on health and lifestyle websites over 3.5 million times and was played 3.7 million times at 336 pharmacies across Australia.

Social media

Throughout 2022-23 we published 16 social media posts highlighting alleged breaches of the Act and the Advertising Code.

The 5 posts with highest engagement reached 31,771 people on Facebook.

The most viewed post on an advertising compliance action (10,013 views) was in relation to a company's alleged unlawful use of restricted and prohibited representations in advertising of listed complementary medicines.

These posts placed a spotlight on instances where non-compliant advertising could have detrimental consequences for Australian consumers, and reminded businesses they must comply with the [requirements for advertising](#) and [post-market vigilance and monitoring](#).

Advertising enquiries

Providing an efficient enquiry management function is part of our [compliance education strategy](#) and is a key educational tool.

Enquiries are received from a wide range of stakeholders, from consumers to industry representatives and sponsors. There was a slight increase in the number of enquiries in 2022-23 compared to 2021-22 as shown in Table 4.

Table 4 – Volume of advertising enquiries received in 2022-23 compared to 2021-22.

	2021-22	2022-23
Advertising enquiries received #	494	516

Table 4 figures are based on enquiries received directly by our [Make an enquiry about advertising portal](#) and do not include general advertising enquiries received and answered by our general contact centre or other areas of the TGA.

While 516 enquiries were received in 2022-23, a total of 572 enquiries were closed during the same period. All the enquiries received in the reporting period have been closed.

The key themes across enquiries included:

- the use of testimonials and endorsements in advertisements
 - There was a reduction in the number of these enquiries following the publication of related educational guidance, reflecting an increase in an understanding of the legislative requirements
- medicinal cannabis
 - About 25% of all enquiries received were seeking clarification about how medicinal cannabis clinics could advertise their services without illegally promoting the use or supply of medicinal cannabis. As a result of this trend an update to the existing guidance for these products was included in the [Advertising and Compliance Education Plan 2023](#).

Restricted and prohibited representations

Approval or permission from the TGA (on behalf of the Secretary of the Department) is required before advertisers can use representations which refer to a serious form of a disease, condition, ailment, or defect in consumer advertising of a therapeutic good.

This allows us to consider whether the advertising will be accurate and balanced and not misleading before it is used in advertising, thereby protecting the unique vulnerabilities of Australian consumers and their families who have, or who are facing, a serious disease or condition.

Assessment against the public interest criteria set out in section 29 of the Advertising Code is an important part of these considerations.

Permissions made under section 42DK of the Act

In 2022-23, 6 new permissions were made under section 42DK of the Act.

- The [Therapeutic Goods \(Restricted Representations - COVID-19 Vaccines\) Permission 2022](#) replaced an earlier version of this permission. Consequential amendments were also made to the Advertising Code which does not apply to advertisements made in accordance with this permission.
- The [Therapeutic Goods \(Restricted Representations - COVID-19 and Influenza Test Kits\) Permission 2022](#) updated an earlier permission that related solely to COVID-19 Rapid Antigen Tests.
- The [Therapeutic Goods \(Restricted Representations - COVID-19 Oral Treatments\) Permission \(No. 3\) 2022](#) enables pharmacies to publicly indicate that they can dispense prescriptions for oral COVID-19 treatments.
- The [Therapeutic Goods \(Restricted Representations - Government Health Campaigns\) \(COVID-19\) Permission 2022](#) permits Australian governments to use references to COVID-19 and other serious diseases in advertising goods related to COVID-19 (including hand sanitiser, personal protective equipment or safety apparel) in the context of government health campaigns (other than COVID-19 vaccines).
- The [Therapeutic Goods \(Restricted Representations - Government Health Campaigns\) \(COVID-19 Treatments\) Permission 2022](#).
- The [Therapeutic Goods \(Restricted and Prohibited Representations – IVD Medical Devices\) Permission \(No. 2\) 2022](#) advertisers to use restricted representations in advertising for IVD's that cannot be purchased by the general public.

We publish section 42DK permissions on our website at [notices of approved and permitted representations](#).

Applications to use restricted representations under section 42DF of the Act

If an advertiser wants to use restricted representations in advertising a therapeutic good, but there is no relevant advertising permission or approval in force, an application must be made to the TGA. The representation can only be used after the application has been approved.

In 2022-23 we received 20 applications to use restricted representations under section 42DF of the Act. We approved 12 applications. One further application was partially approved because some of the proposed representations did not meet the relevant criteria. Four applications were withdrawn. Three applications remain under assessment.

We publish section 42DF approvals on our website at [notices of approved and permitted representations](#).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	July 2023

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