



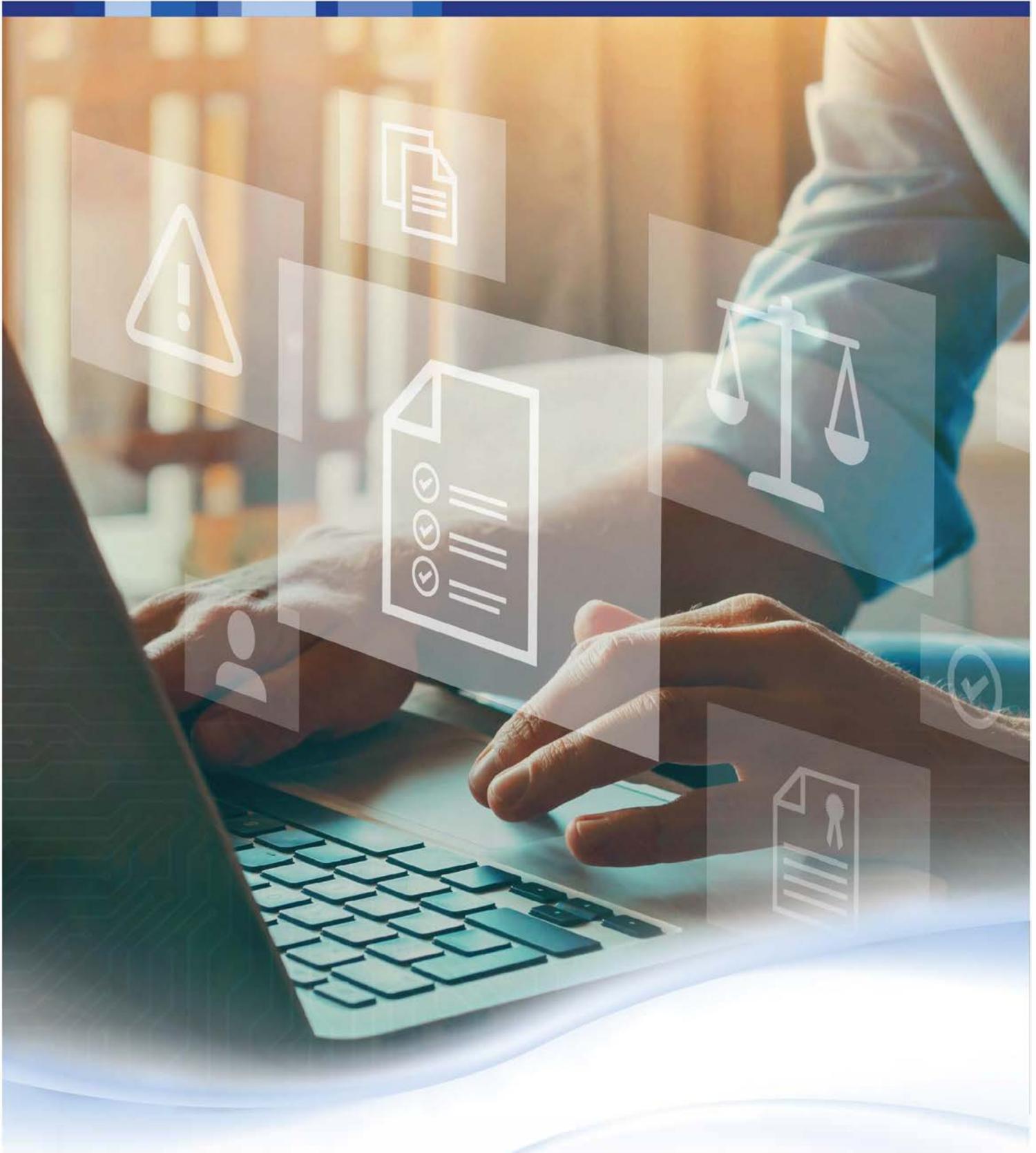
Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Advertising Compliance

Annual Report 2021–22



Copyright

© Commonwealth of Australia 2022

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Executive summary	5
About this report	6
About the advertising framework	6
Advertising regulation in 2021-22	7
Working with others	7
The Therapeutic Goods Advertising Consultative Committee	7
Advertising Code 2021	8
Our compliance and enforcement approach	8
Significant court decisions	9
Education and training	10
Advertising enquiries	11
Social media	11
Restricted and prohibited representations	11
Overview	12
Applications to use restricted representations under section 42DF of the Act	12
Compliance data and information	13
Detecting non-compliance	13
Reports of alleged non-compliance, volume and sources	13
Advertiser compliance following TGA action (the compliance rate)	14
Allegations in relation to compliance priorities	15
Compliance assessment and outcomes	17
Advertising of nicotine vaping products	18
Further actions taken	19
Case study - Advertising of nicotine vaping products	21
Advertising of therapeutic goods associated with COVID-19	22
Details of non-compliance	22
Actions taken	22

Case study – Advertising of therapeutic goods associated with COVID-19 -----	24
Advertising of medicinal cannabis _____	24
Details of non-compliance-----	24
Actions taken-----	25
Case study – Advertising of medicinal cannabis -----	26
Advertising of sports supplements _____	26
Details of non-compliance-----	27
Actions taken-----	27
Advertising of therapeutic goods used in the cosmetic and beauty industry _____	27
Details of non-compliance-----	27
Actions taken-----	27
Advertising of weight loss products _____	28
Details of non-compliance-----	28
Action taken-----	28
Individual high-risk cases _____	28
Case study – Advertising of an off-label indication contributing to prescription medicines shortage-----	29
Case study – food-medicine interface product – mushroom products -----	30

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 and regulations. By assessing whether advertisements for therapeutic goods meet regulatory requirements and taking compliance and enforcement action as appropriate, we seek to uphold our mandate to safeguard and enhance the health of the Australian community.

Since 2018-19 the TGA has published an annual report on the regulation of therapeutic goods advertising. The 2021-22 report explains how we prioritised our efforts to curb non-compliant advertising based on risk and informed by our compliance priorities.

The report details the actions we have taken where compliance issues are identified and provides several detailed case studies. The report also details the guidance we have put in place throughout 2021-22. Guidance assists both regulated and unregulated entities to interpret and apply the regulatory requirements and support the effective and consistent regulation of the advertising of therapeutic goods. Reporting on our compliance and educational activities fosters transparency and accountability.

Two of the compliance priorities we focussed on during the year included:

- COVID-19 products: the report provides information about how we have facilitated, through advertising exemptions, appropriate advertising in relation to COVID-19 vaccines to support the Australian Government vaccine roll-out and details other advertising regulatory work we have conducted in relation to the pandemic, and
- nicotine vaping products: which became an advertising compliance priority following a regulatory change on 1 October 2021 which made these products prescription medicines and thus requiring a valid doctors' prescription for their supply. The report provides examples of the types of non-compliance identified and actions taken in relation to their import, advertising and supply.

The report also provides examples of compliance and enforcement activities that did not fall within a particular compliance priority, but which presented a risk to consumer safety or the integrity of the regulatory framework. This included for example, advertising off-label use of prescription medicines.

Additionally, in 2021-22 the review of the [Therapeutic Goods Advertising Code \(No.2\) 2018](#) was completed, culminating in the making of the [Therapeutic Goods \(Therapeutic Goods Advertising Code\) Instrument 2021](#) which came into effect on 1 January 2022. We undertook extensive consultation throughout the review and published extensive guidance to support the application of the new Code. We also conducted several online seminars and gave presentations to varied audiences to assist advertisers to transition to the updated Code.

About this report

This is the fourth annual report on advertising compliance and covers the 2021-22 financial year. The report provides information about:

- the advertising compliance and enforcement activities conducted, including how the TGA categorises reports of non-compliance, prioritises work and interprets and applies the legislation
- an overview of advertising compliance data, which indicates the sources of reports of non-compliance, the types of products most implicated in reports and the most common breaches found
- how the TGA focussed its regulatory efforts according to our compliance priorities and according to where the highest risks to consumer health and safety were identified
- case studies that demonstrate the TGA's interpretation and application of the legislative requirements
- the TGA's stakeholder engagement and education activities, and
- the work we have conducted to facilitate communications about COVID-19 and nicotine vaping therapeutic goods.

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 also in place because therapeutic goods (such as medicines and medical devices) have risks above and beyond ordinary consumer goods. The legal requirements for advertising therapeutic goods specified in the [Therapeutic Goods Act 1989](#) and in the Therapeutic Goods Advertising Code support consumers making rational and informed decisions about purchasing or using therapeutic goods.

The Therapeutic Goods Advertising Code requires advertising to consumers to be ethical and not misleading or deceptive. The current version is the [Therapeutic Goods Advertising Code 2021](#).

During 2021-22, investigations into alleged non-compliance were undertaken either because:

- the matter was related to a compliance priority, or
- the matter was deemed to pose a high level of risk and was therefore selected as an individual case for investigation.

Advertising regulation in 2021-22

In conjunction with our COVID-19 compliance and enforcement activities and in addition to the [Therapeutic Goods \(Restricted Representations - COVID-19 Vaccines\) Permission \(No. 4\) 2021](#) which enables advertising, including the availability of COVID-19 vaccines, the TGA issued several other COVID-19 advertising permissions in 2021-22:

- [Rapid Antigen Tests and Nucleic Acid Amplification tests](#) (both in the context of Government Health Campaigns and in other advertising)
- [COVID-19 oral treatments](#) (both in relation to advertisements advising of supply information for consumers and in the context of Government Health Campaigns), and
- [COVID-19 testing advice](#) (advice to 'get tested for COVID-19' in advertisements for therapeutic goods).

These permissions were issued to ensure that members of the public have access to important information in relation to testing and treatment products.

Working with others

Collaboration with therapeutic goods industry peak bodies, sales platforms, other regulators and law enforcement is essential for promoting preventative compliance.

We have continued our cooperative work with other Australian Government authorities throughout 2021-22, including with the Australian Competition and Consumer Commission, the Australian Border Force and the Australian Federal Police. These activities have covered a range of issues, including COVID-19 and nicotine vaping matters, to help ensure a consistent and cohesive approach.

The TGA also engaged with several online retail platforms to remove non-compliant advertising from these sites with 1,147 advertisements taken down throughout 2021-22. Steps are underway to encourage these companies to automatically remove such advertising without intervention by the TGA. One major online retailer has already implemented a new complementary medicines policy outlining which products may and may not be listed on its platform. The TGA continues to engage with similar companies to encourage such strategies aimed at preventing non-compliant listings.

Input from peak industry bodies over the past financial year has helped the TGA craft guidance on the application of the Code and helped to identify areas of concern with respect to advertising compliance priorities.

The Therapeutic Goods Advertising Consultative Committee

The [Therapeutic Goods Advertising Consultative Committee](#) (TGACC) represents a diverse range of stakeholders from consumer, health professional, media, industry and other government bodies and is a key forum for engagement on advertising policies and emerging issues. The TGACC met three times during 2021-22 and a communique was published on the [TGA website](#) following each meeting.

In its fourth year of operation, the TGACC provided valuable input to the review of the Advertising Code.

Advertising Code 2021

The Advertising Code 2021 was implemented following a lengthy consultation and review process. This included feedback from an external review of the changes to advertising regulation made under [the Sinclair review](#); stakeholders with a direct interest in the Code; the TGACC; and the public. An independent consumer-based assessment and consumer testing project was commissioned to Orima Research into the effectiveness of certain mandatory advertising statements and requirements. The findings were used to inform the requirements in the 2021 Code.

The changes to the Advertising Code have improved clarity, reduced complexity, and resolved inconsistencies, along with improving messaging for consumers.

Following its commencement on 1 January 2022, a 6-month transition period applied where advertisers could apply either the 2018 Code or the 2021 Code. The transition period ended on 30 June 2022. All advertising must now comply with the 2021 Advertising Code. To assist advertisers to comply we published guidance and hosted several training webinars throughout the first half of 2022 (see [Education and training](#) below).

Our compliance and enforcement approach

During 2021-22, the TGA undertook advertising compliance and enforcement activities using a risk-based, intelligence-informed approach, focussed on non-compliance assessed to be of greatest concern.

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. The compliance priorities are determined in alignment with these plans.

To determine our annual compliance priorities (see Table 1), we collect and analyse data from a range of information sources, including feedback from the community, other regulators and stakeholders including the members of the TGACC, results from monitoring activities, trends in non-compliance, and open-source information.

Table 1 – 2021-22 compliance priorities

Priority 1	Therapeutic goods associated with COVID-19
	Nicotine vaping products
Priority 2	Stem cell products
	Medicinal cannabis
	Performance and image enhancers
	Therapeutic goods used in the cosmetic and beauty industry
	Hangover cures
	Weight loss products
Priority 3	Mental/learning acuity products
	Bioresonance products

Significant court decisions

The TGA's resolve to disrupt and deter non-compliant advertising of therapeutic goods has been supported by the Federal Court of Australia in *Secretary, Department of Health v Oxymed Australia Pty Ltd* [2021] FCA 1518 where Rofe J confirmed the TGA's regulatory posture by stating:

"It is the responsibility of anyone who wishes to engage in a business which involves the use of therapeutic goods or the provision of health services to be aware of the applicable statutory scheme, the conduct that is prohibited, and to comply with the relevant regulatory requirements established under the TG Act, from the time they start the provision of those services, if not before."

On 27 July 2022 the Federal Court handed down its decision in a matter involving non-payment of an infringement notice issued to Enviro Tech Holdings Pty Ltd for unlawful importation of face masks. Hespe J stated:

"The contravention in this case was by persons who were inexperienced in dealing with therapeutic goods and were unfamiliar with the requirements of the TG Act. Although their acts relating to the importation of the masks were intentional, their contravention of the TG Act was not."

"... Ignorance of the requirements of the TG Act and regulations, and inexperience in dealing with the regulatory regime, are not an excuse. Those who wish to engage in business involving therapeutic goods have a responsibility to be aware of the applicable statutory scheme and to comply with the relevant regulatory requirements (Secretary, Department of Health v Oxymed Australia Pty Ltd (2021) 397 ALR 241; [2021] FCA 1518 at [251])."

Education and training

The [compliance education strategy](#) provides an overview of our education efforts which aim to maximise compliance and minimise inadvertent non-compliance with the advertising rules by:

- providing information and educational resources
- leading and participating in education and training opportunities
- generating targeted compliance and enforcement-based communications, and
- providing an efficient enquiry management function.

Using a range of means and channels to reach our intended audiences, our education activities are based on:

- the advertising compliance priorities
- stakeholder input and needs, and
- emerging trends and issues.

Throughout the year we provided education face to face, via webinar and through seminars and continued to add guidance material to the [Advertising Hub](#).

We also published the following educational materials and information:

- [Guidance on applying the Advertising Code rules](#)
- [Testimonials and endorsements in advertising](#)
- [Advertising Code FAQs](#)
- [Webinar presentation: 2021 Therapeutic Goods Advertising Code, 20 January 2022](#)
- [Webinar presentation: 2021 Therapeutic Goods Advertising Code, 17 February 2022](#)
- [The Advertising Code and naming therapeutic goods](#)
- [Advertising nicotine vaping products to the Australian public](#)
- [Nicotine vaping products: Compliance and enforcement](#)
- [Regulatory changes to importing nicotine vaping products](#)
- [Regulatory changes to importing, supplying and advertising nicotine vaping products](#)
- [Obtaining approved COVID-19 rapid antigen tests](#)
- [Importing COVID-19 rapid antigen tests \(RATs\)](#)
- [Advertising: when cosmetics are regulated as therapeutic goods.](#)

Advertising enquiries

Table 2 shows the number of advertising enquiries received in 2021-22 compared to 2020-21.

Table 2 – Advertising enquiries volume

	2020-21	2021-22
Advertising enquiries received	455	494

Enquiries were received from a variety of stakeholders including consumers, industry and third-party advertisers (e.g. retailers). There was a slight increase in the number of enquiries received in 2021-22 compared with the previous year.

The updated Advertising Code generated a large number of enquiries this year, particularly from industry and third-party advertisers (such as pharmacies) seeking clarification about the correct interpretation of its provisions. In particular, enquiries were received in relation to testimonials and endorsements, resulting in updated guidance being published. Enquiries in relation to COVID-19 product advertising continued but to a lesser extent than the previous two years.

The figures in Table 2 are based on enquiries received directly by the advertising regulation section of the TGA and do not include general advertising enquiries received and answered by the TGA's general contact centre.

Social media

Throughout 2021-22 the TGA published 51 social media posts highlighting alleged breaches of the Act and the Code.

The five posts with highest engagement reached 42,497 people on Facebook in total. The most viewed post on advertising compliance action was in relation to a company for unlawful advertising of an unapproved COVID-19 vaccine (12,378 views).

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](#).

Restricted and prohibited representations

Authorisation 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.

This allows the TGA to consider whether the advertising will be accurate and balanced and not misleading before it is used, thereby protecting the unique vulnerabilities of Australian consumers and their families who have, or who are facing, a serious disease or condition. Reflection on the public interest criteria set out in section 29 of the Advertising Code is an important part of these considerations.

Overview

In 2021-22, 14 new permissions were made under section 42DK of the Act, the kind that advertisers cannot apply for. Five of these permissions related to COVID-19 and were issued to enable advertisers to disseminate information about the use and availability of goods used in the detection, prevention and treatment of COVID-19.

Additionally, the TGA issued three permissions of note:

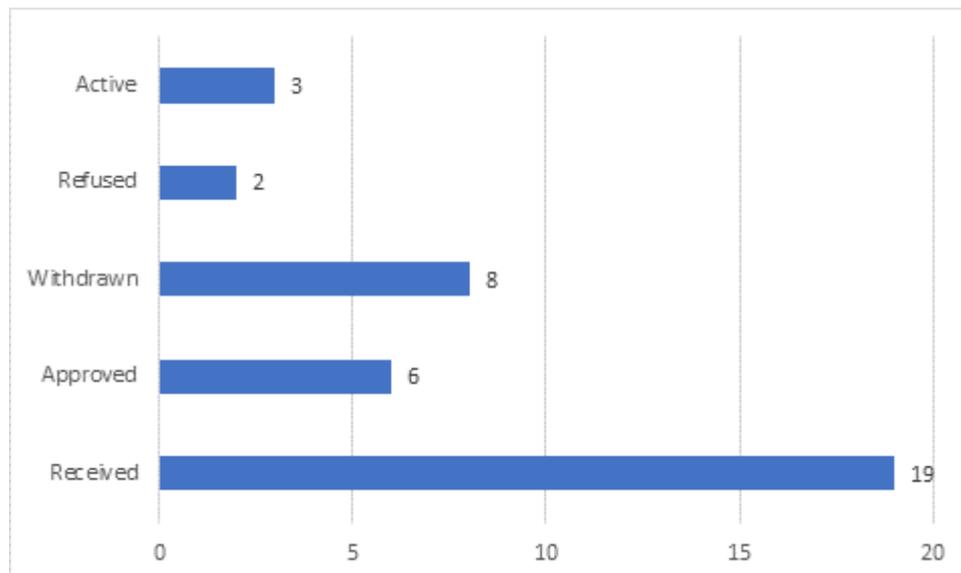
- in collaboration with the Australian Federation of Aids Organisations (AFAO), we issued an updated permission enabling the advertising by AFAO and its member organisations and by pharmacies that promote the use and supply of [HIV self-test kits](#)
- a permission enabling approved vaccination providers to indicate the availability of [influenza](#) vaccines, and
- a permission enabling pharmacies and other dispensers to identify for consumers the availability of the new oral [COVID-19 treatments](#) for timely supply on presentation of a valid prescription.

The TGA publishes section 42DK permissions on its website at [notices of approved and permitted representations](#).

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

If an advertiser wishes to use restricted representations in advertising (including on labels) but there is no relevant permission under section 42DK of the Act in force, they must apply to the TGA for approval to use a restricted representation in advertising. We approved 6 uses of restricted representations under section 42DF of the Act.

Figure 1 – Applications to use restricted representations 2021-22.



Note: withdrawn applications include those where the request has been met through the use of a section 42DK permission and instances where the application was voluntarily withdrawn by the applicant.

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 TGA's jurisdiction before risk assessing and prioritising cases in accordance with our compliance and enforcement policy.

Reports of alleged non-compliance, volume and sources

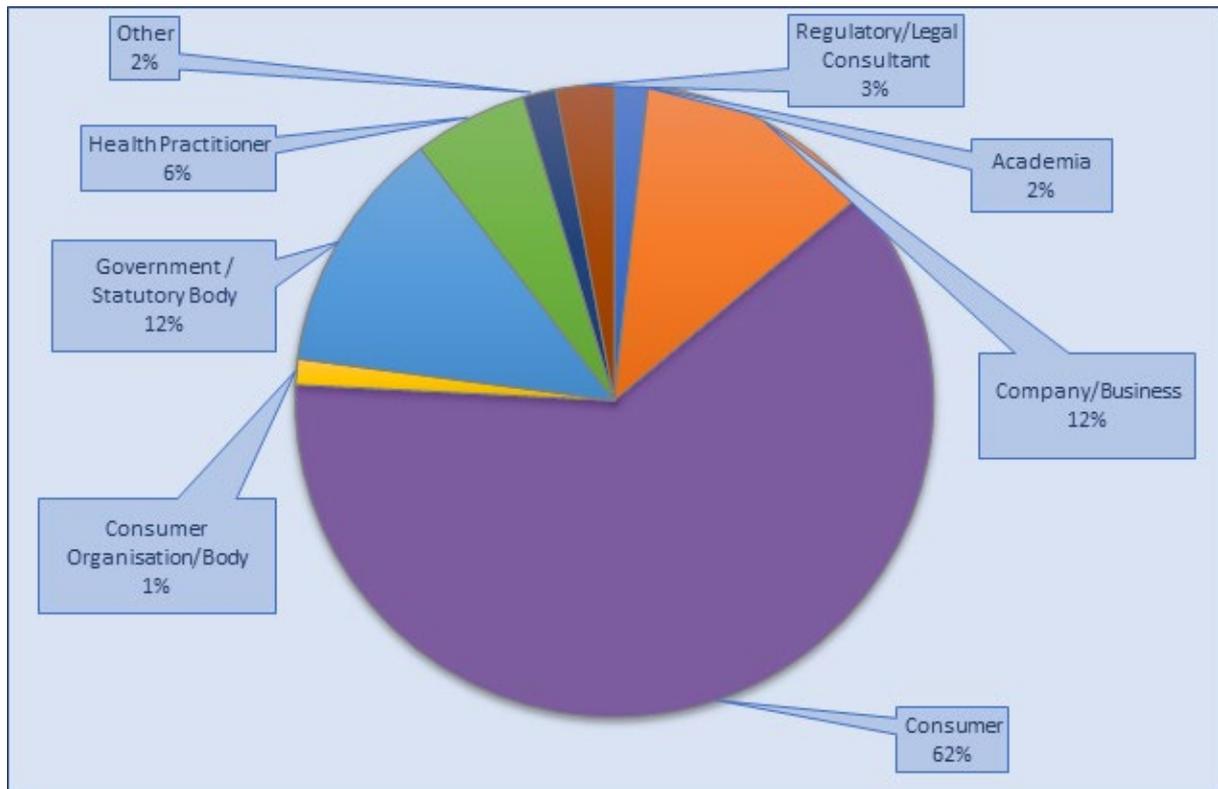
The following table sets out the number of reports of non-compliance received in relation to alleged advertising breaches in 2021-22 compared with 2020-21. It is important to note that reports received does not equate to cases created. The higher number of cases closed in 2020-21 is a consequence of the transition from the former complaints-driven model to the new intelligence-led risk-based model of case prioritisation, resulting in a high number of older matters being closed.

Table 3 – Alleged advertising contraventions report volumes

	2020-21	2021-22
Reports received	2,074	2,991
Cases created ^b	1,140	1,360
Cases closed in the reporting period	2,354	850

In 2021-22, reports were received from the following sources.

Figure 2 – Sources of reports of non-compliance



Advertiser compliance following TGA action (the 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.

It involves checking a portion of online advertising listed by advertisers a specified period after the TGA has raised concerns with them. Where the TGA has requested the removal of advertising, we will confirm that the material has been removed and not relisted.

During 2021-22, we assessed 263 closed advertising cases and noted a 96 per cent compliance rate. One hundred and thirty-two of these cases related to COVID-19 product related advertising where we noted a 98 per cent compliance rate for this sub-group.

Allegations in relation to compliance priorities

The following table outlines the numbers of allegations received in 2021-22 in relation to the published compliance priorities.

Table 4 – Allegations and cases by compliance priority

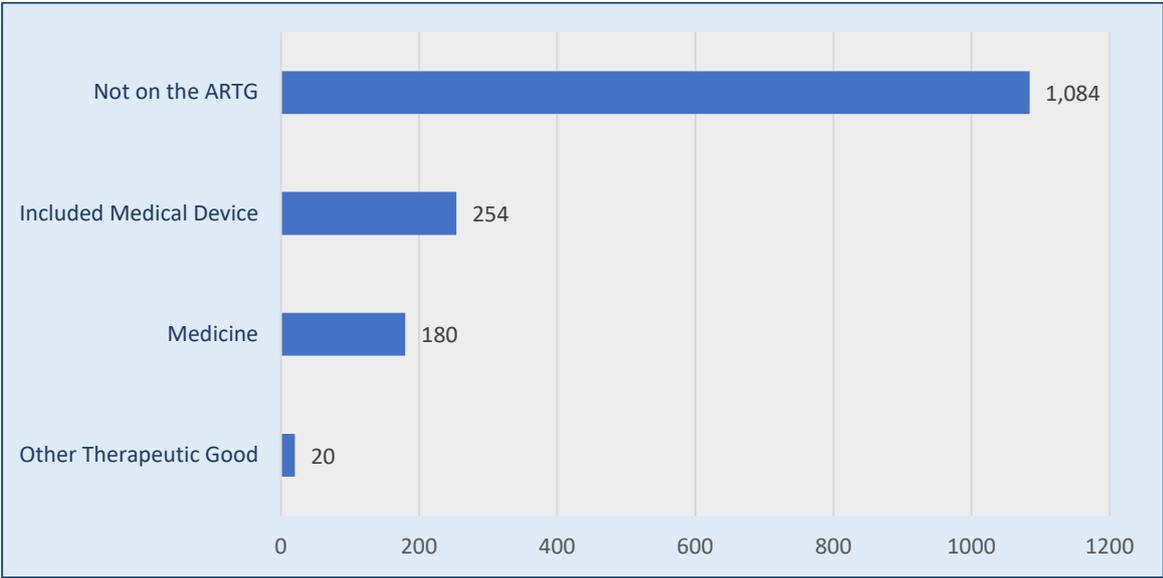
Tier	Priority	Allegations received	Cases created*	Cases closed
1	COVID-19	747	433	377
	Nicotine vaping products	263	133	80
2	Stem Cells	5	3	-
	Medicinal Cannabis	226	101	66
	Performance and image enhancers	143	84	20
	Therapeutic goods used in the cosmetic industry	211	69	20
	Hangover cures	8	1	1
	Weight loss products	56	26	3
3	Mental/learning acuity	11	9	1
	Bioresonance	280	149	43
Other ^a		1,041	352	239
Total		2,991	1,360	850

**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.*

^a The category type 'Other' relates to allegations and cases that are not one of the stated compliance priorities.

Figure 3 shows the category of goods that were included in compliance priority cases in 2021-22. Seventy per cent of the associated products were not on the Australian Register of Therapeutic Goods (ARTG).

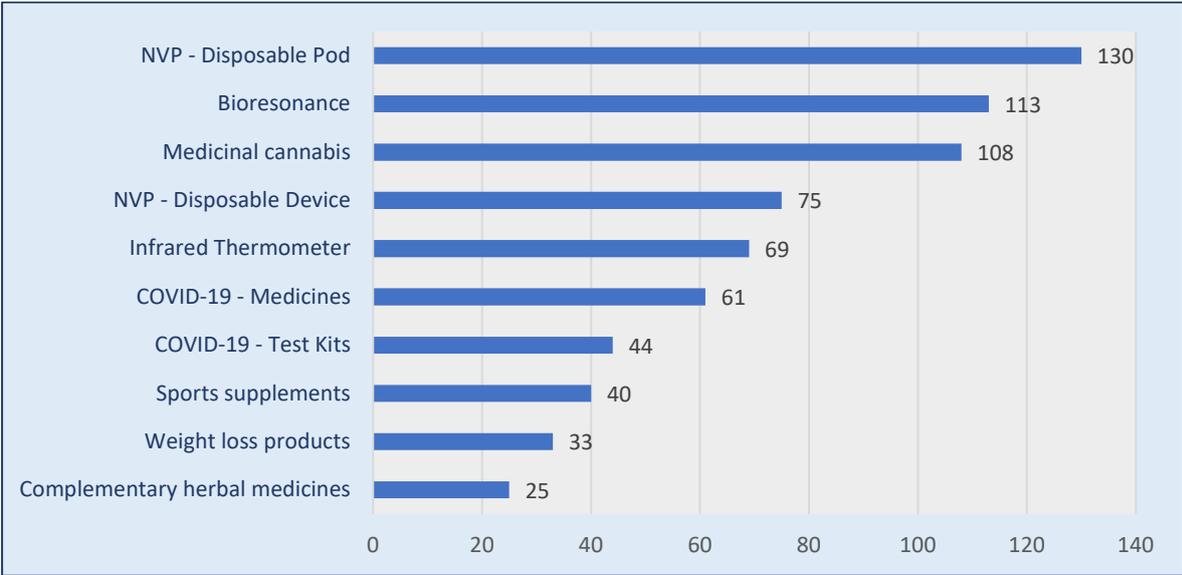
Figure 3 – Product categories in relation to cases attached to a compliance priority area



*Note. Multiple products may relate to the same case therefore these statistics do not correlate to cases created in Table 4.

Figure 4 expands the 'Not on the ARTG' product category showing the associated product types.

Figure 4 – Top 10 product types for products 'Not on the ARTG'



*Note. Multiple products may relate to the same case therefore these statistics do not correlate to cases created in Table 4).

Compliance assessment and outcomes

The initial assessment of reports of non-compliance includes an examination to determine:

- if there was an applicable offence; including if it was within the TGA's jurisdiction to take action on the matter
- the likelihood that the offence occurred
- any relevant history of non-compliance by the entity
- the likely consequences and seriousness of the non-compliance including:
 - the risk of harm to consumers from the alleged contravention
 - the nature of the alleged breach
 - the vulnerability of the target market
 - alignment with the advertising compliance priorities, and
 - the size, reach and compliance history of the advertiser.

The appropriate level of investigation and compliance response is determined based on the outcome of the initial assessment.

The TGA may:

- elect not to pursue the matter further (for example, where an allegation does not relate to a breach of the law)
- take action to increase awareness and encourage compliance (such as using educational materials and engaging relevant stakeholder groups)
- use a compliance response (such as directing an illegal advertisement is removed or modified, or working with online platforms to remove illegal advertising), and/or
- proceed with further investigation.

Investigations are carried out to:

- determine whether the law has been breached
- improve compliance to ensure the objects of the legislation are being met
- deter further or similar non-compliance
- maintain confidence in the integrity of the regulatory system, and
- gather additional evidence that would assist in taking appropriate compliance and enforcement outcomes.

When the TGA chooses to use an enforcement measure, we consider factors such as:

- the nature and severity of the harm caused
- the cooperation and intent of the alleged offender, and
- the threat to the objectives of the legislation.

A matter may also be referred to the Australian Federal Police or other enforcement agencies. When this happens, we support the investigating agency as needed. Table 5 provides a summary of the assessment of allegations and subsequent actions taken in 2021-22.

Table 5 – Compliance actions recorded

Action taken	Total
No breach identified	334
Referred to another agency	6
Advertisements removed from online platforms	1,174
Warnings issued ^a	343
Infringement notices issued	110
Civil matters commenced	1
Civil matters in progress	1
Criminal matters finalised	2
Civil matters finalised	2
Total	1,976

^a The term "warnings issued" relates to all correspondence advising advertisers of an alleged breach of the legislation.

Advertising of nicotine vaping products

On 1 October 2021, the entry for nicotine in Schedule 4 to the Poisons Standard was amended to capture all nicotine vaping products such as nicotine e-cigarettes, nicotine pods and liquid nicotine as prescription only medicines. The advertising of prescription medicines to consumers is generally prohibited in Australia.

The focus of Australia's approach to nicotine vaping products is to prevent children and young Australians from using these products while enabling adults to have access to them under a doctor's prescription for the purpose of smoking cessation.

In the lead up to 1 October, the TGA sent educational fact sheets about the changes to 1,300 known personal importers of these products and several commercial entities assessed to be of potential compliance risk. The fact sheets are published on the TGA website. The TGA also published a compliance and enforcement plan outlining its activities for nicotine vaping products.

The TGA is using a range of deterrence and disruption strategies to address four concerning behaviours:

- **The deliberate omission of references to nicotine on product packaging and labelling**

The TGA laboratories assist in determining the regulatory status of products and our ability to escalate enforcement action. The removal of 'nicotine' from product labelling advertising is the subject of current court proceedings against a company and its director.

- **Widespread advertising by social media influencers**

We are targeting advertising of nicotine vaping products by social media influencers on Instagram, Facebook, Snapchat and Tiktok. This involves seeking the cooperation from various social media platforms to remove advertisements alleged to be non-compliant.

- **"Cloaking" and "phoenixing" of websites**

The TGA is seeing a trend in persons responsible for a website cloaking their identity by, for example, not registering their website to an Australian domain (.com.au) or moving their operations to overseas-domiciled websites. Website registrants who are easily identifiable are not necessarily those responsible for supplying or advertising the largest number of products or engaging in the most egregious behaviour.

There is also a rise of phoenixing activity by entities which, upon being contacted by the TGA, remove the relevant website only to create a new, usually identical, website under a new domain name.

The TGA targeted cloaking and phoenixing behaviour in May 2022 by issuing six infringement notices totalling \$79,920 to two NSW based companies and commencing civil penalty proceedings in the matter of Vapor Kings Pty Ltd and their director Amir Kandakji.

- **Supply of products through promotion of prescription services**

The TGA has issued a direction notice in addition to infringement notices for prescription service providers alleged to have unlawfully advertised nicotine vaping products. This approach has allowed a more effective educational approach as the publication of a direction notice creates a deterrence to promoting health services in a way that contravenes the Act and the [Therapeutic Goods \(Restricted and Prohibited Representations - Nicotine\) Permission \(No. 2\) 2021](#).

In June 2022, three direction notices were issued directing the relevant entities to cease using words in the website URL and the company trading name such as 'vape' or 'vaping' in conjunction with 'prescription', 'script', 'pharmacy' or 'medical'.

In March 2022 the TGA issued three infringement notices to a company (\$39,960) for the alleged unlawful advertising of nicotine vaping products on the company's website.

Further actions taken

As part of its strategy to address alleged unlawful advertising by some in the nicotine vaping products industry, we issued over 40 warning notices requiring action to advertisers and issued 75 infringement notices totalling over \$600,000.

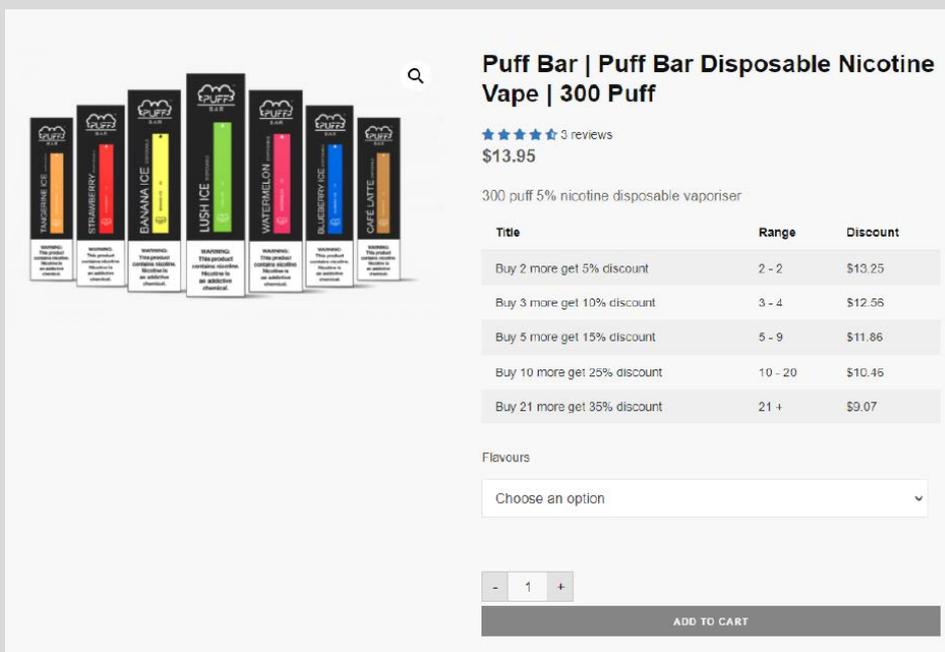
On 16 June 2022 the TGA commenced Federal Court proceedings against Prefixx Pty Ltd and its sole director Mr Brad Anthonisz for alleged unlawful advertising of nicotine vaping products. This was followed on 27 July 2022 by the commencement of Federal Court proceedings against Vapor Kings Pty Ltd and its director Amir Kandakij for similar alleged behaviour. Further cases are being considered for civil penalty proceedings.

The TGA is committed to disrupting and addressing 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 targeting unlawful advertising of these products to Australians.

Case study - Advertising of nicotine vaping products

Since 1 October 2021, nicotine vaping products have been regulated as prescription only medicines in Australia and must not be directly advertised to Australian consumers unless the advertising meets the conditions of the [Therapeutic Goods \(Restricted and Prohibited Representations - Nicotine\) Permission \(No. 2\) 2021](#). Unlawful advertising of these products may constitute a criminal offence and contravene a civil penalty provision under the Act.

The TGA identified a website allegedly advertising over 200 nicotine vaping products across three websites and social media. This website was of particular concern as it was advertising disposable vaping products available in several different flavours in such a way that made it clear it was being promoted to children and young Australians. An extract of one the products advertised is below.



Title	Range	Discount
Buy 2 more get 5% discount	2 - 2	\$13.25
Buy 3 more get 10% discount	3 - 4	\$12.56
Buy 5 more get 15% discount	5 - 9	\$11.86
Buy 10 more get 25% discount	10 - 20	\$10.46
Buy 21 more get 35% discount	21 +	\$9.07

The advertiser was advertising to supply disposable nicotine vaping products through a New Zealand subsidiary directly to Australian consumers. However, it is alleged the individual advertiser was responsible for the advertising and this individual was in Australia.

It is alleged that this business model had been set up in an attempt to avoid Australian regulatory obligations. The advertiser remained non-compliant after warnings, and a direction notice was issued to them directing them to cease advertising the nicotine vaping products. We suggested that one way of complying would be to geoblock the websites and social media so Australians could not view the advertising.

The proposed direction, however, did not bring the advertiser into compliance, and instead it is alleged that changes were made on the website to remove express references to "nicotine" as an ingredient in the advertising material. Further correspondence was sent indicating that this may result in the supply of counterfeit therapeutic goods.

A range of actions were used to attempt to bring the website into compliance and change the behaviour of the advertisers. These included the:

- sending of a warning letter requiring the immediate removal of the advertisements
- a regulatory phone call to discuss the matter further with the advertisers

- a proposed direction to the advertisers.

As none of these tools brought about the required changes, the TGA commenced civil penalty proceedings in June 2022 seeking, amongst other things, the imposition of a significant financial penalty.

Advertising of therapeutic goods associated with COVID-19

The TGA has continued to take advertising non-compliance in relation to therapeutic goods associated with COVID-19 very seriously and employs a range of education and compliance approaches to address alleged breaches of the advertising requirements.

Details of non-compliance

The most common non-compliant advertising behaviour observed related to:

- the promotion of medicines or products for the treatment, prevention, or cure of COVID-19, without a restricted representation permission to refer to the serious disease, including disinfectants and hand sanitisers, hydroxychloroquine and ivermectin, and
- the promotion of therapeutic goods not entered in the ARTG.

Actions taken

In July 2021 a company was issued with infringement notices totalling \$93,240 for alleged unlawful advertising of an unapproved product. Following a warning, the company has taken steps to remediate their online advertising and has paid the infringement notices. In the same month an ACT individual was issued an infringement notice for \$2,664 in relation to alleged unlawful advertising of a homeopathic medicine with COVID-19 claims.

In November 2021 two sets of infringement notices were issued for alleged unlawful advertising of ivermectin, zinc and homeopathic medicines for COVID-19. One set was issued to a New South Wales individual for \$7,992, another to a Queensland individual for \$2,664.

In the same month, a reminder was issued to over 50 sponsors of COVID-19 rapid antigen tests asking them to review their websites against relevant guidance and the advertising requirements under the Act; in particular, the 2018 Code, and the Therapeutic Goods (Restricted Representations – COVID-19 Rapid Antigen Tests) Permission (No. 3) 2021. We followed up between December 2021 and March 2022 targeting over thirty advertisers in relation to alleged unlawful advertising of COVID-19 rapid antigen tests that were not included in the ARTG.

A high voluntary compliance rate was achieved through this effective use of regulatory phone calls and warning notices. Compliance action was escalated where appropriate through, for example, the issuing of an infringement notice to a company in the amount of \$13,320 for alleged non-compliance with the [Therapeutic Goods \(Restricted Representations – COVID-19 Rapid Antigen Tests\) Permission \(No.2\) 2022](#).

In December 2021, Oxymed Australia Pty Ltd and the company's director Malcolm Hooper were ordered by the Federal Court of Australia to pay \$3 million for unlawful advertising of hyperbaric oxygen therapy devices. The devices were advertised for the treatment of serious diseases and

medical conditions, including Alzheimer's disease, cerebral palsy, dementia, COVID-19, stroke, HIV/AIDS, cancer, depression and post-traumatic stress disorder. The court action arose as a result of Oxymed electing not to pay infringement notices in relation to the alleged contraventions.

In February 2022, a Chinese Medicine practitioner based in New South Wales was given an infringement notice relating to the alleged unlawful advertising of homemade medicines for COVID-19. The advertising material included that the product was a 'miracle cure' for COVID-19.

In March 2022 an infringement notice for \$13,320 was issued to South Australian company Vaxine Pty Ltd in relation to alleged unlawful advertising of an unapproved COVID-19 vaccine which, at the time, was the subject of a clinical trial. The advertising was alleged to have occurred on the company's Facebook page and YouTube. The company remedied its advertising and has paid the infringement notice.

The TGA has issued warning notices (and achieved voluntary compliance) in relation to a range of alleged unlawful advertising behaviour involving:

- an unapproved encapsulated turmeric product in connection with COVID-19
- personal protective equipment, and for making representations that these goods were effective in preventing the transmission of the coronavirus
- a facial steamer in relation to COVID-19 on social media
- Etsy advertising of handcrafted earrings made from empty COVID-19 vaccine vials
- an asthma device included on the ARTG being advertised as preventing the coronavirus and COVID-19, and
- a range of unregistered disinfectants as being effective against the coronavirus and COVID-19.

In June 2022 an enforceable undertaking was negotiated with a company in relation to alleged advertising breaches that implied face masks advertised on their website were approved by the TGA. The undertaking is enforceable for a period of three years. Two infringement notices were also issued to the company. This is in addition to previous infringement notices issued in 2020 in relation to alleged advertising breaches for disinfectants and hand sanitisers.

Case study – Advertising of therapeutic goods associated with COVID-19

About the advertising

On 1 November 2021 the TGA approved COVID-19 self-tests (home use tests) for supply in Australia. This triggered a range of compliance activities in relation to consumer advertising of the tests.

Details of non-compliance

On 5 January 2022, the TGA responded to several reports received by the Irish Health Products Regulatory Agency (IHPR) concerning the performance of rapid antigen tests. Of concern, those reports alleged that 550 people who had tested positive for COVID-19 using the tests did not have their results confirmed through a PCR test they subsequently undertook.

Cognisant of the pressure that false results would have on Australia's health system and on the individuals involved, we commenced enquiries into how the antigen tests were advertised in Australia, noting they had not been included in the ARTG and the TGA therefore could not vouch for the safety, efficacy and quality of those particular products.

Actions taken

On the same day of the international alert, the TGA identified and contacted an Australian company advertising the test kits on their website. The company removed the advertising from their website that day.

The effective use of regulatory phone calls and succinct warning notices has resulted in voluntary compliance by all advertisers contacted during that period in relation to their advertising of unapproved test kits.

Advertising of medicinal cannabis

Consumer advertising of medicinal cannabis products is prohibited in Australia. These products are regulated as prescription medicines and can only be accessed through TGA pathways for unapproved medicines following a doctors' prescription.

A multipronged strategy has been adopted in addressing identified non-compliant advertising across the medicinal cannabis industry, this includes individual suppliers, clinics, pharmacies and the licensed industry. We increased enforcement efforts where entities have received prior education or warnings.

Details of non-compliance

The TGA has observed (and is addressing) an increase in the following trends:

- the use of media outlets, websites and social media platforms (e.g. Instagram and Twitter) to unlawfully promote the supply and use of medicinal cannabis products. For example, the use of infotainment programs to broadcast good news stories about the use of unapproved medicinal

cannabis products and the promotion of those products through URL addresses and 'hashtags' across social media platforms

- the interface between health services and the promotion of therapeutic goods resulting in non-compliance with the advertising legislation, and
- companies promoting a combination of unapproved prescription medicines (e.g. medicinal cannabis and nicotine vaping products).

Actions taken

In September 2021, seven infringement notices were issued totalling \$18,648 to the individual responsible for the Invigorate Labs website for alleged unlawful advertising of products containing cannabidiol (CBD). The relevant advertising allegedly claimed that a CBD cream product is an effective treatment for "palindromic rheumatoid arthritis". As a serious condition, this is a restricted representation that would require prior approval of the TGA before being used in advertising. In this case, no approval had been granted.

In November 2021, the TGA updated its industry guidance about the lawful importation, manufacture, and supply of unapproved medicinal cannabis products through approved pathways. As an unapproved good, the supply of medicinal cannabis must comply with Schedule 5A to the Therapeutic Goods Regulations 1990, including the requirement that the sponsor maintain 'direct control' of the goods until supplied under an approved pathway.

In December 2021, the TGA published guidance and a reminder to businesses to comply with the Advertising Code when naming therapeutic goods. If the name of the good appears in advertising, it is a part of the advertisement and therefore must comply with the Code. For example, it cannot be misleading or imply miraculous results.

In the same month, three infringement notices were issued totalling \$39,960 to a Western Australia-based company for alleged unlawful advertising of medicinal cannabis products. Three infringement notices totalling \$7,992 were issued to an individual from South Australia for similar behaviour.

On 21 December 2021, a Safety Advisory was published relating to Rick's Hemp Oil Full Spectrum Hemp Supplement 500 mg on the basis that the product posed a serious risk to consumer health. Test results of the product found the undeclared substances cannabidiol and the cannabinoid cannabichromene in the oil, and high levels of the undeclared substance delta-9-tetrahydrocannabinol.

The TGA is progressing civil penalty proceedings in relation to entities alleged to be advertising unapproved medicinal cannabis products directly to consumers, including behind a firewall, and is progressing a number of cases for escalation where entities have received prior education about the advertising requirements.

Moving forward, the TGA will continue to ensure compliance with the advertising requirements across the medicinal cannabis industry by ongoing engagement with the industry; gathering and using intelligence to identify non-compliance; and targeting unlawful advertising, as well as supply, where it is not in accordance with the requirements for unapproved therapeutic goods.

Case study – Advertising of medicinal cannabis

About the advertising

The TGA has warned a number of prescription service providers about their advertising in-store, online and on social media platforms where the providers purported to advertise a health service but, in the TGA's view, were advertising the use and supply of the products themselves.

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 the advertisement for a health service is not also considered an advertisement for therapeutic goods.

Details of non-compliance

Consumer advertising of medicinal cannabis products is prohibited in Australia. These products are regulated as prescription medicines and can only be accessed through approved pathways.

Action taken

The TGA escalated its compliance action in relation to one provider and issued three infringement notices totalling \$39,960 to a company for alleged unlawful advertising of medicinal cannabis products. In that case, the TGA alleged that the company had advertised the products on a poster displayed in its shop, and that the company's advertisement on its Facebook page contained a restricted representation for the treatment of fibromyalgia. The company had not been granted relevant authorisation to refer to the serious condition in advertising.

This case was used to remind advertisers that all consumer advertising, including websites, social media and on-site advertising (e.g. banners, sandwich boards, posters, window decals and show windows) must be compliant with the regulations surrounding the advertising of therapeutic goods, which are in place for consumer protection. Advertisers are also reminded not to promote medicinal cannabis products through URL addresses and hashtags across social media platforms.

Advertising of sports supplements

A further priority is disrupting and addressing the unlawful import, manufacture, advertising and supply of unapproved performance and image enhancing therapeutic goods, including sports supplements with a focus on products containing prescription medicine substances. This involves:

- educating the community about the dangers of taking unapproved products containing these substances
- gathering and using intelligence to identify non-compliance
- targeting unlawful import, manufacture, advertising, compounding and supply of unapproved products
- collaborating with other health and law enforcement agencies as appropriate, and
- targeting online platform advertising of unapproved products.

Details of non-compliance

The TGA is progressing a number of investigations relating to the advertising and supply of unregistered sports supplement products with a number of products both imported and manufactured domestically subject to TGA laboratory analysis. The alleged unlawful behaviour primarily relates to advertisers misrepresenting the formulation of sport supplements to Australian consumers.

Actions taken

In July 2021, the Federal Court of Australia imposed penalties of \$11 million on Evolution Supplements Australia Pty Ltd and \$1 million on its sole director for unlawfully advertising therapeutic goods containing substances included in schedules 4 (prescription medicines) and 10 (Substances of such danger to health as to warrant prohibition of sale, supply and use) to the Poisons Standard. These substances included cardarine, dimethylamylamine, testosterone, and selective androgen modulator receptors that are commonly found in products marketed as sports supplements. These penalties are the largest ever imposed by the Federal Court in relation to contraventions of the Act.

In September 2021, the Brisbane District Court convicted HealthHub247 Pty Ltd and its director for the unlawful manufacture, counterfeiting, advertising, and supply of sports supplements that contained prohibited substances. The director was sentenced to 12 months imprisonment and released on a two-year good behaviour bond. The Court noted that if not for the director's serious ill-health, the director would have served time in custody.

Advertising of therapeutic goods used in the cosmetic and beauty industry

Details of non-compliance

Prescription medicines cannot be advertised to the public. Between November 2021 and February 2022, the TGA investigated over forty cases advertising prescription-only cosmetic therapeutic goods. The majority of the cases related to cosmetic injectables (e.g. botulinum toxins and hyaluronic acid), with some cases relating to other types of 'cosmetic therapeutic goods' such as LED facemasks, dermal needling system, a silver-containing facemask and other devices.

Actions taken

The alleged unlawful behaviour related to advertising of prescription only substances as well as advertising of unapproved therapeutic goods. The TGA, through the effective use of warning notices and regulatory phone calls, achieved a voluntary compliance rate of eighty percent.

We will continue to target unlawful advertising of unapproved medicines and medical devices used in the beauty and, particularly, the cosmetic dental industry. This includes liaising with the Australian Health Practitioner Regulation Agency in matters that involve medical practice and procedures.

Advertising of weight loss products

Details of non-compliance

Weight loss products regulated as therapeutic goods must be included in the ARTG before being supplied or advertised. In the context of the priority area, a market scan was conducted which identified advertising of a number of weight loss products not entered on the ARTG.

Action taken

In April 2022 three infringement notices were issued totalling \$39,960 to Cat Media Pty Ltd for alleged unlawful advertising of three complementary medicines that were not entered on the ARTG.

Advertising of bioresonance products

Bioresonance devices are therapeutic goods promoted as being able to diagnose and / or treat various health conditions through the application of certain electrical frequencies to the human body. There are no bioresonance devices included in the ARTG.

The key areas of concern in the project included:

- advertising of goods not included in the ARTG
- inappropriate use of restricted and prohibited representations without permission
- off-label advertising or false advertising of a medical device (particularly in relation to TENS machines inappropriately advertised for purposes not reflected in the ARTG), and
- Advertising Code breaches such as misleading advertising, inappropriate safety claims and non-compliant use of testimonials; and implied government endorsement.

In March 2022, two infringement notices were issued totalling \$26,640 to a company for the alleged unlawful advertising of an analgesic TENS system where the advertising was alleged to be inconsistent with the purpose for which the device was included in the ARTG. This action triggered a targeted sector-wide compliance intervention to address non-compliant advertising.

Between April and July 2022, over 240 advertisements were assessed and 95 cases were identified requiring action. Warning notices were issued to each entity, providing guidance, examples of the alleged non-compliance, and instructing the entity to review their advertising and come into compliance within three days. Ninety percent of the entities achieved compliance concerning the identified issues, with the remaining cases facing potential regulatory action.

Individual high-risk cases

We also investigated individual unlawful advertising that presented a risk to consumer safety or the integrity of the regulatory framework. Examples include:

- **advertising of prescription medicines for “off label” indications** – in June 2021 we investigated five entities in relation to alleged unlawful advertising of Ozempic for a weight-loss indication which is not the indication for which the medicine is approved by the TGA. All entities have come into voluntary compliance in response to the warning letters
- **food-medicine interface products** – in June 2021 we caused the removal of advertising from a website and associated social media advertising a mushroom product assessed to be a therapeutic good

- **anti-ageing supplements** – in June 2021 we issued an infringement notice to a NSW based individual for allegedly advertising anti-ageing supplements being a medicine that was not included in the ARTG and was not exempt from that requirement.
- **anti-cancer wipes** – in May 2022 we caused the disabling of a website operated by a company which promoted decontamination wipes for use by fire fighters to remove cancer causing substances and metals from the skin. The product was not on the ARTG, the advertising included a prohibited representation (cancer) and there was no information related to scientific testing to substantiate the claims made in the advertising, and
- **essential oils** – in April 2022 we caused the removal of alleged unlawful advertising of essential oil products from online platforms. We alleged a range of breaches under the Act and the Code, including endorsements and testimonials by a health professional.

Case study – Advertising of an off-label indication contributing to prescription medicines shortage

About the advertising

In May 2022 the TGA released a joint statement on the [prioritisation of semaglutide \(Ozempic\) supply for people with type 2 diabetes during shortage](#). The statement was triggered by the increase in consumer demand for the product due to promotion and prescribing for obesity management for which Ozempic is not indicated in Australia. Following the release of the joint statement, five entities were investigated for alleged unlawful advertising.

Details of non-compliance

Prescription medicines cannot be advertised, including for an indication which is not the ARTG for that medicine.

Action taken

A review of the advertising on the websites resulted in issuing each entity a warning letter requiring them to review their website and to stop advertising the product in a way that contravened the advertising requirements for therapeutic good within 72 hours. A subsequent review showed that each entity had complied with the warning letter.

The TGA has observed a trend in media networks and social media platforms facilitating the direct or indirect consumer advertising of prescription medicines and is engaging with those organisations to strengthen regulatory best practice and compliance with the Act.

Case study – food-medicine interface product – mushroom products

About the advertising

In June 2022 the TGA conducted a food-medicine interface assessment of an advertiser's mushroom products. It was determined that the products were therapeutic goods and not foods because, among other things, the products did not fall within an applicable Food Standard, the advertising made therapeutic claims about the products and the method of processing the products was inconsistent with food processing.

Examples of claims made in the advertising of the products included therapeutic use of the products for immune system support, cardiovascular support, liver health, cholesterol reduction, inflammation reduction and cancer prevention and treatment. Some of the claims were also prohibited representations and restricted representations within the meaning of the Act. The TGA had not authorised the use of those representations in advertising.

Details of non-compliance

The TGA sent the advertiser correspondence that:

- explained why we considered the mushroom products to be therapeutic goods not foods
- outlined examples of non-compliant advertising and contraventions of the Act
- provided links to educational information on the TGA's website about the advertising of therapeutic goods, and
- warned the advertiser that if the advertising was not removed from the online platforms, escalated regulatory action may be taken.

The advertiser promptly complied with the advertising requirements.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Compliance Branch	September 2022

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Publication reference # D22-5660500