



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Advertising Compliance Annual Report 2020-21



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Executive summary

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health, is responsible for regulating 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 2020-21 report explains how we prioritise our efforts to curb non-compliant advertising based on risk and informed by the newly introduced compliance priorities. The report details the action we have taken where compliance issues are identified and provides several detailed case studies. Additionally, the report details the guidance we have put in place throughout 2020-21. Guidance assists regulated entities to interpret and apply the regulatory requirements and ensures we regulate the advertising of therapeutic goods effectively, fairly and consistently. Reporting on our compliance and educational activities fosters transparency and accountability.

During 2020-21, COVID-19 has continued to be a focus. The report provides information about how we have facilitated, through an advertising exemption, appropriate advertising in relation to COVID-19 vaccines to support the Australian Government vaccine roll-out and details other regulatory work we have conducted in relation to the pandemic.

Additionally, in 2020-21 we formally commenced a review of the Therapeutic Goods Advertising Code (No.2) 2018. The review is focussed on areas of the Code identified by stakeholders and the TGA (through our own experience with administering it) as being unclear, inconsistent or difficult to work with. The TGA consulted with the Therapeutic Goods Advertising Consultative Committee to inform the scope of the review and conducted a public consultation on proposed improvements to the Code; two webinars were held during the consultation period to assist stakeholders in preparing their submissions. The review is ongoing, with a new Code expected to be made by late 2021.

About this report

Since 1 July 2018, the TGA has been the single body responsible for receiving and acting on complaints about advertising of therapeutic goods. This is the third annual report on advertising compliance and covers the 2020-21 financial year. The report promotes transparency by providing information about:

- the advertising compliance and enforcement activities conducted, including how the TGA categorises complaints, prioritises work and interprets and applies the legislation
- an overview of advertising compliance data, which indicates the sources of complaints, the types of products most implicated in complaints and the most common breaches found
- how the TGA focussed its regulatory efforts according to our newly established compliance priorities and according to where the highest risks to consumer health and safety were identified
- case studies that demonstrate TGA's interpretation and application of the legislative requirements
- stakeholder engagement and education activities, and
- the work we have conducted to facilitate communications about COVID-19 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). However, additional safeguards are 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 Act 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 \(No.2\) 2018](#) (the Code), which took effect on 1 January 2019. This version of the Code is currently under review. It is anticipated the new Code will be clearer and easier to interpret than the current version.

During 2020-21, investigations into alleged non-compliance were determined in one of the following ways:

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

The advertising environment in 2020-21

COVID-19 vaccine restricted representation permission

At the commencement of the Government's national COVID-19 vaccine roll-out, advertising of COVID-19 vaccines was enabled by the [Therapeutic Goods \(Restricted Representations – Government Health Campaigns\) Permission 2019](#). However, advertisers were limited to using government produced materials when communicating about COVID-19 vaccines.

In recognition of the need for health professionals and business to contribute to the national conversation about COVID-19 vaccines, on 5 June 2021, the TGA issued the [Therapeutic Goods \(Restricted Representations – COVID-19 Vaccines\) Permission 2021*](#) (the 2021 Permission) to facilitate communications regarding approved COVID-19 vaccines.

The new arrangements, which are in place until 31 December 2022, enable any party (including health professionals, corporate entities, media outlets and others) to develop their own materials about TGA approved COVID-19 vaccines, as long as they are consistent with Commonwealth Government messaging and certain other conditions. Organisations are also able to offer a range of rewards (excluding tobacco and medicines other than listed medicines) to people who have been fully vaccinated.

Working with others

Regulatory and law enforcement

Collaboration with other regulators and law enforcement bodies has been particularly important during the COVID-19 pandemic. In addition to the cooperative work conducted for preventative compliance actions, we have also worked closely with the Australian Competition and Consumer Commission (ACCC) to respond to certain advertising.

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 the 2020-21 financial year. A communique is published on the [TGA website](#) following each meeting.

In its third year of operation, the TGACC provided valuable input to the Independent Review of the Therapeutic Goods Advertising Framework conducted by Rosemary Sinclair AM (published in June 2020) as well as feedback on the findings and recommendations of the internal review of the advertising complaints handling framework. The TGACC also contributed to the ongoing review of the Therapeutic Goods Advertising Code.

Advertising Code review

Consistent with recommendations of the Sinclair Review, the areas identified for improvement were confirmed through discussions with the TGACC. The TGACC was consulted on the scope of the review at meetings held on 4 September and 27 November 2020, and on 31 March 2021. In addition, an extraordinary meeting of the TGACC was held on 12 June 2020 regarding the Code requirements for testimonials, with an invitation to members to provide follow-up written submissions. TGACC working groups were convened in August 2020 to explore this and other Code issues in more detail.

On 7 May 2021, a public consultation paper: *Proposed improvements to the Therapeutic Goods Advertising Code*, was [published](#) on the TGA website. Written submissions on the proposed changes were invited from interested stakeholders. The public consultation process was widely publicised, including via the TGA website, stakeholder contact lists, TGACC member associations and through a presentation at the Association of Regulatory and Clinical Scientists (ARCS) Australia conference in June 2021. The consultation period closed on 18 June 2021.

To assist stakeholders prepare their submissions, the TGA held public webinars on 26 May and 6 June 2021. The webinars included a one hour presentation on the proposed changes, followed by questions and answers. There were 309 and 80-plus attendees at the 26 May and 3 June 2021 webinars respectively. In addition, the TGA responded to clarifying questions on the proposed changes through a dedicated advertising-consultation email inbox. Sixty-seven submissions to the consultation process were received from a range of stakeholders, including consumer, health professional, media and industry peak bodies, as well as direct selling stakeholders.

The proposed changes are aimed at making the Code easier to read, use, understand and comply with; improving definitions and clarity, reducing complexity, and resolving inconsistency and improving messaging for consumers.

Consideration of the public consultation submissions and final recommendations for amending the Code are expected to be completed in the second half of 2021, for commencement in late 2021 or early 2022 (subject to any applicable transition period).

Education and training

The TGA continues to support advertisers to meet their compliance obligations through our comprehensive education materials.

Throughout the year, a [compliance education strategy](#) was developed to provide an overview of our education efforts. Our education strategy aims to maximise compliance and minimise inadvertent non-compliance with the advertising rules by:

- providing fit for purpose 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 will be based on:

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

Our strategy is driven by:

- advertising policy and legislation in Australia
- the TGA's regulatory compliance framework and approach to managing advertising compliance
- the advertising compliance priorities (listed on the TGA website), and
- emerging information on stakeholder needs and areas of non-compliance.

Throughout the year we provided education face to face, via webinar and through seminars and continued to add guidance material to the Advertising Hub at [Presentations | Therapeutic Goods Administration \(TGA\)](#).

We also published the following educational materials and information to inform the public:

- Promotion of COVID-19 vaccinations: further information for healthcare practitioners and other advertisers | Therapeutic Goods Administration (TGA)
- COVID-19 vaccine advertising and import compliance | Therapeutic Goods Administration (TGA)

- Warning to consumers and advertisers about COVID-19 test kits | Therapeutic Goods Administration (TGA)
- Reminder: supply and advertising controls on medicinal cannabis | Therapeutic Goods Administration (TGA)
- TGA to review advertising of stem cell therapies to the Australian public | Therapeutic Goods Administration (TGA)
- TGA warns consumers about potential harm from unlawfully supplied medicinal cannabis | Therapeutic Goods Administration (TGA)
- General advertising requirements | Therapeutic Goods Administration (TGA)
- How we manage advertising compliance | Therapeutic Goods Administration (TGA)
- Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG) | Therapeutic Goods Administration (TGA)
- Is your advertising for therapeutic goods compliant? | Therapeutic Goods Administration (TGA)
- Advertising compliance checklist - consumer advertising | Therapeutic Goods Administration (TGA)
- Advertising to the public | Therapeutic Goods Administration (TGA)

Advertising enquiries

The following table provides the number of advertising enquiries received in 2020-21 in comparison to 2019-20:

	2019-20	2020-21
Advertising enquiries received	564	455

Table 1 – Advertising enquiries volume

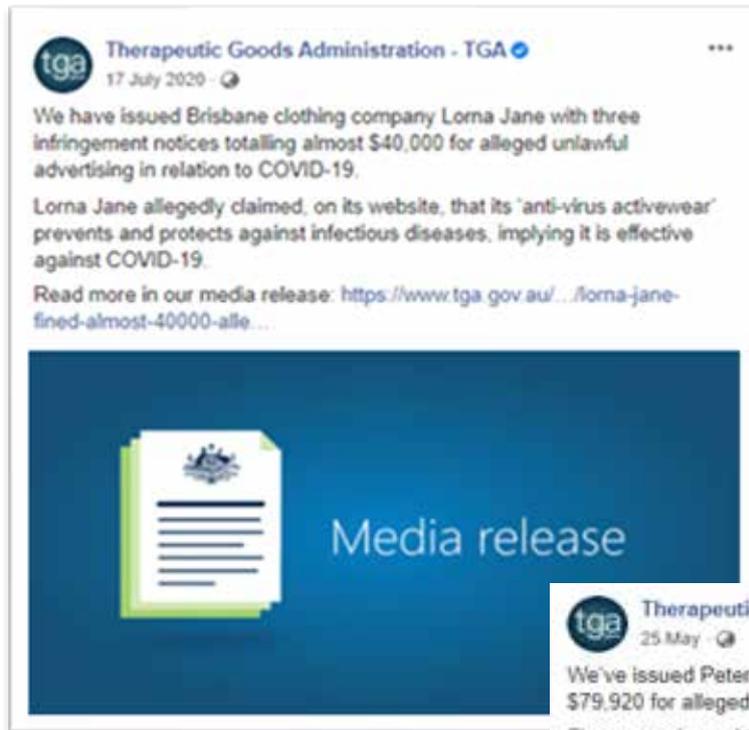
Enquiries are received from a variety of stakeholders including consumers, industry and third-party advertisers (e.g. retailers). Table 1 shows a decline in the number of enquiries received in 2020-21 from the previous year. However, during the COVID-19 pandemic the complexity and urgency of enquiries has increased. These figures do not include general advertising enquiries received and answered by the TGA's Regulatory Assistance section.

Social media

Throughout 2020-21 the TGA published 23 social media posts highlighting alleged breaches of the *Therapeutic Goods Act 1989* and Therapeutic Goods Advertising Code.

The five highest performing posts reached¹ over 125,927 people on Facebook. The top two most viewed posts highlighted compliance action taken against Lorna Jane (63,314 views) and Pete Evans Chef (45,125 views) making unauthorised COVID-19 claims in relation to their products.

These posts placed a spotlight on instances where advertising claims made about therapeutic goods could have detrimental consequences for Australian consumers and reminded businesses they must comply with the [requirements for advertising](#).



¹ Reach, as defined by Facebook, is the estimated number of people who saw a post at least once. Reach is different to impressions, which may include multiple views of a post by the same person.

Restricted and prohibited representations

Authorisation from the TGA (on behalf of the Secretary of the Department of Health) 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 or likely to be 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. Reflection on the public interest criteria set out in section 29 of the Code is an important part of these considerations.

Overview

In 2020-21, 12 permissions were made under section 42DK of the Act. Generally, the TGA will only issue a section 42DK permission allowing the use of certain restricted or prohibited representations where it is satisfied that the restricted or prohibited representations are in the interests of public health. However, the TGA may also issue a 'category' permission in relation to a specified group of products or substances.

Three category permissions were issued in 2020-21, to allow all advertisers of registered [low dose aspirin](#), [oral iron supplements](#), and [melatonin](#) medicines to use restricted representations consistent with the medicines' indications. Issuing category permissions of this nature reduces regulatory burden on advertisers by removing the need to seek individual approval from the TGA to advertise their goods to consumers.

In 2020-21, the TGA also issued two category permissions allowing the use of restricted representations in advertising [medical devices with irregular heartbeat notifications](#) and [automated external defibrillators \(AEDs\)](#).

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

Advertising nicotine vaping products

In Australia, nicotine vaping products for smoking cessation are regulated as prescription medicines. The advertising of prescription medicines or unapproved therapeutic goods to consumers is generally prohibited.

However, to facilitate necessary communications about the availability of nicotine vaping products, on 23 June 2021, the TGA issued the [Therapeutic Goods \(Restricted and Prohibited Representations - Nicotine\) Permission 2021](#), which allows pharmacies and pharmacy marketing groups to indicate that they can supply nicotine vaping products for smoking cessation on presentation of a valid prescription, subject to strict conditions.

To mitigate against broad and uncontrolled promotion of nicotine vaping products, the permission limits the advertising of nicotine vaping products to information necessary to convey the location at which the nicotine vaping products are available, the kinds and forms of nicotine vaping products available and the concentrations.

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

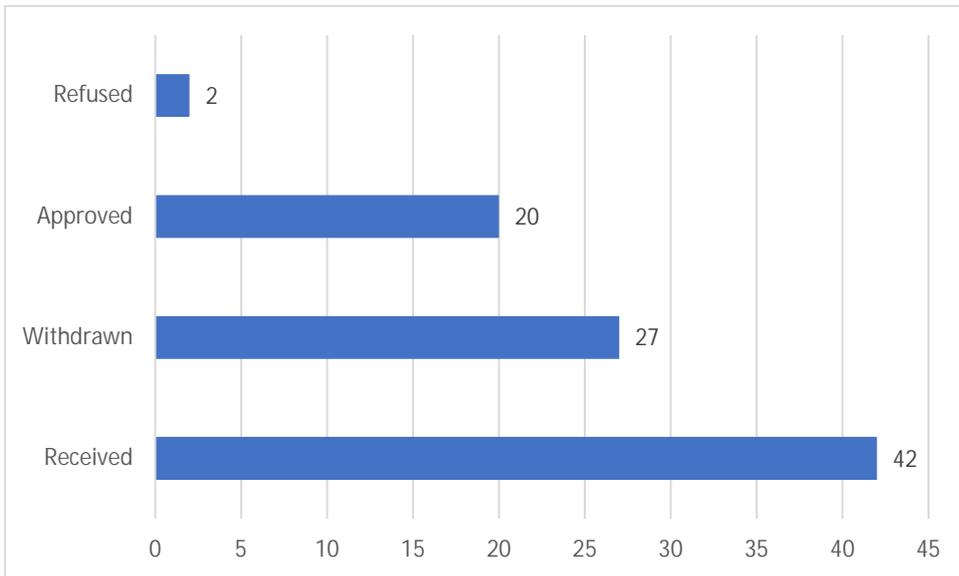


Figure 1 – Applications processed

Withdrawn applications include those where the request has been met through the use of a section 42DK permission.

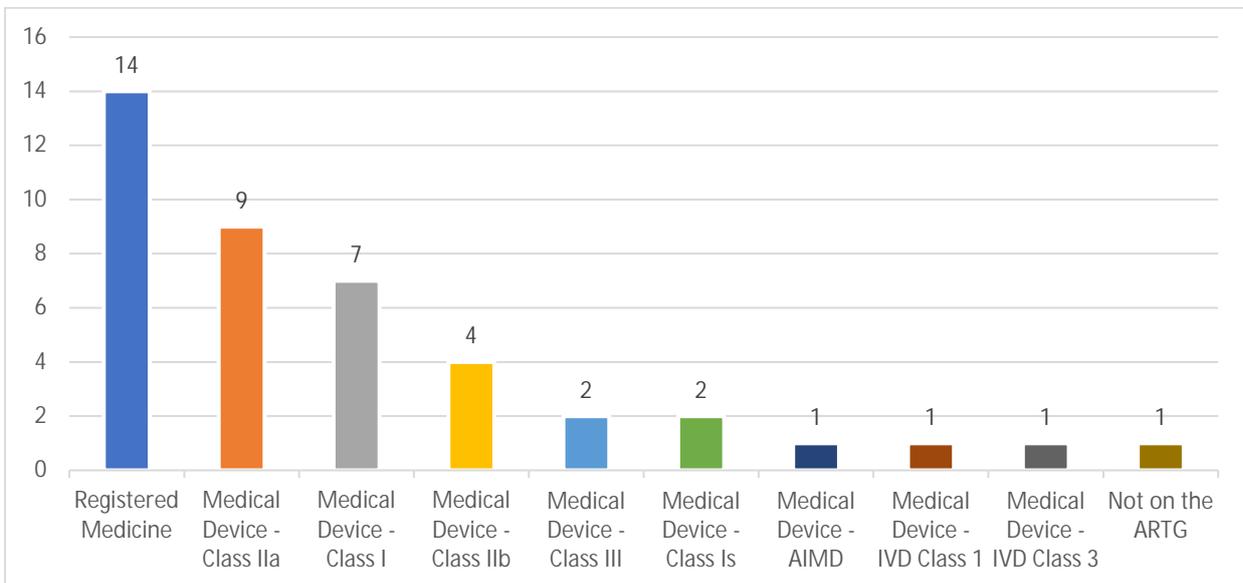


Figure 2 – Applications received by product type

Key compliance data

During 2020-21, the TGA continued to undertake compliance and enforcement activities in relation to breaches of the advertising requirements under the legislation. Following the findings of the Sinclair Review, advertising compliance activities transitioned from a complaints handling program to the new Advertising Compliance Framework. This shift has resulted in advertising compliance activities being risk based, intelligence informed and focussed towards non-compliance assessed to be of greatest concern. In November 2020, compliance priorities were published to indicate where the TGA's advertising compliance effort would be focussed and as a result, this report contains information on two data sets; the first from 1 July 2020 to 1 November 2020; and the second from 1 November 2020 to 30 June 2021.

Detecting non-compliance

The TGA collects information about the import, export, supply, manufacture and advertising of therapeutic goods in Australia to identify non-compliance trends.

We receive valuable insights from the community, industry and the media which, combined with our own monitoring activities, informs our compliance priorities.

Once received, all alleged contraventions are assessed for further action.

We assess all allegations of non-compliance to determine jurisdiction being risk assessing and prioritising cases in accordance with our compliance and enforcement policy.

Alleged non-compliance report volumes and sources

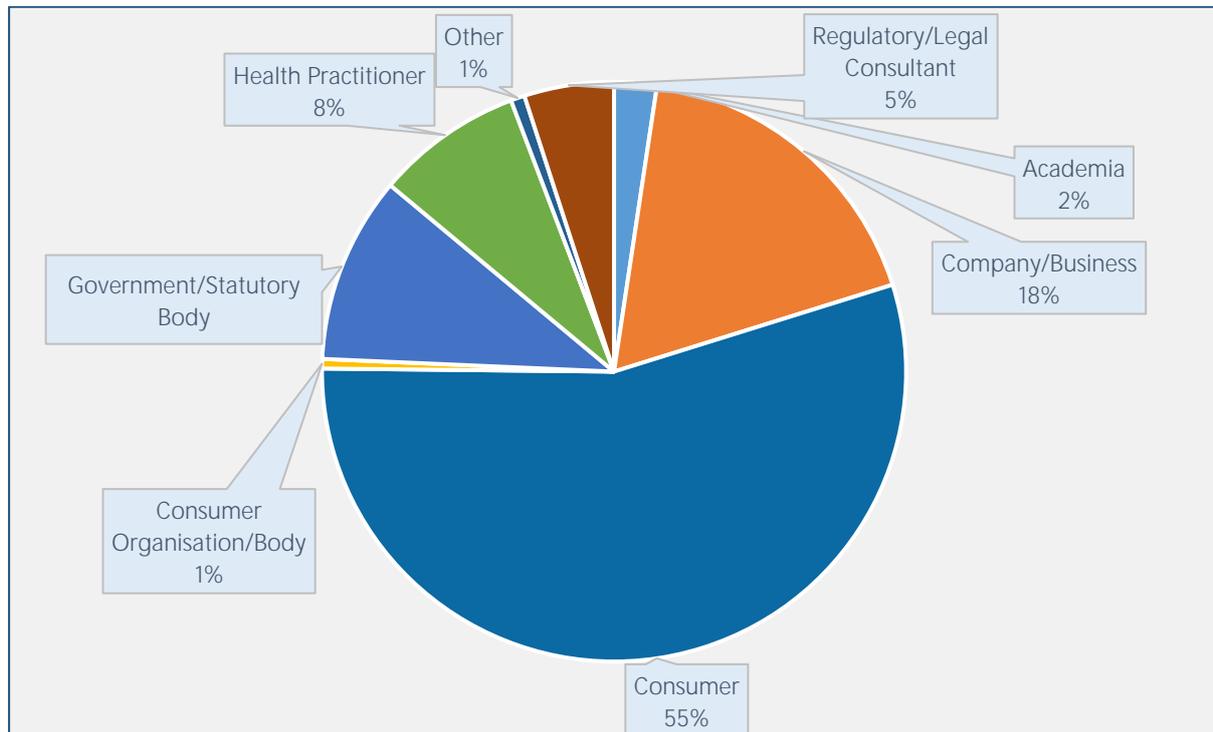
The following table sets out the volume of reports of non-compliance received by the TGA for alleged advertising breaches in 2020-21 compared to 2019-20:

	2019-20	2020-21
Reports received	2,227	2,074
Cases created ^a	3,047	1,140
Cases closed in the reporting period	1,608	2,354

^a Note: the number of reports processed is not directly linked to the number of cases raised. One report can give rise to multiple cases, or multiple reports can be covered by one case.

Table 2 – Alleged advertising contraventions report volumes

In 2020-21, reports were received from the following sources:

**Figure 3 – Sources of non-compliance reports**

How we managed allegations of non-compliance in 2020-21

Allegations received from July to October 2020

Under our previous advertising complaints handling policy in effect to October 2020:

- we gave priority to cases where the risk to consumers posed by a product, or the way in which a product was being advertised, was high
- our regulatory response was commensurate to the risk posed by the non-compliance, and
- each complaint was triaged to create cases categorised as critical, high, medium or low, based on the risk to public health and safety.

A summary of the criteria used to categorise complaints and the number of cases in each category for that period, is shown under Figure 4:

Note: there were no critical cases received for this period.

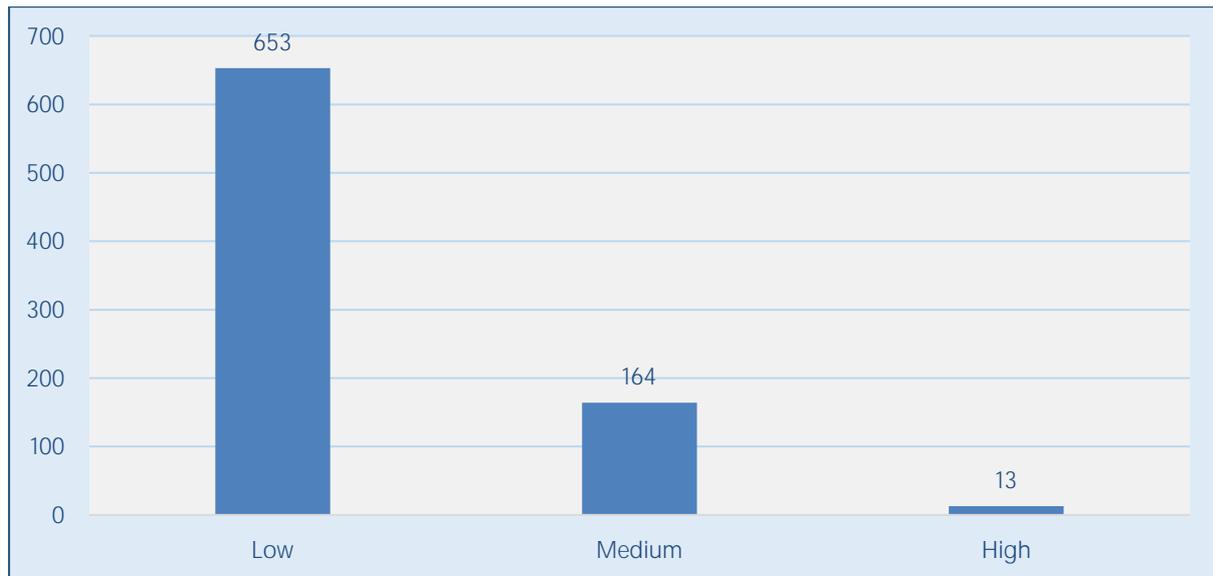


Figure 4 – Number of cases created from July to October 2020 by risk category

Low cases involved the following:

- one off or isolated non-compliance
- low risk of harm from ad and advertised goods
- advertiser has not previously come to our attention.

Medium cases where both:

- the advertiser was made aware of their obligations in the past but the advertising breaches were ongoing
- the advertising was not likely to lead to inappropriate or excessive use.

High Cases where either:

- there was ongoing non-compliance, despite advertiser being aware of their obligations and the non-compliance was more serious in nature (e.g. use of restricted representations)
- advertising was likely to lead to excessive use or impact on the ability to use the therapeutic goods safely.

Allegations received from November 2020 to June 2021

From 1 November 2020, the TGA moved to its new compliance framework. The framework continues to feature risk based, intelligence informed compliance operations. Compliance priorities were published on the TGA website to highlight those matters of greatest compliance concern to the TGA and to indicate where compliance effort will be focussed.

Compliance priorities

To identify the TGA's compliance priorities, we collect and analyse data from a range of information sources, including feedback from the community, co-regulators and industry partners, results from monitoring activity, trends in non-compliance, open source information, and consultation with the TGACC.

The table below sets out the current advertising compliance priorities:

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

Table 3 – List of compliance priorities

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 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 2020-21, we assessed 391 closed advertising cases against the compliance issues of concern and noted a 95 per cent compliance rate. One hundred and ninety of these cases related to COVID-19 advertising where we noted a 94 per cent compliance rate for this sub-group.

Timely action and achievement of compliance on high risk and critical cases

The time to action a complaint (time-to-action) is the period of time commencing from when an allegation of non-compliance is received, and ending on our initial engagement with the advertiser. The time taken to close a case (time-to-close) means the period of time from when an allegation was received, assessed and progressed as a case, to when the case is completed. The target period of time for the TGA to action or close an allegation will depend on the assessed risk of the alleged non-compliance.

The following table sets out our performance against the KPIs for cases closed within 2020-21. Further information about our KPIs can be found in [Measuring our performance](#).

Table 4 – Number of completed advertising cases meeting key performance indicators

High	
Total completed cases	447
Time to action (target 95% in 20 days)	447 (100%)
Time to close (target 90% in 90 days)	447 (100%)
Critical	
Total completed cases	None detected
Time to action (target 100% in 10 days)	None detected
Time to close (target 90% in 60 days)	None detected

for 'time to action' and 'time to close'

Allegations against compliance priorities

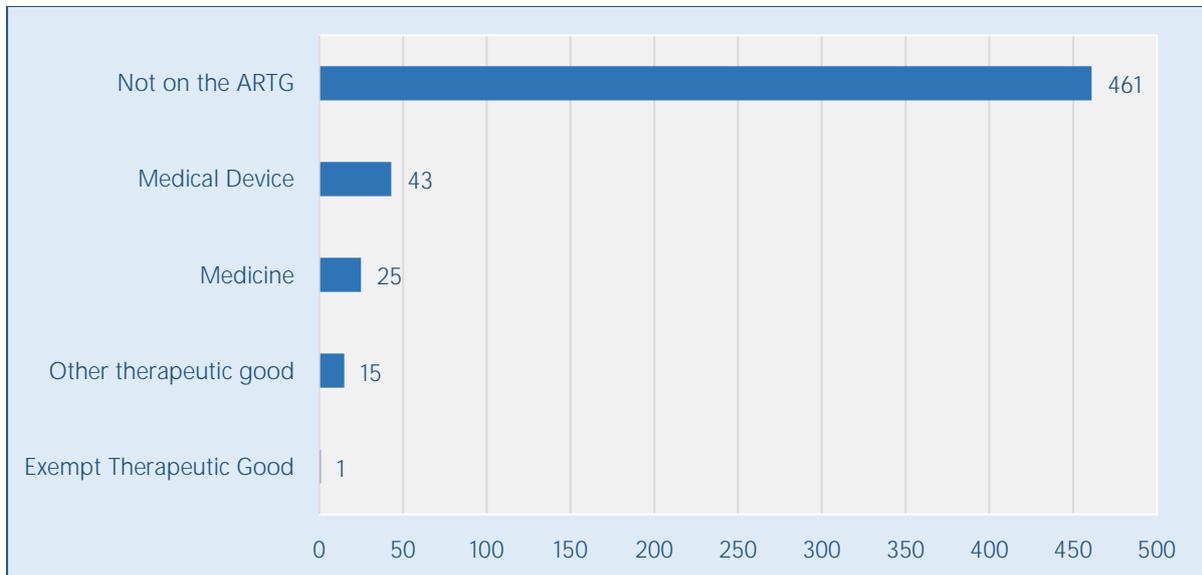
The following table outlines the volume of allegations received by the TGA against the published compliance priorities between November 2020 and 30 June 2021:

Tier	Priority	Allegations received	Cases created*	Cases closed
1	COVID-19	341	129	585
2	Stem Cells	7	4	0
	Medicinal Cannabis	158	61	54
	Performance and image enhancers	43	9	6
	Therapeutic goods used in the cosmetic industry	109	5	0
	Hangover cures	9	2	1
	Weight loss products	27	11	3
3	Mental/learning acuity	14	0	0
	Bioresonance	5	0	0
Total		713	221	649

*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.

Table 5 – Allegations and cases by strategic compliance priority

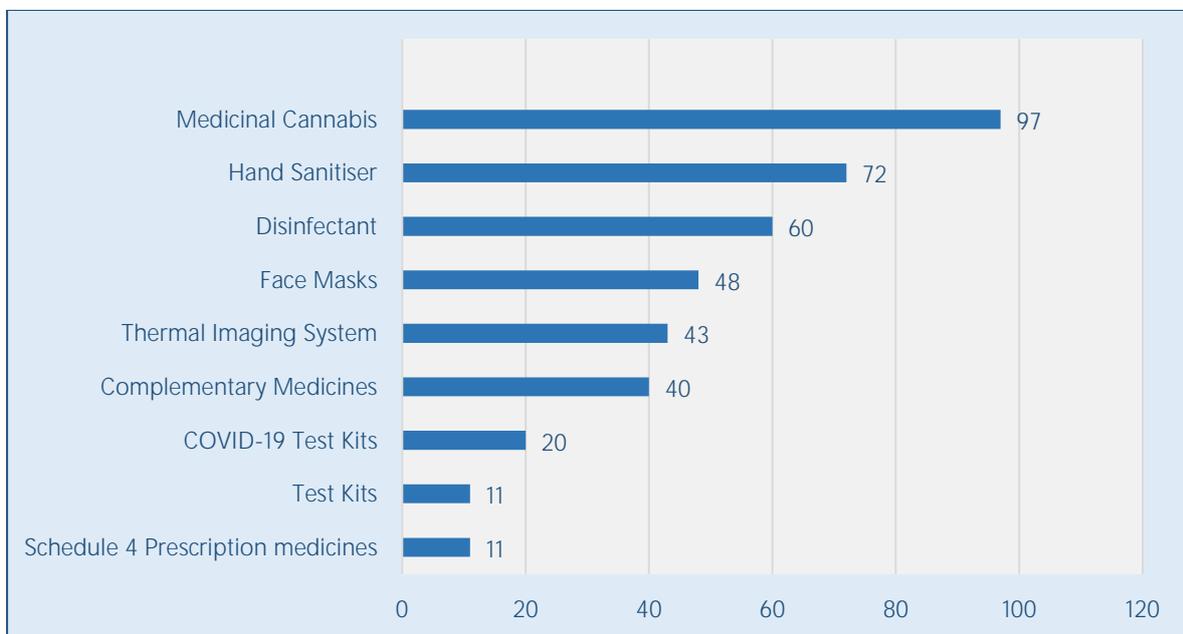
Figure 5 specifies the category of goods that were included in compliance priority cases closed from 1 November 2020. As the chart shows 84 per cent of the products associated with the compliance priorities are not on the Australian Register of Therapeutic Goods (ARTG).



**Note. Multiple products may relate to the same case therefore these statistics do not correlate to cases closed statistic in Table 5.*

Figure 5 – Product categories for compliance priority cases

Figure 6 expands the 'Not on the ARTG' product category showing the product types associated.



**Note. Multiple products may relate to the same case therefore these statistics do not correlate to cases closed statistic in Table 5.*

Figure 6 – Top 10 product types for products 'Not on the ARTG'

Compliance assessment and outcomes

All allegations of non-compliance received by the TGA were assessed for further action.

The TGA's initial assessment included a preliminary examination to determine:

- if there was an applicable offence; including if it was within our 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 TGA determined the appropriate level of investigation and compliance response 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.

The TGA investigates to:

- determine whether or not 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, it considers 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.

The TGA may also refer a matter to the Australian Federal Police or other enforcement agencies as required by Australian Government laws and guidelines. When this happens, we may support the investigating agencies as needed. We only share information as required or permitted by law.

The table below provides a summary of the assessment of allegations and subsequent actions taken from November 2020 to 30 June 2021:

Action taken	Total
Assessment determined no breach identified	328
Referred to other regulator for action	68
Advertising removed from online platform	569
Warnings issued ^a	421
Enforceable undertakings negotiated	2
Infringement notices issued	127
Civil matters commenced ^b	1
Civil matters continued	3
Total	1519

^a The term "Warnings issued" relates to all correspondence advising advertisers of an alleged breach of the legislation, including warning letters, cease and desist letter, regulatory obligations letter, education letters, emails, and phone calls.

^b the matter commenced this year is still active therefore is included in this statistic.

Table 6 – Compliance Actions recorded against all cases.

Compliance outcomes for 2020-21

Infringement notices

During 2020-21, the TGA issued 127 infringement notices for alleged breaches of the therapeutic goods advertising legislation or conditions of registration related to advertising.

The top reasons for issuing an advertising related infringement notice include:

- promotion of illegal therapeutic goods to consumers (i.e. therapeutic goods that should have been included in the ARTG but were not), and
- unauthorised use of prohibited and restricted representations.

Court action

Civil court action commenced

Civil action commenced in the Federal Court of Australia during September 2020 against Oxymed Australia Pty Ltd for advertising unapproved hyperbaric oxygen therapy chambers. The TGA issued Oxymed Australia with five infringement notices totalling \$63,000 in relation to alleged unlawful advertising. These notices were not paid, and the alleged unlawful advertising continued to be present on the Oxymed Australia website after the notices were issued.

The TGA therefore initiated court proceedings to obtain an injunction restraining Oxymed Australia and Mr Hooper (the Respondents) from advertising hyperbaric oxygen therapy chambers. The TGA further seeks orders that the Respondents pay penalties for alleged contraventions of the Act.

Civil court action continued from previous financial years

Civil action has continued in the Federal Court of Australia against MMS Australia Pty Ltd in response to the alleged unlawful advertising of therapeutic goods not included in the ARTG (including a type of bleach for oral consumption) and advertising that referred to restricted and prohibited representations without permission. The Federal Court Action commenced in May 2020.

On 3 June 2020, the Federal Court of Australia heard an application by the Secretary of the Department of Health seeking orders requiring MMS Australia and Mr Barton to cease advertising and supplying certain therapeutic goods, including MMS, dimethyl sulfoxide (DMSO) and another product containing yohimbine. This legal action is ongoing.

Civil court action completed

On 29 July 2021, the Federal Court of Australia ordered Evolution Supplements Australia Pty Ltd (Evolution Supplements Australia) to pay \$11 million for unlawfully advertising a range of unapproved sports supplement products, including references to steroids, Selective Androgen Receptor Modulators (SARMs) and pre-workout products containing DMAA and other amphetamine derivatives, in breach of the Act.

The Court also ordered Mr Cumhuri Keskin, the sole director of Evolution Supplements Australia, to pay \$1 million in penalties for failing to comply with an advertising direction issued by the TGA and failing to prevent Evolution Supplements Australia's breaches of the Act.

These penalties are the largest ever imposed by the Federal Court in relation to contraventions of the Act. The Court also ordered that Evolution Supplements Australia and Mr Keskin pay the costs related to the court proceedings.

This order followed the Court's finding earlier in the year that Evolution Supplements Australia and Mr Keskin had unlawfully advertised prescription only substances and therapeutic goods not entered in the ARTG to consumers. The Court also found that Evolution Supplements Australia and Mr Keskin had failed to comply with a direction from the TGA to stop advertising these goods.

COVID-19 matters

COVID-19 continued to be the major focus for advertising compliance for the first three quarters of the year. This included a range of strong and timely actions with warnings, cease and desist notices and a number of cases proceeding to infringement notices.

Some of the actions taken included:

- issuing 39 infringement notices to 16 entities totalling \$412,056
- contacting more than 189 entities and issuing warnings regarding alleged non-compliance
- issuing a directions notice for the unlawful advertising of Ivermectin as a cure for COVID-19
- the removal of several social media posts that were unlawfully promoting the use of Ivermectin and/or Hydroxychloroquine for COVID-19
- the remediation of a website, including removal of references to a homeopathic COVID-19 immunisation product, and references to HIV and EBV. This matter resulted in infringement notices being issued, and
- the finalisation of an investigation into a website which, while not operational, was marketed as a website for other companies to purchase COVID-19 test kits. This website was removed.

Other matters

Action taken on other matters included:

- issuing 88 infringement notices to 12 entities totalling \$943,344
- contacting more than 232 entities and issuing warnings regarding alleged non-compliance
- the removal of prohibited and restricted representations about non-compliant complementary medicines advertised on a website. The entity was of particular concern given it had an application for a manufacturing licence refused. The website is now compliant, however we will continue to monitor it as part of our assurance program
- the remediation of several websites unlawfully advertising. The entity took immediate steps to remove the alleged advertising and were 'extremely disappointed to acknowledge the complaint [had] merit'. The entity further indicated that 'compliance is very important to this Company and all entity staff (globally) will receive a letter reminding them of their obligations', and
- the removal of several hundred advertisements from online shopping platforms.

Alleged contraventions identified

For those cases closed in 2020-21, where the TGA identified non-compliance, the issues were categorised into breaches. We identified 935 alleged breaches of the Act from 259 cases and 157 alleged breaches of the code from 54 cases. The top five breaches identified against the Act are represented in Figure 7 and the Code in Figure 8:

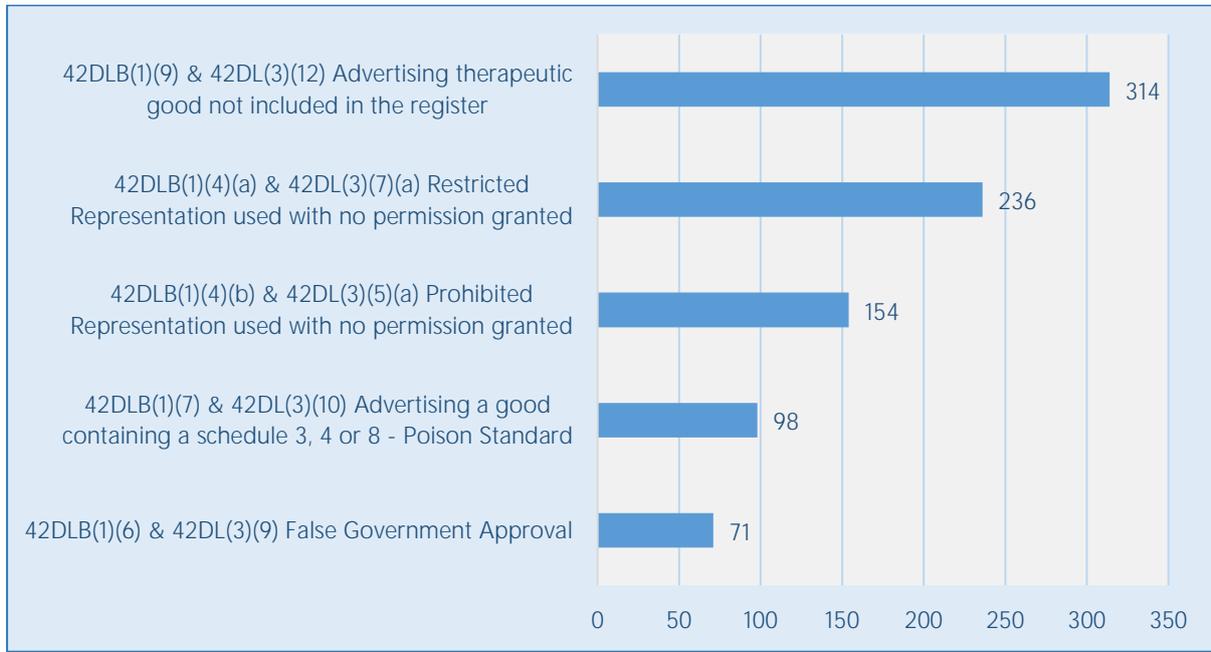


Figure 7 – Top 5 alleged contraventions of the *Therapeutic goods Act 1989*



Figure 8 – Top 5 alleged contraventions of the Advertising Code No.2 2018

Compliance outcome examples

Compliance outcome 1: Weight Loss Products

Key points:

- Weight loss products regulated by the TGA must be included in ARTG before being supplied or advertised

Background

The TGA considered the underlying risks posed by the advertising of weight loss products and identified a significant risk area; the online advertising of unregistered weight loss products by product sponsors and online retailers (e.g. community pharmacies and eBay Australia sellers). The TGA cannot vouch for the safety, quality or efficacy of such products. This is the case even if those products were previously included in the ARTG.

Details of non-compliance

A TGA market scan identified advertising of unregistered weight loss products by a product sponsor and online retailers. Some of the products had previously been included in the ARTG but were no longer. Another product appeared to be on the Food-Medicine Interface and was assessed and determined to constitute a therapeutic good. There was no applicable exemption or exclusion to the requirement that these goods be listed in the ARTG. On this basis, each advertisement was alleged to contravene section 42DLB(9) of the Act (goods not entered in the ARTG).

Actions taken

The TGA undertook sector-wide compliance intervention by:

- gathering relevant evidence and issuing 38 cease and desist notices to retail advertisers regarding three identified products (37 advertisers complied by the two-day deadline, however two entities subsequently republished the non-compliant advertising)
- issuing nine infringement notices to four entities totalling \$119,880
- reinforcing the relevance and seriousness of the non-compliance to advertisers by including information about infringement notices issued to similar entities for comparable breaches in cumulative iterations of cease and desist letters
- engaging with eBay Australia to remove six product listings within 24 hours
- information sharing on actions and outcomes on the TGA's website and social media pages; this information was picked up and shared by industry media organisations, and
- reinforcing regulatory messaging in subsequent correspondence with non-compliant advertisers.

The TGA has re-evaluated advertising of unlisted weight loss products online and identified a marked reduction in non-compliant advertising of these products. Further follow-up action is underway and escalated regulatory action is possible. It is important that both sponsors and retail advertisers exercise due diligence in ensuring that their advertising of therapeutic goods complies with the regulatory framework.

Further reading

Cat Media Pty Ltd – one (1) infringement notice issued regarding advertising of 'Fatblaster Original'
<https://www.tga.gov.au/media-release/cat-media-fined-13320-alleged-unlawful-advertising>

Cat Media Pty Ltd – one (1) infringement notice issued regarding advertising of 'Fatblaster Apple Cider Vinegar and Garcinia Max'
<https://www.tga.gov.au/media-release/cat-media-pty-ltd-fined-13320-alleged-unlawful-advertising-fatblaster-complementary-medicine>

Junction Rx trading as My Community Pharmacy – one (1) infringement notice issued regarding 'FatBlaster Apple Cider Vinegar and Garcinia Max'
<https://www.tga.gov.au/media-release/pharmacy-fined-13320-alleged-unlawful-advertising>

CW IP Pty Ltd - Chemist Warehouse and My Chemist Websites – four (4) infringement notices issued regarding advertising of 'Fatblaster Clinical'
<https://www.tga.gov.au/media-release/cw-ip-pty-ltd-fined-53280-alleged-advertising-breaches-chemist-warehouse-and-my-chemist-websites>

Epharmacy Group Pty Ltd – two (2) infringement notices issued regarding advertising of 'Fatblaster Clinical'
<https://www.tga.gov.au/media-release/epharmacy-group-pty-ltd-fined-26640-alleged-unlawful-advertising-epharmacy-website>

Compliance outcome 2: Medicinal Cannabis

Key points:

- The TGA is focussing its efforts on higher level compliance and enforcement action particularly where entities have received prior education around the regulation of medicinal cannabis in Australia

Background

The TGA takes advertising non-compliance in relation to medicinal cannabis products very seriously and employs a range of education and compliance approaches to address alleged breaches of the advertising requirements. All medicinal cannabis products contain substances captured in the current Poisons Standard as Schedule 3, 4, or 8 substances. The majority of these products are not entered in the ARTG and the TGA cannot vouch for their quality, safety, or efficacy. The TGA does

not allow unlawful advertising and supply of medicinal cannabis products to the general public but supports patient access to medicines supplied through approved pathways.

Details of non-compliance

The TGA has reviewed over 450 complaints and conducted market scans, including risk assessments, to identify Australian entities unlawfully advertising medicinal cannabis. The advertising appeared on websites, social media platforms, labelling and packaging, shopfronts, signage, printed publications and ASX listings. The TGA identified key areas to address breaches of the Act such as advertising of medicinal cannabis products not entered in the ARTG or advertising that targets vulnerable consumers with references to serious illness, conditions, or diseases that require medical management.

Actions taken

Recognising the need to support legal pathways for access, the TGA engaged in extensive education around the regulation of medicinal cannabis in Australia to help ensure individuals and industry understand the approved pathways through which medicinal cannabis products may be accessed. This has included the publication of guidance, webinars and engagement with industry representative bodies and forums, including:

- guidance on [Advertising guidance for businesses involved with medicinal cannabis products and Supply and wholesaling of medicinal cannabis products \(MCP\)](#)
- industry guidance regarding [the controls on medicinal cannabis](#)
- public education, a [short video](#) and an [infographic](#) for consumers, and
- webinars on advertising compliance and legitimate pathways for supply.

The TGA is now focussed on escalated compliance and enforcement action and is progressing its investigations particularly where entities have received prior education. The TGA has:

- issued over 80 cease and desist letters
- shared actions and outcomes on the TGA's website and social media pages, with information re-published by industry media organisations and individual members of the public, and
- issued infringement notices, including: <https://www.tga.gov.au/media-release/man-fined-10656-alleged-unlawful-advertising-cannabidiol-including-covid-19-claims>.

Case study 1: Weight Loss Products

Key points:

- Weight loss products are a priority area under the Advertising Framework. One of the key underlying risks for this priority is the advertising of unregistered weight loss products, i.e. therapeutic goods not included in the ARTG
- Advertisers are responsible for ensuring their therapeutic goods advertising is compliant with the Act prior to publication
- Advertising of therapeutic goods by retailers (including online retailers) is subject to the same rules as the advertising conducted by the sponsors of the products

About the advertising

On 14 December 2020, the TGA identified that CW IP Pty Ltd t/a Chemist Warehouse and My Chemist (CW IP) allegedly advertised a cancelled therapeutic good (FatBlaster Clinical, AUST L 295575) on four URLs on two of its websites. Each advertisement referred to a therapeutic good that was not entered in the ARTG and was not subject to an exemption, approval or authority under the Act or regulations made under the Act.

Details of non-compliance

The TGA's cancellation of FatBlaster Clinical (the Product) from the ARTG took effect on 20 December 2019. A month prior to that, the TGA issued the cancellation notice and a directions notice, directing the sponsor to cease advertising the Product. On 28 September 2020, the TGA identified two advertisements of the Product on two websites owned and operated by CW IP. The Act provides that it is a civil contravention and a criminal offence to advertise therapeutic goods that are not included on the ARTG unless a relevant exemption applies. As no such exemption applied to the Product, it was alleged that CW IP had contravened subsection 42DLB(1) of the Act, where subsection 42DLB(9) applies.



Actions taken

Notice to CW IP requiring the removal of the advertisements before 5pm on 21 October 2020. CW IP appeared to have complied as the advertisements were removed before the deadline. However, on 14 December 2020, the TGA found that similar advertisements of the Product occurred on four URLs from two websites owned and operated by CW IP. On 22 March 2021, the TGA issued four infringement notices to CW IP totalling \$53,280. CW IP paid the notices on 16 April 2021. <https://www.tga.gov.au/media-release/cw-ip-pty-ltd-fined-53280-alleged-advertising-breaches-chemist-warehouse-and-my-chemist-websites>

Case study 2: Food-Medicine Interface Products

Key points:

- Products on the 'food-medicine interface' need to be carefully assessed to ensure they are meeting the relevant regulatory requirements
- Products deemed to be therapeutic goods must be included in ARTG before being supplied or advertised
- Representations regarding (inter alia) the treatment, cure or prevention of mental illness, such as depression, in the advertising of a therapeutic good are prohibited and must not be used in advertisements for therapeutic goods unless such use is authorised by the TGA

Background

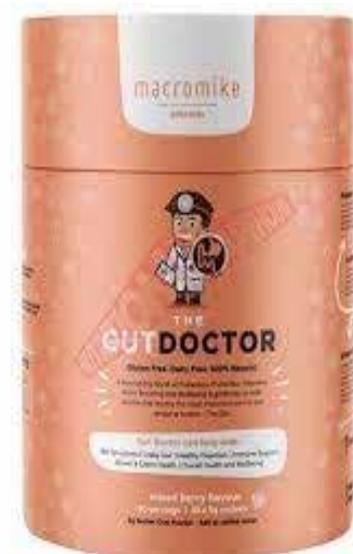
The TGA received a number of reports concerning the line of 'Doctor' products being advertised on a website. The products were advertised as 'The Brain Doctor', 'The Adrenal Doctor' and 'The Gut Doctor'.

To ascertain if the products would be correctly categorised as foods or therapeutic goods the TGA conducted a Food-Medicine Interface (FMI) assessment. This involved evaluating potentially applicable Food Standards or whether there is a tradition of use as a food for the goods in the form they were presented. The existence of an applicable Food Standard or a tradition of use as a food would make the products a 'foods', not subject to TGA regulation. In this case, it was determined the goods were not foods and were therefore therapeutic goods within the TGA's jurisdiction.

About the advertising

Numerous therapeutic claims were being made about the products in the advertising material. Claims were made in relation to the nervous system and depression, immunity, mental clarity, hormone support, adrenal fatigue and irritable bowel syndrome. These therapeutic claims, in combination with the inclusion of 'Doctor' in the product names, the presence of testimonials supporting apparent effect in relation to a range of conditions, and ingredients common in other therapeutic goods, led to a conclusion that the products were being represented for therapeutic use.

These factors contributed to the decision that these products were more likely to be therapeutic goods and not foods.



Details of non-compliance

A search of the ARTG did not identify any products listed under the brand names presented. It was also established there were no exemptions or other approvals or authority under the Act that would apply. This means the products were not entered in the ARTG and there was no lawful reason for them not to be entered.

The advertisement for 'The Brain Doctor' unlawfully contained a prohibited representation because of references to 'depression'. Advertisements for 'The Adrenal Doctor' and 'The Gut Doctor' were considered to contain restricted representations, because of the use of representations which referred to adrenal fatigue and irritable bowel syndrome (IBS), which are medically accepted to require diagnosis or treatment or supervision by a suitably qualified health professional. The unauthorised use of 'restricted representations' in advertising of therapeutic goods is unlawful. In this instance, the TGA had not authorised the use of the 'restricted representations'.

Accordingly, the advertisements were considered to have breached s 42DL(3) of the Act where ss 42DL(12), 42DL(5)(a) and 42DL(7)(a) applied, and s 42DLB(1) of the Act, where ss 42DLB(9), 42DLB(2)(a) and 42DLB(4)(a) applied.



Actions taken

As it was considered reasonable to assume that the advertiser may not have been aware of the regulatory requirements for therapeutic goods, the TGA wrote to the advertiser explaining how Food-Medicine Interface products are assessed by the TGA and provided details about how these particular products had been assessed by the TGA as being therapeutic goods.

The TGA advised the advertiser to conduct a comprehensive review of all advertising material, including testimonials, on the website and on any other online platforms they controlled, including social media platforms, to ensure compliance with the advertising requirements.

The advertiser was requested to cease advertising the products on the website and on any other online platforms and advertising they controlled and to cease supply.

The advertiser promptly complied with the request.

Compliance outcomes – COVID-19 related

COVID-19 compliance outcome 1: Body Temperature Measuring Products

Key points:

- Effective compliance achieved through direct and targeted education to advertisers of temperature measuring products
- Medical devices regulated by the TGA must be included in the ARTG before being supplied or advertised
- Advertising medical devices is strictly regulated by restrictions that apply to referring to serious forms of a disease, condition, ailment or defect (such as COVID-19)

Background

The TGA received reports indicating an increase in the advertising of body temperature measuring products, including those used for screening people in public places and workplaces. In a number of cases, body temperature measurement was only one of a number of a product's functions. For example, some of the products included functions for facial recognition, building attendance monitoring and building access control. The advertising appeared on websites, social media platforms and in printed publications. The reports concerned advertisements for temperature measurement products that were not included in the ARTG and which, in some cases, also contained references to COVID-19.

Details of non-compliance

The TGA considered that products used to screen potentially febrile individuals during the COVID-19 pandemic were medical devices within the definition of that term in the Act because the intended purpose of those products was for use on humans for the prediction of disease and investigation of a physiological or pathological process or state. Accordingly, the products were required to be included in the ARTG prior to being supplied or advertised. The products advertised were not included in the ARTG, thus breaching section 42DLB(9) of the Act. Some of the products advertised also referred, directly or indirectly, to COVID-19, which, as a reference to a serious form of a disease, condition, ailment or defect, is a restricted representation. As TGA approval to make this reference had not been sought or obtained, this breached section 42DLB(4) of the Act.

Actions taken

Conscious of community interest in COVID-19 safety measures and the need to raise regulatory awareness especially for businesses not previously involved in the supply of therapeutic goods, the TGA:

- provided detailed information about the regulation of temperature measuring medical devices on the TGA's website. The guidance was aimed to assist manufacturers and suppliers of

temperature measuring devices to ascertain whether or not their product was likely to be a medical device and therefore regulated by the TGA

- provided specific information to advertisers about thermal imaging systems and devices being used to screen people in public places that include an infrared radiation measurement technique. The information clarified that body temperature measuring devices, such as those used for screening people in public places that include an infrared radiation measurement technique are regulated as Class IIa medical devices, and are required to be included in the ARTG prior to their importation and supply, and
- advertisers reported to the TGA for non-compliance were provided the above-mentioned educational information along with an opportunity for them to review and amend their advertising.

The TGA's direct educative engagement with advertisers resulted in swift compliance with the advertising requirements. The targeted educative approach was considered appropriate given the rapidly changing environment prompted by the pandemic, particularly with respect to temperature measurement products.

COVID-19 compliance outcome 2: Disinfectant products

Key points:

- Compliance achieved through direct and targeted education to advertisers for disinfectants promoted for use in relation to COVID-19
- Representations that a disinfectant has an effect against any virus must be permitted by the TGA before the representation can be advertised to consumers in connection with the relevant product
- Consumers can search the TGA database at <https://www.tga.gov.au/disinfectants-use-against-covid-19-artg-legal-supply-australia> for disinfectant products which have been approved to advertise their product as having an effect against SARS-Cov-2 and COVID-19

Background

The TGA received 212 reports indicating an increase in the advertising of disinfectant products promoted for use in relation to COVID-19. The advertising appeared on websites, social media platforms, labelling and packaging and in some cases printed publications. The reports concerned advertisements for disinfectants that were not included in the ARTG, contained references to COVID-19 and other viruses as well as making government endorsements about the goods. Accordingly, the products were required to be included in the ARTG prior to being supplied in Australia and advertised to the Australian public. Advertisers of the products were also reminded that claims referring to COVID-19 must not be used without prior authorisation by the TGA and that claims that state or imply the advertised good is endorsed by government are unlawful.

Details of non-compliance

The TGA considered that the disinfectant products were therapeutic goods within the definition of that term in the Act because they made therapeutic use claims about the product. These claims were

mainly concerned with the product's alleged effect against SARS-Cov-2 and COVID-19. The products advertised were not included in the ARTG, thus breaching subsection 42DLB(9) of the Act. The products advertised also referred directly to COVID-19 which, in relation to disinfectants, is a prohibited representation because it is a virucidal claim about the goods. As TGA approval to make this reference had not been sought or obtained, this breached subsection 42DLB(2) of the Act. There were also statements in the advertising implying the goods had been recommended or approved by or on behalf of a government or government authority, such as including the words 'TGA approved, or 'FDA approved' in the advertising. As these references were not a statement of the availability of the goods as a pharmaceutical benefit nor authorised or required by a government authority, this breached subsection 42DLB(6) of the Act.

Actions taken

Conscious of community interest in COVID-19 safety measures and the need to raise regulatory awareness especially for businesses not previously involved in the supply of therapeutic goods, the TGA:

- provided extensive guidance about the regulation of disinfectants, including how to obtain the relevant approvals and authorisations on the TGA website. This guidance was communicated in 39 warning letters which referred businesses to the relevant material on the TGA website and bespoke information where appropriate. The letters often included explanations of the differences between consumer hand sanitisers, hand sanitisers regulated as therapeutic goods, the various types of disinfectants, antiseptic hand scrub products and how certain claims and formulations would impact the classification of the relevant good. By providing this information we hoped to make the regulatory obligations clearer to those new to the regulation of therapeutic goods and on the whole were able to achieve this by writing to the relevant businesses
- received feedback during this period that the relevant information on the TGA website was at times hard to locate, and the distinctions between these goods was not as clear as it could be. Therefore the TGA recently published clearer guidance on the TGA website to assist sponsors and manufacturers of borderline disinfectants and related products that make antiviral claims (including in relation to COVID-19) Regulation of borderline disinfectant and related products with antiviral claims including COVID-19 | Therapeutic Goods Administration (TGA)
- notes that all 39 businesses who received warning letters came into compliance, with most of these coming into compliance within a couple of days of acknowledging their obligations. However, four entities received infringement notices after failing to bring their advertising into compliance, and
- sent educational material, including 39 warning letters to advertisers reported to the TGA along with an opportunity for them to review and amend their advertising.

Four entities received infringement notices after failing to bring their advertising into compliance:

- Strapit Medical and Sports Supplies Pty Ltd – three (3) infringement notices issued regarding advertising of disinfectant and hand sanitiser product in relation to COVID-19 claims <https://www.tga.gov.au/media-release/strapit-fined-37800-alleged-advertising-breaches-disinfectant-and-hand-sanitiser-relation-covid-19>

- Italian Princess Coffee Pty Ltd – three (3) infringement notices issued regarding advertising of disinfectant product in relation to COVID-19 claims <https://www.tga.gov.au/media-release/zafe-zone-fined-almost-40000-alleged-advertising-breaches-disinfectant-products-relation-covid-19>
- Yarra Valley Cleaning Co Pty Ltd – three (3) x infringement notices issued regarding advertising of disinfectant product in relation to COVID-19 claims <https://www.tga.gov.au/media-release/yarra-valley-cleaning-co-fined-39960-alleged-unlawful-advertising-disinfectant-product-relation-covid-19>
- Sydney Man – three (3) infringement notices issued regarding advertising of disinfectant and hand sanitiser product in relation to COVID-19 claims <https://www.tga.gov.au/media-release/sydney-man-fined-7992-alleged-unlawful-advertising-disinfectant-and-hand-sanitiser-relation-covid-19>

The TGA's direct engagement with advertisers resulted in swift compliance with the advertising requirements. The targeted educative approach was considered appropriate given the rapidly changing environment prompted by the pandemic, and escalation was only invoked when in very limited cases education failed to bring about the required changes.

COVID-19 Case study 1: Disinfectants for use against COVID-19

Key points:

- In line with the TGA's 2020-21 Advertising Compliance Plan, the TGA took action to ensure advertising and supply of disinfectant products for use against COVID-19 was in compliance with the Act

About the advertising

Between February and October 2020, the TGA received 60 reports of non-compliance with the Act in relation to advertising for a hospital grade disinfectant product. The product was included in the ARTG but advertised for a prohibited representation, being an unapproved indication that a disinfectant product had an effect against viruses, including COVID-19.

Details of non-compliance

Following an investigation, the TGA found the non-compliant promotional material was supplied by an Australian sponsor (the primary source) and circulated to its Australian distributors.

Claims that a disinfectant has an effect against any virus must be expressly permitted by the TGA before being used in consumer advertising (including on the label).

Actions taken

Driven by its new advertising framework, the TGA undertook sector-wide compliance intervention by:

- gathering evidence on the Australian sponsor and the 20 distributors, all of whom were advertising the disinfectant product referencing the same and consistent promotional material

- engaging with Australian businesses and suppliers to provide education and guidance on the regulation of disinfectant and sterilant products
- issuing three infringement notices totalling \$39,960 to an advertiser that had failed to comply with the Act. All of these notices were paid, and
- information sharing actions and outcomes on its website and social media pages.

The TGA has observed changes in advertising of disinfectant products online and identified a marked reduction in non-compliant advertising of these products. It is important that both sponsors and retailer advertisers exercise due diligence in ensuring that their advertising of therapeutic goods complies with the regulatory framework. The TGA can take regulatory action with little or no notice in some instances, such as in issuing infringement notices.

Further reading

- Medial release: [Zafe Zone fined almost \\$40,000 for alleged advertising breaches for disinfectant products in relation to COVID-19](#)
- TGA guidance about disinfectants, sterilant and sanitary products found at the following links – <https://www.tga.gov.au/disinfectants-sterilants-and-sanitary-products> and <https://www.tga.gov.au/publication/guidance-regulation-exempt-disinfectants-australia>.



Conclusion

This report promotes transparency and accountability by providing detailed information on how the TGA prioritises compliance and enforcement activities, and by describing the actions we have taken and the outcomes we have achieved. Additionally, this report provides detailed case studies, gives updates on our educational efforts and describes the work we have conducted throughout the year to improve the Code and to facilitate regulated entities to be able to communicate effectively about matters related to public health when that has been required.

By reporting on our activities year to year we aim to demonstrate our efforts to continually improve the effectiveness of our compliance efforts and educational activities. We envisage the setting of compliance priorities will become refined in future years through enhanced intelligence and data analytics processes and look forward to future reports demonstrating this achievement.

It is anticipated COVID-19 will continue to be central to our work in the 2021-22 year and we will continue to be able to demonstrate our responsiveness and agility in our regulatory approach. Now more than ever, we must continue to direct our focus toward public health and safety and ensuring that Australians can continue to be confident that advertisements are truthful and support the appropriate use of therapeutic goods.

Appendix 1 – Acronyms and abbreviations

ARTG	Australian Register of Therapeutic Goods
TGA	Therapeutic Goods Administration
TGACC	Therapeutic Goods Advertising Consultative Committee
The Act	<i>Therapeutic Goods Act 1989</i> (Cth)
The Code	Therapeutic Goods Advertising Code No.2 2018

Version history

Version	Description of change	Author	Effective date
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