Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic goods advertising compliance

2019-20 Annual Report

Contents

Executive summary

As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods to ensure they are of high quality, safe to use and work as intended. We do this by administering the *Therapeutic Goods Act 1989* (the Act), which sets out requirements and obligations for the manufacture, supply, import, export and advertising of therapeutic goods.

The regulation of therapeutic goods advertising is an important element of the TGA's mandate to safeguard public health. The TGA regulates advertising for therapeutic goods to ensure it is socially responsible. We aim to protect Australians from advertising that does not support informed product choice. Choosing therapeutic goods wisely depends on advertising that is accurate and balanced and that does not seek to mislead or take advantage of the vulnerability of consumers in the health product market.

This report promotes transparency and helps to set clear benchmarks for advertisers. In addition to providing data about complaints received, details about actions taken and outcomes reached and information about how the TGA prioritises its work, this report supplements the extensive educational resources we make available through various avenues. Engaging with, and educating, the regulated community to promote high levels of voluntary compliance is a critical element of the TGA's approach to advertising regulation.

The emergence of the COVID-19 pandemic significantly shaped our priorities during 2019-20 and challenged us in developing responsive and proactive strategies to address advertising compliance in a time of heightened consumer vulnerability, including by:

- taking timely proactive compliance action wherever possible to alert advertisers to the advertising requirements
- issuing the permission needed for sponsors and advertisers of certain regulated hard surface and medical device disinfectants to be able to lawfully use references to SARS-CoV-2 (COVID-19) on the labels and in broader advertising
- taking a pragmatic approach to complaints about hand sanitiser advertising, ensuring that we focused on those that represented a safety risk (whether through the product itself or advertising that conflicted with public health messaging), and
- issuing infringement notices to advertisers where illegal references to COVID-19 were being made, both about regulated therapeutic goods and goods not included in the Australian Register of Therapeutic Goods (ARTG) to achieve compliance and deter others.

During the 2019-20 reporting period, the TGA received 2,227 complaints. This is a 52% increase on 2018-19, which is attributable in part to the increase of non-compliant adverting in relation to COVID-19. The advertising of illegal therapeutic goods and the use of references to serious forms of diseases, conditions, ailments or defects (prohibited and restricted representations) without TGA authorisation were the most common breaches of the Act. This year has also seen unprecedented enforcement outcomes for non-compliance – the TGA issued 155 infringement notices for alleged advertising contraventions, totalling nearly $1.6 million.

Additionally, this report outlines a number of changes that will significantly affect the advertising compliance framework in 2020-21.

Changes to the Act came into effect on 1 July 2020, removing the statutory requirement for pre-approval of medicine advertisements to the public appearing in 'specified media'. This change places greater onus upon advertisers to understand their advertising obligations. The Therapeutic Goods Advertising Code (No.2) 2018 will also be reviewed in the year ahead.

Following two years of operation under a new advertising framework, reviews were completed into the implementation of the reforms to the therapeutic goods advertising framework, including the way in which the TGA addresses reports about advertising non-compliance. These reviews yielded a range of recommendations, which will be implemented in 2020-21 and will involve new key performance indicators, as well as more strategic and intelligence led approaches to compliance and compliance education. There are also opportunities to consolidate and implement learnings from the TGA's compliance work during COVID-19 for further improvements and refinements to our processes. The Therapeutic Goods Advertising Consultative Committee (TGACC), which provided key input into these reviews and other work during the year, will play an ongoing role in guiding the implementation of the recommendations.

About this report

Since 1 July 2018, the TGA has been the single body responsible for receiving and acting on complaints about advertising. This is the second annual report on advertising compliance and covers the 2019-20 financial year. The report promotes transparency by providing information about the TGA's advertising compliance and enforcement work throughout the year, including:

- 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 where the highest risks to consumer health and safety were identified, with particular emphasis on the COVID-19 pandemic
- case studies that demonstrate TGA's interpretation and application of the legislative requirements, approach to regulatory engagement and subsequent outcomes of complaints
- stakeholder engagement and education activities
- how the TGA worked with other agencies, and
- emerging shifts in, and improvements to, the advertising compliance framework.

Information about the TGA's performance in the first year under the new arrangement is in the inaugural Therapeutic Goods Advertising Compliance 2018-19 Annual Report.

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 and there is a need to protect people faced with serious, or potentially serious, diseases or conditions from unethical advertising. The requirements particular to advertising therapeutic goods are specified in the Act, with additional requirements for advertising to the public in the Therapeutic Goods Advertising Code.

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.

During 2019-20, the TGA utilised complaints from external stakeholders as its primary means of identifying non-compliant advertising. Applying the TGA's advertising complaints handling policy, we took a risk-based approach to complaints received, prioritising matters that posed a risk to public health and safety. Ultimately though, every complaint received was assessed. Where necessary, we took compliance and enforcement actions, proportionate to the relevant non-compliance and the harm that may result. Our compliance and enforcement actions were evidence-based and dependent on the types of behaviours identified, including demonstrated willingness of the advertiser to be compliant with the Act.

Review of MMDR reforms to advertising regulatory framework

The Expert Review of Medicines and Medical Device Regulation (MMDR), accepted by Government in 2016, made recommendations to improve Australia's medicines and medical device regulatory framework. The reforms specific to advertising included clarifications and improvements to the advertising requirements in the Act, including enhanced sanctions and penalties, effective from March 2018. In addition, as a result of the MMDR recommendations, we implemented:

- the Therapeutic Goods Advertising Code (No.2) 2018
- the establishment of the TGA as the single complaints management body with a new advertising complaints management system, and
- a continuing comprehensive educational campaign for advertisers.

During 2019-20, Ms Rosemary Sinclair AM led an independent review of these advertising reforms and related changes (the Sinclair review).

The Sinclair review considered the impact of amendments to the Code, the effectiveness of the TGA as the single body responsible for managing advertising complaints and the TGA's use of broadened sanctions and penalties to address non-compliance. The Review also assessed the impact of stakeholder education efforts, the suitability of key performance indicators and the effectiveness of the Therapeutic Goods Advertising Consultative Committee (TGACC).

The Sinclair review involved consultation with stakeholder groups, including those represented on the TGACC, and departmental staff and examined the effectiveness of changes to the advertising framework.

All 22 recommendations of the Sinclair review were accepted by Government and will be implemented in 2020-21. This includes the introduction of a new intelligence-led advertising framework. For further details about future changes, see Lessons learnt and looking ahead.

The Australian advertising environment in 2019-20

COVID-19: challenges and key compliance concerns

The COVID-19 pandemic has led to businesses with no prior therapeutic goods expertise entering this space to assist in addressing critical product demand (e.g. hand sanitisers, face masks). However, the pandemic has also unfortunately opened the door to some seeking to take advantage of fears within the community, including through the promotion of products for which there is a lack of scientific evidence. Given the large number of complaints received in 2019-20 about COVID-19 and related claims in the last quarter of 2019-20, it has been necessary for us to prioritise our efforts to ensure the protection of consumers from misleading and exploitative promotional material.

In March 2020, the TGA published a warning about illegal advertising to consumers relating to COVID-19. Generally, references to COVID-19 must not be made about therapeutic goods. Claims that a disinfectant or antiseptic has an effect against the virus that causes COVID-19 (SARS-CoV-2) are prohibited representations and other references to COVID-19 are restricted representations under the Act. A restricted representation refers to a serious disease, condition or disorder. The use of prohibited and restricted representations in advertisements for therapeutic goods is unlawful without prior authorisation by the TGA in order to protect the vulnerable.

In addressing the high demand for certain types of products, such as hand sanitisers and disinfectants during the pandemic, the TGA enabled manufacturers of certain products to reach the market more rapidly through a range of legislative instruments. For example, we granted a prohibited representation permission under s.42DK of the Act to facilitate the use of a SARS-CoV-2 virucidal claim in advertising of disinfectants that are included in the ARTG with the appropriate indication/intended purpose. We also published information to assist new and potential sponsors of therapeutic goods to meet their regulatory and legislative obligations, including advertising requirements.

Part of our approach to the pandemic was aimed at educating consumers about misleading advertising claims in relation to the treatment, cure or prevention of COVID-19 and encouraged consumer reporting of perceived illegal advertising. Recognising the high degree of consumer vulnerability, the TGA has:

- issued warnings to consumers to be alert to false and misleading advertising
- reminded consumers that using products in ways that differ from the directions or instructions for use can be dangerous
- advised consumers to exercise caution when considering advertising claims related to COVID-19 and to consult a health professional for advice
- advised consumers that testing for COVID-19 should only be conducted by a health professional, and
- warned consumers that hand sanitisers vary in composition and effectiveness and that some advertisers have made inappropriate and misleading claims about ingredients and effect on specific organisms.

COVID-19 compliance concerns

The TGA identified a range of compliance concerns with the advertising of therapeutic goods in relation to COVID-19, including advertising that:

- undermined public health messaging regarding the need for social distancing and personal hygiene to prevent the transmission of SARS-CoV-2
- promoted therapeutic goods that were not entered in the ARTG, and/or
- used references to SARS-CoV-2, COVID-19 and/or related terms without the TGA's authorisation to use prohibited or restricted representations.

The TGA received many complaints about the advertising of goods with claims of an effect against SARS-CoV-2 that were, on face value, highly improbable or unlikely to be capable of substantiation. In most of these cases, it was not necessary for the TGA to request or consider the evidence to support such claims, as the goods concerned were generally not in the ARTG and could not be promoted to the public.

See Case studies for examples of actions the TGA took in relation to illegal advertising.

Size of Australian therapeutic goods advertising market

As at 30 June 2019, there were around 92,000 therapeutic goods entered in the ARTG by nearly 4,800 separate sponsors. Of these goods, around 71,000 can be marketed directly to the public (i.e. they are not prescription-only medicines and they are not biologicals).

However, the actual number of therapeutic goods that can be lawfully advertised to consumers will be larger as some therapeutic goods are exempt from inclusion in the ARTG (e.g. certain homeopathic preparations).

Additionally, therapeutic goods that can be lawfully advertised to the public can be marketed by the sponsors of the goods, but are often also marketed by a broader range of retailers, including pharmacies, supermarkets, eBay and social media sellers, health practitioners and health food shops. As at 30 June 2019, there were 5,762 pharmacies approved to supply pharmaceutical benefits in Australia[1] as well as around 8,940 supermarkets and grocery stores[2] which, together with a range of other retailers which sell (and advertise) therapeutic goods to the public in Australia, constitute a very large market.

In the second half of 2019-20, the TGA also witnessed an unprecedented rate of new sponsor registrations (in preparation for inclusion of goods in the ARTG), with over 1,900 sponsors registering with the TGA (compared with 425 new sponsor registrations in the first half of the year). This is consistent with local businesses and companies moving into the therapeutic goods space in order to meet high community demands for goods central to COVID-19.

[1] PBS Expenditure and Prescriptions Report 1 July 2018 to 30 June 2019 - https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report

[2] Statista report on Number of operating supermarkets and grocery stores in Australia in the financial year 2019, by state, accessed 24 August 2020 - https://www.statista.com/statistics/932677/australia-number-supermarket-and-grocery-stores-by-state/#:~:text=At%20the%20end%20of%20the,in%20the%20Australian%20Capital%20Territory.

Key advertising data

Complaint volumes and sources

The following table sets out the advertising complaint volumes in 2019-20:

	2018-19	2019-20
Advertising complaints received (multiple advertisers may have been identified in each complaint)	1,468	2,227
Cases created from the complaints received (one advertiser per case*)	2,436	3,047
Cases closed in the reporting period	1,601	1,608

Table 1 – Advertising complaint volumes.

** When we receive a complaint, it is recorded in our Advertising Management System. Each complaint is then assessed and the advertisement examined to determine the responsible entity or entities involved, with a case created for each entity.*

Of the 2,227 complaints received in 2019-20, 3,047 cases were created. This is due to some complaints identifying more than one advertising entity responsible for a potential breach of the Act. Where this occurs, multiple cases can be created as result of one complaint. Additionally, complaints can identify more than one advertised good.

The volume of complaints received in 2019-20 was a significant increase over the number received in 2018-19. While the number of complaints received prior to the start of the pandemic indicated that complaint numbers for 2019-20 would likely surpass the number received in 2018-19 (see Figure 1), complaints about COVID-19 related advertising have still significantly contributed to the increase in advertising complaints.

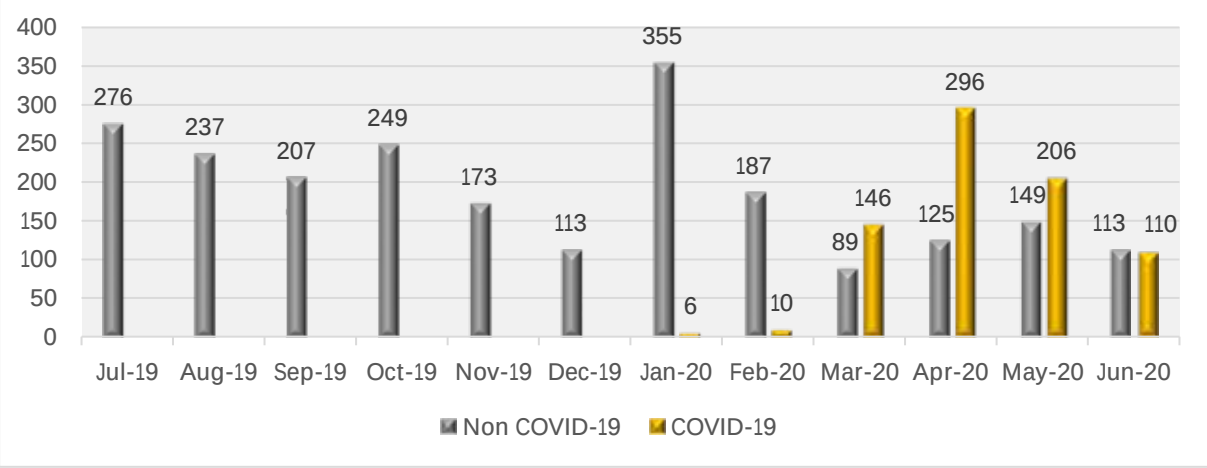


Figure 1 – Non COVID-19 v COVID-19 complaint volume comparison.

The 2,227 complaints received in 2019-20 alleging non-compliant advertising of therapeutic goods came from various sources, as detailed in Figure 2. We have seen modest increases in the proportion of complaints from consumers and health professionals (up by 7% and 2% respectively from 2018-19).

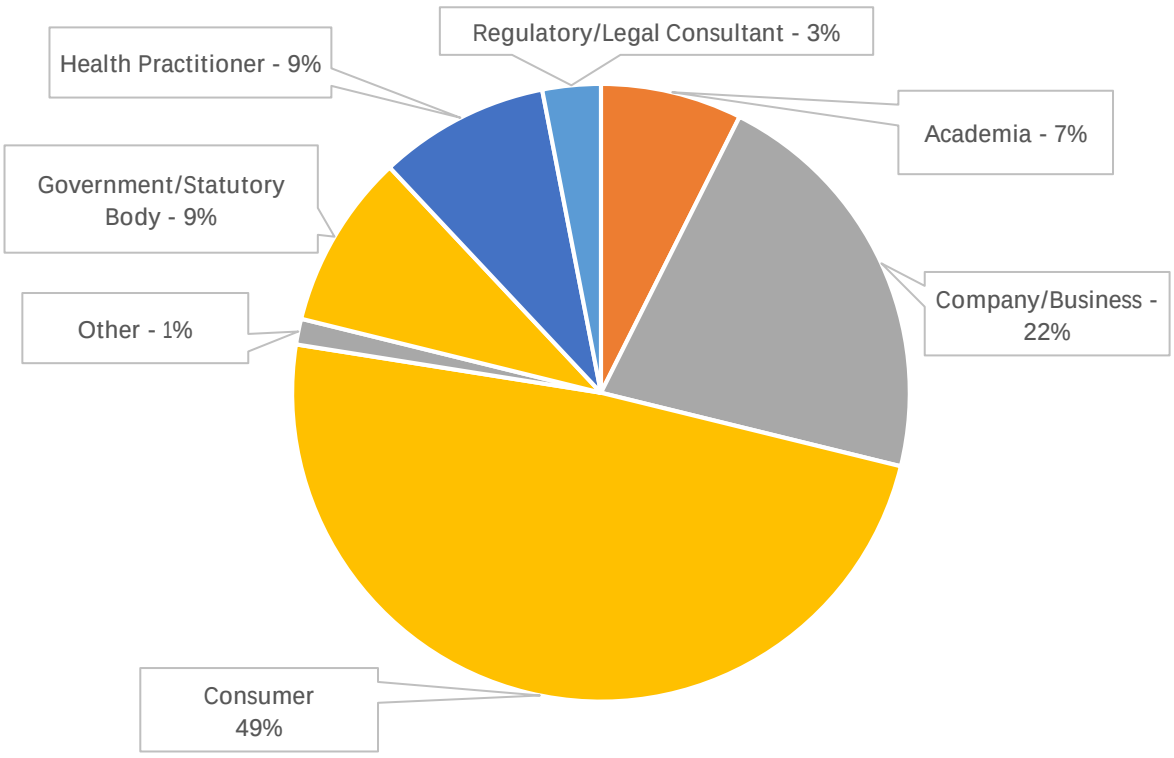


Figure 2 – Source of complaints by self-reported complainant type.

The 'other' category of complaint sources includes consumer organisations/bodies, peak industry bodies and peak healthcare bodies and organisations.

How complaints were processed over the financial year

Like other regulators, the TGA takes a risk-based approach to complaints and case handling. This means that, under our advertising complaints handling policy:

- we give priority to cases where the risk to consumers posed by a product, or the way in which a product is being advertised, is high, and
- our regulatory response is commensurate with the risk posed by the non-compliant advertising.

Each complaint we receive is triaged and cases are categorised as critical, high, medium or low, based on the risk to public health and safety. A summary of the criteria we use to categorise complaints, and the number of cases in each category for 2019-20, is shown in Figure 3.

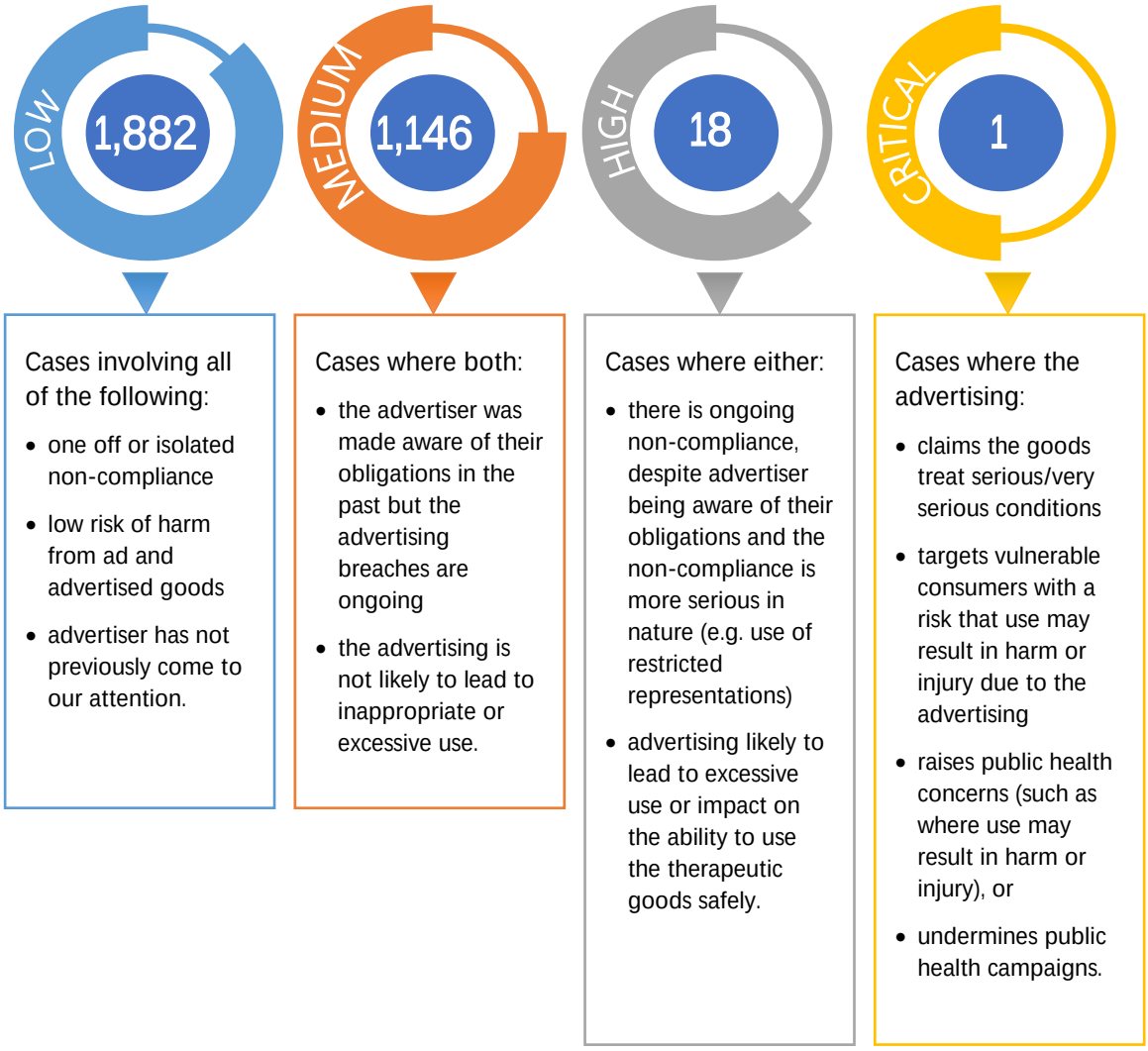


Figure 3 – Number of cases created in 2019-20 by risk category.

Performance against key performance indicators

The time to action a complaint (time-to-action) is the period of time commencing from when a complaint is received, including categorisation, and ending on initial engagement with the advertiser. The time taken to close a case (time-to-close) means the period of time from when a complaint was received, categorised and progressed as a case, to when no further action is required and the case is completed. The target period of time for the TGA to action or close a complaint will depend on the priority categorisation of the complaint.

The following table sets out our performance against the KPIs for cases initiated and subsequently closed within 2019-20. Further information about our KPIs can be found in Measuring our performance.

2019-20	Non COVID-19	COVID-19
Low		
Total completed cases	1,163	343
Time to Action (target 95% in 14 days)	718 (62%)	227 (66%)
Time to Close (target 90% in 20 days)	843 (72%)	270 (79%)
Medium		
Total completed cases	71	29
Time to Action (target 95% in 40 days)	35 (49%)	17 (59%)
Time to Close (target 90% in 90 days)	53 (75%)	29 (100%)
High		
Total completed cases	1	N/A
Time to Action (target 95% in 20 days)	1 (100%)	N/A
Time to Close (target 90% in 90 days)	0 (0%)	N/A
Critical		
Total completed cases	1	N/A
Time to Action (target 100% in 10 days)	0 (0%)	N/A
Time to Close (target 90% in 60 days)	1 (100%)	N/A
Total closed cases	**1,236**	**372**

Table 2 – Number of completed advertising cases meeting key performance indicators for 'time to action' and 'time to close'.

Performance against KPIs in 2018-19 and 2019-20

Low category

Overall, there has been a reduction in the number of low category cases meeting time to action and time to close KPIs. This is a result of the rapid influx of COVID-19 complaints (starting in late January 2020) which necessarily diverted resourcing away from issuing obligations letters and closing low category complaints. The priorities shifted to entering and acknowledging an increase in the volume of complaints and enquiries, while targeting complaints posing the greatest risk to safety and ensuring priority and effective enforcement outcomes were being delivered. At the end of the current reporting period, there were 376 complaints of low category awaiting action (see Figure 3).

Medium category

There was a minor (3%) improvement in 'time to action' KPIs for non-COVID-19 cases in the medium category. While the 'time to close' KPIs target for non COVID-19 cases was not met, we exceeded our 'time to close' target for COVID-19 cases. The TGA's regulatory focus during these unprecedented times was to limit the spread of misinformation, prevent the exploitation of consumers and respond with enforcement actions where appropriate. We have prioritised illegal advertising relating to COVID-19. Notwithstanding there is a large number of medium category COVID-19 related cases not recorded as 'closed' (and therefore not reflected in this year's report), this year's COVID-19 KPIs reflect our swift action in response to illegal advertising in this space. The

majority of breaches that the TGA investigated in relation to the COVID-19 cases related to breaches of the Act for promoting illegal therapeutic goods or for using unauthorised restricted or prohibited representations (see Figure 15 below). These types of investigations can be concluded rapidly as they do not depend on time-consuming evaluation of scientific data as would be the case in allegations of claims not being substantiated.

It is also noteworthy that advertising cases relating to medicinal cannabis represented 23 of the non-COVID-19 medium cases closed. Taking action against the illegal advertising of medicinal cannabis to consumers has been an additional priority in 2019-20. In November 2019 we clarified how the advertising legislation applies to the medicinal cannabis industry and this year we have dedicated resources to ensure industry compliance. This work has been prioritised to both protect consumers from products that have not undergone the appropriate regulatory checks and to ensure that the use of medicinal cannabis for serious diseases and conditions is not promoted to consumers.

High category

The one high category non-COVID-19 case that did not meet the time to close KPI related to a complaint about the advertising of a bioresonance device.

Advertising compliance cases

The following figures break down the types of goods that were implicated in cases based on both non-COVID-19 and COVID-19 related matters, as well as the actions that we took in relation to cases. The figures in this section of the report relate solely to cases that were both initiated and closed in 2019-20.

Non-COVID-19 related cases

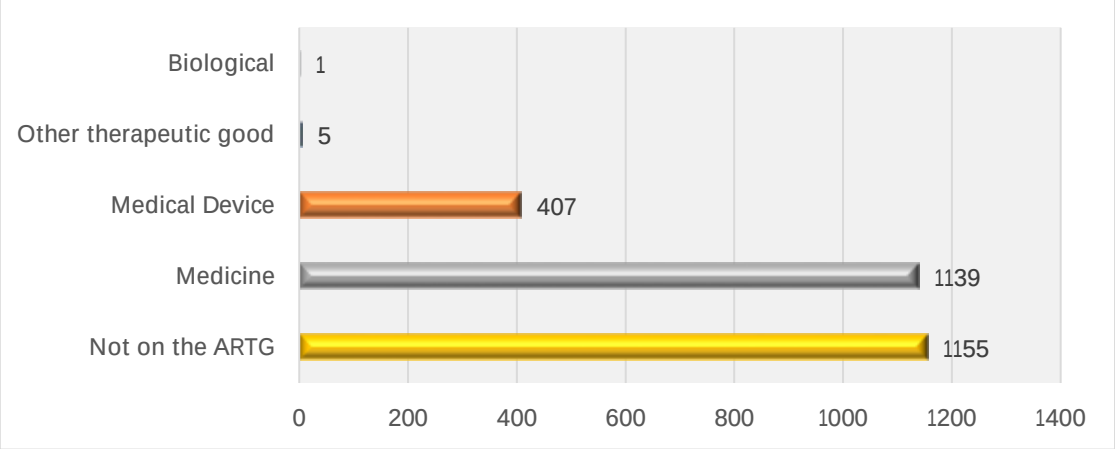


Figure 4 – Number of cases unrelated to COVID-19 by category of good.

The following figure shows the top ten 'complaint categories', as observed across the full spectrum of good categories:

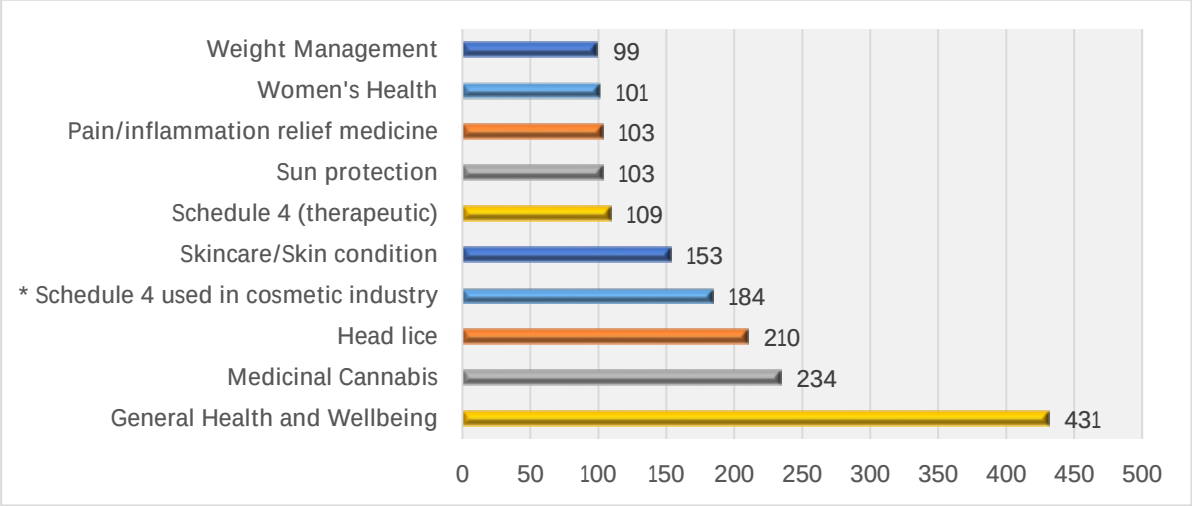


Figure 5 – Top 10 complaint categories for non-COVID-19 cases: all categories of goods.

** Schedule 4 used in cosmetic industry relates to prescription-only medicines that are typically used for cosmetic applications. For example anti-wrinkle and dermal filler injectables.*

A case can be allocated multiple complaint categories, for example if the advertising contains multiple products or the product is being advertised for a multiple therapeutic purposes, e.g. medicinal cannabis for pain/inflammation relief.

The 'general health and wellbeing' category represents advertising for the use or supply of therapeutic goods for the maintenance of health and not for the treatment or symptomatic relief of a health condition. The following figure breaks this category down further, showing the types of products captured in the cases.

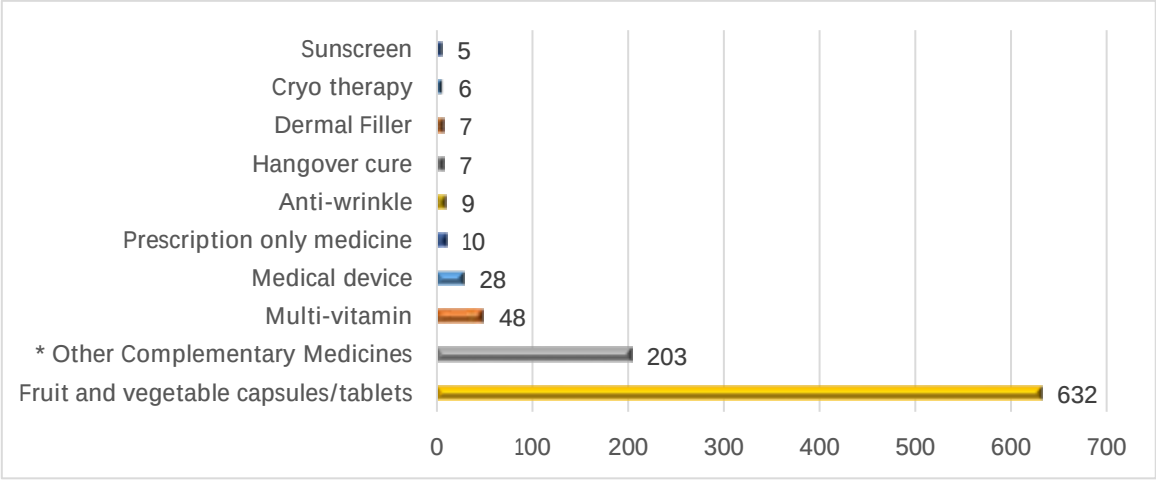


Figure 6 – Top 10 product types for the 'general health and wellbeing' category.

** Sunscreens, hangover cures, multi-vitamins and fruit and vegetable capsules/tablets are complementary medicines with sufficient numbers of associated complaints to be reported separately. All other complementary medicines are combined as 'other complementary medicines'.*

The top five complaint categories for the 'medical device' category from Figure 4 are as follows:

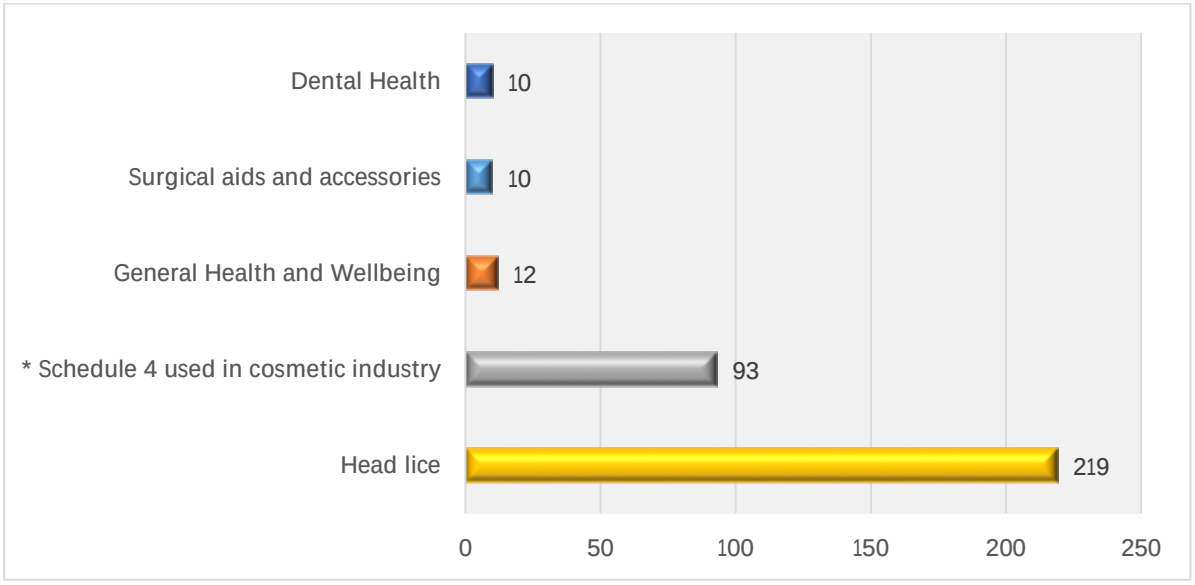


Figure 7 – Top five complaint categories for medical devices (non-COVID-19).

** Schedule 4 used in cosmetic industry relates to prescription-only medicines that are typically used for cosmetic applications. For example anti-wrinkle and dermal filler injectables.*

The top ten complaint categories for the 'medicines' category from Figure 4 are as follows:

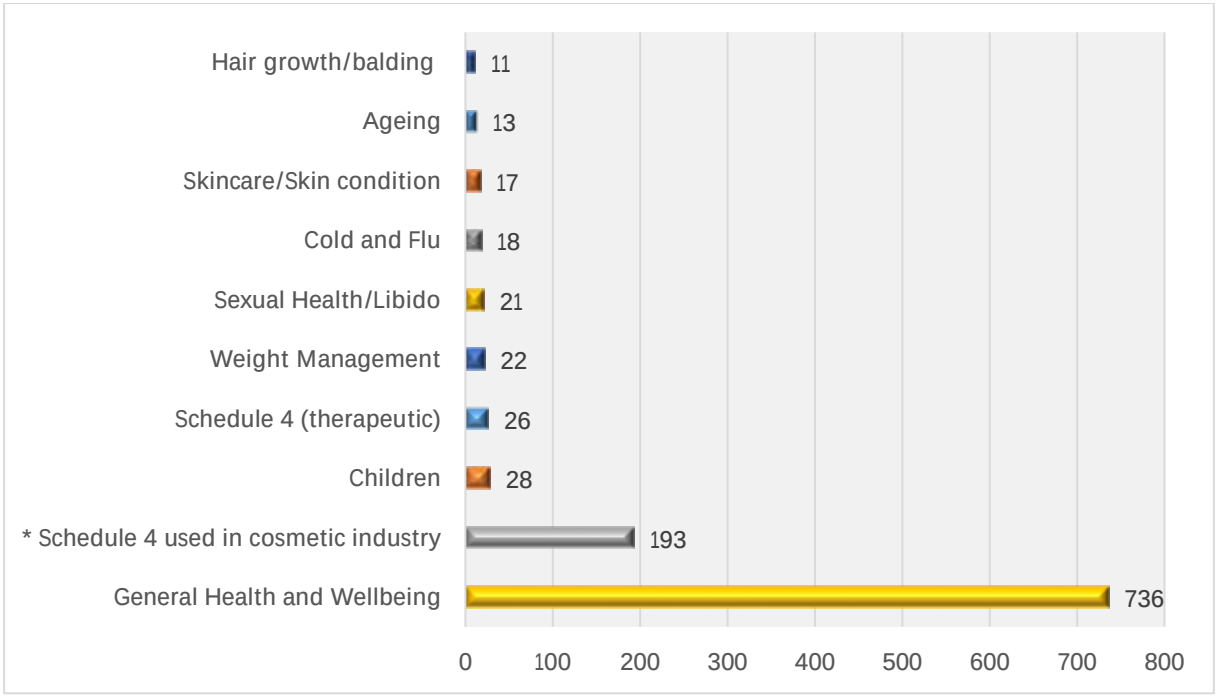


Figure 8 – Top 10 complaint categories for medicines (non-COVID-19).

** Schedule 4 used in cosmetic industry relates to prescription-only medicines that are typically used for cosmetic applications. For example anti-wrinkle and dermal filler injectables.*

The ‘general health and wellbeing’ category for medicines incorporates the following:

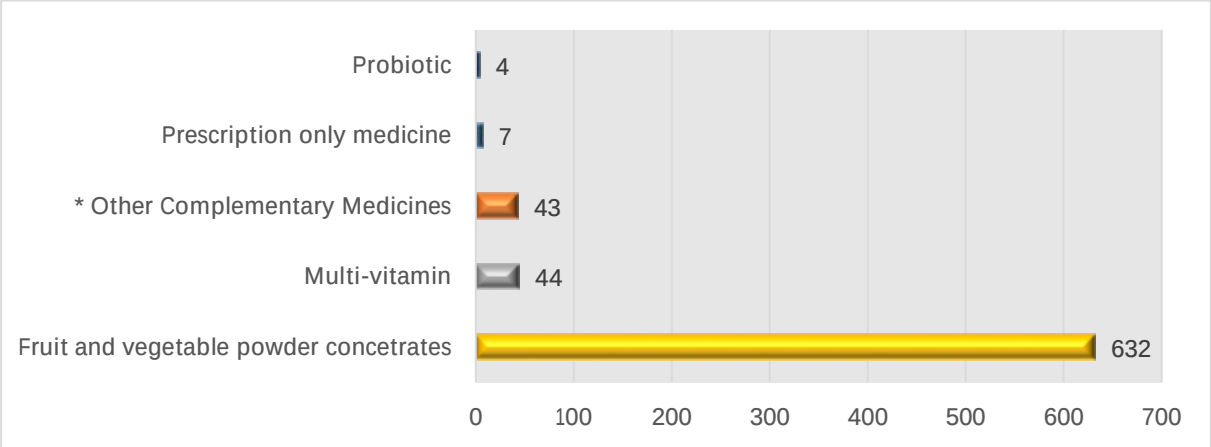


Figure 9 – Top five product types for the ‘general health and wellbeing’ (non-COVID-19) category for medicines.

** Probiotics, multi-vitamins and fruit and vegetable powder concentrates are complementary medicines with sufficient numbers of associated complaints to be reported separately. All other complementary medicines are combined as ‘other complementary medicines’.*

The following figure breaks down the types of products in the ‘not on the ARTG’ category from Figure 4.

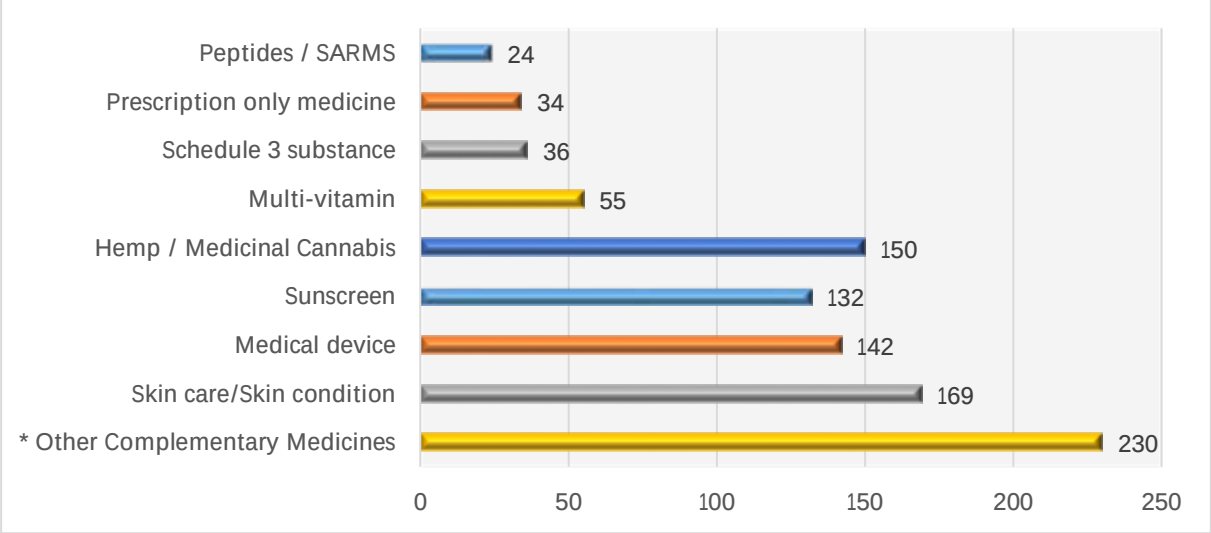


Figure 10 – Types of products in the ‘not on the ARTG’ (non-COVID-19) category.

** Multi-vitamins and sunscreens are complementary medicines with sufficient numbers of associated complaints to be reported separately. All other complementary medicines are combined as ‘other complementary medicines’.*

For those medium, high and critical non-COVID-19 cases where the TGA identified non-compliance, the issues were categorised into breaches of the Act:

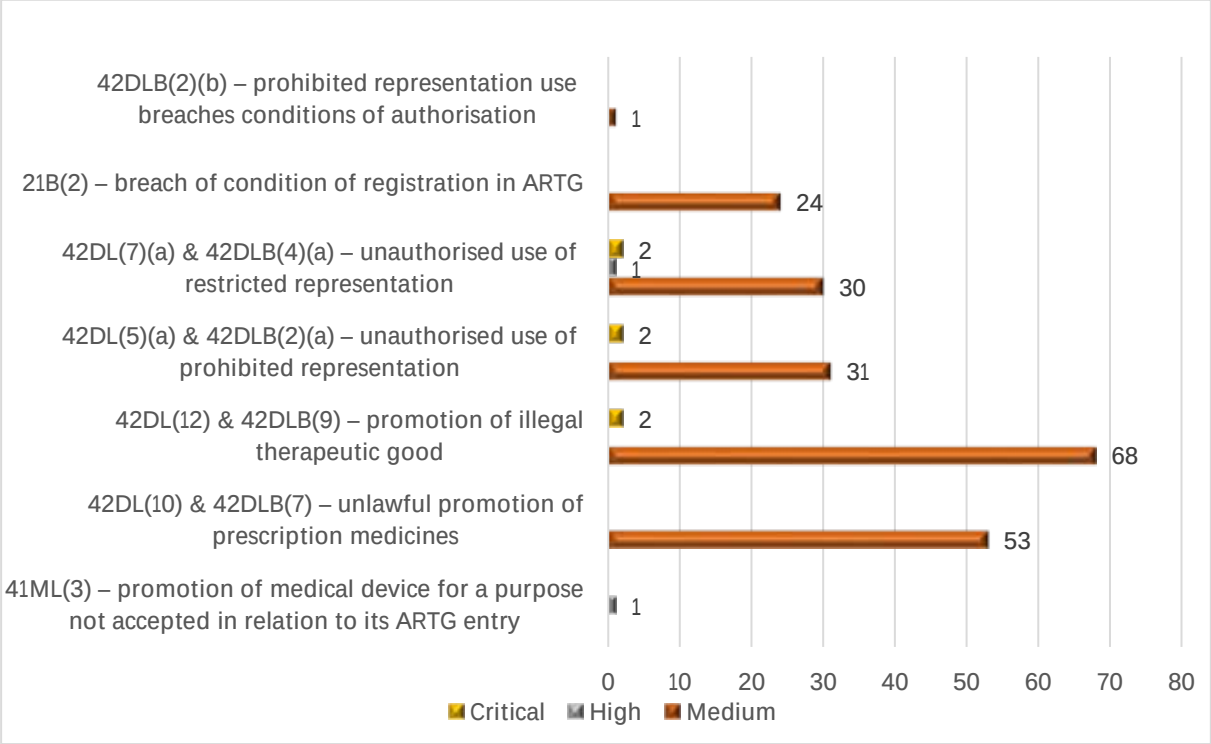


Figure 11 – Breaches of the Therapeutic Goods Act 1989 identified in non-COVID-19 cases.

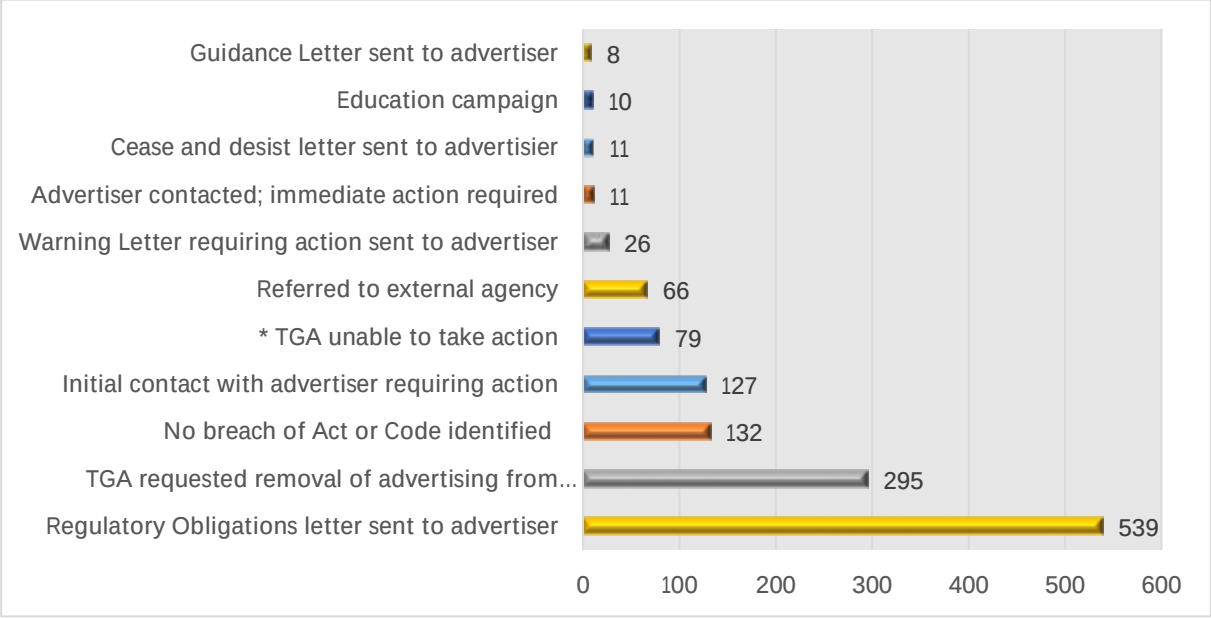


Figure 12 - Completed non-COVID-19 related compliance cases by action taken.

** 'TGA unable to take action' includes cases where the advertiser was based overseas and outside TGA's jurisdiction or insufficient information was provided/available to identify and contact the advertiser.*

COVID-19 related cases

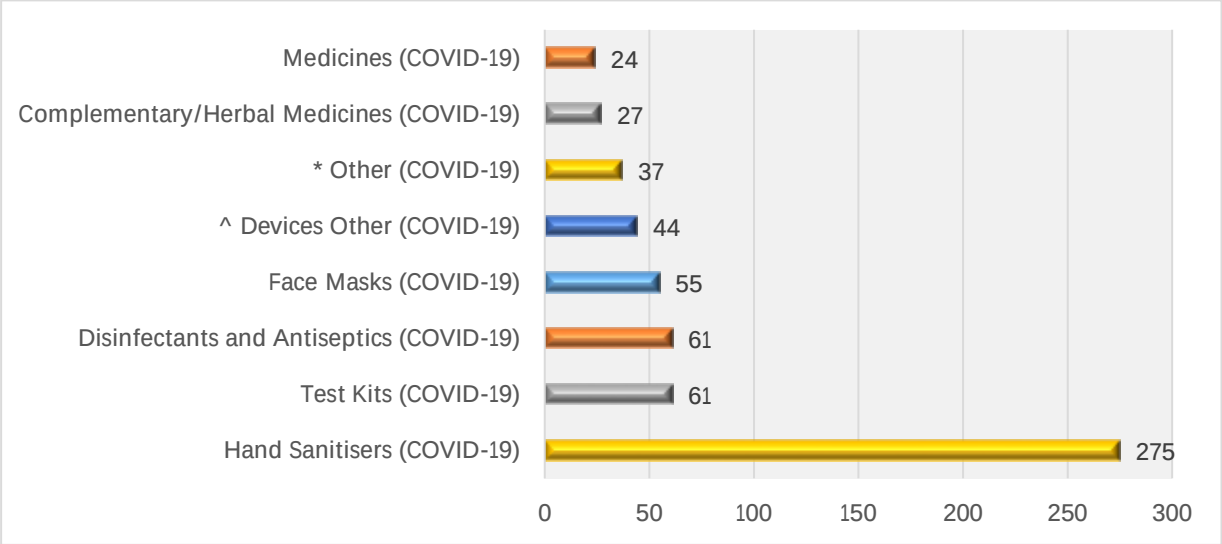


Figure 13 – Number of cases related to COVID-19 by type of good.

** Other (COVID-19) includes products that are not considered medicines, devices, or other therapeutic goods.*

^ Face masks and test kits are devices with sufficient numbers of associated complaints to be reported separately. All other devices are combined as 'other devices'.

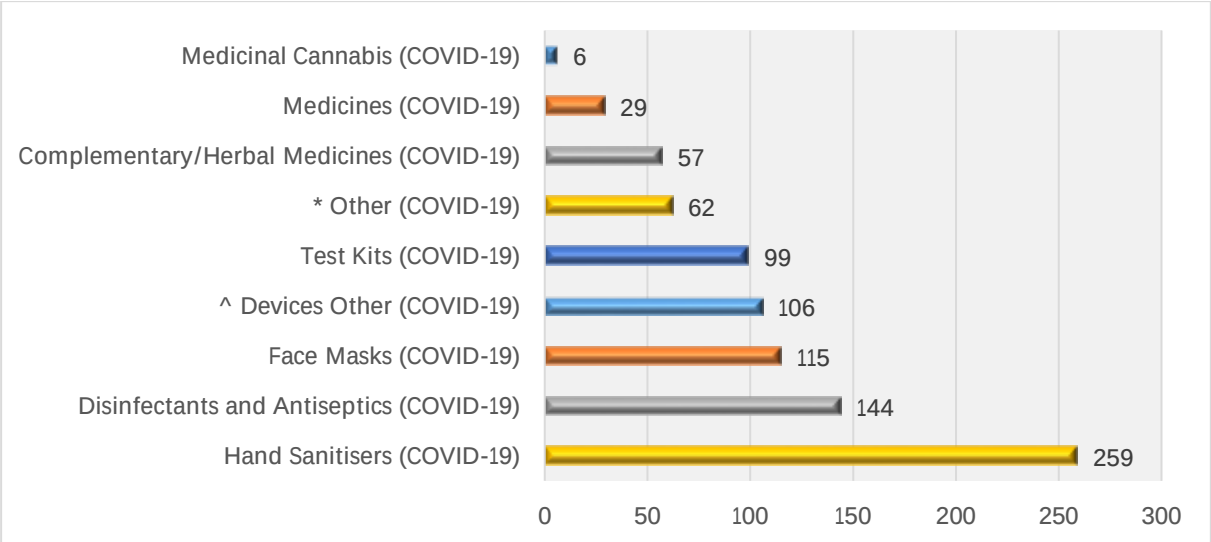


Figure 14 – Top 10 complaint categories for COVID-19 related cases.

** 'Other (COVID-19)' includes products that were advertised using therapeutic claims but would otherwise not be considered therapeutic goods.*

^ Face masks and test kits are devices with sufficient numbers of associated complaints to be reported separately. All other devices are combined as 'devices other (COVID-19)'.

For those medium and high COVID-19 cases where the TGA identified non-compliance, the issues were categorised into breaches of either the Act in Figure 15 or the Code in Figure 16:

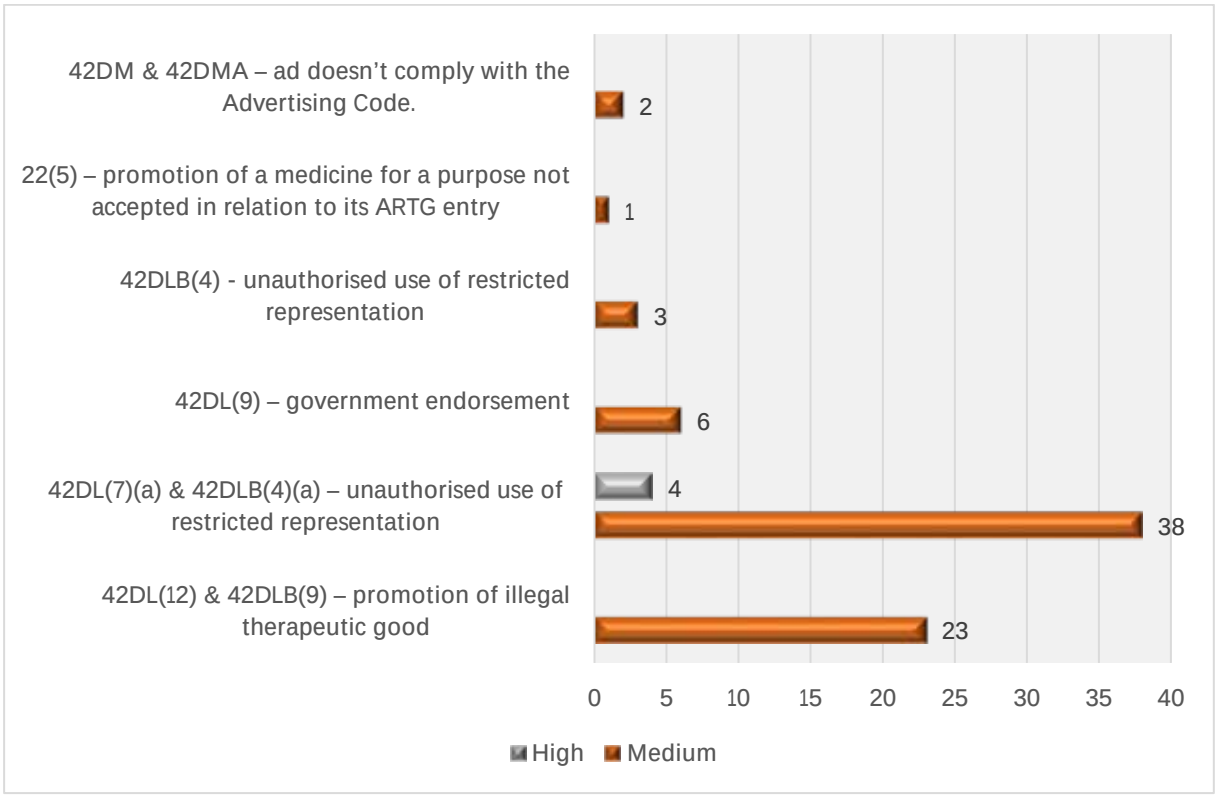


Figure 15 – Breaches of the Therapeutic Goods Act 1989 identified in COVID-19 related cases.

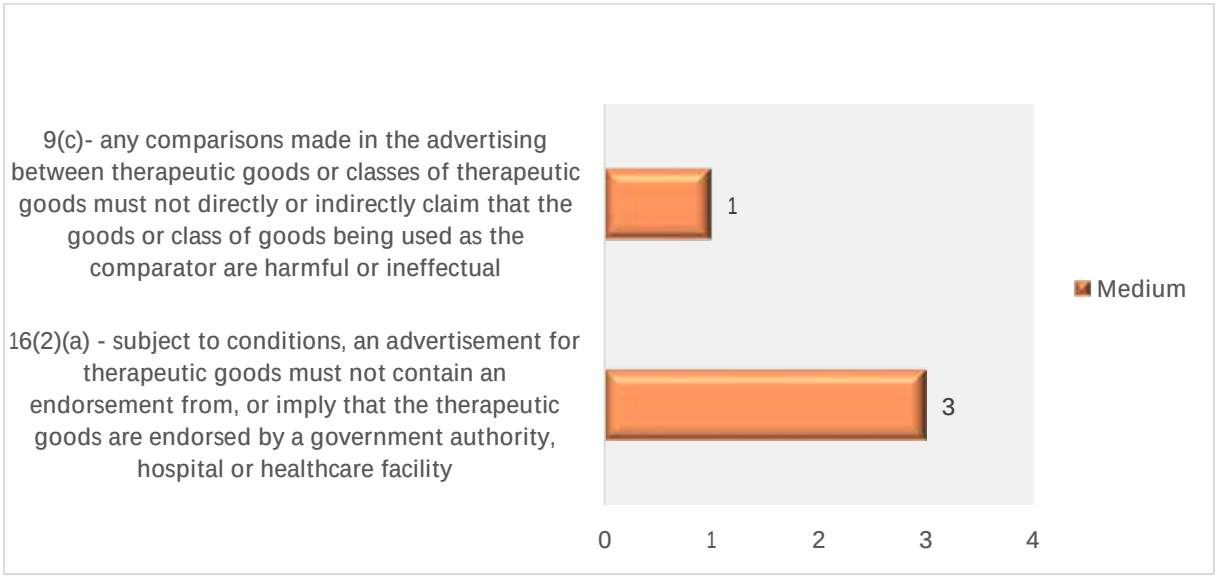


Figure 16 – Breaches of the Therapeutic Goods Advertising Code (No.2) 2018 identified in COVID-19 cases.

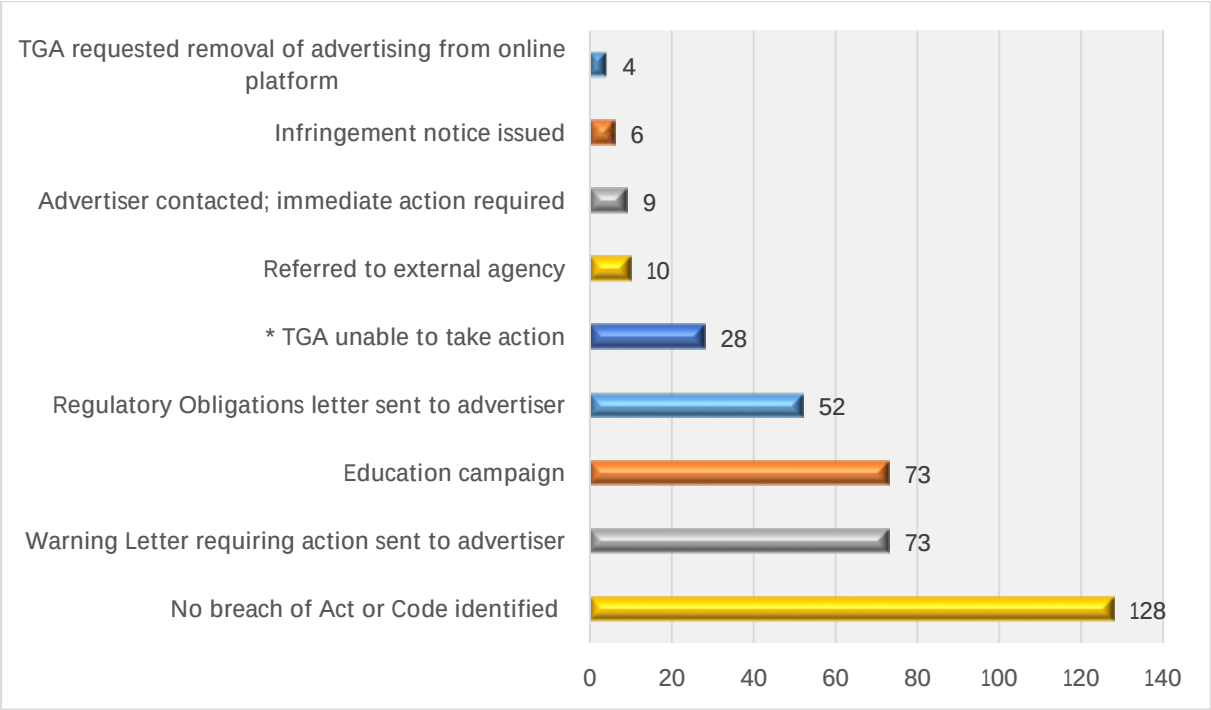


Figure 17 – Completed COVID-19 related compliance cases by action taken.

** 'TGA unable to take action' includes cases where the advertiser was based overseas and outside TGA's jurisdiction or insufficient information was provided/available to identify and contact the advertiser.*

Explaining the low number of Code breaches

Contraventions of the Code are taken seriously by the TGA. Focus has been on the highest risk areas and particularly those involving outright contravention of the Act, such as advertising therapeutic goods not in the ARTG (including goods advertised in relation to COVID-19), prescription-only substances and unauthorised use of restricted or prohibited representations. Numerous infringement notices have been issued and court actions have been initiated and these enhance the deterrent impact of the regulatory framework. Investigations of alleged Code breaches can be complex, with evaluation of scientific evidence to determine whether advertising is misleading often required.

Advertising enquiries

The following table provides the number of advertising enquiries received in 2019-20:

	2018-19	2019-20
Advertising enquiries received	564	455

Table 3 – Advertising enquiries volumes.

Enquiries are received from a variety of stakeholders including consumers, industry and third party advertisers (e.g. retailers). The table above shows a decline in the number of enquiries received in 2019-20 from the previous year. However during the COVD-19 pandemic, the complexity and urgency of enquiries has increased. These figures do not include general advertising inquiries received and answered by the TGA's Regulatory Assistance section.

Compliance and enforcement activities

Preventative compliance actions

The TGA's approach to the COVID-19 pandemic has resulted in increased coordination with other regulatory and law enforcement agencies, allowances in the regulatory framework for medicines and medical devices and an increased focus on the provision of information for industry, advertisers and consumers.

We established the TGA COVID-19 Enforcement Taskforce to coordinate a consistent compliance approach in relation to testing kits, hand sanitisers, face-masks and disinfectants. The Taskforce also coordinates a joint information and intelligence-sharing group between the TGA and other regulatory and law enforcement bodies to support whole of government compliance and enforcement activities.

The COVID-19 pandemic has seen a marked increase in the production and promotion of products such as hand sanitisers and personal protective equipment. The TGA has been proactive in educating new sponsors and in the first few months of 2020, sent a new sponsor fact sheet to more than 2000 new sponsors registering with the TGA. Other preventative compliance actions have included:

- information to assist manufacturers, suppliers and advertisers of hand sanitisers to understand their obligations under therapeutic goods legislation
- a warning about advertising that conflicts with 'stay at home when sick' advice
- a warning to consumers and advertisers about COVID-19 test kits, and
- warnings about illegal advertising relating to COVID-19.

Infringement notices

During the COVID-19 pandemic there has been an increased need to ensure our responses to non-compliance are effective and timely and to prioritise advertising breaches that pose the greatest risk to the health of consumers. We have taken urgent measures to protect consumers from misleading and unfounded claims about COVID-19, such as ingestion of substances containing a high concentration of sodium chlorite (a chemical used as a textile bleaching agent). We have also reminded advertisers to ensure that advertising claims do not undermine public health campaigns.

Infringement notices provide a timely option to address cases of clear non-compliance. Many breaches that resulted in infringement notices during the pandemic were due to a person or entity advertising therapeutic goods that were not included in the ARTG.

During 2019-20, we issued 155 infringement notices for alleged breaches of the therapeutic goods advertising legislation or conditions of registration related to advertising, with 51 of these infringement notices related to COVID-19 matters.

Payment was not received in relation to three cases where infringement notices were issued and the TGA has taken further compliance action in these matters.

The publication of information about the issuing of infringement notices may act as an additional preventative measure for the recipient and deter others from acting in a similarly non-compliant manner. In response to COVID-19, the TGA published infringements notices and issued media releases to outline the non-compliance.

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 restricted representations.

Court action

In 2019-20, the TGA initiated court action against a number of advertisers of dangerous substances, including prescription-only medicines being promoted as performance and image enhancing supplements.

Criminal conviction – Prodigy nutrition

On 29 July 2020, the ACT Magistrates Court convicted the former owner of a Canberra-based sports supplements company on four charges of unlawful advertising of therapeutic goods. The individual was required to give security of $1,000 and be of good behaviour for a period of 12 months in accordance with the Crimes Act 1914. Charges included three counts of advertising therapeutic goods not entered in the ARTG (ss.42DL(12) of the Act) and one count of advertising prescription-only medicines to the public (ss.42DL(10) of the Act).

Civil penalties ordered – Peptides Clinics Australia

On 23 July 2019, the Federal Court of Australia ordered that Peptides Clinics Australia (Peptides Clinics Pty Ltd) pay $10 million to the Commonwealth for breaches of the mandatory rules for advertising of medicines, including the ban on advertising prescription-only medicines to the public (ss.42DL(7) of the Act).

Civil penalty proceedings and injunction – Evolution supplements

On 13 March 2020, the TGA commenced proceedings against Evolution Supplements Pty Ltd in the Federal Court of Australia. Evolution Supplements and its director are alleged to have advertised therapeutic goods not included in the ARTG (ss.42DL(9)), including goods containing substances listed in Schedule 4 and/or Schedule 10 of the Poisons Standard. The advertising allegedly included references to Selective Androgen Receptor Modulators (SARMs), the use of which has been linked to liver failure and increased risk of heart attack and stroke.

Civil penalty proceedings and injunction – MMS Australia

On 3 June 2020, the Federal Court of Australia issued an injunction restraining Southern Cross Directories Pty Ltd (trading as MMS Australia) from advertising and supplying goods containing potentially dangerous substances including sodium chlorite (Miracle Mineral Solution – or MMS), dimethyl sulfoxide and yohimbine. The TGA also published an updated safety alert to warn consumers about the dangers of ingesting MMS.

Assurance work

Overview of assurance

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.

The function involves checking the online advertising of advertisers at the centre of selected cases, after a specified period of time, for compliance against the issues the TGA raised with them during the handling of the case. Where the TGA requested the removal of an advertisement for a good from an online platform (e.g. eBay), we will confirm that the advertiser has not relisted the good.

Non-COVID-19 assurance work

We utilise a risk-based approach to select and review non-COVID-19 cases for advertising compliance. All cases initially categorised[3] as 'critical' or 'high' are selected for review. Random samples of cases categorised as Low or Medium are selected for review.

The online advertising associated with a non-COVID-19 case is reviewed approximately two months after the case is closed. As such, the assurance data provided below is based on cases closed from June 2019 to April 2020. Following the review of 317 cases, we are currently tracking at a 93% compliance rate across all priorities.

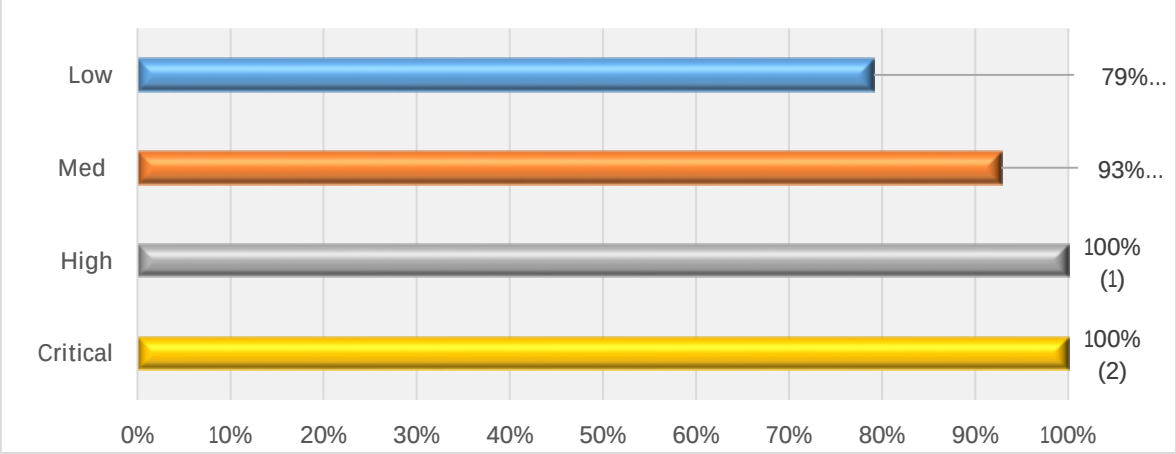


Figure 18 – Percentage of non-COVID-19 related assurance cases found compliant.

[3] See the advertising complaints handling framework - https://www.tga.gov.au/publication/complaints-handling-advertising-therapeutic-goods-australian-public

COVID-19 assurance work

Due to widespread concern about consumer vulnerability in the face of the COVID-19 pandemic, the advertising assurance program captures 100% of COVID-19 cases that have been closed, irrespective of category. We conduct the assurance reviews on COVID-19 related advertising cases two weeks after case closure.

237 eligible cases closed during 2019-20 have been reviewed, with an 80% compliance rate across all cases. Of the reviewed cases:

- 76% of those classified as 'low' were compliant, and
- 100% of the cases classified as 'medium' were compliant.

This work is ongoing.

Assurance reviews are not conducted for those closed cases where:

- the TGA was unable to take action (outside of jurisdiction)
- no breach of the Act or Code was identified, or
- it is a duplicate of case that was investigated or is currently under investigation.

Trends in low category cases

Consistent with the top 10 complaint categories for all COVID-19 related cases (Figure 14), hand sanitisers were the most commonly implicated in the 'low' category cases. The next most commonly identified products were disinfectants, face masks and tests.

The top three complaint categories for non-COVID-19 'low' category cases were:

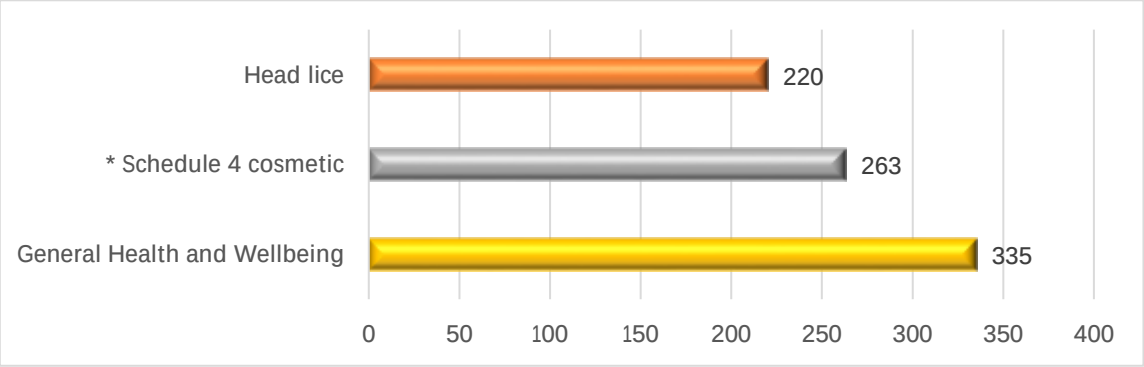


Figure 19 – Top three complaint categories for 'low' category cases.

** Schedule 4 cosmetic relates to prescription-only medicines that are typically used for cosmetic applications. For example anti-wrinkle and dermal filler injectables.*

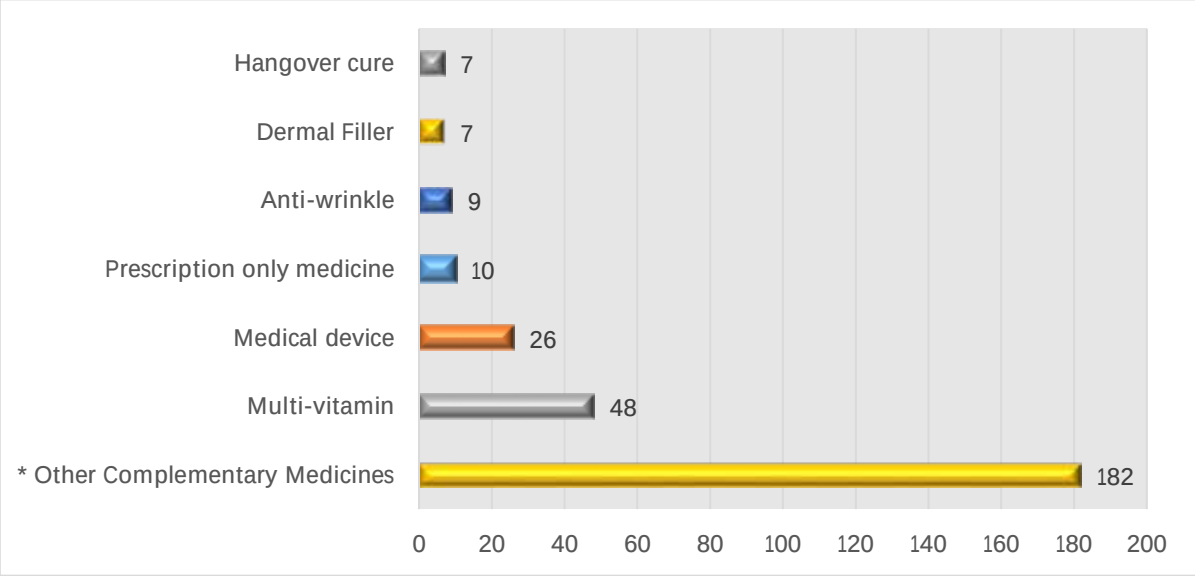


Figure 20 – Top 7 product types in the 'general health and wellbeing' category for 'low' category cases.

** Hangover cures and multi-vitamins are complementary medicines with sufficient numbers of associated complaints to be reported separately. All other complementary medicines are combined as 'other complementary medicines'.*

Case studies – non-COVID-19 related

Case study 1: Weight loss products

Key points:

- The assessment of whether an advertisement complies with the Code must be made based on the total presentation and context of the advertisement and by its likely impact on a reasonable person to whom the advertisement is directed. Changing one aspect of a misleading advertisement may not be sufficient to make it compliant.
- Advertisers must have appropriate evidence to support the claims in their advertising.
- There are special evidence and advertising requirements for weight loss medicines.

About the advertising

On 11 July 2018, the TGA received a complaint about weight loss and related health benefit claims made in the advertising for FatBlaster Clinical, a listed medicine.

The advertising elements communicating these claims included the product name, imagery, packaging, website and other promotional information.

The TGA requested the product sponsor to provide the information it held to substantiate the therapeutic claims made and to support the indications entered in the ARTG for the product. On review of the evidence provided, the TGA determined that the clinical studies were not sufficiently rigorous to substantiate the disputed claims. Of the two studies provided by the sponsor as the primary sources of evidence:

- both were conducted over a short duration and failed to demonstrate meaningful weight loss results
- both were conducted outside Australia and neither could demonstrate that the study population was similar to the composition of the Australian population
- the authors of one study were employed by companies with significant interests in the results of the study, and
- secondary sources of evidence provided were insufficient on their own to support specific indications.

In response, the sponsor updated its promotions to replace claims regarding weight loss with those relating to weight management. However the product name and weight loss indications in its ARTG listing remained unchanged, which were not supported by the evidence provided.

Details of non-compliance

Since the evidence provided by the sponsor was not satisfactory, the TGA considered that the weight-loss claims were unsubstantiated. These claims were therefore found to be inaccurate, likely to mislead and exaggerate product efficacy, breaching sections 9(a), 9(b) and 10(a)(ii) of the Code.

The overall presentation of the product was considered misleading (also section 9(a) of the Code), with the terms 'FatBlaster' and 'Clinical' together with imagery of a slim person and a measuring tape suggesting that consumers could achieve significant weight loss with the use of the product, consistent with results purportedly demonstrated through clinical trials.

In addition to reinforcing the unsubstantiated weight loss claims, the imagery used did not reflect the results that the average user could expect to achieve from using the product. It implied that the individual portrayed by the image had used the goods and had achieved significant weight loss, with a significant reduction in waist circumference. This was not consistent with the evidence provided, therefore breaching section 26(3) of the Code.

Actions taken

The TGA liaised with the sponsor to highlight the areas of compliance that needed attention and considered alternate proposals from the sponsor. However, a satisfactory proposal was not received and, on 20 November 2019, the TGA notified the sponsor of the decision to cancel the product from the ARTG and issued a directions notice to cease making product claims relating to weight loss, including use of the misleading product imagery. The product's entry in the ARTG was cancelled on 20 December 2019.

A review of the sponsor's online advertising of similarly formulated products indicates they do not appear to be advertising these products with the claims that the TGA found to be non-compliant in relation to the original product.

Case study 2: Homeopathic melatonin

Key points:

- Homeopathic medicines are not exempt from the requirement to be entered in the ARTG if they are represented for the treatment of a disease, condition, ailment or defect.
- The exemption from the need to enter a therapeutic good in the ARTG is not an exemption from the need to comply with the advertising requirements.

Melatonin is generally known as a medicine for use in connection with jetlag, sleeplessness and insomnia. However, the presentation of melatonin as a homeopathic remedy for these conditions does not align with the traditionally accepted principles of homeopathy, namely that the substance (in this case, melatonin) can produce in a healthy person the symptoms which it is purported to alleviate (the 'Law of Similars').

Additionally, the term 'homeopathic melatonin' suggests that the medicine contains a sufficient quantity of melatonin to have a similar effect and mode of action as non-homeopathic melatonin medicines. In this way, describing these medicines as homeopathic melatonin could be misleading.

About the advertising

On 12 July 2018, the TGA received a complaint regarding the advertising of homeopathic melatonin products by several sponsors and retailers.

Advertising for these products appeared on each company's branded websites (along with the labelling and packaging elements) and there were many online retailers of the products. Various claims regarding melatonin were used, including its ability to provide relief or treatment of insomnia, sleeplessness, mild anxiety, symptoms from jetlag/travel or stress, help regulate normal healthy sleep and provide stamina and endurance.

The TGA assessed the evidence provided by each sponsor in connection with their product against homeopathic evidence standards. We determined that the evidence provided by each sponsor was not sufficient to substantiate the disputed claims. Slight differences existed between each sponsor's evidence, however all had deficiencies relating to the:

- proving substance description and detailed symptom information
- qualifications and experience of investigative personnel, and
- relevance and strength of the evidence to support indications/claims.

Further, the TGA determined that claims regarding the 'traditional use' of melatonin as a homeopathic medicine could not be substantiated. The assessment also identified that the products did not appear to be homeopathic products because they were not prepared in accordance with homeopathic principles such as 'like cures like'.

Details of non-compliance

Since the evidence provided by each sponsor was not satisfactory, none of the therapeutic claims made could be substantiated. These claims were therefore found to be inaccurate, misleading and exaggerate product efficacy, breaching sections 9(a), 9(b) and 10(a)(ii) of the Code.

In an attempt to achieve compliance, each sponsor sought to amend advertising to remove therapeutic claims being made about its products. However, the Code provides that at least one indication must be included in an advertisement for therapeutic goods. Because the goods were available for purchase directly from websites without physical inspection of the label this allegedly contravened section 12(3)(d) of the Code.

Advertising for each product also included references to the treatment of insomnia, which as a serious form of a disease, condition, ailment or defect, is a restricted representation. As the TGA had not authorised the use of such restricted representations in the advertising of any of these products, this was a breach of sections 42DL(7) and 42DLB(4) of the Act.

Actions taken

The TGA issued correspondence to each sponsor, together with copies of the evidence reviews, alerting them to the alleged legislative breaches identified and the corrective actions needed. These actions included ceasing the use of therapeutic use claims without supporting evidence, advertising with non-compliant product labels, referring to insomnia (restricted representation) and advertising without a relevant indication.

All sponsor advertisers took action to cease the non-compliant advertising of their products. Each also undertook to contact any Australian online retailers that continued to advertise their products in a non-compliant manner.

The TGA is aware of other sponsors and retailers of homeopathic melatonin products making similar claims and work in this sector is ongoing.

Case study 3: Medicinal cannabis prescription services

Key points:

- Medicinal cannabis products are prescription-only medicines, which cannot be advertised directly to consumers in Australia.
- Referring to diseases and conditions in promotional material for a clinic that mentions medicinal cannabis is likely to result in the material being considered to be advertising therapeutic goods to consumers.

About the advertising

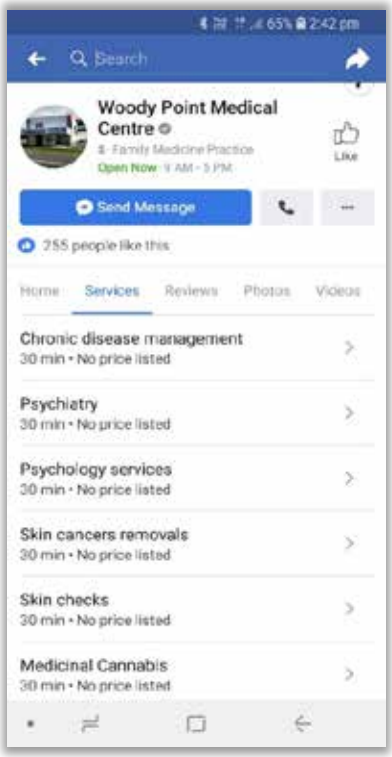
On 28 October 2018, the TGA received a complaint about advertising by a clinic, which offered medical services, including services involving medicinal cannabis.

Advertising on its Facebook page, it promoted the use of medicinal cannabis for treating conditions including chronic pain, palliative care, epilepsy, chemotherapy induced vomiting/nausea, multiple sclerosis, neuropathic pain, cancer pain, PTSD, depression, fibromyalgia, autism, schizophrenia, Alzheimer's, anorexia and wasting associated illness, Parkinson's Disease, seizure management, Tourette's and tremors.

Details of non-compliance

By promoting medicinal cannabis, the clinic advertised a prescription-only medicine which cannot be advertised to the public, breaching sections 42DL(10) and 42DLB(7) of the Act.

It is also an offence to advertise therapeutic goods to consumers with references to serious health conditions that are either restricted or prohibited representations; these may only be used with prior TGA authorisation. For restricted representations, this is a breach of sections 42DL(7) and 42DLB(4) of the Act while the use of prohibited representations is a breach of sections 42DL(5) and 42DLB(2) of the Act.



Actions taken

The TGA issued a cease and desist letter, advising the clinic to remove non-compliant advertising from its Facebook page. The TGA also provided guidance to the broader cannabis industry to help it continue its services without illegally promoting the prescribed product. The advertiser addressed the advertising compliance concerns.

Case study 4: Advertising to health professionals

Key points:

- To avoid misleading claims when advertising to any audience, advertisers should ensure the meaning of claims is absolutely clear and leaves no room for interpretation or ambiguity.
- Prescription-only medicines registered in the ARTG are subject to a condition of registration requiring promotional materials to comply with the Medicines Australia Code of Conduct.
- The TGA has access to a range of tools, including infringement notices that can be used to address a suspected breach of a condition of registration.

Background

All sponsors of prescription-only medicines must comply with the Medicines Australia (MA) Code of Conduct when promoting to health professionals, whether they are MA members or not. The TGA makes sponsors aware of this requirement as part of the process for registering medicines in the ARTG.

The MA Code of Conduct requires that the content of all promotional material must be balanced, accurate, correct, referenced and fully supported by the Product Information (which is approved by the TGA) and any other relevant information source. It also states all information, claims and imagery used must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

About the advertising

In July 2019, the TGA was alerted to concerns about promotional materials for health professionals regarding advertising by pharmaceutical company Mundipharma for its Targin range of prescription-only medicines. In its materials, the company stated that:

1. opioids should be used as part of a multimodal pain management plan and in an ongoing trial, as they are associated with potential harms, including unsanctioned use, addition and overdose, and

2. the Royal Australian College of General Practitioners (RACGP) suggests the use of weak opioids (e.g. codeine) should also be considered cautiously as these preparations are less effective than strong opioids with the same adverse effects.

Following the receipt of advice from the MA Code of Conduct Committee, the TGA considered these statements were likely to be unbalanced, inaccurate and/or incorrect, and otherwise were likely to mislead.

In relation to the first statement, the TGA considered that while there were two possible interpretations, it was possible that some readers would interpret it, as 'opioids are an integral part of a multimodal pain management plan'. However, opioids should not be represented as a core component of the multi-modal management of chronic non-cancer pain, and the decision to prescribe opioids should be approached with significant caution.

Further, the materials using the first statement specifically referenced guidelines from the Faculty of Pain Medicine, Australia and New Zealand and featured strong imagery of a patient with a pained expression. The TGA determined that in this context, the overall effect would have been to positively encourage the prescription of these medicines on the basis that the company represented their use as being supported by the guidelines of the Faculty of Pain Medicine, Australia and New Zealand.

In relation to the second statement, the phrase 'should also be considered cautiously' could have the effect of encouraging the use of strong opioids in preference to weak opioids. It was viewed as selectively narrow and omitted other balancing cautionary statements from the RACGP guidelines.

Details of non-compliance

The company was considered to have contravened the MA Code of Conduct and therefore the standard conditions of ARTG registration regarding compliance with the MA Code of Conduct.

Failure to comply with the requirements of the MA Code of Conduct is a breach of subsection 21B(2) of the Act.

Actions taken

The TGA issued 24 infringement notices totalling $302,400 for non-compliant advertising to health professionals. The company accepted and paid these infringement notices. The company has ceased using the claims and promotional materials at the centre of this matter.

Case study 5: Food-medicine interface

Key points:

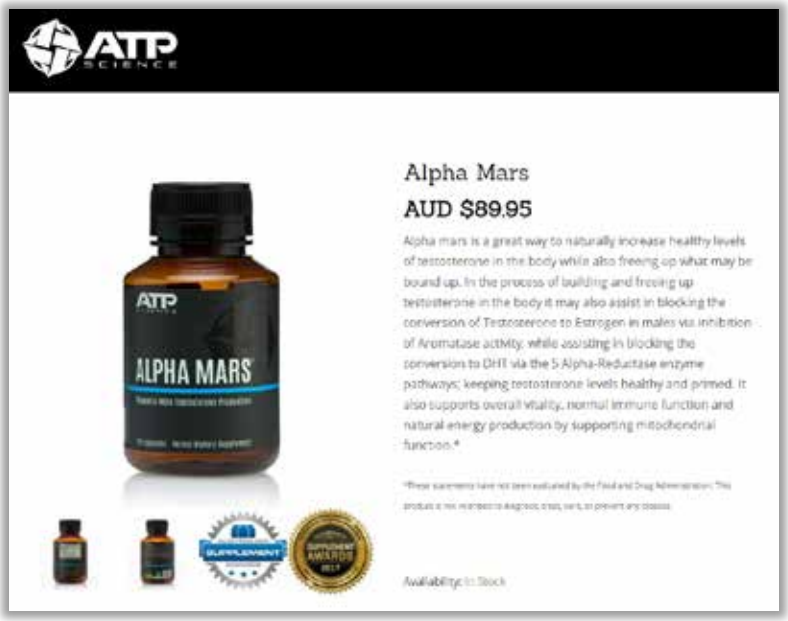
- The food-medicine interface is a complex area. The TGA website provides a decision tree to assist you in making a preliminary assessment. However, before marketing a product that consumers would reasonably be likely to see as a medicine (e.g. a capsule) you should seek regulatory advice.

About the advertising

On 21 February 2019, the TGA received a complaint about advertising by a nutrition company for therapeutic goods positioned as sports supplements.

The company advertised its products on its website, including reviews, testimonials and blog posts, along with podcasts via social media platforms including YouTube and SoundCloud.

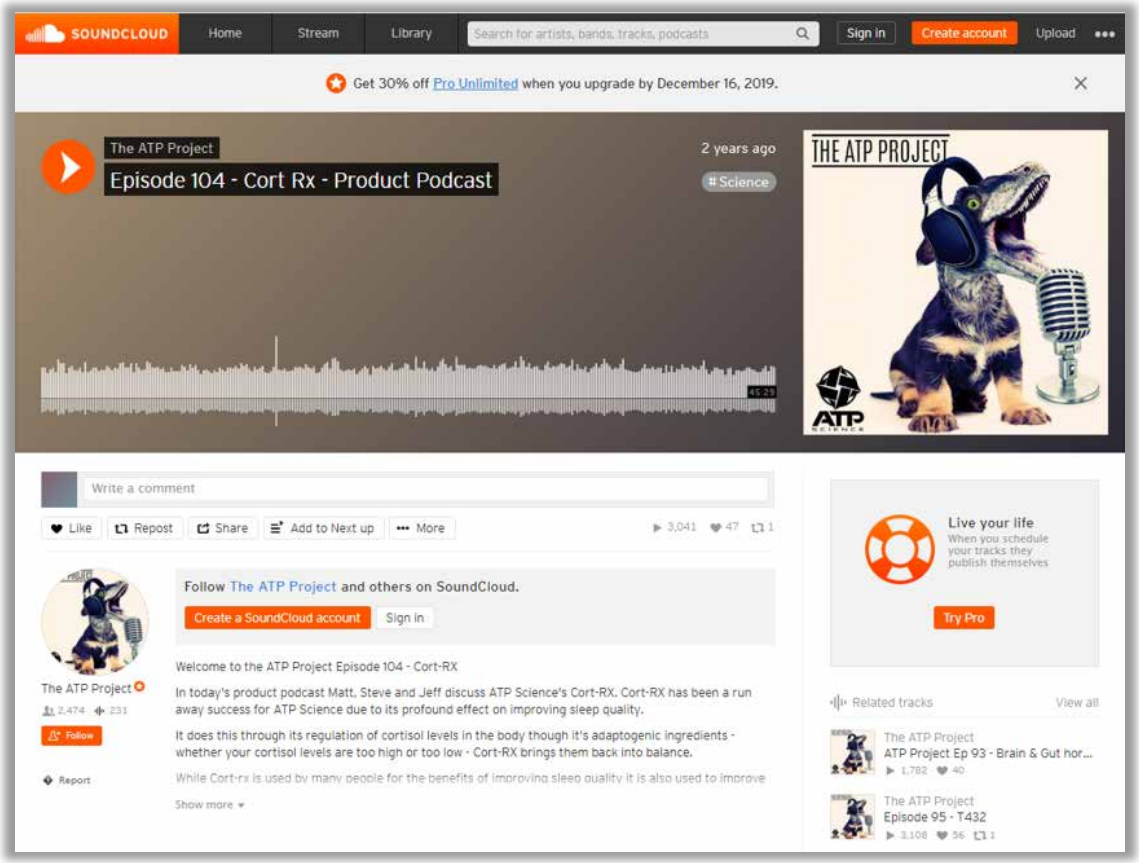
The company sponsored one therapeutic good entered in the ARTG, however, the advertising for most of its products (some of which were described as 'formulated supplementary sports foods') included claims of a therapeutic nature. Following a review of the company's advertising, the TGA identified multiple therapeutic goods that were not entered in (or exempt from the need to be entered in) the ARTG.



These products included Prototype 8, Subcut, BlockE3, Alpha Venus, T432 Plus, AJpha Mars and Aurum Oil. The TGA also noted that advertising for Capzea, which was in the ARTG was not consistent with the indications in its listing and made claims of efficacy beyond those permitted.

Details of non-compliance

Advertising for Cort Rx and Alpha Mars included references to managing depression, which is a prohibited representation regarding the treatment of mental illness. The TGA had not authorised the use of this representation and therefore this was alleged to breach section 42DLB(2) of the Act.



Advertising for Resilience included references to the treatment of autoimmune conditions, which as a serious form of a disease, condition, ailment or defect, is a restricted representation. There was no TGA authorisation to make this reference in advertising for any of these products, in alleged breach of section 42DLB(4) of the Act.

After initial engagement by the TGA, the company continued to advertise 13 therapeutic goods not entered in the ARTG, allegedly breaching section 42DLB(9) of the Act. These were AMP-V, Alpha Mars, Alpha Prime, Alpha Venus, Aurum Oil, Block E3, Cort Rx, Multifood, Prototype 8, Resilience, Subcut, T432 Plus and ZMST.

Actions taken

The TGA alerted the company to the presence of non-compliant advertising content on its website and advised to have it removed.

The company confirmed it had amended its non-compliant advertising for Capzea, updating its product description, reviews and testimonials for consistency with indications in the ARTG listing. As a result, no further action relating to Capzea was required.

However, the company did not take sufficient action to address the other outstanding issues. As such, the TGA issued 24 infringement notices totalling $302,400 for 21 counts of advertising therapeutic goods not on the ARTG, two counts of using a prohibited representation and one count of using a restricted representation without TGA authorisation. The company accepted and paid these infringement notices.

Further, the TGA accepted a request from the company to enter into an enforceable undertaking, which is a type of regulatory action that is an alternative to the pursuit of court action. The undertaking included a list of stringent requirements for the company to introduce defined compliance activities and demonstrate ongoing compliance with therapeutic goods legislation. Enforceable undertakings are enforceable by courts.

Case studies – COVID-19 related

Case study 1: Advertising by a health professional

Key points:

- All advertisers, including medical practitioners and other health professionals, must comply with the advertising prohibitions and requirements when advertising therapeutic goods to consumers.
- In the absence of express authorisation from the TGA, the advertising of medicines for the prevention or cure of COVID-19/coronavirus is unlawful.

About the advertising

On 13 April 2020, the TGA was alerted to issues with advertising for a range of therapeutic goods by a Perth-based doctor.

Advertising on the doctor's website and Facebook page included claims that a number of therapeutic goods could prevent, treat or kill COVID-19/coronavirus, including Longevity Ozone Sauna Systems, Quicksilver Scientific Liposomal Melatonin, Quicksilver Scientific Liposomal Vitamin C with R-lipoic acid and Seeking Health Optimal Liposomal Vitamin C Plus with Quercetin.

The TGA identified many other therapeutic goods in the advertising that were not entered in or exempt from the requirement to be entered in the ARTG. These included Oriental Botanicals ViraForce, NutriBiotic: High Potency GrapefruitSeed Extract with Echinacea and Artemisia Annua, Now Foods Andrographis Extract, Seeking Health Optimal Zinc Lozenges, Seeking Health Optimal Liposomal Vitamin C, HealthWest Pure Ionic Silver, Quicksilver Scientific Methyl Charge+, Quiksilver Scientific Artemisinin Emulsion, True Silver Colloid Spray, Fit For Life Andrographis Immune Defense and a 'transcranial electrostimulation device'.

As a health professional, the doctor was not permitted to endorse therapeutic goods in advertising.

Details of non-compliance

The doctor advertised therapeutic goods not entered in the ARTG, allegedly breaching section 42DLB(9) of the Act.

Advertising for several products included references to the prevention of coronavirus. In the current context, consumers would interpret 'coronavirus' as a reference to COVID-19, which as a serious form of a disease, condition, ailment or defect, is a restricted representation. As there was no TGA

authorisation to make this reference in advertising and it had not been obtained, the TGA alleged these were breaches of section 42DLB(4) of the Act.

Actions taken

The TGA issued the doctor with 15 infringement notices totalling $37,800 for 11 counts of advertising therapeutic goods not on the ARTG and four counts of using a restricted representation without TGA authorisation. The doctor accepted and paid these infringement notices. The TGA is continuing to monitor the advertising.

Details of the doctor's conduct as a registered medical practitioner was referred to the Medical Board of Australia for potential action.

Case study 2: Prohibited representations

Key points:

- Advertisers cannot promote therapeutic goods as a treatment (or aiding in the treatment of) cancer, irrespective of whether such a use is supported by evidence.
- These references are known as prohibited representations.
- The TGA only authorises the use of prohibited representations where there is a clear public interest to do so.
- References to coronavirus in advertising during the COVID-19 pandemic will be taken by consumers to refer to 'COVID-19'.

About the advertising

On 15 April 2020, the TGA received a complaint about advertising for Molecular Hydrogen/Oxygen Generators and Nanobubble Infusion Pumps. The TGA considered this device to be a therapeutic good that was not entered in (or exempt from the requirement to be entered in) the ARTG.

Advertising on the technology company's website and Facebook page included claims that the device was 'the best medicine to resist and recover from the coronavirus' and could treat a range of conditions including cancer and diabetes. In the current context, consumers would interpret 'coronavirus' as a reference to COVID-19.

Details of non-compliance

It was alleged that the company advertised a therapeutic good not included in the ARTG, breaching section 42DLB(9) of the Act.

Advertising on its website included references to the treatment of cancer, which is a prohibited representation regarding the treatment of a neoplastic disease. The TGA therefore alleged that the company breached section 42DLB(2) of the Act.

Also on its website and via Facebook, advertising for the device included references to the prevention of coronavirus and treatment of diabetes, which as serious forms of diseases, conditions, ailments or defects, are restricted representations. As TGA authorisation to use these references had not been issued, it was alleged that the company breached section 42DLB(4) of the Act.

Actions taken

The TGA issued the company with four infringement notices totalling $50,200 - two for allegedly using a restricted representation without TGA authorisation and one each for allegedly advertising therapeutic goods not in the ARTG and using a prohibited representation without TGA authorisation. The company accepted and agreed to pay these infringement notices.

The TGA also issued a cease and desist letter, instructing the company to cease all advertising for this product and making claims that it was capable of treating COVID-19, cancer, diabetes and other serious diseases, conditions or disorders. The company took corrective action as instructed.

Case study 3: Restricted representations

Key points:

- Referring to serious forms of a disease, condition, ailment or defect in advertising therapeutic goods is restricted.
- These references are known as 'restricted representations'

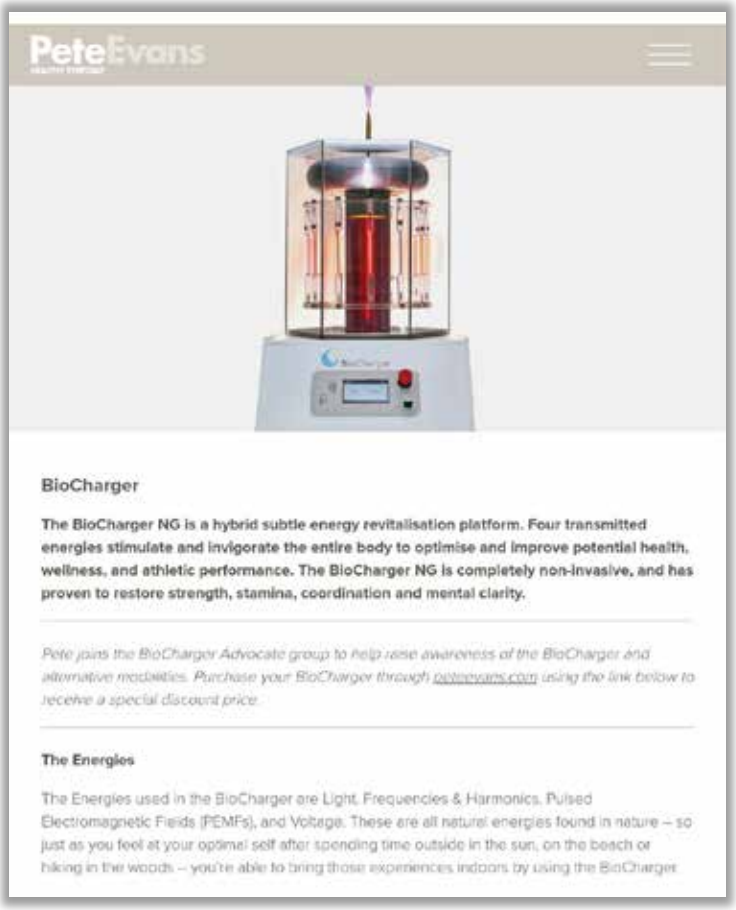
About the advertising

During April 2020, the TGA received multiple complaints about advertising for the BioCharger, a medical device that emitted light. The TGA considered this device to be a therapeutic good, which was not entered in the ARTG, nor was it exempt from the requirement to be entered in the ARTG.

On the company website, advertising included the following health benefit claims about the device:

- 'proven to restore strength, stamina, coordination and mental clarity'
- 'sharpening your mental clarity'
- 'recovery…[from] an injury, stress', and
- 'accelerate muscle recovery, and reduce stiffness in joints'.

Advertising via Facebook live video included claims that implied the BioCharger was capable of having an effect in relation to COVID-19, as it was 'programmed with about a thousand different recipes, there's a couple on there for Wuhan coronavirus'. In the current context, consumers would interpret 'coronavirus' as a reference to COVID-19.



Details of non-compliance

It was alleged that the company advertised a therapeutic good not included in the ARTG, breaching section 42DLB(9) of the Act.

Advertising for the BioCharger device included the term coronavirus, which as a reference to a serious form of a disease, condition, ailment or defect (COVID-19), is a restricted representation. As TGA approval to make this reference had not been sought or obtained, this is a breach of section 42DLB(4) of the Act.

Actions taken

The TGA issued the company with two infringement notices totalling $25,200. The company accepted and paid these infringement notices and the material that was the subject of the complaint removed.

Working with others

COVID-19

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 four times during 2019-20. A communique is published on the TGA website following each meeting.

In its second year of operation, the TGACC provided valuable input to the Independent Review of the therapeutic goods advertising framework as well as feedback on the findings and recommendations of the review of the advertising complaints framework.

Educational partnerships

The TGA collaborated with Pharmacy Guild Learning and Development to produce a Continuing Professional Development accredited e-learning module to improve pharmacists' understanding of the rules that apply to advertising therapeutic goods.

Throughout the year, we also partnered with other organisations in key sectors to deliver training and educational materials.

Education and training

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

Throughout the year, we provided formal educational (face to face, via webinar and participation at seminars) and continued to add guidance material to the Advertising Hub. This included a webinar on supplying and advertising therapeutic goods for COVID-19, which complements the information sent to new sponsors that register with the TGA during COVID-19.

We also published information to assist:

- medicinal cannabis businesses to promote their services without also illegally advertising medicinal cannabis
- businesses and other entities to provide information about health conditions and their management through disease education activities
- providers of stem cells and other human cell and tissues (HCT) products to promote their services while still complying with the prohibition on advertising HCT to consumers.

The TGA worked with Direct Selling Australia to produce a fact sheet suitable for direct sellers on complying with the therapeutic goods advertising requirements.

New guidance materials published include the TGA social media advertising guide and fact sheets to assist advertisers to understand the rules surrounding:

- using scientific or clinical claims (representations) in therapeutic goods advertising
- advertising pharmacist-only (Schedule 3) medicines
- directing advertising exclusively to health professionals.

To support the cessation of the advertising pre-approval process, we published a list of Questions and Answers to assist advertisers to understand the impact of the changes. 'Advertising basics' content is also being developed to aid advertisers to understand the rules and their obligations post pre-approvals.

In May and June 2020, the TGA conducted its first paid social media campaign on 'How to spot a dodgy health product ad' campaign. The five-week campaign, consisting of five promoted posts, reached[4] almost 2.6 million people on Facebook and almost 2.4 million people on Instagram. The total number of impressions for Facebook and Instagram posts was 7.0 million and 6.3 million respectively. The objective of the campaign was to raise awareness of misleading advertisements and to educate consumers about some of the common ways advertisers of therapeutic goods entice consumers into buying products. The campaign also included a post urging caution around advertising by social influencers and products promoted for COVID-19 (see Figure 21).

[4] **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 people. People who see a post do not necessarily read the post or engage with it, however, reinforcement through multiple impressions can lead to greater message recall. Both metrics are therefore relevant.

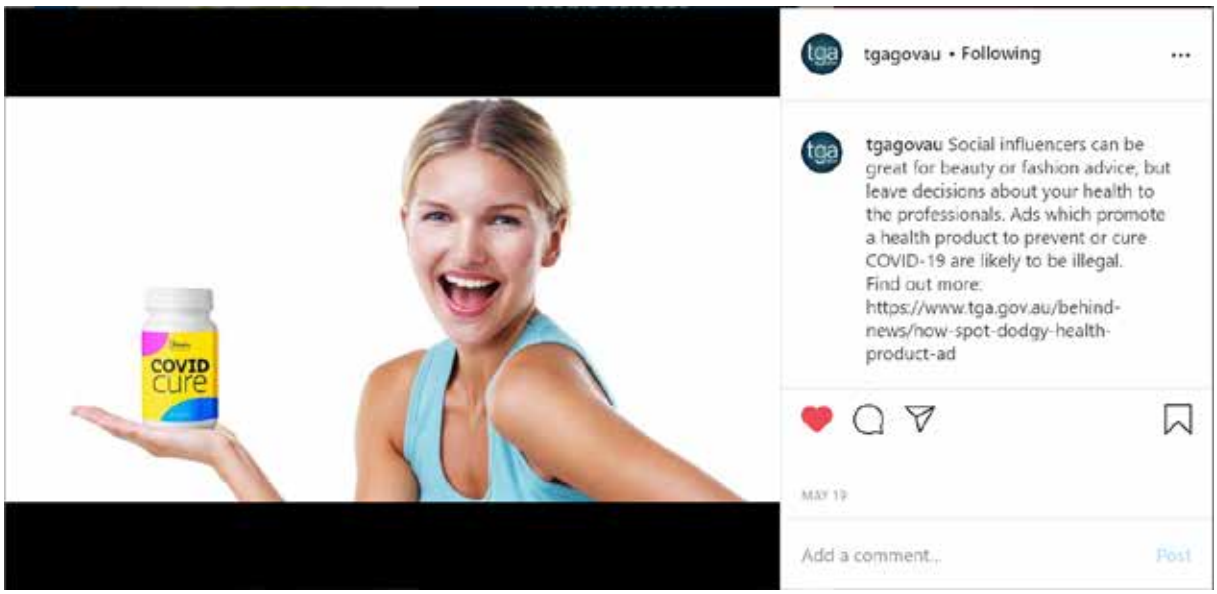


Figure 21 – Example of an Instagram post used in the TGA's 'How to spot a dodgy health product ad' campaign.

We have commenced a project to refine the Advertising Hub content and improve user experience. Case studies will illustrate examples of non-compliance and support guidance.

Lessons learnt and looking ahead

COVID-19: lessons learnt and future

The TGA has sought to take a pragmatic approach to the regulation of advertising of therapeutic goods related to COVID-19 to ensure consumers have access to appropriate hygiene and other relevant therapeutic products while being protected from both illegal products of unknown reliability and incorrect or inappropriate messaging. We have also worked to ensure that advertisers and sponsors have access to information about the advertising requirements in a COVID-19 context.

Key lessons for the TGA from the handling of advertising compliance issues related to COVID-19 include:

- the value of timely preventative actions in supporting the TGA's compliance work and pro-actively assisting advertisers and sponsors to understand their obligations before they act – for example, the new sponsor fact sheet
- while it may be preferable (from an advertiser education or procedural fairness perspective) to review advertising for compliance with all applicable legislative requirements, this is not feasible in an environment requiring rapid action in relation to advertising compliance matters – there is a need to focus on the key threshold offences (e.g. advertising a good not entered in the ARTG or seriously misleading claims which pose a high risk to human health and could undermine the Government's public health response)
- most advertisers want to comply and requiring a response from them within 48 hours generally drives urgent attention to compliance
- how public health emergencies can alter product and advertising risk assessments e.g. goods that ordinarily are considered low risk goods (such as face masks) but are critical in times of emergency can require additional scrutiny
- taking strong enforcement action where necessary and publicising the results of that action early (e.g. through publishing infringement notices on issue, rather than on payment) to reinforce the deterrent effect of such action
- the role of proactive and collaborative intelligence gathering to inform how and where our efforts can be the most productive and effective
- how to streamline the implementation of a surge capacity through the rapid mobilisation of staff from other areas within the TGA, as well as from other departments, and
- the importance of working closely with other regulators to ensure a coordinated response.

COVID-19 will continue to be a priority for as long as the pandemic continues. As new treatments (and possibly vaccines) emerge, this will present new challenges in the regulation of advertising. We will continue to monitor for opportunities for preventative compliance actions and be agile in responding to advertising compliance issues.

Reviews

The Sinclair review of the reforms to the therapeutic goods advertising framework was conducted during the first half of 2020. The review is now complete and the report has been published. Our future work will be significantly shaped by the recommendations from this review.

Response to the review

The Government has accepted all 22 recommendations. The agreed actions, once implemented, will deliver improvements and refinements to the therapeutic goods advertising framework, including:

- the development, in consultation with stakeholders, of annual advertising compliance priorities, to drive an intelligence-led, outcomes-focused and consumer focused approach to compliance
- implementation of a more strategic advertising complaints handling system, grounded in compliance priorities, that utilises complaints primarily as a source of intelligence
- the development and publication of new key performance indicators focused on priorities and outcomes rather than processes and deadlines
- the publication of case studies based on case experience to assist advertisers and consumers to understand the legal requirements for advertising therapeutic goods, in conjunction with the ongoing publication of policy clarification through guidance as needed
- improved flexibility, so we can adapt to emerging issues, and improved transparency through media and publications, as modelled on our response to compliance during the COVID-19 pandemic
- implementation of an education and stakeholder engagement strategy, aligned with compliance priorities, which focuses on consumer and industry benefit
- enhanced collaboration and engagement with other Australian regulators to help inform compliance priorities and enforcement, and
- enhancing the operation of the TGACC.

The TGA is developing a plan to implement these recommendations in the timeframes specified in the Government's response. The TGACC will be integral to the design of key aspects of the implementation.

Further updates on implementation progress will be published on the TGA website.

Advertising compliance is integral to the TGA's broader compliance function. The COVID-19 pandemic has uniquely tested our responsiveness, adaptability and effectiveness. It has highlighted the importance of open collaborative work practices both within the TGA and more broadly. The importance of the regulated community being compliant has never been more apparent.

We look forward to implementing the Government accepted recommendations from the Sinclair review. Improvements in intelligence gathering, strategic triaging and integrated response capabilities together with a renewed focus on compliance outcomes will benefit both those who are subject to regulation and the wider Australian community.

Appendix 1 – Glossary of advertising provisions

Therapeutic Goods Act 1989

Subsection	Description
42DL(12)	**Advertising offences—general:** This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the ARTG and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
42DL(7)	**Advertising offences—general:** This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies: (a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation; (b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.
42DL(10)	**Advertising offences—general:** This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
42DL(5)	**Advertising offences—general:** This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies: (a) no permission under section 42DK is in force in relation to the prohibited representation; (b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.
42DLB(9)	**Civil Penalty provision:** This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
41ML(3)	**False advertising about medical devices:** A person commits an offence if the person, by any means, advertises a medical device as being for a purpose; and the device is of a kind included in the Register; and the purpose is not a purpose accepted in relation to that inclusion.
42DLB(7)	**Civil Penalty provision:** This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Subsection	Description
42DLB(4)(a)	**Civil Penalty provision:** This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation.
42DLB(2)(a)	**Civil Penalty provision:** This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and no permission under section 42DK is in force in relation to the prohibited representation.
42DMA	**Civil penalty provision:** Non-compliance with the Therapeutic Goods Advertising Code.
42DM	**Offences:** Non-compliance with the Therapeutic Goods Advertising Code.
42DL(9)	**Offences:** Suggesting goods approved by government authority.
22(5)	**General offences relating to this Part:** A person commits an offence if: (a) the person, by any means, advertises therapeutic goods for an indication; and (b) the therapeutic goods are included in the Register; and (c) the indication is not an indication accepted in relation to that inclusion.
42DM(3)	**Offences—non-compliance with the Therapeutic Goods Advertising Code:** A person commits an offence if: (a) the person: (i) advertises, by any means, therapeutic goods; or (ii) causes the advertising, by any means, of therapeutic goods; and (b) the advertisement does not comply with the Therapeutic Goods Advertising Code.
42DLB(5)	**Civil penalty provision:** This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.
42DLB(4)	**Civil penalty relating to advertisements—general:** This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies: (a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation; (b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.
41ML(1)(d)(ii)	**Offences False advertising about medical devices:** A person commits an offence if the use of the medical device for the advertised purpose, if the medical device were so used, would result in, or would be likely to result in, harm or injury to any person.
42DLB(2)(b)	**Civil Penalty provision:** This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods where a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.
21B(2)	**Civil penalty provision:** A person contravenes this subsection if: (a) therapeutic goods are registered or listed in relation to the person; and (b) the person does an act or omits to do an act that breaches a condition of the registration or listing of the goods.

Subsection	Description
42DL(2)	**Offences:** A person commits an offence if: (c) the person: (i) advertises, by any means, therapeutic goods; or (ii) causes the advertising, by any means, of therapeutic goods; and (d) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement
42DL(1)	**Offences:** A person commits an offence if: (a) the person: (i) advertises, by any means, therapeutic goods; or (ii) causes the advertising, by any means, of therapeutic goods; and (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement and either: (i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or (ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.
42DLB(9)	**Civil penalty provision:** This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Therapeutic Goods Advertising Code (No.2) 2018

Subsection	Description
7(2)	Prescription price information must comply with the requirements of Schedule 4 of the Code.
8	Medicine advertisements to appear in magazines, newspapers or displays about goods must display the approval number in legible and standalone text in the bottom right-hand corner of the advertisement.
9(a)	Any claims made in the advertising must be valid and accurate, and all information presented must have been substantiated before the advertising occurs.
9(b)	Advertising must be truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons.
9(c)	Any comparisons made in the advertising between therapeutic goods or classes of therapeutic goods must not directly or indirectly claim that the goods or class of goods being used as the comparator are harmful or ineffectual.
9(d)	For therapeutic goods entered in the Australian Register of Therapeutic Goods, the advertising must be consistent with the entry for those therapeutic goods.
10(a)(i)	Advertising for therapeutic goods must support the safe and proper use of therapeutic goods by presenting the goods in accordance with directions or instructions for use.
10(a)(ii)	Advertising for therapeutic goods must support the safe and proper use of therapeutic goods by not exaggerating product efficacy or performance.
10(b)	Advertising for therapeutic goods must not be likely to lead to people delaying necessary medical attention or delaying the use of, or failing to use, treatment prescribed by a medical practitioner.
10(c)	Advertising for therapeutic goods must not encourage inappropriate or excessive use of the therapeutic goods.
10(d)(i)	Advertising for therapeutic goods must not contain any claim, statement, implication or representation that the therapeutic goods are safe or that their use cannot cause harm, or that they have no side-effects.

Subsection	Description
10(d)(ii)	Advertising for therapeutic goods must not contain any claim, statement, implication or representation that the therapeutic goods are effective in all cases of a condition or that the outcome from their use is a guaranteed or sure cure.
10(d)(iii)	Advertising for therapeutic goods must not contain any claim, statement, implication or representation that
10(d)(iv)	Advertising for therapeutic goods must not contain any claim, statement, implication or representation that the therapeutic goods are infallible, unfailing, magical or miraculous.
10(d)(v)	Advertising for therapeutic goods must not contain any claim, statement, implication or representation that harmful consequences may result from the therapeutic goods not being used — unless the claim, statement, implication or representation has been authorised by the TGA as part of an authorisation to use prohibited or restricted representations in advertising.
11	Subject to limited exceptions, advertisements for goods consisting of, or containing, a substance included in Schedule 3 of the current Poisons Standard and Appendix H of that Standard, must contain the following statement, prominently displayed or communicated: ASK YOUR PHARMACIST—THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU
12	Mandatory information to be included in advertisements for therapeutic goods that are not available for physical examination by the consumer before or at the time of purchase, other than advertisements to which section 11 applies.
12(3)(d)	An advertisement for a medicine must contain at least one of the indications of the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label.
13	Mandatory information to be included in all other types of advertisements for therapeutic goods.
15(2)(a)	Where an advertisement makes a scientific or clinical representation, any scientific or clinical terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.
15(2)(b)	Where an advertisement makes a scientific or clinical representation, the representation must be consistent with the body of scientific or clinical evidence applicable to the advertised therapeutic goods.

Subsection	Description
15(3)(a)	Where an advertisement contains a citation to scientific or clinical literature, either explicitly or impliedly, any research results must identify the researcher and financial sponsor of the research, where the advertiser knows, or ought reasonably to have known, that information.
15(3)(b)	Where an advertisement contains a citation to scientific or clinical literature, either explicitly or impliedly, the study must be sufficiently identified to enable consumers to access it.
16(2)	An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by: (a) a government authority, hospital or healthcare facility (other than a community pharmacy); or (b) an employee or contractor of a government authority, hospital or healthcare facility; or (c) a health practitioner, health professional, medical researcher or a group of such persons.
16(3)(a)	An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by an organisation that: (i) represents the interests of healthcare consumers; or (ii) represents the interests of health practitioners, health professionals or medical researchers; or (iii) conducts or funds research into any disease, condition, ailment or defect.
16(3)(b)	An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by an employee or contractor of an organisation mentioned in paragraph 16(3)(a), other than: • an employee or contractor of a government authority, hospital or healthcare facility; or • a health practitioner, health professional, medical researcher or a group of such persons, unless the advertisement names the organisation; and discloses: • the nature of the endorsement; and • whether the organisation, or employee, has received, or will receive, any valuable consideration for the endorsement.

Subsection	Description
17(2)	Requirements that must be met in order for a testimonial to be used in therapeutic goods advertising.
17(3)	Information that must be disclosed in a testimonial in an advertisement.
18	An advertisement must not offer any personal incentive to a pharmacy assistant, or any retail sales person who is not a health professional, to recommend or supply therapeutic goods.
19(2)	An advertisement for therapeutic goods must not be primarily directed to children under the age of 12 years in any circumstances.
19(3)	An advertisement for therapeutic goods must not be primarily directed to children aged 12 years or over, other than those goods listed in Schedule 2 and provided they are advertised in accordance with any applicable conditions in that Schedule.
20	An advertisement for therapeutic goods must not contain an offer of a sample, other than where the goods are mentioned in Schedule 3 and advertised in accordance with any applicable conditions in that Schedule.
21	If a relevant public health campaign of which the advertiser knows, or ought reasonably to have known, is or will be current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign.
23	If an advertisement for a complementary medicine includes a claim or group of claims based on evidence of a history of traditional use, the reliance on this traditional use and paradigm must be disclosed in the advertisement and the disclosure must be prominently displayed or communicated in the advertisement.
24(1)	An advertisement for an analgesic must contain the following warning statement, prominently displayed or communicated: INCORRECT USE COULD BE HARMFUL
24(2)	An advertisement for an analgesic must not imply that analgesic consumption is safe; or analgesics will relax, relieve tension, sedate or stimulate.
25	An advertisement for vitamin or mineral supplements must not claim or imply that the supplements are a substitute for good nutrition or a balanced diet; or are in any way superior to or more beneficial than dietary nutrients.

Subsection	Description
26(1)	An advertisement for therapeutic goods containing any claim relating to weight management must balance the claims with the need for a healthy energy-controlled diet and physical activity.
26(2)	Advertising of therapeutic goods containing any claim relating to weight management must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over-consumption of any food or drink.
26(3)	An advertisement for therapeutic goods containing any claim relating to weight management must not: (a) feature individuals in images or visual representations; or (b) use individuals' statistics or testimonials; unless the results achieved by those individuals from the use of the goods would be expected to be achieved on average by users of the goods.
27	Advertising of sunscreens must: (a) depict sunscreens as being only one part of sun protection; and (b) include statements or visual representations, prominently displayed or communicated, to the effect that: (i) prolonged high-risk sun exposure should be avoided; and (ii) frequent re-application or use in accordance with directions is required for effective sun protection.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising Compliance Section	September 2020

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