



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Therapeutic goods advertising compliance 2018-19 Annual Report



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## Introduction

As part of the Australian Commonwealth Department of Health, the Therapeutic Goods Administration (TGA) contributes to the protection and promotion of public health through the regulation of therapeutic goods advertising.

Therapeutic goods are subject to special advertising requirements beyond those required for everyday consumer goods. These requirements are specified in the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code (the Code). The Act and the Code are administered by the TGA.

Therapeutic goods are, by definition, goods intended to have a therapeutic effect on the health and wellbeing of the people that use them. In addition, people who seek information about therapeutic goods can often be in a vulnerable position due to health concerns, including facing a serious disease or condition. This means it is vital they have accurate information about products and treatments they may access, as misleading information could seriously compromise their health outcomes.

Regulating the advertising of therapeutic goods also protects people who may not be able to critically evaluate advertising (including labels), especially those with a health condition who may be particularly susceptible to being misled.

## About this report

On 1 July 2018, the TGA became the sole advertising complaints handling body as a result of recommendations from the [Medicine and Medical Devices Regulation Review \(MMDR\)](#). This report is the inaugural report on the TGA's work as the sole advertising complaints handling body.

It aims to give an overview of complaint handling activity in the 2018-19 financial year, highlighting compliance concerns in terms of industry sector (product category), the types of breaches, and actions taken by the TGA. This information will benefit advertisers by highlighting those areas where the TGA has needed to focus its efforts, and will assist our stakeholders to understand how we prioritise our work and manage our resources to most effectively contribute to the TGA's mandate to protect public health and safety.

This report builds on the update on the [first six months of the new regulatory framework](#) published on the TGA website in January 2019.

## Size of Australian therapeutic goods advertising market

The size and scope of the therapeutic goods' market is vast, with a substantial proportion of the market consisting of products that can be advertised directly to consumers.

As of 30 June 2019, there were around 88,438 therapeutic goods included in the Australian Register of Therapeutic Goods (ARTG) by 4,126 sponsors. Of these goods, around 70,000 can be marketed directly to the public.

However, determining the precise size of the entire advertising market is difficult because:

- some therapeutic goods that can be advertised directly to the public are exempt from inclusion in the ARTG (e.g. certain homeopathic preparations), and
- a proportion of goods advertised to the public are illegal therapeutic goods (i.e. not in the ARTG when they are required to be).

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. There are over 5,700 pharmacies<sup>1</sup> and 1,966 supermarkets and grocery stores<sup>2</sup> which, together with a range of other retailers which sell (and advertise) therapeutic goods to the public in Australia, constitute a very large, and growing, market. Without estimating the numbers of other retailers, it is evident that the potential market for advertising therapeutic goods to the public in Australia is very large.

## Background to the TGA's advertising framework

The MMDR examined the medicines and medical devices regulatory framework and processes, and made specific recommendations. The implementation of these recommendations has resulted in a broad advertising framework with four key pillars:

- clarifications and improvements to the advertising requirements in the Act, including enhanced sanctions and penalties, effective from March 2018
- the [Therapeutic Goods Advertising Code \(No.2\) 2018](#) (Code), which commenced on 1 January 2019
- a streamlined advertising complaints handling scheme, which commenced on 1 July 2018 and established the TGA as the single complaints management body with a new advertising complaints management system, and
- a continuing comprehensive educational campaign for advertisers.

Although the underlying principles have not changed, the Code provides greater objectivity than the Therapeutic Goods Advertising Code 2015 (2015 Code). This helps advertisers apply the requirements and supports the TGA's use of the sanctions and penalties where needed to achieve compliance. In addition, some long-standing key requirements have been clarified, such as the need to include certain mandatory information in advertising.

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<sup>1</sup> CommBank Pharmacy Insights 2018 -

<https://www.commbank.com.au/content/dam/commbank/assets/corporate/industries/pharmacy-insights-report-2018.pdf>

<sup>2</sup> BankWest Future of Business: Focus on Supermarkets 2019 -

<https://www.bankwest.com.au/content/dam/bankwest/documents/business/insights/focus-on-supermarkets-report-2019.pdf>

During 2018-19, two Advertising Codes were in effect:

- the Therapeutic Goods Advertising Code 2015 (the 2015 Code) was in effect until 31 December 2018,
- the Therapeutic Goods Advertising Code (No.2) 2018 (the Code) came into effect 1 January 2019.

The applicable Code will depend on the type of product, type of advertisement and when the advertisement was published or broadcast<sup>3</sup>.

To assist advertisers with the transition from the 2015 Code, the TGA implemented a [compliance and enforcement discretion](#) approach, where complaints received about advertising that fully complied with the 2015 Code, other than the mandatory information requirements, were treated with an element of discretion.

Following feedback from industry and the Therapeutic Goods Advertising Consultative Committee (the Committee), we identified and made minor corrections and further clarifications to the Code. These amendments took effect on 30 July 2019.

We have conducted or presented at twelve face-to-face training sessions on Code basics and presented three webinar education sessions. We have published improved advertising guidance, including guidance on the Code. Recent developments include [guidance for advertisers](#) in relation to making claims that a therapeutic good or ingredient is 'natural' without misleading consumers. See [educational activities](#) for information about our work on education and guidance.

More information about how the advertising of therapeutic goods is regulated in Australia can be found on our website <[www.tga.gov.au](http://www.tga.gov.au)>.

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<sup>3</sup> The 2015 Code continues to apply to certain advertisements after 1 January 2019, such as medicines advertising for specified media that were pre-approved before this date. For more information, see [Repeal and transitional arrangements](#).

## Key advertising data

From 1 July 2018, the TGA commenced its use of a new Advertising Management System (AMS), through which complainants can lodge their complaints online on any issues related to the advertising of therapeutic goods.

In 2018-19, we received 1,468 complaints about alleged non-compliant advertising of therapeutic goods from various sources, as detailed in the figure below.

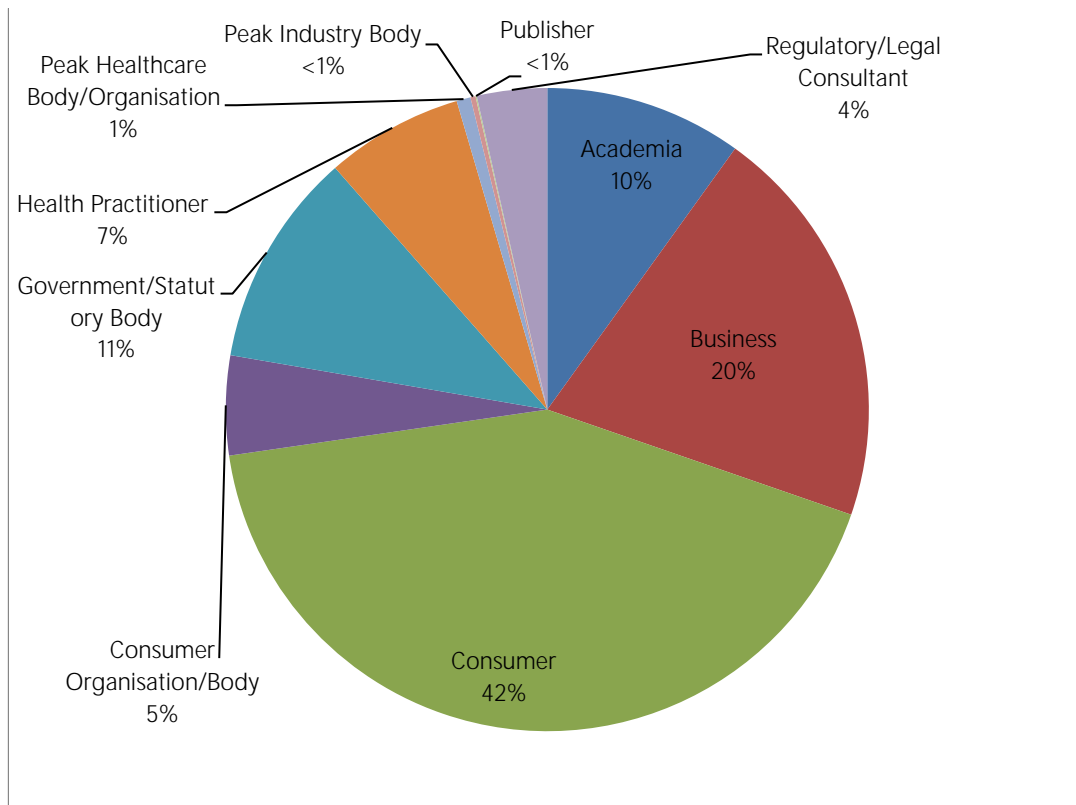


Figure 1 - Source of complaints by self-reported complainant type

When we receive a complaint, it is recorded as a 'lead' within the AMS. Each lead is then assessed to determine the responsible parties involved and a case is then created for each party. The complaints received generated 2,436 cases. Of these, 1,601 cases were completed during the reporting period.

The following information is about these completed cases.

### How the TGA handles cases

Cases are handled in accordance with the TGA's [advertising complaints handling policy](#).

Like other regulators, we take a risk-based approach to complaints and case handling. This means that:

- 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 2018-19, is shown in Figure 2.

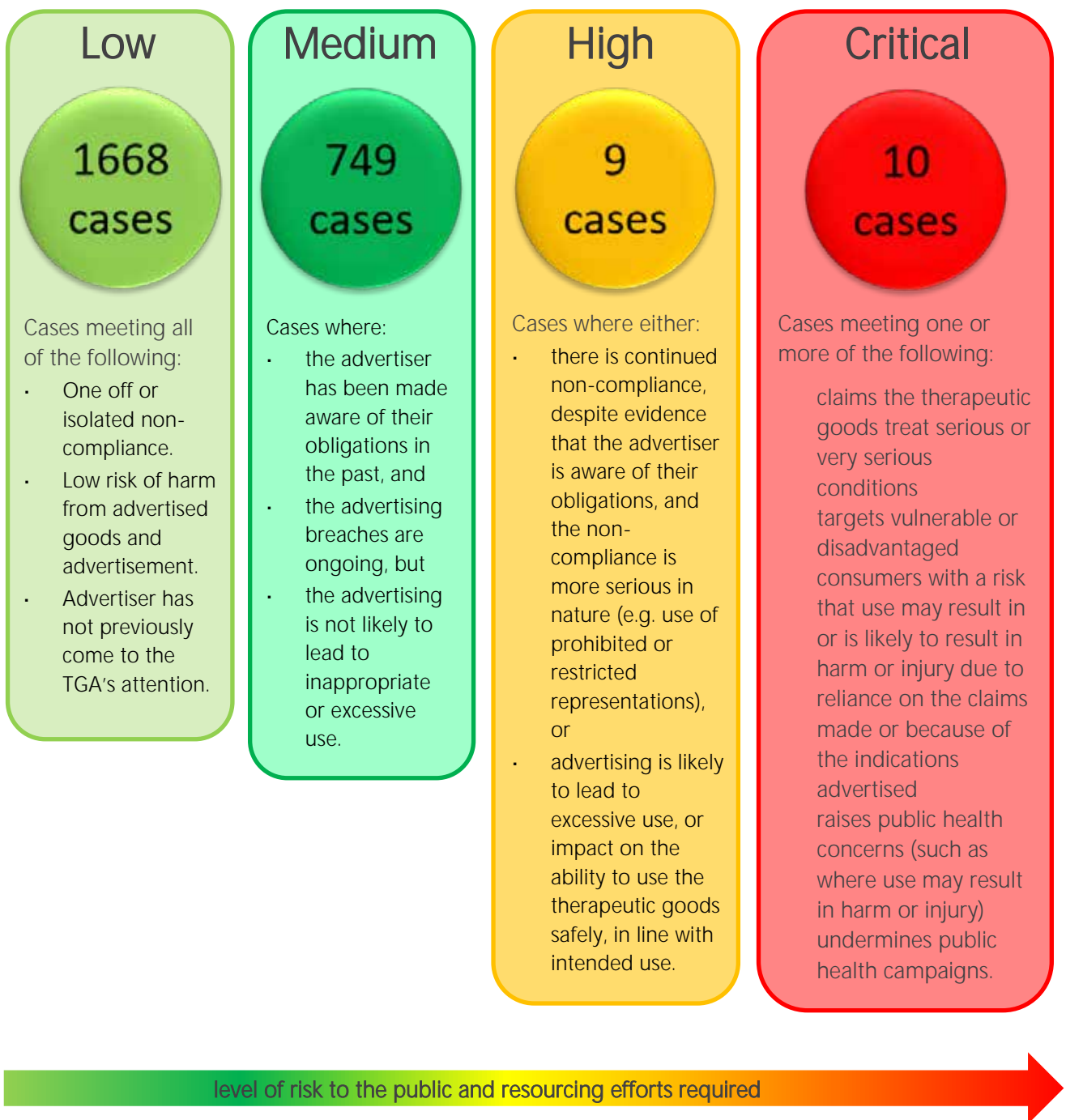


Figure 2 - Advertising Case Risk Categorisation (Low – Medium - High – Critical)

## Performance against key performance indicators

Table 1 below sets out the number of cases that were completed within our key performance indicators (KPIs).

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 that will apply for the TGA to action or close a complaint will depend on the priority categorisation of the complaint.

Further information about our KPIs can be found in [Measuring our performance](#).

**Table 1. Number of completed advertising cases meeting key performance indicators for 'time to action' and 'time to close'**

| Jul 2018-Jun 2019                       |              |
|-----------------------------------------|--------------|
| <b>Prioritisation category</b>          |              |
| <b>Low</b>                              |              |
| Total completed cases                   | <b>1,480</b> |
| Time to action (target 95% in 14 days)  | 1,214 (82%)  |
| Time to close (target 90% in 20 Days)   | 1,436 (97%)  |
| <b>Medium</b>                           |              |
| Total completed cases                   | <b>111</b>   |
| Time to action (target 95% in 40 days)  | 51 (46%)     |
| Time to close (target 90% in 90 Days)   | 17 (15%)     |
| <b>High</b>                             |              |
| Total completed cases                   | <b>2</b>     |
| Time to action (target 95% in 20 days)  | 2 (100%)     |
| Time to close (target 90% in 90 Days)   | 2 (100%)     |
| <b>Critical</b>                         |              |
| Total completed cases                   | <b>8</b>     |
| Time to action (target 100% in 10 days) | 7 (87.5%)    |
| Time to close (target 90% in 60 Days)   | 7 (87.5%)    |

While we have met some of the KPIs in time to action for high cases and time to close for low and high cases, this has not been the case for the medium and critical cases. As a higher than anticipated number of complaints has been received during this period, the TGA has prioritised resourcing to focus on the high and critical cases and this has resulted in delays in commencing investigations and taking actions for a large number of the medium cases. With respect to the single critical case that did not meet the time to action and time to close target time frame, this was due to changing of the categorisation of the case from medium to critical on further review, resulting in missing the target timeframe set for the critical category.

During this reporting period, the TGA successfully obtained orders from the Federal Court of Australia awarding \$10 million in civil penalties against Peptide Clinics Pty Ltd (see [illegal peptides](#)). This addressed ongoing advertising non-compliance in a high priority case, in an area (performance and image enhancement) which has been a focus of recent TGA compliance activity. The large penalties awarded are likely to assist in deterring non-compliance by other advertisers in the industry.

These statistics will also be reported in the TGA's Annual Performance Statistics report, to be released later in 2019.

## Most common breaches

Cases categorised as being medium, high or critical risk are investigated for compliance with the therapeutic goods advertising legislation—specifically, the Act and the Code.

### Number of products represented across closed compliance cases

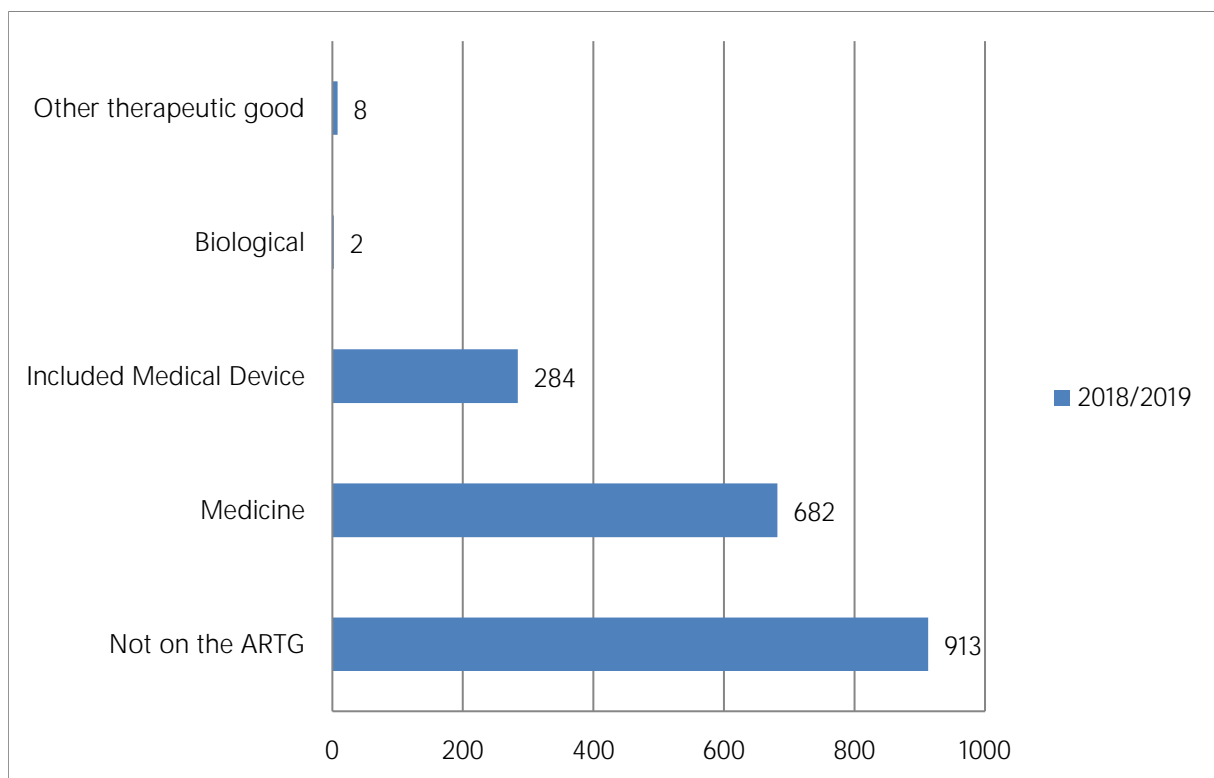


Figure 3 - Number of products subject to closed compliance cases by product category

The 'Not on the ARTG' category mainly represents cases about the alleged advertising of illegal therapeutic goods – i.e. those therapeutic goods that are not included in the ARTG. However, this also includes some goods that are exempt from the requirement to be included e.g. homeopathic preparations. Exempt therapeutic goods are also captured under the medicine (e.g. homeopathic preparations) or medical device category (as relevant).

The Other Therapeutic Goods category includes disinfectants, tampons and menstrual cups.

The TGA is refining the granularity of the categories used which will improve the transparency of product categorisation in future.

A case may have more than one product recorded for it. Each product is assigned to a product category. The total of all categories therefore exceeds the total number of cases completed.

### Breaches of the Therapeutic Goods Act 1989

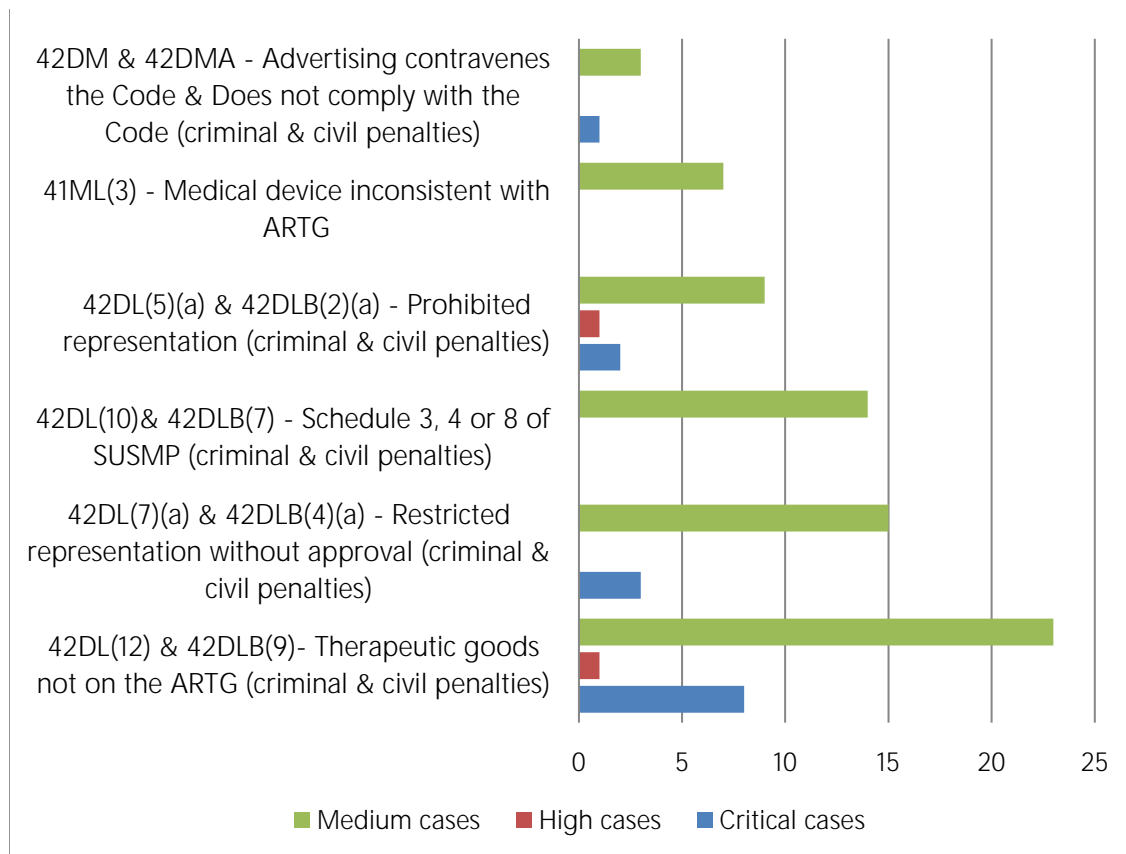


Figure 4 - Number of completed cases with breaches of the Act

The most common contravention of the Act shown in Figure 4 is section 42DL(12), which applies to advertisements for therapeutic goods that are not entered in the ARTG but are required to be.

Note that a case may have more than one breach recorded for it. For example, a case may relate to breaches of several provisions of the Act. The total of all breaches will then exceed the total number of cases completed or the total of all risk categories will exceed the total number of cases completed for that risk category.

More detailed descriptions of the Act provisions are set out in Appendix 1.

## Breaches of the Therapeutic Goods Advertising Code 2015

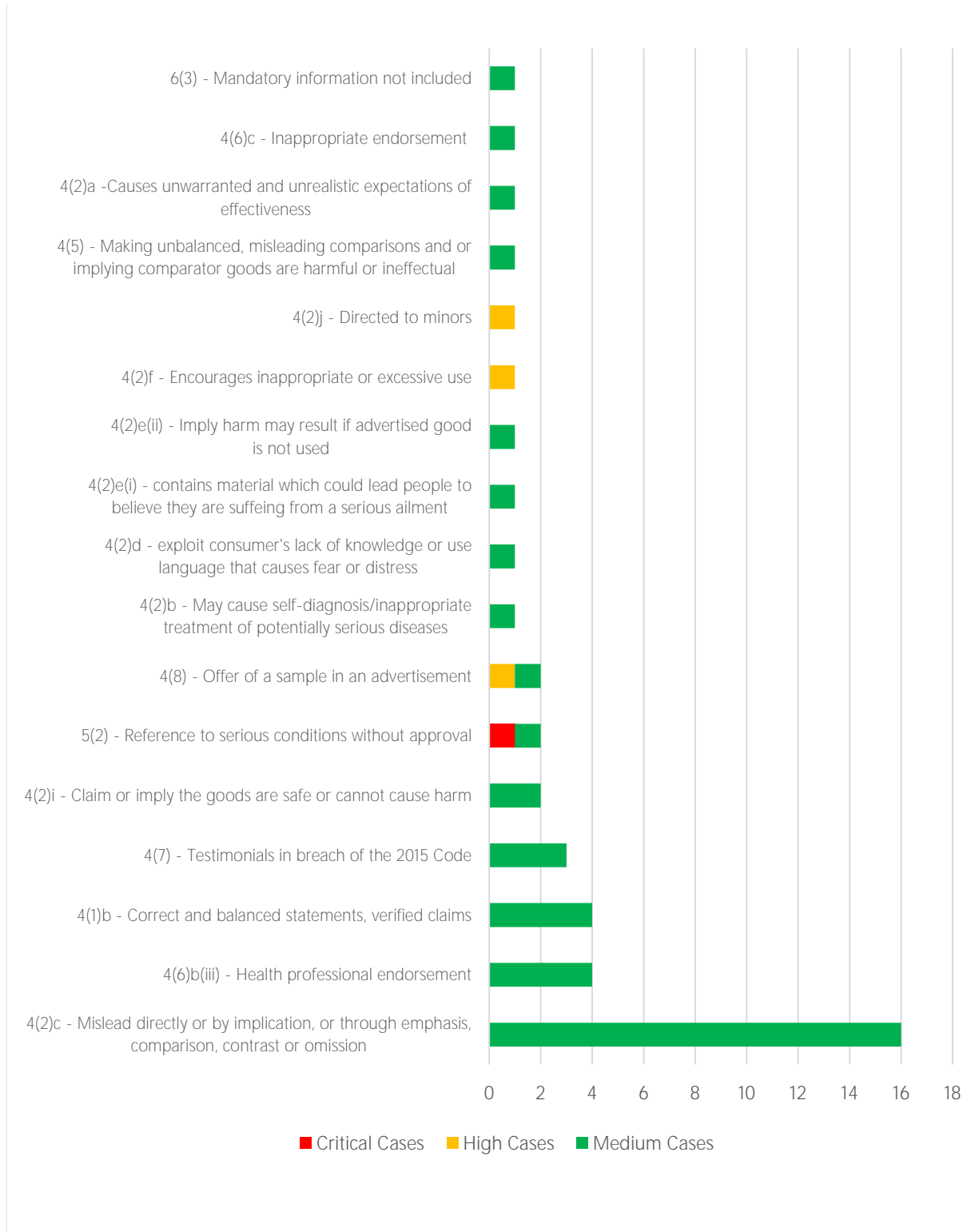


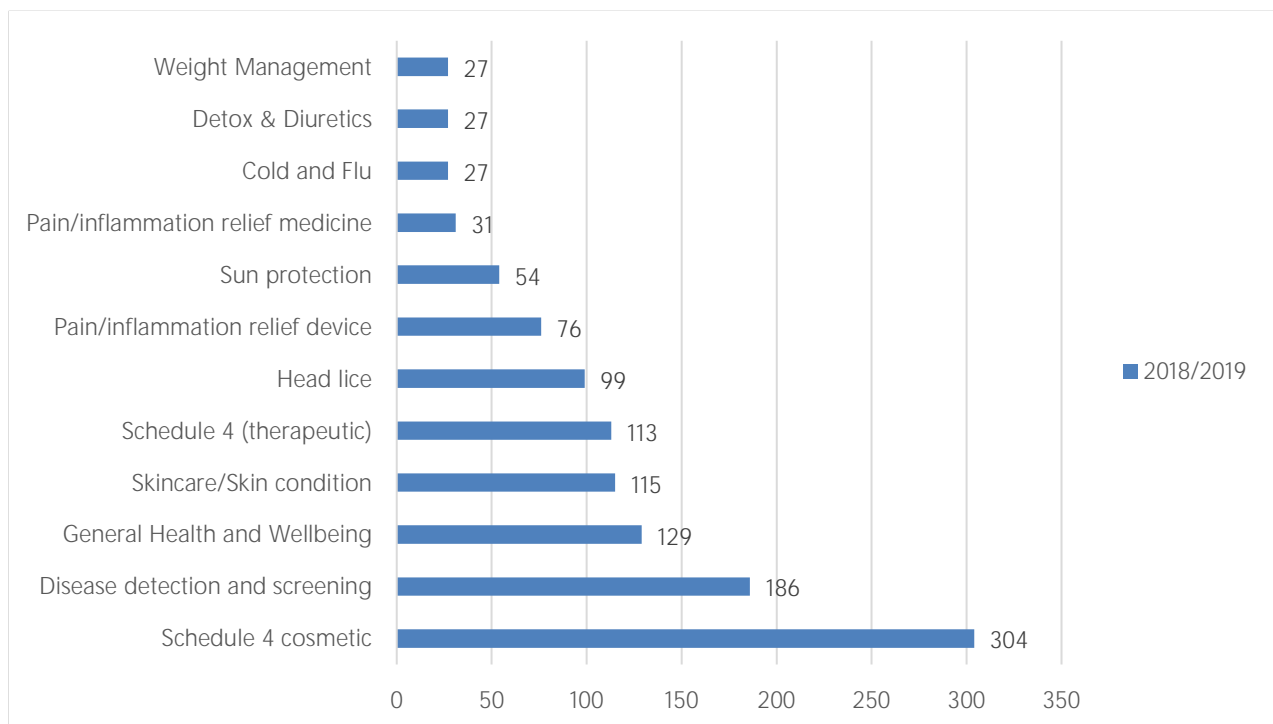
Figure 5 - Breaches of the Therapeutic Goods Advertising Code 2015

## Breaches of the Therapeutic Goods Advertising Code (No.2) 2018

As the 2018 Code only came into effect on 1 January 2019 we have not yet completed a sufficient number of cases to reliably inform trends in breaches in relation to these new provisions – especially those cases that are dependent upon evaluation of scientific or clinical evidence to establish whether the advertising at the centre of the complaints was unsubstantiated or misleading. Only two cases were completed where there were breaches of the 2018 Code. Both these cases were medium-risk categorisation with collective Code breaches of sections:

- 9(a) – claims are truthful, balanced and not misleading,
- 9(b) – advertising is valid, accurate and substantiated,
- 10(d)(iv) – advertising must not imply harm may result if the good is not used,
- 15(2)(b) - scientific or clinical misrepresentation, and
- 15(3)(b) - citation required to scientific or clinical literature.

## Number of cases in top 10 complaints categories



**Figure 6 - Total cases for top ten complaint categories**

Figure 6 sets out the number of cases in each of the top ten complaint categories, as assessed across all product categories. Similar information for individual categories (medicines, included medical devices etc.) is in Figures 7-9. The Schedule 4 cosmetic category captures advertising to the public for prescription medicines used for cosmetic procedures (such as wrinkle reduction and filling). The products concerned include botulinum toxins, hyaluronic acid, and polycaprolactone. With the exception of botulinum toxins, these products are generally regulated as medical devices. The Schedule 4 (therapeutic) category refers to advertisements to the public for prescription medicines that are not being promoted for cosmetic purposes.

The disease detection and screening category consists largely of cases about the advertising of a range of different medical devices for this purpose, including [bioresonance and live blood analysis devices](#).

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 cases captured in this category generally relate to the advertising of medicines.

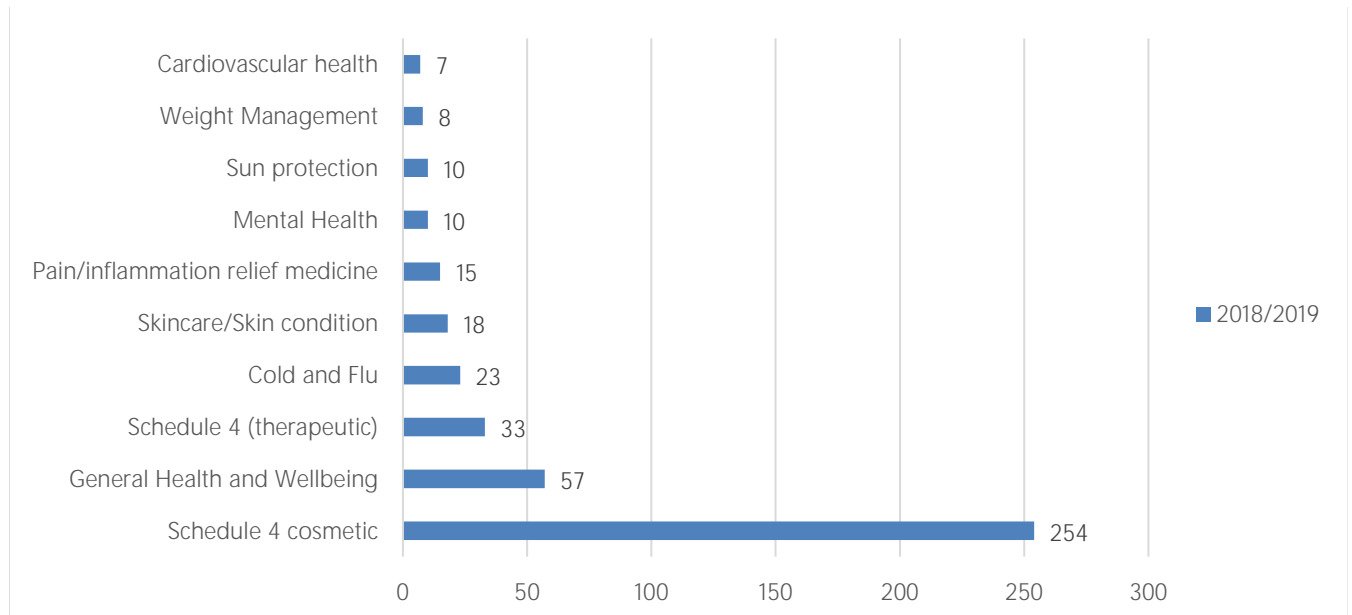
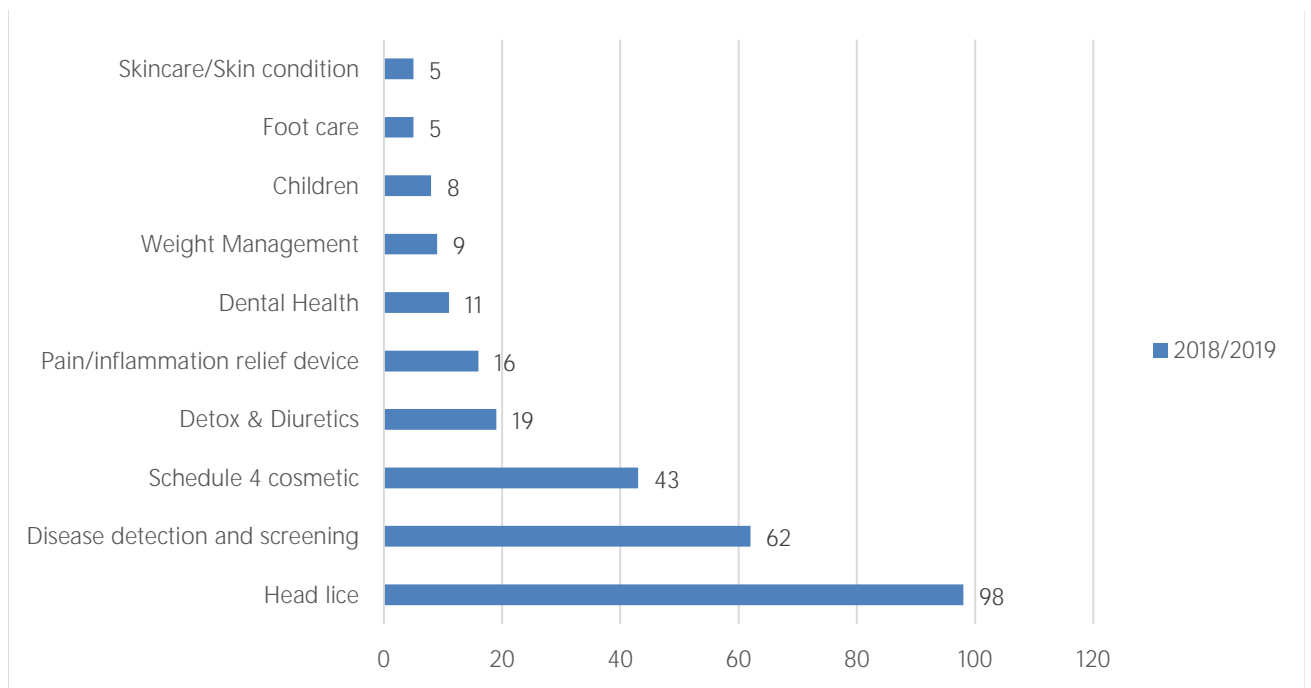


Figure 7 - Top 10 Complaint categories for the medicine product category

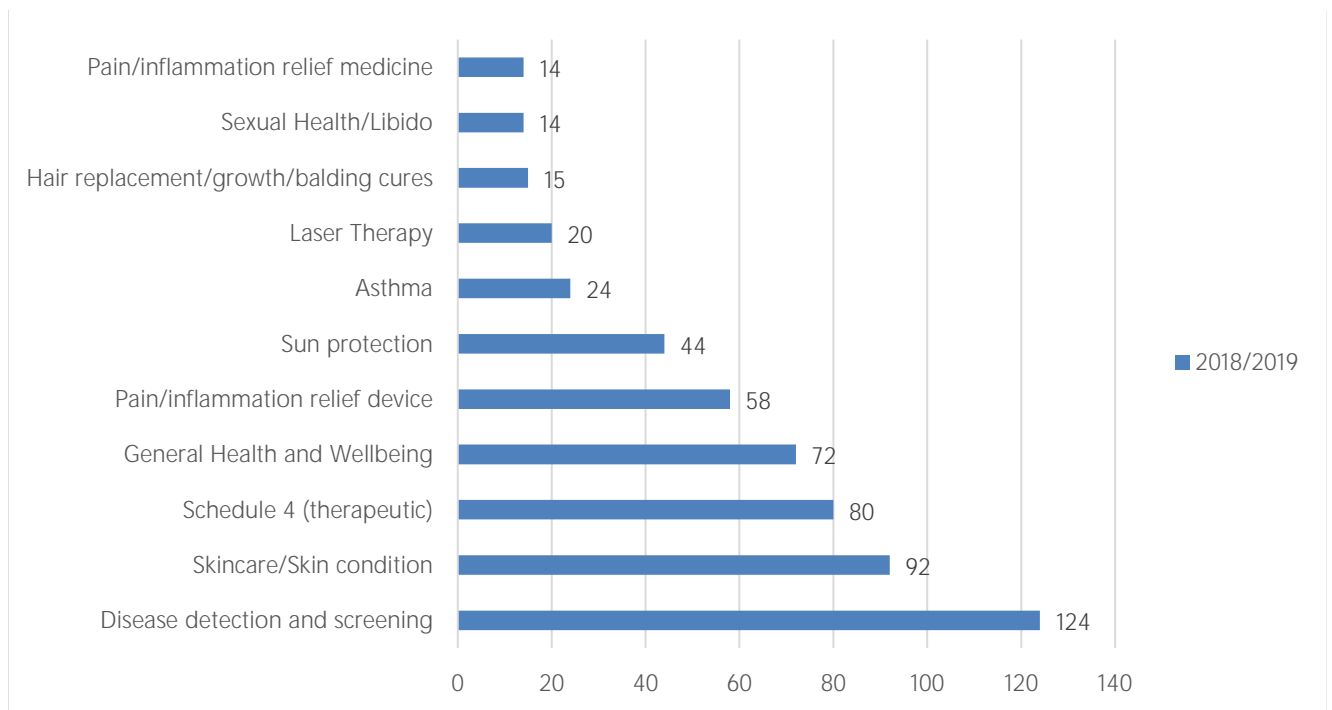
Despite the bulk of goods included in 'Schedule 4 cosmetics' being classed as devices, botulinum toxin (a medicine) continues to generate a large proportion of the cases in the Schedule 4 cosmetic category.



**Figure 8 - Top 10 Complaint categories for the Included Medical Device product Category**

The head lice treatment class of devices includes those for both physical removal (such as combs) and goods that smother the lice (such as those containing essential oils). The majority of cases in the dental health category relate to the advertising of “invisible” orthodontic appliances followed by cases about dental impression materials.





**Figure 9 - Top 10 Complaint categories for the "Not on the ARTG" product Category**

The Schedule 4 cosmetic class includes procedural devices for a range of face and body enhancement and modification procedures. Skincare and skin conditioning devices include thermogenic RF and laser, physically abrasive and suction devices for skin rejuvenation and resurfacing. 'Schedule 4 (therapeutic)' in this context includes illegal advertising of compounded prescription medicines and promotion of unregistered prescription medicines for athletic and body enhancement.

## Completed compliance cases by action taken

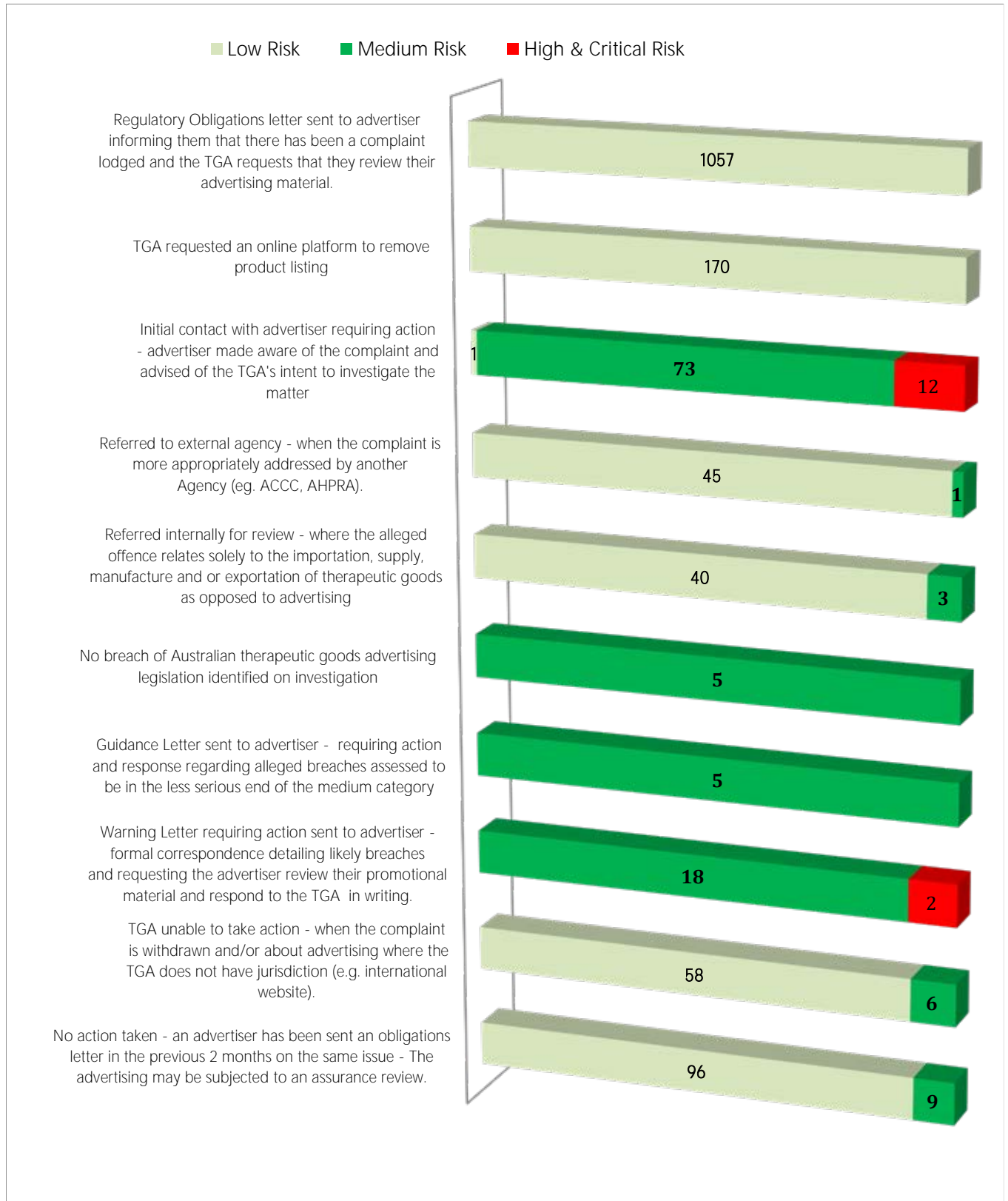


Figure 10 - Completed compliance cases by action type

Please also refer to the section of this report 'Compliance and enforcement activities' for further information on higher level compliance actions.

## Educating advertisers about compliance with the new advertising code and procedures

Changes to the Code governing the advertising of therapeutic goods have meant a period of transition for the TGA and our industry partners.

Our aim has been to streamline and simplify the complaints process, whilst making information about advertising requirements and protocols clear and accessible, for both consumers and suppliers of therapeutic goods and treatments.

We want to be clear about the regulations, about how to comply and about our decisions and actions when non-compliance occurs.

The TGA is very committed to transparency and access to clear advice in relation to therapeutic goods advertising and how we interpret and apply the legislation.

Our [advertising hub](#) is designed to be an important source of information, including publishing:

- [complaint outcomes](#)
- performance statistics for managing alleged non-compliant advertising cases
- [guidance](#) and [educational events](#)
- [regulatory decisions and announcements](#).

To supplement these valuable sources of information, we have selected the following case studies from the archive of advertising complaint cases completed to date. They are designed to guide advertisers on how the TGA applies the Act and Code, as well as how cases are categorised, from low to critical.

As a guidance tool, these case studies are best used in conjunction with other resources such as guidance and fact sheets, seminars and the advertising hub.

The majority of cases where advertisers have disputed the alleged breaches or concern allegations of misleading claims remain under consideration and a more comprehensive analysis will be available in the next Annual Report.

## Cases categorised as Critical

### Case study 1: Sawyer Extractor Bite and Sting Kit

*'The most powerful suction available for the safe extraction of venoms and poisons'*

The Extractor Pump Kit was a product advertised by Backpacking Light, Survival Australia and Outdoor You. It claimed to remove poisons from snake bites, bee and wasp stings and more.

#### About the complaint and advertisement

A complaint against the advertising of this product was made on 30 July 2018, and was categorised as critical. The claims the advertisers made about this product were highly misleading and conflicted with contemporary first aid procedures for bite and sting treatment. The likelihood of harm, or even death, if these claims were believed by a consumer was high.

#### Summary of breaches

The product had not been included in the ARTG, and did not have an exemption from being included. Products not included in the ARTG cannot be advertised to the public.

Full details of the breaches for each advertiser can be found in the [Advertising Complaints and Investigations Portal](#), by searching for "Sawyer".

#### Actions taken

The TGA contacted the sponsor demanding immediate action and the product advertising and supply was ceased. The case was completed on 27 August 2018.



## Case study 2: Gumby Gumby Capsules

*"Treat all kinds of cancer"*

'Gumby Gumby' (*Pittosporum angustifolium*) has been traditionally used for therapeutic purposes by Aboriginal and Torres Strait Islander peoples.

However, it is not included in the ARTG, and has not been approved for therapeutic supply in Australia.



### About the complaint and advertisement

On 3 August 2018, TGA received a complaint about Gumby Gumby capsules being advertised as a cure for various cancers and other serious conditions (including emphysema, autoimmune diseases and arthritis) across Ken Murray's personal social media platforms, including Facebook, YouTube and Vimeo.

This complaint was categorised as critical due to the high risk of physical and clinical harm that was posed to extremely vulnerable individuals. As the advertising contained many claims about the product's ability to treat cancer without side effects, the TGA was particularly concerned that the advertising would entice consumers to delay conventional cancer treatments posing real risks to their health and lives. Documented evidence of substantial sales of the product prompted TGA to act quickly.

### Summary of breaches

At least eight serious breaches of the Act and Advertising Code were identified, including that many claims made by the advertiser were misleading and false. These included references to cancer (prohibited representations) and other serious conditions, diseases ailments or defects (restricted representations), as well as advertising products that had not been included in the ARTG, and did not have an exemption from being included.

Full details of the breaches can be found in the Advertising Complaints and Investigations Information, reference number [AC-BULV109Q/2018](#).

### Actions taken

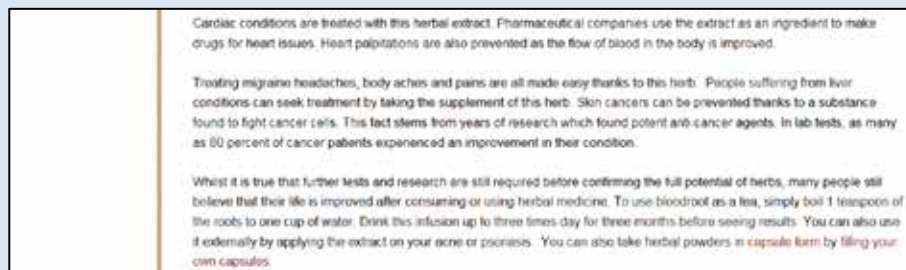
The TGA advised that immediate action was required to cease advertising of this product. When this did not occur, a [direction notice](#) was issued to the advertiser, to permanently cease all advertising of Gumby Gumby capsules. The advertiser then agreed and the case was completed on 17 September 2019.

### Case study 3: Black salve

*"Inexpensive, safe answer to cancer"*

Black salve, red salve and cansema are products containing an active ingredient called sanguinarine, which comes from Bloodroot (*Sanguinaria canadensis*). Sometimes zinc chloride is also present.

These products have been sold in Australia as an alternative treatment for cancer, including skin cancer. The TGA is not aware of any credible, scientific evidence which shows that any black or red salve preparation is effective in treating cancer and has issued [alerts](#) about the use of these products.



#### About the complaint and advertisement

On 20 May 2019, the TGA received a complaint about black salve being advertised as an 'inexpensive, safe answer to cancer'. The advertiser, Plant Essentials, also included instructions on how to make black salve and sold the ingredients needed to make it.

The complaint was categorised as critical due to the high risk of potential harm to extremely vulnerable individuals.

As black salve is unproven for cancer treatment, it may result in ineffective treatment of otherwise treatable cancers, to the extent that those patients are no longer treatable with conventional interventions. As it is corrosive, people using black salve may be left with significant damage to their skin and tissue.

In addition to cancer, the material indicated bloodroot could also treat bronchitis, bleeding lungs, cardiac conditions and other serious conditions. The material did include some balancing information concerning the limited evidence to support the claims made in relation to cancer and the advertising was mainly limited to a single website rather than being spread across multiple platforms.

#### Summary of breaches

The TGA reviewed the material provided by the complainant and the advertiser and confirmed that the advertised products including Black Salve were being promoted for therapeutic use. These therapeutic goods were not included in the ARTG and were not exempt from the requirement to be included in the ARTG.

The advertising included references to the treatment of 'cancer', which is considered a prohibited representation, as well as other serious conditions, diseases, defects or ailments (restricted representations). Prohibited and restricted representations require approval from the TGA prior to their actual use in advertising – the advertiser did not have these permissions.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information, reference number [AC-QMUBSLLI/2019](#).

### **Actions taken**

The TGA required the advertiser to amend their website to remove the representations about black salve and other therapeutic goods not included in the ARTG and to cease using prohibited and restricted representations without permission or approval.

The advertiser removed the identified non-compliant advertising from their website. The majority of the material related to Black Salve was removed shortly after contact by the TGA. The other issues such as the advertising of numerous unapproved therapeutic goods were resolved by the Advertiser following further contact by the TGA. The case was completed 20 May 2019.

## Misleading claims

In the absence of legislative definitions, the meaning of a word is taken both from the context in which the word is used and from *The Macquarie Dictionary*. The Macquarie Dictionary defines 'misleading' as:

1. to lead or guide wrongly; lead astray.
2. to lead into error of conduct, thought, or judgement.

In the context of advertising therapeutic goods, any claim that is likely to lead a consumer into an error of conduct, thought or judgement and therefore compromise the consumer's otherwise rational judgement and informed decisions about the use of therapeutic goods could be misleading.

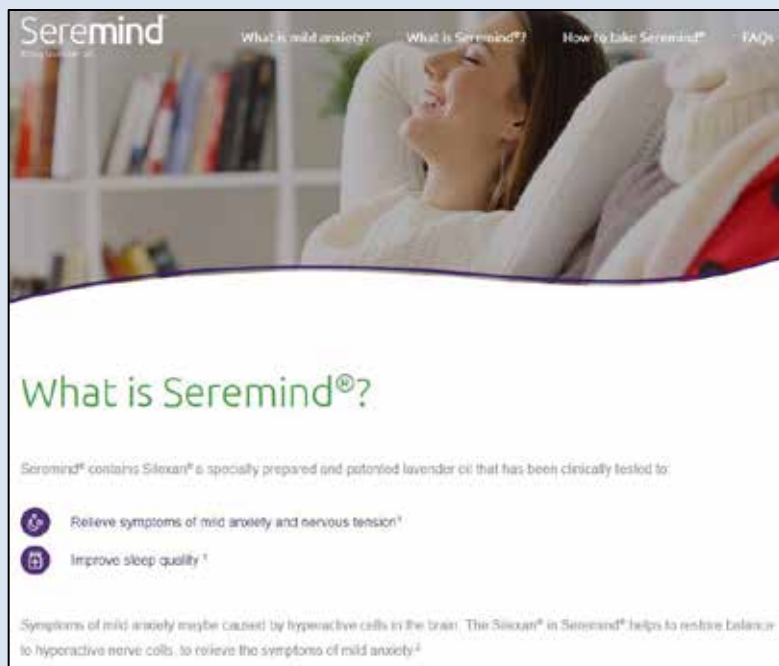
A claim can mislead in various ways including:

- the omission of important information
- the inappropriate use of statistics and by using claims which are ambiguous and open to different interpretations

Accurate claims can also be found to be misleading, depending on the context in which the claims are made. The following case studies highlight a number of complaints in which the TGA considered allegations of misleading claims.

## Case study 4: Seremind

*"Clinically tested"*



### About the complaint and advertisement

On 16 October 2018, the TGA received a complaint about Seremind, a listed complementary medicine that contains lavender oil as an active ingredient. It is indicated for relieving nervous tension, mild anxiety and sleeplessness in adults.

The complaint was categorised as medium, as the advertiser, A Menarini Australia Pty Ltd, made references to the product being 'clinically tested' for specific therapeutic uses, implying there were well-established, clinically certain health benefits associated with the product.

### Summary of breaches

The breaches occurred through:

- the references cited in the advertisement for the therapeutic claims, and
- the use of the claims about the 'clinically tested' effects of the product.

When used in advertising to the public, the term 'clinically tested' is considered to be an implied citation to clinical or scientific literature, as are related terms like 'clinically trialled' and 'clinically proven'. When used in conjunction with claims of therapeutic benefits, such terms become a clinical representation, implying a proven and significant impact on the health of consumers. There are additional requirements in the Code for both implied literature citations and clinical representations, over and above the general requirements for claims to be accurate, substantiated and not misleading.



The therapeutic claims in the advertisement, combined with the 'clinically tested' term, are clinical representations with implied citations of scientific literature. The references apparently included:

1. a consumer leaflet for Seremind, and
2. a published study in mice.

Following contact by the TGA, the advertiser also provided a randomized, double-blind, multicentre trial testing the possible anxiolytic effects of Silexan (80mg/day) in 221 adults 18-65 years old suffering from anxiety disorders.

#### Consumer leaflet

The leaflet provided general information about the medicine and how to take it; it was not a clinical study. The Code requires that citations in advertising to scientific or clinical literature, either explicitly or impliedly, must be sufficiently identified to enable consumers to access it. The citation to the consumer leaflet, which in itself is not scientific or clinical literature, failed to identify the study relevant to the implied citation requirement. As such, this aspect of the advertisement contravened section 15(3)(b) of the Code.

#### Animal study

Pre-clinical (animal) studies are not, in isolation, adequate support for scientific indications for listed medicines (see [Evidence Guidelines](#)). While such studies may provide support for the biological plausibility of the mechanism of action for a medicine, they are not sufficient support for clinical representations.

#### Clinical trial

The TGA requested the advertiser to provide the evidence it held in support of the 'clinically tested' claim. The advertiser provided a single clinical study that investigated a relatively small number of participants. The study was also funded by the manufacturer of the product. The TGA advised the advertiser that the evidence they provided was not an adequate and appropriate body of evidence to support the claim of 'clinically tested'. The advertiser subsequently advised that other clinical studies were available, however, they did not consider them to be relevant to the product advertised. The TGA considered that the use of the claim 'clinically tested' without the support of appropriate clinical evidence was also likely to mislead and therefore breached section 9(b) of the Code.

As the clinical representations were inappropriately referenced, the TGA considered that the representations were inaccurate and invalid and therefore a breach of subsection 9(a) of the Code).

The use of the term 'clinically tested' claim in this advertisement (like 'clinically proven') implied there is a high level of certainty in the health benefits reported for the advertised product – i.e. it has been clinically trialled (tested in humans) and proven to be effective for the purposes identified. To be able to use such a claim, there would need to be unequivocal, robustly designed, published peer-reviewed clinical trial(s) conducted on the actual advertised product, or an identical formulation and dose (see the [Advertising Code guidance for subsection 9\(b\)](#)).

Otherwise, such a claim is considered unsubstantiated and likely to mislead consumers about the effectiveness of the product.

The Code sets out the requirements that all claims must be valid and accurate, truthful, not misleading. The Code also requires that clinical representations made in an advertisement must be consistent with the body of scientific or clinical evidence applicable to the advertised therapeutic goods.

Therefore, this advertisement was also found to be unsubstantiated and misleading, in breach of sections 9(a) and 9(b) of the Code.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information, reference number [AC-CE8WFJYQ/2018](#).

Generally, this case demonstrates the importance of providing appropriate citations in advertising to studies that reflect the nature of the claim (an animal study is not a clinical study) and the importance of having evidence of a sufficient rigour to support the strength of the therapeutic claim. Additionally, advertisers should be aware that they must hold all of the evidence needed to substantiate a claim before using it in advertising and that they need to provide all of that evidence to the TGA if requested. The TGA will not conduct literature searches looking for evidence to support a particular claim should an advertiser fail to provide sufficient evidence.

#### **Actions taken**

The advertiser was issued with a warning letter and required to amend their website to remove reference to 'clinically tested'. This occurred, as well as changes to packaging to ensure it complies with the Code. The case was completed on 20 June 2019.

## Case study 5: PRP Stem Cell Therapy, Stem Cell Hair Technology Factors

*'Restore, repair and rejuvenate to maximise cell life'*

Advanced Hair Studio of Australia advertised Stem Cell Hair Growth Factors to treat hair loss on their website.

### About the complaint and advertisement

A complaint against the advertising of this product was made on 21 September 2018, and was categorised as medium. The claims the advertiser made about this product were highly misleading, claiming clinically proven efficacy, video footage of endorsement by a 'medical professional, and images of people having benefited from using the product to improve hair growth.

### Summary of breaches

The TGA determined that the advertising had breached ten sections of the Code by advertising that was found to be misleading and untruthful, making scientific claims that were not valid and easily disproved.

Specifically, there had been no proper human trials of the product, the product claimed to contain stem cells but did not, and used imagery unrelated to the product to give the false impression that the product had produced good results for patients.

In addition, the product was neither included in the ARTG nor exempt from inclusion and therefore also breached the Act.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information Portal, reference number [AC-BJXBKMT6/2018](#).

### Action taken

The TGA sent a warning letter to the advertiser to remove non-compliant material from their website. This warning was complied with and the material was removed. The case was completed on 21 June 2019.

## Case study 6: Ease-A-Cold Cough, Cold & Flu

*'Clinically proven'*

The Health365 website, operated by PharmaCare Laboratories Pty Ltd, promoted the Ease-A-Cold Cough, Cold & Flu Day & Night product as "clinically proven" and "scientifically formulated" to [help] shorten a cold.



### About the complaint and advertisement

A complaint about the advertising of this product was

received on 5 July 2018. The complaint alleged that the Health365 website, as well as a range of other websites (with some operated by pharmacies), breached the Code by using claims that had been found to be misleading under the previous complaints handling framework. These claims included that the product was "clinically proven" and "scientifically formulated" to shorten a cold.

#### What Are EASEaCOLD Cough, Cold & Flu Day/Night 24s For?

EASEaCOLD Cough Cold & Flu is scientifically formulated to help shorten a cold, help reduce the severity of symptoms and help reduce the impact of a cold on your daily life.

EASEaCOLD Cough Cold & Flu helps relieve symptoms including: Cough, sore throat, runny nose and sneezing. Help shorten your cold and get better quicker. For non-drowsy daytime relief plus night time relief to assist rest.

### Summary of breaches

Consistent with Case study 4 (Seremind), the TGA considers the use of the term 'clinically proven' in therapeutic goods advertising implies a level of certainty in the health benefit associated with the advertised product, in that it has been tested in humans and proven to be effective. Such terms are not acceptable unless supported unequivocally by robustly designed, published peer-reviewed clinical trial(s) conducted on the actual medicine being advertised, or an identical formulation and dose (as a minimum). Similarly, the use of the terms 'clinical', 'clinically', 'scientifically', coupled with 'trialled', 'tested' or 'formulated', implies a higher level of certainty associated with the health benefit of the advertised product. Unless supported by well-designed clinical studies on the specific advertised product, such claims also may mislead consumers about the effectiveness of the product. Previous TGA assessment of the scientific evidence provided by the advertiser identified that it was not of sufficient quality to support strong claims, including 'clinically proven'. The TGA therefore considered that the use of the terms "clinically proven" and "scientifically formulated" breached the Code.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information Portal, reference number [CC-Q5FQMAI9/2018](#). Details of the cases involving the other advertisers identified in the complaint can be located by searching the [portal](#) for 'AL-B81GN1V3/2018'.

### Action taken

The TGA required the advertiser to amend web site to remove the references to "clinically proven" and "scientifically trialled", reminding them of the sanctions and penalties which may apply. The advertiser complied and removed the material. The case was completed on 3 October 2018.

## Prohibited and restricted representations

The Act tightly controls the use of references to serious forms of diseases, conditions, ailments and defects (collectively, conditions). People suffering from, or concerned about, such conditions are likely to be particularly vulnerable. As such the Act prohibits the use of references to such conditions without express permission from the TGA to ensure that any advertising making reference to them will not take advantage of consumer vulnerabilities, as well as being accurate, balanced and not misleading.

Certain references to the most serious types of conditions – namely, cancer, mental illness, HIV/AIDS, hepatitis C and sexually transmitted infections – are prohibited. Where there is a public health interest concerned (e.g. being able to promote the use of condoms for the prevention of HIV and STI transmission), the TGA can permit the use of these prohibited representations. References to serious forms of other conditions (e.g. diabetes, asthma) are restricted representations.

As demonstrated in Case studies 1 to 3, complaints about advertisements referring to prohibited or restricted representations without permission that hold significant public health and safety implications (e.g. by promoting an unregistered good that is likely to harm patients) are categorised as 'critical'. However, in accordance with the TGA's [complaints handling framework](#), references to prohibited or restricted representations, in the absence of significant public health and safety concerns, may be captured in a lower category.

## Case study 7: Sensitive Imago Biofeedback Machine

*'Restore proper communication between cells and organs in your body'*

Bioresonance is based on the belief that human beings emit electromagnetic waves, which can only be measured by bioresonance devices. Advertisers claim these devices can measure these waves to detect illness in the human body as well as sending 'rehabilitated bad' waves to the patient to alleviate illness.

### CONDITIONS THAT MAY BE ASSISTED WITH BIORESONANCE THERAPY

- Allergies
- Asthma
- Sinus/Hay Fever
- Chronic Fatigue Syndrome
- Chemical Sensitivities
- Parasites
- Viral infections
- Bacterial infections
- Heavy Metal Toxicity
- Skin Conditions

### About the complaint and advertisement

On 16 October 2018, the TGA received a complaint about True Medicine's promotion of Sensitive Imago Biofeedback Machine, a bioresonance device.

### Summary of breaches

Upon investigation, TGA found that the device was not included in the ARTG and there was no exemption from inclusion. The TGA also reviewed the material provided, and found that the advertisement also contained unapproved prohibited representations (including references to assisting with anxiety and panic attacks) and restricted representations (including asthma, recurrent infections and thyroid conditions).

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information Portal, reference number [CC-B1XL8AAN/2018](#).

### Action taken

True Medicine was required to amend its website to remove any reference to treatments being 'clinically proven' and to remove reference to the unapproved device from their website. This case was completed on 27 March 2019.

## Safety and 'no side effects' claims

Therapeutic goods may have unintended consequences or trigger an adverse event. For these reasons, the Code specifically prohibits therapeutic goods from being advertised as safe or having no side-effects, even if qualified or supported by evidence. Similarly, advertising claims that imply a therapeutic good is "safe" are also prohibited.

### Case study 8: Compounded PEA and Sublingual Hormone Spray

*'Safe... no adverse effects'*

#### About the complaint and advertisement

On 1 August 2018, the TGA received a complaint about a local pharmacy, Visionary Health Compounding Chemist, advertising palmitoylethanolamide (PEA) 'for nerve pain' as well as a 'new diet spray'. The diet spray contained Human Chorionic Gonadotrophin, a Schedule 4 (prescription-only) substance.

The advertising occurred through the chemist's website, and in the chemist's premises itself.

The case was categorised as medium.

#### Summary of breaches

The products were not included in the ARTG and were not the subject of an exemption. One product contained a substance that is not permitted to be advertised or used without clinical authority. The advertisement contained claims that the products could assist with serious conditions such as Diabetic Neuropathy, Carpal Tunnel Syndrome, Multiple Sclerosis, Irritable Bowel Syndrome and stroke. No approval had been granted by the TGA to make reference to restricted representations. Therefore, the advertisement breached multiple sections of the Act and also the Code.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information Portal, reference number [AL-EON1Z6US/2018](#).

#### Action taken

The advertiser removed all references to the product from their website. The case was closed 6 September 2018.



## Disease education activities

The purpose of disease education activities is to provide information and increase public awareness about health conditions and their management.

These activities can be a valuable source of information for Australian consumers as they raise awareness about diseases, aid recognition of symptoms and encourage consumers to seek appropriate advice if necessary.

Disease education activities must not however promote therapeutic goods. It can sometimes be difficult to distinguish between material that may have the effect of promoting particular therapeutic goods and material that is only providing disease information.

The party responsible for the material must ensure that the material would not stimulate demand for specific therapeutic goods.

While a disease education activity may make reference to a range of treatment options, this information must not be likely to encourage consumers to either seek to obtain a particular medicine, or seek a prescription for a particular medicine.

A disease education activity also must not encourage consumers to seek to obtain a particular medical device or seek from a health professional the use of a particular medical device. Special care is required for activities where there is not a range of treatment options, as the information may draw attention to one specific therapeutic good, whether that good is named or not.

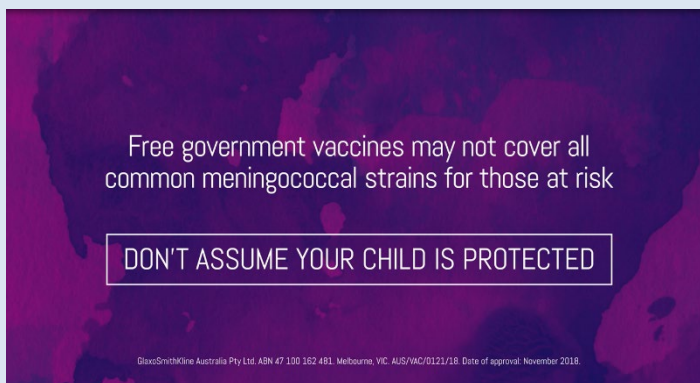


## Case study 9: Know Meningococcal

*'Don't assume your child is protected'*

### About the complaint

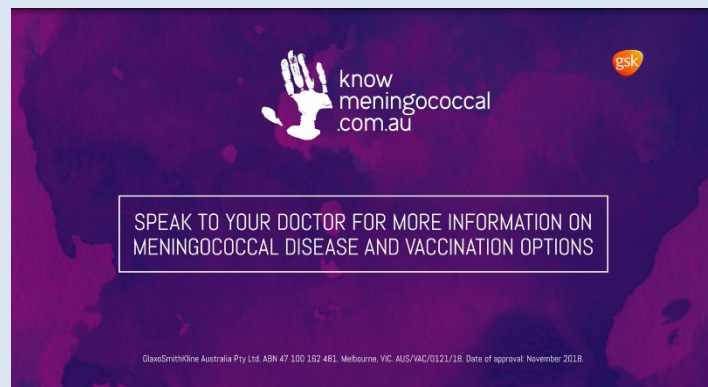
In December 2018 the TGA received a complaint from a healthcare professional about the "Know Meningococcal" campaign run by GlaxoSmithKline Australia Pty Ltd, alleging that it may cause fear and distress in a consumer as it was a form of direct to consumer advertising. A subsequent complaint was received in February 2019 noting that, in the complainant's view, the material was a product or brand advertisement presented as a community service advertisement. The complainant queried why the company was allowed to promote a single vaccine brand.



The categorisation decision for this case was not straightforward. This case involved an extensive advertising campaign across multiple media. It appeared that the campaign was intended to be a 'disease education activity', a type of activity that normally falls outside the jurisdiction of the TGA, as it did not relate directly to therapeutic goods.

However, in this particular case the TGA assessed the campaign materials and determined that they met the definition of 'advertise' in the Act they promoted the use or supply of therapeutic goods, including goods sponsored by the advertiser.

The TGA viewed increased public knowledge concerning meningococcal disease as being a positive outcome for the Australian public, and that, in principle, an education campaign about meningococcal disease might be consistent with government public health messaging. However, because the material constituted advertising of therapeutic goods it contravened the Act and Code.



### Summary of breaches

The TGA assessed the material and determined that it met the definition of 'advertise' in the Act because it promoted the use or supply of meningococcal B vaccines and was not simply promoting consumer awareness of meningococcal disease. This meant that the advertisement was promoting prescription only medicines (vaccines) and referred to a restricted representation, meningococcal disease, without permission – both contraventions of the Act.

The advertising also implied that harm would occur if the product was not taken, in breach of the Code.

Full details of the alleged breaches can be found in the Advertising Complaints and Investigations Information, reference numbers [AC-HCEUITSO/2018](#) and [AC-ZLV1JXC9/2019](#).

### Action taken

The TGA contacted the advertiser. The advertiser immediately removed the campaign upon being advised of the TGA's concerns and during the course of the management of the complaint modified the disease awareness campaign to address those concerns and ensure the campaign did not constitute promotion of vaccines. In this instance, the TGA accepted that the Know Meningococcal campaign could be reinstated following removal of those elements promoting vaccines, to focus instead on improving public awareness of meningococcal disease, with emphasis on seeking medical professional advice.

## Low category cases

As set out in the TGA's [advertising complaints handling framework](#), cases categorised as low are not subjected to a formal investigation and no formal regulatory finding is made in these cases.

For low cases an obligations letter will be sent to the advertiser. The obligations letter will inform the advertiser of the alleged non-compliance and will provide information and guidance to rectify the advertising and to assist with future advertising compliance. It does, however provide an opportunity for the advertiser to be assisted with their compliance without penalty or sanction.

Once closed, low category cases are published in the [advertising complaints and investigations database](#). However, for reasons of natural justice, the outcome will not specify the details of the advertiser or the goods involved because the TGA has not fully investigated nor made a formal finding in relation to the advertising.

The following de-identified case studies provide examples of low category cases handled by the TGA during the reporting period.

## Case study 10: Bioresonance device

*Implied TGA endorsement, good represented as 'having no harmful side effects'*

### About the complaint and advertisement

On 16 August 2018, the TGA received a complaint about an online advertisement to the public for a 'bioresonance' device. The advertisement made a claim to the effect that the device had been approved by the TGA. The advertisement also made a claim that the use of the device would not result in side-effects.

The case was categorised as low as the advertisement did not represent the device for use in relation to serious forms of diseases, ailments, defects or disorders. While representing that a good has been 'approved by the TGA' and that the good is free of side-effects are advertising contraventions, these representations were not considered to pose any risk to the public. Additionally, the case appeared to be an isolated advertising non-compliance by an advertiser who had not come to the attention of the TGA prior to the complaint being received.

### Summary of actions taken

The TGA issued an obligations letter to the advertiser, advising of the complaint. The letter requested the advertiser to review the identified advertisement and other relevant advertising of therapeutic goods to ensure full compliance with the law. The letter highlighted in particular the following requirements under the *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code 2015:

- S.42DL(9) of the Act – Advertisements for therapeutic goods must not contain a suggestion or implication that the goods have been recommended or approved by or on behalf of a government or government authority
- S.4(2)(i) of the 2015 Code – An advertisement for therapeutic goods must not contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.
- S.4(6)(b)(i) of the 2015 Code- An advertisement for therapeutic goods must not contain or imply endorsement by and government agency.

The TGA is also, as part of its assurance activities, undertaking a systematic approach to bringing about compliance in the sector involved with ['bio-resonance'](#) devices.

### Learning for advertisers

While this advertisement was required to comply with the 2015 Code, advertisers should note that the requirement that advertisements must not contain an endorsement from, or imply that the therapeutic goods are endorsed by a government authority is also provided at S.16(2)(a) of the Therapeutic Goods Advertising Code (No.2) 2018. Additionally, it is a contravention of the Act to suggest or imply that the therapeutic goods have been recommended or approved by a government authority. Therefore, statements such as 'TGA approved' and 'included on the ARTG as a Class 1 medical device' are not permitted to be used in advertisements for therapeutic goods.

The TGA has provided [guidance](#) on how advertisers can compliantly advise the public that an advertised good is entered in the ARTG.

The requirement of the 2015 Code that **an advertisement for therapeutic goods must not contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects** is the same as the requirement at S.10(d)(i) of the Therapeutic Goods Advertising Code (No.2) 2018. Advertisers should note that representations about the goods being safe or having no-side effects can be implied (i.e. not overtly stated). For further information, see [Safety and 'no side effects' claims](#) above and the TGA's [guidance](#) on this requirement.

## Case study 11: Online advertisement for herbal medicine

*References not provided on request*

### About the complaint and advertisement

On 27 June 2019, the TGA received a complaint about an online advertisement to the public for an herbal medicine, which was entered in the ARTG. The advertisement claimed that laboratory testing on the active ingredient in the medicine demonstrated that the ingredient worked by triggering the body's own anti-oxidant pathways. No details of the scientific studies were provided in the advertisement that would enable the reader to identify the studies. However, the advertisement invited readers to request the references. The complainant approached the advertiser for the references but their request was refused.

The case was categorised as low as it appeared to be an isolated advertising non-compliance and there were no concerns that the advertising was misleading as to the content or proper use or identification of the therapeutic goods.

### Summary of actions taken

The TGA issued an obligations letter to the advertiser, advising of the complaint. The letter requested the advertiser to review the identified advertisement, and other relevant advertising for therapeutic goods, as soon as possible to ensure they comply with the law. The letter highlighted in particular the following requirements under the Therapeutic Goods Advertising Code (No.2) 2018 that may be of concern:

- S.9(b) – Advertising for therapeutic goods must be truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons.
- S.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.

### Learnings for advertisers

Advertisers should note that the requirements set out in section 15 of the Code must be met wherever an express or implied reference to scientific or clinical literature is appears. A reference to 'laboratory testing' purporting to demonstrate the mechanism of action of a medicine is an implied reference to scientific literature. While offering to provide a copy of references on request may be acceptable to meet the requirements of section 15 where that information is not in the public domain, such a claim will be likely to be misleading if the advertiser does not provide the information when requested by a member of the public.

# Compliance and enforcement activities

## Preventative compliance activities

Where the TGA becomes aware that an advertiser is planning a promotion that is likely to contravene the Act or the Code, we can take preventative action. As with our complaints handling, we apply a risk-based approach to these activities.

### Chemist Warehouse

Section 20 of the 2018 Code sets out that an advertisement must not contain an offer of a sample (with some exceptions for certain therapeutic goods).

In September 2018, it came to the TGA's attention that Chemist Warehouse was proposing to provide sample bags, the contents of which included samples of therapeutic goods, in the form of seat cushions at the 2018 AFL and NRL Grand Finals.

The TGA assessed that the giving of the sample bags was a promotional activity that met the definition of 'advertise' in relation to therapeutic goods and that the advertisement offered a sample which would have contravened the 2015 Code.

The TGA intervened and requested that Chemist Warehouse not include therapeutic goods in the sample bags. Chemist Warehouse consequently did not include therapeutic goods in the sample bags, other than some approved sunscreen samples (which because of the inclusion of sunscreens in Schedule 3 of the 2018 Code, may be offered as a sample).

This [outcome](#) was published on the TGA website.

## Court action

### Illegal peptides

In 2018-19, the TGA investigated Peptide Clinics Pty Ltd for breaches of the mandatory rules for advertising of medicines, including the ban on advertising prescription-only medicines to the public. The [Federal Court of Australia ordered a \\$10 million penalty](#) against the company.

### Counterfeit goods

In 2018, the TGA [investigated a South Australian man in relation to illegal acts involving counterfeit therapeutic goods](#). He was charged with various offences, including a criminal charge under section 42DL(1) of the Act for advertising these goods in a way that could cause harm or injury to a person.

## Infringement notices

### Advertising cancelled goods

On 21 June 2019, the [TGA issued an infringement notice to PharmaCare Laboratories Pty Ltd](#) for contravening Section 42DLB of the Act. PharmaCare had advertised a product (Sambucol Kids Cold & Flu Liquid, AUST L 205425) that was cancelled from the ARTG on 3 June 2019.

### Advertising goods not on the ARTG

On 3 January 2019, the [TGA issued an infringement notice to a Sydney man](#) for contravening section 42DL(3) of the Act. This decision was based on the reasonable belief that the man was publishing or broadcasting an advertisement on the internet about therapeutic goods that were not, at the time of publishing or broadcasting, registered or listed goods, or otherwise the subject of an exemption, approval or authority under the Act.

## Emerging trends in compliance

Under the advertising risk-based activity model, the categorisation of the complaint as low is applied in the following circumstances:

- the alleged breach was the first time the advertiser had come to our attention,
- the alleged breach was not considered to be seriously misleading as to the proper identification or use of the goods, and
- there were no prohibited or restricted representations in the advertising.

Seriously misleading claims include falsely claiming that a device was TGA approved, or if the advertising was for a product not on the ARTG, nor exempt from inclusion on the ARTG.

Low level non-compliance is addressed in the following ways:

- through providing education and training as well as guidance material
- partnering up with sponsors, industry group and relevant sponsors, industry groups, relevant practitioner peak bodies and other regulatory agencies to assist in achieving compliance.

In reviewing the low level complaints that have been received to date, a number of sectors and common advertising issues have been identified which the TGA has flagged for future compliance efforts.

## Bioresonance devices

In May 2019, the TGA began work on a sector-wide compliance assurance priority relating to the advertising of 'bioresonance' devices (which are sometimes promoted as 'bio-energy' or (mistakenly) 'biofeedback' devices).

This sector has been identified as having a high rate of non-compliance and was the subject of previous regulatory compliance actions, including issuing individual advertisers with warning letters advising that their advertising was non-compliant.

Bioresonance devices are being promoted as being able to detect illness in the human body as well as to treat illness, including serious forms of illness. Through complaints, the TGA has been alerted to concerns about the scientific credibility of both the diagnostic and therapeutic use of these devices and is currently assessing this aspect of the complaints. Although this assessment is not yet complete, the TGA has cancelled five bioresonance, bio-energy and related devices from the ARTG.<sup>4</sup> Reasons for cancellation include failing to respond to the TGA's requests to provide information or documents. Two sponsors also voluntarily cancelled their devices from the ARTG in advance of the TGA's assessment.<sup>5</sup>

While the scientific basis for these devices remains under consideration, the TGA is, as a priority, working to address other concerns about the advertising of these devices by a large number of health practitioners, such as promoting them for the detection and treatment of serious ailments, diseases and conditions (which are restricted representations).

We are approaching this as a [sector-wide compliance activity](#), which includes:

- working closely with our counterparts, including other federal regulators and state and territory government bodies, and professional bodies to share the information on our activities on bioresonance device non-compliance issues, and
- writing to relevant practitioner peak bodies and sponsors of bioresonance devices to alert them to the advertising compliance issues faced by their sector and seek their assistance with disseminating information and rectifying these issues.

## Multi-level marketing and direct selling

The TGA has received a number of complaints about advertising by multi-level marketers and direct sellers under both the new and previous regulatory frameworks.

The TGA considers that the nature of multi-level marketing and direct selling poses particular risks in relation to the advertising of therapeutic goods, largely because of the high degree of independence of the end seller from the 'parent' company and the often high number of 'end sellers'.

As highlighted in the encapsulated powdered fruit and/or vegetable products matter below, this independence presents particular challenges in:

- ensuring the sector is appropriately educated on the legislative requirements for the marketing of therapeutic goods,
- taking appropriate and equitable regulatory action against a large number of seller/advertisers all advertising the same products with same or similar claims, and
- ensuring our regulatory action is effective across the whole sector.

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<sup>4</sup> See the database Medical devices and IVDs: Cancellations from the ARTG, available from <https://www.tga.gov.au/medical-devices-and-ivds-cancellations-artg>. Devices cancelled include Rayonex biofeedback system (ARTG 224787) and E-Lybra Bio-energy mapping system (ARTG 310955).

<sup>5</sup> See the database Cancellations requested by the sponsor - regulatory actions, available from <https://www.tga.gov.au/ws-sc-index>.



## Encapsulated powdered fruit and/or vegetable products

From October 2018 to June 30 2019, the TGA received 28 complaints, from both consumers (93%) and medical practitioners (7%), about the advertising of a range of encapsulated powdered fruit and/or vegetable products being marketed with therapeutic claims and supplied only through multi-level marketing.

The complainants asserted the advertisers were making false and misleading claims in support of the product across various social media platforms and YouTube. The complainants took issue with the inclusion of both 'restricted' and 'prohibited' representations, false and misleading scientific claims, indications not included in the products' ARTG inclusions and the use of health professional endorsements in the advertising.

Initial investigations confirmed the individual sellers advertising the products were using prohibited representations including cancer, and restricted representations such as anxiety, autism, depression, diabetes, Crohn's disease and heart disease. Further investigations confirmed the involvement of medical practitioner endorsements and claims that the particular range of therapeutic goods was superior to dietary nutrients. Claims of 'scientifically proven,' 'most researched,' and '100% safe' were found to be used extensively in the advertising material.

When contacted by the TGA, the product advertisers advised they had all copied one another in relation to the therapeutic claims for the product. A small proportion of the advertisers conveyed that the training they received from the parent company was minimal or non-existent while others stated that they were regularly trained by those who recruited them.

### Action taken by the TGA

- The TGA issued each seller/advertiser with a warning letter outlining the breaches identified in their advertising. They were given 14 days to correct or remove the advertising.
- The TGA will continue to monitor each seller/advertiser that was warned that further breaches will result in infringement notices being issued.
- Several medical practitioners advertising the product in a way which contravenes the Act and the Code have been referred to AHPRA.

### Future work

Encapsulated powdered fruit and/or vegetable products are not the only area of concern in relation to advertising compliance in this sector. For example, a TGA Facebook post on 25 July 2019 about the dangers of ingesting essential oils generated a significant number of comments from stakeholders that expressed concerns about the inappropriate promotion of essential oils by multi-level marketers and other retailers.

The TGA is working to develop and disseminate educational material to both parent companies and their sellers/advertisers, including on the use of endorsements and testimonials in advertising therapeutic goods. The TGA will also release more detailed guidance for multi-level marketers and direct sellers on advertising of therapeutic goods generally.

## Competitor complaints

In the year ended 30 June 2019, the TGA received 23 complaints regarding 10 different vendors of a Class 1 Medical Device. All complainants self-identified as consumers when submitting their complaints, yet scrutiny of the data revealed 48% of all complainants were vendors with competing products. The complainants all referenced the use of 'restricted representations' such as anxiety, autism, depression and post-traumatic stress disorder in their complaints.

Initial investigations revealed all vendors to be advertising the product using 'restricted representations'. Following initial contact by the TGA, warning letters were issued in respect of five vendors. This resulted in a number of those who received warning letters raising complaints against other vendors. Of these, all complaints referenced the three entities who are the leading sellers of the medical device. All 10 vendors stated they had seen other vendors using the same claims and restricted representations and had followed suit.

The TGA intends to undertake regulatory action against those entities who have demonstrated their awareness of their advertising obligations and have remained non-compliant.

## Educational activities

In our role overseeing the advertising of therapeutic goods, the TGA is very committed to supporting stakeholders to be able to meet their compliance obligations.

We have developed a range of educational material and activities to help our stakeholders understand their obligations under the Act, which we continue to adapt and refine as stakeholders provide feedback and as policies and legislation changes.

As well as formal educational training (such as face-to-face training sessions and webinars), the TGA website contains detailed information to assist advertisers. For more information, visit the [Advertising Hub](#).

The TGA is currently developing guidance material relating to how businesses can:

- disseminate information to the public about their activities as medicinal cannabis manufacturers
- provide information on services associated with stem cell therapy, or
- conduct disease education activities

without raising concerns under the advertising requirements set out in the Act.

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## Collaboration

### The Therapeutic Goods Advertising Consultative Committee

The [Committee](#) is the key advisory committee for the regulation of advertising. It is made up of members representing consumer, health professional, industry, media and government bodies. The Committee's member organisations were appointed by the Hon. Greg Hunt, MP, Minister for Health.

The role of the Committee is to:

- provide input to policies relating to the administration of the Therapeutic Goods Advertising Code
- provide a forum for engagement on emerging issues with respect to therapeutic goods advertising
- assist with shaping TGA reporting activities with respect to advertising compliance
- review Key Performance Indicators for advertising complaints handling
- provide input on the development of education and compliance priorities to address non-compliance of advertising for particular categories of therapeutic goods.

The Committee meets quarterly. The first meeting was held on 18 October 2018. Following each meeting a communique is published. The [Committee's communiques](#) are available on the TGA website.

### Other regulators

Often a complaint raises issues that are best dealt with by, or overlap with, other regulators.

While the advertising of therapeutic goods to consumers must comply with the therapeutic goods legislation, it also must comply with Australian Consumer Law, which is administered by the Australian Competition and Consumer Commission (ACCC).

In some cases, complaints about the advertising of therapeutic goods may be best addressed by the ACCC – for example, where the misleading nature of advertising concerns pricing.

Complaints sometimes raise concerns about the behaviour of regulated health professionals or other health practitioners. These complaints may be best dealt with by the relevant health professional board (e.g. the National Medical Board) or the relevant state or territory health complaints department.

Some types of products that are not ordinarily regulated as therapeutic goods, such as foods, cosmetics and consumer goods (interface products), may be captured by the definition of therapeutic goods if promoted for therapeutic use. Because of the nature of interface products, we work closely with state and territory health and fair trading agencies and the National Industrial Chemical Notification and Assessment Scheme to resolve complaints about these types of products.

The TGA works collaboratively with the ACCC and state and territory agencies, including where necessary to address all aspects of complex and multi-faceted complaints. For example, see [bioresonance devices](#).

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## Future direction

As we look ahead, there will be ongoing opportunities to refine and strengthen the therapeutic goods advertising framework and the TGA's role as a responsive regulator. Collaboration with all our stakeholders is an important aspect of this process as we work to ensure the safety, health and wellbeing of all Australians.

We will be working to build our data set and reporting functions to better support us in identifying trends in non-compliance and tailoring education and assurance activities. This will include continuing education and assurance efforts, developing and refining educational material to ensure it has the most effective regulatory impact, and improving our ability to identify targets for sector-specific assurance activities.

In addition, the TGA will continue to deliver new and updated guidance material, including guidance needed to support advertisers through any future legislative changes (e.g. in the event of an update to the Code), as well as respond to trends in non-compliance. Additional educational and guidance work will also be required to ensure advertisers are prepared for the removal of the pre-approval process on 1 July 2020 (see [Extension of pre-approval process](#) for more information).

We recognise the many challenges faced by advertisers in an increasingly digital environment. A key area of focus for us will be improving the guidance available to advertisers on applying the Code to online testimonials and paid social media influencers. We are collaborating with Committee members to ensure marketers in this space have an understanding of the legislative requirements for advertising therapeutic goods, and how it is most appropriately applied specifically in relation to digital and social media platforms.

We will continue to handle complaints about advertising of therapeutic goods in accordance with our risk-based activity model, described in the [complaints handling framework](#). This ensures that the matters representing the greatest health and safety risk to Australian consumers receive timely and effective attention.

However, the number of complaints received in the first year of the new framework's operation has exceeded expectations. This may in part be due to the simplification and streamlining of the complaints process, as well as the escalating impact of online and direct marketing. The higher numbers of complaints will necessarily inform the kinds of strategies we may employ to strengthen and refine the framework. Any refinements or other changes to our complaints handling policies will be subject to consultation, in particular with the Committee.

The analysis we conducted on breaches of the [2015 Code](#) and the [Code](#) highlights that we have found many allegations that advertising claims are unsubstantiated, to be correct. This is consistently observed across all categories of therapeutic goods. Advertisers must be mindful that appropriate evidence is required to satisfy a number of Code requirements. Detailed information about the levels and types of evidence required to be held by the advertiser in order to meet their regulatory obligations is in the Code guidance material - see [Accuracy](#).

In relation to listed medicines and therapeutic claims, the newly implemented [permitted indications](#) provide transparency on what indications are suitable for listed medicines. The transition to permitted indications is expected to help improve protections for consumers from misleading and

inappropriate claims about listed medicines. The TGA anticipates that the implementation of permitted indications will lead to improved compliance by advertisers.

Advertising compliance is an integral component of the TGA's broader compliance functions (see the TGA's [Regulatory compliance framework](#) on our website). In this context, there are many opportunities to further develop and refine the use of our enforcement powers, which enable us to prosecute offenders whose advertising and compliance attitude puts the Australian public at a high risk of harm. This will serve to set examples in line with the practices of other regulatory bodies, and improve advertiser compliance attitudes.

## Appendix 1 – Glossary of advertising provisions

### Therapeutic Goods Act 1989

| Subsection  | Description                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 42DL(12)    | <b>Advertising offences—general:</b> 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).                            |
| 42DL(7)(a)  | <b>Advertising offences—general:</b> 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.                                                                                                    |
| 42DL(10)    | <b>Advertising offences—general:</b> 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)(a)  | <b>Advertising offences—general:</b> 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.                                                                                                                              |
| 42DLB(9)    | <b>Civil Penalty provision -</b> 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)     | <b>False advertising about medical devices:</b> 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)    | <b>Civil Penalty provision -</b> 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).     |
| 42DLB(4)(a) | <b>Civil Penalty provision -</b> 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) | <b>Civil Penalty provision -</b> 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—non-compliance with the Therapeutic Goods Advertising Code                                                                                                                                                                                                                                                                                                                                                        |

| Subsection     | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 42DM           | Offences—non-compliance with the Therapeutic Goods Advertising Code                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 42DL(9)        | Suggesting goods approved by government authority                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 22(5)          | <b>General offences relating to this Part:</b> 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)        | <b>Offences—non-compliance with the Therapeutic Goods Advertising Code:</b> A person commits an offence if 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)       | <b>Civil penalty relating to advertisements—general:</b> 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)       | <b>Civil penalty relating to advertisements—general:</b> 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) | <b>False advertising about medical devices:</b> 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.                                                                                                                                                                                                                                                                                                                                                                                                         |

## Therapeutic Goods Advertising Code 2015

| Subsection | Description                                                                                                                                                                                                                                                                                                                      |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4(2)c      | <b>General Principles</b> - An advertisement for therapeutic goods must not: mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions                                                                                                                               |
| 4(6)b(iii) | <b>Professional Recommendation</b> - Advertisements must not contain or imply endorsement by: individual or groups of health professionals referred to in section 42AA of the Act or any other person or group of persons represented directly or indirectly to be health professionals, other than where the emphasis is on the |
| 4(1)b      | <b>General Principles</b> - An advertisement for therapeutic goods must: contain correct and balanced statements only and claims which the sponsor has already verified.                                                                                                                                                         |
| 4(7)       | Testimonials: Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.                                                                                                                                                                                         |
| 4(2)i      | An advertisement for therapeutic goods must not: contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects                                                                                                                                       |
| 5(2)       | Prohibitions: An advertisement for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in Part 2 of Appendix 6, unless prior approval is given under the Act.                                                                                 |
| 4(8)       | Samples: An advertisement for therapeutic goods (other than therapeutic devices and sun screening preparations) must not contain an offer of a sample.                                                                                                                                                                           |
| 4(2)b      | An advertisement for therapeutic goods must not: be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases                                                                                                                                                                         |
| 4(2)d      | An advertisement for therapeutic goods must not: abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress                                                                                                                                                      |
| 4(2)e(i)   | An advertisement for therapeutic goods must not: contain any matter which is likely to lead persons to believe that they are suffering from a serious ailment                                                                                                                                                                    |
| 4(2)e(ii)  | An advertisement for therapeutic goods must not: contain any matter which is likely to lead persons to believe that harmful consequences may result from the therapeutic good not being used.                                                                                                                                    |



| Subsection | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4(2)f      | An advertisement for therapeutic goods must not: encourage, or be likely to encourage, inappropriate or excessive use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 4(2)j      | An advertisement for therapeutic goods must not: be directed to minors, except the therapeutic goods listed in Appendix 5.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 4(5)       | Comparative advertisements must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual.                                                                                                                                                                                                                                                                                               |
| 4(2)a      | An advertisement for therapeutic goods must not: be likely to arouse unwarranted and unrealistic expectations of product effectiveness                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4(6)c      | Advertisements must not contain or imply endorsement of the goods by bodies or peak health professional associations that: (i) represent the interests of health consumers; (ii) conduct or fund research into a disease, condition disorder or syndrome; or (iii) represent health professionals, unless: (iv) the advertisement names the body or association; (v) the endorsement is authenticated; (vi) the nature of the endorsement is clearly disclosed; and (vii) the endorsement is based upon an objective assessment of available scientific data supporting the use of that product. Where this is not the case and where the body or association has received valuable consideration for the endorsement, the advertisement must acknowledge that consideration. |
| 6(3)       | An advertisement for therapeutic goods shall contain: the trade name of the goods; a reference to the approved/permitted indication(s) for the use of the goods; information outlined in 6(3)c to f                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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## Version history

| Version | Description of change | Author                         | Effective date  |
|---------|-----------------------|--------------------------------|-----------------|
| V1.0    | Original publication  | Advertising Compliance Section | 25 October 2019 |

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