Advertising cosmetic injection services

Complying with therapeutic goods legislation

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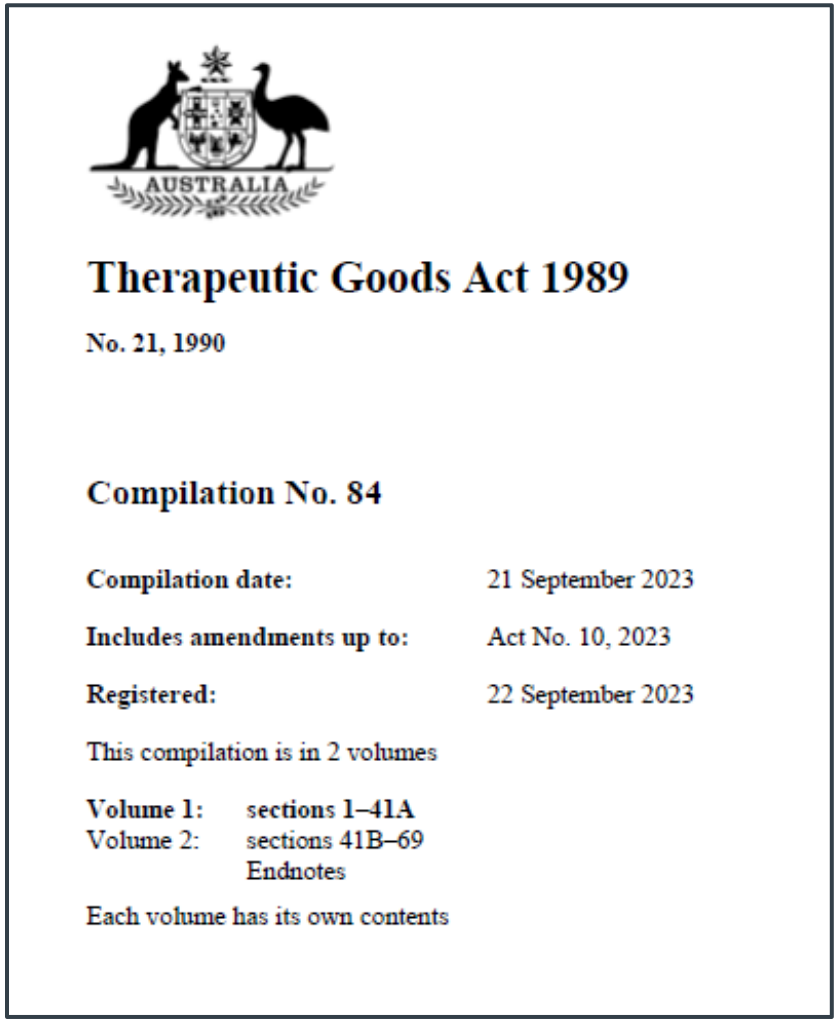
Role of the Therapeutic Goods Administration (TGA)

Regulating therapeutic goods

- Safeguarding Australian consumer's health and safety in relation to therapeutic goods
- Therapeutic goods includes medicines and medical devices
- We regulate the manufacture, supply, import, export and **advertising** of these goods
- We do **not** regulate
    - Foods
    - Cosmetics (e.g. foundation/make up)
    - Veterinary medicines
    - Health practitioners



AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 84

Compilation date:	21 September 2023
Includes amendments up to:	Act No. 10, 2023
Registered:	22 September 2023

This compilation is in 2 volumes

Volume 1: **sections 1–41A**
Volume 2: sections 41B–69
Endnotes

Each volume has its own contents

Why regulate advertising of therapeutic goods?

- To protect consumers
  - vulnerable consumer segments
  - information asymmetry, low health literacy
- The Act prohibits the advertising of prescription-only medicines as this may disrupt the doctor-patient relationship and create an inappropriate demand for these goods
- Ads should support consumers to make informed health care choices
- Ensure ads promote the safe use of products and reduces risk of misuse or overuse
- Ensure ads are not misleading or deceptive and provide a realistic expectation of product performance
- Australian Consumer Law also applies

What is advertising?

Under section 3 of the Act, advertise in relation to therapeutic goods includes making:

- any **statement, pictorial representation or design** that is intended, whether directly or indirectly, to **promote the use or supply of the goods**, including where the statement, pictorial representation or design:
  - is on the label of the goods; or
  - is on the package in which the goods are contained; or
  - is on any material included with the package in which the goods are contained.

If members of the public would reasonably consider that the information is intended to promote the use **or** supply of the identified goods, then the TGA would likely consider it to be an advertisement.

- This is considered on a case-by-case basis

Requirements for advertising to the public

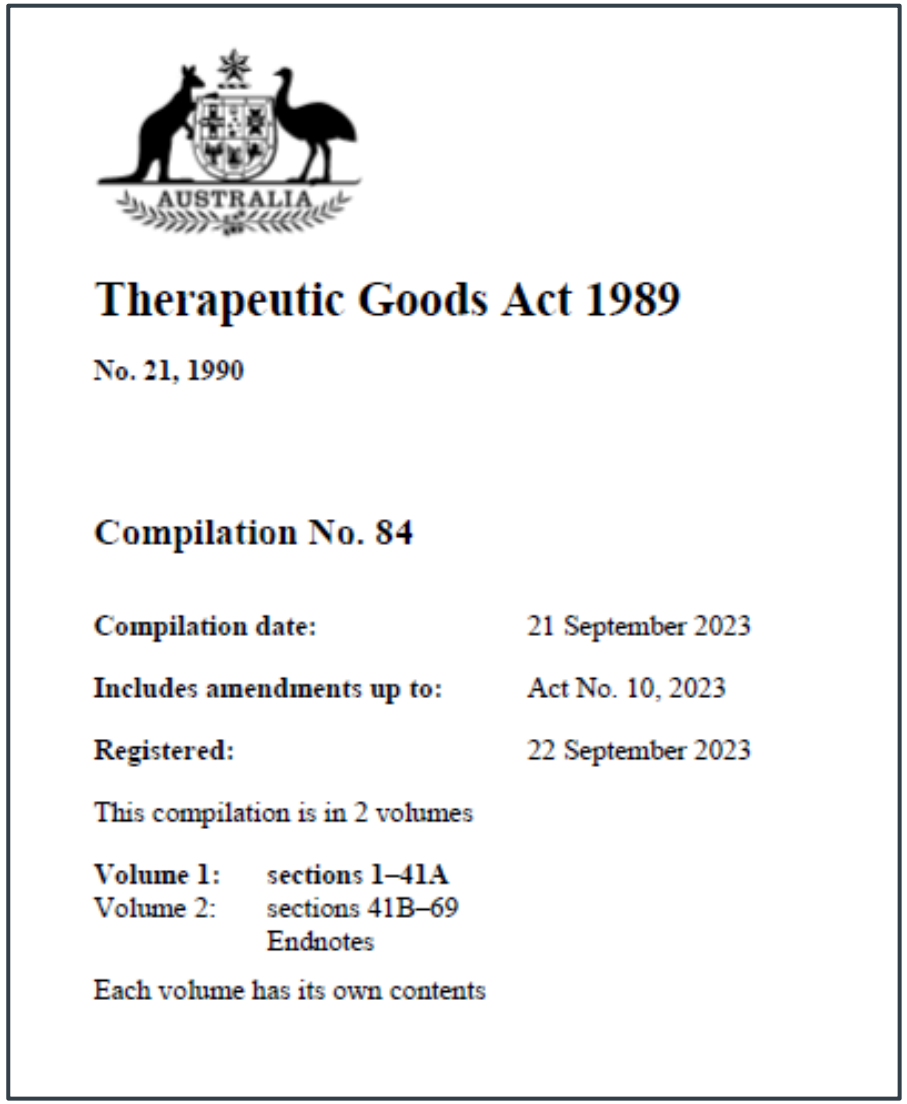
Therapeutic Goods Act 1989 (the Act)

Advertisements must **not:**

- Refer to a serious conditions without TGA permission or approval (known as restricted and prohibited representations)
- Advertise indications other than those included on the ARTG
- **Refer to substances in schedule 3, 4, or 8 of the Poisons Standard (except Appendix H)**
- Refer to biologicals
- Refer to unapproved therapeutic goods
- State or imply Government endorsement

The Act also:

- Authorises the Advertising Code
- Provides compliance powers including offences and civil penalty provisions.



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Activities exempt from the advertising restrictions

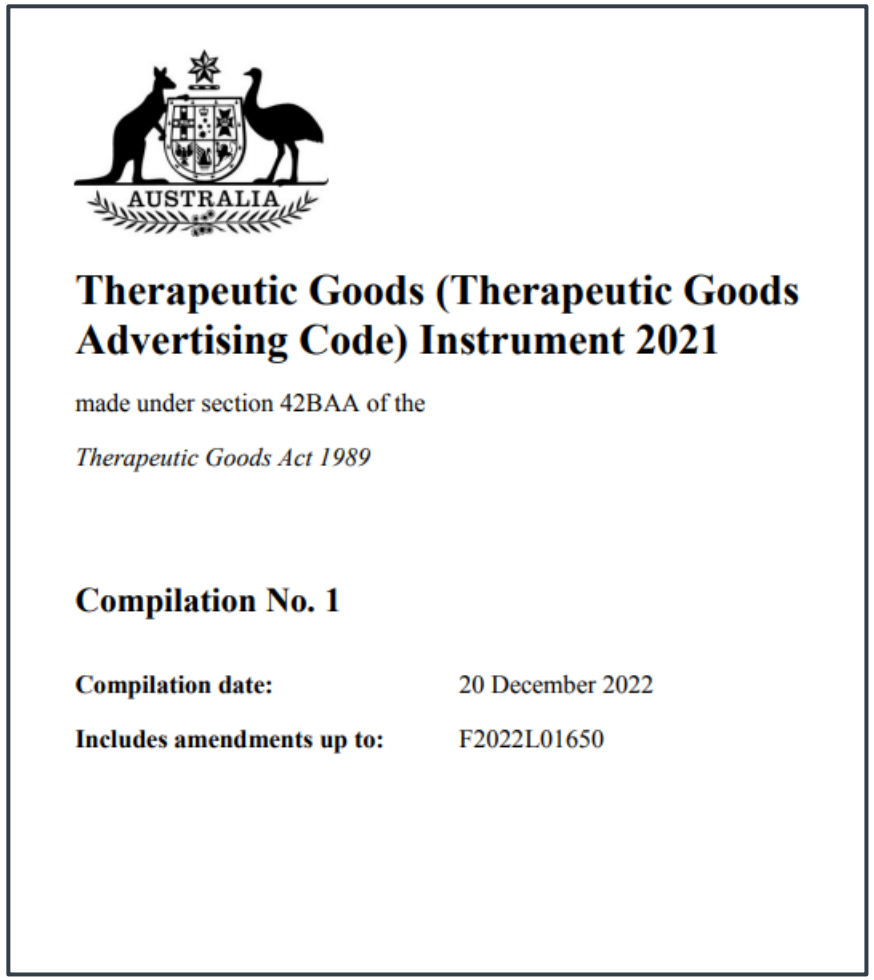
Therapeutic Goods Act 1989 – section 42AA

- Information shared between a health practitioner and their patient during a 1:1 consultation

Recognises that the training and expertise of health professionals means they have the appropriate knowledge to critically evaluate information for their patients.

Reminder that goods that can be advertised to the public must comply with the Therapeutic Goods Advertising Code

- Promote safe and proper use of health products
- Accurate, not misleading, consistent with intended purpose
  - **cannot claim safe or without side effects, effective in all cases, unfailing, magical or miraculous**
- Consistency with public health messaging
- Mandatory statements and health warnings
- How to use testimonials and endorsements lawfully



AUSTRALIA

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

made under section 42BAA of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 20 December 2022

Includes amendments up to: F2022L01650

Is it promotional or information?

Would a reasonable person objectively view the material as being promotional?

Advertising

- References a product or brand to draw attention / raise awareness
- Creates a favourable impression – focuses on benefits or qualities
- Uses persuasive language to motivate a response – encourage a consumer to seek out
- Provides supply information – where goods can be purchased / obtained / prescribed

Non-promotional information

- Presents a balanced view of the information by communicating risks and benefits, e.g. genuine news
- Doesn’t use promotional language

Information in one context may become promotional when used in another context

Advertising therapeutic goods versus a service

- The TGA does not regulate the advertisement of health services
- An advertisement can be for both a service and a therapeutic good
- Advertisers should be mindful that their ads may be regulated by:
  - Therapeutic Goods Administration – medicines and medical devices (unless the ad is solely for a service)
  - Australian Competition and Consumer Commission – Australian consumer law requirements will apply to products and services
  - Ahpra – regulates advertising made by healthcare practitioners

Advertising a regulated health service

Anyone advertising regulated health services must comply with the **Health Practitioner Regulation National Law (the National Law)**.

If you are advertising a regulated health service your advertising must not:

- be false, misleading or deceptive or likely to be misleading or deceptive.
- offer gifts, discounts or other inducements unless the terms and conditions of the offer are also stated
- use testimonials or purported testimonials about the service or business(NB: ‘testimonials’ has a particular meaning in Ahpra’s advertising guidelines)
- create an unreasonable expectation of beneficial treatment
- directly or indirectly encourage the indiscriminate or unnecessary use of regulated health services

Ahpra has developed guidelines to help advertisers understand their obligations when advertising a regulated health service. More information and a copy of the advertising guidelines is available on Ahpra’s advertising hub.

Ahpra has recently consulted on specific guidelines for advertising of non-surgical cosmetic procedures and will publish the guidelines following consideration of feedback.

1. **Advertise**: Any information intended, directly or indirectly, promoting the use **or** supply of a therapeutic good

2. Schedule 3, 4, or 8 substances **cannot** be advertised to the public

   This includes prescription-only medicines

3. Unapproved therapeutic goods **cannot** be advertised to the public

4. Advertisements for health services that promote therapeutic goods will likely be considered ads for the good

Key points

Advertising requirements

- These requirements apply to **both** websites and social media
- Certain information is **exempt** from advertising rules under Part 5-1 of the Act
  - Information provided to a patient in the course of a private consultation
  - Advertisements **exclusively** to health professionals
- See sections 42DL and 42DLB of the Act for offences

Updated guidance on Advertising health services

We have updated our guidance on advertising health services, which includes treatments involving prescription-only medicines, to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Advertising for services that inherently involve therapeutic goods, need to comply with the legislative requirements.

https://www.tga.gov.au/resources/resource/guidance/advertising-health-services

Why now?

- Observed increase in clinics and health services across multiple industries advertising the availability of prescription-only medicines
- Typically, by referring to a class of goods;
  - ‘weight loss injections’
  - ‘medicinal cannabis’
  - ‘nicotine vaping products’
- The TGA has interpreted that promoting health services as a means to obtain a prescription-only medicine is also an advertisement for a therapeutic good that refers to prescription medicines, which is unlawful

Cosmetic injections are high risk products

Most cosmetic injectables contain prescription-only substances (in Schedule 4 to the Poisons Standard).

They involve injecting a substance under the skin to change an aspect of appearance such as:

- reducing the appearance of wrinkles or lines on the face
- putting filler into the lips to make them fuller.

As with all prescription-only medicines these products come with risks and potential side effects.

Require consultation with an appropriately qualified health professional to ensure informed consent regarding procedure, risks, alternatives

Risks observed – advertising cosmetic injectables

- Advertising for a health service which identifies prescription-only medicines is unlawful.
- Clinics advertising benefits of prescription-only medicines to consumers
- Advertising to the public can lead to inappropriate demand and disrupt the health professional/patient relationship.
- An increase in reports of adverse events and harm caused to patients.
- Increase in the unlawful importation of cosmetic injectable products by registered health professionals from overseas.

What is in the updated guidance?

Treatments involving prescription-only medicines

- Sections 42DL and 42DLB of the Act prohibit public advertising of therapeutic goods containing prescription-only medicines and substances.
- The promotion of a health service (including telehealth) as a means to obtain a medicine is likely to amount to advertising.
- Any **direct or indirect** reference to a prescription-only medicine in the context of an advertisement for a health service will risk the advertisement becoming an advertisement in relation to a therapeutic good.

What is in the updated guidance?

Referring to prescription-only medicines in business names

- If you are a business that promotes treatment services, take care to ensure that you are not, in addition to promoting your services, also promoting prescription-only medicines through your business name.
- In general, if a business name includes a reference to a prescription-only good (even generically) it is likely that a consumer viewing the promotion of the service would reasonably consider that the service includes the use of these prescription-only goods.
- Assessment of business names needs to be considered in context on a case-by-case basis.

What is in the updated guidance?

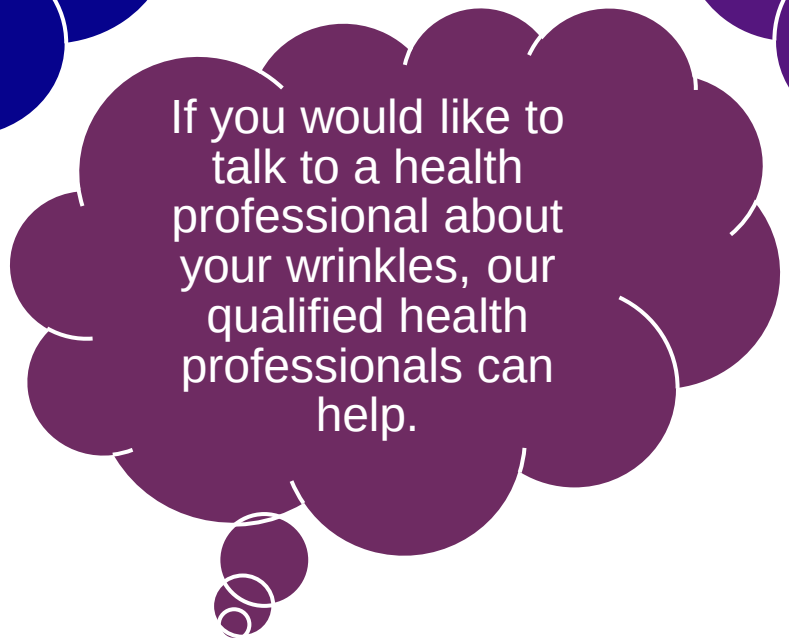
Advertising cosmetic services including injectables

- Most cosmetic injectables contain substances that are in Schedule 4 to the Poisons Standard and cannot be advertised to the public.
- This includes through **direct references** to prescription-only substances or to product trade names.
- Also includes through **indirect references** acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to a specific prescription-only medicine or substance.
- Examples:
  - anti-wrinkle injections
  - dermal fillers
  - injectable products used for improvement of the appearance of submental fat.

What terms can I use?

Advertisers should only refer to the type of consultations the service offers

These examples do not focus on a product



These examples do not suggest that a prescription product is involved

It is important to assess your advertising

Does it:

- Refer to therapeutic goods used in the delivery of the service?
- Refer to prescription-only medicines or substances, in a direct or indirect way?
- Lead a potential patient to understand that they could obtain a prescription for those goods?

If you can answer yes or maybe to any question, then that advertising would be likely to be considered as advertising for a prescription-only good that is unlawful.

How can I communicate with my patients?

The most credible information around what cosmetic procedure is right for a specific patient comes from a private consultation between a patient and their appropriately trained and qualified health professional.

The advertising requirements do not apply to:

- Information shared between a health practitioner and their patient **during a private consultation or treatment**

However, communications, such as by email or text message, are unlikely to be exempt.

Reminders

Advertising do's and don'ts for cosmetic injection services

Do

- Follow TGA guidance
- Ensure your advertising is directed *exclusively* to health professionals or given directly to a patient during a consultation
- Remove testimonials or endorsements and third-party materials from social media and websites
- Report perceived breaches to the TGA
- Seek regulatory advice

Don't

- **Advertise products containing prescription-only substances to the public**
- Assume the examples in the guidance are exhaustive and are the only activities that are considered unlawful advertising
- Follow what your competitors if their advertising is non-compliant
- Disregard emails or phone calls from the TGA

Role of the TGA

The TGA's role is to enable the Australian public timely access to safe, high quality and effective therapeutic goods

What we can do	What we can't do
• Identify and refer you to relevant guidance • Provide general advice and factual information • Explain the process and procedure relating to regulation of therapeutic goods • Clarify existing guidance	• Give definitive advice on specific issues relating to your particular circumstance, for example, appropriateness of indications, formulation, manufacturing or compliance • Offer interpretation of the legislation and its applicability to your circumstance • Confirm that a business decision is appropriate and compliant with requirements

See TGA customer service standards

- Continue to take strong action to deter and disrupt unlawful advertising of high-risk medicines and medical devices
- Gather and use intelligence to identify higher-risk behaviours
- Continue to engage with industry about their regulatory obligations
- Maximise disruption through collaboration with Ahpra and other agencies

How we are combatting unlawful advertising of cosmetic injectables

To report on emerging trends or forms of advertising:

- Report a breach

To make an enquiry:

- email Advertising.Enquiries@tga.gov.au

TGA compliance priorities – cosmetic injectables

In July 2023, the following priority was published:

Detect and disrupt unlawful advertising of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries including those intended to alter the body's performance and appearance.

Australians seeking to enhance their physical… appearance may be vulnerable to advertisements promoting therapeutic goods as 'health and beauty products'.

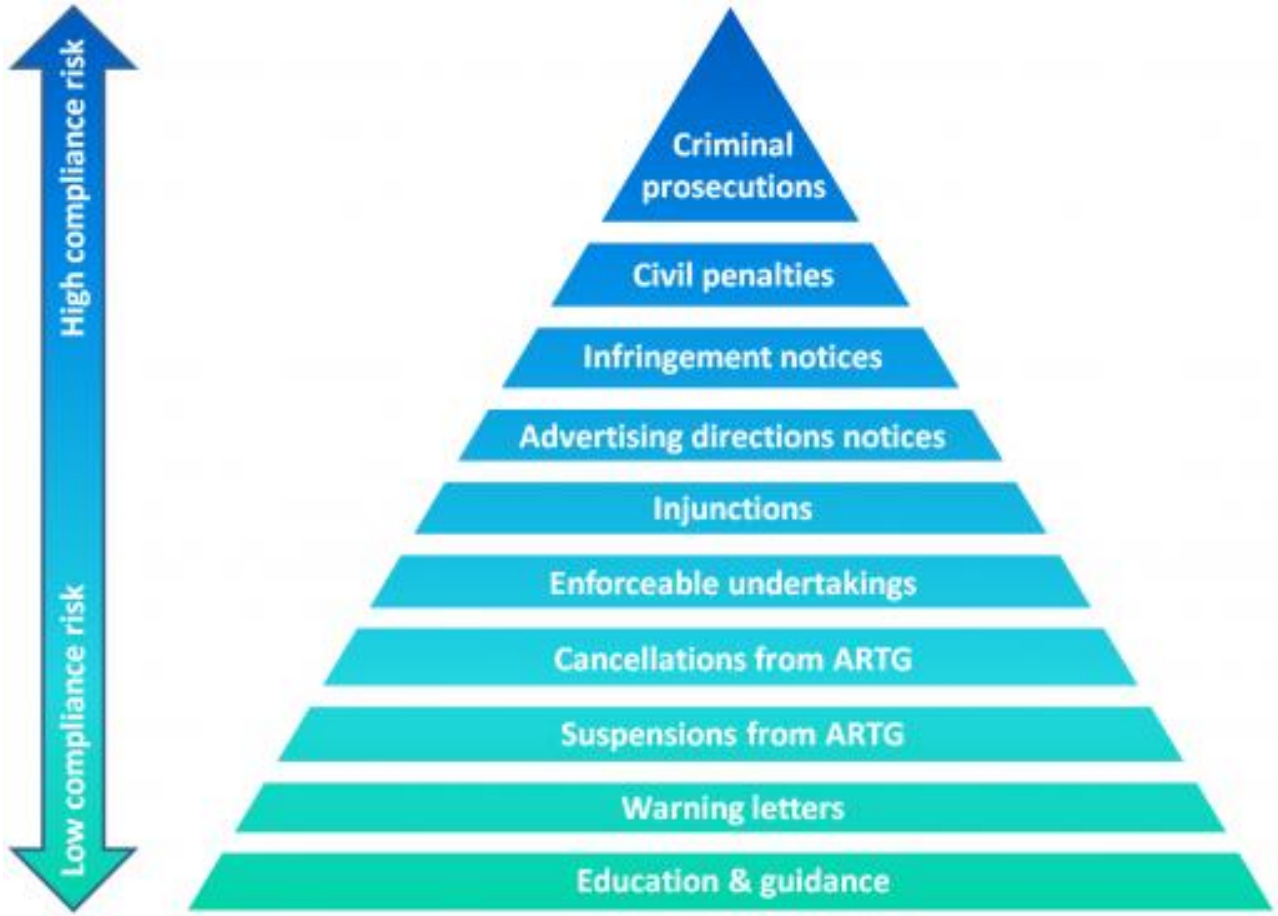
These include… **cosmetic injectables** and other medications or medical devices intended to alter the body's appearance.

[Import, Advertising and Supply Compliance Priorities 2023-24 | Therapeutic Goods Administration (TGA)]

What will the TGA do if alleged breaches are found?

The regulatory ‘tools’ can be used individually or in combination

- Education and guidance are key to compliance
- Education and advice are often the first steps to assist an entity to achieve compliance
- Escalation of regulatory action considered if:
  - the entity has repeat breaches and is not willing to comply, and/or
  - the alleged breach is such that there is a likely impact on the consumers' ability to use therapeutic goods safely or appropriately



Common Questions

From enquiries & pre-webinar submissions

Advertising health services and cosmetic injections: frequently asked questions

Regulation of Sculptra – Can it be advertised?

Correction of previous response by the TGA

- In an email to a particular industry group the TGA **incorrectly** noted that Sculptra was a Class III medical device which does not contain a substance in schedule 3, 4, or 8 of the Poisons Standard and therefore could be advertised
- **Please note**
  - Sculptra contains the substance Poly-L-lactic acid
  - Polylactic acid is covered under Schedule 4 of the Poisons Standard when used in preparations for injection or implantation: (a) for tissue augmentation; or (b) for cosmetic use.
  - Making Sculptra a good containing a substance included in schedule 4 of the Poisons Standard, **which cannot be publicly advertised**

FAQs

Before and After photos

Under the Act, advertisers are not prohibited from using ‘before’ and ‘after’ photos to advertise their health service. However, they must not, directly or indirectly, refer to prescription only substances or goods containing such substances used in the delivery of that service.
If it is apparent to the consumer that the ‘after’ photo is due to the administration of a prescription-only substance or good, this is likely to amount to an advertisement for a therapeutic good that would contravene the Act.

Historical social media content

Due to the nature of social media posts and their ready accessibility to consumers regardless of the date posted, all social media posts, historical and new, are required to comply with the requirements.

Business names

Businesses that promote treatment services need to take care to ensure that they are not, in addition to promoting their services, also promoting prescription-only substances or goods containing such substances. Whether or not a particular business name would be likely to result in a contravention of the Act must be considered in context on a case-by-case basis.

FAQs

Booking systems, terms, prices, and more

If a publicly available booking system draws consumers to a service on the basis of that service offering specific prescription-only medicine or substance it is likely to be an advertisement of therapeutic goods as it promotes the supply of therapeutic goods. Where the advertisement also refers to prescription-only medicines or substances it would be unlawful. For example:

- providing a form or other facility from which the consumer self-selects from a list of treatments involving prescription-only medicines or substances
- providing price information for a prescription only medicine or substance.

Whether the use of a prescription-only medicine or substance is appropriate for an individual should be discussed with a patient during consultation with an appropriately trained health practitioner. Such a consultation also allows the practitioner to discuss risks and contra-indications with their patient.

Private groups on social media and private mailing lists

The use of ‘private groups’ on social media or private mailing lists to restrict advertising material about therapeutic goods or services promoting therapeutic goods (including prescription-only medicines) is **unlikely** to exclude this material from being considered advertising under the Act, subsequently the advertising prohibitions and restrictions in the Act will apply.

FAQs

Grace period? Enforcement?

Consistent with the TGA's approach to compliance, we will seek high levels of voluntary compliance by engaging with and educating industry in the first instance and will run industry information sessions in the coming months.

The TGA will continue to publish educational material to assist industry transitioning their advertising and run information sessions for the impacted stakeholders over the next couple of months.

Any future compliance action we take will be consistent with our regulatory framework. This means it will be evidence-based and will adjust to respond to the nature and seriousness of the alleged non-compliance.

Further information on the types of actions we may take can be found on the Compliance actions and outcomes page on the TGA website.

Specific products including profhilo, Sculptra, Radiesse, Juvederm, Restylane, etc.

The Act prohibits public advertising referring to substances, **or goods containing substances**, included in Schedule 3, 4 or 8 to the current Poisons Standard (except those in Appendix H). This includes goods on the ARTG as medical devices where the device is a **good containing a Schedule 4 substance.**

Questions are now open

How to access and use Slido

Through the Slido application in Webex

- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)

Using the QR code

Scan the QR code to access Slido from your mobile device

FAQs

Ahpra guidelines or TGA rules? Which to comply with?

Both.

If an advertiser is subject to requirements under both Ahpra and the *Therapeutic Goods Act 1989*, then they are required to comply with both sets of requirements.

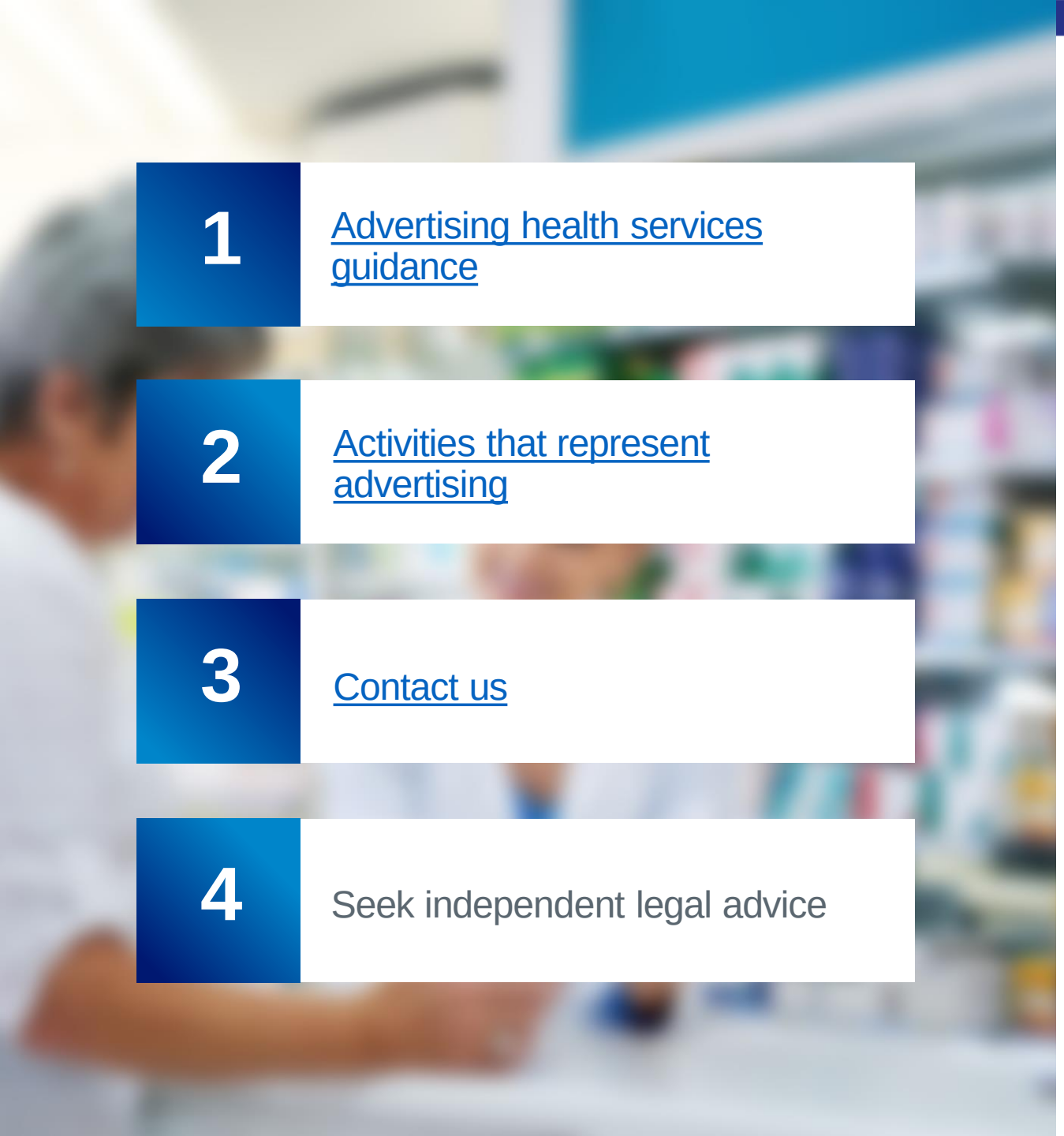
The TGA is unable to comment or advise on Ahpra's guidelines, questions in relation to these should be directed to Ahpra.

Answering phone enquiries from customers/patients

If the information would be reasonably taken by its audience to be intended to promote the use or supply of a prescription-only substance or good, the information would meet the Act's definition of 'advertise' in relation to therapeutic goods.

Solicited information is less likely to meet the legislative definition of 'advertise' than indiscriminately disseminated information. However, this will depend on what is communicated in the telephone conversation.

Information given to a patient in the course of treatment of that patient is not subject to the restrictions on advertising prescription-only goods to consumers.



1. Advertising health services guidance
2. Activities that represent advertising
3. Contact us
4. Seek independent legal advice

Further Resources

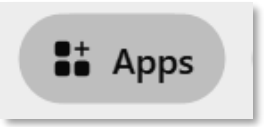
- Medicinal Cannabis Guidance
  - Different industry but relevant legislation and guidance
- Regulation of platelet-rich plasma (PRP), platelet-rich fibrin (PRF) and conditioned serum
- Advertising guidance for businesses involved with intravenous (IV) vitamin and related therapies
- Australian Health Practitioner Regulation Agency

Website and link references

Therapeutic Goods Act 1989	https://www.legislation.gov.au/C2004A03952/latest/versions
Therapeutic Goods Advertising Code	https://www.legislation.gov.au/F2021L01661/latest/versions
Ahpra advertising hub	https://www.ahpra.gov.au/Resources/Advertising-hub.aspx
Advertising health services guidance	https://www.tga.gov.au/resources/resource/guidance/advertising-health-services
The Poisons Standard	https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons-standard-susmp
Customer service standards	https://www.tga.gov.au/tga-customer-service-standards
Report a breach page	https://www.tga.gov.au/resources/resource/forms/report-perceived-breach-or-questionable-practices
Media releases	https://www.tga.gov.au/news/media-releases
Compliance actions and outcomes	https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-actions-and-outcomes
Compliance priorities	https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-24
Cosmetic Injectables FAQ's	https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/special-topic-pages/advertising-health-services-and-cosmetic-injections-frequently-asked-questions
Activities that represent advertising guidance	https://www.tga.gov.au/resources/resource/guidance/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg/activities-represent-advertising
Contact us	https://www.tga.gov.au/about-tga/contact-us
Medicinal cannabis guidance	https://www.tga.gov.au/resources/resource/guidance/advertising-guidance-businesses-involved-medicinal-cannabis-products
PRP, PRF, Conditioned serum guidance	https://www.tga.gov.au/resources/resource/guidance/regulation-platelet-rich-plasma-prp-platelet-rich-fibrin-prf-and-conditioned-serum
IV Drips advertising guidance	https://www.tga.gov.au/resources/resource/guidance/advertising-guidance-businesses-involved-intravenous-iv-vitamin-and-related-therapies

How did we go?

Take a moment to complete our survey

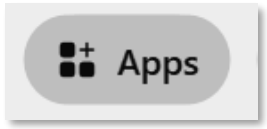


Use the app in Webex

Use the QR code

Questions?

As us through Slido



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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration