

Advertising health services and cosmetic injections

Frequently Asked Questions and answers

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About these Frequently Asked Questions (FAQs)

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Advertisers are encouraged to read our updated guidance on <u>Advertising health services</u> for detailed information on how to advertise health services, including cosmetic injection services, without unlawfully advertising therapeutic goods.

This page provides advertisers with answers to frequently asked questions in relation to these products.

It is the responsibility of each advertiser to ensure their advertisement does not promote therapeutic goods in a way that is not compliant with the legislative requirements. To obtain advice specific to your circumstances you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant. Please note, these consultants are not endorsed by us.

General questions about referring to cosmetic injectables in advertising

Why have guidelines for advertising cosmetic injections been updated?

We have updated our guidance on advertising cosmetic injectables to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods.

Detailed information on the background to these changes is provided in our media release <u>Referring</u> to cosmetic injectables in advertising.

What has changed?

The legislation regarding cosmetic injectables has not changed. Most cosmetic injectables contain substances that are in Schedule 4 to the <u>Poisons Standard</u> and, in accordance with the *Therapeutic Goods Act 1989* (the Act), cannot be advertised to the public.

We no longer expressly permit references to terms such as 'wrinkle reducing injections' or 'dermal fillers' where those terms would result in a reasonable consumer understanding the intention of the content is to promote the use or supply of a prescription-only medicine or good containing such as substance. This includes through acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to a specific prescription-only medicine or substance.

This does not apply to cosmetic injectables that do not contain any prescription-only substances.

Can you provide me with a list of acceptable terms for describing the cosmetic injection services I offer?

In line with the <u>TGA customer service standards</u>, we do not give advice on specific issues, or advice specific to individual circumstances. Therefore, we cannot advise in specific terms what can be done by industry or provide a list of 'acceptable' or 'substitute' terms.

As outlined in our guidance on <u>Advertising health services</u>, clinics should focus their advertising on the types of consultations available instead of referring to prescription-only medicines or substances used in the treatments they offer.

Advertisers must determine if the information they are disseminating would meet the Act's definition of 'advertise' in relation to therapeutic goods. In doing so, they should consider if the viewer would reasonably consider the intention of the information is to promote the use or supply of a therapeutic good.

How can I communicate treatment options with my patients?

Prescription-only medications carry higher risks than goods available for self-selection. It is important that all patients can make informed and accurate decisions about which cosmetic treatment is right for them.

The most credible information around whether a prescription-only medicine is right for a specific patient comes from a consultation between a patient and their appropriately trained and qualified health professional.

While the advertising of therapeutic goods is within the jurisdiction of the Act, it does not extend to the education of patients and clients, provided the information is non-promotional.

Additionally, information shared between a health practitioner and their patient during a private consultation or treatment, is not subject to the advertising rules for therapeutic goods.

Are phone consultations allowed with patients?

The regulation of health services, including telehealth (phone) consultations between a patient and their treating health practitioner, is not within our jurisdiction.

Additionally, information shared between a health practitioner and their patient during a private consultation or treatment, including through telehealth consultation, is not subject to the advertising rules for therapeutic goods.

How can I advertise my cosmetic injection service without advertising therapeutic goods?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. This would have to be considered in context as other information in the promotional material could make it clear to consumers that what is being offered (promoted) are prescription-only substances or goods that contain such substances.

Can non-medical staff at a clinic answer direct questions from patients or potential patents about which cosmetic injectables are offered at the clinic?

If information provided by non-medical staff would be reasonably taken by its audience to be intended to promote the use or supply of a prescription-only medicine or substance, the information is likely to be considered advertising.

Generally, solicited information (requested or asked for by a patient) is less likely to meet the legislative definition of 'advertise' than unsolicited information that is published or widely disseminated. Giving information necessary to answer a direct question (without providing additional information that could be taken to be intended to be promotional) is unlikely to be advertising. However, this will depend on what is communicated in the telephone conversation or in person.

Can I refer to cosmetic injectables in my client booking system?

Publicly available booking systems that draw consumers to a service on the basis that specific therapeutic goods are used in the delivery of the service are likely to be an advertisement for **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.

Is educational content about 'cosmetic injectables' or 'injectables' considered to be an advertisement?

Not all information released to the public about therapeutic goods is advertising. However, if the intention of the information (from the end viewer's point of view) is to promote the use or supply of a therapeutic good then we would likely consider it to be advertising and it must meet the legislative requirements as set out in the Act.

Whether or not information is an advertisement or not must be considered in context on a case-by-case basis. In general, the following types of information are unlikely to be considered advertising:

- information about the risks that may be associated with using cosmetic injectables
- information about training courses or training material for health care professionals.

Educational information for patients that is purely factual and balanced (communicates risks and benefits) and is non-promotional in nature is also unlikely to be considered advertising. Examples include 'before' and 'after' care instructions.

Why have surgeons and surgical procedures not been addressed in this change?

We regulate the advertising, manufacture, import, export and supply of therapeutic goods, which include medicines, medical devices and biologicals.

By contrast, the regulation of the promotion of health services is not within our jurisdiction.

The <u>Australian Health Practitioner Regulation Agency (Ahpra)</u> and the National Boards regulate health practitioners and their practices/services which encompasses surgeons and surgical cosmetic procedures.

Why has the cosmetic industry come under more scrutiny than other industries?

We have updated our guidance on Advertising health services, including cosmetic injection services, to ensure advertising rules are applied consistently across all industries that deal with therapeutic goods. The legislation regarding cosmetic injectables has not changed.

Recently we have witnessed the widespread promotion of health services (including telehealth) which seeks to attract consumers on the basis that particular prescription-only medicines (for example 'weight loss injections', 'nicotine vaping products', or 'medicinal cannabis'), can be prescribed at, and in some cases supplied by, the health service.

We interpret that this type of advertising is an advertisement for a therapeutic good that refers to prescription-only medicines, which is unlawful. We were concerned to resolve any inconsistency in interpretation across all industry areas.

We have taken enforcement actions against entities across a number of industry areas for alleged unlawful advertising of prescription-only medicines. More information can be found at Compliance actions and outcomes.

FAQs about advertising specific products and treatments

How can I find what substances are part of the Schedule 4 drugs list?

Information relating to how prescription-only substances are scheduled, along with a link to the current version, can be found on the Poisons Standard (the SUSMP) webpage.

Can I advertise a bio-stimulator such as Sculptra?

Sculptra contains the substance Poly-L-lactic acid, which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Sculptra (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise REJURAN?

In Australia, Rejuran is regulated as a Class III medical device. Rejuran is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (does not contain a prescription-only or pharmacist only medicine) and is not prohibited from being advertised to the public.

Can I advertise polydioxanone (PDO) threads?

PDO threads are regulated as a Class III medical device. Polydioxanone is not covered by an entry in Schedule 3, 4 or 8 to the Poison Standard (do not contain a prescription-only or pharmacist only medicine) and are not prohibited from being advertised to the public, provided the product is included in the <u>Australian Register of Therapeutic Goods (ARTG)</u>.

Can I advertise Masseter treatment?

Advertisers cannot make any reference, directly or indirectly, in their advertisement to prescriptiononly substances or to the trade names of prescription-only goods. This includes acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to the specific good or substance.

If a reference to the 'Masseter treatment' is likely to be taken by the audience to be a reference to a prescription-only substance or good containing such as substance this would likely contravene the Act.

Please note that advertising a therapeutic good for an indication that has not been accepted in relation to the inclusion of the good on the register, for example advertising Botox for an off-label use, is also prohibited by the Act.

Can I advertise Profhilo?

Profhilo contains hyaluronic acid which is included in Schedule 4 to the Poisons Standard and is prohibited from being advertised to the public. References to Profhilo (however made) in a clinic's promotional material are likely to result in the promotional material also being an advertisement in relation to a therapeutic good and would likely contravene the Act.

Can I advertise Platelet Rich Plasma (PRP), bio-remodellers and monothreads?

PRP, bio-remodellers and monothreads are outside the scope of these changes if they do not contain any substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard (i.e. do not contain a prescription-only or pharmacist only medicine).

It should be noted that the application of the legislative requirements around advertising PRP is complex – we encourage stakeholders to seek independent advice if necessary.

Can I advertise energy-based medical devices used in cosmetic procedures such as lasers, ultrasound and radio frequency devices?

In general, medical devices that do not contain substances covered by an entry in Schedule 3, 4 or 8 of the Poison Standard may be lawfully advertised to the public (subject to meeting applicable regulatory requirements which may include inclusion in the ARTG). Advertisements for these devices

must comply with all applicable legislative requirements, including the Therapeutic Goods Advertising Code.

How can I explain to patients that we can assist with medical conditions such as migraines, hyperhidrosis, TMJ etc?

To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement. It is the advertiser's responsibility to focus on the service being provided at the practice and not the medicine being administered to treat the condition.

As a general guide, promoting the type of health practitioner consultations being offered at a health service would be unlikely to make the promotional material an advertisement about therapeutic goods. For example, 'call our clinic for a consultation to discuss treatment options for migraines'.

Questions about specific types of advertising

Can I provide price lists for 'anti-wrinkle injections' and 'dermal fillers'?

The prohibition on advertising therapeutic goods containing prescription-only substances to the public applies to any 'statement, pictorial representation or design' that promotes the use or supply of the goods. Generally, stating a price in reference to a prescription-only cosmetic injectable (irrespective if it is total cost of treatment or cost per unit) is likely to be considered an advertisement for that product.

Under the advertising legislation price lists may be published for prescription medicines subject to strict requirements. These include price lists/pricing information:

- may only be published or disseminated by a retail pharmacy or agent acting on behalf of a retail pharmacy
- must contain no less than 25 medicines
- must be in alphabetical order and grouped into their specific scheduling.

It is unlikely that a cosmetic clinic would meet the definition of a retail pharmacy and therefore publication of price lists/pricing information (for prescription-only medicine or substance) by cosmetic injection services is likely to contravene the Act.

Can I place advertisements in the reception area?

Information shared between a health practitioner and their patient during a private consultation or treatment, is not subject to the advertising rules for therapeutic goods.

However, this is unlikely to extend to the displaying of advertisements in the reception area and therefore doing so is likely to contravene the Act.

Can I refer to cosmetic injectables to describe 'before and after' photos?

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.

Advertisers of cosmetic injection services have an obligation to comply with the legislative requirements for advertising therapeutic goods as well as any requirements governing the advertising of services, which are administered by Ahpra.

Where 'before and after' photos are used and it is apparent that the 'after' photo is due to the administration of a prescription-only cosmetic injectable, this is likely to amount to an advertisement for a therapeutic good that would contravene the Act.

Do I need to update old social media content that refers to cosmetic injectables?

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.

For more information about advertising on social media, please review our <u>social media advertising</u> guide which should be read in conjunction with the guidance on advertising health services.

Am I responsible for social media posts where a patient has referenced my clinic?

Business owners are responsible for the content of social media pages created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

Although it is up to the party responsible for the advertising to ensure compliance with the requirements, we recommend that businesses also provide corrective information if they become aware of misinformation from third parties on social media channels for which they are not responsible and endeavour to remove any identifying factors (such as hashtags).

Advertisers should ensure any corrective information also complies with the advertising requirements if it is used within an advertisement or is an advertisement in its own right.

For more information, please visit our social media advertising guide.

Can I refer to 'injectables' in my business name?

Consistent with guidance we have provided for other industries, advertisers that promote treatment services need to take care to ensure that they are not, in addition to promoting their services, also promoting prescription-only medicines or substances.

Whether a business name would be likely to result in a contravention of the Act must be considered in context on a case-by-case basis and depends on the surrounding information and materials that accompany the clinic or business name. As is always the case, the likely consumer take-out of any representation (including a business name) must be considered in its entirety.

In general, if a business name includes a reference to a prescription-only good (even generically using terms such as 'injector' or 'injectables') it is more likely that a consumer viewing the promotion of the service would consider that the service includes the use of these prescription-only goods. This includes references made directly or indirectly to prescription-only goods through references such as:

- a trade names
- an abbreviation or acronym
- a colloquial name.

Can suppliers of cosmetic injectables advertise to clinics?

The advertising of prescription-only cosmetic injectables directed exclusively to health professionals (and other persons mentioned in section 42AA of the Act) is not prohibited. This includes advertising directed to medical practitioners, nurses, purchasing officers and practice managers.

This reflects the position that the training and expertise of health professionals means they have the appropriate knowledge to critically evaluate information contained in advertisements. It also recognises that those who are responsible for purchasing therapeutic goods used by health professionals in a medical or dental practice or a hospital (such as practice managers and hospital purchasing officers) should not be prohibited, for pragmatic purposes, from viewing advertisements for prescription-only goods.

Allowing persons other than health professionals to view advertising intended for health professionals (or the other individuals mentioned in section 42AA of the Act) will generally be considered unlawful advertising to the public. Such advertising may disrupt the doctor/patient relationship and create an inappropriate demand for a good or encourage inappropriate self-diagnosis.

Businesses must ensure that information provided for health professionals is not in the public domain or publicly accessible. See advertising to health professionals for more information.

Questions about compliance and enforcement

How long do I have to comply with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the new guidance. However, we understand that it will take time for industry to embed the changes into their business practices.

Future enforcement will be consistent with our approach to <u>compliance management</u> and we will seek high levels of voluntary compliance by engaging and educating the industry in the first instance.

How will you monitor and enforce compliance with the updated guidance?

We expect industry to take prompt steps to review their existing advertising of cosmetic injectables to bring it into line with the updated <u>Advertising health services</u> guidance.

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. For more information on the types of actions we may take, please see the Compliance and enforcement hub on our website.

If you suspect non-compliance in relation to therapeutic goods, we encourage you to report illegal or questionable practices and suspected non-compliant advertising to us using our <u>reporting portal</u> form.

What are the consequences or penalties if you become aware a business or practitioner is non-compliant with the Act?

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

We understand the clarifications will take time for industry to embed into their business practices and we will continue to assist industry to bring their advertising into compliance. Consistent with the our approach to compliance, we will seek high levels of voluntary compliance by engaging with and educating industry in the first instance.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section	April 2024
V2.0	Updated questions and answers following the webinar 'Advertising cosmetic injection health services compliant with therapeutic goods legislation' on 10 April 2024	Advertising and Compliance Education and Policy Section	May 2024

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