



Overview of the TGA's planned cosmetic injectable mailout

The Therapeutic Goods Administration (TGA) safeguards the health of the Australian community through effective and timely regulation of therapeutic goods. Appropriate regulation helps ensure that the medicines and medical devices that millions of Australians rely on are safe and fit for purpose.

Our compliance functions support the broader regulatory objectives, including consumer protection, and enable a fair market for industry. We monitor, and enforce where necessary, compliance with the legislation, regulations and rules for therapeutic goods, import, manufacture, advertising, supply, and export.

The rapid advancement of technology and the increase in sophisticated, data-driven advertising campaigns has resulted in a significant volume of non-compliant advertisements. To address this increase, the Regulatory Compliance Branch (RCB) within the TGA has formed a new Targeted Compliance Unit (TCU).

This TCU will concentrate on monitoring and addressing non-compliant advertising, by focussing on identified non-compliance outside our published compliance priorities.

To ensure compliance, the team will soon launch a targeted letter campaign addressing non-compliant advertising of cosmetic injectables. Each reported entity and individual will receive:

- **Guidance Letter:** Informing and guiding on how to be compliant with advertising rules, referencing relevant legislation, best practices, and guidance. Encouraging voluntary review and removal of non-compliant advertising.
- **Top 10 Fact Sheet (attached):** Information on the most common questions asked by advertisers.

The recipients will be given four weeks to adjust their advertising, during which we will monitor for behavioural changes. Those who consistently or deliberately exhibit severe misconduct will undergo assessment for potential compliance or enforcement actions. The TCU will address the remaining reports on in subsequent rounds. An initial, 50 reported individuals and entities will receive letters in the first round, the remaining reports will be contacted in a future round.

We encourage you to share this information with your members and urge them to review their advertising to ensure it is compliant. Further guidance is available at:

- [Regulation basics | Therapeutic Goods Administration](#)
- [Advertising health services](#) and [cosmetic injections: FAQs](#)
- [Presentation: Advertising cosmetic injection health services compliant with therapeutic goods legislation](#)
- [Cosmetic Injectables: Import and Supply in Australia](#)

We welcome your feedback. If you have any questions or concerns, please contact us by email at Targeted.Compliance@TGA.gov.au

From: [TGA Info](#)
To: [TGA Advertising](#)
Subject: FW: Report of breach of Act or questionable practices - Dermal fillers and injectable cosmetic treatments [SEC=OFFICIAL] CCEMS:02960007056
Date: Tuesday, 3 June 2025 10:06:29 AM

Dear Team

Please find the below email correspondence for your action from: tga.no-reply@govcms.gov.au.

If your area has received this incorrectly, please let us know.

Kindly ensure that any internal correspondence, including this forwarding email, is deleted prior to sending the response.

If you are responding directly to an external enquiry, you are responsible for ensuring that the [TGA customer service standards](#) are met.

If your area does not have access to a generic email address, the TCC can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.

If you have any questions about this email, please contact us.

Kind regards,

s22

TGA Contact Centre

Regulatory Assistance Section

Regulatory Engagement Branch

Phone: 1800 020 653 | Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration

Department of Health, Disability and Ageing

PO Box 100

Woden ACT 2606

www.tga.gov.au



This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

----- Original Message -----

From: Therapeutic Goods Administration ;

Received: Fri May 30 2025 20:39:57 GMT+1000 (Australian Eastern Standard Time)

To: TGA Info ; info-Queue ;

Subject: Report of breach of Act or questionable practices - Dermal fillers and injectable cosmetic treatments

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Report of a perceived breach of the Therapeutic Goods Act or questionable practices

relating to therapeutic products

Submitted on Friday, May 30, 2025 - 20:39

Contact details

Reporter's name: Pseudonym doctor

Reporter's email:

Reporter's telephone number:

Reporter's mobile phone number:

Reporter's fax number:

Details of problem

Date problem was encountered: 2025-05-30

Name of product of concern: Dermal fillers and injectable cosmetic treatments

AUST R or AUST L number on product label, if known:

Name of company/person supplying the product: The Skin Doctor - Dr Chris Irwin

Address of company/person, if known: Unit 1/1065 Heidelberg Rd, Ivanhoe VIC 3079

Contact details of company/person, if known (telephone, fax website, etc.):

<https://theskindoctor.melbourne/doctors/dr-chris-irwin/>

Details of problem - please be as specific as possible:

<https://theskindoctor.melbourne/dermal-fillers/>

<https://theskindoctor.melbourne/anti-wrinkle-injections/>

<https://theskindoctor.melbourne/bio-remodelling/>

This clinic is advertising dermal fillers by name, anti-wrinkle injections and bio remodelling injections using the hyaluronic acid names. Their online information and marketing potentially breaches the guidelines for Non-surgical cosmetic procedures. The SEO for these pages is "Learn about Eczema and the Treatment", indicating a decision to hide this information from Google searches to avoid impressions when searching for this information online.

Do you have a sample of the product or any other supporting material? No



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

<<Advertising Entity Name>>

By Email only:

<<entity email>>

<<Date of Letter>>

Dear Proper Officer

TGA Guidance Letter

Who we are

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods and forms part of the Australian Government Department of Health and Aged Care. We are responsible for regulating therapeutic goods, including **prescription medicines and cosmetic injectables** in accordance with the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations), and the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the Code).

Commented [scg 1]: Tranche specific

Why you are receiving this letter

This letter is to inform you that the TGA has received a **report** about your alleged advertising of **cosmetic injectables**.

Commented [scg 2]: Tranche specific

In Australia, advertising prescription-only medicines directly to the public is prohibited under the Act, subject to very limited exceptions.

The TGA intends to review your website **four weeks** from the date of this letter to ensure it complies with the requirements. You will be notified of the outcome following the review.

Your advertising will be reviewed

As a general rule advertisements should not:

- Refer to prescription medicines including substitute terms and nicknames.
- Refer to a serious condition 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 of the Poisons Standard)
- Refer to biologicals
- Refer to therapeutic goods that are not entered in the ARTG
- State or imply Government/TGA endorsement

What you need to do

- **Familiarise** yourself with the Act, the Code, and the Regulations. You are encouraged to read our guidance on [advertising health services](#) for detailed information on how to advertise health services, including [cosmetic injection services](#), without unlawfully advertising therapeutic goods. For more details on our regulatory practices, please visit the [advertising section of the TGA website](#).
- **Review** your website and any associated advertising (including social media) to ensure it meets all the requirements.
- **Stop** any advertising that contravenes the advertising requirements for therapeutic goods
- **Ensure** that any therapeutic goods, including medicines and medical devices, that you use in procedures are entered in the Australian Register of Therapeutic Goods (ARTG). If you cannot find your product or device on the register, contact the supplier or manufacturer.
- **Seek further guidance:** If you need general information on advertising a therapeutic good, make an enquiry through our [online portal](#).
- If you are unsure about your obligations in relation to the advertising of therapeutic goods, seek advice from a lawyer or regulatory affairs consultant.

Commented [s22]3]: Tranche specific

Resources to support you

- For further information on regulation, please visit [TGA Regulation Basics](#).
- [The TGA has prepared a frequently asked questions page on advertising health services and cosmetic injections](#).
- [In April 2024, the TGA conducted an online seminar on advertising cosmetic injection health services compliant with therapeutic goods legislation. For further information on this seminar, including the presentation slides, please visit TGA Online Education Events](#).
- [To help understanding of the rules surrounding importation of cosmetic injectables, please visit Cosmetic Injectables: Import and Supply in Australia](#)
- The attached Factsheet - 10 Tips for Complying with TGA Advertising Rules.

Commented [s22]4]: Tranche specific

We welcome your feedback

As a regulator, the TGA is unable to provide formal, definitive advice regarding specific advertising scenarios. If you need specific advice, we encourage you to seek advice from a lawyer or regulatory affairs consultant.

You do not need to reply to this letter. If you have any questions or feedback, including suggestions, please contact my team via email at targeted.compliance@tga.gov.au.

Yours sincerely,

Targeted Compliance Unit
Therapeutic Goods Administration



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Advertising Entity Name
ACN

Our Reference: CRM case
number

By Email only: entity email

Date of Letter

Dear Proper Officer

TGA Notification Letter

Who we are

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods and forms part of the Australian Government Department of Health, Disability and Ageing. We enforce the import, supply, and advertising requirements relating to therapeutic goods, including <Tranche specific>, in accordance with the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations), and the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the Code).

Why you are receiving this letter

We previously wrote to you in relation to the alleged advertising of <<cosmetic injectables>>. ¹ We have now reviewed your advertising of therapeutic goods, including <Tranche specific> on <<website/social media/store>> and are concerned that you are advertising therapeutic goods in a way that contravenes the Act.

As a general rule advertisements should not:

- Refer to prescription medicines including substitute terms and nicknames.
- Refer to a serious condition 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 of the Poisons Standard)
- Refer to biologicals
- Refer to therapeutic goods that are not entered in the ARTG
- State or imply Government/TGA endorsement

Contraventions of the advertising requirements under the Act can result in criminal penalties of up to 5 years imprisonment or \$1.32 million or both, for individuals and \$6.6 million for corporations. Civil penalties of up to \$1.65 million for individuals or \$16.5 million for corporations can apply.

¹ TGA guidance letter dated <date of guidance letter>

What you need to do

- **Review the Guidance:** The import, export, manufacture, supply and advertising of therapeutic goods in Australia is subject to the requirements of the Act and the Regulations. Please read the [TGA guidance](#) on therapeutic goods advertising.
- **Review your Advertising:** We ask that you immediately **review** the advertising on all websites, social media and physical signage and **cease** any advertising that contravenes the advertising requirements for therapeutic goods.
- **Seek Advice:** Consider engaging a regulatory affairs consultant or independent legal adviser to ensure lawful operation within Australia's regulatory framework for therapeutic goods.
- **Seek further guidance:** If you need general information on advertising a therapeutic good, make an enquiry through our [online portal](#).

Next Steps

- The TGA intends to undertake a further review of your advertising **four weeks** from the date of this letter. You will be notified of the outcome following the review. If you have not taken action to voluntarily cease any non-compliant advertising at that time, the TGA's Serious Non Compliance Team may consider compliance or enforcement action in accordance with our [regulatory compliance framework](#).

Important information

- Please note there have been recent Federal Court decisions in which the Court clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse for contravening the Act.² Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those laws from the outset³

We welcome your feedback

As a regulator, the TGA is unable to provide formal, definitive advice regarding specific advertising scenarios, if you need specific advice, we encourage you to seek advice from a lawyer or regulatory affairs consultant.

You do not need to reply to this letter. If you have any questions or feedback, including suggestions, please contact my team via email at targeted.compliance@tga.gov.au and quote the reference number at the top of this letter.

Yours sincerely,

Targeted Compliance Unit
Therapeutic Goods Administration

² [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865 \(fedcourt.gov.au\)](#) at paragraph [76].

³ [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

#	Assigned to	Received Date	Case Number	TRM Folder	Advertiser Name	Associated Advertiser Name	ACN/ABN	Email	URL	Report Good	Reporter type	Review of advertising completed	Requires letter	Guidance & Fact Sheet Date	TRIM	Responded	4 week review	Supervisor approval	Date closed	Notification Letter Date	TRIM	4 week review	Date closed	Date escalated
		03.06.2025	AC-000000046946	025-417545	Jun 25 - The Skin Doctor	The Skin Doctor	17 189 454 376	team@thelocalsdoctor.com.au	https://thepinkdoctor.mg/bounce	Dermal filler	Consumer	12.08.2025 - Website 'Cosmetics and Skin Treatments' tab references 'hyaluronic' 'dermal fillers' and 'hyaluronic acid'.	Y	19-Aug-25	025-389 1045		15/10/2025 MM - Proceeded with Notification letter - Website appears largely unchanged. References to 'Dermal fillers and Cosmetic hyaluronic'.			17-Oct	025-409 1230	15-Nov		