

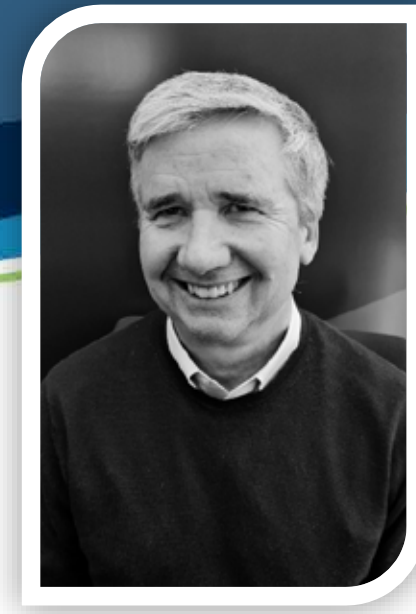
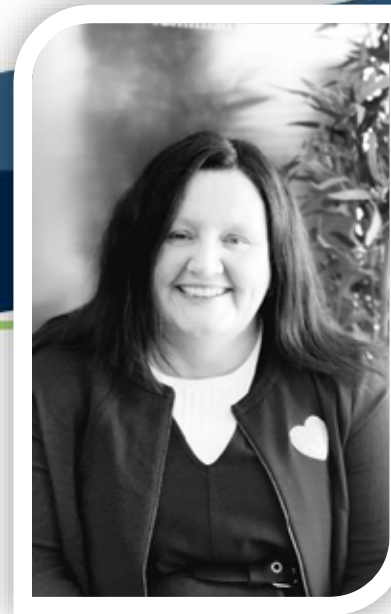


Australian Government  
Department of Health  
Therapeutic Goods Administration

# Proposed improvements to the Therapeutic Goods Advertising Code

Information session

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Regulatory Compliance Branch  
Therapeutic Goods Administration



3 June 2021

**TGA** Health Safety  
Regulation

# Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question to the **speaker** – Please use the **Q&A** tool
  - Messages will only be visible to the moderator and speaker
  - Questions will be answered at the end of the presentation
- If you need to contact the moderator – please use the **‘Chat’** function
- Relevant links will be sent to you via the chat function box
- Live polls will be conducted throughout this event.



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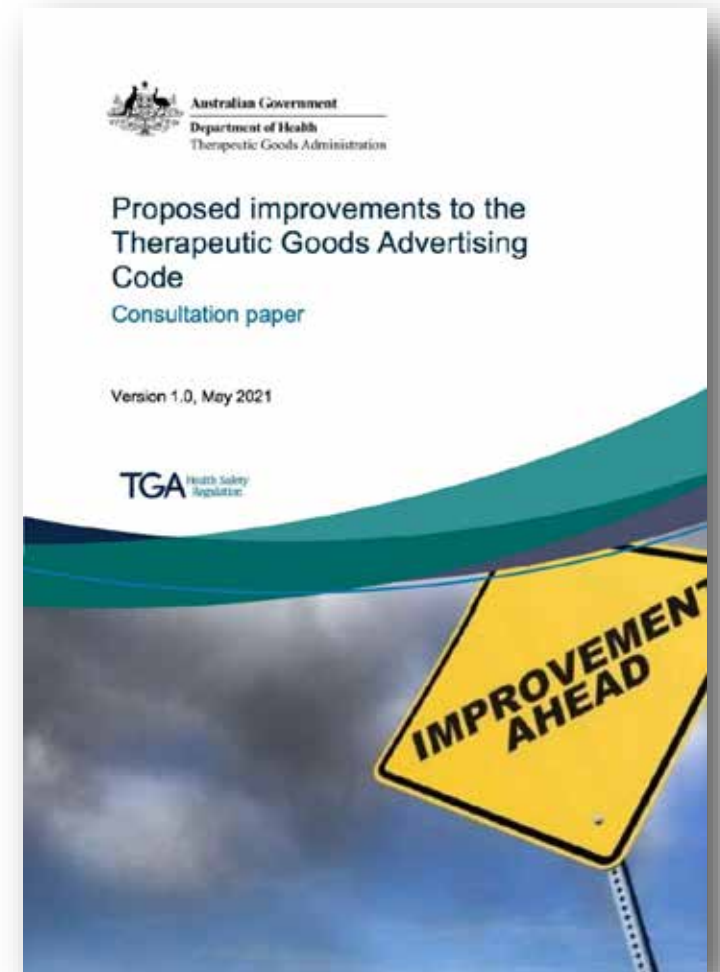
OR

**Dial:** +61-2-9338-2221

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# Objectives of today's webinar

- Provide an overview of the key issues canvassed in the public consultation paper
- Provide support to stakeholders in considering the consultation paper
- Overview of next steps in process
- Opportunity for Q&A



# Background - Therapeutic Goods Advertising Legislation

- The advertising requirements are set out in the
  - Ø *Therapeutic Goods Act 1989*
  - Ø Therapeutic Goods Regulations 1990
  - Ø Therapeutic Goods Advertising Code (No.2) 2018
- Advertising is also subject to:
  - *Competition and Consumer Act 2010* (Australian Consumer Law)
  - Health Practitioner National Law (regulated health services)

# Therapeutic Goods Advertising Code

- The Code is the compliance standard for advertisements for therapeutic goods
- It sets out the rules for:
  - what is and is not acceptable content in an advertisement
  - the requirements for mandatory information to be included in an advertisement
  - the conditions that apply to certain content and certain advertisers
- The TGA can, and does, take enforcement action against advertisers who breach the Code

# Why review the Code?

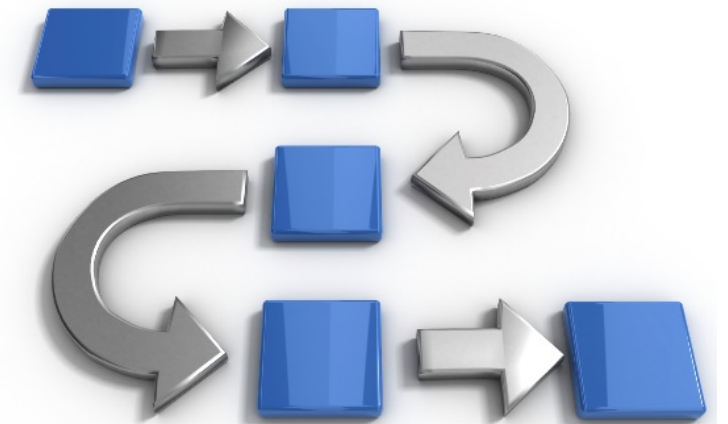
- Current Code in force for 2 years
- Opportunities identified for improvements:
  - Therapeutic Goods Advertising Consultative Committee (TGACC)
  - TGA experience administering the Code
  - Independent review (Sinclair) recommendations





# Consultation process to date

- Initial consultations with TGACC to identify issues and options
  - Divergent views of TGACC membership on particular issues
- Public consultation seeks feedback from a broad range of stakeholders



## Section 4 - Definitions

- Additional definition to provide clarity:
  - **Claim**
    - all claims (therapeutic or otherwise) are captured by the Code
- Adding a Note to section 4 to clarify these definitions:
  - **Indication**
  - **Intended purpose**



# Section 10 – Prohibition on causing fear or distress

- 2018 Code lacks 2015 Code prohibition on causing **fear or distress**
  - Concerns advertisers may seek to take advantage of a lack of consumer knowledge
  - COVID-19 pandemic has provided examples of this type of advertising
- **Proposal to reinstate:**
  - ‘Advertising for therapeutic goods must not exploit consumers’ lack of knowledge or contain language that could bring about fear or distress’***

# Section 11- Alternative mandatory statement

## Scenario 1- new mandatory statement for goods that cannot be purchased by the public

- Words to the effect of:

***“This product is / these products are only available for purchase by health professionals.”***

**OR**

***“This product / these products cannot be purchased by the general public.”***

- For use in situations where products are unable to be purchased by the general public at all in Australia (but the advertising appears in the public domain)
- Would exclude these advertisements from the operation of sections 12 and 13



# Section 11- Alternative mandatory statement

## Scenario 2 - new mandatory statement for therapeutic goods promoted as part of a health service

Example: ad by radiology clinic for a medical imaging machine

- The new statement:
  - for use in situations where the good used in the service is not being promoted for supply (but it does promote use)
  - enables advertisement to more readily (sensibly) comply with the Code



# Section 12 – Goods not available for physical examination

## Section 12 statements used where:

- Goods are not available for examination at the point of (or consideration of) purchase - e.g. online store, mail order catalogue
- Health warning applicable

## Issues identified:

- Complexity and the number of mandatory statements
- Space limitations
- Ambiguity about where the health warnings are to be placed

# Options

- Where ad is limited by physical space e.g. ad on mobile-friendly website
  - Ø “**This medicine may not be right for you**”
  - Ø “**[click here](#) for important health warnings**”
- Allow an image of the label of the product
  - Ø **This medicine may not be right for you. Read the warnings before purchase**
  - Ø **Immediately followed by an image of the label showing warnings**

## Section 13 – Mandatory statements in other types of advertisements

These statements:

- Remind consumers to always read the label (or instructions for use); and
- Where the good has one or more health warnings, alert consumers to the possibility of an issue through either:
  - The statement **‘This medicine (or product) may not be right for you, read the label before purchase’**, or
  - The inclusion of the applicable health warnings in the advertisement

# Wording of mandatory statements

Issues raised:

- Combining or consolidating mandatory statements
- ‘Grouped’ mandatory statements
- Symptom statements

Options:

- Replace/combine mandatory statements
- Other alternatives?



## Combined mandatory statement for advertisements of one or more medicines with medical device(s) and/or other therapeutic good(s)

**‘These *medical products* may not be right for you. Read the label/instructions for use before purchase.’**

The reference to ‘medical products’ is proposed as a way to reinforce to consumers that the advertised products are not standard consumer goods and a decision to purchase and use them should be carefully considered.

# Catalogue example

*Autumn is*

PARACETAMOL PARACETAMOL PARACETAMOL

Always read the label. Follow the directions for use. If symptoms persist, worsen or change unexpectedly, talk to your health professional. Incorrect use may be harmful.

**FISH!** 40

Always read the label. Follow the directions for use. If symptoms persist, talk to your health professional.

**FISH!** 80

100 mg  
**GLUCOSAMINE**  
 30

Always read the label. Follow the directions for use. If symptoms persist, talk to your health professional.

**Beat the itchy nose woes**

*Pharmacy Pharmacy*  
*Autumn health care tips*

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**SALE**

**BLACK COHOSH** 40

**Block Cohosh** 40

Always read the label. Black Cohosh can harm the liver in some people. Follow the directions for use. If symptoms persist, talk to your health professional.

**IBUPROFEN** 20

XX mg

**Great value**

**IBUPROFEN** 20

XX mg

**IBUPROFEN** 20

XX mg

**IBUPROFEN** 20

**IBUPROFEN** 20

This product may not be right for you. Read the instructions for use before purchase.

abdominal pain, nausea, vomiting or diarrhoea. Follow the directions for use. If symptoms worsen or change unexpectedly, talk to your health professional.

This medicine may not be right for you. Read the label before purchase. Follow the directions for use. If symptoms persist, worsen or change unexpectedly, talk to your health professional. Incorrect use may be harmful.

Pharmacy Pharmacy - p.6

# Symptom statements

- **If symptoms persist, talk to your health professional; or**
- **If symptoms worsen or change unexpectedly, talk to your health professional**
  
- Code allows for these to be shortened and combined to avoid duplication
- Not required in radio advertisements 15 seconds or less in duration/text only advertisements 300 characters or less

## **For consideration:**

- How useful are these statements?
- Do they prompt consumers to seek health professional advice?

# Schedule 1 – health warnings

- Issues reported with using Schedule 1
  - complex
  - resource intensive
  - etc
- A new approach has been suggested for determining the relevant health warnings for a medicine advertisement

## Proposed new process – identifying health warnings

Step	Action
1	Check the label of the medicine to see if it includes a health warning(s) of a type similar to those listed in the new Table 1.
2	Check the label of the medicine to see if there are any specific health warnings applicable to the advertised product (new Table 2).
3	Check the label of the medicine for required health warnings when a medicine contains a substance known to cause an allergic reaction, or is otherwise contraindicated for use in susceptible individuals (new Table 3).

# Example: proposed new process in action

## Ibuprofen product





# Ibuprofen warning panel

- WARNINGS:
- Do not exceed the recommended dose.
- Excessive use can be harmful.
- DO NOT USE IF:
- you have a stomach ulcer, or other stomach disorders, kidney, liver or heart problems
- you are allergic to ibuprofen, aspirin or other anti-inflammatory medicines
- in the last 3 months of pregnancy.
- UNLESS A DOCTOR HAS TOLD YOU TO, DO NOT USE:
- for more than 3 days at a time if you have asthma if you are taking other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines
- if you are trying to become pregnant, or during the first 6 months of pregnancy
- if you are taking medication regularly if you are aged 65 years or over.
- STOP USE AND SEE YOUR DOCTOR IMMEDIATELY IF:
- you have an allergic reaction.
- ADVISORY STATEMENTS:
- Contains lactose.





## How the label statements translate into health warnings in an advertisement:



### WARNINGS:

Do not exceed the recommended dose. Excessive use can be harmful.

### DO NOT USE IF:

**S you have a stomach ulcer, or other stomach disorders, kidney, liver or heart problems S you are allergic to ibuprofen, aspirin or other anti-inflammatory medicines S** in the last 3 months of pregnancy.

### UNLESS A DOCTOR HAS TOLD YOU TO, DO NOT USE:

S for more than 3 days at a time S if you have asthma S if you ....

From Table 1: **pre-existing medical conditions**

### HEALTH WARNINGS:

**Do not use if you have a stomach ulcer, impaired kidney function, heart failure, or allergy to ibuprofen or other anti-inflammatory medicines.**



## How the label statements translate into health warnings in an advertisement:



### WARNINGS:

Do not exceed the recommended dose.  
Excessive use can be harmful.

### DO NOT USE IF:

s you have a stomach ulcer, or other stomach disorders, kidney, liver or heart problems s you are allergic to ibuprofen, aspirin or other anti-inflammatory medicines s **in the last 3 months of pregnancy.**

### UNLESS A DOCTOR HAS TOLD YOU TO, DO NOT USE:

s for more than 3 days at a time s if you have asthma s if you are taking other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines s **if you are trying to become pregnant, or during the first 6 months of pregnancy** s if you are taking medication regularly s if you are aged 65 years or over.

...

From Table 1: **pregnancy and breastfeeding**

### HEALTH WARNINGS:

Do not use if you have a stomach ulcer, impaired kidney function, heart failure, or allergy to ibuprofen or other anti-inflammatory medicines.

**Do not use during the last 3 months of pregnancy.**

**Do not use if you are trying to become pregnant, or during the first 6 months of pregnancy, except on the advice of a health professional.**

## How the label statements translate into health warnings in an advertisement:



### WARNINGS:

Do not exceed the recommended dose.  
Excessive use can be harmful.

### DO NOT USE IF:

if you have a stomach ulcer, or other stomach disorders,  
kidney, liver or heart problems if you are allergic to  
ibuprofen, aspirin or other anti-inflammatory medicines  
if you are in the last 3 months of pregnancy.

### UNLESS A DOCTOR HAS TOLD YOU TO, DO NOT USE:

if you use for more than 3 days at a time if you have **asthma** if you are taking other medicines containing **ibuprofen, aspirin or other anti-inflammatory medicines** if you are trying to become pregnant, or during the first 6 months of pregnancy if you are taking medication regularly if you are **aged 65 years or over**.

...

### From Table 1: seek medical advice

### HEALTH WARNINGS:

Do not use if you have a stomach ulcer, impaired kidney function, heart failure, or allergy to ibuprofen or other anti-inflammatory medicines.

Do not use during the last 3 months of pregnancy.  
Do not use if you are trying to become pregnant, or during the first 6 months of pregnancy, except on the advice of a health professional.

**Talk to your health professional before use if you have asthma, are taking other products containing aspirin or anti-inflammatory medicines, or are aged 65 years or over.**

# Then...

- Check **Table 2** to see if there are any specific health warnings required for specific ingredients
  - for our example ibuprofen product, Table 2 doesn't apply
- Check **Table 3** to see if the medicine contains any ingredients that require a warning (e.g. allergens or other substances that may be contra-indicated)
  - our example ibuprofen product contains lactose
  - s.12 ads for this product would require the health warning from Table 3: “Contains lactose”
  - if there was a significant amount of lactose (i.e. would cause a glycaemic effect), Table 3 also requires the health warning “Contains sugars” in s.12 ads

# Qualifiers...

- The above process is to identify the relevant health warnings for this product.
- The mandatory statements also need to be added to the advertisement.
- For section 12 advertisements, the health warnings must appear somewhere in the ad, with the mandatory statements.
- For section 13 advertisements, there is an option to include the health warnings in the ad with the mandatory statement *ALWAYS READ THE LABEL*; or include only the mandatory statement *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE.*
- The Table 3 ‘substance warnings’ are not required for ads covered by section 13.

## Mandatory statements and health warnings in a s.12 advertisement

Bean's Pain Relief capsules \$10.99

For the temporary relief of pain and fever.

Always read the label.

Follow the directions for use.

Incorrect use could be harmful.

### HEALTH WARNINGS:

Do not use if you have a stomach ulcer, impaired kidney function, heart failure, or allergy to ibuprofen or other anti-inflammatory medicines.

Do not use during the last 3 months of pregnancy.

Do not use if you are trying to become pregnant, or during the first 6 months of pregnancy, except on the advice of a health professional.

Talk to your health professional before use if you have asthma\*, are taking other products containing aspirin or anti-inflammatory medicines, or are aged 65 years or over.

Contains lactose.



**BUY NOW!**

## Mandatory statements and health warnings in a s.13 advertisement

For the temporary relief of pain and fever.  
Available from all good pharmacies.  
Always read the label.  
Follow the directions for use.  
Incorrect use could be harmful.

### HEALTH WARNINGS:

Do not use if you have a stomach ulcer, impaired kidney function, heart failure, or allergy to ibuprofen or other anti-inflammatory medicines.  
Do not use during the last 3 months of pregnancy.  
Do not use if you are trying to become pregnant, or during the first 6 months of pregnancy, except on the advice of a health professional.  
Talk to your health professional before use if you have asthma\*, are taking other products containing aspirin or anti-inflammatory medicines, or are aged 65 years or over.

### Bean's Pain Relief capsules





# Section 16 Endorsements and Section 17 Testimonials

## Endorsement issues

- Proposal to prohibit endorsements by former health professionals
- Prohibition on endorsements by consumer organisations for uses/indications not included in the product's ARTG entry or instructions for use
- The need to distinguish in the Code between endorsements and testimonials to facilitate compliance

## Testimonial issues

- Prohibition on testimonials from those involved in the direct sale or marketing of therapeutic goods to the public
- Clarity of disclosure requirements
- Clarity of verification requirements

# Testimonial and endorsement options

## Option 1: Maintain the existing requirements, with some changes

- Prohibit former health professionals from making endorsements
- Changes to clarify:
  - that the advertising of health benefits inconsistent with indications or instructions through testimonials or endorsements is prohibited
  - the requirements to ‘verify the details’ of testimonial providers
  - that paid testimonials are considered ‘marketing’ and not permitted

# Testimonial and endorsement options continued

## Option 2: Broaden the range of people that can provide testimonials

- Follows the approach proposed in Option 1, with three changes:
  - persons involved solely in the marketing of therapeutic goods (including brand ambassadors) would be permitted to provide testimonials;
  - family members of those involved in the manufacture or supply of the therapeutic goods would be permitted to provide testimonials; and
  - testimonials would require new mandatory statements

# Proposed testimonial statements

Statement	Situation
“Testimonials may not be reliable in determining whether a product is appropriate for others”	All testimonials
“This is a paid testimonial”	When the person providing the testimonial receives payment/valuable consideration
“This testimonial has been provided by a family member of someone involved in the manufacture or supply of this product”	Testimonials provided by a family member of those involved in the manufacture or supply of the advertised therapeutic good/s

# Testimonial and endorsement options continued

## Option 3: Removal of prohibition on testimonials from direct sellers

- builds on the approach proposed in Option 2, with one further change:
  - direct sellers would be permitted to use their own testimonials in or as advertisements for therapeutic goods
    - § **provided** the testimonial is accompanied by a statement to the effect that the person making the testimonial has a stake in the sale of the good
- new mandatory statement proposed:
  - § **“I benefit from the sale of these goods”**




**Sally Seller**  
12 August 2021

Bean's moisturiser cream. A must for my family as we head off to the beach! This hydrating and moisturising cream feels amazing, is non-greasy and has SPF 20 protection. I use it every day. Get in touch and try some for yourself!

**Testimonials may not be reliable in determining whether a product is appropriate for others.**

**I benefit from the sale of these goods.**

**Always read the label. Follow the directions for use.**



10 likes 1 comment 2 shares

Like Comment Share

Most relevant

Write a comment...

George Smith  
Thank you  
Like Reply 1d

# Section 20 and Schedule 3

## Clarification of samples requirements and additional eligible goods

- Provide clarity for advertisers and consumers
- Proposal to amend Section 20 to specify that both the offer, and provision, of a sample are prohibited (the provision of a sample can be an ad in itself)
- Permit applications for therapeutic goods to be considered for inclusion in Schedule 3
- Application and assessment process to be designed
  - Would need to meet the guiding principles
    - § Clear health benefit
    - § Class of goods (not a brand)
    - § Lawful goods only



# Next steps

- Consultation closes 18 June 2021
- Assessment of submissions
- Drafting Code changes
- Further consultation with TGACC
- Update guidance for TGA website
- Communications about progress, implementation
- Making of Code
- Conduct training (format likely to include webinars and face-to-face sessions)



# Contact us

[Advertising.consultation@tga.gov.au](mailto:Advertising.consultation@tga.gov.au)

# Website and link references

Proposed Improvements to the Therapeutic Goods Advertising Code

<https://consultations.health.gov.au/tga/proposed-improvements-to-the-therapeutic-goods-adv/>

Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG)

<https://www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg>

Advertising to the Public: Complying with the Therapeutic Goods Advertising Code

<https://www.tga.gov.au/publication/advertising-public>

TGA Advertising hub

[www.tga.gov.au/advertising-hub](http://www.tga.gov.au/advertising-hub)

Leanne & Graham are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation in our live poll.

**LIVE POLL**

# More information



TGA website [www.tga.gov.au](http://www.tga.gov.au)



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TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>

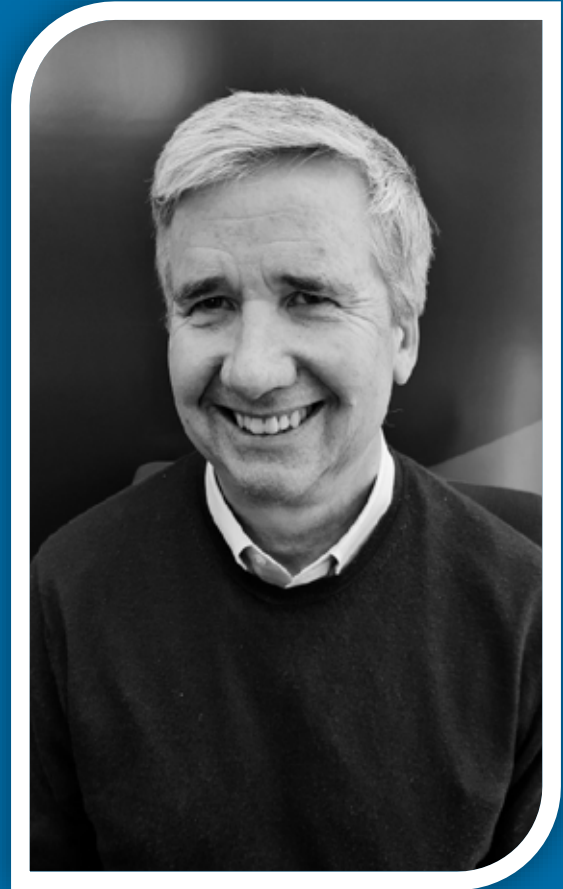


TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>





# Questions?





**Australian Government**

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**Department of Health**  
Therapeutic Goods Administration