



Australian Government

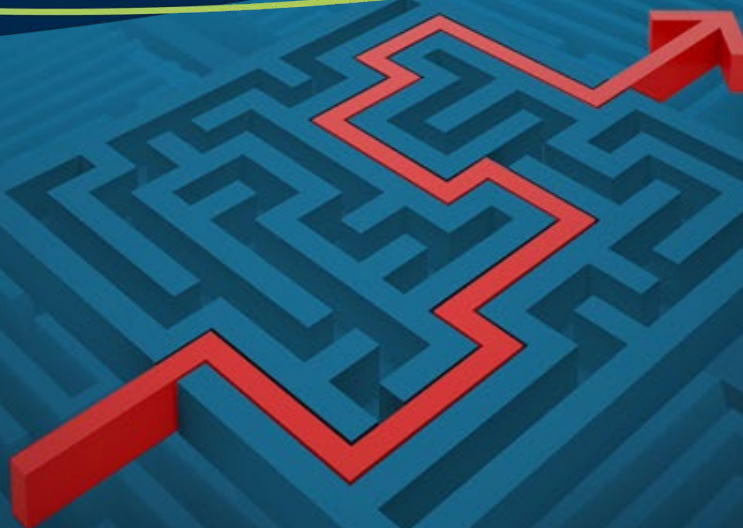
Department of Health

Therapeutic Goods Administration

# SME Assist – ‘Meeting Your Obligations’ Advertising

Faye Lux  
SME Assist

6 December 2019



**TGA** Health Safety  
Regulation



# Disclaimer

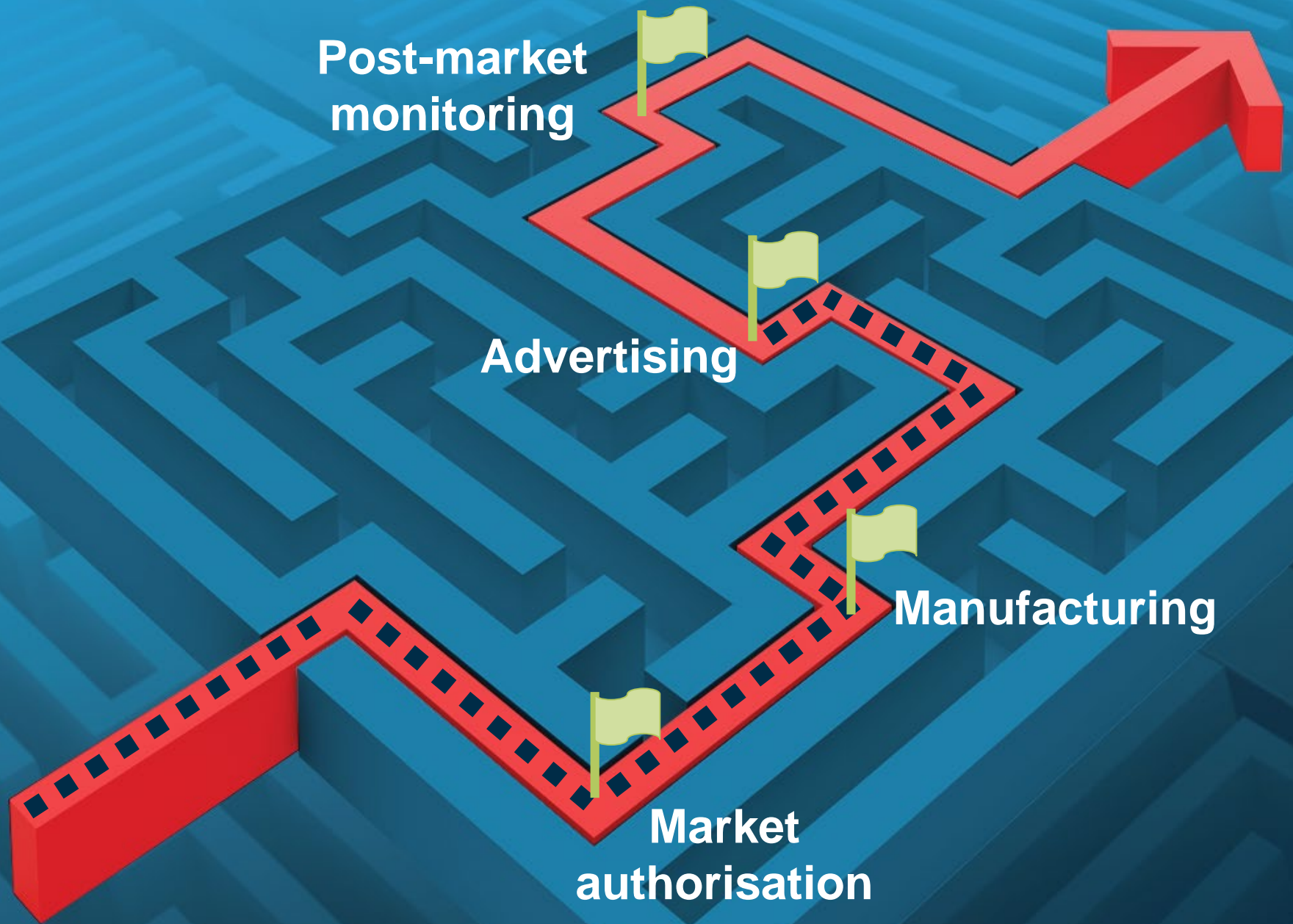
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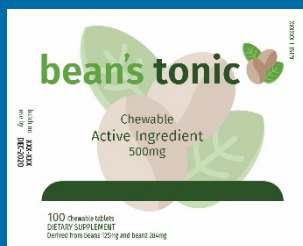
# Advertising





# Advertising requirements apply to all therapeutic goods

Advertising is any promotional material



The Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods Advertising Code (No. 2) 2018.



# Advertising

## Your responsibility

- Advertising requirements vary according to the type of therapeutic good
- Familiarise yourself with the relevant sections of the Act and the Code
- Make sure all of your claims and indications have supporting evidence to back them up
- Don't wait until a complaint or post-market review of your advertising to be compliant
- If in doubt, we have resources for you!



# Therapeutic Goods Advertising Code (No.2) 2018

## Key sections:

- Preliminary - definitions, object, application
  - **Section 4** - Definitions
- General requirements for advertising therapeutic goods
  - **Section 9** - Accuracy
  - **Section 15** - Scientific or clinical representations
  - **Section 16** - Endorsements
  - **Section 17** - Testimonials
- Specific rules relating to particular therapeutic goods
- Prohibited & restricted representations





# Why do we regulate advertising?

A false claim can not only be misleading to the public, it can be unsafe!



This says 'cure all' – I won't bother going to the Dr now.

I don't see a warning on here. This must be fine for me to take while pregnant.





# CASE STUDY:

## Advertising Dan's Bean's Tonic





# What not to do...

The image shows a mock-up of a medicine box for 'bean's'. Several callouts point to specific elements on the box that are prohibited:

- No endorsements from health professionals:** A callout points to the text 'Dr Seuss loves beans!' on the box.
- No use of 'restricted representations' – serious forms of conditions, ailments and/or diseases:** A callout points to the text 'This will help beat diabetes.' on the box.
- Only use indications that are on your ARTG entry:** A callout points to the text 'This will help beat diabetes.' on the box.
- No endorsements from government agencies:** A callout points to the Australian Government Coat of Arms on the box.

Other visible text on the box includes 'bean's', 'Active', 'AUST L XXXXX', 'bat no XXX-XXX', 'DEC-2020', and 'nd beanz 284mg'.



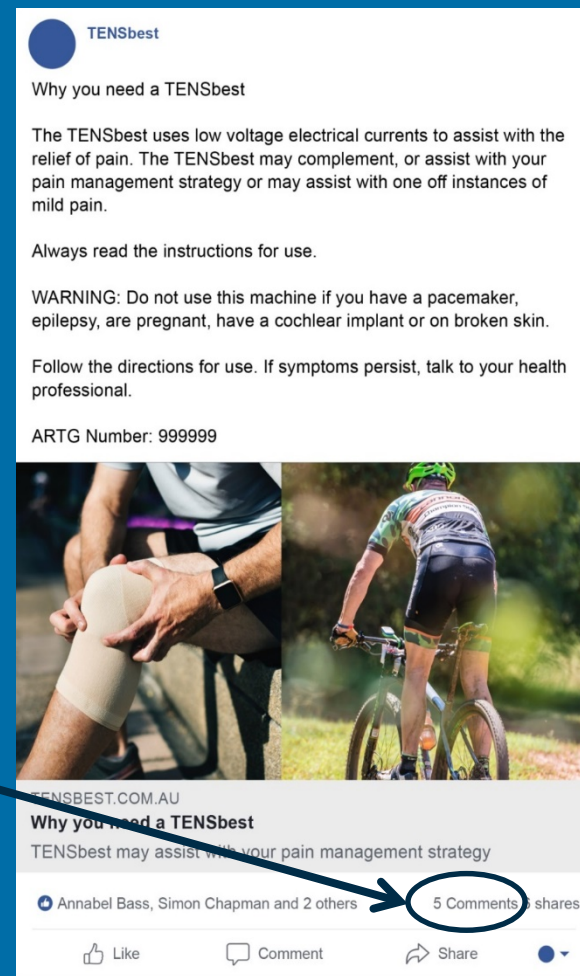
# CASE STUDY: Daphne's Facebook page





# Social media – spot the problem

## Where's the advertising issue?





# Comments are testimonials

Oldest



**Mr Bikeman** I can't wait to try this!



Like . Reply . Message . 3h



**Simon C** I've been using this for a week and it's been great. I see that my bones are getting much thicker and stronger. This is great for preventing rheumatoid arthritis, I'm going to recommend it to my grandma.

Like . Reply . Message . 2h



**Ana B** I've used many TENS with sport accidents over the yrs but this is the ONE! So easy to use & effective, I push through the physio sessions like a boss.



Like . Reply . Message . 2h

**DELETE**

Testimonials must:

- be from verified users
- illustrate typical cases
- comply with all other requirements





# TGA Advertising Hub

- Contains information for both consumers and advertisers, including:
  - advertising basics
  - complaints (now solely handled by TGA)
  - forms for reporting non-compliant advertising and submitting enquiries
  - e-learning modules and decision tools

Contact: ***TGA.advertising@tga.gov.au***



## Advertising hub

**Update:** The Therapeutic Goods Advertising Code (No.2) 2018 [Complying with the Therapeutic Goods Advertising Code \(No. 2\) 2018](#)

**News item:** The TGA is [taking legal action against Peptide Clinics](#)

The advertising hub brings together news and information about therapeutic goods advertising for both consumers and advertisers, including fact sheets, e-learning modules and decision tools. It also provides information about the changes to the framework for advertising therapeutic goods from 2018 and 2020.



**Advertising basics, general information and decision tools**  
I'm looking for general information about advertising therapeutic goods.



**Advertising Code and guidance**  
I am an advertiser and I want to make sure my ad is compliant with the Advertising Code. I'd like to submit an enquiry or request to advertise in specified media. I attended Advertising Code training.



**Complaints and outcomes**  
I saw an ad that I think breaks the rules and I want to make a complaint. I want to know what timeframes, or see the outcome of a complaint.



**Sanctions and penalties**  
I want to know what consequences or penalties advertisers can face for non-compliance.



**Education, training and events**  
I want some training to help me understand everything about therapeutic goods advertising legislation.



**Regulatory decisions and announcements**  
I want to know about notices relating to advertisements or advertising.





# SME Assist

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

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Home Safety information Consumers Health professionals Industry About the TGA News room

## TGA Topics

Learn more about the activities of the TGA on our blog.  
Find out more »

**Consumers**

- Personal importation
- For travellers
- Buying online

**Health Professionals**

- Reporting problems
- Unapproved products
- Special access scheme

**Industry**

- SME Assist**
- Regulation basics
- Scheduling basics

**Recalls and suspensions**

- 'Sartan' blood pressure medicines  
26 February 2019  
TGA investigation - potential contamination with N -nitroso compounds
- Infections associated with heater-cooler devices  
21 February 2019  
Statement on the post-market review of heater-coolers has been updated
- Jurnista (hydromorphone hydrochloride) prolonged-release  
13 February 2019  
Product defect correction - potentially damaged tablets
- ConvaTec Australia devices  
25 January 2019  
Recall of multiple products - potential for breaches of sterile packaging

More safety information »

**? I want to ...**

- Report a problem
- Ask a question
- Login to TGA Business Services
- Subscribe to TGA updates

**☆ Popular**

- Access to medicinal cannabis products
- For travellers & visitors
- Fees & charges
- Poisons Standard (SUSMP)
- Employment & job vacancies
- Regulatory compliance
- New prescription medicine registrations
- Forms
- Publications

**Search databases**

- Australian Register of Therapeutic Goods (ARTG)
- Adverse events (DAEN)
- Recalls (SARA)



# SME Assist

[www.tga.gov.au/sme-assist](http://www.tga.gov.au/sme-assist)

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