

Advertising example

Issues explored in this example

- Substantiation of claims
- Product details
- Mandatory statements
- Endorsements
- Testimonials
- Consistency with ARTG entry
- Miracle cure
- Restricted representations

These advertising examples are intended to be used as an educational aid to illustrate potential non-compliance with the therapeutic goods advertising requirements in Australia. The Australian Government Department of Health (of which the TGA is a part) advises that these examples should not be relied upon as representing a comprehensive description of the regulatory requirements.

The compliance of each advertisement has to be assessed on a case by case basis. To obtain further assistance regarding your advertising and what is required to address non-compliance with the requirements of the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990 and the Therapeutic Goods Advertising Code (No. 2) 2018, you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant.



Why you need a TENSbest

Do you want to be pain free? Do you want a TENS machine that actually works? Reduce inflammation? Heal fast? Revitalise cells? Help with circulation? Our machine is the best product on the market. It is so effective it is approved by the TGA proving they are 100% safe for use at home.



TENSBEST.COM.AU

Why you need a TENSbest

Find out why our product is the best machine on the market

Bikeman Mercer, Simon Chapman and 2 others

5 Comments 6 shares



Advertising example

Substantiation of claims

- Includes claims to:
 - 'revitalise cells'
 - be 'so effective' and '100% safe'
 - help someone 'be pain free', 'heal fast'
- The advertiser must hold appropriate evidence to support these claims. Without substantiation, they are **exaggerations of efficacy**, not accurate or truthful and therefore **false and misleading**
- Plus, advertising for therapeutic goods **must not claim that the goods are safe, cannot cause harm or have no side-effects**
- Refer to Code sections 9(a), 9(b), 10(a)(ii) and 10(d)(i)



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Like



Comment



Share



Advertising example

Product details

- Ads for this medical device must include:
 - an accurate **description** of the device
 - the **name** of the device
 - at least one **indication** as it appears on the product label or packaging
- Refer to Code sections 12(4)(a), 12(4)(b) and 12(4)(c)



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Mandatory statements

- Statements required in relation to the type of therapeutic goods specified are missing
- As this device requires a **health warning**, it must include the statement: ALWAYS READ THE INSTRUCTIONS FOR USE, plus the relevant health warning statement
- Ads including a **claim relating to a symptom of a disease, condition, ailment or defect** must contain the statement: IF SYMPTOMS PERSIST, TALK TO YOUR HEALTH PROFESSIONAL
- Ads for **all devices** must include the statement: FOLLOW THE DIRECTIONS FOR USE
- Refer to Code sections 12(4)(e), 13(6) and 13(7)



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Advertising example

Endorsements

- Includes a claim to be:
 - 'approved by the TGA'
- References to **the TGA**, use of a government logo, or any suggestion that a **government authority endorses** a therapeutic good in any advertisement to the public are not permitted
- Refer to Code section 16(2)(a)



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Advertising example

Endorsements

- A comment on the post includes an endorsement from someone identified as a pharmacist
- Endorsements from **health care professionals** are not permitted
- Refer to Code section 16(2)(c)

Oldest



Bikeman Mercer This machine is the only one that has fixed my fibromyalgia! I am finally back to cycling every day and it's all because of this machine. I feel great!

Like · Reply · Message · 3h



Sandra Boxtton I'm a pharmacist and I recommend the TENSbest machine for pain relief.

Like · Reply · Message · 3h



Simon Chapman Awesome product!

Like · Reply · Message · 3h



Annabel Bass The TENSbest machine is the best TENS I've tried, and I've tried heaps. I really love how easy it is to put on and the variety of settings. It makes me feel good all day.

Like · Reply · Message · 2h



Caleb Hodgson This machine works like magic to make me feel better when I have nerve pain. I'm sure my circulation gets better every time I use it. If only everything in life was this way.

Like · Reply · Message · 2h

Testimonials

- Any testimonials used in advertising must be documented, verified, not misleading and illustrate typical cases only
- Comments on the post include statements which appear to be testimonials, but the **source is not documented or verified**
- Plus, they don't disclose whether **valuable consideration** has been or will be received in exchange for providing the testimonials
- Refer to Code sections 17(2) and 17(3)

Oldest



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Like · Reply · Message · 3h



Simon Chapman Awesome product!

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Annabel Bass The TENSbest machine is the best TENS I've tried, and I've tried heaps. I really love how easy it is to put on and the variety of settings. It makes me feel good all day.

Like · Reply · Message · 2h



Caleb Hodgson This machine works like magic to make me feel better when I have nerve pain. I'm sure my circulation gets better every time I use it. If only everything in life was this way.

Like · Reply · Message · 2h

Consistency with ARTG entry

- Advertising must be **consistent with the ARTG entry** for the goods, including indications
- As the treatment of 'nerve pain' is not an **accepted indication** for the device, this comment promotes 'off-label' use which is not permitted
- Refer to Code section 9(d)

Oldest



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Like · Reply · Message · 2h



Caleb Hodgson This machine works like magic to make me feel better when I have **nerve pain**. I'm sure my circulation gets better every time I use it. If only everything in life was this way.

Like · Reply · Message · 2h

Advertising example

Miracle cure

- Comments include a statement that the device:
 - 'works like magic'
- Advertising must not promote therapeutic goods as **infallible, unfailing, magical or miraculous**
- Refer to Code section 10(d)(iii)

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Like · Reply · Message · 2h



Caleb Hodgson This machine is **works like magic** to make me feel better when I have nerve pain. I'm sure my circulation gets better every time I use it. If only everything in life was this way.

Like · Reply · Message · 2h

Restricted representations

- Comments include a reference to the treatment of 'fibromyalgia', which as a serious form of a disease, condition, ailment or defect, is a **restricted representation**
- Making this reference in advertising is **not permitted without TGA approval**
- Refer to Act sections 42DL(7) and 42DLB(4)

Oldest



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Like · Reply · Message · 2h

Advertising example

Compliance

In this version

- Claims are accurate and **not exaggerated**
- Claims to be 'safe' or 'magic' are **not used**
- ARTG number is included, but references to TGA are **not used**
- Required **product details** are included
- **Mandatory statements** for devices are included, correct for the goods and prominently displayed
- Endorsements are **not used**
- Testimonials are **not used**
- Indications are **consistent** with the ARTG entry
- Restricted representations are **not used**

TENSbest

Why you need a TENSbest

The TENSbest uses low voltage electrical currents to assist with the relief of pain. The TENSbest may complement, or assist with your pain management strategy or may assist with one off instances of mild pain.

Always read the instructions for use.

WARNING: Do not use this machine if you have a pacemaker, epilepsy, are pregnant, have a cochlear implant or on broken skin.

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

ARTG Number: 999999

TENSBEST.COM.AU

Why you need a TENSbest

TENSbest may assist with your pain management strategy

Annabel Bass, Simon Chapman and 2 others 5 Comments 6 shares

Like Comment Share



Australian Government

Department of Health
Therapeutic Goods Administration