Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Advertising Code (No. 2) 2018

The Code basics

Leanne McCauley & Alexandra Dance
Advertising Education and Assurance Section
Regulatory Education and Compliance Branch
Regulatory Practice and Support Division
Health Products Regulation Group

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TGA Health Safety Regulation

Website and link references

- Details of the TGA's advertising complaints handling framework has been published: https://www.tga.gov.au/publication/complaints-handling-advertising-therapeutic-goods-australian-public
- TGA statement on its approach to compliance and enforcement discretion in the changeover to 2018 Code: https://www.tga.gov.au/therapeutic-goods-advertising-update-29-october-2018

- Advertising hub – www.tga.gov.au/advertising-hub
  - Online training module – more to come
  - Australian Regulatory Guidelines for Advertising Therapeutic Goods
- Regulatory affairs consultant / legal advice

- TGA Online advertising inquiry form - https://compliance.tga.gov.au/advertising-enquiry/

Role of the Advertising Code

- The Code is the cornerstone of the advertising framework
  - Requires that advertising supports appropriate use of therapeutic goods and does not mislead or deceive
- Current version is 2015 Code – until 31 December 2018
- The Code was revised to provide clarity and more objective tests to support sanctions and penalties

Compliance with Advertising Code

- Advertising to the public for therapeutic goods MUST comply with the Advertising Code
- Requirement to comply with the Code is specified through a criminal offence and civil penalty provision in the Act:
  - Section 42DM – criminal offence
  - Section 42DMA – civil penalty
- For an ad to be approved under the Regulations, the delegate must be satisfied that it complies with the Code

About the 2018 Code

- The 2018 Code was made on 31 October 2018, to take effect on 1 January 2019
- Principles underpinning 2015 and 2018 Codes are similar
- The 2018 Code is supported by specific guidance

Code version for pre-approvals

- Ads for medicines to appear in specified media require pre-approval under Regulation 5G
- For pre-approval decisions made:
  - On or after 1 January 2019: 2018 Code applied
  - On or before 31 December 2018: 2015 Code applied
- You must allow time for the process, any revisions and Christmas shut downs

Code version applied in compliance

- For ads with current approval: version of Code approved under
- For ads (other than pre-approved ads) that occurred:

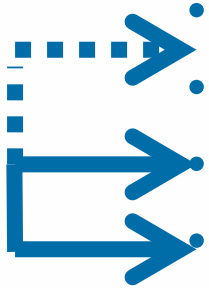
Advertising occurred	Assessed against
On or after 1 January 2019	2018 Code
Before 1 January 2019 and is no longer occurring	2015 Code
Before 1 January 2019 and is still occurring	2018 Code

Compliance approach

- Details of the TGA's advertising complaints handling framework has been published: https://www.tga.gov.au/publication/complaints-handling-advertising-therapeutic-goods-australian-public
- TGA statement on its approach to compliance and enforcement discretion in the changeover to 2018 Code: https://www.tga.gov.au/therapeutic-goods-advertising-update-29-october-2018

Scheduling of medicines

- No advertising to consumers
- S3 – only Appendix H can be advertised
- Can be advertised to consumers



- S8 - Drugs of Dependence – by prescription
- S4 - By prescription only
- S3 - Pharmacist only – behind the counter
- S2 - Pharmacy only
- Unscheduled – General sales item

The Therapeutic Goods Advertising Code 2018 in detail

Structure of the 2018 Code

- Part 1 – Preliminary – definitions, object, application
- Part 2 – General requirements for advertising therapeutic goods
- Part 3 – Specific rules relating to particular therapeutic goods
- Part 4 – Prohibited & restricted representations
- Schedule 1 – Medicines with specific health warnings
- Schedule 2 – Advertising to children
- Schedule 3 – Samples
- Schedule 4 – Price information
- Schedule 5 – Repeals

Part 1 - Preliminary

Section 4 - Definitions

- It is important to read the Code in conjunction with the Act and the Therapeutic Goods Regulations 1990
  - Terms that are not defined in the Code may be defined in the Act and Regulations (e.g. ‘advertise’)
- Most Code definitions straightforward but there are some that we will explore in detail:
  - Health warning
  - Prominently displayed or communicated

What are health warnings?

- In some cases, health warnings need to be included in ads
- Concept of ‘health warning’ is defined in s.4 of the Code
- The purpose of health warnings is to alert consumers to information that will be critical to the consumer's assessment of whether the advertised product is right for them before purchase

Health warning definition - medicines

- Health warnings for medicines are prescribed in Schedule 1 of the Code
- Schedule 1 health warnings are:
  - an exhaustive list but may be updated from time to time
  - based on RASML, permitted ingredients determination, TGO69 and TGO92
  - divided into different parts for warnings for registered medicines, listed medicines and both types of medicines

Example of medicine health warnings

1. Ingredients	2. Circumstances	3. Health warning
Hydroxyanthracene derivatives such as those from: • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna	In preparations for oral use where the MRDD contains MORE than 10mg	Do not use if you have abdominal pain, nausea, vomiting or diarrhoea
Ibuprofen/Paracetamol combinations	In preparations for oral use	Do not use if you have a stomach ulcer, impaired kidney function, heart failure, allergic to anti inflammatory medicines, pregnant or trying to become pregnant

Health warning definition – devices/OTGs

…a statement that is required under the Act or Regulations or Medical Devices Regulations to be included on the label or in instructions for use that warns that a person who takes or uses the device or goods as intended may:

(i) die; or

(ii) require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken or used the device or goods; or

(iii) require a medical practitioner to treat or prevent injury, disability, incapacity or impairment of any bodily function, organ or structure as a consequence of taking or using the device or goods

Prominently displayed or communicated

‘prominently displayed or communicated’ is defined as:

(a) either:

(i) for a visual statement-standing out so as to be easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement-able to be clearly heard and understood; and

(b) repeated as often as is necessary to ensure that it is likely to be noticeable for a viewer or listener.

Section 5 – Object of the Code

"...to ensure that the advertising of therapeutic goods to consumers is conducted in a manner that:

(a) promotes the safe and proper use of therapeutic goods by minimising their misuse, overuse or underuse; and

(b) is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and

(c) supports informed health care choices; and

(d) is not inconsistent with current public health campaigns."

Section 6 – Application

- Applies to:
  - The advertising of therapeutic goods (ss.6(1))
  - By any person advertising or causing advertising (ss.6(5))
- Does not apply to:
  - Genuine news (ss.6(6)) by certain bodies (ss.6(7)) – including broadcasters, datacasters and publishers
  - Advertising directed exclusively to health professionals (ss.6(2))

Section 6 – Application

- How to apply the Code to a particular advertisement:
  - consider its **likely impact** on a **reasonable person** to whom the advertisement is **directed** (ss.6(3))
  - the total **presentation** and **context** of the advertisement is to be taken into account (ss.6(4))

Audience advertisement directed to

- Advertising may be directed to the public in general or a sub-population
- A direction may be made in many forms, including:
  - An overt statement e.g. “Do you suffer from cold sores?”, “For the relief of psoriasis”
  - An implied call to capture the attention of a sub-population e.g. for the measurement of blood pressure
  - The location of the ad e.g. in a magazine for diabetics

Total presentation & context

- Total presentation: the advertisement as a whole
- Context includes:
  - What other information is provided around the advertisement that could change the take-out message? e.g. an editorial on a page opposite the advertisement
  - Does the environment in which it is displayed have the potential to alter the take-out message? E.g. a billboard ad that is viewed when passing in a car at speed

Example – reasonable consumer

Are you looking for a cough & cold remedy for the whole family?

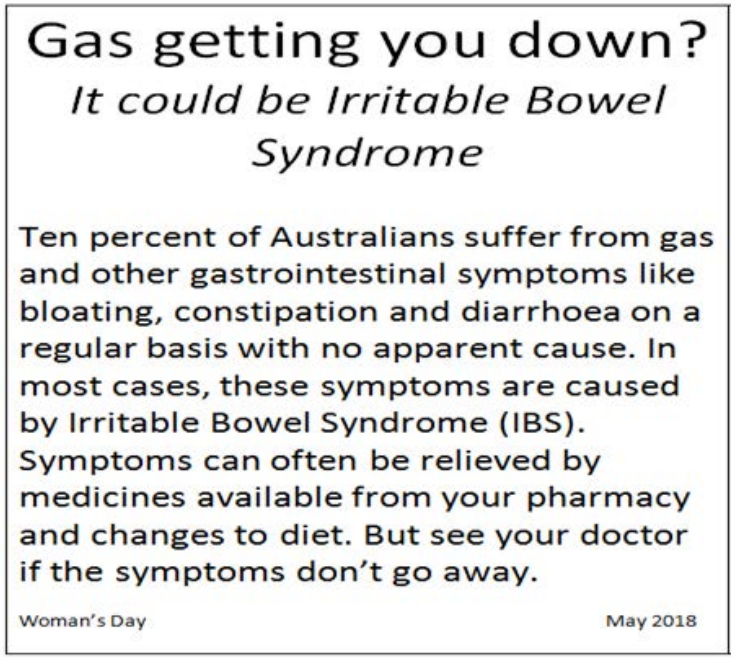
Splutter liquid is suitable for infants, children, adults and the elderly

Tweet  your best sneezy face photo #splutterface

RED FROG
BLOOD GLUCOSE MONITORS

Unsurpassed accuracy
Easy to use – no needles
Ask your doctor

Example – Bean's Tonic



Gas getting you down?

It could be Irritable Bowel Syndrome

Ten percent of Australians suffer from gas and other gastrointestinal symptoms like bloating, constipation and diarrhoea on a regular basis with no apparent cause. In most cases, these symptoms are caused by Irritable Bowel Syndrome (IBS). Symptoms can often be relieved by medicines available from your pharmacy and changes to diet. But see your doctor if the symptoms don't go away.

Woman's Day May 2018

Section 6A & 6B – Repeals & transition

- Section 6A, by reference to Schedule 5, repeals the 2015 Code and the original 2018 Code
- Section 6B allows for a transition period for ads pre-approved under the 2015 Code – i.e.
  - Complaints about such ads will be assessed against the 2015 Code for the life of the approval

Section 7 - Price information

- Price information – definition in s.4 of Code – relates to prescription medicines and pharmacist-only medicines only
- S.42DL(10) of the Act – advertising of prescription medicines to the public prohibited “other than a reference authorised or required by a government or government authority”
- Section 7 of the Code authorises the dissemination of price lists that comply with Schedule 4 of the Code – i.e. not an offence under the Act
- Schedule 4 replaces Price information code of practice

Part 2 - Requirements for advertising all therapeutic goods to the public

Section 8 – Approved ads

- Ads for medicines for ‘specified media’ (e.g. free-to-air television, newspaper, billboard) require prior approval under Regulation 5G
  - Ø Arises from offence under section 42C of Act
- S.8 requires ads appearing in print media and billboards to display the approval number in the advertisement as set out in ss.8(3) – must be legible

S.9 – Accuracy: validity & substantiation

Advertising for therapeutic goods must satisfy the following:

(a) any claims made in the advertising are valid and accurate, and all information presented has been substantiated before the advertising occurs

Example: An ad promotes a medical device for identifying allergies from a non-invasive sample from the patient. The advertiser states the claim is supported by a small clinical trial conducted in the 1960s. Subsequent larger studies failed to reproduce the positive findings. The claims are not valid.

S.9 – Accuracy: truthful & not misleading

Advertising for therapeutic goods must satisfy the following:

(b) it is truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons

Example: an imaging device is advertised as producing 5 times less radiation than other devices but fails advise that the amount of radiation produced by such devices is very small. It is likely to mislead consumers:

- into thinking other imaging devices are harmful
- as to the order of magnitude of the difference in radiation produced by the devices – even if the claim is substantiated.

S.9 – Accuracy: comparisons

Advertising for therapeutic goods must satisfy the following:

(c) any comparisons made in the advertising between therapeutic goods or classes of therapeutic goods do not directly or indirectly claim that the goods or class of goods being used as the comparator are harmful or ineffectual;

Example: A head lice product is promoted as being more effective and safer than the leading brand, which has an ingredient shown to cause birth defects

S.9 – Accuracy: consistency with ARTG

Advertising for therapeutic goods must satisfy the following:

(d) if the goods are included in the Register - it is consistent with the entry for the therapeutic goods in relation to that inclusion.

Example: A product is included in the ARTG for the relief of pain in adults aged 18-65 only. If the product was promoted for pain relief for children, it would contravene s.9(d).

S.10 – Effect: support proper use

(a) Advertising for therapeutic goods must support the safe and proper use of therapeutic goods by:

(i) presenting the goods in accordance with directions or instructions for use; and

(ii) not exaggerating product efficacy or performance;

Example: A topical preparation for the relief of symptoms of eczema is promoted for oral consumption as it works faster

S.10 – Effect: delaying appropriate treatment

(b) Advertising for therapeutic goods must…not be likely to lead to people delaying necessary medical attention or delaying the use of, or failing to use, treatment prescribed by a medical practitioner;

Example: a herbal medicine is promoted as an alternative to antibiotics and people should use it as first line treatment for conjunctivitis and other infections instead of antibiotics

S.10 – Effect: encourage inappropriate use

(c) Advertising for therapeutic goods must not encourage inappropriate or excessive use of the therapeutic goods

Example: A medical device for alleviating snoring is promoted for alleviating sleep apnoea. The advertising would be likely to encourage inappropriate use.

S.10 – Effect: safe or cannot harm

(d) Advertising for therapeutic goods must not contain any claim, statement, implication or representation that:

(i) the therapeutic goods are safe or that their use cannot cause harm, or that they have no side-effects

Example: A herbal medicine is promoted as having a safe mode of action and that millions of people have bought it and there have been no adverse reports.

S.10 – Effect: sure cure

(d) Advertising for therapeutic goods must not contain any claim, statement, implication or representation that…

(ii) the therapeutic goods are effective in all cases of a condition or that the outcome from their use is a guaranteed or sure cure;

Example: A medical device is promoted as guaranteed to improve lung function by 75% in COPD patients

S.10 – Effect: miraculous

(d) Advertising for therapeutic goods must not contain any claim, statement, implication or representation that…

(iii) the therapeutic goods are infallible, unfailing, magical or miraculous;

Example: A testimonial on a website for a medicine for relieving cystitis states the product is miraculous and the symptoms were gone within two hours and did not return.

S.10 – Effect: harmful consequences

(d) Advertising for therapeutic goods must not contain any claim, statement, implication or representation that…

(iv) harmful consequences may result from the therapeutic goods not being used - unless the claim, statement, implication or representation is permitted under section 42DK of the Act or approved under section 42DF of the Act.

Example: An ad for a supplement for 65+ year olds is promoted by stating that retirees won't be able to continue playing golf and keeping up with their grandkids unless they use the supplement

Sections 11 - 13

Mandatory information and statements

Overview: application of sections

	Section 11	Section 12	Section 13
Ad for S3 (App H) medicine	þ		
Ad for non-S3 therapeutic good that allows purchase without seeing the good		þ	þ (selected items only)
Any other ad for non-S3 therapeutic good			þ

Note: other provisions in the Code, including Part 3, will still apply in each case

S.11: Required statement – S3s

- An advertisement for a medicine containing a substance included in Schedule 3 of the Poisons Standard and Appendix H must prominently display or communicate:

ASK YOUR PHARMACIST -THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU

- This is the only mandatory statement required by Part 2 for S3 medicines advertising
  - Part 3 still applies – e.g. analgesics warning
- Does not apply to labels, CMIs or PILs

Section 12 & 13 requirements

Ad must prominently display or communicate:

- Basic info about the goods
- Important health information (or a prompt to consumers to read it)
- Advice to follow directions
- A symptom statement (if there are claims about symptoms

S.12: What must ads contain (goods not available for inspection)

- This section is only for ads for goods that are not available for physical examination by the consumer before or at the time of purchase (e.g. internet, mail order marketing)
- Does not apply to:
  - advertisements subject to section 11
  - a label, consumer medicine information or a patient information leaflet

Section 12 mandatories: medicines

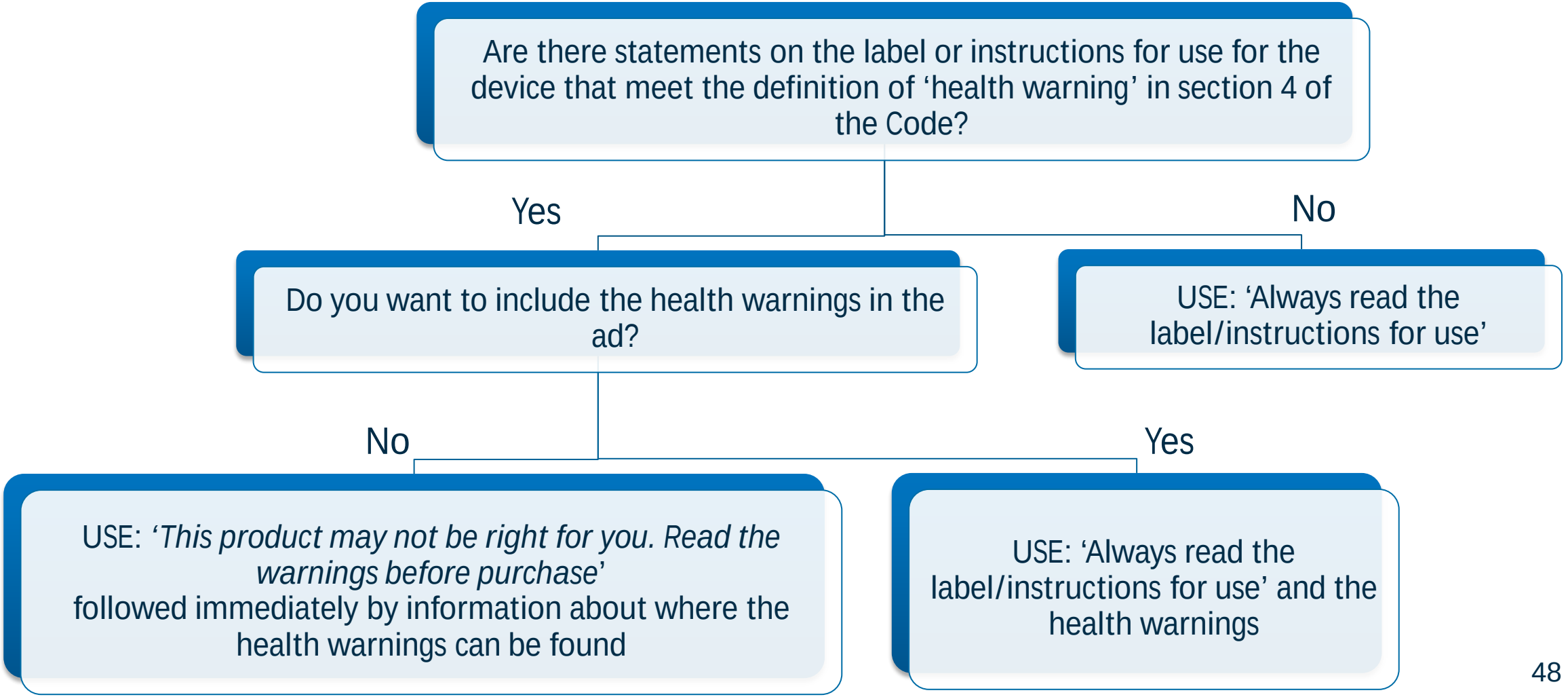
Type of information	Provision and the information required in ad
Basic information about the goods	• ss.12(3)(a) – (c) – the name of the medicine, dosage form, the quantity of the medicine • ss.12(3)(d) - one or more of the indications for the medicine, as they appear on the medicine's label • ss.12(3)(e) - a list of certain ingredients – see definition in s.4
Important health information	• ss.12(3)(f) – an alert to the consumer to read the label or warnings (as appropriate for the nature of the medicine)
Follow the directions statement	• ss.12(3)(g) – 'Follow the directions for use' or 'Follow the instructions for use' from ss.13(6)
Symptom statement	• ss.12(3)(h) - If there are symptoms claims in ad, include appropriate statement/s from ss.13(7)

ss.12(3)(f): Important health info for medicines

Section 12 mandatories: devices

Type of information	Provision and the information required in ad
Basic information about the goods	• ss.12(4)(a) – (b) – an accurate description and a reference to EITHER the trade name or another name for the device • ss.12(4)(c) – the intended purpose or indications for the device as they appear on label or primary packaging • ss.12(4)(d) - a list of the ingredients if applicable
Important health information	• ss.12(4)(e) – an alert to the consumer to read the label, instructions or warnings (as appropriate for the device)
Follow the directions statement	• ss.12(4)(f) – 'Follow the directions for use' or 'Follow the instructions for use' from ss.13(6) as appropriate for the device
Symptom statement	• ss.12(4)(g) - If there are symptoms claims in ad, include appropriate statement/s from ss.13(7)

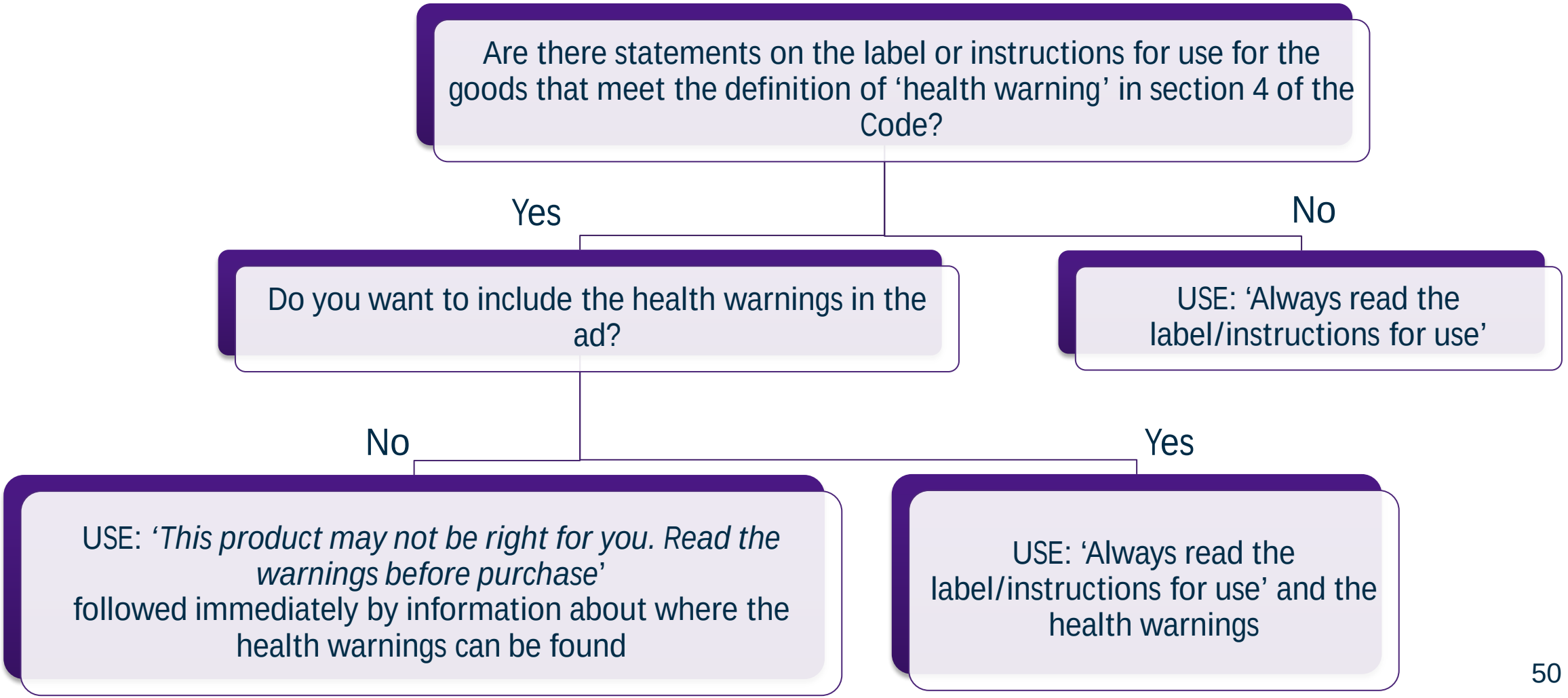
ss.12(4)(e): Important info for devices



Section 12 mandatories: OTGs

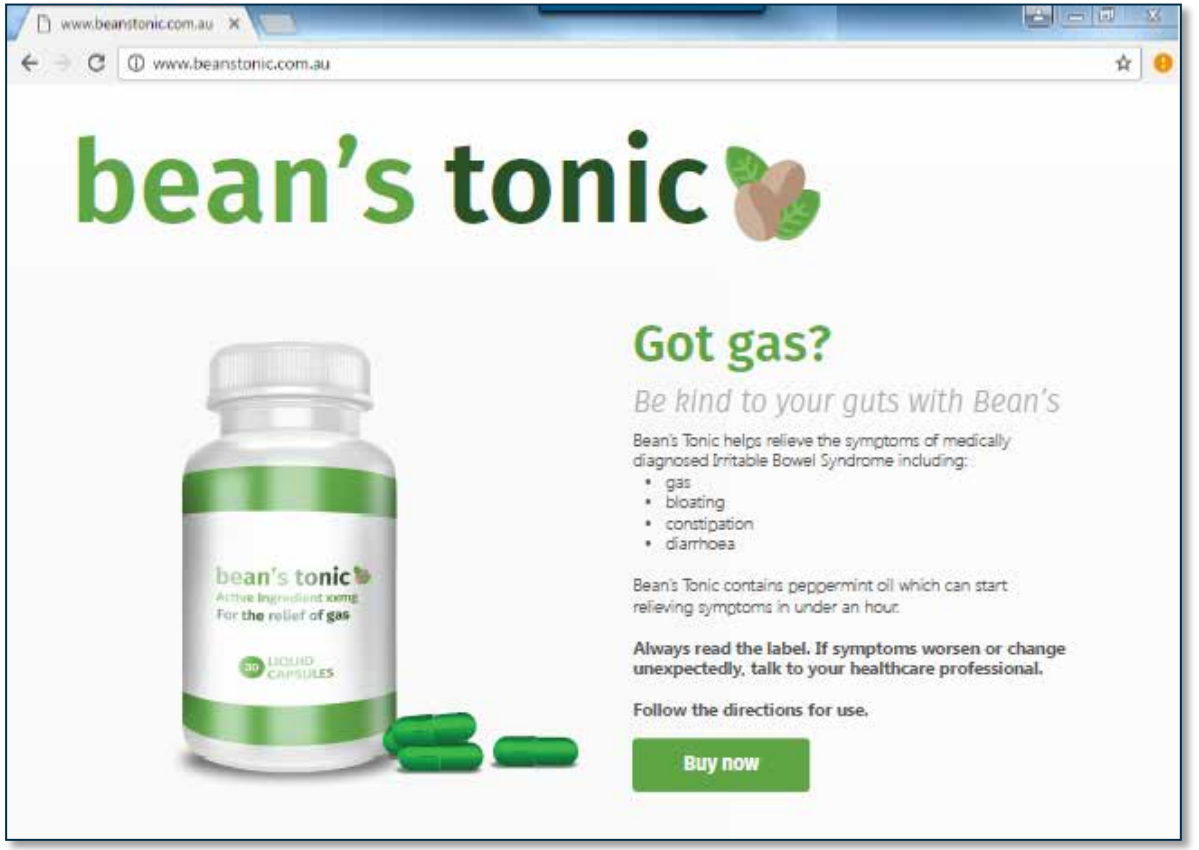
Type of information	Provision and the information required in ad
Basic information about the goods	• ss.12(5)(a) – (b) – an accurate description and a reference to EITHER the trade name or another name for the goods • ss.12(5)(c) – the intended purpose or indications for the goods as they appear on label or primary packaging • ss.12(5)(d) - a list of the ingredients where relevant
Important health information	• ss.12(5)(e) – an alert to the consumer to read the label, instructions or warnings (as appropriate for the goods)
Follow the directions statement	• ss.12(5)(f) – 'Follow the directions for use' or 'Follow the instructions for use' from ss.13(6) as appropriate for the goods
Symptom statement	• ss.12(5)(g) - If there are symptoms claims in ad, include appropriate statement/s from ss.13(7)

ss.12(5)(e): Important info for OTGs



Examples: Bean's Tonic internet marketing

Example – Bean's Tonic internet marketing



S.13: What must ads contain (general)

- This section is only for ads that:
  - are for goods other than Schedule 3 medicines (see s.13(1)(d) - section 11 applies to these)
  - do not facilitate purchase of the goods without the consumer being able to inspect them (see s.13(1)(e) - section 12 applies to these)
- This section does not apply to labels, consumer medicine information or a patient information leaflet (s.13(1)(a) & (b))

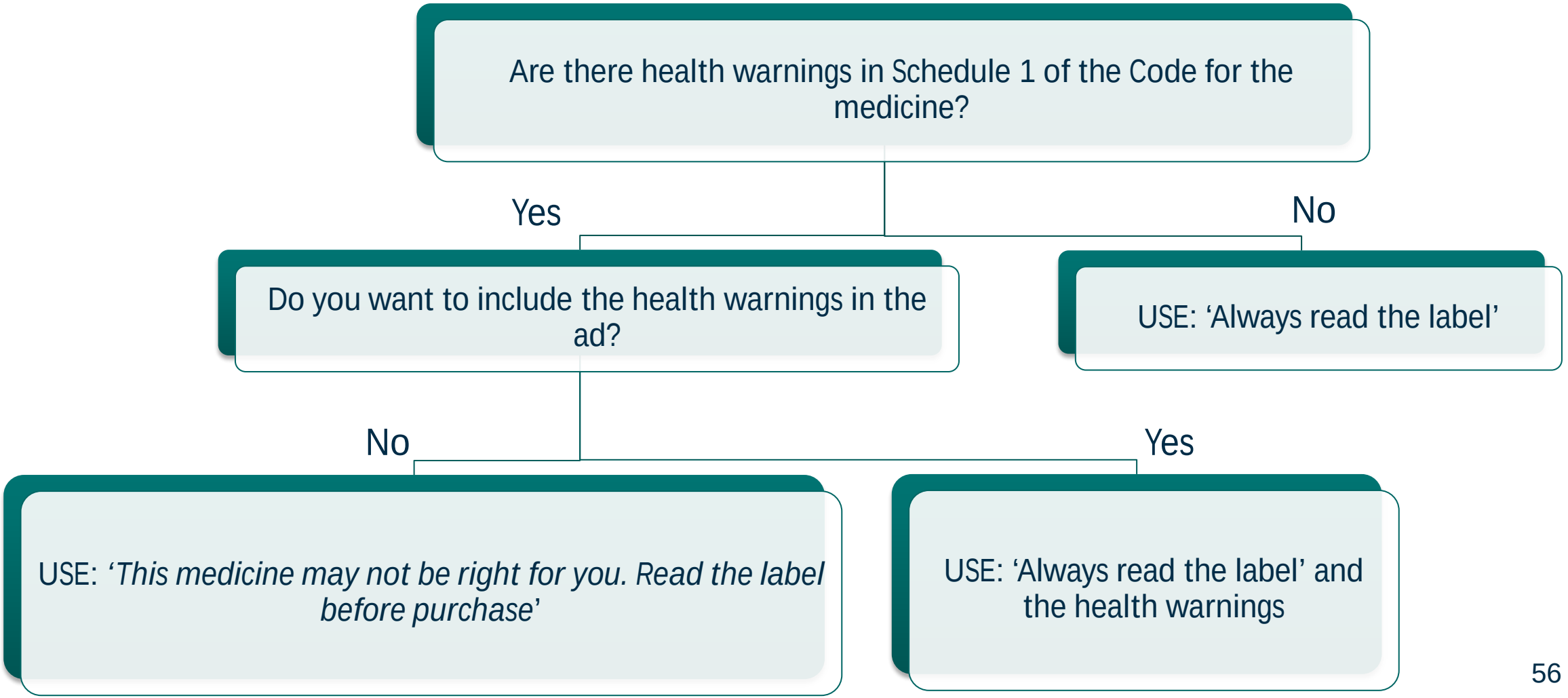
S.13: What must ads contain (general)

- This section also does not apply to picture/price/point of sale ads (see s.13(1)(c)) – i.e.:
  - an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, or any combination of these, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation

Section 13 mandatories: medicines

Type of information	Provision and the information required in ad
Basic information about the goods	• ss.13(2)(a) – (b) – a reference to the trade name of the medicine and one or more of the indications as they appear on label
Important health information	• ss.13(2)(c) – an alert to the consumer to read the label, instructions or warnings (as appropriate for the goods)
Follow the directions statement	• ss.13(6) – 'Follow the directions for use' or 'Follow the instructions for use' as appropriate for the goods
Symptom statement	• ss.13(7) - If there are symptoms claims in ad, include appropriate statement/s

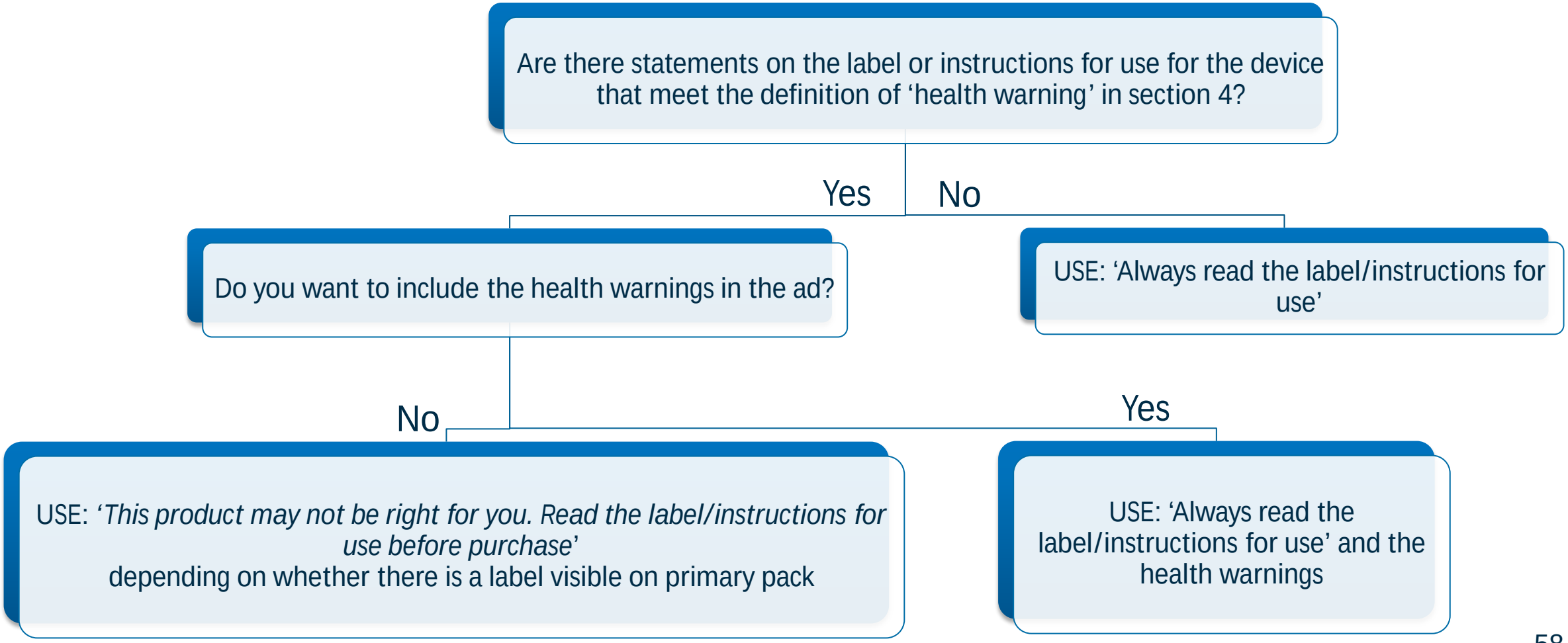
ss.13(2)(c): Important info for medicines



Section 13 mandatories: devices

Type of information	Provision and the information required in ad
Basic information about the goods	• ss.13(3)(a) – (b) – an accurate description and a reference to EITHER the trade name or another name for the device • ss.13(3)(c) – the intended purpose or indications for the device
Important health information	• ss.13(3)(d) – an alert to the consumer to read the label, instructions or warnings (as appropriate for the device)
Follow the directions statement	• ss.13(6) – 'Follow the directions for use' or 'Follow the instructions for use' as appropriate for the device
Symptom statement	• ss.13(7) - If there are symptoms claims in ad, include appropriate statement/s

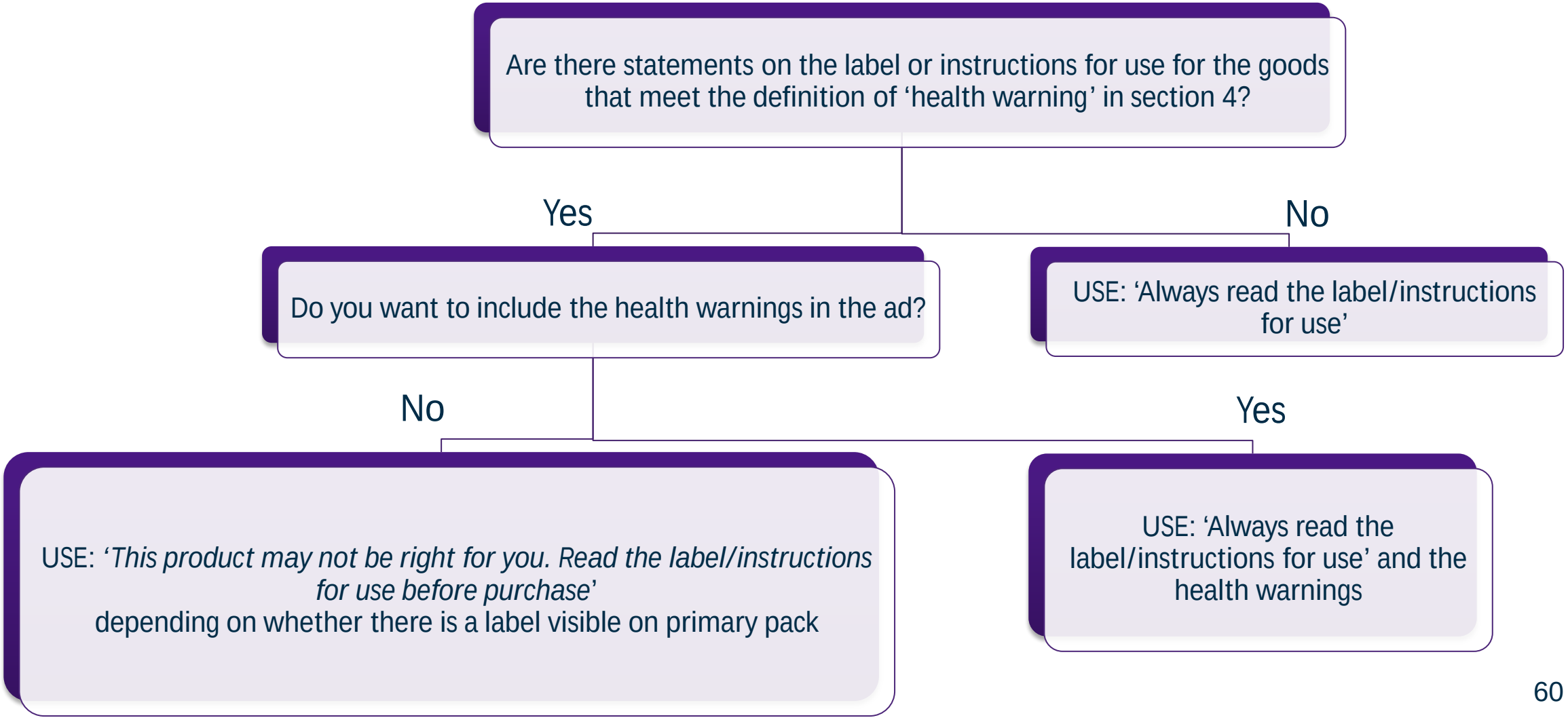
ss.13(3)(d): Important info for devices



Section 13 mandatories: OTGs

Type of information	Provision and the information required in ad
Basic information about the goods	• ss.13(4)(a) – (b) – an accurate description and a reference to EITHER the trade name or another name for the goods • ss.13(4)(c) – the intended purpose or indications for the goods
Important health information	• ss.13(4)(d) – an alert to the consumer to read the label or instructions (as appropriate for the goods)
Follow the directions statement	• ss.13(6) – 'Follow the directions for use' or 'Follow the instructions for use' as appropriate for the goods
Symptom statement	• ss.13(7) - If there are symptoms claims in ad, include appropriate statement/s

ss.13(4)(d): Important info for OTGs



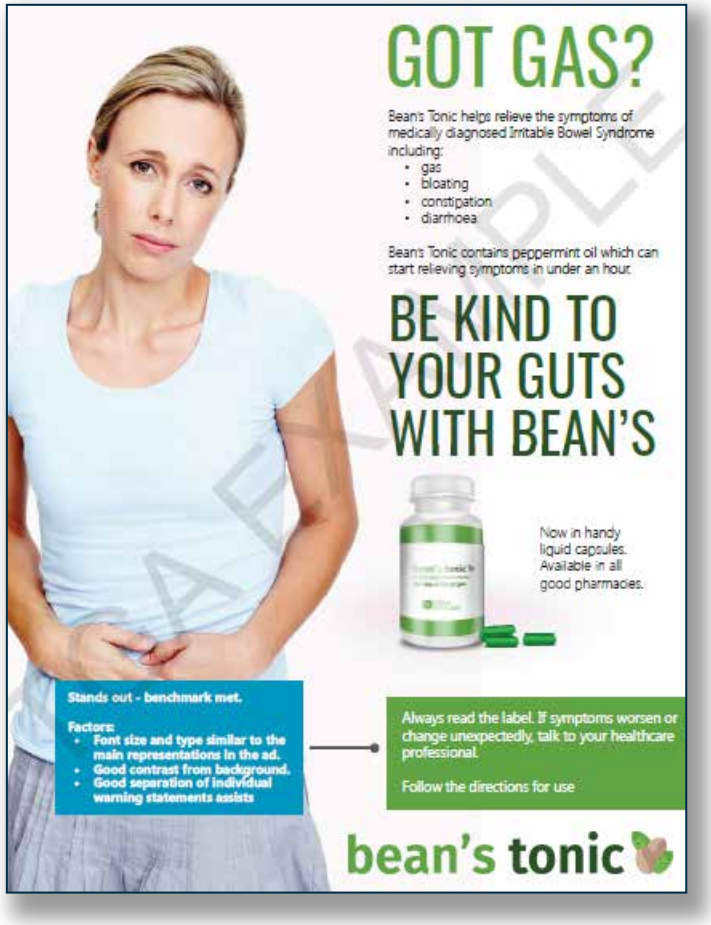
Exemptions from parts of section 13: short form ads

- "Short form ads" are:
  - Radio commercials 15 seconds or less duration
  - Text-only ads of 300 characters or less with no ability to include pictures, logos or other imagery
- Short form ads are exempt from:
  - The calls to action – 'Always read the label' etc
  - Symptoms statement (ss.13(6))

Examples: Bean's Tonic magazine ads

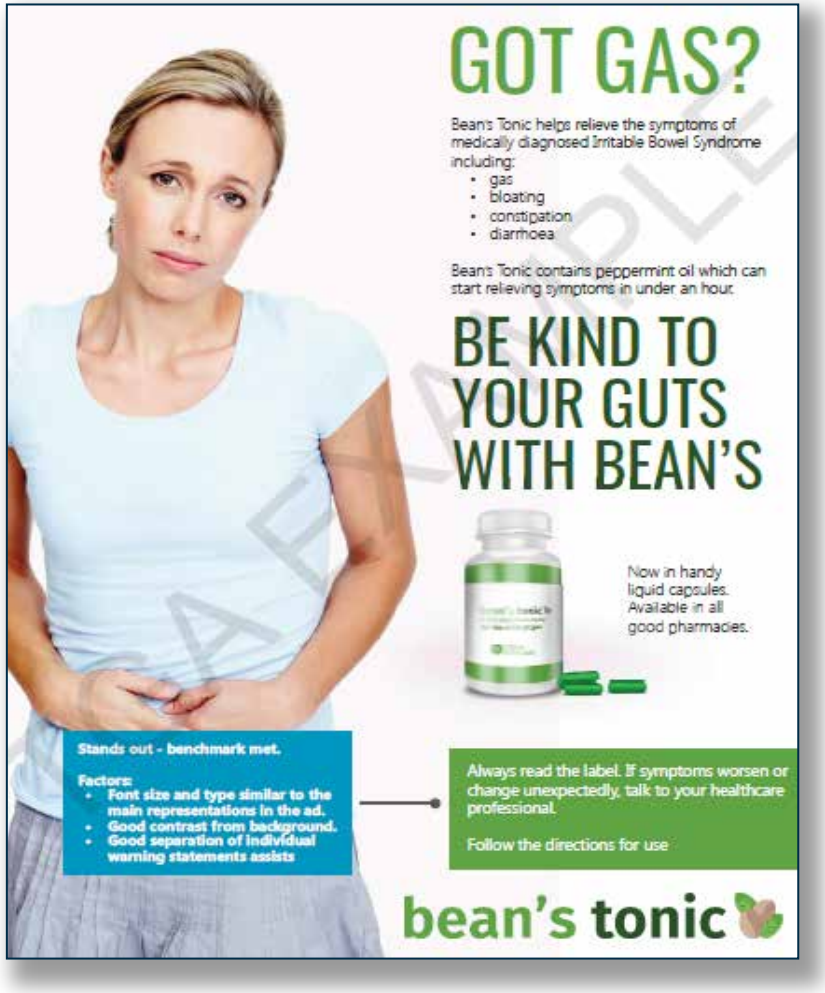
Example 1 – Bean's Tonic

An example of prominently displayed mandatories for a medicine without health warnings



Example 2 – Bean's Tonic

An example of prominently displayed mandatories for a medicine with health warnings - using mandatories option 1 and 2



Example 4 – Bean's Tonic

Will not be compliant under the Code

S.15: Scientific or clinical representations

- Ss.15(1) - this section does not apply to labels, CMIs or PILs
- This section is in two parts:
  - Requirements for use of scientific or clinical claims (ss.15(2))
  - Requirements for use of citations (ss.15(3))

S.15(2): Scientific or clinical claims

Where an advertisement makes a scientific or clinical claim:

- (a) any scientific or clinical terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed; and
- (b) any scientific or clinical representation must be consistent with the body of scientific or clinical evidence applicable to the advertised therapeutic goods.

S.15(3): Scientific citations

Where an advertisement contains a citation to scientific or clinical literature, either explicitly or impliedly:

- (a) any research results must identify the researcher and financial sponsor of the research, where the advertiser knows, or ought reasonably to have known that information; and
- (b) the study must be sufficiently identified to enable consumers to access it.

Example

NOT COMPLIANT

Scientific information is inappropriate and won't be readily understood

Stellar is clinically proven to relieve gastro upsets in 10 minutes

The active ingredient in Stellar, hydroxyexpialedocious, works on the gastrointestinal system to suppress X2 receptor activity

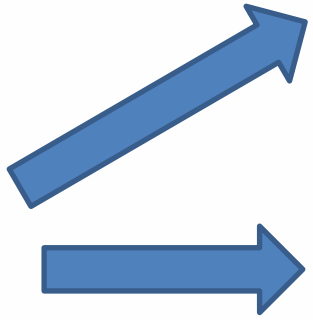
In convenient chewable tablets at your pharmacy

Implied scientific citation – reference needs to be provided

These would need to reflect the body of evidence available

Example

Provided these claims reflect the body of evidence available about the product or ingredient, this would likely comply with s.15



Stellar is clinically proven* to relieve gastro upsets in 10 minutes

Stellar contains an ingredient to slow down the spasms in your gastrointestinal tract to help you feel better

In convenient chewable tablets at your pharmacy

* Research conducted by John Jones, University of Canberra and was funded by Stellar Inc. Study available from Jones J. (2010) Effect of hydroxyexpialidocious on the human gastrointestinal tract. Journal of Internal Medicine Vol 2: 127 - 135

S.16(1): Endorsements

- The endorsement provisions in section 16 do not apply to:
  - Testimonials captured by section 17 (s.16(1)(a))
  - Claimer for efficacy assessed non-prescription medicines – as described in Regulations (s.16(1)(b))

S.16(2) and (2A): Endorsements

- Endorsements (express or implied) from the following are prohibited:

  (a) a government authority, hospital or healthcare facility; or

  (b) an employee or contractor of a government agency, hospital or healthcare facility; or

  (c) a health practitioner, health professional, medical researcher or a group of such persons.

- Health care facilities do not include community pharmacies

S.16(3): Endorsements

Subject to conditions, endorsements from the following are permitted:

(a) an organisation that:

(i) represents the interests of healthcare consumers; or

(ii) represents the interests of health practitioners, health professionals or medical researchers; or

(iii) conducts or funds research into any disease, condition, ailment or defect; or

(b) an employee or contractor of an organisation mentioned above, other than an individual mentioned in paragraph (2)(b) or (c)

S.16: Endorsement conditions

- Endorsements made under s.16(3) are subject to the conditions that the advertisement:
  - names the organisation concerned; and
  - discloses:
    - (i) the nature of the endorsement; and
    - (ii) whether the organisation or employee, has received, or will receive, any valuable consideration for the endorsement
- 'Organisation' defined in s.16(4) – any group, association etc

S.17: Testimonials

- Testimonial = a statement about a therapeutic good made by a person that claims to have used that good (s.17(1))
- This section specifies three types of requirements:
  - Characteristics of the person making testimonial (s.17(2)(a))
  - Obligations of the advertiser before using testimonial in advertising (s.17(2)(b) and (c))
  - Information that must be disclosed in the ad about the testimonial (s.17(3))

Who can make a testimonial for use in ads?

s.17(2)(a) - a person:

(i) whose details are verified prior to the advertising occurring; and

(ii) who has used the goods for their intended purpose; and

(iii) who is not:

(A) involved with the production, sale, supply or marketing of the goods; or
(B) an employee or officer of a corporation that is involved with the production, sale, supply or marketing of the goods; or
(C) a corporation; or
(D) mentioned in subsection 16(2) (e.g. health professionals, staff from government agency, hospital or healthcare facility)

Advertiser obligations when using testimonials

s.17(2)(b) and (c) – the advertiser needs to ensure that they have:

- verified as to the use of the goods and the claims made by the person prior to the advertising occurring; and
- checked that the testimonial is typical of the results to be expected from the use of the goods in accordance with the directions for use, or purpose, of the goods.

Information re testimonials to be included in ads

s.17(3) – An ad containing a testimonial must:

(a) disclose whether the person providing the testimonial has received, or will receive, any valuable consideration for the testimonial;

(b) disclose where another person is taking the place in the advertisement of the person providing the testimonial; and

(c) disclose where the person providing the testimonial is an immediate family member of an individual who is involved with the production, sale, supply or marketing of the goods.

Example acceptable use policy

- We welcome your comments on our page but we ask that you help us comply with the Therapeutic Goods Advertising Code (the Code).Please consider these guidelines before commenting. We will remove any comments that may result in us breaching the Code.
- We love when you comment and tag your friends and family on our posts but we ask that you do not:
- endorse our product if you are:
  - an employee or contractor of a government authority, a hospital or a healthcare facility
  - a health practitioner, health professional or medical researcher
  - involved with the production, sale, supply or marketing of our product
  - not using your own name on this social media platform.
- imply that a government authority, a hospital or a healthcare facility endorse our product
- make comments about how a product works for you outside of its intended purpose, as these comments can be dangerous or misleading.—our products are developed for particular purposes, as stated on the label and/or in our advertising, and these comments can be dangerous and misleading
  - make comments about serious conditions, diseases, ailments or defects, such as comments about how a product helped with your cancer treatment or how it will relieve a tagged person’s rheumatoid arthritis pain
- We also have an obligation to make sure any advertisements we make, including endorsements and testimonials, are not misleading. Therefore we promise to disclose:
- where a person has been, or will be, compensated for making a testimonial
- where we have actors making the testimonial, such as in cases where the original person who made the testimonial does not want to appear in our advertisement
- where the person making the testimonial is an immediate family member of anyone employed by our business

S.18: Incentives

- Ads must not offer any personal incentive to a pharmacy assistant, or any retail sales person who is not a health professional, to **recommend** or **supply** therapeutic goods.
- Pharmacy assistants and other retail staff do not meet the criteria for ‘health professionals’ for the purposes of the advertising (s.42AA)
- Ads for these audiences must comply with the Code – including this provision

S.19: Advertising to children

- Advertising must not be **primarily** directed to children under the age of 12 years at all
- Advertising must not be **primarily** directed to children aged 12 years or over, EXCEPT for those products listed in Schedule 2 of the Code, which include tampons and condoms
- Labels are excluded from this provision
- ‘primarily directed’ does not include incidental exposure

S.20: Samples

- An ad must not contain an offer of a sample EXCEPT for those products listed in Schedule 3:
  - ü condoms
  - ü Sunscreens
  - ü Stoma devices for self-management
  - ü Continence catheter devices for self-management
- Samples can in themselves be an ad – consider Act definition of ‘advertise’
- Some samples may also be subject to state and territory laws – e.g. scheduled substances

S.20: Samples example

NOT COMPLIANT

Have you been diagnosed with IBS recently?

Wondering if you will ever find anything to help your symptoms?

You **can** feel better in just two weeks – take the Bean's challenge!

Sign up at www.beanstonic.com.au and we will email you a voucher for a free one month supply of Bean's Tonic from your local pharmacy

S.21: Consistency with public health campaigns

- If a relevant public health campaign of which the advertiser knows, or ought reasonably to have known is or will be current at the time of advertising therapeutic goods, the advertising must not be inconsistent with the public health campaign
- Campaigns can be current but not necessarily active – e.g. respiratory hygiene campaigns only run in cold & flu season
- Guidance contains more information on establishing current public health campaigns

S.21: Consistency with public health campaigns

Example: There are a range of current initiatives in Australia to encourage responsible alcohol consumption

NOT COMPLIANT

Drinkers Delight
liver tonic

- improves liver function
- protects the liver from damage from alcohol consumption – especially on a big night out!

Cheers!

S.21: Consistency with public health campaigns

Example: National tobacco campaign – an ongoing campaign to promote the quit smoking message across the national population

NOT COMPLIANT

SmokeProtect

Natural antioxidants to protect the lungs from toxins in cigarette smoke

Just one daily dose
provides all the protection you need

Part 3 - Requirements when advertising particular types of therapeutic goods

S.22 - Application

- Part 3 of the Code does not apply to:
  - Labels (as defined in s.3 of the Act)
  - Consumer medicine information leaflets (patient information documents as defined in Regs)
  - Patient information leaflets (implantable medical devices – see s.4 - Definitions)
- These documents can still be considered promotional and have to comply with all other relevant Code provisions

S.23 – Complementary medicines

If an advertisement for a complementary medicine includes a claim or group of claims based on evidence of a history of traditional use, the reliance on this traditional use and paradigm must be disclosed in the advertisement and the disclosure must be prominently displayed or communicated in the advertisement.

- This provision provides clarity around expectations for medicines advertised on the basis of traditional use

S.23 – Complementary medicines

- Some medicines rely on multiple paradigms – if this is the case, they need to be included in the ad.
- **Example:**

þ Traditionally used in Ayurvedic medicine to relieve sleeplessness. Traditionally used in western herbal medicine to soothe restlessness.

ý Ingredient X is traditionally used in Ayurvedic and western herbal medicine to soothe sleeplessness and restlessness.

S.24 – Analgesics

- Oral analgesic ads must prominently display or communicate:

  INCORRECT USE COULD BE HARMFUL

- The ad must not imply that analgesic consumption is safe or they can relax, relieve tension, sedate or stimulate
- Definition of analgesic in s.4 – excludes combinations of analgesic and other ingredients for self limiting conditions
- Needs to be used in conjunction with other mandatories
- For radio ads 15s or less - *FOLLOW THE DIRECTIONS FOR USE. INCORRECT USE COULD BE HARMFUL*.

S.25 – Vitamins and minerals

An advertisement for vitamin or mineral supplements must not claim or imply that the supplements:

- (a) are a substitute for good nutrition or a balanced diet; or
- (b) are in any way superior to or more beneficial than dietary nutrients.

S.26 – Goods for weight management

(1) An advertisement for therapeutic goods containing any claim relating to weight management must balance the claims with the need for a healthy energy-controlled diet and physical activity.

(2) Advertising of therapeutic goods containing any claim relating to weight management must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over-consumption of any food or drink.

S.26 – Weight management

(3) An advertisement for therapeutic goods containing any claim relating to weight management must not:

(a) feature individuals in images or visual representations; or

(b) use individuals' statistics or testimonials; unless the results achieved by those individuals from the use of the goods would be expected to be achieved on average by users of the goods.

S.27 – Sunscreens

For an ad for a therapeutic good that is or contains a sunscreen that is claimed to prevent sunburn or skin cancer, the ad must:

- depict sunscreens as being only one part of sun protection; and
- include statements or visual representations, prominently displayed or communicated, to the effect that:
  - prolonged high-risk sun exposure should be avoided; and
  - frequent re-application or use in accordance with directions is required for effective sun protection.

Part 4 – Restricted and prohibited representations

Prohibited and Restricted Representations

- The Act makes it a criminal offence, and provides civil penalties, where an advertiser makes reference certain conditions (explicitly, or by implication) in advertising of therapeutic goods without prior approval:
  - S. 42DL(7) and 42DLB(4) – restricted representations
  - S. 42DL(5) and 42DLB(2) – prohibited representations
- The Act also provides that the Secretary may approve the use of these representations under certain circumstances (s.42DF and s.42DK)

s.29(1)(a) – medically accepted to be a form requiring diagnosis, treatment or supervision by a suitably qualified health professional?

YES

s.29(1)(a) - Once medically diagnosed, is it medically accepted to be suitable for self-treatment and management?

YES

NO

s.29(1)(b) - Is there a diagnostic/screening, or other kind of test for the form which requires medical interpretation or follow-up?

YES

The form IS a serious form

NO

NOT a serious form

Restricted representations

- A range of examples of what are and are not considered serious conditions are provided in the Guidance.
- The conditions included in the Guidance make for a fairly easy assessment of whether or not they need to be medically diagnosed.
- Where the serious condition is implied by the representation, this may be more difficult to assess

Group discussion:

Which conditions are prohibited or restricted representations?

Permitted restricted representations

- TGA has permitted the use of certain restricted representations by all advertisers of therapeutic goods, where the ad and product meets the characteristics and requirements specified.
- Permitted restricted representations include:
  - Neural tube defect risk reduction in pregnancy when advertising medicines with at least 400µg folic acid/day
  - representations about sleep apnoea, Obstructive Sleep Apnoea (OSA) and Central Sleep Apnea/Apnoea (CSA) in relation to Continuous Positive Airway Pressure (CPAP) equipment

Restricted representation approvals and permissions are published on the TGA website

Advertising exemption: Symbion - Nebulizer products

14 December 2017

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Symbion Pty Ltd

I, Simon Waters, Delegate of the Secretary to the Department of Health, on receipt of an application from Symbion Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (a) below for use in advertisements directed to consumers, for the product identified in paragraph (b), provided the condition identified in paragraph (c) is met:

a.
1. Words to the effect of "delivers prescribed medication related to asthma and other chronic respiratory conditions".
2. Words to the effect of "helps deliver Asthma and COPD medications efficiently and effectively into the lungs".
3. Nebuliser therapy systems offer delivery of prescribed medication related to asthma and other chronic respiratory conditions and are recommended for people who:
   - May have difficulty using metered dose inhalers (MDI/puffer)
   - Use large doses of bronchodilators
   - Take medication that cannot be formulated as a metered dose spray.

b.
- Nebulizer, non-heated (ARTG No.: 98386);
- Tubing set, nebulizer (ARTG No: 290689);
- Tubing set, nebulizer (ARTG No: 290690);
- Mask, air/oxygen (ARTG No: 290691); and
- Nebulizer, non-heated (ARTG No: 290692).

c. The statement *'Nebuliser delivery of therapy is not suitable for all medications and conditions. Use only on the*

S.30 - Prohibited representations

- Representations (express or implied) about the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to:
  - Neoplastic diseases (i.e. all types of cancer)
  - Sexually transmitted disease
  - HIV/AIDS
  - Hepatitis C virus
  - Mental illness
- Abortifacient action

Using prohibited representations

- The use of a prohibited representation may be authorised where it is necessary for either:
  - Public health interest; or
  - The appropriate use of the goods (packaging & labelling only)
- There is no process for applying to use prohibited representations
  - TGA will identify where it is needed
- Representations about preventing transmission of STDs/HIV/AIDS and prevention of skin cancer through sunscreen use are prohibited representations but will be permitted

Summary & finding more information

Top tips for compliant 2019 advertising

- þ Ensure ads contain the correct mandatory statements and information with appropriate prominence
- þ Check advertising for complementary medicines, analgesics, vitamins, weight loss products and sunscreens carefully to ensure full compliance with the express provisions
- ý Don’t use advertising with references to diseases, conditions, ailments or defects before checking if you need restricted representation approval

Top tips for compliant 2019 advertising

- þ Ensure testimonials, endorsements and scientific representations fully comply with clarified requirements
- ý Don’t use advertising that is inconsistent with the product’s ARTG entry, directions, or instructions for use
- ý Don’t use advertising that encourages people to delay seeking medical advice or cease prescribed therapies
- ý Don’t use advertising that conflicts with public health campaigns

More information on the 2018 Code

- The 2018 Code:
  - Search “Advertising Code” on the TGA website
- The 2018 Code guidance
  - Available from the Advertising Code page on the TGA website
- The 2018 Code explanatory statement
  - Open the 2018 Code and click on ‘Explanatory statement’ button
- More face to face and webinar education activities planned
- Online training module planned

More general advertising information

- Advertising hub – www.tga.gov.au/advertising-hub
  - Online training module – more to come
  - Australian Regulatory Guidelines for Advertising Therapeutic Goods
- Regulatory affairs consultant / legal advice
- TGA Online advertising inquiry form - https://compliance.tga.gov.au/advertising-enquiry/

More on TGA visit……..

- TGA website www.tga.gov.au
- TGA Advertising Hub https://www.tga.gov.au/advertising-hub
- Facebook https://www.facebook.com/TGAgovau/
- Twitter https://twitter.com/TGAgovau
- youtube https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw

Questions on the 2018 Code?

Australian Government

Department of Health

Therapeutic Goods Administration