Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on applying the 2021 Advertising Code rules

Part 7 – Samples and incentives
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TGA Health Safety Regulation

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Part 7 – Samples and incentives

Section 25 and Annexure 2 of the Code outline the rules around when and what samples can be included in an advertisement, or used as an advertisement, for therapeutic goods.

Samples are therapeutic goods given for free. The sample can be the advertisement or be offered in an advertisement. The advertisement must not contain, consist of or be an offer of a sample if any conditions in the Code, including Annexure 2, are not met.

Samples must be included on the ARTG or be excluded or exempt from the requirement to be included on the ARTG. The sample must be in a pack size that is accepted in relation to the ARTG entry. =

The rules only apply to the offer of samples that are therapeutic goods.

What samples can I offer?

Advertisers are not permitted to promote or distribute samples of any therapeutic goods that are not listed in Annexure 2. The therapeutic goods that advertisers CAN offer as a sample are:

- Condoms and personal lubricants
- Continence catheter devices for self-management
- COVID-19 rapid antigen tests for self-testing
- Disinfectants
- Face masks and gloves for preventing the transmission of disease in persons
- Hand sanitisers
- Lancets and blood glucose strips for use in connection with measuring blood glucose
- Nicotine replacement therapies administered by oromucosal or transdermal means, including sprays, patches, gums, lozenges, sachets and tablets
- Oral hygiene goods
  - toothpaste, mouthwash and interdental brushes
- Oral rehydration goods
- Stoma devices for self-management
- Sunscreens and other therapeutic goods containing sunscreen
- Tampons and menstrual cups
- Wound care dressings for superficial wounds, including first aid items and antiseptics

The Code is updated periodically. Please view the most current version of the Code for the complete list in Annexure 2.

Under the Code, a sample does not include therapeutic goods offered under a 'buy one, get one free' arrangement, provided the free therapeutic goods are the same as the purchased therapeutic goods. Therefore, the rules surrounding samples would not apply to this arrangement.

What conditions need to be met to advertise using therapeutic good samples?

When intending to give a sample you must ensure that the sample:

- is a good listed in Annexure 2
- is included in the ARTG (unless excluded or exempt from the requirement to be on the ARTG)
  - of a pack size as listed on the ARTG (where applicable)
- if provided to children 12 years and over
  - complies with the products that may be advertised to children as listed in Annexure 1 of the Code
- does not contain substances included in Schedule 2, 3, 4 or 8 of the Poison Standard.

Example

Beans Pty Ltd (Beans) claim their new Vitamin B12 product assists with concentration.

A Beans representative hands out two tablets as a sample at a career's day for Victorian high school students.

✘ The product cannot be advertised to children. It is not listed in Annexure 1 of the Code.

✘ The product cannot be given as a sample as it is not included in Annexure 2 of the Code, nor is the product being offered in a pack size as included in the ARTG.

Example

Kate is the marketing manager for a therapeutic goods company. She gives out samples of her company's nicotine replacement lozenges at a women's health convention.

A typical pack size is 2 sleeves of 10 lozenges. Kate is giving out only two lozenges per person.

✓ the sample is listed in Annexure 2 so can be given as a sample

✘ the samples given are not of a product size accepted in relation to its entry in the ARTG.

Example

Beans Pty Ltd advertises on a poster in pharmacies that with every purchase of their probiotic capsules the customer will receive a free packet of their new condoms.

✓ the sample is listed in Annexure 2 so can be offered as a sample.

Example

Beans Pty Ltd advertises on a poster in pharmacies that with every purchase of their probiotic capsules the customer will receive a free packet of Reishi capsules product.

✘ the sample is not the same product purchased by the consumer and so this does not fall under a 'buy-one, get one free' arrangement

✘ the Reishi capsules are not included in Annexure 2 as a permitted sample

✓ if the offer was of another packet of probiotic capsules then this is permitted as a 'buy one get one free arrangement' as it would be the same product.

A permitted sample in Annexure 2 does not allow for:

- the advertising of the goods to children
- providing the samples to children.

These rules do not apply to healthcare professionals who provide a sample to their patient during the course of a consultation and treatment.

For details refer to Part 7, Section 25 and Annexure 2 of the Code.

How can I add to the list of permitted samples in the Code?

Advertisers can apply to the TGA to have a sample added to the list of permitted samples in Annexure 2.

The application should be submitted via an advertising enquiry and should fully address the principles below.

The sample product must:

- have clear health or social welfare benefits when offered as a sample
  - any proposal to add medicines to Annexure 2 should include how it is consistent with the Quality Use of Medicines principles. The existing entries in Annexure 2 include very limited categories of medicines that have well established efficacy, public health

benefits and safety profiles and are consistent with the government policy on Quality Use of Medicines

- not be brand-specific
- be entered on the ARTG
  - or be excluded from the requirement to be included on the ARTG
- not require health professional advice to be used appropriately or safely
- be capable of complying with the Code when offered as a sample.

A clear public health benefit

To include a new therapeutic good in the list of permitted samples, there must be an overriding public or individual health benefit for a defined group of individuals associated with the offer of the sample.

That benefit must outweigh the risk of inappropriate use of the goods, including any potential for misuse or diversion into illicit use.

To be able to establish a health benefit you should consider:

- the nature and intended purpose of the goods
- if there is a clear benefit compared to the same advertising that does not include samples.

The public health benefits of the proposed samples should:

- be clearly set out
- be additional to any assumed therapeutic benefit for individual people
  - this is more important for proposals for a complementary medicine where the efficacy of the goods has not been formally assessed by the TGA
- discuss any potential harms or risk arising from access to the proposed samples by the public
- take into consideration the option of including limiting conditions, or conditions that must be met in the advertising of the samples, if appropriate
  - this might include, for example, reference to the condition for which the goods are appropriate
- for the case of proposed samples of medicines, address how making these medicines available to the public as samples, and advertising that availability, is consistent with The National Strategy for Quality Use of Medicines 2002.

Not brand or range specific

New entries in Annexure 2 cannot be for specific therapeutic goods or a class of goods that are only available from a single sponsor.

To assist with excluding inappropriate goods from being available as samples the application for adding a sample to Annexure 2 must provide a detailed description of the range of goods.

Must be of lawful goods

Therapeutic goods supplied in Australia must be included in the ARTG or be excluded or exempt from this requirement. The supply via advertising (including the offer and provision of a sample) of goods that are not in the ARTG, or are not the subject of an exemption, is unlawful.

Goods will not be included in the list of permitted samples if they are not capable of being lawfully advertised in Australia at the time of consideration.

This is expressed through the restrictions on samples set out in section 25(1) of the Code.

The same standards apply to both medicines offered for sale and for samples of those medicines:

- they must be entered on the ARTG at the pack size and dosage intended to be provided
- they must meet the requirements that apply to:
  - manufacturing
  - containers
  - labelling
  - packaging
  - any inserts provided with the medicine.

It is an offence to supply or advertise a good that is not included in the ARTG or otherwise exempt from that requirement.

The exempt goods must be lawfully advertised or supplied consistent with the original order that exempt the good.

Must not require health professional advice for safe and appropriate use

Goods for inclusion in the list of permitted samples must not require advice from an appropriate health professional in order to use the goods safely and appropriately.

In the case of medical devices, consumables (accessories) routinely used by patients in relation to a more complex device may be appropriate for samples.

Must be capable of complying with the Code

The object of the Code is to ensure that the advertising of therapeutic goods to consumers is conducted in a manner that:

- promotes the safe and proper use of the goods by minimising their misuse, overuse or underuse
- is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance
- supports informed health care choices
- is not inconsistent with current public health campaigns.

All advertising must comply with the Code. This includes advertising through provision of the samples themselves, through to the offer of a sample within an advertisement for the goods.

A submission for a new entry in Annexure 2 must consider whether the sample or its offer can always comply with the Code, in particular the general requirements in Part 3. Where issues are identified, the submission should also propose conditions that will mitigate these issues.

Can I give an incentive to promote my product?

Section 26 of the Code specifies that advertisements about therapeutic goods must not offer any personal incentive or commission to:

- a pharmacy assistant
- any other retail salesperson who is not a health professional

in exchange for their recommending or supplying the goods.

Example

Badawi is a Beans Pty Ltd (Beans) sales representative. He meets with Julie, a pharmacy manager, to discuss a new vitamin C product.

Badawi explains to Julie that Beans is running a competition. Badawi provides flyers to the staff detailing the competition and the product.

The pharmacy with the highest quarterly sales for the new vitamin C product will win a paid dinner for up to 6 staff.

Julie discusses this offer with her pharmacy staff who start recommending Bean's vitamin C product.

✘ the pharmacy staff have been incentivised to promote this product over other goods which is in breach of the Code.

Part 8 - Restricted representations

Read this section together with Section 27 of the Code.

What are restricted representations?

A restricted representation is a representation (a statement or claim) in an advertisement for a therapeutic good which refers to (expressly or by implication) to a serious form of a disease, condition, ailment or defect.

A **serious** form means:

- that the disease, condition, ailment and/or defect is medically accepted to require diagnosis or treatment or supervision by a suitably qualified health professional
  - except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management
- there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test)
  - which requires medical interpretation or follow-up.

A representation does not have to be a therapeutic claim to be considered a restricted representation. For example, these representations are all considered to be restricted representations:

- 'Do not use this product if you have **diabetes**'
- 'We proudly support **Osteoporosis** Australia'
- 'May help relieve pain associated with **arthritis**'.

The table below provides further examples of restricted representations.

Statement	Guidance
Source of iron for the treatment and prevention of medically diagnosed iron deficiency and iron deficiency anaemias	Iron deficiency and iron deficiency anaemias are conditions that require diagnosis by a health professional and ongoing medical supervision.
Suitable for asthma patients	Asthma is not suitable for self-treatment or management. It must be medically diagnosed and requires monitoring.
Please SEEK ADVICE before using this product if you are diabetic as your foot condition may require treatment by a healthcare professional	Diabetes is a serious condition that must be medically diagnosed and requires monitoring and treatment by a qualified health professional. Secondary conditions associated with diabetes can be prevented through careful management of the condition supervised by health professionals.

Statement	Guidance
This medicine can be used for the temporary relief of pain associated with arthritis, osteoarthritis and fibrositis pain	Arthritis, osteoarthritis and fibrositis are conditions that require diagnosis, monitoring and treatment by a health professional.
To provide effective relief of ear pain associated with Otitis Media	Otitis Media (middle ear infection) is a condition that requires to be diagnosed, treated and monitored by a health professional.
May help reduce the risk of transmission of sexually transmissible disease (STD)	STD's require monitoring and treatment by a qualified health professional. STD's are also classified as a prohibited representation which must not be referred to in advertising without approval.
Assists with temporary relief of pain associated with mild arthritis	The use of the qualifier 'mild' may be interpreted as being a less serious form of arthritis and therefore not a restricted representation.

What is not considered a restricted representation?

The following are not restricted representations:

- pregnancy, other than pregnancy with a medical, obstetric, or surgical complication
- any of the diseases mentioned in Schedule 2 of the Regulations as these are prohibited representations.

Can I use a restricted representation in advertising?

Restricted representations can only be used in advertisements for therapeutic goods that are available to consumers if TGA has permitted or approved the use of that representation.

Approval to use a restricted representation under section 42DF of the Act can be granted following a successful application from the advertiser.

Prior to commencing an application, advertisers should familiarise themselves with the related guidance and checklist.

How do I apply to use a restricted representation?

Applications to use a restricted representation in advertising are submitted using an online application form.

The application form is comprised of two (2) parts. Advertisers should ensure they have the necessary information and supporting documents prior to commencing their application. The application form cannot be saved and accessed at a later time.

Each application is assigned a unique identification number. Include the application number for any queries regarding your application. Send these by email to advertising.exemptions@tga.gov.au(link sends e-mail).

What are the public interest criteria associated with a restricted representation application?

When deciding whether to approve or refuse the use of a restricted representation in advertising the Secretary takes into consideration the public interest criteria set out in the Code.

The public interest criteria asks whether the reference to a serious form of a disease in an advertisement would be likely to:

- take advantage of the vulnerability of consumers or particular groups of consumers, when faced with the disease, condition, ailment or defect
- result in consumers not seeking medical advice
- have a negative impact on public health.

The public interest criteria provides a framework against which the Secretary can assess the suitability of the restricted representation for use in advertising to consumers.

The Secretary can also consider other aspects of the public interest that may be appropriate.

Prior to commencing an application, advertisers should familiarise themselves with the related guidance and checklist.

Will a restricted representation approval or permission be limited to a particular product?

An applicant applies for permission to use a restricted representation in advertising for a specific therapeutic good. The application is made under section 42DE of the Act.

The application specifies the product (with ARTG number if applicable) and the type of restricted representation they want to make in advertising. The application includes justification for the use of the representation. Detailed guidance on how to apply for approval is available at Guidance for submitting an application for approval to use a restricted representation.

The approval given to the applicant is given under section 42DF of the Act. The approval can only be given to the applicant for a specific product/s. The TGA notifies the applicant of the result of their application as required under section 42DG of the Act.

The Secretary can however choose to issue a permission under section 42DK of the Act that permits the use of the restricted representation by a group of permitted advertisers, not only the applicant, where it is in the public interest for this to occur.

Examples of section 42DK permissions that have been issued include for the following classes of therapeutic goods:

- condoms
- broad spectrum 30+ sunscreens

- meters for monitoring blood glucose levels
- vitamin D supplements
- iron supplements
- calcium supplements
- rapid antigen tests for COVID-19
- low-dose aspirin products.

The TGA publishes approvals and permissions for both 'restricted' and 'prohibited' representations on its website at Notices of approved and permitted restricted representations.

Example

Albus applies to use the following statement in his advertising for the (fictional) Beans Tonic Lung Formula.

May assist with symptoms of cystic fibrosis by loosening and clearing lung mucus.

The ARTG indication for the product includes clearing mucus and supporting the immune system, however

- ✘ the applicant did not provide any justification that the representation is balanced and not misleading
- ✘ there is no evidence to support use of the product in any specific disease or condition.

The application is refused under section 42DF(2) of the Act. The delegate is not satisfied that the restricted representation is accurate, balanced and not misleading or likely to be misleading.

Example

Mohammad applies on behalf of a pharmacy marketing group to advertise an automated external defibrillator. The representation he proposes to use has already been permitted under a section 42DK of the Act. The TGA informs Mohammad of the existing s42DK permission. He withdraws his application.

What are prohibited representations?

Prohibited representations must not be used in advertising unless permitted by the TGA.

Prohibited representations are those representations that refer to the following:

- neoplastic diseases (e.g. all types of cancer)
- sexually transmitted diseases
- HIV/AIDS
- Hepatitis C virus
- mental illness
- an abortifacient action.

Other prohibited representations apply to other specific types of therapeutic goods including:

- analgesics
- disinfectants and antiseptics
- vitamins and minerals.

For details about prohibited representations refer to Schedule 2 of the Regulations. Schedule 2 applies to all advertising of therapeutic goods.

The TGA publishes approval and permissions for both 'restricted' and 'prohibited' representations on its website.

When can a prohibited representation be used?

In limited circumstances, the TGA may permit the use of prohibited representations if the representation is:

- in the interest of public health

  OR

- necessary for the appropriate use of the goods
  - this applies to packaging, labelling or material included with the goods.

Examples of section 42DK permissions that have been issued for prohibited representations include:

- Sunscreens
- Condoms
- HIV self-test kits.

Part 9 – Price information

Read this section of the guidance together with Part 9 of the Code.

Prescription and pharmacist-only medicines are ARTG registered goods that contain a substance that is included in Schedule 3, 4 or 8 of the Poison Standard (but not in Appendix H). They are prohibited from being advertised to the general public.

Part 9 of the Code sets out the conditions in which the price of prescription and certain pharmacist-only medicines only can be lawfully advertised.

The benefits of facilitating this include to:

- promote competition amongst retailers
- provide additional information for consumers to consider when purchasing their medicines.

The conditions of Part 9 of the Code must be met for this form of advertising to be lawful.

Who can publish price information?

Price lists of prescription-only and pharmacist-only medicines can be made available to the public under certain conditions.

Price information can only be produced and distributed by:

- retail pharmacists or their agents
- pharmacy marketing groups
- certain authorised medical practitioners that are approved under section 92 of the *National Health Act 1953.*

Pharmacy marketing groups (banner groups) are permitted to provide price information on behalf of their marketing group. All applicable Code requirements must be met.

All other medical practitioners and health professionals cannot provide price information to the public.

What format can price information be published in?

Price information	Forms of advertising
✓ can be published or disseminated in…	✓ Newspapers ✓ Magazines ✓ Leaflets ✓ Internet
✘ can't be published or disseminated in…	✘ Radio or television transmission, including pay and streaming services ✘ Digital or non-digital displays, including but not limited to displays: – in shopping malls outside individual pharmacies – in or on public transport – on billboards ✘ Cinema advertising
✘ About unregistered medicines (products not on the ARTG)	✘ cannot be advertised or included in a price list

Note: Special requirements are specified for online price information identified through a search function.

Search function price lists

Price lists can be published or disseminated through searchable functions such as an electronic sales system. In this instance the search result must only produce:

- a list of the names of the searched for medicine
- a list of medicines that contain a searched for ingredient.

The results must be in alphabetical order.

How can price information be presented?

There are three conditions in the Code for how price information must be presented:

List size

A price list is intended to show a consumer what medicine they can purchase and at what price. This must be done in a way that does not influence the choice of a specific product.

The list of medicines must contain:

– 25 medicines or more

AND

– the name and contact details of the retailer who is selling the product listed.

Alphabetical order

Medicines must be listed in alphabetical order by either:

- name of the medicine

OR

- the names of active ingredients

OR

- by schedule – see medicine group below.

Medicine group

Where the price list includes a range of medicines that are in different schedules of the Poison Standard, then the medicines can be grouped by schedule.

Each sub-list must contain three or more

- medicines from each schedule – in alphabetical order

AND

- the name of the person who entered to medicine on the ARTG (the sponsor).

Description of medicines in price information lists

Section 34 of the Code provides for how medicines must be described in price information. They should be described using the name of the medicine as defined in:

- *Therapeutic Goods Order No. 91* - Standard for labels of prescription and related medicines, or
- *Therapeutic Goods Order No. 92* - Standard for labels of non-prescription medicines

as appropriate to the Schedule of the Poisons Standard for the medicine.

Price information for each medicine must include:

- ✓ the strength of each active ingredient as it appears on the label of the medicine
- ✓ the dosage form in which the medicine is presented
- ✓ the quantity in the pack
- ✓ the price for the relevant number of units of the sponsor's standard pack
  - the relevant number of units of the sponsor's standard pack is either:
    - one unit

    OR

    - the maximum number of units that may be prescribed under the Pharmaceutical Benefits Scheme or Repatriation Pharmaceutical Benefits Scheme, where they permit more than one unit of the sponsor's pack to be prescribed.
- ✓ A price list may include a statement that a prescription is required for particular medicines.

What do I avoid when presenting price information?

When preparing a price information list, you should avoid any presentation that may guide consumers to choose a particular medicine over another. That rule applies whether or not that particular medicine is also referred to in the price information.

In your price information list do not use:

- rewards or offers
- embellishments
- promotional claims
- comparative statements
- any reference to therapeutic uses
- photographs or other reproductions of medicines
- restricted representations in relation to any medicine
- different text sizes or fonts to draw attention to one product over others
- prescription or pharmacist-only medical devices.

For full details see the expanded form of this guidance in section 35 of the Code.

Example

Our prices will never be beaten - up to 70% off medicines!

BarryBobs Paracetamol 500mg – 90 tablets - $1.50

Beans Paracetamol 500mg + codeine 8mg – 40 tabs - $11.99

Beans Paracetamol 500mg + codeine 15mg – 30 tabs - $13.50

AppleTree amoxicillin/clavulanic acid 875/125mg – 12 capsules - $10.95

BobCats Paracetamol 500mg + codeine 10mg – 30 tabs - $11.50

Turnips Paracetamol 625mg + codeine 15mg – 50 tabs - $21.89

Carrots Paracetamol 500mg + codeine 30mg – 25 tabs - $20.70 – good for pain

Beans blood glucose test strips – box 200 - $10.99

Beans Pharmacy – 10 Bean Street Beansville NSW – 02 6123 1234

- ✘ use of a claim
- ✘ out of alphabetical order
- ✘ includes a non-scheduled device (the test strips)
- ✘ less than 25 medicines included in list
- ✘ general promotional statements are not permitted
- ✘ price lists must not include medicines that are able to be advertised to consumers (BarryBobs Paracetamol 500mg).

Medicines listed in the pharmaceutical benefits scheme (PBS)

Price lists which include a PBS subsidised medicine must include:

- an indication that the price is subsidised by the Australian Government
- the price only applies when prescribed for the medical conditions listed in the PBS Schedule for that medicine
  - that actual condition must not be mentioned.
- the total purchase price for the medicine. This may be the discounted PBS (full or concessional) price up to the extent permitted by the PBS
  - must be clearly identified as the general or concessional price.
    - Both prices may be provided.

How can a pharmacy marketing group publish price information?

Section 36 of the Code provides that when a pharmacy marketing group can publish price information. This ensures that 'house brands' sold by a retail supplier cannot be given prominence over other comparable brands.

When their price list includes both:

- a PBS subsidised medicine with a brand premium or therapeutic group premium, and
- the group's own generic medicine

that price information list **must** also include at least one other benchmark price brand of that medicine (where such products exist).

Example

Beans Group Price List – PBS Listed Medicines

Active Ingredient (Trade Name, Strength, Pack Size) – PBS discounted price (PBS concession price)

Erythromycin (Beans generic erythromycin, 250 mg, 25 capsules) - $17.50 ($5.80*)

Erythromycin (Original erythromycin, 250 mg, 25 capsules) - $21.50 ($12.80*)

Telmisartan (Beans generic telmisartan, 40 mg, 30 tablets) - $19.80 ($5.80*)

Telmisartan (Maroon telmisartan, 40 mg, 30 tablets) - $21.80 ($7.80*)

Telmisartan (Original telmisartan, 40 mg, 30 tablets) - $25.80 ($10.80*)

Telmisartan (Scarlet generic telmisartan, 40 mg, 30 tablets) - $19.80 ($5.80*)

**Purchase price is subsidised by the Australian Government for specific medical conditions as per the PBS schedule.*

Available from Beans Pharmacies in Beansville, Mudville and Dustville.

✓ the place where the goods may be purchased

✓ presentation in alphabetical order by active ingredient

✓ in alphabetical order in reference to active ingredient

✓ Beans telmisartan 40 mg is a benchmark price brand and another benchmark price brand is included

✘ there is at least one other benchmark priced brand available for erythromycin that was not included

  – Apples generic erythromycin, 250mg, 25 capsules - $17.50 ($5.80*)

✘ there are fewer than 25 medicines in the list.

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