Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance on applying the 2021 Advertising Code rules

Part 7 – Samples and incentives

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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 consumers CAN be offered 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 Annexure 2 of Code for the current list of therapeutic goods that can be offered as samples. Annexure 2 is not updated independently of the Code.

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.

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)
  - is provided in the original container for the goods; advertisers must not provide samples independently of the container for the goods eg individually packed foils sachets or packets for the goods.
- 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.

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

û The product cannot be given as a sample as it is not included in Annexure 2 of the Code,

û The product is not 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 sheets of 10 lozenges. Kate is giving out only two lozenges per person.

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

û 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.

ü 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.

û 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

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

ü 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.

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 therapeutic goods that can be offered as samples in Annexure 2 of the Code.

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

The sample product must meet the following criteria:

- 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.

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	June 2022
V1.1	Minor updates, guidance for Restricted Representations (Part 8) and Pricing information (Part 9) published in separate documents.	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	February 2023

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