

AdHelp Information Service

COVID-19 and Advertising Therapeutic and Health Products or Services

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(please discard previous versions)

Please Note: AdHelp is the ASA's user pays service for advertisers and agencies to support responsible advertising. The ASA is publishing this AdHelp, free of charge, via its website, as a reminder of the importance of code compliance when promoting products or services that may have a therapeutic or health benefit.

It is not legal advice or binding on the Complaints or Appeal Boards. If a complaint is received and accepted, the Complaints and Appeal Boards are the arbiters of code compliance.

SUMMARY

- COVID-19 has not resulted in any changes to the legislation or codes that advertisers of therapeutic and health products or services are expected to adhere to (with the exception of the *New Zealand Gazette* notice of 22 April 2020 which prohibits the importation, manufacture, sale, supply and use of COVID-19 point of care* test kits and materials, unless authorised by Medsafe).
- *Point of care test kits use a blood sample to detect antigens or antibodies in the blood.
- The legislation and codes apply to both actual and implied claims in advertisements.
- Only products and services specified in the Medicines Act 1981 are able to make therapeutic purpose claims in advertisements, including any therapeutic purpose claims to test, diagnose, prevent, treat or cure COVID-19. Any therapeutic purpose claims must be able to be substantiated by the advertiser.
- Other products and services may make health benefit claims in advertisements only if such claims can be substantiated by the advertiser. Advertisements for products or services that make health benefit claims should not include references to COVID-19 or imply references to COVID-19.
- Claims for hand sanitiser products that refer to COVID-19 or imply a reference to COVID-19 must be able to be substantiated by the advertiser.

Prior to preparing and placing their advertisements, advertisers are expected to;

- Be familiar with the relevant legislation and codes; and
- Observe a high standard of social responsibility; and
- Ensure their advertisements are truthful and they must not be misleading; and
- Ensure their advertisements do not confuse consumers, abuse their trust, exploit their lack of knowledge or, without justifiable reason, play on fear; and
- Ensure their advertisements do not exaggerate or raise unrealistic expectations or outcomes.

BACKGROUND

This AdHelp provides advertisers of therapeutic and health products or services with information to help them comply with the [ASA Codes](#) when making claims in their advertisements that may relate to COVID-19.

Therapeutic and health products include medicines, medical devices, dietary supplements and natural health products.

Therapeutic and health services include conventional and complementary and alternative services.

There is also information included for hand sanitiser products.

These are unprecedented times for New Zealand and the rest of the world. To date, however, COVID-19 has not resulted in any changes to the legislation or codes that advertisers of therapeutic and health products or services are expected to adhere to (with the exception of the *New Zealand Gazette* notice of 22 April 2020 which prohibits the importation, manufacture, sale, supply and use of COVID-19 point of care* test kits and materials, unless authorised by Medsafe).

*Point of care test kits use a blood sample to detect antigens or antibodies in the blood.

Please read the [Advertising Standards Code](#) and the [Therapeutic and Health Advertising Code](#) for the all the principles and rules.

Claims in advertisements

Claims in relation to COVID-19 may be actual or implied.

Actual claims are usually obvious to consumers. For example, 'this product helps treat the symptoms of COVID-19 infection'.

Implied claims are less obvious to consumers. Implied claims can be present in advertisements through the use of words, phrases, sounds and imagery (or a combination of these) such that a consumer who views or hears the advertisement draws the conclusion that the claim is related to COVID-19. For example, 'this product will help protect you from the currently circulating viruses and other bugs'.

Another example of an implied claim is when information about COVID-19 is part of the advertisement for a product or service. There may not be actual claims about the product or service in relation to COVID-19 though consumers may conclude the product or service advertised has a role in testing or diagnosing or preventing or treating or

curing COVID-19.

Like all claims in advertisements, claims relating to COVID-19 must be able to be substantiated. Advertisers must have suitable substantiation on hand prior to making claims about a product or service in an advertisement. See Appendix 1 for more information on substantiating claims.

Therapeutic Claims about COVID-19 in advertisements

An actual or implied therapeutic claim relating to COVID-19 is likely to fit the definitions of ‘Therapeutic Purpose’ and ‘Disease’ in the ASA’s Therapeutic and Health Advertising Code (and as provided in the [Medicines Act 1981](#)).

Therapeutic Purpose –

1. *preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or*
2. *influencing, inhibiting, or modifying a physiological process; or*
3. *testing the susceptibility of persons to a disease or ailment; or*
4. *influencing, controlling, or preventing conception; or*
5. *testing for pregnancy; or*
6. *investigating, replacing, or modifying parts of the human anatomy.*

Disease includes any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind.

In addition, if you are advertising a **Dietary Supplement**, the Dietary Supplements Regulations 1985, Section 11 includes the following;

11. Therapeutic claims

Except as permitted by the [Medicines Act 1981](#) and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

- (a) treating or preventing disease:*
- (b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:*
- (c) altering the shape, structure, size, or weight of the human body:*
- (d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.*

What therapeutic and health products or services are permitted to make Therapeutic Purpose claims in advertisements?

The Medicines Act 1981 restricts Therapeutic Purpose claims in advertisements to certain products and services, including Therapeutic Purpose claims in relation to COVID-19. They are;

1. Medicines with consent to sell and advertise

The minimum substantiation for a therapeutic purpose claim about a medicine is the product data sheet, consumer medicine information or approved label

2. Medical Devices listed on the Medsafe WAND database (where required)

The minimum substantiation for a therapeutic purpose claim about a medical device is the WAND listing including the listed intended purpose where listing on WAND is required. Advertisers of medical devices should also be able to provide suitable published clinical trials or studies to support the claims in the listed intended purpose.

3. COVID-19 Test Kits that are approved for use in New Zealand.

Please note, from 22 April 2020, the importation, manufacture, sale, supply and use of COVID-19 point of care* test kits and materials is prohibited, unless authorised by Medsafe. Further background information provided by Medsafe is available [here](#). The *New Zealand Gazette* notice is available [here](#).

*Point of care test kits use a blood sample to detect antigens or antibodies in the blood.

4. Methods of Treatment

The ASA’s Therapeutic and Health Advertising Code definition for a ‘Method of Treatment’ (and as provided in the Medicines Act 1981) is:

*‘Method of Treatment’ – Any method of treatment for reward undertaken, or represented to be undertaken, for a **therapeutic purpose**.*

It is important to note that there is no Regulatory body that gives approval for a ‘Method of Treatment’ or decides which Health Services are, or are not, a ‘Method of Treatment’. This is determined by what the service provides and by how the service is advertised.

The minimum substantiation for a therapeutic purpose claim about a method of treatment is suitable published clinical trials or studies.

See the [ASA Guidance Note on Advertising Health Services](#) for more information.

See Appendix 1 for more information on substantiating claims.

Examples of Therapeutic Purpose claims

The following examples of claims (and other similar claims or to claims that imply the same) relating to COVID-19 may be considered Therapeutic Purpose claims and are not permitted for use in advertisements unless the product or service meets the criteria noted above. These examples are not an exhaustive list.

- Prevents COVID-19
- Treats COVID-19
- Treats the symptoms of COVID-19
- Cures COVID-19
- Tests for COVID-19
- Reduces the symptoms of COVID-19

- Reduces the length of time to recover from COVID-19
- Increases or improves the body’s immune response
- Prevents viruses taking hold in the respiratory system
- Protects against viral infections
- Prevents viral infections
- Anti-viral product
- Improves lung function to better cope with the symptoms of COVID-19
- Soothes and calms the symptoms of COVID-19 infection
- Boosts the immune system to be able to fight the COVID-19 virus
- Opens the airways to relieve shortness of breath resulting from COVID-19
- This product will help protect you from the currently circulating viruses and other bugs.

What is a Health Benefit claim?

The definition of a health benefit in the Therapeutic and Health Advertising Code is as follows:

‘Health Benefit’ – Means any one of the following benefits:

1. *the maintenance or promotion of health or wellness*
2. *nutritional support*
3. *vitamin or mineral supplementation*
4. *maintaining the normal structure or function of the body*

Products that are not Medicines or Medical Devices and Health Services that are not ‘Methods of Treatment’ may only make health benefit claims, not therapeutic purpose claims, in their advertisements. **Please note, these health benefit claims may not be actual or implied claims about COVID-19 or about any other disease, injury, ailment, deformity, disorder, or adverse condition, whether of body or mind.**

Examples of Health Benefit claims that may be appropriate (providing they can be substantiated by the advertiser) include, but are not limited to;

- Supports a healthy immune system
- Support healthy lung function
- Nutrition and support for normal / healthy airways
- Nutrients for a healthy body / immune system / lung function
- A holistic approach to good health
- A whole body approach to a well-functioning immune system
- Support for the immune defenses

The minimum substantiation for a Health Benefit claim about a product or health service

may include published scientific studies, research and other published evidence.

See Appendix 1 for more information on substantiating claims.

What about hand sanitiser products?

These products are not ‘consumed’ for internal purposes so they do not strictly fit the definition of a therapeutic or health product or service. They are applied on the surface of the skin.

The ASA Codes do apply to advertisements for these products and of course, the Fair Trading Act also applies. Any claims specific to COVID-19 made in an advertisement about a hand sanitiser or similar product must be able to be substantiated with scientific proof.

There is an exemption in the Medicines Regulations 1984 that allows a general claim to be made for the prevention of the spread of bacteria. This may be considered a ‘therapeutic purpose’ despite these products not being medicines or medical devices. It is important to note, that even this general claim must be able to be substantiated by the advertiser and it does not extend to any named virus such as COVID-19.

The relevant section of the Medicines Regulations 1984 is Part 12, Section 58 A (1) (e);

Substances that are not medicines or related products for purposes of Act

(1) The following classes of substances are not medicines or related products for the purposes of the Act:

(e) anti-bacterial skin products, provided that—

(i) the product does not contain a medicine specified in [Schedule 1](#); and

(ii) the product is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium); and

(iii) the product is not presented as being for use in connection with—

(A) any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or

(B) either of the procedures specified in subclause (2); and

(iv) the product is not recommended for use in connection with the provision of health services (as defined in [section 2](#) of the Health and Disability Commissioner Act 1994).

(2) The procedures referred to in subclause (1)(e)(iii)(B) are—

(a) piercing the skin or mucous membrane for any purpose; and

(b) venipuncture, or the delivery of an injection.

Advertising Standards Complaints Board Decisions

See Appendix 2 for information about responding to a complaint.

Social responsibility in advertising is embodied in the Principles and Rules of the Codes. In interpreting the Codes, emphasis must be placed on compliance with both the spirit and intention of the Codes. It is possible for advertising to be in breach of one or more of the Principles in the Codes without being in breach of a specific Rule.

In determining whether a Principle has been breached, the Complaints Board will have regard to all relevant matters, including;

- generally prevailing community standards;
- previous decisions;
- the consumer takeout from the advertisement;
- the context, medium and intended audience; and
- the product or service being advertised.

TAPS (Therapeutic Advertising Pre-Vetting Service)

The ASA strongly recommends advertisers make use of the Therapeutic Advertising Pre-Vetting Service (TAPS) user-pays service to help minimise the risk of breaching the ASA Codes, as well as other industry codes and relevant legislation. TAPS is available to all advertisers making therapeutic or health claims in advertisements. Information about TAPS is available at the [ANZA website](#) including a range of useful [advertising guidelines](#).

If you have any questions on advertisements outside the scope of TAPS, you can email us asa@asa.co.nz.

The following links are considered relevant

Many pieces of legislation apply to advertising along with the ASA Codes and industry sector codes. Legal advice for advertisements is recommended, particularly in high risk sectors.

The following links are considered relevant.

- [Medicines Act 1981](#)
 - [Meaning of a Method of Treatment](#)
 - [Meaning of a Medical Device](#)
 - [Meaning of a Medicine](#)
 - [Meaning of a Therapeutic Purpose](#)
 - [Restrictions on the sale or supply of new medicines](#)
 - [Restrictions on Advertisements](#)
 - [Further Restrictions on Advertisements](#) (relevant to customer reviews / testimonials)
- [22 April 2020 New Zealand Gazette Notice Under Section 37 of the Medicines Act 1981](#)
- [Medsafe background information COVID-19 – point of care test kits – restriction on importation, manufacture, supply and use](#)
- [Medicines Regulations 1984](#)
- [Dietary Supplements Regulations 1985](#)
- [Fair Trading Act 1986](#)
- [ASA Advertising Standards Code](#)

- [ASA Therapeutic and Health Advertising Code](#)
- [ASA Guidance Note on Advertising Health Services](#)
- [Medicines New Zealand Code of Practice](#)
- [Self-Medication Industry Association Code of Practice](#)
- [Natural Health Products NZ Code of Conduct](#)
- [Natural Health Practitioners New Zealand Code of Ethics](#)

APPENDIX 1: What are the rules for substantiating therapeutic purpose or health benefit claims in advertisements?

What are the rules for substantiating therapeutic purpose or health benefit claims in advertisements?

Any claim made in an advertisement must be able to be substantiated. Advertisers should hold the substantiation for their claims prior to placing the advertisement. Advertisers are expected to be able to provide this substantiation when responding to a complaint about misleading claims.

This requirement is contained in Rule 2 (a) of the Therapeutic and Health Advertising Code, which states:

Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated. Substantiation should exist prior to a claim being made. For medicines and medical devices, therapeutic claims must be consistent with the approved indication(s) (for medicines) or the listed intended purpose (for medical devices).

It is also important to note that it is an offence under the Fair Trading Act 1986 to make a claim in an advertisement that cannot be substantiated, and advertisers must be able to prove a claim is true before that claim is made. This Commerce Commission [Fact Sheet](#) provides an overview of the substantiation provisions of the Fair Trading Act 1986.

Substantiation provided to the ASA by advertisers will be assessed by the Complaints Board or Appeal Board for the quality of the evidence. It is important to note that the boards are not the arbiters of scientific fact.

As noted in a previous section, the minimum substantiation for a therapeutic purpose claim about a medicine is the product data sheet, consumer medicine information or approved label. The minimum substantiation for a therapeutic purpose claim about a medical device is the WAND listing including the listed intended purpose where listing on WAND is required. Advertisers of medical devices should also be able to provide suitable published clinical trials or studies to support the claims in the listed intended purpose.

Advertisers responding to a complaint alleging misleading claims must also provide the ASA with the full paper(s), printed or scanned and 'marked up' *i.e. the advertiser must highlight the exact part(s) of the study(s) or trial or research that they believe substantiates their claims.*

In light of the principle that advertisers should hold the substantiation for their claims prior to placing advertisements, it should not take the advertiser long to produce evidence when asked to substantiate a claim. The evidence should be immediately available and should not need to be assembled in order to respond to a complaint. If advertisers require time to produce their evidence, it should not be a long period (*i.e. a matter of days rather than weeks*).

APPENDIX 2: Responding to a complaint

Once the ASA has accepted a complaint we write to the advertiser and other parties to the advertisement (such as the advertising agency or the media placement organisation) and ask for a response. The options available to advertisers include;

Settling the Complaint

There are two options to consider with regard to settling a complaint.

1. Advertisers can **remove** the advertisement or the part of the advertisement that has been raised in the complaint. Advertisers would need to confirm in writing the advertisement has been removed and provide the ASA with an undertaking not to use the advertisement again (or the part of the advertisement that has been removed).
2. Advertisers can **amend** the advertisement to address the issue(s) raised in the complaint. If advertisers choose to amend the advertisement a copy of, or a link to, the changed advertisement is sent to the ASA. The Chair of the Complaints Board considers the amendments and decides whether they are sufficient to settle the complaint. Alternatively, the complaint along with the changed advertisement may be referred to the Complaints Board for a decision.

Defending the Complaint

Advertisers may choose to defend the complaint, in writing, to the ASA.

If the complaint is about unsubstantiated therapeutic or health benefit claims, the response will need to include appropriate **substantiation** for these claims.

Once received, the advertiser's response, the advertisement and the complaint are referred for consideration by the Complaints Board. The Board decision will be sent to parties before it is published on our website.