
Advertising Guidelines

St Vincent’s Hospital Melbourne 2020

Contents

Introduction	2
Basic Rules for Advertising	2
Advertising Using Poster, Flyers, Pamphlets	3
Advertising Using Flyers Examples.....	4
Advertising Using Traditional Media Formats	4
Advertising Using Websites	4
Advertising Using a Website Example	5
Advertising Using Social Media	5
Business Owners’ Responsibilities in Social Media Advertising	6
Business Owners’ Responsibilities in Social Media Advertising for Therapeutic Goods ...	6
Recommendations for Social Media Influencers in Advertising Therapeutic Goods	7
Advertising Using Social Media Examples	8
Reference Documents	9

Introduction

Challenges associated with participant recruitment are many and varied, however, lack of awareness and access to trial opportunities are key reasons for poor participation rates. Additionally, effective communication through advertising can sometimes be challenging.

All information for consumers should be scannable, accessible and presented in plain language. The use of medical terminology or technical jargon can be a barrier to involvement, and you can counter this by ensuring that the language used to communicate with potential participants and patients is presented in a readable way and adapted to the appropriate level of technical knowledge.

- Avoid jargon so the user can understand the content the first time they read it.
- Use active voice — not passive.
- Use the shorter, plain English word, term, sentence and paragraph over the longer.
- Minimise punctuation. Use several short sentences instead of a long sentence broken up with punctuation.
- Aim for an age 9 reading level

Click [here](#) for more information on writing in Plain English.

Infographics can also be a useful way to present technical content wherever feasible or relevant— this is an effective way of communicating more complex, important, or time-sensitive information.

Use inclusive language and be mindful and respectful of consumers when using medical terminology. For example, describing expectant mothers as ‘patients’ might incorrectly imply illness or disease. Similarly, it is insensitive and stigmatising to define patients by their illness; refer to ‘people with schizophrenia’ instead of ‘schizophrenics’ and to ‘people with diabetes’ instead of ‘diabetics.’

Basic Rules for Advertising

When advertising a product or study, please ensure that the advertisement:

- is conducted in a manner that promotes the quality use of the product or study
- is socially responsible, and
- does not mislead or deceive the consumer
- is accurate, balanced and verified
- makes claims that are consistent with the advertised indication or intended purpose

Advertisements of **Therapeutic Goods** should additionally:

- contain certain mandatory warning statements, which vary depending on the type of therapeutic good being advertised
- only use testimonials that comply with the Code - testimonials must comply with all applicable aspects of the Code, not just the requirements set out in section 17 of the Code
- not claim that a product can diagnose, treat or cure a serious condition without prior permission or approval from the TGA.

Consider the Ethics requirements for any advertising material that you create. **If it is study specific advertising, you will require sponsor and ethics approval.** Generic advertising does not require

ethics. Always include contact information in both study specific and general advertising material so that people have an immediate pathway for enquiries.

Some therapeutic goods, including prescription and certain pharmacist-only medicines are prohibited from being advertised directly to the public. These goods are high risk and their safe and appropriate use requires health professional oversight to ensure the benefits outweigh the harms for each individual.

Before advertising your study, it is your responsibility to understand the relevant legislative requirements:

- [Australian Code for the Responsible Conduct of Research \(2018\)](#)
- [National Statement on Ethical Conduct in Human Research \(2018\)](#)
- [Medicines Australia Code of Conduct \[Ed. 19 \(2020\)\]](#)
- [Australian Regulatory Guidelines for Advertising Therapeutic Goods \(ARGATG\) – Guidance for Advertisers \(2020\)](#)
- [Therapeutic Goods Act 1989](#)
- [Therapeutic Goods Advertising Code \(No.2\) 2018](#)

Advertisements of therapeutic goods are required to comply with the advertising requirements set out in the *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code (No.2) 2018.

Additionally, *The US Food & Drug Administration (FDA)* has useful guidance tools for advertising and promoting therapeutic goods. Please click here to review.

- [Advertising and Promotion Guidelines](#)
- [Glossary of Terms](#)
- [Basics of Drug Ads](#)
- [Using Social Media](#)

Advertising Using Poster, Flyers, Pamphlets

This is a very useful and efficient method of advertising at hospitals and clinics as they can be displayed in an area that may be frequented by the types of participants you may be hoping to recruit.

Areas you may want to consider displaying your advertisements include but are not limited to:

- Staff/patient noticeboards
- Lifts
- Waiting room areas
- Consulting rooms
- Treatment rooms
- Rest rooms

Advertising Using Flyers Examples

Good	Bad
<p data-bbox="300 412 596 450">‘The IDEAL Study’</p> <p data-bbox="196 468 699 535">‘The very long, official stuDy titlE that hAs compLex wording (IDEAL)’</p> <p data-bbox="240 589 655 680">We are seeking research participants</p> <p data-bbox="196 728 699 804">This study aims to evaluate the effects of a novel therapeutic to treat ‘a debilitating illness,’ to hopefully lead to more efficacious treatment.</p> <p data-bbox="196 851 699 927">Participation includes 20 study visits to St Vincent’s Hospital Melbourne ‘Department,’ including reimbursement for travel.</p> <p data-bbox="196 1003 699 1057">We are seeking participants over 18 years of age who have been diagnosed with ‘the illness’ within the last 12 months.</p> <p data-bbox="196 1090 660 1108">Please contact us for further information or to see if you may be eligible:</p> <ul data-bbox="212 1117 517 1155" style="list-style-type: none">▪ principal.investigator@institutionemail.com▪ 03 9999 9999	<p data-bbox="970 403 1331 441">‘The not-IDEAL Study’</p> <p data-bbox="906 459 1393 526">‘The very long, official stuDy titlE that hAs compLex wording (IDEAL)’</p> <p data-bbox="978 573 1321 611">\$4,000 to participate</p> <p data-bbox="906 660 1393 736">This study aims to test a brand-new, safe drug ‘name of unapproved therapeutic’ to cure your ‘debilitating, incurable illness.’</p> <p data-bbox="914 779 1385 855">Participation will earn you \$4,000 if you visit St Vincent’s Hospital Melbourne ‘Department’ 20 times – that’s \$400 a visit to cure your ‘illness.’</p> <p data-bbox="914 929 1393 1005">We are seeking anybody who has had no luck with other treatments to try this better, safer drug with <i>no severe side effects</i>.</p> <p data-bbox="898 1039 1118 1057">Please contact us to sign up today:</p> <ul data-bbox="922 1066 1206 1104" style="list-style-type: none">▪ principle.investigator@personalemail.com▪ 0400 000 000

Advertising Using Traditional Media Formats

Traditional advertising is not as common as it once was due to the rise of digital advertising. If your target audience is older than it may be beneficial to consider traditional advertising.

This includes advertising such as:

- Radio
- TV
- Print

Advertising Using Websites

Website advertising is a useful way to advertise a study, or set of studies, for companies who are running multiple trials at any time. A website can be used to list all active trials that the public can then easily navigate to see whether any study is right for them.

In addition to a private website listing all the trials a particular company may be running, national websites exist collating all active trials in Australia, including:

- [Australian Clinical Trials](#)
- [Australian Cancer Trials](#)
- [ANZCTR \(Australian New Zealand Clinical Trials Registry\)](#)

Advertising Using a Website Example

Study name	Criteria for participation	Drug/Device?	Number of visits
<i>'The Ovarian Cancer Study'</i>	<ul style="list-style-type: none"> ○ Biological sex non-pregnant female ○ Age Over 18 years of age ○ Medical history Have been diagnosed with ovarian cancer 	✓	30
<i>'Assessing Attitude Toward Injury Severity in the ED'</i>	<ul style="list-style-type: none"> ○ Biological sex males or females ○ Age Over 18 years of age ○ Medical history Have visited the St Vincent's Emergency Department in 2020 	X	1

Advertising Using Social Media

Advertising, as defined by the TGA, is any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods is an advertisement. A social media post that promotes the use or supply of therapeutic goods is an advertisement.

If considering using Social Media as your advertising media, please consider the below points:

- Consider the multiple advertising options available before recruitment starts. Be mindful of the social media platforms you wish to use, as certain images or wording can be rejected by the platform. Ensure to check the social media advertising policies of each platform intended for use.
- You will need to include your Social Media Advertising template in your ethics application or submit an amendment to the study prior to utilising that form of advertising.
- It is important to note that social media is not set and forget. Social media campaigns require regular review and adjustment to ensure that the correct audience is being reached, and that you are getting the most out of your ad. You also need to ensure that you have enough resources to manage comments/enquiries that filter through from ads and posts. If campaigns are not managed correctly, they can be harmful to your study and institution reputation.

Business Owners' Responsibilities in Social Media Advertising

Business owners are responsible for the content of any social media page created or managed by them, including websites, social media channels, blog posts, hashtags or discussion forums. This responsibility extends to user-generated content, such as third party comments posted on those social media platforms that are controlled by the business.

To allow a reader to identify the source of information provided on a website the company name must appear on the home page of any site developed by a pharmaceutical company. This includes sites for healthcare professionals, patients and the general public. In the case of a sponsored site, for example a college, society or health consumer organisation website that has been developed with financial assistance from a pharmaceutical company, in the interest of transparency an acknowledgement that it has been prepared with assistance through an educational grant from [Company X] should be included on the home page of the site.

Business Owners' Responsibilities in Social Media Advertising for Therapeutic Goods

(As outlined on the TGA website)

- All advertising for therapeutic goods must promote the safe and responsible use of those goods and must not take advantage of consumers, including through third party comments on social media.
- Compliance with the advertising requirements under therapeutic goods legislation means that social media advertisements for therapeutic goods must meet the following requirements (as listed on the TGA website).
- Advertisements must include the relevant mandatory statements, including health warnings where applicable
- Advertisements must not promote a therapeutic good for a purpose other than the purpose accepted by the TGA and entered in the Australian Register of Therapeutic Goods entry for the good.
- Advertisements must not contain prohibited or restricted representations without prior permission or approval from the TGA.
- Advertisements must not promote goods with therapeutic use claims if those goods are not included in the Australian Register of Therapeutic Goods (unless the goods are exempt from that requirement). Making therapeutic use claims about a product in an advertisement will generally make the advertisement subject to the legal requirements for advertising therapeutic goods, even if the product may not ordinarily be considered a therapeutic good. An exception applies for foods for which there is a food standard. To find out if a food standard applies, go to the 'food medicine interface' guidance tool on the TGA website.
- Advertisements must only use testimonials that are compliant with the Code, including the requirement to disclose, where applicable, that the testimonial provider has received 'valuable consideration' for the provision of the testimonial. 'Valuable consideration' is payment of some value (such as monetary payment or free product). Advising consumers that a testimonial provider has received an incentive to provide a testimonial will assist consumers in making an informed decision about the weight they give such testimonials. Further information about testimonials and 'valuable consideration' is available in the Code guidance.

- Advertisements must not contain testimonials or endorsements which breach the Code. Such testimonials and endorsements must be removed within a reasonable timeframe. What is considered a reasonable timeframe depends on factors such as the size of the company and the number of followers the page has. Between 24-48 hours is considered a 'reasonable timeframe' for large companies with dedicated regulatory staff. Smaller companies with a smaller following may require a longer period (up to 5 days). The ACCC has provided further guidance on their website.

Recommendations for Social Media Influencers in Advertising Therapeutic Goods

(As outlined on the TGA website)

If you are an influencer who is involved with a therapeutic goods company (for example, you have been paid or given a product by the company to promote their products), you should consider the following tips.

- Any post about a therapeutic good that you make may be considered advertising. If it is, you have an obligation to comply with the advertising requirements for therapeutic goods.
- Any comments you make about your personal experience with therapeutic goods amounts to a testimonial. Testimonials are not permitted by those involved in the production, sale, supply or marketing of the goods. This includes influencers who are engaged by a therapeutic goods company to promote the goods.
- Your social media posts may have an impact on your followers' beliefs, attitudes, preferences and behaviours. Your comments about therapeutic goods can influence consumers' choices. Therapeutic goods should be chosen on the basis of clinical need, not through the persuasion of influencers.
- Understand what the approved purpose of the good is and do not advertise the good for a purpose other than that, even if your experience with the good is otherwise. For more information about the intended purpose of a therapeutic good, see the Australian Register of Therapeutic Goods.
- Seek advice from a lawyer or regulatory affairs consultant if you are unsure about your obligations in relation to social media advertising of therapeutic goods. For more information about advertising therapeutic goods, visit the TGA Advertising Hub.

For more information about advertising Therapeutic goods, please visit the [TGA Advertising Hub](#).

Advertising Using Social Media Examples

Good	
	<p>The IDEAL Study</p> <p>Have you or a loved one been diagnosed with 'an illness' and are 18 years or older? Learn more about a research study aiming to assess novel treatments for 'the illness.'</p> <div data-bbox="470 501 1152 781" style="border: 1px solid black; padding: 10px; text-align: center;"><p>*A picture related to the study*</p></div> <div data-bbox="470 784 1152 891" style="border: 1px solid black; padding: 5px;"><p>The Ideal Study www.theidealstudy.com.au Click to learn more about the study and assess your eligibility</p></div>
Bad	
	<p>The not-IDEAL Study</p> <p>Are you watching a loved one suffer from 'an illness' and wish there was a cure? Our research team believes our clinical trial can help!</p> <div data-bbox="488 1205 1134 1473" style="border: 1px solid black; padding: 10px; text-align: center;"><p>*A picture not related to the study, with potential to evoke emotion for engagement*</p></div> <div data-bbox="488 1476 1134 1574" style="border: 1px solid black; padding: 5px;"><p>The not-Ideal Study www.thenot-idealstudy.com.au Contact us for the cure!</p></div>

Reference Documents

- [Australian Code for the Responsible Conduct of Research \(2018\)](#)
- [National Statement on Ethical Conduct in Human Research \(2018\)](#)
- [Medicines Australia Code of Conduct \[Ed. 19 \(2020\)\]](#)
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- [Therapeutic Goods Act 1989](#)
- [Therapeutic Goods Advertising Code \(No.2\) 2018](#)
- [FDA Advertising and Promotion Guidelines](#)
- [FDA Glossary of Terms](#)
- [FDA Basics of Drug Ads](#)
- [FDA Using Social Media](#)