



Australian Government
Department of Health
Therapeutic Goods Administration

Firstname Surname
Company
Address line 1
Address line 2
Address line 3

Sample Only

Our Reference: Xxxx/xxxxx

Dear

**YOUR LEGAL OBLIGATIONS WHEN ADVERTISING
THERAPEUTIC GOODS**

The Therapeutic Goods Administration (TGA) is writing to remind you of your legal obligations when advertising therapeutic goods, such as medicines and medical devices. Advertisements for therapeutic goods must comply with the Therapeutic Goods Act 1989 (the Act), Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods Advertising Code (No. 2) 2018 (the Code).¹ Your advertising has come to the TGA's attention through a complaint.

IMPORTANT INFORMATION

- Review your advertising material (based on the information in this letter) to ensure it complies with the therapeutic goods advertising requirements.
- New and increased sanctions and penalties came into force on 6 March 2018 for non-compliant advertising – see Attachment 2 for a summary.

A copy of the Code can be found at <https://www.tga.gov.au/publication/therapeutic-goods-advertising-code>

Copies of the Act and Regulations can be accessed via the TGA website – see <https://www.tga.gov.au/legislation-legislative-instruments>.

¹ The Therapeutic Goods Advertising Code 2015 (the Code) was replaced with the Therapeutic Goods Advertising Code (No. 2) 2018 on 1 January 2019. The 2018 Code can be found [here](#). In some limited circumstances the previous Code, the Therapeutic Goods Advertising Code 2015, may apply. If this is the case, we will advise you below.

Advertising requirements

Through a range of criminal offences and civil penalty provisions, the Act specifies the requirements that advertisers must comply with when advertising therapeutic goods to the public. These include:

- the requirements set out in the criminal offence provisions in section 42DL of the Act (which are replicated in the civil penalty provisions at section 42DLB), and
- the requirements set out in the criminal offence provision at section 42DM (and replicated in the civil penalty provisions at section 42DMA) which specify that advertisements to the public must comply with the Code.

Where there is a section 22(5) or section 41ML matter further information is inserted here, for example:

- *Section 22(5) of the Act states that a person commits an offence if, by any means, they advertise a therapeutic good for an indication that is not accepted in relation to the Australian Register of Therapeutic Goods (ARTG) entry for the good.*
- *Section 41ML - A person commits an offence if:*
 - (a) the person, by any means, advertises a medical device as being for a purpose: and*
 - (b) the device is of a kind included in the ARTG; and*
 - (c) the purpose is not a purpose accepted in relation to that inclusion*

Where advertising does not comply with these requirements, the TGA may use a range of sanctions before pursuing court action under the criminal or civil penalty provisions. Where non-compliance continues, the TGA may escalate its actions. The sanctions and penalties that the TGA may pursue, with the possible consequences for advertisers, is described in Attachment 2.

The complaint

The complaint we received concerned the advertising of [product name/s] in or on [media in which it appeared] on [date].

Information on the complaint is inserted here.

Compliance with the Act

An explanation of what the complainant raised in relation to the Act, including the provisions, for example:

- *Section 42DL(9) of Act - representations in your advertising that implied the therapeutic goods being advertised are endorsed by a government agency*
- *representations in your advertising that stated or implied that the therapeutic goods being advertised...*

Compliance with the Code

An explanation of what the complainant raised regarding the Code, including provisions, for example:

- *Section 10(d)(i) of the Code - representations in your advertising that stated or implied that the therapeutic goods being advertised are safe or cannot cause harm*
- *representations in your advertising that stated or implied that the therapeutic goods being advertised...*

Information on other advertising Code compliance issues identified is also provided here.

Compliance with the 2015 Code

While the Therapeutic Goods Advertising Code (No.2) 2018 took effect on 1 January 2019, certain advertisements are still required to comply with the Therapeutic Goods Advertising Code 2015 (2015 Code).

Explanation of which ad/s need to comply with the 2015 Code and why.

An explanation of what the complainant raised regarding the 2015 Code, including provisions, for example:

- *Section 4(2)(i) of the Code - representations in your advertising that stated or implied that the therapeutic goods being advertised are safe or cannot cause harm*
- *representations in your advertising that stated or implied that the therapeutic goods being advertised...*

Information on other 2015 Code advertising compliance issues identified is also provided here.

We ask that you review the identified advertisement, and other relevant advertising for therapeutic goods, as soon as possible to ensure they comply with the law.

Further relevant information and materials are provided here, for example:

To assist, I refer you to:

- <https://www.tga.gov.au/advertising-cosmetic-injections>
- <https://www.tga.gov.au/book-page/advertising-therapeutic-goods-related-services>
- <https://www.tga.gov.au/advertising-guidance-advertisers>
- <https://www.tga.gov.au/book-page/advertising-and-endorsements>
- <https://www.tga.gov.au/what-does-it-mean-advertise-therapeutic-goods>
- <https://www.tga.gov.au/book-page/about-code-and-guidance>

The TGA will not be pursuing this complaint any further at this time. However, your advertising may be monitored for compliance or under an assurance review, and any future complaints will be considered having regard to this correspondence.

The TGA is notifying you of this complaint so you can ensure your advertising is compliant with the law.

Further information on the new complaints framework and other reforms to the advertising framework for therapeutic goods is available from

<https://www.tga.gov.au/reforms-therapeutic-goods-advertising-framework>.

We have attempted to confirm the currency of the advertising at the centre of the complaint before sending this letter. However, we acknowledge that the advertising could have been removed or made compliant since the TGA received the complaint.

Need assistance?

We can provide some assistance in relation to the original complaint. However to obtain further assistance and an assessment of your advertising, you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant. You can find a list of organisations that may be able to assist you in finding a consultant on the TGA website². These consultants are not endorsed by the TGA.

About the TGA

The TGA is part of the Australian Government Department of Health and is responsible for regulating the advertising of therapeutic goods by administering the Act, the Regulations and the Code. The TGA's advertising compliance unit can be contacted through the publicly available enquiry lodgement form at <https://compliance.tga.gov.au/advertising-enquiry/>, by email TGA.Advertising@tga.gov.au or by phone 02 6232 8757.

Yours sincerely

<signed electronically>

Date

Attachment 1 - Example of advertisement'

Attachment 2 - Therapeutic goods advertising-compliance and enforcement tools

Attachment 3 - Relevant legislative extracts

Attachment 4 – If needed

² See <https://www.tga.gov.au/regulatory-affairs-consultants>

Attachment 1

Examples of Advertisement

Attachment 2 - Therapeutic goods advertising - compliance and enforcement tools

The following table sets out the key compliance and enforcement tools that the TGA may use to address advertising of therapeutic goods that does not comply with requirements.

Directions Notice	<ul style="list-style-type: none">•TGA can direct an advertiser to take steps to address non-compliant advertising and/or retract or correct advertising.•Failure to comply with a direction may result in other compliance actions. Directions will be published on the TGA website.
Infringement notice	<ul style="list-style-type: none">•TGA can issue an infringement notice with a fine where an advertiser contravenes an advertising requirement. Multiple infringement notices can be issued, depending on the number of matters identified.•The advertiser will need to address the non-compliant advertising that resulted in the infringement notice in order to avoid further action.
Public Warning Notice	<ul style="list-style-type: none">•TGA can issue a Public Warning Notice to alert consumers about suspected non-compliant advertising if it is in the public interest to do so.
Injunctions	<ul style="list-style-type: none">•TGA can seek injunctions from the Federal Court to restrain a person from advertising in a way that contravenes the advertising requirements or to compel a person to comply with the requirements.
Civil & Criminal Sanctions and Penalties	<ul style="list-style-type: none">•If convicted by a court for criminal advertising offences (including failure to comply with a direction), it can impose penalties of up to 5 years imprisonment, 4,000 penalty units, or both.•Where civil action is pursued, a court can impose maximum penalties of 5,000 penalty units (for an individual) or 50,000 penalty units (for a body corporate).•Multiple advertising offences may be pursued.

* The value of a penalty unit is currently \$210 as set out in section 4AA of the *Crimes Act 1914*.

The TGA's approach to advertising compliance is described in the [Advertising Complaints Handling Policy](#), available from the TGA website.

Attachment 3

Relevant legislative extractsⁱ

Therapeutic Goods Act 1989

Section 3 Interpretation

(1) *Advertise*, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or:

- (a) is on the label of the goods; or
- (b) is on the package in which the goods are contained; or
- (c) is on any material included with the package in which the goods are contained.

therapeutic goods means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:
- (c) goods declared not to be therapeutic goods under an order in force under section 7; or
- (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
- (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or
- (f) goods (other than goods declared to be therapeutic goods under an order in force under section (7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

therapeutic use means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- (b) influencing, inhibiting or modifying a physiological process in persons; or
- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons.

42C Offences relating to publication of advertisements

(1) A person is guilty of an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast; in specified media, an advertisement that is required by the Therapeutic Goods Regulations to be an approved advertisement; and

(b) the advertisement is not an approved advertisement.

Penalty: 60 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(2) A person is guilty of an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast; an advertisement in specified media; and

(b) the advertisement is not an approved advertisement in that it differs, in any respect, from the advertisement that was approved.

Penalty: 60 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(3) It is a defence to a prosecution under subsection (2) if:

(a) the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business; or

(b) the particular advertisement to which the prosecution relates differs only in respect of a matter mentioned in paragraph 5C(2)(b), (e) or (f) of the Therapeutic Goods Regulations.

Note: A defendant bears an evidential burden in relation to the matters in subsection (3) (see subsection 13.3 of the *Criminal Code*).

(4) A person is guilty of an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast; a particular advertisement in specified media referred to in paragraph (a), (c) or (d) of the definition of **specified media**; and

(b) the advertisement:

(i) does not display its approval number; or

(ii) displays a number purporting to be its approval number but that is not its approval number; or

(iii) displays an approval number that has expired.

Penalty: 30 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(5) It is a defence to a prosecution under subsection (4) if the person prosecuted:

(a) is a publisher who received the advertisement to which the prosecution relates for publication in specified media referred to in paragraph (a), (c) or (d)

of the definition of *specified media*; or

(b) is a broadcaster who received the advertisement to which the prosecution relates for broadcasting in visual broadcast media; in the ordinary course of business.

Note: A defendant bears an evidential burden in relation to the matters in subsection (5) (see subsection 13.3 of the *Criminal Code*).

(6) A person is guilty of an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast; in specified media, an approved advertisement; and

(b) the person's action is in contravention of a condition to which the approval of the advertisement is subject.

Penalty: 60 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(7) It is a defence to a prosecution under subsection (6) if the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business.

Note: A defendant bears an evidential burden in relation to the matters in subsection (7) (see subsection 13.3 of the *Criminal Code*).

(8) An offence against this section is an offence of strict liability.

42DKB Certain representations not to be advertised

(1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to a person apparently responsible for:

(a) advertising the therapeutic goods; or

(b) causing the advertising of the therapeutic goods;

prevent that person from advertising the therapeutic goods, or causing the advertising of the therapeutic goods, in circumstances where the advertisement contains that representation (whether in express terms or by necessary implication).

Note: See sections 42DLA and 42DLC for criminal offences and a civil penalty for contravening the notice.

(2) A notice under subsection (1) is not a legislative instrument.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause the notice to be published on the Department's website.

42DL Advertising offences - general

(1) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11), or (12) applies to the advertisement; and

(c) either:

(i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods in reliance on the advertisement, if the goods were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11), or (12) applies to the advertisement.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11), or (12) applies to the advertisement.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Contravening provisions

(5) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

(a) no permission under section 42DK is in force in relation to the prohibited representation;

(b) a permission under 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(6) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(7) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

(a) neither an approval under 42DF nor a permission under section 42DK is in force in relation to the restricted representation;

(b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(8) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

(9) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

(a) a statement of the availability of the goods as a pharmaceutical benefit; or

(b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or

(c) a statement, pictorial representation or design prescribed by the regulations

for the purposes of this paragraph.

(10) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(11) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(12) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised by a government or government authority (not including a foreign government or foreign government authority).

Continuing offences

(13) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day which the contravention

(14) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DLA Advertising offences – contravening section 42DKB notice

(1) A person commits an offence if:

- (a) the Secretary has given notice to the person under section 42DKB in relation to therapeutic goods; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the notice; and
- (d) either:
 - (i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or
 - (ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and
- (e) the harm or injury has resulted, will result, is likely to result, would result or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

- (a) the Secretary has given a notice to the person under section 42DKB; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

- (a) the Secretary has given notice to the person under section 42DKB; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the notice.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence under strict liability.

42DLB Civil penalty relating to advertisements—general

(1) A person contravenes this subsection if:

- (a) the person:
 - (i) advertises, by any means, therapeutic goods; or
 - (ii) causes the advertising, by any means, of therapeutic goods; and
- (b) subsection (2), (3), (4), (5), (6), (7), (8) or (9) applies to the advertisement.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

Contravening provisions

(2) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

- (a) no permission under section 42DK is in force in relation to the prohibited representation;
- (b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(3) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(4) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

- (a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;
- (b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(5) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

(6) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

- (a) a statement of the availability of the goods as a pharmaceutical benefit; or
- (b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or
- (c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

(7) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(8) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(9) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Exception

(10) Subsection (1) does not apply if:

- (a) the person is a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the regulations for the purposes of this paragraph; and
- (b) as a result of steps taken by the person, it was reasonable for the person to assume that subsections (2) to (9) did not apply to the advertisement.

(11) In this section:

broadcaster has the meaning given by clause 3 of Schedule 2 to the Broadcasting Services Act 1992.

datacaster means a person who holds a datacasting licence (within the meaning of the Broadcasting Services Act 1992).

SBS has the same meaning as in the Special Broadcasting Service Act 1991.

42DLC Civil penalty relating to advertisements—contravening section 42DKB notice

A person contravenes this section if:

- (a) the Secretary has given a notice to the person under section 42DKB; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the notice.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

42DM Offences—non-compliance with the Therapeutic Goods Advertising Code

(1) A person commits an offence if:

- (a) the person:
 - (i) advertises, by any means, therapeutic goods; or
 - (ii) causes the advertising, by any means, of therapeutic goods; and
- (b) the advertisement does not comply with the Therapeutic Goods Advertising Code; and
- (c) either:
 - (i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or
 - (ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

- (a) the person:
 - (i) advertises, by any means, therapeutic goods; or
 - (ii) causes the advertising, by any means, of therapeutic goods; and
- (b) the advertisement does not comply with the Therapeutic Goods Advertising Code. Penalty: Imprisonment for 12 months or 1,000 penalty units, or

both.

(3) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code. Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Continuing offences

(5) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(6) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DMA Civil penalty—non-compliance with the Therapeutic Goods Advertising Code

(1) A person contravenes this section if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception

(2) Subsection (1) does not apply if:

(a) the person is a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the regulations for the purposes of this paragraph; and

(b) as a result of steps taken by the person, it was reasonable for the person to assume that the advertisement complied with the Therapeutic Goods Advertising Code.

(3) In this section:

broadcaster has the meaning given by clause 3 of Schedule 2 to the *Broadcasting Services Act 1992*.

datacaster means a person who holds a datacasting licence (within the meaning of the *Broadcasting Services Act 1992*).

SBS has the same meaning as in the *Special Broadcasting Service Act 1991*.

ⁱThese extracts are provided for informational purposes only. The current legislation should be read in context with the regulatory framework. The full documents from which the extracts above are derived are available on the Commonwealth Attorney General's website (www.legislation.gov.au). If you are unfamiliar with the therapeutic goods regulatory framework and legislation, you may wish to engage independent legal advice or the services of a regulatory affairs consultant.

Attachment 4

For discretionary use. Present photos etc. here