



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DIRECTION UNDER SECTION 42DV

ISSUED TO:

CHOLREM PTY LTD ACN 628 804 197

and

MR KYLE HODGETTS

[REDACTED]

ON: 22 September 2025

**ABOUT: Advertising a medicine not included
in the Register, advertising
restricted representations without
the relevant approvals, advertising
a medicine to imply it has been
approved by a government agency,
and advertising a medicine in
contravention of the Therapeutic
Goods Advertising Code**

BY: Avinash Clarke

**Delegate of the Secretary of the
Australian Government Department of
Health, Disability and Ageing**

Therapeutic Goods Administration

PO Box 100

Woden ACT 2606

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[REDACTED]

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nonprescriptionmedicines@health.gov.au

DIRECTION ABOUT AN ADVERTISEMENT

Made Under Section 42DV of the *Therapeutic Goods Act 1989*

TO: CHOLREM PTY LTD
ACN 628 804 197
[REDACTED]
And

MR KYLE HODGETTS
[REDACTED]

By express post and email: [REDACTED]

I, Avinash Clarke, delegate of the Secretary of the Australian Government Department of Health, Disability and Ageing in the Therapeutic Goods Administration (**TGA**), being satisfied that there have been contraventions of sections (ss) 42DL, 42DLB and 42DMA of the *Therapeutic Goods Act 1989* (the **Act**)¹ in relation to the advertising of Remchol or ArteryFixer (which are represented to contain CAVADEx™) (hereafter referred to as ‘**Cavadex or Remchol**’), being therapeutic goods, by Cholrem Pty Ltd (**Cholrem**) and Mr Kyle Hodgetts as follows:

- a. advertising that contains references to Cavadex or Remchol, a therapeutic good that is not included in the Australian Register of Therapeutic Goods (the **Register**), in circumstances where the good is prescribed by the *Therapeutic Goods Regulations 1990* (the **Regulations**) for the purposes of subsection (**subs**) 42DL(12) and 42DLB(9) and where the reference was not authorised or required by a government or government authority;
- b. advertising of Cavadex or Remchol, a therapeutic good, where the advertisement contains restricted representations (within the meaning of s 42DD of the Act) whether in express terms or by necessary implication, including, but not limited to, heart disease and benefits in stroke patients, where no relevant approval (under s 42DF of the Act) or permission (under s 42DK of the Act) is in force in relation to the restricted representations;
- c. advertising of Cavadex or Remchol, a therapeutic good, where the advertising contains statements that suggest or imply the goods have been recommended or approved by or on behalf of a government authority, being the TGA, where the statements were not authorised or required by a government authority, or prescribed by the Regulations;
- d. advertising of Cavadex or Remchol, a therapeutic good, where the advertising does not comply with the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the **Code**)², namely that.

¹ A copy of the Act can be viewed at www.legislation.gov.au

² A copy of the Code may be viewed at www.legislation.gov.au

- i. an advertisement about therapeutic goods must be accurate, balanced and not misleading or likely to be misleading;
- ii. an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication, represents the goods to be safe, or without harm or side effects;
- iii. an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication, represents the goods to be infallible, unfailing, magical or miraculous;
- iv. an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication delays or discourages, or is likely to delay or discourage, persons from seeking necessary medical attention;
- v. an advertisement about therapeutic goods must not be inconsistent with a public health campaign;
- vi. an advertisement about therapeutic goods must not contain a testimonial if the testimonial is made by a person who is engaged in the production, marketing or supply of the goods; and
- vii. an endorsement about therapeutic goods must not be given, whether expressly or by implication by a current or former health practitioner, health professional or medical researcher.

DIRECT Cholrem and Mr Kyle Hodgetts, as the persons apparently responsible for the advertising, to:

1. **Cease** making all claims or representations, including claims made in text or audiovisual materials, referred to in the column entitled ‘Claims, representations and statements’ of the table at **Attachment A**, on any websites, including but not limited to:
 - a. [REDACTED];
 - b. [REDACTED];
 - c. [REDACTED];
 - d. [REDACTED];
 - e. [REDACTED].
2. **Cease** making any of the following audiovisual materials publicly available, either in full or in part, on any websites:
 - a. the video located at Uniform Resource Locator (**URL**) “[REDACTED]” (**the Cholrem Website**) immediately underneath the heading, “This 5 minute video is a must to watch”;

- b. the video located on the Cholrem Website immediately underneath the heading, “Great little video explains Cavadex (made in 2021)”;
 - c. the video located on the Cholrem Website immediately underneath the heading, “Fascinating interview! Explains everything.”;
 - d. the video located at the URL “[REDACTED]” (**Cholrem Science Webpage**) immediately underneath the heading, “Dr. [REDACTED] agrees to be filmed talking about Cavadex”;
 - e. the video located at the Cholrem Science Webpage immediately underneath the heading, “Professor [REDACTED] agrees to be filmed talking about Cavadex”;
 - f. the video located at the Cholrem Science Webpage immediately underneath the heading, “Dr. [REDACTED] explains the science behind Cavadex - December 2024”;
 - g. the video located at the Cholrem Science Webpage immediately underneath the heading, “Interview Founder of Cavadex November 2024”;
 - h. the video located at the Cholrem Science Webpage immediately underneath the heading “Patients are getting better” and above the text reading “[REDACTED] has been using RemChol for 18 months”;
 - i. the video located at the Cholrem Science Webpage immediately underneath the heading “RemChol patient” and above the text reading “[REDACTED] calcium score went down.”; and
 - j. the video located at the Cholrem Science Webpage immediately underneath the heading “RemChol patient” and above the text reading “[REDACTED] has been using RemChol for 2 months.”
3. **Cease** making any claim or representation to the effect that Cavadex or RemChol may treat, alleviate, prevent or otherwise in any way influence any cardiovascular condition including, but not limited to, heart disease, arterial plaque, blood pressure, angina, atherosclerosis or peripheral artery disease.
 4. **Cease** making any claim or representation to the effect that Cavadex or RemChol may treat, alleviate, prevent or otherwise in any way influence the following conditions:
 - a. erectile dysfunction;
 - b. brain/mind fog;
 - c. Niemann-Pick disease; or
 - d. stroke.
 5. Make the following correction with respect to the claims made regarding the TGA and the regulatory status of Cavadex in the video which is displayed at the Cholrem Science Webpage immediately underneath the heading, “Interview Founder of Cavadex November 2024”:

CORRECTION ORDERED BY THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration (**TGA**) has directed Cholrem to make the following correction under section 42DV of the *Therapeutic Goods Act 1989* (Cth) (**Act**).

Cavadex is not entered in the Australian Register of Therapeutic Goods (**ARTG**), and cannot lawfully be imported into, exported from, or supplied or manufactured in Australia unless an exemption, approval or authority applies under the Act.

Medicines for the treatment of serious medical conditions are generally required to be registered on the ARTG before they can be supplied in Australia. The registration process includes an assessment of the safety and efficacy of the medicine by the TGA.

Cavadex has never been registered on the ARTG. No clinical trials were ever submitted to the TGA for assessment and Cavadex has never been assessed for safety or efficacy by the TGA.

Cavadex was previously entered in the ARTG as a listed complementary medicine. Listed medicines are not assessed for safety or efficacy by the TGA before they are entered in the ARTG. The therapeutic claims made by Cholrem about Cavadex were not permitted for a listed medicine and were not accepted by the TGA in relation to the listing of Cavadex. The listing was cancelled at Cholrem's request. At no time did the TGA request 'deregistration' of Cavadex on the basis that it was unable to regulate this product.

The TGA urges anyone who is suffering from any medical condition, or wishes to take steps to prevent any such condition, to seek advice from a suitably qualified medical professional.

The correction must be made by way of a notice displayed on the home page of the Cholrem Website and the home page of any other website controlled by the Directed Persons that has at any time displayed the video that was included on the Cholrem Science Webpage immediately underneath the heading, "Interview Founder of Cavadex November 2024" as of 22 September 2025.

The Directed Persons must take all reasonable steps to ensure that the notice making the correction:

- a. is written in size 14 Arial font;
- b. is of a size that consists of at least 50% of the screen area;
- c. is viewable immediately on screen after the web page is accessed and is not obscured by any pop up or other functionality of the website;
- d. is not blocked by a pop up blocker; and
- e. remains displayed on the screen until closed by the person accessing that website.

The Directed Persons must display the correction required under paragraph 5 on each website for at least 90 days. After the correction has been displayed for 90 days, the correction must continue to be displayed on that website unless and until the Directed Persons cease publishing any content on that website.

CONDITIONS

under subsection 42DV(3) of the Act

6. This **Direction** is subject to the following **conditions** that the Directed Persons must:
- a. Do the things that are the subject of this Direction within 7 calendar days from the date of this Direction, being 5pm 29 September 2025; and,
 - b. Following that day, continue to do those things for an indefinite period; and
 - c. Email evidence of compliance with this Direction to nonprescriptionmedicines@health.gov.au within 14 calendar days from the date of this Direction, being 5pm 7 October.

OTHER INFORMATION

The possible consequences of failing to comply with this Direction are explained in **Attachment B**.

This is an initial decision and is reviewable. Your review rights are set out in **Attachment C**.

Please Note, as required under subsection 42DV(6) of the Act, this Direction will be published on the Department's website as soon as practicable.

DATED: 22 September 2025

(Signed electronically)

Avinash Clarke

Assistant Secretary
Medicines Regulation Division
Therapeutic Goods Administration
Delegate of the Secretary
Australian Department of Health, Disability and Ageing

Attachment A – Examples of advertising

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|--------------------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | Cavadex or Remchol | [REDACTED] | <p>Statements that the goods have specific therapeutic uses including that the goods can:</p> <ul style="list-style-type: none"> • Reverse heart disease^{3,4} • Reduce angina^{3,5} • Reduce peripheral artery disease⁵ • Rapidly reduce or remove arterial plaques^{3,4} • Reduce atherosclerosis⁴ • Benefit stroke patients^{4,5} • Assist with Niemann-Pick disease⁴ | <p><u>Subsection 42DLB(1) where subsection (9) applies</u></p> <p>A person contravenes subs 42DLB(1) of the Act where subs (9) applies in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good, and the advertisement refers to a therapeutic good that is not entered in the Register and is prescribed by the <i>Therapeutic Goods Regulations 1990 (the Regulations)</i> 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).</p> <p>Regulation 7 of the Regulations provides a list of prescribed goods for the purposes of subs 42DLB(9) of the Act, and includes at (i) therapeutic goods that are neither the subject of an exemption, approval or</p> |

³ [REDACTED]

⁴ [REDACTED]

⁵ [REDACTED]

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|--------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>authority under the Act nor an exemption, approval or authority under regulations under the Act.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' promote the use and supply of the goods set out in the 'Therapeutic goods' column as a therapeutic good within the definition provided in the Act.</p> <p>The goods are not entered in the Register, nor subject to any exemption, approval or authority under the Act or regulations made under the Act. The references to those goods in the advertisement were not authorised or required by a relevant government or government authority. The advertisements therefore contravened subs 42DLB(1) where subs (9) applied.</p> |
| 2. | Cavadex or Remchol | [REDACTED] | <p>Statements that the good has specific therapeutic uses including that the good can:</p> <ul style="list-style-type: none"> • Reverse heart disease^{3,4} • Reduce angina^{3,5} • Reduce peripheral artery disease⁵ | <p><u>Subsection 42DLB(1) where subsection (4) applies</u></p> <p>A person contravenes subs 42DLB(1) of the Act where subs (4) applies in circumstances where the person advertises, by any means, or causes the advertising, by any means, of a therapeutic good and the advertisement contains a restricted representation (whether in express terms or by necessary implication), and neither an approval under s 42DF of the Act nor a</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|-------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | <ul style="list-style-type: none"> • Rapidly reduce or remove arterial plaques^{3,4} • Reduce atherosclerosis⁴ • Benefit stroke patients^{4,5} • Assist with Niemann-Pick disease⁴ | <p>permission under s 42DK of the Act is in force in relation to the restricted representation.</p> <p>An advertisement about therapeutic goods that refers to a form of a disease, condition, ailment or defect identified in the Code as a serious form of a disease, condition, ailment or defect is a restricted representation (see s 42DD of the Act). Section 28(a) of the Code provides a form of a disease, condition, ailment or defect is a serious form if it is medically accepted that the form requires diagnosis or treatment or supervision by a health practitioner who is suitably qualified, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements are provided in the column 'claims/representation/statements' promote the use and supply of the goods, set out in the 'Therapeutic goods' column, in relation to heart disease, stroke and Niemann-Pick disease. Heart disease, stroke and Niemann-Pick disease are serious medical conditions within the meaning of s 28 of the Code, and references to such conditions are restricted representations, which must not be used in advertising unless expressly</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | | <p>approved or permitted by the Secretary under s 42DF or 42DK of the Act.</p> <p>There are no current approvals or permissions under ss 42DF or 42DK of the Act which apply to the representation made concerning the goods in relation to treating or reducing heart disease, nor the claims with respect to stroke or Niemann-Pick disease.</p> |
| 3. | Cavadex or Remchol | [REDACTED] | <p>Statements that suggest or imply the good has been recommended or approved by or on behalf of a government authority, including the following statements from the video located at the Cholrem Science Webpage⁴ underneath the heading 'Interview Founder of Cavadex November 2024':</p> <p><u>Interviewer:</u></p> <p>'So why do you think the TGA are leaving you alone?'</p> <p><u>Kyle Hodgetts:</u></p> <p>'I think it's because they know our product is a cure for heart disease. Now can you imagine the public backlash if the TGA was to try and shut down a product that cures heart disease, saves</p> | <p><u>Subsection 42DLB(1) where subsection (6) applies</u></p> <p>A person contravenes subs 42DLB(1) of the Act where subs (6) applies in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement 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:</p> <p>(a) a statement of the availability of the goods as a pharmaceutical benefit; or</p> <p>(b) a statement, pictorial representation or design authorised or required by a government or government</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | lives. They shut it down. And can you imagine a year later It's proven that product actually worked. Could you imagine the backlash the TGA would get? They know for a fact we're not harming anyone. They know it works. The science is there. We publish papers.' | <p>authority (not including a foreign government or foreign government authority); or</p> <p>(c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' imply the goods, set out in the 'Therapeutic goods' column, are recommended or approved by the TGA. None of subparagraphs 42DLB(6)(a)-(c) apply in relation to the advertisement.</p> |
| 4. | Cavadex or Remchol | [REDACTED] | <p>Statements including the following statements from the video located at the Cholrem Science Webpage4 underneath the heading 'Interview Founder of Cavadex November 2024':</p> <p><u>Kyle Hodgetts:</u></p> <p>'In 2020, I registered my product – Cavadex – with the TGA ... The TGA, because our product is an excipient not an active ingredient, they didn't know where to put us in their normal drug regulations. So they said to Professor</p> | <p><u>Subsection 42DMA(1) of the Act (subparagraph 8(1)(a) of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not comply with the Therapeutic Goods Advertising Code (the Code).</p> <p>The Code includes, at subparagraph 8(1)(a), that an advertisement about therapeutic goods must be</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | <p>[REDACTED] to deregister our product from the TGA because, while it's registered, they were obliged to regulate it but they didn't know how to regulate it so they said can you just deregister it. They knew it was harmless.'</p> <p>...</p> <p><u>Interviewer:</u></p> <p>'So why do you think the TGA are leaving you alone?'</p> <p><u>Kyle Hodgetts:</u></p> <p>'I think it's because they know our product is a cure for heart disease ... They know for a fact we're not harming anyone. They know it works.'</p> | <p>accurate, balanced and not misleading or likely to be misleading.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' are likely to be misleading for reasons including that they imply:</p> <ul style="list-style-type: none"> • Cavadex was registered in the Australian Register of Therapeutic Goods (ARTG), in circumstances where Cavadex has not been registered on the ARTG and instead was previously listed; • the Therapeutic Goods Administration (TGA) asked Cholrem to 'deregister' its products in the ARTG because the TGA did not know how to regulate the relevant goods, in circumstances where the TGA did not make such representations; and • the TGA had determined that Cavadex is safe and effective as a cure for heart disease, in circumstances where the TGA has not made any such determination. |
| 5. | Cavadex or Remchol | [REDACTED] | Statements that suggest or imply the good is safe and without side effects, including: | <u>Subsection 42DMA(1) of the Act (subparagraph 9(1)(a) of the Code)</u> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|--------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | <ul style="list-style-type: none"> Patients using RemChol report : ... No side-effects³ You can't hurt yourself with it [Cavadex] (Video located at the Cholrem Science Webpage⁴ underneath the heading 'Interview Founder of Cavadex November 2024'). Dr [REDACTED] reports all patients getting better and that Remchol-Cavadex reduced arterial plaques in his patients without any adverse side-effects.⁴ | <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not comply with the Therapeutic Goods Advertising Code (the Code).</p> <p>The Code includes at subparagraph 9(1)(a) that an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication, represents the goods to be safe, or without harm or side effects.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' imply or expressly represent the goods, set out in the 'Therapeutic goods' column, are safe and without harm or side effects.</p> |
| 6. | Cavadex or Remchol | [REDACTED] | <p>Statements that suggest or imply the good is infallible or miraculous, including:</p> <ul style="list-style-type: none"> Dr [REDACTED] reports all patients getting better⁴ <p>And the following statements from the video located at the Cholrem Science Webpage⁴</p> | <p><u>Subsection 42DMA(1) of the Act (subparagraph 9(1)(c) of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | <p>underneath the heading 'Interview Founder of Cavadex November 2024':</p> <p><u>Kyle Hodgetts:</u></p> <p>'After I did the trial, did an angiogram and my plaque had reduced, my cholesterol, my liver, everything went back to normal it was like a miracle.'</p> <p><u>Kyle Hodgetts:</u></p> <p>'All our product goes through, but now a lot of doctors are talking to the FDA saying this is a miracle treatment, people are going off their statins, people are going off their blood pressure medication.'</p> | <p>comply with the Therapeutic Goods Advertising Code (the Code).</p> <p>The Code includes at subparagraph 9(1)(c) that an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication, represents the goods to be infallible, unfailing, magical or miraculous.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' imply the goods, set out in the 'Therapeutic goods' column, are infallible or miraculous.</p> |
| 7. | Cavadex or Remchol | [REDACTED] | <p>Statements that delay or discourage, or are likely to delay or discourage, persons from seeking necessary medical attention, including:</p> <ul style="list-style-type: none"> No more need for by-pass surgery.⁵ | <p><u>Subsection 42DMA(1) of the Act (subparagraph 9(3)(b) of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not comply with the Therapeutic Goods Advertising Code (the Code).</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | | <p>The Code includes at subparagraph 9(3)(b) that an advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication delays or discourages, or is likely to delay or discourage, persons from seeking necessary medical attention.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' may delay or discourage persons using the goods, set out in the 'Therapeutic goods' column, from seeking necessary medical attention.</p> |
| 8. | Cavadex or Remchol | [REDACTED] | <p>Statements that are inconsistent with a public health campaign, including:</p> <ul style="list-style-type: none"> [REDACTED] was refused stents by his doctors because he was a heavy drinker and smoker. After just 2 months on RemChol his condition improved dramatically without any lifestyle changes.⁵ | <p><u>Subsection 42DMA(1) of the Act (section 10 of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not comply with the Therapeutic Goods Advertising Code (the Code).</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | | <p>The Code includes at section 10 that an advertisement about therapeutic goods must not be inconsistent with a public health campaign.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' state that if taking the goods, set out in the 'Therapeutic goods' column, there is no longer a need to undertake lifestyle changes such as reducing alcohol intake and ceasing smoking to manage and control heart disease. This message goes expressly against health campaigns regarding smoking (National Tobacco Campaign Australian Government Department of Health and Aged Care) and excessive drinking (National Alcohol Strategy 2019–2028 Australian Government Department of Health and Aged Care) to maintain good health.</p> |
| 9. | Cavadex or Remchol | [REDACTED] | <p>Testimonial statements made by a person who is engaged in the marketing and supply of the goods.</p> <p>The entirety of the video located at the Cholrem Science Webpage⁴ underneath the heading 'Interview Founder of Cavadex November 2024'. This interview with Kyle Hodgetts provides a testimonial of his experience with Cavadex, including the claimed reversal of heart disease.</p> | <p><u>Subsection 42DMA(1) of the Act (subparagraph 24(4)(a) of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|--------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | <p>Kyle Hodgetts is also the founder of Cholrem, the company responsible for Cavadex.</p> | <p>comply with the Therapeutic Goods Advertising Code (the Code).</p> <p>The Code includes at subparagraph 24(4)(a) that an advertisement about therapeutic goods must not contain a testimonial if the testimonial is made by a person who is engaged in the production, marketing or supply of the goods.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements that are provided in the column 'claims/representation/statements' about the goods, set out in the 'Therapeutic Goods' column, are made by Kyle Hodgetts, the founder of Cholrem Pty Ltd, and are therefore made by a person who is engaged in the marketing and supply of the goods.</p> |
| 10. | Cavadex or Remchol | [REDACTED] | <p>Statements that, either expressly or by implication, endorse the use of the good by current or former health practitioners, including:</p> <p>Dr [REDACTED], MD, FACC, FAARFM</p> <ul style="list-style-type: none"> USA cardiologist Dr. [REDACTED] MD FACC FAARFM trialed Cavadex on himself with similar results. He then went on and supplied his patients with Remchol tubes... Dr. | <p><u>Subsection 42DMA(1) of the Act (subparagraph 24(6)(d) of the Code)</u></p> <p>A person contravenes subs 42DMA(1) of the Act in circumstances where the person advertises, by any means, or causes the advertising, by any means of a therapeutic good and the advertisement does not comply with the Therapeutic Goods Advertising Code (the Code).</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
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| | | | <p>[REDACTED] reports all patients getting better and that Remchol-Cavadex reduced arterial plaque in his patients without any adverse side-effects. He also reported several other benefits for stroke patients and brain fog.⁴</p> <p>Professor [REDACTED], MB, BS, PhD, FRACP, FCSANZ</p> <ul style="list-style-type: none"> In relation to Cavadex, ‘Prof. [REDACTED] writes a report about Cavadex. <i>“It will be the greatest therapeutic advance in cardiovascular medicine since the introduction of the statins.”</i>’⁴ <p>And the following statements from the video located at the Cholrem Science Webpage⁴ underneath the heading ‘Interview Founder of Cavadex November 2024’:</p> <p><u>Dr [REDACTED]</u></p> <p>‘I was certainly impressed by Kyle’s results and what the medication had done for him. When I looked at his blood tests, everything was improving. His cholesterol, his triglycerides, all of his blood markers were improving out of sight. His</p> | <p>The Code includes at subparagraph 24(6)(d) that an advertisement about therapeutic goods must not contain an endorsement about therapeutic goods must not be given, whether expressly or by implication by a current or former health practitioner, health professional or medical researcher.</p> <p>The advertisements found at the link set out in the column ‘Website page URL’ and example statements that are provided in the column ‘claims/representation/statements’ about the goods, set out in the ‘Therapeutic goods’ column, are made by current or former health practitioners and a medical researcher.</p> <p>The statements made by three health practitioners, either expressly or impliedly, endorse the use of Cavadex.</p> |

| No. | Therapeutic goods | Website page URL | Claims/representations/statements | Relevant contravention |
|-----|-------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| | | | <p>cholesterol went from ten, you know, down to six and then eventually down to four which was impressive to me. Perhaps the most surprising result of all was the fact that Kyle's liver function tests were improving and this is despite being an incredibly heavy drinker. It was at this point that I realised this medication had massive potential in being a game changer in the treatment of heart disease.'</p> <p><u>Dr. [REDACTED]:</u></p> <p>'I use Cavadex in my patients with advanced and recurrent coronary disease...I've been delighted with the results...I've treated up to 150 of my patients with Cavadex...Cavadex is now the most important anti-atherosclerotic therapy in my armamentarium...'</p> <p><u>Professor [REDACTED]:</u></p> <p>'Hi, I'm [REDACTED]. I've been a professor of medicine for over 40 years now, specialising in cardiology and in particular and cardiovascular pharmacology. Cyclodextrin in the form of Cavadex. At this stage has more safety data and</p> | |

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| | | | <p>more knowledge about the pharmacology than what we knew about the statins when they were first introduced.'</p> <p>'I think that there's a potential for this treatment to be even more important and have a greater impact than what statins have, and certainly it's the greatest advance that we've had in cardiovascular pharmacology for the treatment of atheromatous plaques since the statins came on the scene.'</p> | |

Attachment B**Effect of not complying with this direction**

If you contravene a direction or a condition of a direction made under subsections 42DV(1) or (2) of the Act, you may breach criminal offence provisions under section 42DW or contravene a civil penalty provision under section 42DX which could lead to court action against you.

The TGA could also issue you an infringement notice as an alternative to these actions.

In conjunction with pursuing civil or criminal sanctions, the TGA may also seek an injunction from a Federal Court to immediately cease your advertising.

The TGA can also alert the public to its concerns about particular therapeutic goods advertising through the use of public warning notices (section 42DY).

Attachment C

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a ‘reviewable’ initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister’s delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister’s delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

A list of all attachments in the submission, or a table of contents, would also be appreciated, particularly for requests involving a significant number of supporting materials sent in multiple emails.

All requests for reconsideration should be given to the Minister by email:

Email: ‘**decision.review@health.gov.au**’

Subject: “<**insert name of person/company making request**> - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989”

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. “... - Email 1 of 3”, “... - Email 2 of 3” etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister’s delegate) must be to either ‘confirm’, ‘revoke’ or ‘revoke and substitute’ the initial decision. The Minister (or the Minister’s delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister’s delegate) fails to give such notice within 60 days, the Minister (or the Minister’s delegate) is deemed to have confirmed the initial decision.

Subject to the *Administrative Review Tribunal Act 2024* (ART Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister’s delegate), you can apply to the [Administrative Review Tribunal \(ART\)](#) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister’s delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the ART or is otherwise overturned or stayed.