

Outcomes and Publication

To be completed for every case.

Case Reference #/s:	Senator Malcolm Roberts MP
	CC-PUVHB1RM/2021*
TRIM Container #:	E21-309408
A. Is this case to be publish?	☒ YES Complete items 1-7 only or ☐ Publish as “LOW” Complete B & C only
B. Reason publishing as LOW	Choose an item.
C. Outcome to complainant:	<i>Provide text to be issued to complainant or link a TRIM doc. Only required when a decision is made to NOT investigate the complaint or other non-standard response is warranted</i>

1. Responsible Entity (only record company or business name. For sole traders/individuals that do not have a business name, use “Not published”).

Not Published
2. ALLEGED BREACHES e.g. 42DL(3)(7)
42DLB(1)
42DLB(4)
42DLB(7)
42DMA
Code 10(d)(i)
3. TGA Assessment Free Text description <i>Explain the reasons for your decisions about the breaches. Keep it simple for straight forward cases and where a more detailed investigation was conducted and/or more detailed consideration was given to the breaches (such as for many of the Code breaches “misleading” etc), this information should read more like a story.</i> https://compliance.tga.gov.au/investigations-database/ search for text about similar breaches by searching for similar cases under “ breaches and offences ” published in the medium or above Risk Category
The TGA received a complaint about alleged unlawful advertising in relation to COVID-19. The advertisement published on the ‘Twitter’ social media platform claimed that a medicine containing ivermectin is effective for the treatment of COVID-19. Any claims or references to COVID-19 in the advertising of therapeutic goods are restricted representations under the Act. A restricted representation refers to a serious form or a disease, condition, ailment or defect. The use of restricted representations in advertisements for therapeutic goods is unlawful without the permission of the TGA. It was determined that

Interim ACAR used for COVID-19 Cases – used to communicate publishing information

no permission under section 42DK of the Act nor approval under 42DF of the Act was in force at the time of the representation. Accordingly, the TGA alleged that the entity contravened subsection 42DLB(1) of the Act, where subsection 42DLB(4) of the Act applied.

The advertisement also referred to a substance, being Ivermectin, that is included in Schedule 4 to the Poisons Standard as made under section 52D of the Act. Accordingly, the TGA alleged that the entity contravened subsection 42DLB(1) of the Act, where subsection 42DLB(7) of the Act applied. In most circumstances, prescription only medicines cannot be advertised to the public in Australia.

The advertisement contained a claim the Ivermectin is safe in contravention of 42DMA of the Act, where 10(d)(i) of the Code applies as advertising for therapeutic goods must not contain any claim, statement, implication or representation that the goods are safe or that their use cannot cause harm, or that they have no side-effects.

The alleged illegal post was removed from social media after the TGA issued a warning letter requiring it be removed.

4. ACTIONS – Drop down option

If the matter was escalated following the first contact e.g. initial contact -> warning letter -> direction notice, please record the multiple actions and the relevant dates.

Warning Letter requiring action sent to advertiser 8/06/2021

[Click to select from list](#) [Click to select date of action](#)

5. Outcome – Drop Down (use “closed” only for paid infringement notice outcomes and court outcomes)

Case resolved

From: [Advertising Compliance](#)
To: senator.roberts@aph.gov.au
Subject: FOR YOUR ACTION - TGA Advertising complaint - Senator Malcolm Roberts ; Ivermectin ; Case # CC-PUVHB1RM/2021* [SEC=OFFICIAL]
Date: Tuesday, 8 June 2021 5:34:34 PM
Attachments: [image007.emz](#)
[image008.png](#)
[image009.png](#)
[image010.emz](#)
[image011.png](#)
[image012.png](#)
[08.06.2021 - Notice to cease advertising - Malcolm Roberts.pdf](#)
Importance: High

Dear Mr Roberts

Please find attached correspondence from the Therapeutic Goods Administration concerning a complaint made about your advertising material.

The Therapeutic Goods Administration is the part of the Australian Government Department of Health that is responsible for the regulation of the safety, quality, efficacy and advertising of therapeutic goods. We perform this through administration of the relevant legislation, the *Therapeutic Goods Act 1989* and related legislation such as the Therapeutic Goods Regulations 1990 and the [Therapeutic Goods Advertising Code \(No.2\) 2018](#). Click [here](#) for guidance on the application of the Code.



Thank you for your assistance in this matter.

Kind regards

 on behalf of

Advertising and Product Investigations Section

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606

www.tga.gov.au



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

This response contains general information given to you without prejudice, it is not binding on the TGA, and it does not constitute legal advice. You may need to get your own independent advice to ensure that all of the legislative requirements are met.



Australian Government
Department of Health
Therapeutic Goods Administration

Senator Malcolm Roberts
L36 Waterfront Place
1 Eagle St
Brisbane QLD 4000

Advertising reference: E21-309408
CC-PUVHB1RM/2021*

By Email only: senator.roberts@aph.gov.au

Dear Mr Roberts

NOTICE TO CEASE ADVERTISING OF IVERMECTIN

1. The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and is responsible for regulating of the safety, quality and efficacy of therapeutic goods, along with the advertising of therapeutic goods.
2. The TGA is writing to you in relation to a complaint we received about a tweet which appeared on your Twitter feed on 21 May 2021 at approximately 6:13am, <https://twitter.com/MRobertsQLD/status/1395472647228510209> concerning Ivermectin (**the Tweet**). The Tweet states:
Because Ivermectin 3.7 billion doses over the last 60 years proves it is safe. Plus it's affordable. Plus it's recent use in many countries proves it's effective as a cure & as a prophylactic in treating Covid
3. We are also aware of a post on Facebook on 3 June 2021 promoting the use of Ivermectin where you stated, "[w]e've had requests from people for locating a doctor who prescribes Ivermectin. Dr Mark Hobart in Melbourne does. His work number is (03) 9311 5977" (**the Post**). However, we note that the Post appears to have been removed from your Facebook page (and associated social media pages).
4. A copy of the Tweet and the Post is included at **Attachment 1**.
5. For the reasons set out below, you should **immediately** remove any promotion of the use of Ivermectin for human therapeutic use from Twitter, Facebook, any other online platforms, including social media accounts under your control, and cease making similar representations in the future.
6. The representations made concerning COVID-19 are of significant concern to the TGA and the Australian Government more broadly, given the current pandemic.

The Tweet and the Post advertise therapeutic goods

7. The TGA considers the Tweet and the Post (collectively, **the Advertising**) amount to advertising within the meaning of the *Therapeutic Goods Act 1989* (**the Act**) because they promote Ivermectin, a therapeutic good within the meaning of subsection 3(1) of the Act.
8. 'Advertise', in relation to therapeutic goods, includes to 'make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods'.
9. The TGA is of the view that having regard to your well-known, and publicly conveyed interest in Ivermectin as a medicine in connection with COVID-19, viewers of the Advertising will not view the Advertising as simple reports of factual information about Ivermectin, but rather, will consider that the Advertising promotes the use or supply of medicines containing Ivermectin in connection with the treatment of COVID-19.
10. Division 3A of Part 5-1 of the Act contains offences and civil penalty provisions relating the advertising of therapeutic goods, including sections 42DLB and 42DMA of the Act.

The Advertising contravenes subsections 42DLB(1) of the Act

11. The TGA considers that the Advertising contravenes section 42DLB of the Act (and the corresponding criminal offences in section 42DL of the Act) because it:
 - (a) contained a restricted representation, being a reference to a disease (COVID-19) that is a serious form of a disease within the meaning of section 28 of the Therapeutic Goods Advertising Code (**the Code**) (with the result that subsection 42DLB(4) of the Act applied to the advertisement). Restricted representations require the prior permission of the TGA before they can be used in advertising; and
 - (b) refers to a substance, being Ivermectin, that is included in Schedule 4 to the current Poisons Standard (with the result that subsection 42DLB(7) of the Act applied to the advertisement). The advertising of prescription only medicines in Australia is prohibited (unless an exemption applies).

Restricted Representation

12. Subsection 42DLB(4) of the Act applies to an advertisement if it contains a restricted representation, and neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act is in force in relation to that restricted representation.
13. Section 42DD of the Act relevantly provides that a representation in an advertisement about therapeutic goods that refers to a form of a disease identified in the Code as a serious form of a disease is a restricted representation. Section 28 of the Code provides that a form of a disease is a serious form if '*it is medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management*'.

14. COVID-19 requires diagnosis and treatment by a suitably qualified medical professional. Consequently, the TGA is of the view that the express references to COVID-19 in the Tweet was a restricted representation within the meaning of the Act, and that subsection 42DLB(4) of the Act applies to the Tweet.
15. In relation to the Post, having regard to your well-known interest in Ivermectin as a medicine (promoted) in connection with COVID-19, which explains why requests were made to your office for information concerning doctors who prescribe Ivermectin, the TGA is of the view that the Post contained a reference to COVID-19 by necessary implication and therefore subsection 42DLB(4) of the Act applies to the Post.
16. No permission was in force under section 42DK of the Act, and no approval was in force under section 42DF of the Act, in relation to those restricted representations.

Reference to a substance included in Schedule 4 to the current Poisons Standard

17. Subsection 42DLB(7) of the Act applies to an advertisement if it, relevantly, refers to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard, other than a reference required by a government or government authority.
18. The current Poisons Standard, *Poisons Standard June 2021*,¹ contains the Standard for the Uniform Scheduling of Medicines and Poisons No. 33 (**the current Poisons Standard**).
19. Poisons (i.e. substances) are classified according to public health risk in Schedules. Relevantly, Schedule 4 includes substances included in prescription only medicines and are classified as '[s]ubstances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription'.
20. Ivermectin is included in Schedule 4 to the current Poisons Standard as a prescription-only medicine, or as a substance included in prescription only medicines. Therefore, this substance, and medicines containing this substance, is prohibited from being advertised to the public.
21. For completeness, I note that the reference to Ivermectin was not required by a government or government authority and therefore subsection 42DLB(4) of the Act applies to the Advertising.

Therapeutic Goods Advertising Code – Prohibition on 'safe' claims

22. The TGA is also of the view that the Tweet contains a claim that Ivermectin is 'safe' in contravention of subsection 42DMA(1) of the Act (and can constitute an offence under section 42DM). This is because it contravenes the requirement in paragraph 10(d)(i) of the Code that an advertisement for therapeutic goods must not contain any claim, statement, implication or representation that 'the therapeutic goods are safe or that their use cannot cause harm, or that they have no side-effects'.

¹ <https://www.legislation.gov.au/Details/F2021L00650>

23. For more information about the advertising requirements on this issue, please consult the guidance document, 'Advertising to the public: Complying with the Therapeutic Goods Advertising Code (No.2) 2018'.²

Action Required

24. You should **immediately** remove the Advertising and any other promotion of the use of Ivermectin for human therapeutic use from Twitter, Facebook, any other online platforms, including social media accounts under your control, and cease making similar representations in the future.
25. Please action and respond in writing to this request by no later than **5pm on Wednesday 9 June 2021**, confirming you have removed the Tweet in the manner outlined in this letter, and any other promotion of the use of Ivermectin for human therapeutic use from Twitter, Facebook and any other online platforms.
26. If necessary, the TGA may proceed to issue a Direction under section 42DV of the Act, and reserves its rights to take other compliance action considered appropriate in the circumstances, including the issue of infringement notices under section 42YK of the Act or the commencement of criminal or civil proceedings (**Attachment 2** refers).
27. If you have any questions, please contact me on 02 6289 3637 or by email at nicole.mclay@health.gov.au.

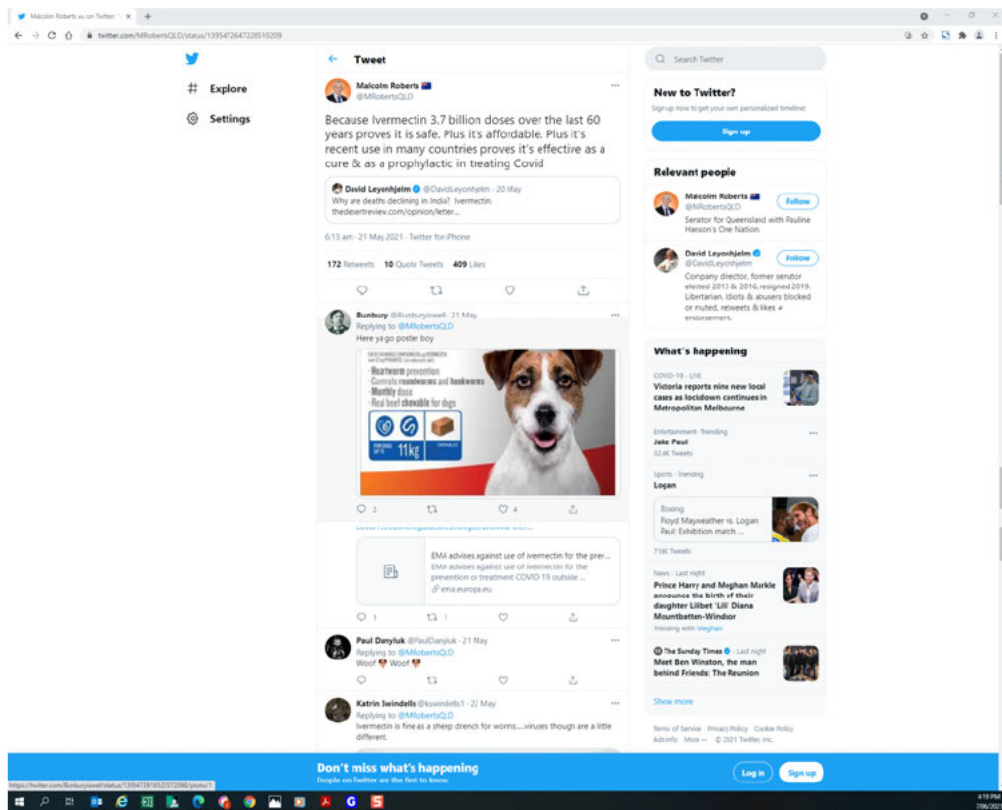
Yours sincerely

<Electronically signed>

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health
8 June 2021

² <https://www.tga.gov.au/sites/default/files/advertising-public.pdf>

Attachment 1 – The Tweet and the Post



We've had requests from people for locating a doctor who prescribes Ivermectin.

Dr s.22 in does.

His work number is

We've had requests from people for locating a doctor who prescribes Ivermectin. Dr in does. His work number is

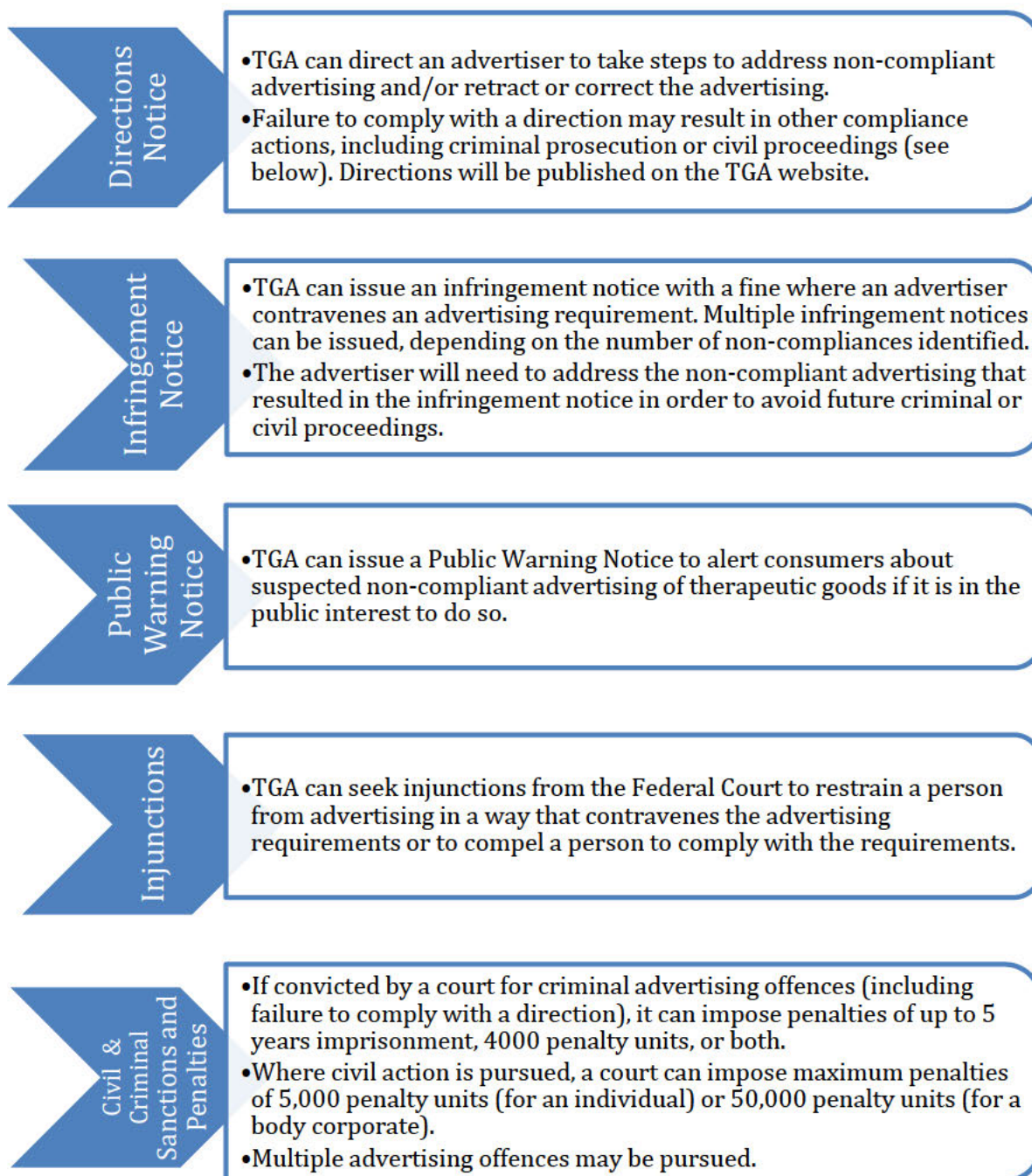
285 79 54

View on Facebook · Share

Comment on Facebook

Attachment 2 – Advertising compliance and enforcement tools

Where the TGA identifies ongoing non-compliant therapeutic goods advertising, it may use one or more of the following key tools to achieve compliance. This is not an exhaustive list of compliance tools and they do not need to be used in sequence.



The value of a penalty unit is currently \$222 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

From: [REDACTED] (Sen M. Roberts)
To: [MCLAY, Nicole](#)
Cc: [Advertising Compliance](#)
Subject: RE: FOR YOUR ACTION - TGA Advertising complaint - Senator Malcolm Roberts ; Ivermectin ; Case # CC-PUVHB1RM/2021* [SEC=OFFICIAL]
Date: Wednesday, 9 June 2021 5:32:04 PM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)
[image005.png](#)
[image009.png](#)
[image012.png](#)
[image003.emz](#)
[image006.emz](#)
[NMclay_TGA_MR090621.pdf](#)

Dear Ms McLay

With reference to your email of Tuesday 8 June 2021, please see attached correspondence from Senator Malcolm Roberts.

Kind Regards

[REDACTED]

Office Manager for Senator Malcolm Roberts

Electorate Office

Level 36, Waterfront Place

[1 Eagle Street, Brisbane QLD 4000](#)

T: [\(07\) 3221 9099](#)

Canberra Office

T: [02 6277 3694](#)

E: [REDACTED] [@aph.gov.au](#)

W: <https://www.malcolmrobertsqld.com.au>



From: Advertising Compliance <advertising.compliance@tga.gov.au>

Sent: Tuesday, 8 June 2021 5:35 PM

To: Roberts, Malcolm (Senator) <Senator.Roberts@aph.gov.au>

Subject: FOR YOUR ACTION - TGA Advertising complaint - Senator Malcolm Roberts ; Ivermectin ; Case # CC-PUVHB1RM/2021* [SEC=OFFICIAL]

Importance: High

Duplicate email



Senator Malcolm Roberts
One Nation Senator for Queensland

9 June 2021

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Department of Health
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Ms McLay

Thank you for your letter of today's date and the Notice to Cease Advertising of Ivermectin.

I am somewhat surprised that some small-minded person complained about my comments, which merely expressed a view that is widely held throughout the world and already confirmed by multiple studies and academic reports worldwide.

Its contribution to the slowing rate of infection in India is further evidence of this.

Ivermectin has already been used by millions of persons safely and is already being used by thousands of Australians safely for several different therapeutic purposes, including me.

Its use in relation to COVID-19 internationally is already proven as an effective treatment and its restrictive use in Australia for that purpose is a national disgrace. The blood is on the government's hands for the hold up in Australia of its use here.

Why the government has not called on its trialling in Australia by now is tantamount to potential manslaughter for holding back a cheap, effective treatment option for Australians at risk.

Unlike many people calling for new treatments for COVID-19, I have no financial connections with any of the medicine manufacturers, or personal reason to promote or advertise Ivermectin as a product.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M Roberts'.

Senator Malcolm Roberts
Senator for Queensland

From: [MCLAY, Nicole](#)
To: [\[REDACTED\] \(Sen M. Roberts\)](#)
Cc: [Advertising Compliance](#); [\[REDACTED\]](#)
Subject: RE: FOR YOUR ACTION - TGA Advertising complaint - Senator Malcolm Roberts ; Ivermectin ; Case # CC-PUVHB1RM/2021* [SEC=OFFICIAL]
Date: Thursday, 10 June 2021 9:13:18 AM
Attachments: [image007.png](#)
[image008.png](#)
[image011.png](#)
[image015.png](#)
[image016.png](#)
[image017.emz](#)
[image018.png](#)
[image019.png](#)
[image020.emz](#)
[image021.png](#)
[image022.png](#)

Thank you for your reply.
I note that the tweet has been removed.

Kind regards
Nicole

Nicole McLay FCPA

Assistant Secretary Regulatory Compliance


Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch
Australian Government Department of Health
T: 02 6289 3637 | E: nicole.mclay@health.gov.au
Location: 136 Narrabundah Lane, Symonston, ACT
PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: [\[REDACTED\] \(Sen M. Roberts\)](#) <[\[REDACTED\]@aph.gov.au](#)>
Sent: Wednesday, 9 June 2021 5:32 PM
To: MCLAY, Nicole <Nicole.McLay@health.gov.au>
Cc: Advertising Compliance <advertising.compliance@tga.gov.au>
Subject: RE: FOR YOUR ACTION - TGA Advertising complaint - Senator Malcolm Roberts ; Ivermectin ; Case # CC-PUVHB1RM/2021* [SEC=OFFICIAL]

Duplicate email

From: [REDACTED]
To: [REDACTED]
Subject: FW: <https://twitter.com/MRobertsQLD/status/1395472647228510209> [SEC=UNOFFICIAL]
Date: Monday, 7 June 2021 3:03:11 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.gif](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)

[REDACTED]

As discussed – could you please take a look at this one?

[REDACTED]

[REDACTED]

[REDACTED] | Advertising and Product Investigations Section
Regulatory Compliance Branch | Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government Department of Health

[REDACTED]

Location: GA-14 Symonston
PO Box 100, Woden ACT 2606, Australia



diversity-logo-combined



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: MCLAY, Nicole <Nicole.McLay@health.gov.au>
Sent: Monday, 7 June 2021 2:59 PM
To: [S.22](#) [REDACTED]@health.gov.au
Subject: FW: <https://twitter.com/MRobertsQLD/status/1395472647228510209>
[SEC=UNOFFICIAL]

Nicole McLay FCPA

Assistant Secretary Regulatory Compliance

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch
Australian Government Department of Health
T: 02 6289 3637 | E: nicole.mclay@health.gov.au
Location: 136 Narrabundah Lane, Symonston, ACT
PO Box 100, Woden ACT 2606, Australia



The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: FRANCIS, Jenny <Jenny.Francis@health.gov.au>

Sent: Monday, 7 June 2021 2:57 PM

To: MCLAY, Nicole <Nicole.McLay@health.gov.au>

Subject: <https://twitter.com/MRobertsQLD/status/1395472647228510209> [SEC=UNOFFICIAL]