

s22



s22



From: s22 <[REDACTED]@health.gov.au>

Sent: Friday, July 5, 2024 3:30 PM

To: s22 <[REDACTED]@chpaustralia.com.au>

Subject: RE: Vitamins not in Regulations Part 3 of Schedule 2 [SEC=OFFICIAL]

Good afternoon s22

Thank you for your patience.

Under the therapeutic goods legislation, representations in consumer advertising (including product labels) that imply a product is or contains a vitamin must meet certain criteria and align with approved terminology.

Relevantly, representing or referring to goods as a 'vitamin' is a prohibited representation unless the goods are composed of, or contain, a substance specified in Part 3 of Schedule 2 to the Therapeutic Goods Regulations 1990 (the Regulations), or a salt or derivative of a relevant

substance. The use of 'prohibited representations' in advertising without prior permission is prohibited under subsections 42DL(5) and 42DLB(2) of the *Therapeutic Goods Act 1989* (the Act). As you are aware, the TGA is reviewing the current list of vitamins following a request from Complementary Medicines Australia (CMA) and their concerns that it does not allow a number of substances that are commonly referred to as vitamins to be labelled as such. This includes vitamin K2.

While this issue is under consideration, I can advise that the TGA does not currently propose to take enforcement action in relation to representations that state or imply that goods are, or contain vitamin K2. We have communicated this position to CHPA a short time ago.

The TGA anticipates completing the broader review within the next 12 months.

Please let me know if you have any questions.

Regards

s22

s22

Advertising Compliance Education and Policy Section
Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group

Australian Government Department of Health and Aging

T: s22 | E s22 @health.gov.au

Location: 27 Scherger Dr Fairbairn ACT 2609

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.

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This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

s22

From: s22 <[REDACTED]@health.gov.au>
Sent: Wednesday, May 15, 2024 5:40 PM
To: s22 <[REDACTED]@chpaustralia.com.au>
Subject: RE: Vitamins not in Regulations Part 3 of Schedule 2 [SEC=OFFICIAL]
Hi s22

Just acknowledging your email.

As I indicated in our meeting, the TGA is currently undertaking a body of work to consider this situation. This will be done in consultation with the Therapeutic Goods Advertising Consultative Committee in the first instance.

I'll consider your request below in discussion with colleagues and get back to you shortly.

Regards

s22

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Advertising Compliance Education and Policy Section
Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health and Aging

s22 <[REDACTED]@health.gov.au>

Location: 27 Scherger Dr Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

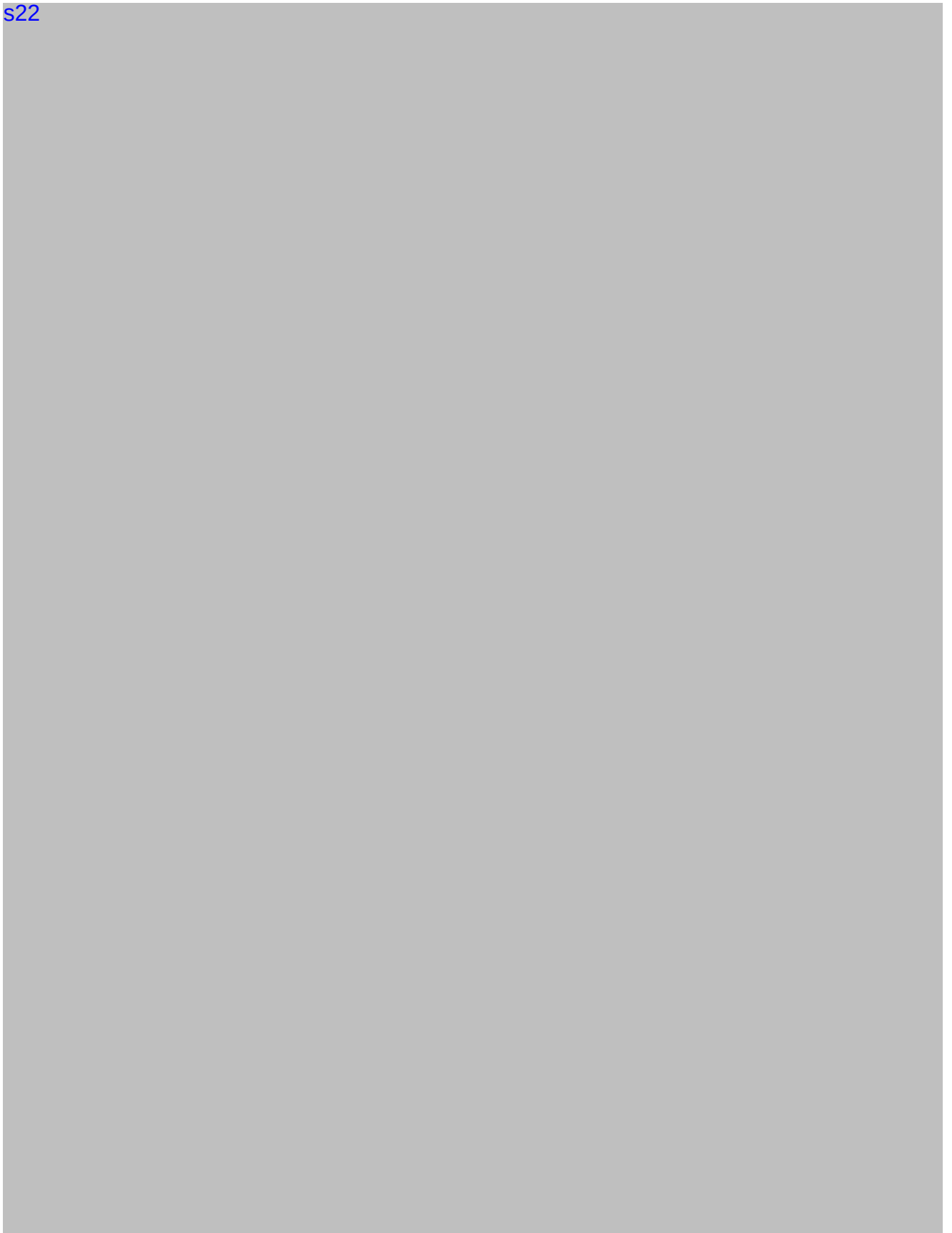
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From: s22

Sent: Thursday, February 13, 2025 4:29 PM

To: s22

Subject: RE: TGA Code Section 11 and one other matter [SEC=OFFICIAL]

Hi s22

Happy to work around your team.

Would any of the following suit?

- Monday 3/3 at 2PM
- Wednesday 5/3 at 11AM or 3 PM

Regards

s22

s22



s22

From: s22 <[REDACTED]@health.gov.au>
Sent: Wednesday, February 12, 2025 9:47 AM
To: s22 <[REDACTED]@chpaustralia.com.au>
Subject: RE: TGA Code Section 11 and one other matter [SEC=OFFICIAL]

Good morning s22

My apologies for not getting back to you sooner. I'm just back from some leave.

We would appreciate meeting with you and the AdCheck team to discuss your questions about the application of Section 11(3) of the TGAC. In terms of available timeslots we have the following:

- Friday 21/2 at 11:30 AM
- Tuesday 25/2 at 10 AM
- Thursday 27/2 at 10 AM or 2 PM

But, please let me if these times don't suit.

Regards

s22

s22

Advertising Compliance Education and Policy Section
Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health and Aging

s22 <[REDACTED]@health.gov.au>

Location: 27 Scherger Dr Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

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s22



s22

Sent: Tuesday, December 17, 2024 1:35 PM

To: s22 @chpaustralia.com.au>

Subject: RE: TGA Code Section 11 and one other matter [SEC=OFFICIAL]

Thanks for your enquiry s22

Apologies for not getting back to you sooner, the team is reviewing and will get back to you shortly with a written response or suggested meeting times.

Kind regards

s22

s22

Advertising Compliance Education and Policy Section
Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health and Aging

T: s22 [REDACTED]@health.gov.au

Location: 27 Scherger Dr Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

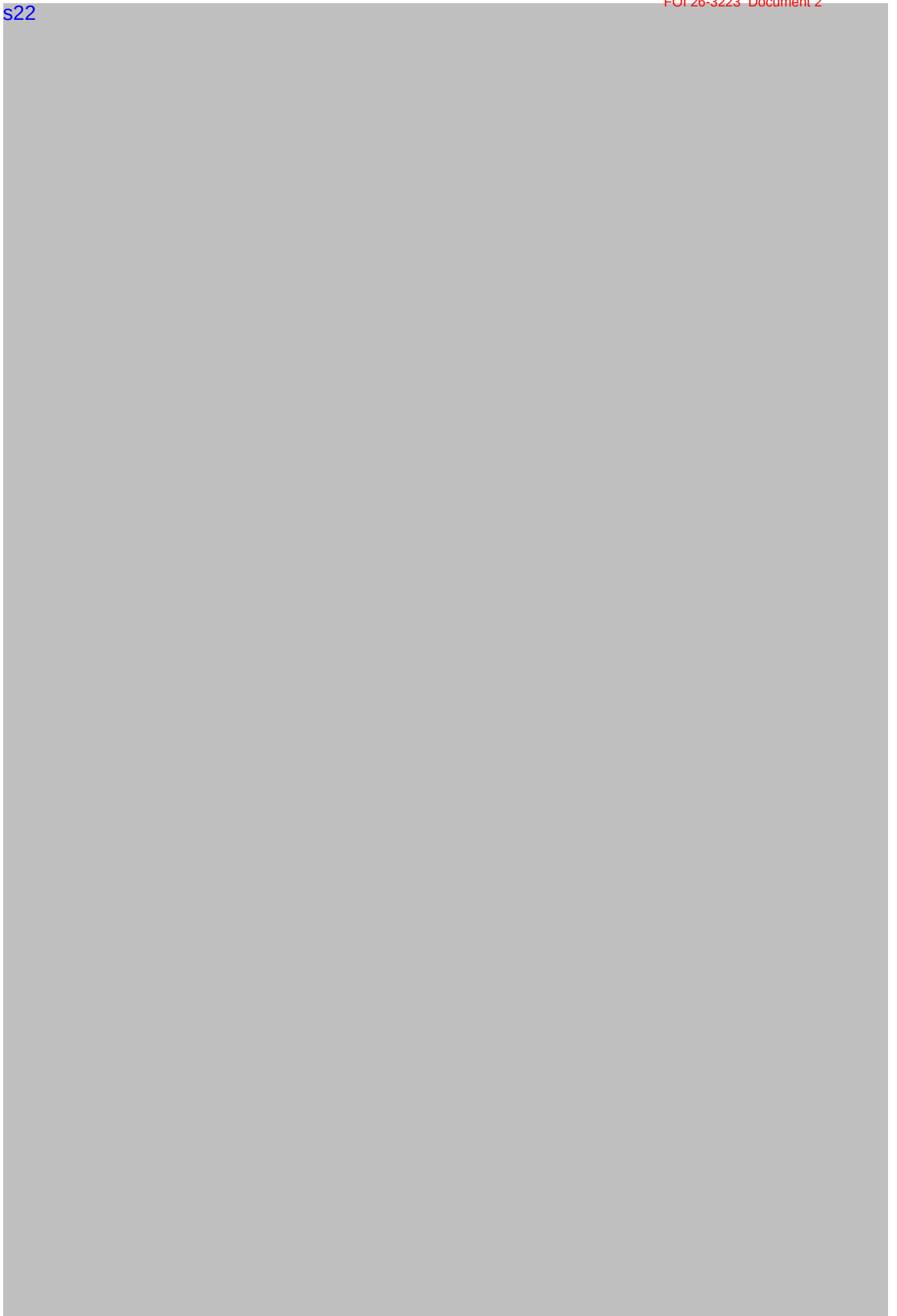
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s22



From: s22
To: s22
Cc: s22
Subject: TGA Code Section 11 and one other matter [SEC=OFFICIAL]
Date: Monday, 3 March 2025 2:49:00 PM
Attachments: [image001.png](#)
[Fundamentals - Using scientific or clinical claims.docx](#)

Good afternoon s22 and colleagues,

Thanks for your time this afternoon to discuss the application of section 11 of the Code.

As discussed, as part of web content updates we are redrafting materials on the advertising hub – where there will be a plain English ('fundamentals') page that sits above our more detailed guidance.

For interest please see the fundamentals page on using scientific and clinical representations which covers off a lot of the issues we discussed today. Appreciate any views you have on the document before we publish in the coming week or two.

Regards

s22

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Advertising Compliance Education and Policy Section
Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health and Aging

T s22 [@health.gov.au](mailto:s22@health.gov.au)

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Using scientific or clinical representations in advertising

There are specific requirements for using scientific or clinical terminology in advertising or giving support to claims by referring to scientific research.

Last updated

22 February 2023

Information here relates to Part 3 of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the Code)

Our guidance material provides more detailed information and examples:

- [Guidance link](#)

The Code is the original legal source of this information:

- [FDL link](#)

Use scientific or clinical representations correctly in advertising

Advertisements which contain scientific or medical terminology can be difficult for consumers to understand. Additionally, referring to scientific or clinical research or implying a claim is supported by a specific study or number of studies, is likely to give claims additional credibility in the eye of the consumer.

While the use of scientific and clinical representations in advertisements is permitted, their use must comply with the requirements set out in section 11 of the Code.

These requirements do not apply to product labels, consumer medicine information or instructions for use.

Scientific or clinical representations

Representations in advertising can include:

- warning statements
- the name of a therapeutic good
- claims about the product, including those conveyed through statements, pictures and videos.

A 'scientific' or 'clinical' representation is one that:

- uses scientific or medical terminology that is not generally used in the everyday language of the audience to whom the advertisement is directed, and/or
- relies on scientific or clinical research (such as 'clinically demonstrated to ...').

While the use of scientific and clinical representations in advertisements is permitted, they must:

- contain appropriate scientific or medical terminology that is easily understood by consumers, and avoid jargon
- only be used where they are consistent with the broader body of scientific or clinical evidence.

In addition, citations must be provided to any scientific or clinical studies that are referred to in the advertisement.

When scientific and clinical representations require a citation

You need to substantiate any claims you make about therapeutic goods with relevant evidence.

However, a citation only needs to be provided where a claim expressly states or implies that it is supported by scientific or clinical research.

An express reference to scientific or clinical research would be one that refers to a particular study such as:

- our clinical trial conducted on 230 adults in NSW showed that ...

An implied reference to scientific or clinical research occurs when a consumer would reasonably expect a statement or claim to be supported by specific research results.

Examples include:

- 'clinically proven'
- 'clinically trialled'
- 'lab studies show....'
- 'scientifically demonstrated to ...'

Advertisements that refer to scientific or clinical research must:

- clearly identify the researcher

- clearly identify the financial sponsor of the research (where the advertiser knows or is reasonably expected to know the financial sponsor)
- be cited in a way that to enables consumers to access the study.

Citations can be tailored to suit the specific media where the advertisement appears. Footnotes and embedded links may be adequate.

Like any other advertising claims, representations that rely on scientific and clinical research must be accurate, balanced and not be misleading. For more information see [General requirements for advertising therapeutic goods to the public](#).

Tips for using scientific or clinical representation compliantly

- Use clear terminology that can be readily understood by the typical consumer.
- Be wary of using statistical data, graphs and scientific jargon.
- Only reference studies that are relevant to the claim.
- Ensure studies are cited correctly in the advertising so that they are accessible by consumers.
- Do not exaggerate or misrepresent the conclusions of a study.

From: s22

Sent: Wednesday, April 9, 2025 5:02 PM

To: s22

Subject: RE: Response to the Fundamentals document on scientific and clinical claims

[SEC=OFFICIAL]

H s22

Just confirming that we will review the current guidance, although this will be in amongst other priorities. We don't have a completion date in mind yet, but will keep you updated as this work progresses.

Regards

s22

From: s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>

Sent: Monday, March 17, 2025 3:34 PM

To: s22 [redacted] <[\[redacted\]@chpaustralia.com.au](mailto:[redacted]@chpaustralia.com.au)>

Subject: RE: TGA Code Section 11 and one other matter [SEC=OFFICIAL]

s22 [redacted]

Confirming that this page has been published at [Using scientific or clinical representations in advertising | Therapeutic Goods Administration \(TGA\)](#), but please let us know if you have any comments nonetheless and we'll consider them if we can.

s22 [redacted]

s22

From: s22 <[REDACTED]@health.gov.au>

Sent: Monday, March 3, 2025 2:50 PM

To: s22 <[REDACTED]@chpaustralia.com.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>

s22 <[REDACTED]@Health.gov.au>

s22 <[REDACTED]@Health.gov.au>

s22 <[REDACTED]@chpaustralia.com.au>; s22 <[REDACTED]@chpaustralia.com.au>; s22 <[REDACTED]@chpaustralia.com.au>

s22 <[REDACTED]@chpaustralia.com.au>; s22 <[REDACTED]@chpaustralia.com.au>

Subject: TGA Code Section 11 and one other matter [SEC=OFFICIAL]

Good afternoon s22 and colleagues,

Thanks for your time this afternoon to discuss the application of section 11 of the Code.

As discussed, as part of web content updates we are redrafting materials on the advertising hub – where there will be a plain English ('fundamentals') page that sits above our more detailed guidance. For interest please see the fundamentals page on using scientific and clinical representations which covers off a lot of the issues we discussed today. Appreciate any views you have on the document before we publish in the coming week or two.

Regards

s22

s22

Advertising Compliance Education and Policy Section

Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group
Australian Government Department of Health and Aging

s22 <[REDACTED]@health.gov.au>

Location: 27 Scherger Dr Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

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From: s22 [REDACTED]
To: s22 [REDACTED]
Cc: [Advertising Enquiries](#)
Subject: RE: Restricted Representations
Date: Thursday, 23 October 2025 5:10:00 PM

Thanks for your enquiry s22 [REDACTED]

I've passed on to the team for a response and we will get back to you shortly.

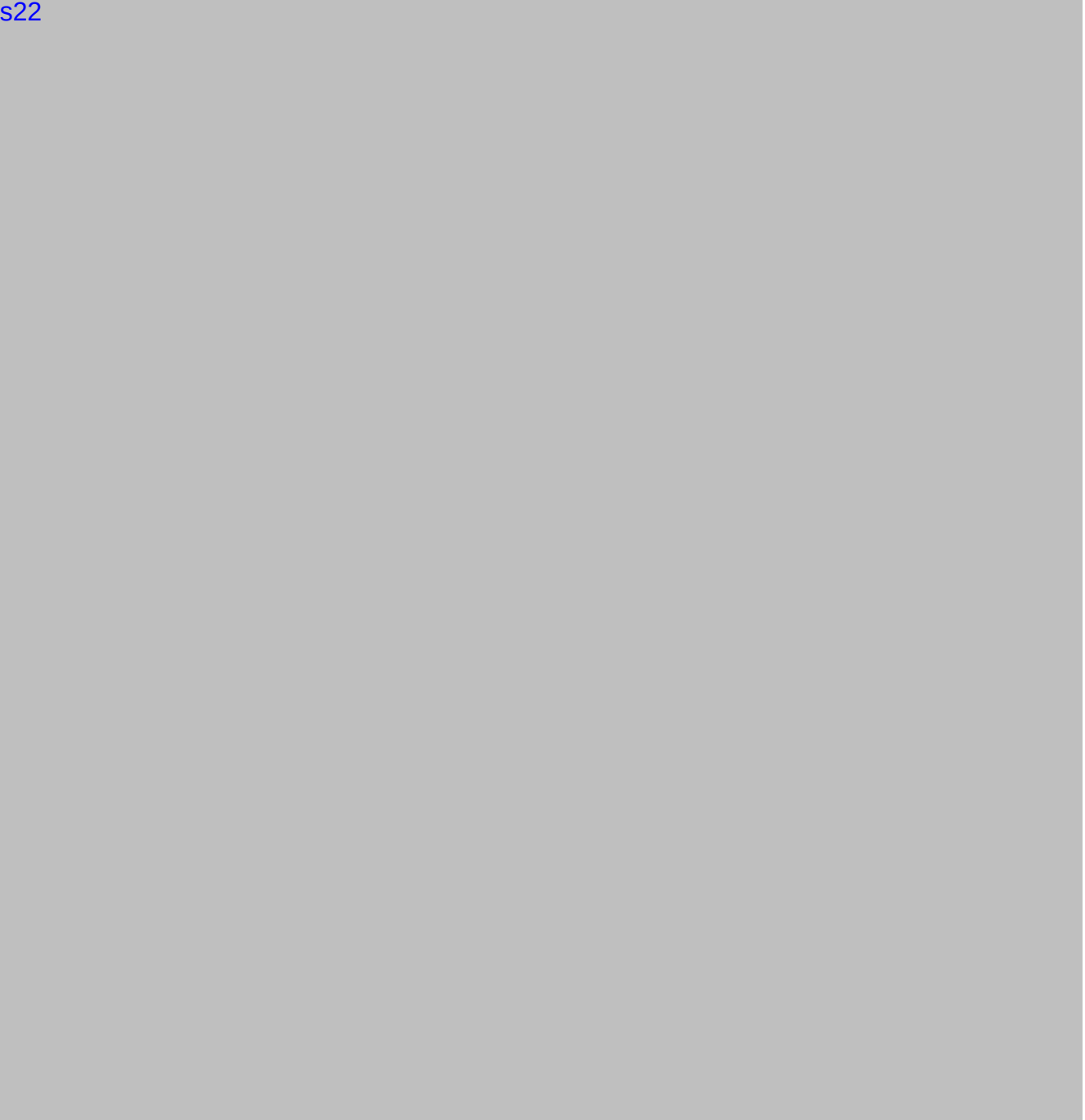
Regards

s22 [REDACTED]

s22



s22



s22

From: s22

Sent: Wednesday, 4 February 2026 15:09

To: s22

Cc: s22

Subject: RE: Advertising of NMN Products - Additional Question [SEC=OFFICIAL]

Caution: This email originated from outside CHP Australia.

OFFICIAL

Good afternoon s22

Thanks for sending these examples through.

As your enquiries relate to the applicability of permitted indications for NMN products I have passed on to colleagues in the Complementary and Over-the-counter Medicines Branch for a response.

Regards

s22

s22

Education, Policy and Guidance Section

Regulatory Compliance Branch

Regulatory Practice & Support Division | Health Products Regulation Group

Australian Government Department of Health, Disability and Ageing

T: s22 @health.gov.au

Location: 27 Scherger Dr Fairbairn ACT 2609

PO Box 100, Woden ACT 2606, Australia

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s22



s22



s22



From: [Advertising Enquiries](#)
To: [s22](#) [@chpaustralia.com.au](#)
Subject: [s22](#) - Restricted representations - Response email - AC-000000061592
Date: Wednesday, 29 October 2025 1:51:30 PM
Attachments: [image001.png](#)

Dear [s22](#)

Thank you for your enquiry (our reference AC-000000061592) to the Therapeutic Goods Administration (TGA) relating to restricted representations. A copy has been included at the bottom of this email for ease of reference. Please accept our sincere apologies for the delay to respond to your enquiry.

The TGA has engaged in discussions with the [Australian Centre for Disease Control](#). While RSV is less likely to severely affect adults, it poses significant risks to young children and has an underestimated impact on older Australians, particularly those in institutional settings.

Therefore, the TGA currently considers representations which refer to RSV as restricted representations.

It should also be noted that the current permission <https://www.tga.gov.au/resources/advertising-permissions/therapeutic-goods-restricted-representations-covid-19-and-influenza-test-kits-permission-2022> relates to 3 in 1 tests (COVID-19 and Influenza A&B Antigen Test Kits) only and not RSV, however there are intentions for the near future to extend the permission to cover specified representations which refer to RSV.

The information in this email is intended as guidance and is not legally binding on the TGA. To obtain advice specific to your circumstances you may wish to seek independent legal advice or the assistance of a [regulatory affairs consultant](#). Please note, these consultants are not endorsed by the TGA.

For future reference, please ensure you have considered the information on the [TGA Advertising Hub](#) before submitting an enquiry.

Yours sincerely,

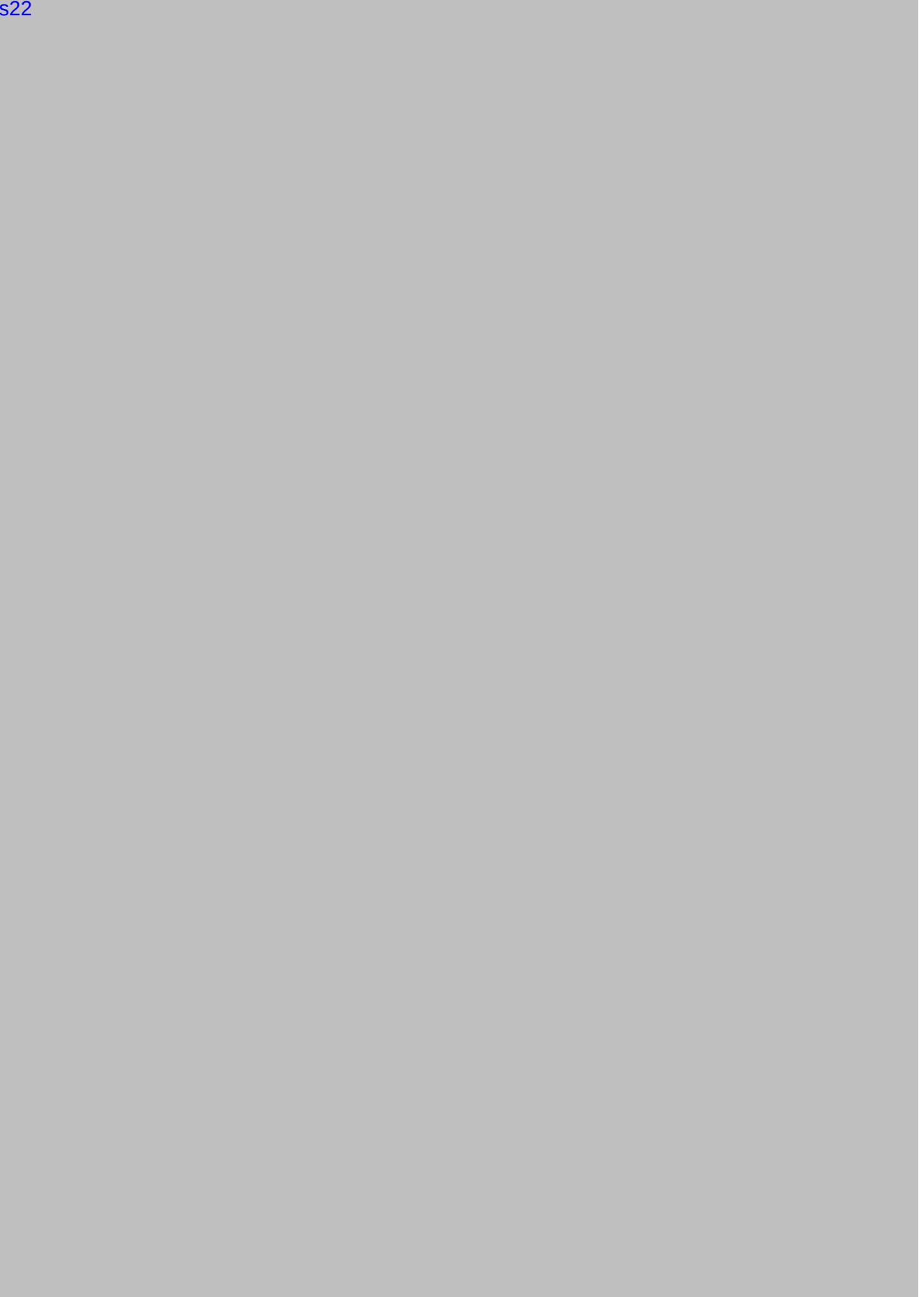
Advertising Enquiries Team
Advertising and Compliance Education and Policy Section (ACEPS)

Regulatory Compliance Branch | Regulatory Practice and Support Division
 Australian Government, Department of Health, Disability and Ageing
 Location: Fairbairn Office, Canberra, ACT
 PO Box 100, Woden ACT 2606, Australia

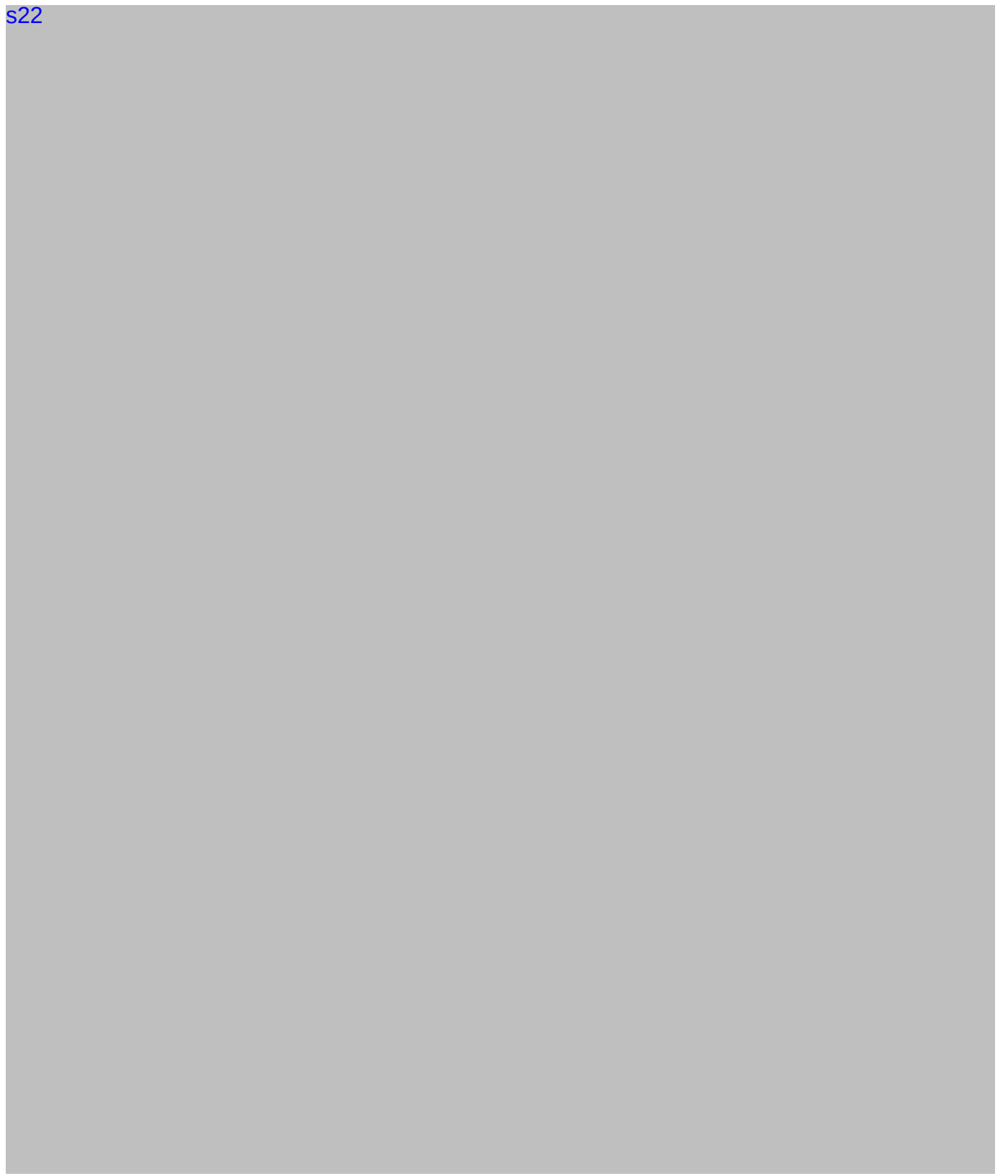
The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

OFFICIAL

s22



s22



From: [Non-prescription Medicines](#)
To: [s22](#) [r@chpaustralia.com.au](#)
Subject: RE: Advertising of NMN Products - Additional Question [SEC=OFFICIAL]
Date: Thursday, 12 February 2026 10:35:24 AM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)

Dear [s22](#)

Thank you for your emails on 3 and 4 February 2026 to the Therapeutic Goods Administration (TGA), which has reached the Complementary and OTC Medicines Branch.

We appreciate your proactive engagement with the TGA in seeking to understand the obligations in relation to the advertising of listed medicines containing nicotinamide mononucleotide (NMN), particularly in relation to claims relating to nicotinamide adenine dinucleotide (NAD, NAD+, NADH), the use of longevity-related claims and the use of DNA-helix imagery.

Please note that the TGA is unable to provide you with specific regulatory advice, however, the following information may be of assistance to your enquiry. The information in this email is intended as guidance and is not legally binding on the TGA.

TGA Safety alert for NAD, NAD+, NADH or NMN medicines sold in Australia

As outlined in the TGA's [updated safety advisory](#) dated 3 February 2026, while NMN is now included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) (Permissible Ingredients Determination), NAD, NAD+ and NADH are not currently permitted ingredients. **Listed medicines that make claims about NAD, NAD+, or NADH through their name, labelling or advertising are at risk of breaching the law**, particularly if those claims imply or suggest that the medicine contains NAD, NAD+, or NADH.

Requirements for the use of NMN in listed medicines

As you may be aware, listed medicines must only contain ingredients included in the Permissible Ingredients Determination and comply with any requirements associated with its use.

For completeness, the current requirements for the use of NMN in listed medicines include:

- Nicotinamide mononucleotide's purpose in listed medicine must be as an active ingredient.

- Until 10 December 2027, nicotinamide mononucleotide must only be used in a medicine where:
 - a. SyncoZymes (Shanghai) Co Ltd (Client ID 83759) is the sponsor of the medicine (the primary sponsor); or
 - b. another person is the sponsor of the medicine (the secondary sponsor) and the TGA has been notified that the secondary sponsor has been authorised by the primary sponsor to use the ingredient in the medicine.
- The route of administration for medicines that contain nicotinamide mononucleotide must be oral.
- The maximum recommended daily dose of the medicine must not exceed 500 mg of nicotinamide mononucleotide.
- The recommended duration of use for a medicine containing nicotinamide mononucleotide must be 12 weeks or less.
- Medicines that contain nicotinamide mononucleotide must be indicated for use in adults only and not in pregnant or lactating women.

Please note that the Permissible Ingredients Determination is regularly updated. It is the sponsor's responsibility to remain informed of any regulatory changes and to ensure ongoing compliance with all relevant legislative requirements.

Regulatory obligations when making claims and advertising permitted indications

As listed medicines are not subject to premarket evaluation by the TGA, the [Therapeutic Goods \(Permissible Indications\) Determination](#) (Permissible Indications Determination) is an important mechanism of the listed medicine framework to help ensure listed medicines are 'low risk' and can be safely and effectively used by consumers.

Accordingly, while sponsors may consider certain claims to be factually correct and may hold evidence in support of those claims, this does not necessarily mean that such therapeutic uses can be claimed through the presentation/advertising of the medicine. To lawfully claim therapeutic uses for a listed medicine, those claims must be:

1. covered by the Permissible Indications Determination, **and**
2. included in the medicine's ARTG entry, **and**
3. supported by evidence.

Where a claim is not covered by the Permissible Indications Determination, this may place the sponsor at risk of breaching the conditions of listing. Sponsors are therefore encouraged to carefully consider whether the claims they intend to make are appropriately captured by a permitted indication. The [Permissible indications for listed medicines](#) guidance, particularly the section on 'Acceptable variation of

permitted indications' section (reproduced below) may be of assistance.

You can:

- change the structure or order of the [components of a permitted indication](#)
- use the therapeutic action terms included in a permitted indication interchangeably (e.g. decrease/reduce).

You **must not**:

- modify a selected permitted indication to give it a different, broader or more specific therapeutic target
- modify a mandatory qualifying term (e.g. 'mild', 'medically diagnosed') on your medicine label or other advertising material
- modify a selected permitted indication to infer or imply that a medicine is for the treatment of a serious disease
- modify a selected permitted indication to infer or imply that a medicine is for the prevention or cure of any disease.

You have noted in your response that '*NAD is not technically a nutrient*'. As such, you should consider whether claims regarding NAD would be appropriately covered by the permitted indication that refers to enhancing nutrient levels in the body.

'Longevity' claims

As you have noted, it is a condition of listing that sponsors must not advertise indications other than those included in their medicine's ARTG entry.

In addition, the [Therapeutic Goods Advertising Code](#) (the Code) requires (amongst other things) that the advertising must not be inconsistent with the medicine's ARTG entry; must be accurate, balanced and not misleading, and must not exaggerate efficacy or create unrealistic expectations about performance.

Where longevity-related claims are made, sponsors should carefully consider these requirements of the Code, and whether such claims remain within the scope of an acceptable variation of a permitted indication. If the longevity-related claims suggest outcomes that go beyond the intent or meaning of the permitted indication, such advertising is at risk of breaching the law.

'DNA-helix' imagery

The TGA's approach to advertising considers the overall presentation of the medicine. The guidance on [Applying the Advertising Code rules: general requirements](#) may be of assistance here. As demonstrated in the first example under the heading 'Total presentation and context', images in advertising can be capable of implying a therapeutic use for a medicine, and should be considered carefully to

ensure they are consistent with approved indications, and are not misleading.

Depending on the context, if the type of imagery may contribute to an overall impression that is inconsistent with a permitted indication and/or misleading or non-compliant with the Code, the advertising is at risk of breaching the law. The [Understanding labelling and presentation requirements for listed medicines](#) may also be a useful resource.

We trust this information is of assistance.

Kind regards,
Stakeholder Engagement Team
Non-Prescription Medicines



Complementary and OTC Medicines Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Phone: 02 6289 4627

Email: nonprescriptionmedicines@health.gov.au

PO Box 100, Woden ACT 2606

www.tga.gov.au



The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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