

Background Information. Dietary Supplements (NHP).

Prepared July 2023

(Date of origination: Dec 2022 / Review Date: January 2024)

NHP = Natural Health Products

Dietary Supplements (NHP) | Housekeeping

- If you have a question during webinar please use the CHATROOM Function.

 There are two TAPS Adjudicators who will be monitor all the questions posted on the CHATROOM and will answer any straightforward questions during the webinar
- TAPS will be generating a Q&A document after the meeting based on all questions asked during the webinar via the CHATROOM
- The Slide Resources used during the webinar will be posted on the ANZA TAPS website under TAPS Briefing. https://www.anza.co.nz/taps
- If time allows after the presentation a selection of some of the main questions asked via the chatroom will be addressed in person as well as through the chatroom

Dietary Supplements (NHP) | Content

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Advertising in New Zealand is run on a self-regulatory model whereby the industry which includes the advertiser, advertising / digital agencies and the media ensure that best practice is followed.

In New Zealand all parties involved with publishing an advertisement / promotional item including the media can be held liable if the advertisement is found not to adhere to the principles of best practice.

Best practice advertising adheres to the following principles

- advertisements must comply with the laws of New Zealand
- advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated
- advertisements must observe a high standard of social responsibility.



Background

Sep 96: ASA introduce Code of Therapeutic Advertising

Feb 99: ASA Introduce Code of Therapeutic and Health Advertising

• Expanded to include, non-prescription medicines, medical services, complementary medicines, and food when a therapeutic purpose is claimed

May 99: TAAS (Therapeutic Advertising Advisory Service) introduced by ANZA

 As a response by the industry as a result of political pressure groups and Government pressure to impose restrictions and central regulation on the advertising of therapeutic and health products and services ANZA establish the Therapeutic Advertising Advisory Service (TAAS), which, from 1 May 1999, provided the pharmaceutical industry with advice and a voluntary 'pre-clearance' service (advice on whether proposed advertisements comply with legal and code requirements) for their advertisements on a user-pays basis.



Background

Mar 00: Medsafe published results of compliance survey

• Compliance survey into prescription and non-prescription advertising showed an improvement in compliance from 33% in 1998 prior to TAAS to 69% following TAAS in 2000

Aug 00: ASA / ANZA Consultation on proposal to pre-vet therapeutic advertisement

Nov 00: TAPS introduced by ANZA

 Therapeutic Pre-Vetting Advertising Service for all therapeutic and health advertising including medicines (prescriptions / non-prescription) dietary supplements (Natural Health Products) and medical devices.



Regulatory Bodies



Regulatory Framework

- Medicines Act 1981 and regulations
- Dietary Supplement Regulations 1985
- MedSafe advice and guidance with respect to Dietary Supplements / Natural Health products and what they regard as claims that fall under the Medicines Acts — "therapeutic purpose"
- Commerce Act 1986
- Fair Trading Act 1986
- ASA Therapeutic & Health Advertising Code (primarily)
- ASA Advertising Standards Code (General)

Regulatory Bodies



Regulatory Power of the MedSafe

• Medicines Act 1981 – Section 89
Without limiting subsection (1), if any person referred to in that subsection is convicted of an offence against any of the provisions of sections 57, 58, and 61 in respect of any container, or of any advertising material or labelling material, the court may in its discretion order that person to withdraw from use all containers or material of the same description until the matter in relation to which the offence was committed has been remedied; and in any such case subsections (2) and (3) shall apply with any necessary modifications.

Regulatory Bodies



Regulatory Power of the ASA (NZ)

ASA Complaints Process

• If a complaint is upheld, the advertiser, in accordance with self-regulatory principles, is required to immediately withdraw the advertisement. Additionally the media are similarly required not to publish or broadcast an advertisement which has been held by the Complaints Board to be in breach of the Codes.

Dietary Supplements (NHP) | TAPS Service

Regulatory Bodies



TAPS is a **service which assists advertisers**, advertising agencies and the media to comply with New Zealand legislations and regulations.

TAPS is a **voluntary service administers** by ANZA on behalf of media and industry.

Dietary Supplements (NHP) | TAPS Service

- You need to be registered with ANZA to access the TAPS Service but there is no charge for registration
- TAPS reviews can usually take up to 3 working days from receipt of the materials. If you need a more urgent review it is essential to contact your TAPs Adjudicators ideally by phone as well as email to ensure they are aware of the urgency of the review.
- The cost of a TAPS review is \$95 per 15 minutes for ANZA members and \$140 per 15 minutes for non-ANZA members
- How long does it take to carry out a TAPS review?
 There is no simple answer to this question as every review is different. Larger and more complicated items, such as websites and e-Detail Aids or slide resources can take longer especially if this is for a new client or product.

Dietary Supplement (NHP) | TAPS Review Process

Step 1: TAPS adjudicator is sent a proposed advertisement / promotional item and will undertake a review of that item within 3 days of receiving the item. It is likely the TAPs Adjudicator will make comments and recommendations for any changes that are required to ensure the advertisement is compliant. The review assesses words and the imagery. There can often be quite a lot of feedback before reaching Step 2.

Step 2: Once amends are completed and revised material is provided, a unique TAPS approval number is allocated as an identifier and included on the material. This gives assurance to the media the material is compliant with NZ legislation and Codes and is OK for them to publish. The TAPS approval number is expressed as TAPS Initials ###### eg TAPS PP1234 and must appear on advertising and promotional materials

A TAPS approval number only has a 'life' of 2 years. This helps to ensure historical claims, which may no longer be acceptable, have a natural expiry date.



Dietary Supplements (NHP) | Why use TAPS

Year	Total # of Complaints	Total # of Ads	Total # of Ads complained about under the Therapeutic and Health Advertising Code	Settled / Upheld (Ad removed or amended)	Not Upheld	No Grounds to Proceed
2018	820	425	59	51	1	7
2019	698	463	67	56	5	6
2020	1151	591	70	62	2	6
2021	1245	570	55	42	5	8
2022	843	345	30	22	0	8

ASA Therapeutic and Health Advertising Complaints 2018 – 2022

Search parameters Information in the table is sourced from cases reported on the ASA website that have been considered under the Therapeutic and Health Advertising Code.



Dietary Supplements (NHP) | Why use TAPS

Product Category	2022	2021	2020	2019	2018
Complementary products / Dietary Supplements (NHP)	4	14	25	22	38
Cosmetic	3	7	3	3	1
Pharmacy / OTC medicines	4	5	6	3	1
Prescription	4	2	1	4	2
Medical Devices	9	2			
Weight Management	3	2	1	0	0
Others*	6	7	15	8	6

Breakdown by Product Category

- Others includes Gadgets, Food and Beverage and Toiletries for example.
- Table does not include complaints under ASA-T&HAC in terms of Health Services for which there were 30,



Dietary Supplements (NHP) | Why use TAPS

 There is a very high proportion of complaints against "therapeutic and health" advertisements that are upheld – most (if not all) without TAPS numbers.

 The low number of complaints in 2021/22 in ASA views is probably due to the Society for Science Based Health Claims not being as prolific as it was pre-COVID

Dietary Supplements (NHP) | Guidance on Classification System in NZ

The Dietary Supplements Regulations 1985 provides a definition of dietary supplements and specify requirements for some ingredients. In general, dietary supplements are substance(s) for oral use that are packed in a controlled dosage form and are intended to supplement the intake of that substance(s) normally derived from food.

Dietary supplements cannot:

- contain controlled drugs dietary supplements cannot contain ingredients scheduled as controlled drugs under the Misuse of Drugs Act 1975
- contain substances listed in the First Schedule to the Medicines Regulations 1984 dietary supplements cannot contain ingredients that are scheduled as prescription medicines, restricted (pharmacist-only) medicines or pharmacy-only medicines under the Medicines Act 1981
- have a stated or implied therapeutic purpose the definition of a therapeutic purpose is given in the Medicines Act 1981.

Dietary Supplements (NHP) | Guidance on Therapeutic Purpose

Medicines Act, Section 4: Meaning of Therapeutic Purpose

- In this Act, unless the context otherwise requires, therapeutic purpose means any of the following purposes, or a purpose in connection with any of the following purposes:
 - a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
 - b) influencing, inhibiting, or modifying a physiological process; or
 - c) testing the susceptibility of persons to a disease or ailment; or
 - d) influencing, controlling, or preventing conception; or
 - e) testing for pregnancy; or
 - f) investigating, replacing, or modifying parts of the human anatomy.

The above definition is comprehensive and therefore limiting on the claims that can be made about a product that is not a medicine ie: a Dietary Supplement / Natural Product..



Dietary Supplements (NHP) | Guidance on Therapeutic Purpose

Medicines Act, Schedule 1

List of disease and conditions for which claims can only be made by a medicine

Part 1

 Alcoholism Appendicitis Arteriosclerosis Arthritis Baldness Blood pressure, disorders of Bust, underdevelopment of, Cancer Cataract Central nervous system, disorders of Diabetes Diphtheria, Dropsy, Epilepsy, Gallstones, kidney stones, bladder stones, Gangrene, Glaucoma, Goitre, Heart disease, Infertility, Leukemia, Menopause disorders of, Menstrual flow disorders of, Mental disorders, Nephritis, Pernicious anaemia, Pleurisy, Pneumonia, Poliomyelitis, Prostate gland, disorders of Septicaemia, Sexual impotence, Smallpox, Tetanus, Thrombosis, Trachoma, Tuberculosis, Tumours, Typhoid Fever, Ulcers of the gastro-intestinal tract, Venereal diseases

Part 2

• Asthma, Blindness, Common cold, Dental decay, Disorders arising from the ingestion of alcohol, Gout Haemorrhoids, Hernias, Impaired hearing, Impetigo, Influenza, Obesity, Psoriasis, Pyorrhoea, Rheumatism, Varicose ulcers, Varicose veins



Dietary Supplements (NHP) | Guidance on Advertising

The Advertising Standards Authority (ASA) has updated the definition of Advertising and Advertisement. It now states:

"Advertising and advertisement(s)" are any message, the content of which is controlled directly or indirectly by the advertiser, expressed in any language and communicated in any medium with the intent to influence the choice, opinion or behaviour of those to whom it is addressed."

The rapidly changing world of advertising, particularly the digital world, has provided an opportunity for the ASA to update its definitions to focus on the intent of the advertiser. When an advertiser controls the content of a message — be that directly or indirectly — in order to influence choice, opinion or behaviour — then the published or broadcast activity is likely to be advertising. Advertorials, advertiser websites, advertiser-controlled content within Influencers content e.g. blogs & vlogs and 'native advertising' are all considered advertising under this definition.



Dietary Supplements (NHP) | Guidance on Advertising

The ASA definition of advertising therefore covers a wide range of activities and material.

- TVC's / Videos / Cinema advertising
- Trade display / stand materials
- Magazine advertising and advertorials including CWH catalogues
- Radio advertising
- Product labels (for claims)
- Press Releases
- Sales team materials whether for selling to or education of retailers
- Point of sale material
- Print materials eg: patient / consumer leaflets / brochures

Dietary Supplements (NHP) | Guidance on Advertising

The ASA definition of advertising therefore covers a wide range of activities and material.

- Digital advertising eg: AdWords, web-banners / MREC / OLVs etc
- Social media posts facebook / instagram / linked-in / tik tok etc
- Websites own and Trade websites including advertorials and any copy content on your products
- eMAILS to customers other than commercial information
- Influencer briefs and posts

There is NO distinguishing between 'above' and 'below' the line activity

Dietary Supplements (NHP) | Guidance on Wording

- The word "support" is a neutral word and allowed by Medsafe in describing health claims in relation to Dietary Supplements. This is in line with Medsafe's view that dietary supplements support normal operation of a physiological function.
- Advertisers should avoid words like "improve", "boost", "enhance", "promote" "relieves" "strengthen" "protect" "regulates" "modulates" these would be regarded as over and above the normal operation of a physiological function.
- Medsafe has also commented that wording like "help" "assist" "maintain" are regarded as too active and should not be used. TAPS gained agreement that "supports the maintenance of ..." would be OK in this context. An alternative is "helps contribute to the normal function of"

Dietary Supplements (NHP) | Guidance on Wording

- In the same way wording that implies the inhibition or slowing down of the normal operation of a physiological function should be avoided. This would include wording like "regulate", "inhibit", "slow down", "block", "prevents" "increase" "decrease" as there would all imply a therapeutic purpose.
- A key point is to keep the wording in the positive and not mention possible symptoms or disease states as this would then be likely to imply a therapeutic purpose and the perception/take-up by the consumer would be that the product can treat a condition.
- Since the current pandemic Medsafe have advised that claims concerning immunity are no longer acceptable, acceptable wording is supports immune health/support immune system health or supports immune defences/supports immune function.

Dietary Supplements (NHP) | Guidance on Wording

Unacceptable	Acceptable
Heartburn	Digestive comfort
Indigestion	Digestive comfort
Constipation	Bowel comfort and regularity
Memory Cognition/Cognitive	Brain health Mental clarity and focus
Anxiety	Calmness

Unacceptable	Acceptable
Immunity	Immune defences Immune health
Pain	Comfort
Stiffness	Flexibility, mobility
Inflammation	Comfort
Joint Pain / arthritis	Joint comfort

An AUST L number does not mean that your dietary supplement product claims will be compliant in New Zealand



Dietary Supplements (NHP) | Guidance on Testimonials

- Testimonials for Dietary Supplements must not contain any actual or implied therapeutic claim that it has benefited the health of an individual in any way.
- A testimonial for this group of products would be in breach of the Medicines Act if a therapeutic claim were made in the testimonial. These types of testimonials are therefore prohibited for these products. A testimonial for this type of product should not make a therapeutic claim and should not therefore either directly or by implication suggest that the product has beneficially affected the health of a person through having a therapeutic benefit. Testimonials often stretch the credibility of a product and may be best avoided if the advertiser is uncertain about a possible breach of section 58 (1) (c) (iii) of the Medicines Act.

Dietary Supplements (NHP) | Guidance on Testimonials

- Principle 2, Guideline 2 (f) of the ASA Therapeutic and Health Advertising Code also covers the issue of testimonials with the useful summary that
 - "Testimonials, in advertisements, where not prohibited by law, shall comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable contribution. Exceptional cases should be represented as such."
- It is important to have written consent of the person giving the testimonial to support this section of the code.

Dietary Supplements (NHP) | Guidance on Testimonials

At no time can the person providing the testimonial or endorsement claim or imply in any way that the dietary supplement (NHP) has had a therapeutic benefit on their health. For example.

- Product X has helped keep my active lifestyle going, playing sport and working on the farm
 - This statement implies that without product X the person giving the testimonial would not have been able to have an active lifestyle (in particular playing sport) or continue working so implies to the consumer it can have a therapeutic effect on their health to such an extent that they could again play sport and or continue a manual labour role. The testimonial implies product X goes beyond the definition of a dietary supplement which is to support physiological function neither dimenshing or enhancing it.
 - The statement could be seen as not only breaching Section 58 (1) (c) (iii) of the Medicines Act but also Principle 1 and 2 of the ASA Therapeutic and Health Advertising Code in relation to "high level of social responsibility" and "truthful balanced and not misleading".
- However, it is acceptable to say ...
 - Product X helps support my lifestyle, playing sports and working on the farm....



Dietary Supplements (NHP) | Guidance on Comparative Advertising

The Principle 2 of the ASA Therapeutic and Health Advertising states:

Comparative advertising shall be balanced and shall not be misleading, or likely to be misleading, either about the product, device or service advertised or classes of products, devices or services, with which the comparison is made.

- Comparative advertisements shall not be disparaging and shall be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence.
- Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner.
- Comparative advertisements shall compare 'like with like'. Advertisements for Natural Health
 Products and Dietary Supplements shall not include comparisons with medicines or medical
 devices either specifically or generally.

Dietary Supplements (NHP) | Guidance on Comparative Advertising

Comparative advertising needs to be considered very carefully both in terms of the specific evidence needed to support any claims and the ability of the consumer to assess that evidence. For example:

Are all Joint Support created equal? Judge for yourself

- This headline represents a comparative claim. The ASA Therapeutic and Health Advertising Code Principle 2 c) i) on Comparative Advertising states;
- i. Comparative advertisements shall not be disparaging and shall be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence.
- The advertisement would need to include specific comparative evidence to support the headline that one Dietary Supplement for joint support is better than another. It also needs to be considered that in providing that evidence no therapeutic effect is claimed directly or indirectly.

Dietary Supplements (NHP) | Guidance on Comparative Advertising

Comparative advertising needs to be considered very carefully both in terms of the specific evidence needed to support any claims and the ability of the consumer to assess that evidence.

Are all Joint Support created equal? Judge for yourself

'Judge for yourself' is seen as an implied claim as it implies the product will have a health effect
over and above that of any other dietary supplement for joint support. Dietary Supplements are
only allowed to claim support for normal operation of a physiological function. That means there is
no room for claiming one is better than the other in terms of support of health or wellbeing,
without clinical evidence of the elevated effect, which would then show it had a therapeutic
purpose.

Comparative advertising needs to be considered very carefully both in terms of the specific evidence needed to support any claims and the ability to assess that evidence



Dietary Supplements (NHP) | Guidance on Brand Names

Brand names approval falls outside the terms of reference for TAPS. However brand names that imply a therapeutic effect if used in an advertisement will result in the advertisement not being able to obtain TAPS Approval

- TAPS recommends to seek immediate guidance from the regulator (MedSafe) concerning a brand name that
 - Implies a therapeutic effect or purpose
 - Includes a prefix or suffix name that is also used by a medicine (Prescription or OTC medicine)

Dietary Supplements (NHP) | Guidance on Mandatory Information

Mandatory information is not a disclaimer and is legislated in the regulations : see ASA Therapeutic & Health Advertising Code Principle 1

What Minimum Mandatory Information needs to be on an advertisement?

- If your product only contains minerals and/or vitamins, then the minimum information that needs to be on your advertisement is:
 - Always read the label and used as directed. Dietary Supplements are not a replacement for a balanced diet. Company Name, City in New Zealand.
- If your product contains other natural health ingredients in addition to minerals and/or vitamins the information that needs to be on your advertisement is:
 - Always read the label used as directed. Dietary Supplements are not a replacement for a balanced diet. If symptoms persist see your healthcare professional. Company Name, City in New Zealand



Dietary Supplements (NHP) | Guidance on Mandatory Information

What size does the Minimum Mandatory Information needs to be on an advertisement?

The minimum size of the mandatory information is no longer stated in any legislation or codes. However, this information must be legible.

- In the digital environment just zooming in until you can read the copy is unlikely to be regarded as acceptable. If the copy cannot be read at 100% size on a regular screen size or the screen size that most people will use e.g. smart phone for facebook it is unlikely to be considered legible.
- If the content can only be read a few words at a time before having to scroll left or down then it is unlikely to be considered legible e.g. smart phone / facebook
- There has been a case where it was ruled that although the mandatory information was present on the advertisement its small size meant that it could not be easily read by a customer i.e. illegible and so was considered not compliant.



Dietary Supplements (NHP) | Guidance on Updating Materials etc

During the 2 years of a TAPS Approval materials may often be updated, especially digital materials such as websites and webpages;

- TAPS Approvals relate to the material supplied at the <u>time for review</u> date given on documentation.
- The TAPS Approval does not extend to any update of the material after the date given on documentation without first seeking input from your TAPS Adjudicator.





Thank you

Background Information. Dietary Supplements (NHP)

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