TAPS | therapeutic advertising pre-vetting service

Background Information.
Over-The-Counter Medicines (OTC).

Prepared July 2023

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

OTC Medicine | **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

OTC Medicine | **Content**

- Introduction to TAPS
  - What is TAPS
  - Laws, Codes and Regulations
  - Why do we have TAPS
  - TAPS Service
  - TAPS Review Process
  - TAPS Scope
- Complaints to ASA
- Classification System in New Zealand
- Guidance on Therapeutic Claims
- Guidance on Advertising
- Guidance on Mandatory Information
- Guidance on Umbrella Branding
- Guidance on Online Links on Materials
- Guidance on Testimonials
- Guidance on Comparative Advertising
- Guidance on Updating Websites etc

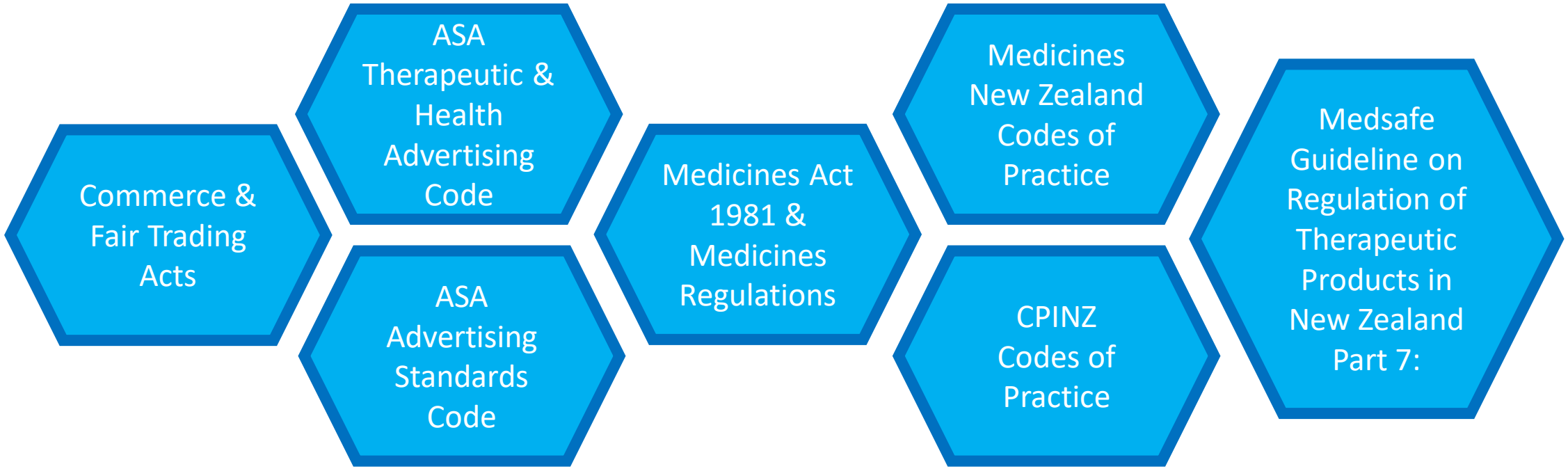
OTC Medicine | **What is TAPS?**

TAPS is a pre-vetting service which assists advertisers, advertising agencies and the media to comply with the:

- ASA - Therapeutic & Health Advertising Code (primarily) / ASA Advertising Standards Code (General)
- Medicines Act 1981 and regulations
- MedSafe Guideline of the Regulation of Therapeutic Products in New Zealand Part 7: Advertising of therapeutic products (Dec 2019)
- Consumer Healthcare Products Association NZ – Code of Practice (Apr 2012)
- Commerce Act 1986
- Fair Trading Act 1986

TAPS is a voluntary service widely supported by the media, and advertising industry. ANZA administers TAPS on behalf of media and industry.

OTC Medicines | **Laws, Codes and Regulations**



OTC Medicines| **Why do we have TAPs?**

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 NZ 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.

OTC Medicines| **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.

OTC Medicines| **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 materials 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. DAs (Designated Authority) can review updates to direct to consumer materials during this two years but not beyond

OTC Medicines| **TAPS Scope**

- The regulators ASA (NZ) and Medsafe as well as therapeutic and health product industry associations such as NZMA, CHP-NZ, MTANZ and NZSCM either advise, recommend or require that advertisers get materials TAPS reviewed to help minimise the risk of breaching codes of practice as well as other industry codes and relevant legislation.

- Prescription Medicines
- Over-the-Counter Medicines (including Pharmacist-Only Medicines & Pharmacy Medicine & General Sales)
- Dietary Supplements / Natural Health Products
- Appearance Medicine
- Medical Devices

OTC Medicines | **Complaints to ASA**

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.*

OTC Medicines | **Complaints to ASA**

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,

OTC Medicines | **Complaints to ASA**

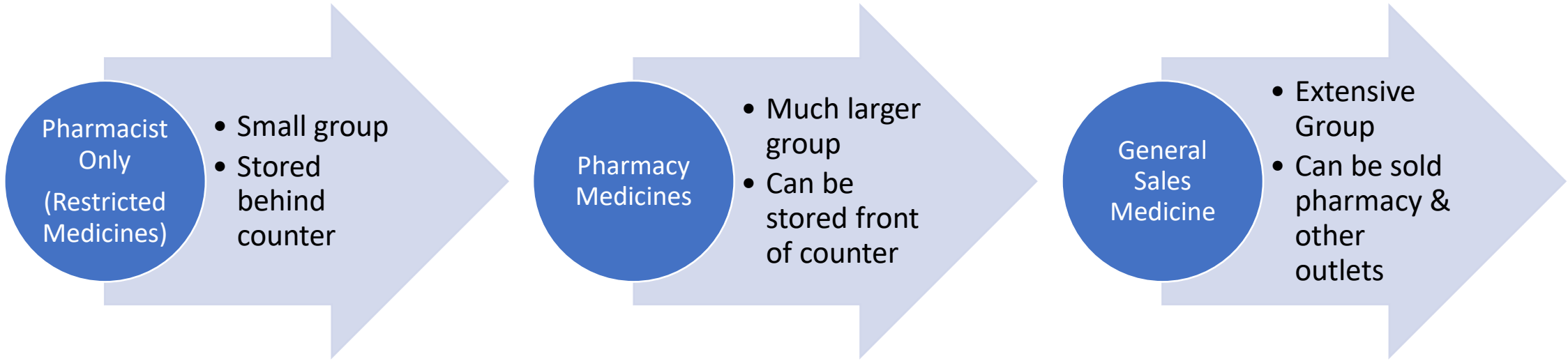
ASA Commentary to these figures

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

- *The Society for Science Based Health Claims has not been as prolific as it was pre-COVID*

OTC Medicines | **Classification System in NZ**

OTC Medicines are either classified as **Restricted Medicines** (also called Pharmacist-Only Medicines), **Pharmacy Medicines** or **General-Sales medicine**



You can check medicine classification by Medsafe at https://www.medsafe.govt.nz/profs/class/classintro.asp

OTC Medicines | **Classification System in NZ**

OTC Medicines are either classified as **Restricted Medicines** (also called Pharmacist-Only Medicines), **Pharmacy Medicines** or **General-Sales medicine**

- **Restricted Medicines -** These medicines are not available for self-selection from the pharmacy shelves, and the sale must be made by a pharmacist. Pharmacists are required to record the sale of these medicines and would need to record details such as the date, name and address of customer, name and quantity of medicine purchased, and name of the pharmacist involved in the sale.
- The following are some of the conditions which can be treated with Restricted medicines: *Cramp / eye infections / fungal infections of the toe or finger nails / hayfever or rhinitis / haemorrhoids / mouth ulcers / nausea caused by migraine / skin problems such as itching, rashes, inflamed fungal infections / thrush of the mouth / thrush of the vagina / warts / COVID-19.*
- A list of Restricted Medicines go to Https://www.medsafe.govt.nz/profs/class/classintro.asp.

OTC Medicines | **Classification System in NZ**

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- **Pharmacy Medicines -** These medicines are available for self-selection from the pharmacy shelves, and the sale can be made by any salesperson. A list of Pharmacy medicines can be found at https://www.medsafe.govt.nz/profs/class/classintro.asp
    - Common Pharmacy Medicines include diclofenac potassium 12.5 mg / paracetamol 500mg / Ibuprofen 200mg, phenylephrine HCL 5mg, fluconazole

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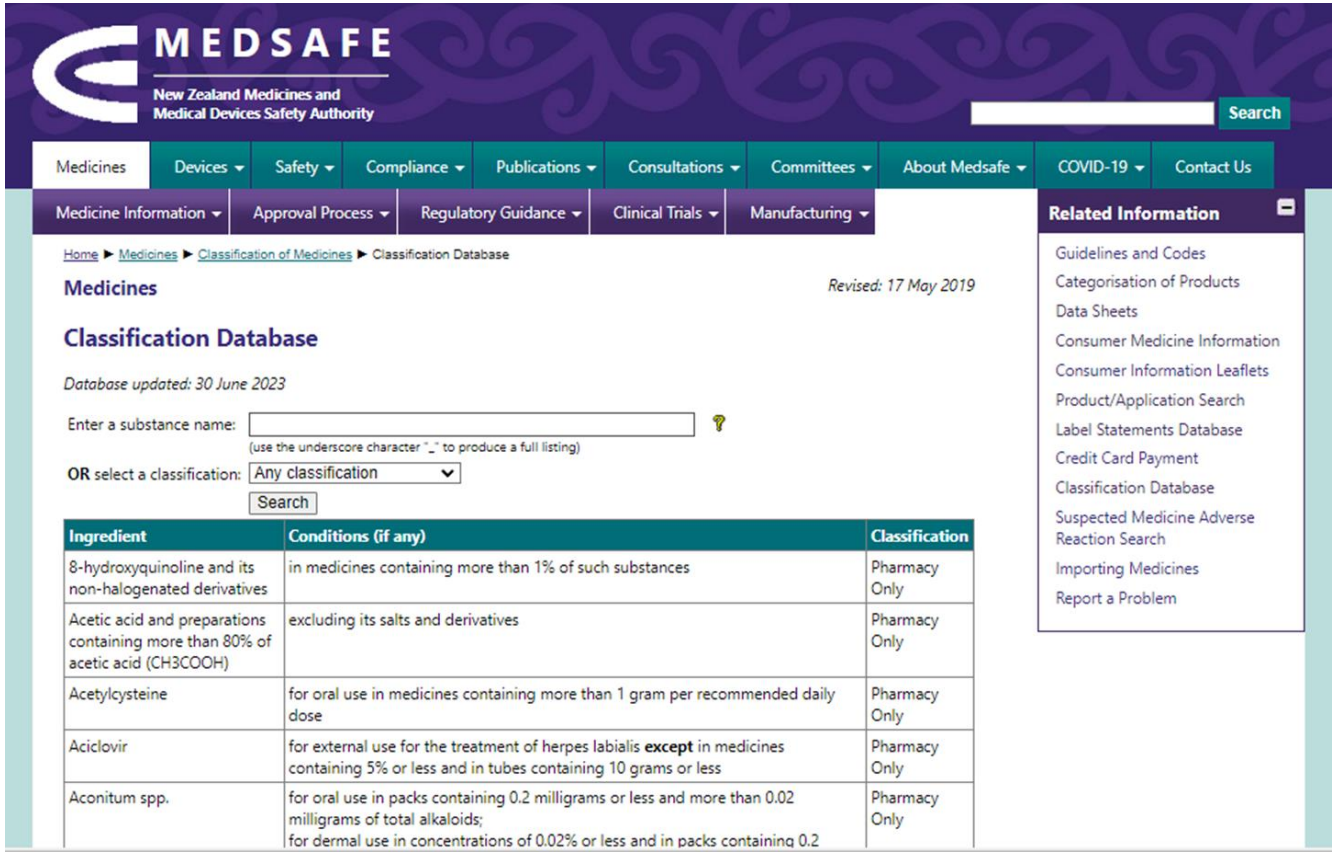
OTC Medicines are either classified as **Restricted Medicines** (also called Pharmacist-Only Medicines), **Pharmacy Medicines** or **General-Sales medicine**

- **General Sales Medicines** – These medicines are not listed in schedule 1 of the Medicines Act and are deemed as unclassified. These medicines may be sold from any outlet. A list of general sales medicines can be found at https://www.medsafe.govt.nz/profs/class/classintro.asp
    - Common General Sales Medicines include acyclovir topical, cetirizine 1mg for allergies, diclofenac for external use, paracetamol 500mg in packs of no more than 10 dose units, ibuprofen 200mg in packs of no more than 25 dose units
    - Even though General Sales Medicines are 'unclassified', they are still viewed by Medsafe as 'medicines' and therefore rules around mandatory information, sales discounts etc still apply.

OTC Medicines | **Classification System in NZ**

New Product Development

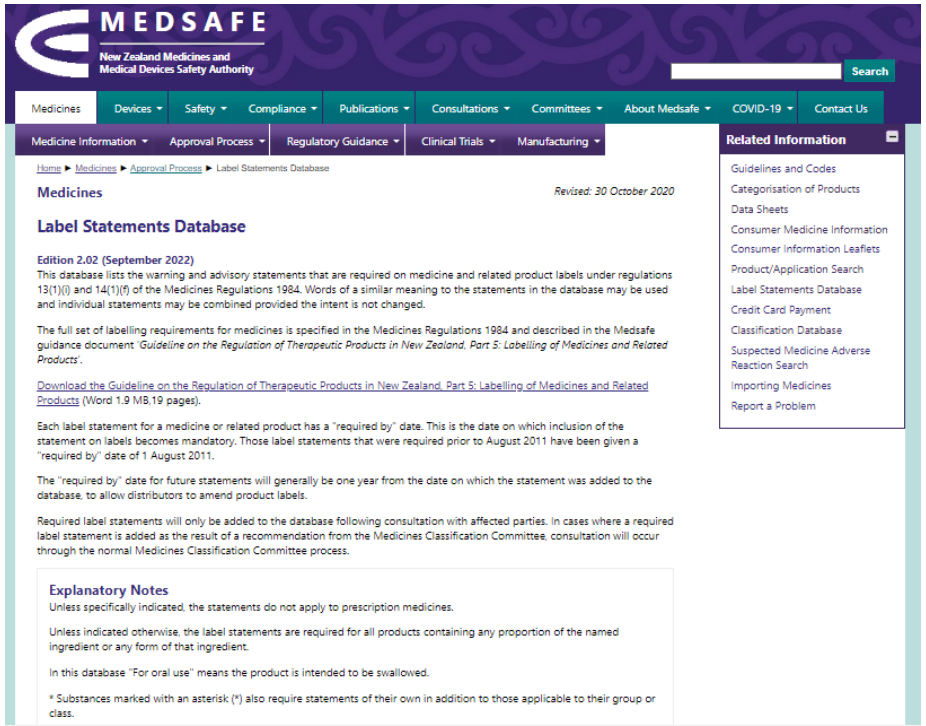
- When considering NPD it is important to remember that product classification system in New Zealand and Australia are different
- A product may be a medical device in AU but its ingredient (e.g. fungal treatment) could be classified in NZ and therefore it would be regarded as a medicine and so companies shouldn't assume and should check first



OTC Medicines | **Guidance on Therapeutic Claims**

Any therapeutic claims/benefits that can be made by an OTC Medicine must be as follow

- Restricted Medicines
  - as per New Zealand Data Sheet
- Pharmacy Medicines
  - as per Medsafe approved New Zealand label
  - or New Zealand Data Sheet if one exists
- General Sales Medicine
  - as per Medsafe approved New Zealand label



When providing promotional materials for TAPS review please send through the New Zealand Medsafe approved label and/or the product's New Zealand Datasheet to support the claims

OTC Medicines | **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.

OTC Medicines | **Guidance on Advertising**

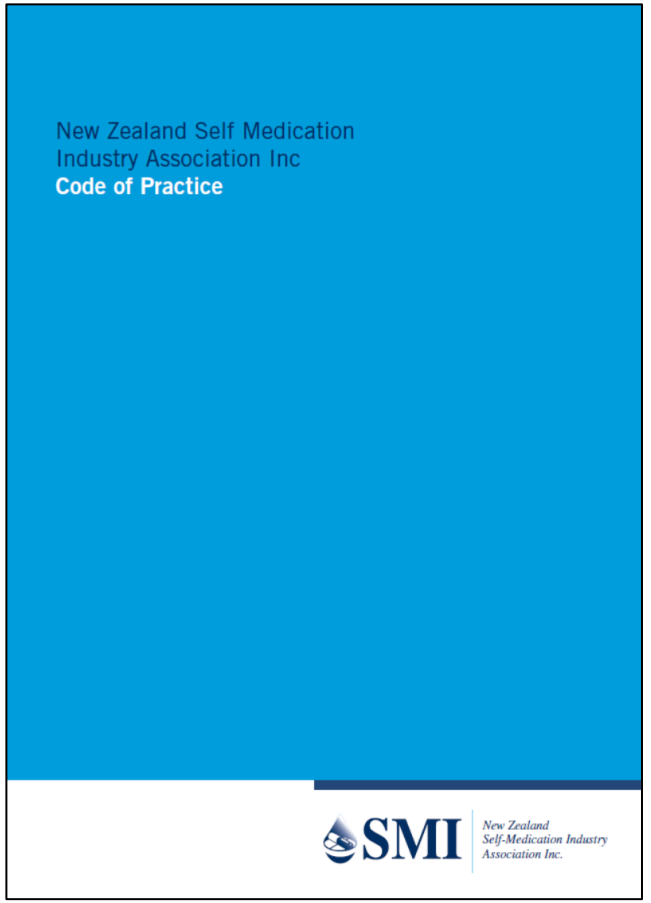
The Consumer Healthcare Products Association of NZ (CHP-NZ) Code of Practice for Apr 2012 states:

- "Advertisement" has the same meaning as assigned to that term by the Medicines Act (except that, for the purposes of this Code, labels are excluded from the definition) and "advertising" has a corresponding meaning. (CHP-NZ 1 Definitions)
- Advertising must inform and educate the public on the availability, purpose, and benefits of Therapeutic Products and Natural Health Products. Advertising must contain only correct valid balanced and verified statements and claims and must not mislead directly or by implication (CHP-NZ 2.8 Introduction)
- An advertisement for any Therapeutic Product or Natural Health Product must comply with the statutory and regulatory requirements and with applicable Codes of the New Zealand Advertising Standards Authority and contain only correct valid balanced and verified statements and claims based on current knowledge and evidence. (CHP-NZ Advertising & Promotion General Principles 5.1.1)

OTC Medicines | **Guidance on Advertising**

The Consumer Healthcare Products Association of NZ (CHP-NZ) Code of Practice for Apr 2012 states

- An advertisement for any Therapeutic Product or Natural Health Product be pre-vetted for compliance with requirements of the Therapeutic Advertising Pre-vetting System (TAPS) established by the Association of New Zealand Advertisers prior to publication and where appropriate or required bear the appropriate approval number issued.



OTC Medicines| **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

OTC Medicines| **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

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TAPS recently issued Guidelines on Google Ad
https://www.anza.co.nz/_files/ugd/077d6b_53d2fad153d946e696d5d24fdb9a5eb7.pdf

OTC Medicines| **Guidance on Mandatory Information**

Mandatory information is not a disclaimer and is legislated in the regulations.

See Medsafe Guideline On Regulation of Therapeutic Products in New Zealand Part 7: Advertising of Therapeutic Products.

OTC Medicines| **Guidance on Mandatory Information**

The mandatory information that needs to be on an advertisement for a Restricted Medicine **to the public (see 2.2.2) is**:

- the statement **"Available only from your Pharmacist"** or **"Your Pharmacist's advice is required"**, or words of similar meaning
- **"If symptoms persist see your Doctor/Healthcare professional"** or words of similar meaning
- **"Use only as directed"** or words of similar meaning
- the name of each active ingredient or the statement "**Always read the label**" or words of similar meaning
- a statement of the purpose for which the medicine is intended to be used
- any warning statement that may be required by guidelines issued from time to time by the Ministry of Health. The required warning statements for advertisements are listed in section 2.2.4
- **the name and address of the person or** on whose behalf the advertisement is published

OTC Medicines| **Guidance on Mandatory Information**

The mandatory Information that needs to be on an advertisement for a Pharmacy Medicine or General Sales Medicine to the public (see 2.2.3) is:

- "**If symptoms persist see your Doctor/Healthcare professional**" or words of similar meaning
- "**Use only as directed**" or words of similar meaning
- the name of each active ingredient or the statement "**Always read the label**" or words of similar meaning
- a statement of the purpose for which the medicine is intended to be used
- any warning statement that may be required by guidelines issued from time to time by the Ministry of Health. The required warning statements for advertisements are listed in section 2.2.4
- **the name and address of the person or business** on whose behalf the advertisement is published

OTC Medicines| **Guidance on Mandatory Information**

Mandatory Statements to appear within advertisements targeting the public	**Restricted Medicine**	**Pharmacy Medicine**	**General Sales Medicine**
Statement on the intended use of the medicine	**YES**	**YES**	**YES**
Use only as directed	**YES**	**YES**	**YES**
Always read the label	**YES**	**YES**	**YES**
If symptoms persist see your Doctor/Healthcare professional	**YES**	**YES**	**YES**
Available only from your Pharmacist	**YES**	NO	NO
Company Name and City	**YES**	**YES**	**YES**

OTC Medicines| **Guidance on Mandatory Information for HCPs**

The mandatory Information that needs to be on an advertisement for a Restricted Medicine or Pharmacy Medicine to healthcare professionals (see 2.3) is:

- the statement “Restricted Medicine” or “Pharmacist-Only Medicine” or “Pharmacy Medicine”
- a statement of the name and quantities of each active ingredient in the medicine
- a statement of the purpose for which the medicine is intended to be used
- a statement of the appropriate precautions to be taken in the use of the medicine
- a statement of any contra-indications to the use of the medicine
- a statement of the known or likely poisonous effects of, or adverse reactions to, the medicine
- a statement of any restriction imposed on distribution

(continues on slide 29)

OTC Medicines| **Guidance on Mandatory Information for HCPs**

The mandatory Information that needs to be on an advertisement for a Restricted Medicine or Pharmacy Medicine to healthcare professionals (see 2.3) is:

- the dosage regimen and mode of administration, or method of use, of the medicine
- information on the effectiveness and limitations of the medicine
- information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences
- the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

Reduced requirements apply to an advertisement that does not enable the health professional to reach a prescribing decision and is intended only to provide information about a major therapeutic indication, a new or changed strength, or a listing in the Pharmaceutical Schedule (see 2.3)

OTC Medicines| **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.

OTC Medicines| **Guidance on Mandatory Information**

Can QR Codes and Hyperlink be used instead on mandatory information on an advertisement?

In New Zealand, the necessary mandatory information that must be on the advertisement in full cannot be replaced with a QR Code. This is stipulated in the legislation that the information must be written so we are unable to change

What about on POS Materials such as shelf strips?

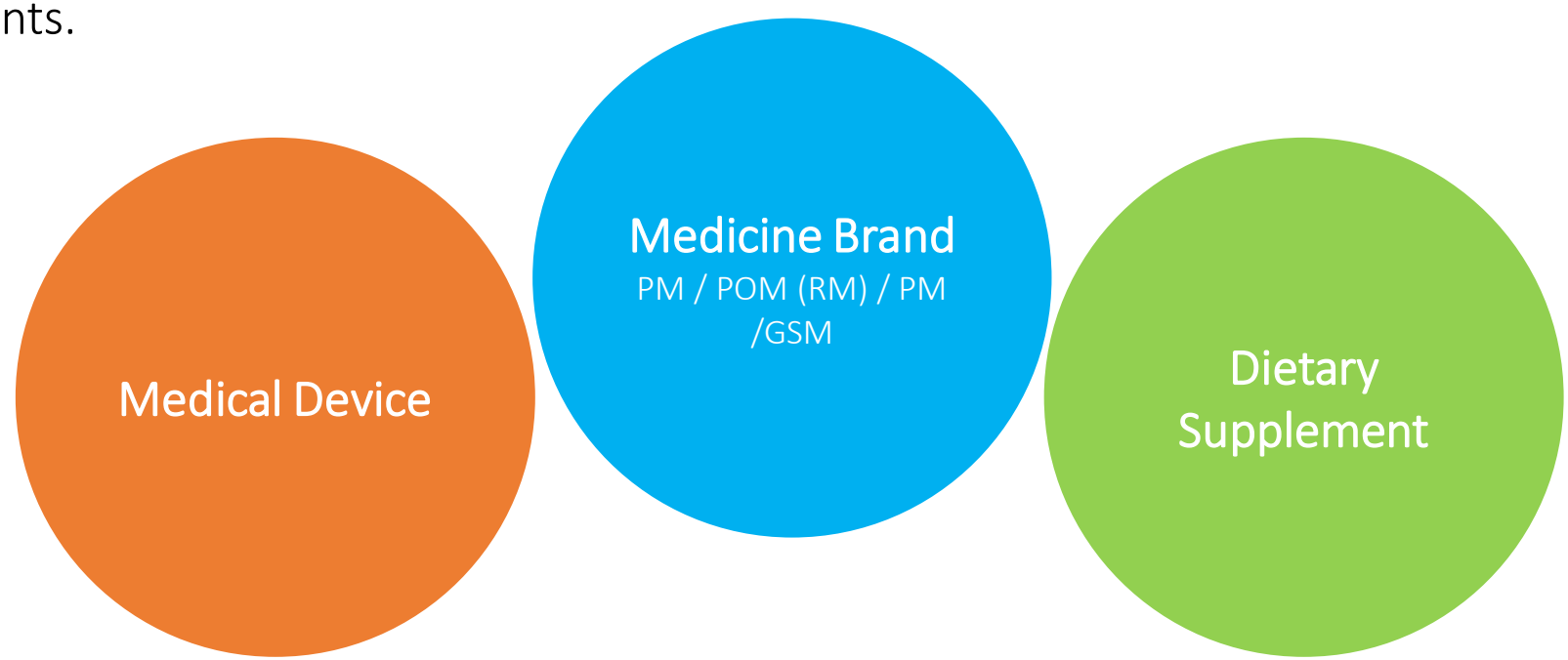
Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand.
Part 7: Advertising of therapeutic products.Section 2.2.7. Point of sale material, labels, and price lists

- Only one of the requirements described in sections 2.2.1 to 2.2.3 applies to point of sale material that is positioned immediately above, below, or next to the product (for example, shelf talkers), or to labels or price lists. This is the requirement to include: the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

OTC Medicines| **Guidance on Umbrella Brands**

Medicine brand names with non-medicine range extension?

The development of range extensions for a brand outside of the brand's original medicine's classification e.g. medical devices and dietary supplements brings significant compliance requirements.



OTC Medicines| **Guidance on Umbrella Brands**

Medical Devices Range Extension

- Claims than may be within the approved indication for the original medicine e.g. ***nasal congestion due to colds and rhinosinusitis*** may not match what is in the WAND for the medical device e.g ***clears nasal passages and mucus***.
- Any advertisement / promotional item that includes both an image of a medicine SKU and a medical device SKU cannot imply, by association that the medical device claim is the same approved indications as the medicine in the advertisement(i.e. be misleading)
- Any advertisement / promotional item that includes an image of a medicine SKU and a medical device SKU must cover the mandatory information requirements for both classifications

OTC Medicines| **Guidance on Umbrella Brands**

Dietary Supplement Range Extension

- Claims than may be within the approved indication for the original medicine e.g. ***for the treatment of coughs and colds*** are not permitted for a dietary supplement.
- Any advertisement / promotional item that includes both an image of a medicine SKU and a dietary supplement SKU cannot imply, by association that the dietary supplement has the same approved indications as the medicine in the advertisement (i.e. be misleading)
- Any advertisement / promotional item that includes an image of a medicine SKU and a dietary supplement SKU must be clearly delineated / separated carry the mandatory information for applicable for both classifications

OTC Medicines| **Guidance on Online Links in Materials**

Whatever online links appears on an advertisement / promotional item needs to comply with New Zealand legislation, regulations and codes

- There is legal precedent that websites, QR Codes (the webpages link to QR Code) and hyperlinks on advertisements in New Zealand are considered part of the advertisement and must comply with New Zealand legislation and codes
- The location of the website or webpage linked to from the advertisement / promotional item does not change this requirement
    - If the content of the website or webpage is based overseas and complies with that country's legal requirements, but not with New Zealand's then it is probably advisable not to include it in your advertisement / promotional item.

OTC Medicines| **Guidance on Testimonials**

Testimonials for OTC Medicines like Prescriptions Medicines are not allowed under Section 58 1) c) of the Medicines Act 1981

Subject to section 60, no person shall publish, or cause or permit to be published, any medical advertisement that—

- directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised—

  (i) **is a panacea or infallible**; or

  (ii) **is or has been used or recommended by a practitioner, nurse, or pharmacist**, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

  (iii) **has beneficially affected the health of a particular person or class of persons, whether named or unnamed**, and whether real or fictitious, referred to in the advertisement; or

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  - (iii) **has beneficially affected the health of a particular person or class of persons, whether named or unnamed**, and whether real or fictitious, referred to in the advertisement; or

This means that influencers cannot be used to promote OTC medicines as having benefitted their health or wellbeing

OTC Medicines | **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'.

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

OTC Medicines | **Guidance on Updating of Websites etc**

Online Materials – Websites etc

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

- TAPS Approvals relate to the material supplied at the time for review – date give 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.
- All direct-to-consumer advertising should be reviewed by a TAPS adjudicator.
    - *This includes all forms of digital advertising (eg: banner ads, static ads, AdWords, social media, professional platforms such as LinkedIn, blogs, websites, video's) for all healthcare products and services (i.e.: prescription medicines, OTC medicines, medical devices, medical services, dietary supplements, and cosmetics).*
- Any new campaign in mainstream media will ALWAYS require TAPS approval

TAPS | therapeutic advertising pre-vetting service

Thank you

Background Information.

Over-The-Counter Medicines (OTC).

Prepared July 2023

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