

A brief introduction to TAPS

Prepared May 2023

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TAPS – Aesthetic / Cosmetic Medicines Webinar Content

TAPS – Therapeutic Adverting Pre-vetting Service – an introduction **Guidance on:**

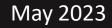
- Laws, Regulations and Codes
- Therapeutic & Health Products Prescription Medicines / Medical Devices
- Advertising ASA Definition and its consequences
- Mandatory Information / Statements
- Approved and Non-Approved Indications
- Wording of Claims
- Testimonial Advertising and Promotion
- Patient Experience Advertising and Promotion
- Professional Endorsement
- Before and After Images / Videos
- Gifts, Give-aways and Discounts
- Comparative Advertising
- PRP Protein Rich Plasma Therapy
- MINT Minimally Invasive Non-surgical Thread (Lifts)

What is TAPS

- TAPS is a pre-vetting service which assists advertisers, advertising agencies and the media to comply with the ASA Advertising Codes of Practice for Therapeutic Products and Services in New Zealand.
- TAPS is a voluntary service widely supported by the media, advertising industry and Therapeutic & Health product industry.
- ANZA administers TAPS on behalf of media and industry.

TOPS

• TAPS Adjudicators are here to help advertisers in creating promotional materials that avoid legislative breaches



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How TAPS Works

- ANZA appoints independent, experienced TAPS Adjudicators to pre-vet advertising material prior to placement with media.
- TAPS Adjudicators provide advice and guidance to advertisers, advertising agencies and the media with respect to the current rules, regulations and codes that effect the advertising of heath and therapeutic products in New Zealand.
- On average each TAPS Adjudicator of which there are four, reviews between 60-90 advertising / promotional items for therapeutic and health products per month.
- The advice given is based on an in-depth understanding of the laws, code and regulations around the advertising of therapeutic and health products as well as an appreciation of the views and opinions of the regulators in New Zealand.

TAPS Service

- You need to be registered with ANZA to access the TAPS Service but there is no charge for registration
- TAPS reviews usually take between 2-3 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 \$120 for 15 minutes for non-ANZA and \$80 for ANZA members
- How long does it take to carry out a TAPS review?

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There is no simple answer to this question but most reviews take between 15 and 30 minutes. 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.

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TAPS Review Process

Step 1: TAPS adjudicator is sent a proposed advertisement / promotional item and will undertake a review of that item within 2-3 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 does not just assess words but also the imagery. There can often be quite a lot of feedback before reaching Step 2.

Step 2: Once amends are completed and the advertisement is compliant, a unique TAPS approval number is allocated as an identifier. This gives assurance to the media the advert is compliant with NZ legislation and Codes and is OK for them to publish.

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.

TAPS – Therapeutic Pre-vetting Advertising Service

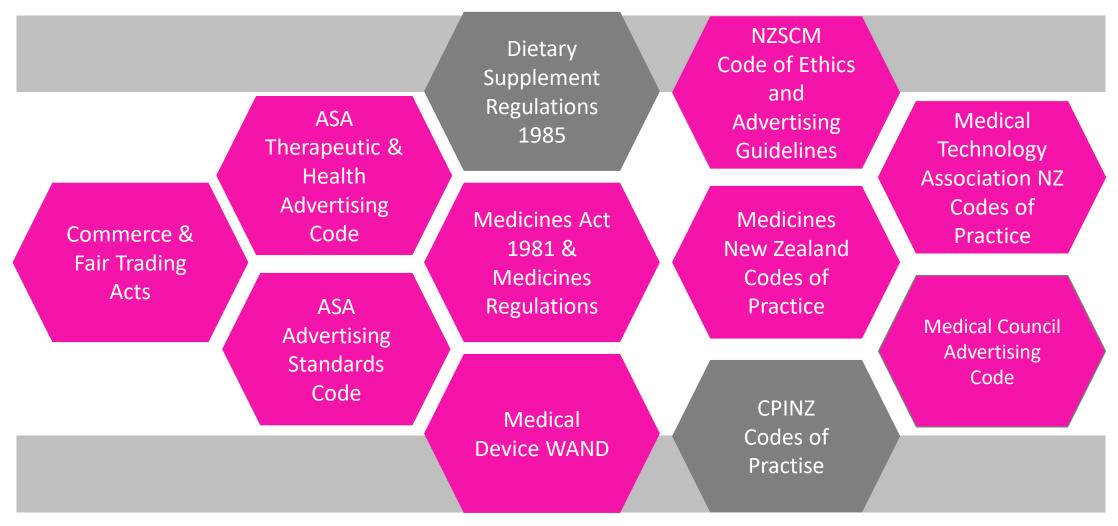
TAPS Scope

 The regulators ASA (NZ) and Medsafe as well as therapeutic and health product industry associations such as NZMA, CHPI-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
- Aesthetic / Cosmetic Medicines
- Medical Devices

Aesthetic / Cosmetic Medicines | Laws, Regulations and Codes



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Aesthetic / Cosmetic Medicines | Therapeutic and health products

- In New Zealand the following are all considered as therapeutic products.
 - Prescription Medicines
 - Pharmacist-Only and Pharmacy Medicines
 - General Sales Medicines
 - Dietary Supplements and Natural Health Products

- Aesthetic / Cosmetic Medicines
 - Prescription Medicines
 - Medical Devices
- Medical Devices
- Toothpastes that contain an API
- API = Active Pharmaceutical Ingredients

The New Zealand Ministry of Health (Manutu Hauora) states: Therapeutic products (medicines, medical devices and natural health products) are used by New Zealanders in their daily lives, and in all parts of the health system.

The new Therapeutics Products Bill submitted to the New Zealand Parliament on the 30/11/2022 states-**A therapeutic product is one of the following:** (a) a medicine: (b) a medical device: (c) an API: (d) an NHP.



Aesthetic / Cosmetic Medicines | Prescription Medicines







All advertising and promotional materials that uses these brand names needs to comply with all the regulations and codes opposite whoever produces the information:

- The manufacturer.
- Any aesthetic / cosmetic clinics.



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Aesthetic / Cosmetic Medicines | Medical Devices



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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.

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

- TVC's / 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 e.g..: patient / consumer leaflets / brochures

- **Digital advertising** e.g.: AdWords, web-banners / MREC / OLVs etc.
- Social media posts Facebook / Instagram / linked-in / tik took etc.
- Websites own and trade websites including advertorials and any copy content on your products
- Letters / emails to customers concerning treatments other than commercial information
- Influencer posts

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

If you are unsure what you are doing is advertising, -IT PROBABLY IS SO PLEASE approach a TAPS Adjudicator for advice during concept development.

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Summary on what is advertising in this online world?



These are all advertising media

If your company or clinic uses any of these or other social media, whatever is posted or reposted or shared, irrespective of it being paid or unpaid, is regarded as advertising under the ASA definition.

If you are unsure what you are doing is advertising, - IT PROBABLY IS SO PLEASE approach a TAPS Adjudicator for advice during concept development.

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Self-regulation encourages the industry to take responsibility to ensure legal, decent, honest and truthful advertising communications to consumers. There are a number of incentives. Most advertisers do not want to deliberately mislead or offend current or potential customers. They understand the importance of responsible advertising of restricted products and engage with prevetting processes and code-compliance prior to the release / publication of advertising. If consumers trust advertising, it is more effective. Advertising self-regulation also works best alongside a legislative framework. There are over 50 pieces of legislation covering advertising content or placement in New Zealand.

Ultimately, the responsibility to comply with all aspects of advertising regulation is shared between all the parties to an advertisement or promotion.

- If you use the brand name of any aesthetic / cosmetic medicines that are Prescriptions Medicines or Medical Devices in any form of advertising/promotional materials (see p12) targeting consumers, you must include the appropriate consumer mandatory information for that brand.
 - Full Consumer Information if the advertisement/promotion contains a therapeutic or promotional claims for the product.
 - Short Consumer Information if the advertisement/promotion does not include any therapeutic or promotional claim and designed only as a brand reminder or when using digital media.
 - You can find the Full and Short consumer mandatory information for all aesthetic / cosmetic medicines (Prescription Medicines / Medical Devices) within the annex and at NZCSM website <u>https://nzscm.co.nz/advertising-regulations</u>
- In New Zealand the mandatory information / statement CANNOT be substitute by a hyperlink or QR Code irrespective of the media channel.

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

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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 ready at 100% size on a regular screen size or the screen size that most people will use e.g.. smart phone for Facebook/Instagram 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 such as on a smart phone when viewing Facebook/Instagram
- There has been a case where it was ruled that although the mandatory information was present on the advertisement it small size meant that it could not be easily read by a customer i.e. illegible and so was considered not be present on the advertisement

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

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Mandatory information can be included in the text content of a Facebook or Instagram post.

Mandatory information can be included as part an the image in a multi-image post so that it can be spread over multiple images that appear in the post to ensure legibility. A single static image post is unlikely to have sufficient space for the mandatory information and brand name / company address and still ensure the legibility of the copy.



• The mandatory information / statement (full or short) must be used for these brands on all advertising / promotional materials across all media



Botulinum Toxin Type A belkyra

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Restylane BELOTERO®





TEOSYAL

PROFHILO®

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Unbranded vs branded (Botulinum toxin)

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- The use of botulinum toxin or terms such as ant-wrinkle injection or wrinkle relaxed injection in place of a specific brand name (BOTOX, XEOMIN, DYSPORT/AZZALURE) does not change the therapeutic claims or approved uses that can be made for the product in an advertisement or promotional item.
- While the need to run specific brand mandatory information / statement is not required the following long and short mandatory information / statement should be included on the advertisement or promotional material.



Unbranded vs branded (Botulinum toxin)

• FULL UNBRANDED CONSUMER MANDATORY INFORMATION / STATEMEMT

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Botulinum toxin injections are prescription medicine for the treatment of frown lines , horizontal forehead lines and crow's feet round the eyes. Botulinum toxin injections have risks and benefits. Ask your doctor if botulinum toxin injection is right for you. If you have side effects, see your doctor. You will need to pay for your botulinum toxin injection and clinic fees will apply. For details on precautions & side effects consult your doctor or go to www.medsafe.govt.nz . Botulinum toxin injections lasts about 4 months and further courses of treatment may be necessary. Should only be administered by trained medical professionals.

Unbranded vs branded (Botulinum toxin)

SHORT UNBRANDED CONSUMER MANDATORY INFORMATION / STATEMEMT
Botulinum toxin injections are Prescription Medicines for the treatment of frown lines, horizontal
forehead lines and crow's feet round the eyes. Botulinum toxin injections have risks and benefits.
Ask your doctor if botulinum toxin injections are is right for you. For further information ask your
doctor or go to www.medsafe.govt.nz.



What happens if you don't include a mandatory statements?

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- The regulator for prescription medicines/medical devices is Medsafe and they could take action if mandatory information not included under the Medicines Act 1981
- A competitor or member of public could take a complaint to the Advertising Standards Authority if mandatory information not included under the ASA Therapeutic & Heath Advertising Code
- A competitor could take a complaint to the New Zealand Society of Cosmetic Medicines in relation to their Code of Practice if mandatory information not included



Aesthetic / Cosmetic Medicines | Approved & Non Approved Indication

Approved uses of Botulinum toxin injections

 The aesthetic / cosmetic indications for botulinum toxin products are (upper facial rhytids), forehead lines, crow's feet and glabellar lines.



Botulinum toxin injections are NOT approved for :

- injection into lips for fullness (lip flip) or gummy smile
- injection into neck and chin (Neck Lift)
- Bruxism or teeth grinding.



Aesthetic / Cosmetic Medicines | Approved & Non Approved Indication



Botulinum toxin injections are NOT approved for :

- injection into lips for fullness
 (lip flip) or gummy smile
- injection into neck and chin (Neck Lift)
- Bruxism or teeth grinding.

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Alternative words/phrases for botulinum toxin such as anti-wrinkle injections / wrinkle relaxer injections does NOT get around the Medicine Regulations.

Images (photo/video) showing injections into the lips to increase volume (lip flip) on websites, social media etc. also contravene Section 20 of the Medicines Act and risk action from MedSafe.

Aesthetic / Cosmetic Medicines | Approved & Non Approved Indication

Section 20 of the Medicines Act states

(2) No person shall—

(a) sell; or

(b) distribute by way of gift or loan or sample or in any other way; or

(c) advertise the availability of-

any medicine to which this section applies before the consent or provisional consent oft he Minister to the distribution of the medicine has been given by notice, or otherwise than in accordance with such conditions as may be imposed by the Minister on giving his or her consent or provisional consent and set out in the notice.

(4) A person who contravenes subsection (2) commits an offence, and is liable on conviction—
(a) in the case of an individual, to imprisonment for a term not exceeding 6 months or a fine not exceeding \$20,000:

(b) in the case of a body corporate, to a fine not exceeding \$100,000.

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Aesthetic / Cosmetic Medicines | Guidance on Wording of Claims

Botulinum toxin products (Prescription Medicine)

- Claims around the anti-wrinkle properties of botulinum toxin can be made for both branded and unbranded consumer or HCP advertisements.
 - This aligns with the datasheets for all the botulinum toxin brands.

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- Claims to be anti-ageing are NOT in line with the approved uses of botulinum toxin products (or unbranded terms such as anti-wrinkle injections etc.). You can talk about *reducing the visible signs* of ageing such as wrinkles, or reducing the visibility of wrinkles, or similar wording.
- The effects of ageing on the face can be discussed in an advertisement / promotional item, however, care should be taken not to imply the products is in anyway anti-ageing.

Aesthetic / Cosmetic Medicines | Guidance on Wording of Claims

Dermal filler products (Medical Devices)

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- Claims for dermal fillers are set out in the product's WAND (Web Assisted Notification of Devices) on the MedSafe database.
- The WAND database content is only accessible by the product sponsor (Allergan Aesthetics (abbvie) Galderma, etc.). Therefore aesthetic / cosmetic clinics need to obtain a copy of the WAND before generating any advertising / promotional materials.
- In order to have any promotional materials approved by TAPS for an aesthetic / cosmetic medicine registered as a Medical Device the WAND for the product must be supplied with the item.

Aesthetic / Cosmetic Medicines | Guidance on Wording of Claims

Cosmetic products (not Prescription Medicines or Medical Devices)

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- Care is needed not to compare the effects of cosmetic product / device / procedure with Prescription Medicines (botulinum injections), or Medical Devices (Dermal Fillers) and Methods of Treatment like Liposuction.
- Prescription medicines, medical devices and methods of treatment all have therapeutic purposes. By comparing a cosmetic product to such products, you are implying a therapeutic purpose and only registered medicines or medical devices and methods of treatment can have a therapeutic purpose so any cosmetic product advertising would breach Section 20 of the Medicines Act 1981

Aesthetic / Cosmetic Medicines | Testimonials

Testimonials are NOT allowed for Prescriptions Medicines i.e. botulinum toxin products or Medical Devices i.e. dermal fillers.

• Medicines Act Section 58. Further restrictions on advertisements

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- (1) Subject to section 60 of this Act, 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-.
 - 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.

Aesthetic / Cosmetic Medicines | Patient's Experience

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Patient experience can be used in advertising / promotional materials e.g.. OLV provided:

- The patient experiences describes their present situation and having to put up with or live with such things as frown lines and a sagging complexion i.e. this is the present tense.
 - They can describe the problems/irritations of living with frown lines and a sagging complexion and the social reasons that they would like to have this fixed.
- Patients can talk about their aspirations for the future., This is essentially what they would like to happen. It is strongly recommended to make use of the future tense as safeguard.
- Do not use videos or images of a patient being injected with any aesthetic / cosmetic medicine by a healthcare profession to illustrate the patient's experience as this could be interpreted as HCP endorsement and Patient Testimonial for a Prescription Medicine or Medical Device.

If you are thinking, of doing patient experience advertising, please make sure you approach a TAPS Adjudicator for advice during concept development.

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Aesthetic / Cosmetic Medicines | Professional Endorsements

Professional endorsements are NOT allowed for Prescriptions Medicines i.e. botulinum toxin products or Medical Devices i.e. dermal fillers.

• Medicines Act Section 58. Further restrictions on advertisements

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- (1) Subject to section 60 of this Act, 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-.
 - 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;.

Aesthetic / Cosmetic Medicines | Professional Endorsement

In advertising / promotional materials for your clinic e.g.. OLV :

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- When using someone to describe the experiences/professional service/ and treatment at the clinic then it is recommended that you should use a professional presenter.
- The presenter should not:
 - in any way be qualified as a health professional to provide therapeutic treatment this includes injectors
 - be a staff member who is a manager and likewise not qualified as a health professional to provide therapeutic treatment.
- In this way you will avoid any implication of healthcare professional endorsement

If you are thinking, of doing patient experience advertising, please make sure you approach a TAPS Adjudicator for advice during concept development.

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Aesthetic / Cosmetic Medicines | Before & After Images/Videos

Exercise caution when using any images in your advertising

Think carefully before including any images in your advertising. Images, particularly "before and after" photos, have a significant potential to mislead or deceive, to give the impression or create an expectation of a successful outcome, and to encourage unnecessary use of services.

If you use "before and after" images/videos you must ensure that they:

- are there solely for the purpose of providing accurate and useful information to patients
- portray a realistic outcome that patients could expect
- only feature patients who have undergone the advertised procedure while under your (or your services') care
- have not been altered in any way
- use the same lighting, contrast, background, framing, camera angle, exposure and other photographic techniques in both the "before" and "after" images
- are consistent in appearance including posture, clothing and make-up
- are only used when the patient featured has given their full informed consent.
- Include the qualifier Individual results may vary

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Aesthetic / Cosmetic Medicines | Before & After Images/Videos

Exercise caution when using any images in your advertising Full face photos are considered to be a testimonial if the patient is identifiable, so the eyes should be covered or blurred.

Alternatively, you may show a cropped part of the face. Fullface photos are still permissible if directed at healthcare practitioners.

Before and after image for non-approved uses are not be used in advertising or promotional materials e.g.. websites

- Medicines Act Section 58
- Medical Council Code of Practice



Always add qualifier-INDIVIDUAL RESULTS MAY VARY

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Aesthetic / Cosmetic Medicines | Gifts, Give-Aways & Discounts

Gifts / Give-aways / Prize Draw/ Discounts for Prescriptions Medicines i.e. botulinum toxin products or Medical Devices i.e. dermal fillers CANNOT be undertaken.

 It is recommended that it is made very clear in any Gift / Give-away / Prize Draw offered by a clinic that prescription medicines / medical devices are not part of the Gift/Give-Away/Prize Draw

If you are thinking, of offering gifts discounts, please make sure you approach a TAPS Adjudicator for advice during concept development.

Medical Council Statement on Advertising

Offering discount coupons, gift certificates, online deals and vouchers

- If you offer inducements such as discount coupons, online deals and vouchers or gift certificates, you must ensure that they do not undermine your relationship with the patient and the informed consent process.
- In particular, you must make it clear that:
 - buying the deal, coupon or certificate does not equate to informed consent from the patient
 - you will assess the patient and discuss treatment options before going ahead with any treatment
 - the patient has the right to opt out of the treatment at any time
 - you will not provide the treatment if your assessment indicates that the patient is not a suitable candidate.
- You should not offer medical assessments or treatments as a prize or gift where your objective is to make money and/or to increase your or your practice's profile

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Aesthetic / Cosmetic Medicines | Comparative Advertising

Advertising Standards Authority (ASA) 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.

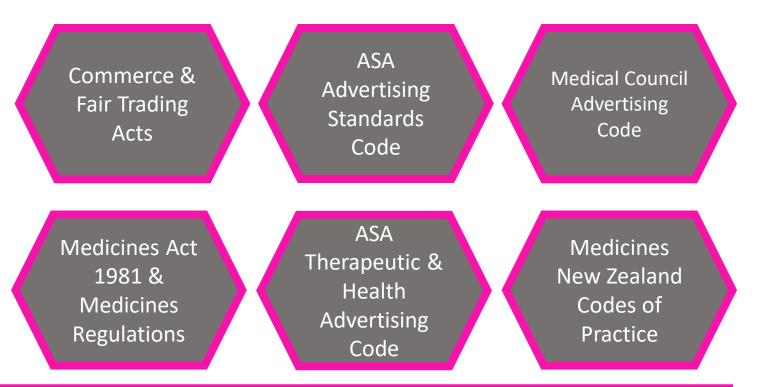
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These requirements includes claims about your clinic its services.

Aesthetic / Cosmetic Medicines | Comparative Advertising

Recommendation

Comparative advertising is a very difficult area that is full of risks especially for clinics. You need to consider a whole raft of laws, regulations, codes.



If you are thinking, of doing comparative advertising, please make sure you approach a TAPS Adjudicator for advice during concept development.

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Aesthetic / Cosmetic Medicines | PRP Platelet Rich Plasma Therapy

Platelets and Plasma are both General Sales Medicines. **Platelet Rich Plasma is a non-approved medicine** i.e. not registered by MedSafe and has no approved therapeutic purpose for the product.

Platelet-Rich Plasma (PRP) therapy is a treatment which involves taking a sample of one's blood, spinning it down, and injecting the plasma back into the soft tissue of the chosen site. It is seen by Medsafe as an **autologous**. Because its autologous it can be administered by a HCP to the patient from whom it was extracted, as a Section 29 medicine.

Claims as to the benefits and therapeutic purpose of the procedure CANNOT be made as these would contravene Section 20 Medicines Act. It is doubtful as to whether the procedure itself can be advertised.

If you are thinking, of doing any advertising or promotion around PRP Therapy of any kind, please make sure you approach a TAPS Adjudicator for advice during concept development.

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Aesthetic / Cosmetic Medicines | MINT – Minimally Invasive Non-surgical Threads

We have contacted MedSafe concerning MINTS

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"These may be medical devices but it depends on exactly what the advertiser claims for them. Sometimes actions are claimed that could only be performed by a medicine. Note that presence on the WAND database does not confirm that a product is definitely a medical device."

In order to have any promotional materials approved by TAPS for a WAND for the product must be supplied with the item.



TAPS - We are here to help you

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The sooner you approach TAPS the easier it is to ensure that your communication concepts and implementations activities are within the laws, regulations and guidelines in New Zealand.



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