

THERAPEUTIC ADVERTISING PREVETTING SYSTEM

Briefing May 2018

New Zealand

- ▶ New Zealand has its own regulatory System
- ▶ Its different from the Australian TGA
- ▶ For our products we have to comply with the NZ Dietary Supplements Regulations and the NZ Medicines Act
- ▶ This means claims and labels that are approved in other jurisdictions may not be compliant for NZ

New Zealand

- ▶ We have a system of Self Regulation to ensure that all advertising and promotion is legal and complies with the NZ regulatory requirements.
- ▶ All people involved in producing advertising material are responsible. That includes the company that owns the product, the media, and any distributors along the line.
- ▶ All can be liable for prosecution.

What does Self Regulation Mean

It means that instead of having a regulatory agency to approve ads, you get advice from TAPS to ensure work complies with Regulatory and Code requirements.

What does Self Regulation Mean

- ▶ It means that you own responsibility for getting it right.
- ▶ TAPS is only part of Self Regulation
- ▶ You are the other part.

- ▶ **The media will accept a TAPS approval as evidence that the work has been checked for compliance.**
- ▶ **This gives them some assurance that they are not going to be liable.**
- ▶ **It means that you as advertisers have to own the responsibility for what you claim in an advertisement.**

Why Self Regulation?

It was adopted by Industry in order to avert another level of Regulatory control.

The ASA and ANZA convinced Government that they could run a competent self regulatory system, using their complaints Board to effectively handle complaints.

What are TAPS Adjudicators

We are part of the Self Regulatory System, working with Industry to help achieve compliance and ensure advertising meets the Legal and Self Regulatory Code requirements.

What are TAPS Adjudicators

- ▶ We are at the top of the cliff.
- ▶ At your request, We aim to give you the assistance you need to avoid jumping off it.
- ▶ The Regulators are at the bottom of the cliff waiting to call you out for non compliance.
- ▶ We don't handle complaints.
- ▶ Anyone can make these to the ASA or Medsafe.
- ▶ We can be useful if you need picking up from the bottom of the cliff.

TAPS supports the principles of self-regulation embodied by the ASA for therapeutic advertisements and endeavours to provide a timely, cost-effective and reasonable method of protection for the consumer.

TAPS APPROVAL

- ▶ Why get TAPS Approval ?
- ▶ Ads in the media will require it.
- ▶ For ads that are not in the media, its is a good assurance of compliance.

- ▶ Often this becomes an issue if there is a complaint, and all advertising material is looked at.
- ▶ Includes -Websites, brochures and in store promotional material, cont..

Pharmacy brochures, Supermarket flyers, newspaper inserts, TV and Radio, Outdoor, Social Media, Facebook

These are all highly visible ads that
Are more likely to attract
complaint.

Everything promotional is an ad.

What makes a product a medicine

- ▶ A product can become a medicine or a medical device simply by the claims it makes.
- ▶ Therapeutic claims require registration as a medicine, or notification as a medical device

Therapeutic Claim

- ▶ Preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect or injury; or
- ▶ Influencing, inhibiting, or modifying a physiological process; or
- ▶ Testing the susceptibility of a persons to a disease or ailment; or

Therapeutic Claim cont

- ▶ Influencing, controlling or preventing conception; or
- ▶ Testing for pregnancy; or
- ▶ Investigating, replacing, or modifying parts of the human anatomy

Therapeutic Claim

- ▶ No person shall publish or cause or permit to be published any medical advertisement that:
- ▶ Claims to prevent, *alleviate or cure* any disease, *prevent, reduce, or terminate* any physiological condition included in Part 1 of Schedule 1 of the Medicines Act
- ▶ Claims to prevent or cure any disease or prevent or terminate any physiological condition in Part 2 of Schedule 1 of the Medicines Act

Unless it has consent for this purpose and is registered as a medicine or medical device.

Therapeutic Claim

- ▶ This is why complementary products are restricted in the claims they can make.
- ▶ The claim alone can make the product a medicine.
- ▶ Be aware that a claim can be made by the imagery as well as the words, or a combination of both

Examples of Therapeutic Claim

- ▶ Acceptable claims are those that claim:
- ▶ Support for the normal operation of a physiological process
- ▶ Support for normal health
- ▶ Nutritional support where ingredients may be lacking in a diet
- ▶ Support for the normal operation of body parts and processes.

Words that are not acceptable

- ▶ Promotes – influences a physiological process
- ▶ Relieves – alleviates or treats
- ▶ Maintains – influences a physiological process
- ▶ Assists/Aids/Contributes – Treats
- ▶ Reduces – alleviates or treats
- ▶ Improves – influences a physiological process
- ▶ Naming diseases – Names physiological conditions prohibited in the Medicines Act
- ▶ Targets – influences a physiological process

Examples of some words that are not acceptable

- ▶ Anti-inflammatory
- ▶ Pain, ache, sore
- ▶ Diuretic
- ▶ Anxiety
- ▶ Colds & Flu
- ▶ Viruses
- ▶ Arthritis
- ▶ Osteoporosis
- ▶ Cancer
- ▶ The list goes on.....

How can you check?

- ▶ Go back to the definition of Therapeutic Purpose
- ▶ Does it mean any of these–
- ▶ Preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect or injury; or
- ▶ Influencing, inhibiting, or modifying a physiological process

How can you check

- ▶ Is it claiming any of these?
- ▶ Claims to prevent, *alleviate or cure* any disease, *prevent, reduce, or terminate* any physiological condition

. Words that are not acceptable

- ▶ Comparing to registered medicines either directly or indirectly
- ▶ Superlatives that overpromise an outcome
 - longer, faster, quicker, better
- ▶ Specific mention of symptoms of a disease
 - Even without mentioning the actual disease
- ▶ Testimonials that make therapeutic claims.

Imagery that is not acceptable

- ▶ Pictures of a disease state.
- ▶ Diagrams that use coloured highlights to describe a disease –
 - Red for Inflamed joints
 - Before and after pictures

Some common traps

- ▶ Using outside media to write your copy. They often have no idea what they can't say. So you pay them and then you pay TAPS to correct it.
- ▶ Focusing on the negative aspects of a disease
- ▶ Using Australian or US copy
- ▶ Associating the product with a registered medicine in any way.
- ▶ Not leaving room for the mandatory statement.

Some common traps

- ▶ Abbreviating already approved copy. Often this misses out the important 'support for' words
- ▶ Thinking the rules don't apply to Social Media
- ▶ Slightly changing approved copy.

Some Common problems

▶ Cough Mixtures

- These are medicines. So its not OK to mention cough in the name or copy

Using the word Medicine

Obviously this describes a medicine and not a dietary Supplement

Focusing on Sickness rather than Wellness

This has the effect of implying a therapeutic purpose

Some Common Problems

- ▶ Issues Currently causing Medsafe Concern:
- ▶ Testimonials making claims
- ▶ Joint products, pushing the claim a bit too far
- ▶ Weight Management products
- ▶ Website copy
- ▶ References

Some common problems

- ▶ Not keeping records
- ▶ This is not surprising given the turnover of staff and ownership, but so often we have to start at square one with new people who aren't able to access previous comments and approved copy for their own products.
- ▶ This is a weekly problem for us with requests for copy of approvals going back a while.

Complaints

- ▶ We cannot act on your complaints about other companies.
- ▶ This is Self Regulation so a big part of your responsibility is to make complaints to the Regulators.
- ▶ TAPS appreciate the verdicts of both Medsafe and the ASA complaints board and the Commerce Commission as they help keep a level playing field.

Where do you complain

- ▶ Complaints can be made to the ASA
- ▶ Follow the instructions on the website
- ▶ www.asa.co.nz
- ▶ Complaints can be made to Medsafe

WHO COMPLAINS

- ▶ Ad complaints come from:–
 - The Public
 - Competitors
 - Health professionals
 - Anyone can make a complaint to ASA or to Medsafe
- Competitors need to identify that they are competitors.

Complaints

- ▶ **What happens after a successful complaint?**
- ▶ Taps take it on board as a guide for future approvals.
- ▶ This means that sometimes previously approved material cannot be used.
- ▶ You can keep up with ASA decisions on the ASA website.

Industry Codes

- ▶ All Industry Codes apply in addition to the requirements of the ASA Codes
- ▶ Industry Codes adopt the ASA Codes as a starting point
- ▶ All Codes refer to the requirements of the Medicines Act as a basic element for compliance

SMI Code

- ▶ The SMI Code covers OTC Medicines and Natural Health Products
- ▶ Including Dietary Supplements.
- ▶ It has an Advertising and Promotion section that you should be aware of.

Pharmacy

- ▶ The Pharmacy Council and The Pharmaceutical Society have a new advertising guideline and Code of Ethics the includes complementary products.
- ▶ Advertisers need to be familiar with this.

Testimonials

- ▶ Testimonials may only be used for Natural Health Products as long as:
- ▶ They do not make a therapeutic claim
- ▶ References may not be used to make a Therapeutic Claim
- ▶ Imagery may not be used to make a Therapeutic claim
- ▶ The safest ones are those that just refer to ease of use, or don't use them at all.

Testimonials

- ▶ Blogs written by influencers will nearly always have testimonial material and unacceptable claims.
- ▶ Make sure you keep control over what they propose to write.
- ▶ Have a go at correcting it before you send to TAPS... best way to learn
- ▶ Check your Facebook Feedback on a daily basis. These can get you into big trouble.

Testimonials

- ▶ ASA Complaints board has recently upheld complaints about user feedback on websites or Digital media where claims are made by the users.
- ▶ This has been very useful in determining what is acceptable in this area.
- ▶ Make sure you have a robust system in place to vet this feedback, or it will get you in trouble.

Unapproved Medicines

- ▶ These are Medicines that have not had consent to be distributed.
- ▶ Your products can become unapproved medicines just by virtue of:–
- ▶ The claims they make
- ▶ The presence of scheduled medicines in the formula
- ▶ Testimonials posted by users.
- ▶ There is a serious fine for this if you are prosecuted.

Unapproved medicines

- ▶ Where do I find a list of scheduled medicines
- ▶ <http://www.medsafe.govt.nz/profs/class/classintro.asp>
- ▶ Just type in the name of the substance and enter
- ▶ You will get a list.

Labels

- ▶ **Dietary Supplement Labels should comply with the NZ Dietary Supplements Regulations.**
- ▶ **Imported products will not necessarily comply.**
- ▶ **NZ does not allow therapeutic claims for Dietary Supplements**

Labels

- ▶ **Be aware that Regulatory action can be taken on non compliant labels, usually following a complaint about advertising.**
- ▶ **Non compliant Pack shots should not be used in NZ adverts.**
- ▶ **If you are doing this, pixilate out any claims on the pack shots first.**

Labels

- ▶ **Cosmetic products labels need to observe the same rules for Therapeutic claims.**
- ▶ **The labeling requirements are less rigorous.**
- ▶ **Topical preparations are not dietary supplements, and as there is no category for them other than medicine, they are generally considered cosmetic unless they make a therapeutic claim.**

Labels

- ▶ Topicals includes:
- ▶ Lotions
- ▶ Creams
- ▶ Oils
- ▶ Essential Oils
- ▶ Anything applied to the skin
- ▶ Aromatherapy
- ▶ Shampoos and hair products

Status of your Product

- ▶ Be clear about whether the product is a:
 - ▶ Dietary Supplement
 - ▶ Food
 - ▶ Supplemented Food
 - ▶ Cosmetic
 - ▶ Medical Device
 - ▶ Method of Treatment
-
- ▶ Make sure you tell TAPS what the product is.

Status of your Product

- ▶ The Medsafe website has some good advice on how to classify your product.
- ▶ Introductory Regulatory Guidelines
- ▶ Dietary Supplements
- ▶ Medical Devices
- ▶ www.medsafe.govt.nz

Ingredients for Dietary Supplements

- ▶ TAPS approves the advertising claims, but not ingredients *This is your responsibility.*

Make sure daily doses are in line with Dietary Supplements Regulations

Make sure your ingredients are not medicines

Make sure you have active ingredients tested

Make sure your product contains no undeclared medicines.

Make sure you have a process for reporting any serious side effects to Medsafe.

High Standard of Social responsibility

- ▶ Remember for all these products the High Standard of Social responsibility applies
- ▶ **ASA Code–**
- ▶ All therapeutic advertisements should be prepared with a High standard of Social Responsibility

Use of References

- ▶ References can only be used provided they do not make therapeutic claims.
- ▶ Often the references relate to a therapeutic purpose, so cannot be used
- ▶ References on Websites which do this have been removed following Medsafe advice.

Websites used in advertisements

- ▶ The inclusion of a website address or a link to social media
- ▶ The websites and links must lead to compliant material
- ▶ They are considered to be a part of the actual advert.
- ▶ There is legal precedent for this.

Website Approvals

- ▶ The approval is good on the day it was issued.
- ▶ Any changes that have not been approved just render the approval null and void.
- ▶ Remember to get the approval updated if you make changes.
- ▶ The approval can be updated.
- ▶ We keep a print out of what we approved on file in case there is an issue.

Non Branded Material

- ▶ Independent articles that discuss current research for ingredients can be used, but there are watch points:
- ▶ Can only be used in independent supplier magazines or websites.
- ▶ Must not be associated with ads for product containing those ingredients.
- ▶ This means an ad for the product must not appear on the same page or an adjacent page.
- ▶ Should not be included in Sponsor websites advertising product

Mandatory Statements

- ▶ These have to be able to be read easily or ASA considers them to be not there
- ▶ Must be horizontal to the ad and not vertical (Up the side of the ad)
- ▶ These are a legal part of the ad so need due prominence in print ads as well as TV
- ▶ Reminder– When you resize an ad, the mandatory size may need to be changed so it can still be read

Mandatory Statements

- ▶ **Always read the label and use as directed.**
- ▶ **Plus either**
- ▶ **Vitamins are supplementary to a balanced diet (if it is only vitamins and minerals)**
- ▶ **OR**
- ▶ **If symptoms persist see your healthcare professional (This one applies to most of your products)**
- ▶ **Company Name and City of location.(This is a legal requirement)**

Absolute Statements

- ▶ Be wary of Absolute Claims
- ▶ ‘Worlds Best’
- ▶ ‘The Strongest’
- ▶ ‘Breakthrough’
- ▶ The High standard of Social Responsibility applies, so you will need to be able to quantitatively prove the claim is true.
- ▶ No room for puffery with Therapeutic Products

Clinical Trials

For Non Medicines:

This statement implies a clinical purpose, so is not acceptable. Usually they are quite large and formulation specific.

Can mention clinical studies, clinical research

Can Not mention a therapeutic purpose

Cannot mention Clinically Proven

Helpful Tips

When sending material to TAPS for approval be clear about the job.

We need to know:

What it is, ie a Poster or a Lightbox, Print ad, electronic media, Flyer, or whatever the description is.

How it will be used– where it is placed

What the status of the product is ie Dietary Supplement, Food, Medicine, Medical Device etc

Helpful Tips

Purchase order number. Remember to get it before work commences. We can give a quote.

Who the responsible person at the company is
What the company's Registered name is.

Helpful Tips

- ▶ If you are on Pre Pay, remind us so we can issue the pro-forma invoice
- ▶ Tell us what size the ad is so we can check the mandatory size.
- ▶ If you have concerns about the copy, share them with us. It will save you time and money if we are singing off the same page
- ▶ If you have had a complaint from ASA or Medsafe and are changing the ad, let us know as much information as possible.

TIP

- ▶ Make sure you have approved copy to give to The Pharmacy, Health Food and Supermarket chains.

Often these come separately to TAPS for approval, and often copy has to be changed.

- ▶ Its better for you to have complaint material that conveys what you want it to, rather than risk a last minute deadline change.
- ▶ We do our best with these often under urgency.

TV Commercials

Process for TVCs..

Storyboard. Mandatory Execution

Concept Approval

Involve TAPS early in Concept of TVC for possible early “red light issues”.

Claims must be compliant.

Check storyboard carefully re issues of implied therapeutic claims.

TV Commercials

Execution of Mandatories.

Clarity and readability are key.

Large Font Size. Bold colour contrast

Time on Screen. Guide is 4 words per second. Be conservative and allow plenty of time.

Use of audio can mean less visuals.

Consider Visually impaired and hard of hearing audiences.

ASA

- ▶ Check out Complaints Board decisions on
- ▶ www.asa.co.nz/database
- ▶ You can search on decisions, codes, or by year, or use keywords

Open these by clicking on them and then clicking on Open Hyperlink

Medsafe info on Dietary Supplements

<http://www.medsafe.govt.nz/regulatory/DietarySupplements/Regulation.asp>

Medsafe info on Medical Devices

<http://www.medsafe.govt.nz/regulatory/DevicesNew/Devices.asp>

Medsafe info on Weight Management

<http://www.medsafe.govt.nz/regulatory/Weight/weightloss.asp>

- ▶ Medsafe Introductory Guidance
- ▶ Is my product a medicine?
- ▶ What do I need to do to sell my medicine in New Zealand?
- ▶ Frequently asked questions
- ▶ <http://www.medsafe.govt.nz/regulatory/RegulatoryGuidance/Introduction.asp>

Open these by clicking on them and then clicking on Open Hyperlink

- ▶ Link to Medicines Act 1981

- ▶ <http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html>

- ▶ Link to Medicines Regulations 1984

- ▶ <http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html>

- ▶ Link to Medical Devices Regulations

- ▶ <http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html>

- ▶ Link to Dietary Supplements Regulations

- ▶ <http://www.legislation.govt.nz/regulation/public/1985/0208/latest/DLM102109.html>

TAPS ADJUDICATORS

- ▶ Peter Pratt tapspeterpratt@gmail.com
▶ 04 938 6409 027 492 1230
- ▶ Nigel Andrews nigel@rubicon.net.nz
▶ 09 836 2680 027 657 9750
- ▶ Maureen Roberts
maureenroberts@extra.co.nz
▶ 09 478 7776 021 687 760

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