Medsafe and Therapeutic Product Advertising Update

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TAPS Industry Briefing - Auckland

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Medsafe and Therapeutic Product Advertising - update

- Medsafe
- Therapeutic products advertising scheme
- Medsafe's role
- What we see
- Points of note
- Avoiding issues

Medsafe

- The New Zealand Medicines and Medical Devices Safety Authority – part of the Ministry of Health
- Relevant legislation – Medicines Act 1981, Medicines Regulations 1984
- Comprises several ‘Branches’
  - Compliance Management
  - Product Regulation
  - Clinical Risk Management

Compliance Management

Functions - about compliance with the legislation

- GMP audit and licensing / certification
- Medicines and Medical Devices complaints & recalls
- Investigations and prosecutions
- Testing programme
- Medical devices listing database
- Advertising complaints and issues

Legislation - summary

- Pre-market assessment of medicines and related products – to international standards
- No pre-market assessment for medical devices – listing only
- Post-market monitoring and action – for all therapeutic products
- Risk-based classification of medicines
- Activity licensing – manufacture, wholesale, pharmacy
- Advertising controls

Key definitions

What makes a product 'therapeutic' and what type of product is it?

For Medsafe - probably the most frequent and important questions in relation to advertising

- 'Therapeutic purpose' is defined in section 4
- 'Medicine' is defined in section 3 of the Act
- Medical device is defined in section 3A of the Act

Key definitions

What makes a product 'therapeutic' and what type of product is it? (2)

- 'Therapeutic purpose' has a broad definition and captures many claims that may not be readily associated with the term 'therapeutic'
- It also captures 'disease' which also has a broad definition (in section 2)

Definition changes
medicine, medical device

- Medicine / medical device now differentiated by mode of action
- A medicine is any substance or article - for a therapeutic purpose – that achieves, or is likely to achieve its principal intended action through pharmacological, immunological or metabolic means

Definition changes
medicine, medical device

- A medical device is a device, instrument, apparatus, appliance or article – for a therapeutic purpose – that does not achieve its principal intended action through pharmacological, immunological or metabolic means; but may be assisted in its function by such means

Impact of definition changes

- Our definitions are more closely aligned with other regulators – but are not the same
- Some products previously regarded as medicines are now medical devices
- There are products that may be either, depending on the interpretation of ‘principal’ and depending on the claimed mode of action
- Shifts the ‘grey’ area – for instance some topical products may now be medical devices, but this will depend on the claimed mode of action

Product Categorisation

- Interface issues, medicine/medical device, medicine/cosmetic, medicine/food
- Principal purpose for product
- Associated mode of action and claims
- Inclusion of scheduled substance
- Dietary Supplements vs Supplemented Foods

Product Categorisation (2)

- Leeches
- Medicated Dressings
- Creams

The Advertising Regulatory Scheme

The Medicines Act 1981

- Part 4 – sections 56 – 62
- The principles and major requirements
- Defines ‘advertisement’ and ‘publish’

The Medicines Regulations 1984

- Part 3 – regulations 7 – 11
- Provides the detailed requirements

Advertisement
section 56

Advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and *advertising* and *advertised* have corresponding meanings

Advertisement (2)
section 56

Medical advertisement means an advertisement relating, or likely to cause any person to believe that it relates, to any medicine or medical device or any ingredient or component thereof, or to any method of treatment

Self-regulation

Modern regulatory scheme where various bodies cooperate to provide an environment that promotes efficient and effective regulation

- Cooperation is the key
- Compliance with the legislation, assisted by the various codes of practice – industry and ASA

Self-regulation (2)

- ASA (Advertising Standards Authority) – code of practice
- ANZA (Association of NZ Advertisers) and TAPS
- ASA complaints process
- Medsafe is the regulator and regulates against the legislation

Relationship with TAPS

(Therapeutic Advertising Pre-vetting Service)

- TAPS provides assistance and certification to the industry
- Medsafe cannot be both a regulator and a consultant to the industry
- Close cooperation ensures that both TAPS and Medsafe decisions and advice correspond
- Agreement on interpretation
- Medsafe will often refer advertisers to TAPS
- Medsafe is available to assist with new or complex issues

Two types of issue

- Advertising of approved products – failure to comply with the detail of the legislation
- Advertising of unapproved products – advertising a therapeutic purpose for a product makes it a medicine – it must, therefore, be approved

Issues of note
approved products

- OTC medicines – keen competition in relation to what can be said about a product
- Alignment of claims and indications with approved indications
- Prohibition on advertising of certain controlled drugs
- When is a communication an advert or patient information?

Issues of note
approved products (2)

- Complaints in relation to detail often best dealt with through the ASA complaint process
- Claims made for a product beyond those approved could result in a breach of section 20
- Products that may be medicines notified to WAND and making claims for registration

Issues of note
unapproved products

The key issue is not whether there has been compliance with the advertising requirements, it is the fact that advertising has taken place!

- Products that have not been approved (that is, the Minister has not given consent under section 20 of the Medicines Act for sale, distribution or advertising) cannot be advertised.

Issues of note
unapproved products (2)

- A breach of section 20 carries a substantial penalty
- This applies to products supplied under section 29 and under any of the other exemptions, for instance, sections 26 & 32
- Note that a product may be a medicine because of the therapeutic purpose claimed for it or because it contains a scheduled substance

Advertising unapproved products

- Frequently these are complementary healthcare products for which therapeutic claims are made
- In many cases the advertiser has been ignorant of the law in this area and has advertised in ‘good faith’
- In some cases companies push the boundaries beyond acceptable limits

Advertising unapproved products (2)

- Sometimes advertisers will remove advertising then re-offend
- A subset may be products that contain an undisclosed scheduled medicine (adulterated)

What occupies us

- Advertising of unapproved medicines – brought to our attention – various sources
- Questions / referrals from other regulators
- TAPS interactions
- Advertiser questions
- Advertisers reporting on the activities of others
- Prioritisation of issues – matching resources with risk

Regulatory action options
Approved products

- Investigation – establishing the facts
- Opportunity for explanation / justification
- Referral of the advertiser to TAPS
- Possible referral to ASA complaints process or industry process
- Further action as appropriate

Regulatory action options
Unapproved products

- Establish the facts
- Communication with the party involved
- Risk prioritisation
- Formal notification of the legal position
- Market action if indicated
- Educate – encourage – enforce
- Other legislation may apply – Fair Trading Act, Consumer Guarantees Act

Responding to Medsafe

How to respond to a ‘regulatory notice’

- Suspend advertising and selling the affected product(s)
- Reply to Medsafe
- Review all products being advertised / sold
- Engage competent advice – for instance, TAPS

Responding to Medsafe (2)

- Provide evidence of having ceased non-compliance
- Provide a plan and commitment to avoid future non-compliance
- Medsafe will consider your response

Avoiding non-compliance
approved products (1)

- Be familiar with the legislation and various guidance documents – we will use the legislation to decide
- Ensure all the ‘mandatories’ are met
- Be practical – ensure that whatever medium is used, the requirements are met
- Indications need to match those that have been approved
- Graphics or just a few words can be enough to cause an issue
- Size of graphics may be important

Avoiding non-compliance
approved products (2)

- Beware of controlled drugs
- Testimonials are not permitted (public)
- Anyone can advertise – but all must meet the requirements – for instance, advertising by pharmacies
- Unapproved products cannot be advertised at gatherings / conferences / trade shows
- Websites are advertising

Avoiding non-compliance
unapproved products (1)

- Why are you selling the product? If it is for a therapeutic purpose and it is not a medical device then it must first be approved
- What may make it a medicine? – it could be the claimed therapeutic purpose or the inclusion of a scheduled medicine (even in the absence of a therapeutic purpose)
- There are 'acceptable' and 'unacceptable' phrases and terms – it is a fine line – for instance mention of diseases and symptoms are likely to be indicative of a therapeutic purpose – TAPS advice most important
- Including disclaimers with therapeutic claims does not negate the effect of the claim

Avoiding non-compliance
unapproved products (2)

The following are all likely to amount to making a therapeutic claim

- A testimonial
- Links to other websites where therapeutic claims are made
- Reference to clinical trials
- References to books or traditional knowledge
- Comparison with other medicines or active ingredients
- A therapeutic purpose as part of a name

Other issues (1)

- Selling medicines by auction is not permitted
- Internet auction information is regarded as advertising
- Use of GMP logos and claims of certification on labels and advertising can be an issue
- Therapeutic claims for cosmetics is a growing trend, some contain scheduled substances

Other issues (2)

- Advertising by both internet and mail that targets vulnerable groups
- Use of social media – this is advertising
- Issues with interactive advertising - feedback
- The advertising legislation also applies to publishers

Dealing with imported products

Important points:

- Use of overseas advertising material may make the product non-compliant
- Links to overseas websites may make the product non-compliant
- Overseas regulatory regimes are likely to be different to that in New Zealand so a product compliant elsewhere may not be compliant here
- You will be responsible for the product including its ingredients, labelling and advertising

Medical devices

- A medical device must be entered onto the WAND database by the sponsor within 30 working days of becoming the sponsor for the medical device
- As medical devices are not pre-market assessed in New Zealand, it is up to the importer / manufacturer (sponsor) to ensure they meet acceptable standards
- It is important to ensure the claims made for their use are scientifically supportable
- Medicine or medical device?

Avoiding non-compliance
medical devices

- A medical device must do what you claim it can do – scientific evidence must be available to prove the claims made for a medical device
- A medical device must be notified to the WAND database – you should be able to provide proof of this
- Note that a successful entry on the WAND database does not mean that Medsafe has approved a product or even agreed that it is a medical device
- Note that the WAND database is not publicly searchable

Some examples of regulatory action

- Most of our prosecutions have an advertising component – breach of section 20(2)(c) of the Medicines Act – advertising of an unapproved medicine
- Cases include the supply of various adulterated medicines and Chinese-style medicines for which there were charges relating to supply of unapproved medicines and often also supply of prescription medicines

Some examples of regulatory action (2)

- An interesting case was that of a pharmacist who manufactured, had manufactured by a factory, sold and advertised his unapproved 'herbal' product that contained a prescription medicine for the treatment of erectile dysfunction. Penalty: 4 months and 2 weeks in prison.

Future regulation

- Looking forward to changes that will bring new legislation which will be more appropriate, flexible and address the needs of the consumer and industry
- Information on the progress of the new regulatory regime and legislation published on the Ministry of Health website:
- http://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

Advertising interaction

Common goal – safe, effective, quality medicines

…..promoted in a responsible, accurate and compliant way

~~ Thank you ~~

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