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New Zealand

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in New Zealand.

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NEW ZEALAND
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The advertising of therapeutic products is regulated by the Medicines Act 1981 and the Medicines Regulations 1984. There are also industry codes that set out the minimum industry standards by which the advertisement of therapeutic products is to be conducted. These industry codes are Medicines New Zealand Incorporated (**MNZ**) *Code of Practice* for prescription medicines, and the Medical Technology Association New Zealand (**MTANZ**) *Code of Practice* for medical devices.

In addition to these specific regulations and requirements, pharmaceutical companies must also comply with general consumer protection laws, namely the Fair Trading Act 1986 which prohibits misleading and deceiving conduct, and requires all therapeutic claims and representations to be substantiated.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Pharmaceutical companies who are members of MNZ are required to comply with its advertising rules as set out in its *Code of Practice* (**MNZ Code**) for both direct-to-consumer and direct-to-healthcare professional medical advertisements.

Medical device companies who are members of MTANZ are required to comply with its advertising rules as set out in its *Code of Practice* (**MTANZ Code**).

These industry standards do not have any legal effect. However, it is common for the terms of a subsidy listing agreement between New Zealand's Pharmaceutical Management Agency (**Pharmac**) and a pharmaceutical or medical device supplier to require that supplier to comply with industry codes for direct-to-consumer advertising, regardless of whether the supplier is a member of the local industry body.

Advertisers of therapeutic products should also comply with the advertising codes published by the Advertising Standards Authority (**ASA**). The *Therapeutic and Health Advertising Code* applies to both direct-to-consumer and direct-to-healthcare professional medical advertisements. The ASA is also a self-regulating body whose members have agreed to be bound by its decisions.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

The Medicines Act defines "advertisement" broadly to mean "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".

An advertisement is a "medical advertisement" if it relates, or is likely to cause any person to believe that it relates, to any medicine or medical device.

The breadth of the statutory definition captures all forms of online and offline promotional materials, activities and communications, whether directed at consumers or healthcare practitioners (or both), as long as the material "relates or is likely to cause a person to believe that it relates" to a medicine or medical device and the

primary purpose of the material, activity or communication is to promote the sale of the therapeutic product. This is ultimately a question of fact and degree and the overall context in which the material, activity or communication is made is relevant to the inquiry.

Whether a disease awareness campaign would be captured by the definition would depend on the scope and nature of the material. The Medicines Act does not specifically define or cover 'disease awareness', although this is defined under the MNZ Code as the following:

Disease awareness activities provide information, promote awareness and educate the public about health, disease and their management. The emphasis must be on the condition and its recognition rather than treatment options (e.g. cover key characteristics of the disease). Such activities must not reference a specific medicine. The awareness activity may make reference to the availability of different treatment options, however, it may not be designed to encourage a patient to request the prescription of a specific medicine.

As long as references are only made in relation to treatment options, no "specific medicine" is mentioned (expressly or impliedly) and the activity is "not designed to encourage a patient to request the prescription of a specific medicine", then such activity would not be considered a "medical advertisement" under either the MNZ Code or the Medicines Act.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases regarding the approval of a new medicine or the approval of a new indication of an already approved medicine are permitted in New Zealand and there are no legal restrictions on the target audience.

A press releases is a medical advertisement under the Medicines Act and must contain the relevant mandatory information required under the Act, and comply with the relevant advertising restrictions and prohibitions.

Press releases regarding the availability of an unapproved medicine is prohibited in New Zealand.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

The Medicines Act does not prescribe any approval process for medical advertisements in New Zealand.

However, it is common industry practice to obtain approval of the Association of New Zealand Advertisers (**ANZA**) through its pre-vetting service, the Therapeutic Advertising Pre-vetting Service (**TAPS**), prior to publication. Pharmaceutical and medical device companies that are members of MNZ and MTANZ (respectively) are required to have their advertisements pre-vetted and approved by TAPS in accordance with their respective Code of Practice.

6. Do companies have to have material approved by regulatory bodies prior to release?

The Medicines Act does not require medical advertisements to be approved by any regulatory body prior to publication. It is common for pharmaceutical and medical device companies to elect to use ANZA's pre-vetting service, but this is not a legal requirement.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative advertising is legally permitted provided that it is not misleading, the representations and claims can be substantiated, and any claim of comparative efficacy or safety must not be solely based on a comparison of the product's data sheet, unless a head-to-head study was conducted, and otherwise complies with the general restrictions and prohibitions under the Medicines Act.

Comparative advertising in relation to prescription medicines are generally not used in direct-to-consumer medical advertisements in New Zealand as this is prohibited by the MNZ Code.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

It is unlawful to "advertise the availability" of any medicine in New Zealand prior to the medicine receiving

Medsafe market approval, unless a statutory exemption applies, including:

- the unapproved medicine is supplied by an HCP to a named patient under the HCP's care;
- the unapproved medicine is supplied for the sole purpose of undertaking a clinical trial approved by the Ministry of Health; or
- the unapproved medicine is imported, supplied or distributed by the New Zealand government.

Not all provision of information relating to an unapproved medicine will constitute an advertisement in breach of the prohibition. For example, the MNZ Code of Practice allows pharmaceutical companies to respond to an unsolicited request for medical and scientific literature on medicines and indications that may be unapproved in New Zealand, provided that the information given is not promotional and is distributed by the pharmaceutical company's medical department.

The provision of information on unapproved medicines to healthcare professionals during a scientific conference may be permitted in some limited circumstances. The provision of information must be part of a genuine exchange relating solely to the medical or scientific nature of the medicine, and must not be promotional in nature. For example, no product branding or promotional claim must be made in respect of the unapproved medicine.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

An advertisement for prescription medicines must include the words "Prescription Medicine", details of the active ingredient including name and quantitative particulars, statements regarding the potential risks and benefits, and explaining how the consumer can find further information regarding the risks and benefits (it is encouraged that this statement points consumers to the Consumer Medicine Information (**CMI**)) found on Medsafe's website or another official forum relating to the sponsor.

An advertisement for restricted medicines must include the words "Available only from your Pharmacist" or "Your Pharmacist's advice is required", "If symptoms persist see your Doctor/Healthcare professional", "Use only as directed", "Always read the label" and the name of each active ingredient. If relevant, any required warnings that may be issued by the Ministry of Health.

Pharmacy-only and general sale medicines have similar requirements to restricted medicines, without the need for the statement "Available only from your Pharmacist".

These advertisements must also comply with the general restrictions and prohibitions under the Medicines Act, including that the medicine cannot be promoted as a cure, the advertisement must not contain any patient or imply that it has been recommended by a healthcare professional.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Pharmaceutical companies that are members of MNZ must also comply with the MNZ Medicines Code when collaborating with patient organisations. All interactions must be ethical, fair and transparent. The principal rules include:

- *Financial or non-financial support:* any support must be provided for 'bona-fide/legitimate patient organisation programmes' such as patient market research surveys or disease awareness campaigns. Any type of support should not be offered or provided in a manner or on conditions that would interfere with the independence of a patient organisation and its members.
- *Funding*: the pharmaceutical company may contribute funding (or be the sole funder) for a patient organisation (or any of its programmes); however, it is prohibited from requesting or requiring that it be the sole funder. There are also general obligations on the pharmaceutical company in terms of the method of funding. For example, all financial payments or other contributions must be made directly to the organisation and not to any individual patient. The terms of the funding arrangement should be fully agreed and documented prior to any support being provided.
- *Sponsorship of patients:* a pharmaceutical company can sponsor patients to attend third-party educational events, so long as sponsorship payments are made to the patient organisation and not directly to the patient. Pharmaceutical companies must have

no direct involvement with the patients who are to benefit from the sponsorship.
- *Advertisements*: any advertising or promotional material intended for viewing or distribution to the members of patient organisations must comply with the advertising controls set out in the Medicines Act and regulations.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

There is no restriction on the type of information that can be sent to a healthcare professional, however if the information is intended to promote the sale of a therapeutic product, then it is a medical advertisement and must contain the following mandatory information required under the Medicines Act:

- Any restriction imposed on distribution of the therapeutic product;
- Its mode of administration or method of use; and
- information on the effectiveness and limitation of the therapeutic product.

The prohibition against the use of patient and healthcare professional testimonials as well as representing the therapeutic product to be a panacea under the Medicines Act do not apply, however such claims and representations must be capable of substantiation and not otherwise misleading.

In addition to the statutory requirement, the MNZ Code further requires that a clear statement regarding the funding status of the therapeutic product (whether the product is or isn't listed on the Pharmaceutical Schedule), any funding restriction(s) that apply to the Pharmaceutical Schedule listing, and the source of any funding restrictions be included in the medical advertisement.

Information regarding clinical trials of a product that has not yet been approved by Medsafe cannot be advertised and can only be provided to an HCP in response to an unsolicited request, and must be provided by the pharmaceutical company's medical department only.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

The financial relationship between pharmaceutical companies and healthcare professionals is largely regulated by industry codes of practice.

The MNZ Code prohibits the provision of gifts and offers by member pharmaceutical companies to healthcare professionals, unless the gift or offer meets certain requirements, such as being an educational material directed to patients or healthcare professionals.

Donations of items of medical utility, grants or financial support may be provided by the pharmaceutical company in certain circumstances. However, their supply must not be conditional upon the healthcare professional agreeing to recommend, prescribe, dispense or administer the pharmaceutical company's product.

MNZ introduced guidelines for the disclosure of transfer of value to healthcare professionals, which became effective on 1 January 2021. MNZ's *Guideline for the Disclosure of Transfers of Value* (**Guidelines**)Medicines_New_Zealand_Transparency_Guidelines__15_Oct_2020_.pdf (medicinesnz.co.nz) only apply to members of MNZ and, even then, compliance is only voluntary for members.

The Guidelines have not been adopted into legislation in New Zealand and there are currently no New Zealand statutory 'sunshine' or transparency requirements in relation to the disclosure of transfers of value between a pharmaceutical company and a healthcare professional or healthcare organisation.

For healthcare professionals, their relationship with pharmaceutical companies may give rise to a conflict of interest, which they must manage according to their relevant codes of ethics and practice. The Medical Council of New Zealand's *Doctors and Health Related Commercial Organisations* and New Zealand Medical Association *Code of Ethics* only require the HCP to disclose a transfer of value from a pharmaceutical company to the patient if that transfer of value constitutes an actual or potential conflict of interest.

There are legislative and public sector procurement rules that prohibit bribery and kickbacks. These cover government officials involved in the purchase of medicines and medical devices.

There is also legislation that is designed to prevent individuals from receiving secret bribes and kickbacks for recommending or selling goods and services, including therapeutic products.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, pharmaceutical companies can provide approved prescription medicine samples to HCPs with appropriate prescribing rights. The samples or starter packs must:

- comply with all relevant regulatory requirements in relation to its labelling;
- only be distributed by pharmaceutical company representatives that hold a Hawker's licence, or be nominated on the company's manufacture or wholesale licence; and
- not be made available at professional trade display stands.

Pharmaceutical companies are required to record the issuing of starter packs to a healthcare professional, and the signature of the accepting the healthcare professional must be obtained.

Any returns of the sample or starter pack must be accepted promptly by the pharmaceutical company.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of healthcare professionals to attend scientific meetings or conferences is permitted under the MNZ Code, subject to the following:

- the event is relevant to the healthcare professional's area of expertise;
- the sponsorship is strictly related to the costs directly involved with attending the event (including cost of attendance, accommodation and travel costs);
- the sponsorship is not conditional upon any obligation by the healthcare professional to recommend, prescribe, dispense or administer a company's product(s);
- the selection criteria for the attending healthcare professional is based on relevance of the scientific area being discussed at the conference to the healthcare professional's vocation; and
- financial support is not offered to compensate the healthcare professional for their time spent attending the conference.

Pharmaceutical companies may provide financial support to assist medical students to attend medical education meetings, provided that the individuals who receive the funds is selected by the academic or training institution.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Corporate sponsorship can be provided by a company to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities. Pharmaceutical companies should ensure that sponsorship activities comply with the highest ethical standards, do not bring the pharmaceutical industry into disrepute, and otherwise comply with the requirements of the MNZ Code.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

There is no statutory prohibition against pharmaceutical companies engaging the services of a healthcare professional. The renumeration of the healthcare professional must not exceed fair market value, and reimbursement of reasonable travel, accommodation and meal expenses incurred as a part of the provision of those services may be paid to the consulting healthcare professional upon presentation of bona-fide recipients.

Pharmaceutical companies may voluntarily document and disclose any transfer of value (whether in cash or in-kind) to the healthcare professional to MNZ. Currently, MNZ will not compel a member company to disclose the transfer of value if it chooses not to do so.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Donations of items of medical utility, grants or financial support may be provided by the pharmaceutical company in certain circumstances. However, their supply must not be conditional upon the healthcare professional agreeing to recommend, prescribe, dispense or administer the pharmaceutical company's product.

As set out in questions 12 and 16 above, the provision of grants or donations may be disclosed to MNZ if the member company chooses to do so.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

As set out in question 12, New Zealand does not currently have any statutory 'sunshine' or transparency requirements in relation to the disclosure of transfers of value between a pharmaceutical company and a healthcare professional or healthcare organisation.

The MNZ encourages its member companies to disclose transfer of values to MNZ in accordance with MNZ's *Guideline for the Disclosure of Transfers of Value* (**Guidelines**). Compliance with the *Guidelines* is currently only voluntary for member companies.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

As set out in question 5, there is no legal requirement that a medical advertisement must be authorised by any regulatory authority prior to its publications. It is however common industry practice to obtain approval of the ANZA through its pre-vetting service prior to publication.

Online advertising of medical products is subject to the same laws and regulations as 'traditional' forms of medical advertising. New Zealand's Medicines Act has not kept pace with technological developments and applying traditional promotional rules to social media platforms and other online forms of advertising can be difficult and raises a variety of issues, including when a sponsor may be responsible for user or AI generated content and how information may be appropriately conveyed on character-limited platforms to ensure regulatory compliance.

The MNZ Code has provided some guidance on how online advertising should be conducted in compliance with industry standards:

- *Click-throughs:* The MNZ Code permits the use of 'click-throughs' to the substantive website to fulfil the mandatory information requirements for both direct-to-consumer and direct-to-healthcare professional advertisements.
- *Short-form mandatory information:* The MNZ Code permits the use of a 'short-form' mandatory information for direct-to-healthcare professional advertisements where the advertisement is designed to remind the healthcare professional of a therapeutic product's existence but must not contain therapeutic or promotional claims.
- *Website message:* Where an embedded link or similar will take the consumer or healthcare professional to a website hosted in another jurisdiction, it must be made clear using a pop-up message, or similar, that the viewer is leaving the local New Zealand company website to another site that the local company has not developed and which may not be consistent with New Zealand legislation or advertising codes.

Websites that are directed-at-healthcare professionals only should have access restrictions to ensure that the information cannot be accessed by the general public.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

New Zealand's bribery laws prohibit any person from "*corruptly giving or offering or agreeing to give any bribe to any person with intent to influence any official in respect of any act or omission by him or her in his or her official capacity*".

This prohibition captures healthcare professionals employed by Health New Zealand (formerly the District Health Boards which are now disestablished) and a 'bribe' is any direct or indirect benefit, whether of a monetary consideration or otherwise.

There is no guidance in the legislation as to what value

the benefit would need to be to constitute the "giving of a bribe…with the intent to influence", as it would ultimately depend on the context.

However a benefit of a "de minimis" value (being the value of a coffee or a named brand reminder item of modest value (ie pen))" would not generally be considered sufficient to satisfy the threshold.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The MNZ Code of Practice prohibit company members from providing or offering any kind of benefit as an inducement to recommend, prescribe, dispense or administer their products.

There is no legislation that specifically prohibits the provision of inducements to a healthcare professional to prescribe a particular medicine or medical device. However, depending on the circumstances, this conduct could breach the Crimes Act 1961 or the Secret Commissions Act 1910.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**) is responsible for compliance with the Medicines Act and its regulations with respect to medical advertisements. Advertisers must also comply with general consumer protection laws, in particular the Fair Trading Act 1986 (**FTA**), which prohibits advertising that misleads or deceives, or is likely to mislead or deceive, consumers. The Commerce Commission is responsible for monitoring compliance with the FTA.

The Advertising Standards Authority (**ASA**), **MNZ** and the **MTANZ** are self-regulating industry associations in which their members have agreed to be bound by the industry code set by those associations.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

If a pharmaceutical company and its competitor are members of MNZ, the pharmaceutical company can lodge a complaint with MNZ if it considers that its competitor has breached the MNZ Code.

The pharmaceutical company also has the option of lodging a complaint with Medsafe (for breach of the Medicines Act), the ASA (for breach of the ASA's *Therapeutic and Health Advertising* **Code**) and the Commerce Commission (for breach of the FTA).

Breach of the FTA carries the highest monetary penalties as compared to the Medicines Act, while the remedies available for infringing the MNZ Code and ASA Code is usually limited to withdrawal of the infringing advertisement.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Liability for breach of the advertising controls under the Medicines Act and its regulations is either imprisonment for a term not exceeding three months for a director or a fine not exceeding NZ$500. If the offence is continuing, then the advertiser is liable for a further fine not exceeding NZ$50 for every day or part day during which the offence has continued. On conviction, a court may order that the relevant medicine, medical device, advertising, labelling or associated material be forfeited to the Crown.

The penalties for a breach of the FTA are a fine not exceeding NZ$200,000 for a director and not exceeding NZ$600,000 for a body corporate.

Sanctions for breach of industry codes are regulated by the specific industry association. For example, the MNZ Code of Conduct provides a number of penalties for breaches of the Code by member pharmaceutical companies, including fines up to NZ$80,000, an order for the pharmaceutical company to discontinue the breach activity, and expulsion from the MNZ. The Code has a complaint resolution process and members of the public can complain to the MNZ about the conduct of a member pharmaceutical company.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

There is no relationship between actions taken by a self-regulatory industry body and procedures taken by a regulatory authority.

Like Australia, it is possible for a pharmaceutical company to lodge a complaint with the MNZ (if it is a member), the ASA, Commerce Commission and the Medsafe all at the same time, as well as simultaneously or subsequently taking independent legal action.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The ASA has been fairly active in responding to complaints from the general public in relation to claims that a medical advertisement is false or misleading.

The most recent ASA decision relates to an advertisement by Health New Zealand / Te Whatu Ora's 'Vaccinate for Life' campaign, which claimed "Protect them for life. Immunise against Covid-19". The ASA considered that the advertising was misleading because it led consumers to believe that the Covid-19 vaccine could provide life-long protection from Covid-19, when the vaccine did not.

We are not aware of any enforcement action taken by any regulatory body in relation to online forms of advertising. However, given it is now commonly used throughout New Zealand's pharmaceutical industry, it is likely that Medsafe will start taking a more active approach to monitoring compliance of online advertisements.

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