taps | therapeutic advertising pre-vetting service

Scientific Exchange.
Rx Medicines

Prepared February 2024

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Rx = Prescription Medicine

TAPS & Scientific Exchange for Rx Medicine | **Housekeeping**

- If you have a question during webinar please use the CHATROOM Function.
  There are two TAPS Adjudicators who will be monitor all the questions posted on the CHATROOM and will answer any straightforward questions during the webinar
- TAPS will be generating a Q&A document after the meeting based on all questions asked during the webinar via the CHATROOM
- The Slide Resources used during the webinar will be posted on the ANZA TAPS website under TAPS Briefing. https://www.anza.co.nz/taps
- If time allows after the presentation a selection of some of the main questions asked via the chatroom will be addressed in person as well as through the chatroom

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Scientific exchange requires a very careful balance of legislation and regulations.

To start this webinar, I want to present a few scenarios to you and ask the simple question for each scenario is it Scientific Exchange or Promotion of a non-registered medicine We will comeback to these scenarios later in the webinar to discuss them.

Then we will go over

- What is the role of TAPS
- What does the legislation, regulation and codes say?
- What does the industry believe?
- What does MedSafe say about marketing of unregistered medicines?
- What does the Medicines Act state about unregistered medicines / unregistered indications?
- What does the MNZ Code of Practice say?
- A Careful balance

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Scientific exchange requires a very careful balance of legislation and regulations.

1. Dissemination of information on a prescription medicine that is registered in Australia but not in New Zealand to New Zealand HCPs via a symposium (in-person / online) at a medical conference in Australia
   - Scientific Exchange or Promotion of an unregistered medicine ?

2. Dissemination of information *during a symposia by speakers* on a prescription medicine that is unregistered in New Zealand to New Zealand HCPs at a medical conference for a condition / disease for which the unregistered medicine is indicated.
   - Scientific Exchange or Promotion of an unregistered medicine ?

3. Dissemination of information *during a conference* in New Zealand in the form of digital or printed material based on a symposia at the conference containing information on an unregistered medicine in New Zealand. The printed or digital material being provided to the New Zealand HCPs by someone in the medical department / Medical Services Liaison member *after the symposia but while still at the conference*
   - Scientific Exchange or Promotion of an unregistered medicine ?

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Scientific exchange requires a very careful balance of legislation and regulations.

4. Dissemination of information in the form of digital or printed material based on a symposia at the conference in which information on an unregistered medicine in New Zealand The printed or digital material being provided to the New Zealand HCPs by someone in the medical department / Medical Services Liaison member *in the days / weeks following the conference*.
   - Scientific Exchange or promotion of an unregistered medicine ?

5. Dissemination of information in any format on an unregistered medicine in New Zealand to New Zealand HCPs :
   A. that are involved in a clinical trial of the unapproved medicine (Investigators) in New Zealand by a CRA or a Medical Services Liaison
   B. that are not investigators for the clinical trial or involved directly / indirectly with the clinical trial by someone in the Medical Department
   C. that are on an advisory board
   D. that wants to prescribe for a patient an unregistered medicine and approaches the manufacturer (unsolicited)?
   - Scientific Exchange or promotion of an unregistered medicine ?

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Scientific exchange requires a very careful balance of legislation and regulations.

6. Company-commissioned content and/or sponsored content publication on a registered medicine in New Zealand
   A. Based on symposia sponsored by the manufacture of the registered medicine at a conference
   B. Based on information provided by the manufacture of the registered medicine
   - Scientific Exchange or promotion of a registered medicine ?

7. Dissemination of information in any format on an unregistered medicine in New Zealand to New Zealand HCPs that has previously attended a manufacturer's symposia and has agreed to received information of the manufacturer's products
   - Scientific Exchange or promotion of an unregistered medicine ?

Scientific Exchange
What is the role of TAPS?

TAPS & Scientific Exchange for Rx Medicine | **Self-Regulation**

Advertising in New Zealand is run on a self-regulatory model whereby the industry, which includes the advertiser, advertising / digital agencies and the media, ensure that best practice is followed.

In NZ all parties involved with publishing an advertisement / promotional item including the media can be held liable if the advertisement is found not to adhere to the principles of best practice.

Best practice advertising adheres to the following principles

- advertisements must comply with the laws of New Zealand
- advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated
- advertisements must observe a high standard of social responsibility.

TAPS & Scientific Exchange for Rx Medicine | **What is TAPS?**

TAPS is a pre-vetting service which assists advertisers, advertising agencies and the media to comply with the legislation, regulations and codes that relate to Therapeutic and Healthcare promotion in New Zealand.

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

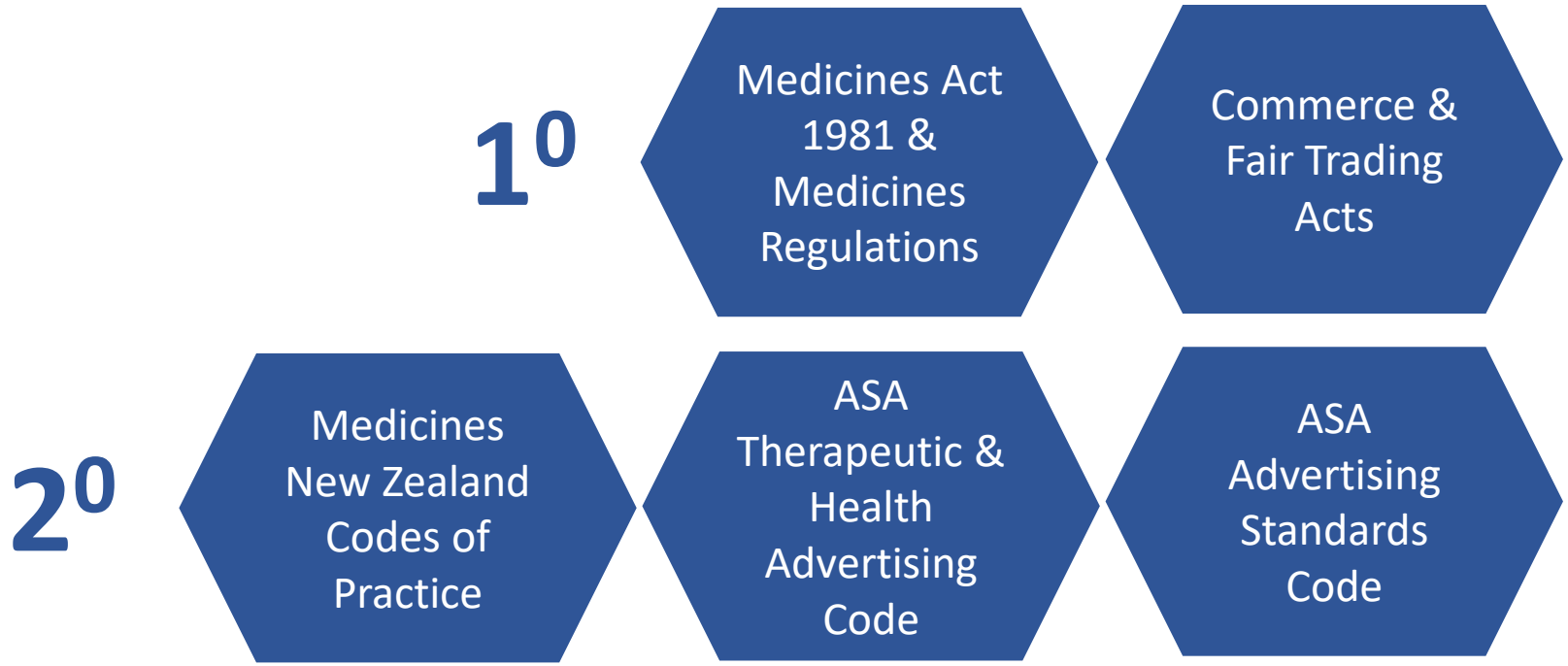
Our aim is to help you not get on the wrong side of the regulators in New Zealand

New Zealand Legislation and Regulations

- Medicines Act 1981 and Regulations with particular focus on MedSafe Guideline of the Regulation of Therapeutic Products in New Zealand
- Medicines New Zealand – Code of Practice (Apr 2019)
- ASA - Therapeutic & Health Advertising Code / ASA Advertising Standards Code
- Fair Trading Act 1986

TAPS & Scientific Exchange for Rx Medicine | **What is TAPS**

This graphic illustrated the hierarchy of legislation and codes by which TAPS reviews and assesses all prescription medicine communications including *scientific exchange*



TAPS & Scientific Exchange for Rx Medicine | **What is TAPS?**

As stated, before the market in New Zealand is SELF REGULATED

But that does not mean the regulator has not got teeth, especially when it comes to “scientific exchange” and respect to unregistered medicines

Section 20.4 of Medicines Act 1981

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.

Scientific Exchange
What does the legislation, regulation and codes say?

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Definition of *"Scientific Exchange"* in New Zealand

- In New Zealand, there is no definition of *"scientific exchange"* in any legislation, regulations or codes
  - *Medicines Act 1981*
  - *Medicines New Zealand Code of Practice 2019*
  - *ASA Therapeutic and Health Advertising Code*

MNZ Code of Practice does not currently define scientific exchange but does say that prior to a product or indication being registered by MedSafe the provision of information to HCPs, public, health officials, patient organisations and general public on a product or indication must be limited to .

- *The legitimate exchange of medical and scientific information (without promotional purpose or intent) by medical, regulatory, or access personnel. This includes but is not limited to, scientific congresses, scientific exchange and advisory boards.*

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Definition of *"Scientific Exchange"* in New Zealand

- In New Zealand, there is no definition of *"scientific exchange"* in any legislation, regulations or codes
  - *Medicines Act 1981*
  - *Medicines New Zealand Code of Practice 2019*
  - *ASA Therapeutic and Health Advertising Code*

- In New Zealand, the definition of advertising is broad in legislation, regulations and codes.
  - *It applies to all entities, which includes anyone advertising a medicine, regardless of whether they are directly involved in sale of the medicine or not. It also applies to all audiences, including advertising targeting the general public and healthcare professionals. This includes publication in newspapers, on websites, in social media, on TV or radio, in presentations and by word of mouth. (see https://www.medsafe.govt.nz/compliance/Marketing.asp)*

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Definition of "*Scientific Exchange*" in New Zealand

- Medicines Act 1981

  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.*

- *MNZ Code of Practice 2019*

  Advertisement *As defined in Section 56 of the Medicines Act 1981, "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." Material that is clearly technical or other data for registration purposes, for in-house company use, or for use by a clinical trial investigator shall not be considered an advertisement for the purposes of this Code.*

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

Definition of "*Scientific Exchange*" in New Zealand

- Advertising Standards Authority

  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.

  The Advertising Standards Authority (ASA) definition of Advertising and Advertisement is as follows:

  "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."

- https://www.asa.co.nz/resources/definition-of-advertising-and-advertisement/#:~:text=%E2%80%9CAdvertising%20and%20advertisement(s),to%20whom%20it%20is%20addressed.%E2%80%9D

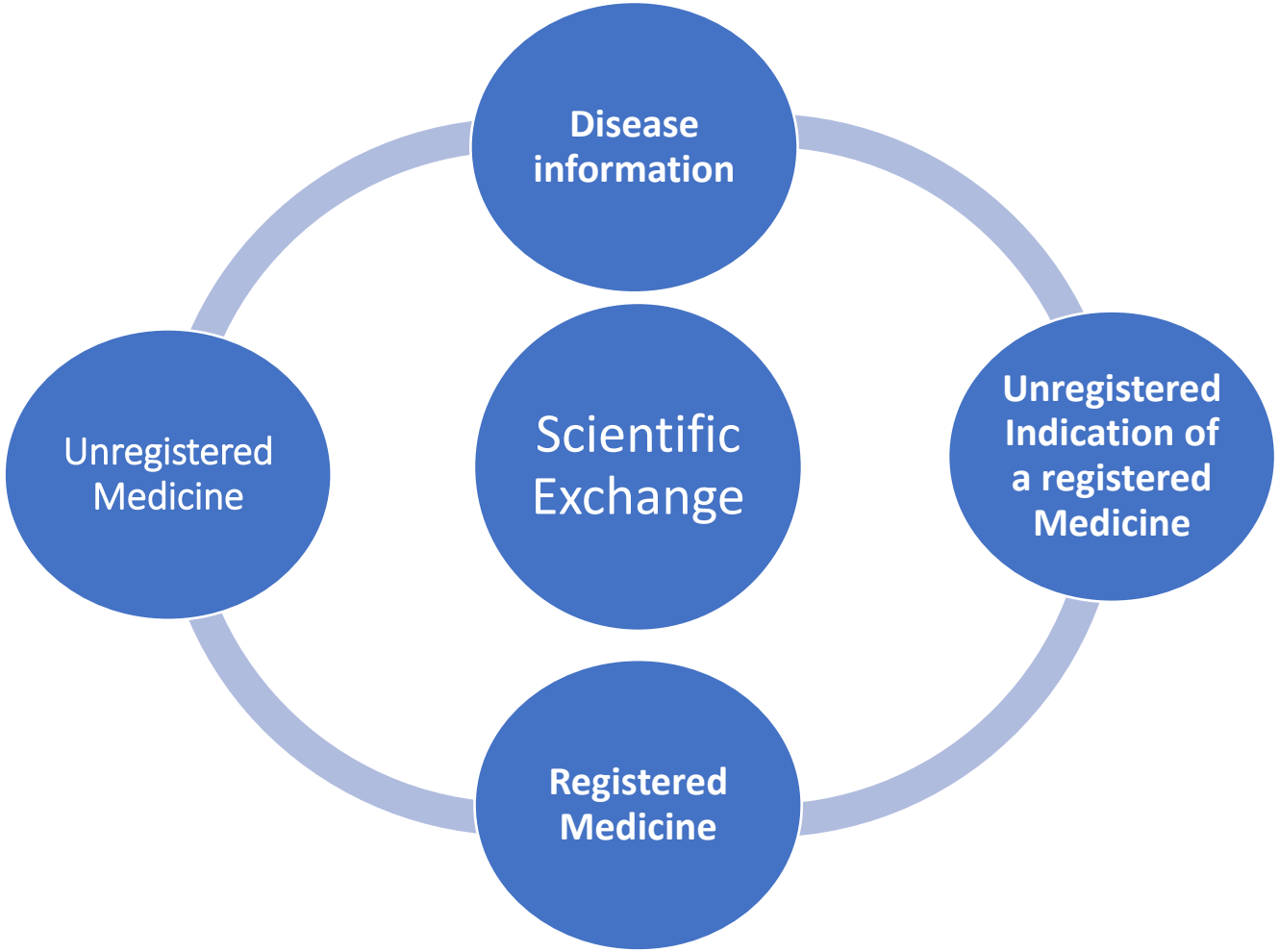
Scientific Exchange
What does the industry believe?

TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

The MNZ Code of Practice (2.2.1) states that

Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:

- the legitimate exchange of medical and scientific information (without a promotional purpose or intent) by medical, regulatory or access personnel. This includes, but is not limited to, scientific congresses, *"scientific exchange"* and advisory boards



TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

"Scientific exchange" means the sharing of scientific information concerning a pharmaceutical product, including sharing investigational findings in scientific media, direct communications and at scientific conferences.

Medicines Australia Code of Conduct

The UK industry does not have a specific definition of "Scientific Exchange" but an 8pp Guidance on Clause 3 which provided advice and specific examples of exceptions on promotion of "unlicensed medicine or indications e.g. International Congresses, to NHS based on savings, allow specified staff to answer questions from HCPs

Prescription Medicines Code of Practice Authority (UK)

Scientific Exchange

What does MedSafe Say about marketing of unregistered medicines?

TAPS & Scientific Exchange for Rx Medicine | **MedSafe**

In November 2019 MedSafe published *Marketing Products Which Are Not Approved Medicines* on the Medsafe website. Marketing products which are not approved medicines (medsafe.govt.nz)

- Unapproved medicines supplied through the exemption provisions in sections 25 to 32 of the Medicines Act 1981. **These cannot be advertised**.

- There are some instances where medicines are exempt from the requirement to be approved before distribution (i.e. exempt from section 20 and 24 of the Medicines Act). Exemptions for these unapproved medicines are defined in the Medicines Act 1981, sections 25 – 33. Although sections 25 – 33 of the Medicines Act provides an exemption in some circumstances from the requirement for approval, this does not include any exemption regarding advertising these unapproved medicines. **These products cannot be advertised**.

TAPS & Scientific Exchange for Rx Medicine | **MedSafe**

In November 2019 MedSafe published *Marketing Products Which Are Not Approved Medicines* on the Medsafe website. Marketing products which are not approved medicines (medsafe.govt.nz)

- The definition of advertisement / advertising in the Medicines Act is broad. It applies to all entities, which includes anyone advertising a medicine, regardless of whether they are directly involved in sale of the medicine or not. It also applies to all audiences, including advertising targeting the general public and healthcare professionals.
  - Publishing the availability, or future availability, of an unapproved medicine is advertising. This includes publication in newspapers, on websites, in social media, on TV or radio, in presentations and by word of mouth.
  - Personal representation is advertising.
  - Provision of any information relating to unapproved medicines, or the potential availability of medicines in the future at scientific / clinical / professional conferences would be regarded as a breach of the Medicines Act, regardless of the content or audience.

TAPS & Scientific Exchange for Rx Medicine | **MedSafe**

In November 2019 MedSafe published *Marketing Products Which Are Not Approved Medicines* on the Medsafe website. Marketing products which are not approved medicines (medsafe.govt.nz)

- Medsafe considers 'marketing materials' to include all types of material:
  - the product label statements and claims,
  - graphical, video and audio material,
  - websites,
  - depictions and context of advertising, for example advertising depicting a pharmacist selling a product to a patient could suggest it has a therapeutic purpose,
  - education sessions,
  - testimonials,
  - provision of, references to or links to information about past or present traditional use,
  - social media posts..

Scientific Exchange

What does the Medicines Act state about unregistered medicines?

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

What sections of the Medicines Act 1981 do TAPS consider as important when considering *Scientific Exchange*

Section 20.2 of Medicines Act 1981

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 of the 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.

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

What sections of the Medicines Act 1981 do TAPS consider as important when considering *Scientific Exchange*

Section 24.5 of Medicines Act 1981

If the Director-General, after considering the particulars, information, or samples required by or under subsection (1) or subsection (4), is of the opinion, at any time within the period specified in subsection (3),—

(a) that the change is of such a character or degree that the medicine ought not, without the consent of the Minister,—

(i) to be distributed in New Zealand; or

(ii) to be represented, recommended, advertised, or labelled in the terms set out in the notice; or

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

What sections of the Medicines Act 1981 do TAPS consider as important when considering *Scientific Exchange*

Section 24.5 of Medicines Act 1981

(b) that he is insufficiently informed, for the purposes of paragraph (a), in respect of—

(i) the strength, quality, purity, safety, or efficacy of the medicine; or

(ii) the methods of manufacture of, or the facilities for testing, the medicine,—

he shall refer the medicine to the Minister, and forthwith inform the importer or manufacturer by notice in writing that he has done so.

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

What sections of the Medicines Act 1981 do TAPS consider as important when considering *Scientific Exchange*

Section 29 of Medicines Act 1981

The provisions in section 29 of the Act only apply to medical practitioners. Section 29 provides access to unapproved medicines that have been imported into New Zealand by licensed wholesalers and pharmacies or that have been manufactured in New Zealand by a licensed medicines manufacturer.

The Act requires medical practitioners to send information back to the importer or manufacturer of the unapproved medicine. The importer/manufacturer must then hold (store) the information.

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

What sections of the Medicines Act 1981 do TAPS consider as important when considering *Scientific Exchange*

Section 30 of Medicines Act 1981

Section 30 of the Medicines Act requires that clinical trials involving new medicines must be approved by the Director-General of Health. This requirement applies to all types of clinical trials of new medicines, including pharmacokinetic, bioequivalence and first-in-human studies. The application and approval process for clinical trials is administered by Medsafe (the medicines and medical devices regulatory authority for New Zealand).

TAPS & Scientific Exchange for Rx Medicine | **Medicines Act 1981**

In summary the primary hierarchical legislation (Medicines Act 1981) is clear.

An unregistered medicine or unregistered indication for a registered medicine CANNOT be promoted / advertised to healthcare professionals

except for → Healthcare professionals that have requested information (unsolicited) on an unregistered medicine for with they are considering or have made an application under **Section 29**

except for → Healthcare professionals (lead investigator / investigator) that are involved in a clinical trial of an unapproved medicine under **Section 30**

Scientific Exchange
What does the MNZ Code of Practice say?

TAPS & Scientific Exchange for Rx Medicine | **MNZ Code of Practice**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2. PRE-REGULATORY APPROVAL COMMUNICATIONS

2.1. Specific Legislative Requirements

2.1.1. As per Section 20 of the Medicines Act 1981, products and indications must not be promoted in New Zealand prior to receiving regulatory approval by Medsafe for use in New Zealand (being registered).

However, MNZ Code of Practice states with respect to product communication prior to regulatory approval there are a number of exceptions.

TAPS & Scientific Exchange for Rx Medicine | **MNZ Code of Practice**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe, provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:

1. The provision of information on unregistered medicines can be provided with HCPs carrying out clinical research (with the product) – MNZ Code 7.1

TAPS & Scientific Exchange for Rx Medicine | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

1. The provision of information on unregistered medicines can be provided with HCPs carrying out clinical research (with the product) – MNZ Code 7.1

This aligns with the exception allowed under Section 30 of Medicines Act 1981. The MedSafe Guideline on the Regulations of Therapeutic Products in New Zealand states this is limited to *Principle Investigators, Lead Investigators* and *Investigators*

TAPS & Scientific Exchange for Rx Medicine | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

2. The provision of information to government agencies or public health officials responsible for healthcare planning (e.g., DHBs, Medsafe, Ministry of Health or PHARMAC)

TAPS & Scientific Exchange for Rx Medicine | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

3. The provision of information to government agencies or public health officials responsible for healthcare planning (e.g., DHBs, Medsafe, Ministry of Health or PHARMAC)

This is self explanatory but TAPS considers the phrase *"responsible for healthcare planning"* as important, clearly restricting who can be approached concerning an unapproved medicine / indication.

Rx Medicine Scientific Exchange | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

3. The provision of a response by a company's medical department to unsolicited information requests

Rx Medicine Scientific Exchange | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

3. The provision of a response by a company's medical department to unsolicited information requests

This aligns with the exception allowed under Section 29 of Medicines Act 1981. TAPS considers the word "unsolicited" as critical.
TAPS recommends companies keep a record of all unsolicited information requested concerning an unregistered medicine / indications. Ideally at every stage of the process from initial contact.

TAPS & Scientific Exchange for Rx Medicine | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

4. the legitimate exchange of medical and scientific information (without a promotional purpose or intent) by medical, regulatory or access personnel. This includes, but is not limited to, scientific congresses, scientific exchange and advisory boards

TAPS & Scientific Exchange for Rx Medicine | **Medicines New Zealand**

What sections of the MNZ Code of Practice 2019 do TAPS consider as important when considering *Scientific Exchange*

2.2.1. Prior to a product or indication receiving regulatory approval from Medsafe provision of information to HCPs, public health officials, patient organisations, and the general public on that product or indication must be limited to:.

4. the legitimate exchange of medical and scientific information (without a promotional purpose or intent) by medical, regulatory or access personnel. This includes, but is not limited to, scientific congresses, scientific exchange and advisory boards

TAPS considers that communication about unregistered medicines / indications by medical / regulatory personnel at advisory boards is similar to 2.2.1.3. Furthermore members of the Advisory Board have signed contracts clearly setting out their obligations and responsibilities

Scientific Exchange
A careful balance

TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

Scientific exchange requires a very careful balance of legislation and regulations.

TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

TAPS Observations

- *"Scientific exchange"* is not recognised in either the Legislation, Regulations or Codes in New Zealand.
- In New Zealand, the definition of advertising is broad in the Legislation, Regulations or Codes and making an exception for *"Scientific Exchange"* will be problematic.
- Any activity around the promotion / information exchange outside Section 29 and Section 30 of the Medicine Act is clearly not allowed and against the wishes of MedSafe.
- Information on unregistered products or indications must not be provided to HCPs in the absence of an unsolicited request from the HCP as this would be considered promotion. ***MNZ Code of Practice - Medical Literature and Reprints 4.2.4***

TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

TAPS Observations

- Companies should not sponsor content where it is reasonably foreseeable (e.g. from knowledge of the topic areas to be covered), that at the time of publication, it will contain significant information on the company's products or indications that are unregistered in New Zealand. ***MNZ Code of Practice - Company-commissioned Content and Sponsored Content 4.3.5***
- Medicines Act and ASA Therapeutic and Health Advertising Code and ASA Advertising Code do not differentiate between brand and generic names with respect to advertising / promotion.
    - *The use of drug class "name" and possibly Clinical Research Code/# maybe a way of discussing important scientific research (Phase II & III) with respect to disease/condition management involving an unregistered medicines.*

TAPS & Scientific Exchange for Rx Medicine | **In New Zealand**

TAPS Observations

"Scientific Exchange" involving a Registered Medicines is advertising and so needs to comply with MNZ Code of Practice and ASA-THAC

"Scientific Exchange" involving an unregistered medicine / indication is not allowed by Medicines Act, and is strongly opposed by MedSafe

"Scientific Exchange" with respect to new and important scientific research findings on a disease state and management involving a phase I-III research products maybe possible if the product's generic and brand name are not used.

Scientific Exchange
Scenario Discussion

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

1. Dissemination of information on a prescription medicine that is **registered in Australia but not in New Zealand to New Zealand HCPs** via a symposium (in-person / online) at a medical conference **in Australia**

   - **Scientific Exchange or promotion of an unregistered medicine ?**

TAPS Recommendation – Scenario 1

This is legitimate scientific exchange.

The seminar is outside New Zealand, so does not fall under New Zealand law and regulations or codes

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

2. Dissemination of information *during a symposia by speakers* on a prescription medicine that is **unregistered in New Zealand to New Zealand HCPs** at a medical conference **in New Zealand** for a condition / disease for which the unregistered medicine is indicated.

   - **Scientific Exchange or promotion of an unregistered medicine ?**

TAPS Recommendation – Scenario 2

The views of speakers at a symposia during a medical conference on a condition / disease represents scientific exchange.

Identification of an unregistered medicine by its generic or brand name in association with information of usage could be seen as breaching **Section 20 Medicines Act 1981.** The unregistered medicine should only be identified in communication resources by the medicine's class or its Clinical Research code.

It is recommended the slide resource for the seminar be TAPS reviewed to help reduce the risk of including content about an unregistered medicine or indication in New Zealand.

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

3. Dissemination of information *during a conference* in New Zealand in the form or digital or printed material based on a symposia at the conference containing information on an unregistered medicine in New Zealand.

   The printed or digital **material being provided to the New Zealand HCPs by someone in the medical department** / Medical Services Liaison member *after the symposia but while still at the conference*

   - **Scientific Exchange or promotion of an unregistered medicine ?**

TAPS Recommendation – 3.1

This scenario is at risk of being promotion of an unregistered medicine.

The communication resources should only be provided to New Zealand HCPs that attended the symposia and requested materials at the time or during the conference (**Section 29 Medicines Act 1981**). TAPS recommends companies keep a record of all unsolicited information requested concerning an unapproved medicine / indications. Ideally at every stage of the process from initial contact.

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

3. Dissemination of information *during a conference* in New Zealand in the form or digital or printed material based on a symposia at the conference containing information on an unregistered medicine in New Zealand.

   The printed or digital material being **provided to the New Zealand HCPs by someone in the medical departm**ent / Medical Services Liaison member *after the symposia but while still at the conference*

   - **Scientific Exchange or promotion of a non-registered medicine ?**

TAPS Recommendation - 3.2

The unregistered medicine should only be identified in communication resources by the medicine's class or its Clinical Research code. Identification of unapproved medicine by its generic or brand name in association with information of usage could be seen as breaching Section 20 Medicines Act 1981

The slide resource and any other communication materials for the seminar be TAPS reviewed to help reduce the risk of including content about an unregistered medicine or indication in New Zealand.

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

4. Dissemination of information in the form of digital or printed material based on a symposia at the conference which included information on an unregistered medicine in New Zealand.

   The printed or digital material being provided to the New Zealand HCPs by someone in the medical department / Medical Services Liaison member *in the days / weeks following the conference*.

   - Scientific Exchange or Promotion of an unregistered medicine ?

TAPS Recommendation 4.1

This scenario is at significant risk of being promotion of an unregistered medicine.

The communication resources should be available at the conference or symposium to reduce the risk and should only be provided to New Zealand HCPs that attended the symposia and requested materials at the time or during the conference (**Section 29 Medicines Act 1981**). TAPS recommends companies keep a record of all unsolicited information requested concerning an unregistered medicine / indications. Ideally at every stage of the process from initial contact.

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

4. Dissemination of information in the form or digital or printed material based on a symposia at the conference which included information on an unregistered medicine in New Zealand.

   The printed or digital material being provided to the New Zealand HCPs by someone in the medical department / Medical Services Liaison member *in the days / weeks following the conference.*

   - Scientific Exchange or promotion of an unregistered medicine ?

TAPS Recommendation 4.2

The unregistered medicine should only be identified in communication resources by the medicine's class or its Clinical Research code. Identification of unapproved medicine by its generic or brand name in association with information of usage could be seen as breaching Section 20 Medicines Act 1981

The slide resource and any other communication materials for the seminar be TAPS reviewed to help reduce the risk of including content about an unregistered medicine or indication in New Zealand.

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

5. Dissemination of information in any format on an unregistered medicine in New Zealand to Kiwi HCPs :

   A. that are involved in a clinical trial (i.e. investigators) of the unapproved medicine in New Zealand by a CRA or a Medical Services Liaison
   B. that are not investigators for the clinical trial or involved directly / indirectly with the clinical trial by someone in the Medical Department
   C. that are on an advisory board
   D. that wants to prescribe for a patient an unregistered medicine and approaches the manufacturer (unsolicited)?
   E. that has agreed to received information on the manufacturer's products

- Scientific Exchange or Promotion of an unregistered medicine ?

TAPS Recommendation – 5.A

This represents *"scientific exchange"* and in this case does not need TAPS approval. **(Section 30 Medicines Act 1981)**

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

5. Dissemination of information in any format on an unregistered medicine in New Zealand to Kiwi HCPs :

   A. that are involved in a clinical trial (i.e. investigators) of the unapproved medicine in New Zealand by a CRA or a Medical Services Liaison
   B. that are not investigators for the clinical trial or involved directly / indirectly with the clinical trial by someone in the Medical Department
   C. that are on an advisory board
   D. that approach the manufacture (unsolicited) for information on the unapproved medicine
   E. that has agreed to received information on the manufacturer's products

- Scientific Exchange or promotion of an unregistered medicine ?

TAPS Recommendation – 5.B

This scenario represents promotion on an unregistered medicine **(Section 20 Medicines Act 1981)**

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

5. Dissemination of information in any format on an unregistered medicine in New Zealand to Kiwi HCPs :

   A. that are involved in a clinical trial (i.e. investigators) of the unapproved medicine in New Zealand by a CRA or a Medical Services Liaison
   B. that are not investigators for the clinical trial or involved directly / indirectly with the clinical trial by someone in the Medical Department
   C. that are on an advisory board
   D. that wants to prescribe for a patient an unregistered medicine and approaches the manufacturer (unsolicited)?

- Scientific Exchange or promotion of an unregistered medicine ?

TAPS Recommendation – 5.C

This represents *"scientific exchange"* and in this case does not need TAPS approval. **(Section 30 Medicines Act 1981)**

TAPS & Scientific Exchange for Rx Medicine | **New Zealand**

5. Dissemination of information in any format on an unregistered medicine in New Zealand to Kiwi HCPs :

   A. that are involved in a clinical trial (i.e. investigators) of the unapproved medicine in New Zealand by a CRA or a Medical Services Liaison
   B. that are not investigators for the clinical trial or involved directly / indirectly with the clinical trial by someone in the Medical Department
   C. that are on an advisory board
   D. that wants to prescribe for a patient an unregistered medicine and approaches the manufacturer (unsolicited)?

- Scientific Exchange or Promotion of an unregistered medicine ?

TAPS Recommendation – 5.D

This scenario represents scientific exchange and in this case does not need TAPS approval. **(Section 29 Medicines Act 1981)**

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6. Company-commissioned content and/or sponsored content publication on registered medicine in New Zealand
   A. Based on symposia sponsored by the manufacture of the registered medicine at a conference
   B. Based on information provided by the manufacture of the registered medicine
   - Scientific Exchange or promotion of a medicine ?

TAPS Recommendation - 6

Scenario 6A and 6B – both represent promotion of a medicine irrespective of whether the article uses the brand name or generic name of the product. The Medicines Act and ASA Codes and MNZ Code do not differential between generic name and brand name in terms or requirements for promotion of a medicine or whether or not the article is edited by a commissioned medical specialist.

The item needs to include mandatory information probably for a full advertisement as most content will contain clinical trials information and results.

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7. Dissemination of information in any format on an unregistered medicine in New Zealand proactively to Kiwi HCPs that has agreed to received information of the manufacturer's products
    - Scientific Exchange or promotion of an unregistered medicine ?

TAPS Recommendation - 6

This is promotion of an unregistered medicine.

The clinician must make an unsolicited request for information as per Section 29 of the Medicines Act, with respect to treatment of a patient

Annex