

# Briefing for decision

## Proposals for regulation of advertising in the Medical Products Bill

<b>Date due to MO:</b>	28 May 2025	<b>Action required by:</b>	6 June 2025
<b>Security level:</b>	IN CONFIDENCE	<b>Reference:</b>	H2024052974
<b>To:</b>	Hon Casey Costello, Associate Minister of Health		
<b>Copy to:</b>	Hon Simeon Brown, Minister of Health Hon David Seymour, Associate Minister of Health		
<b>Consulted:</b>	Health New Zealand: <input type="checkbox"/>		
<b>Proactive release:</b>	This <b>title</b> is proposed by the Ministry of Health for proactive release: <input checked="" type="checkbox"/>		

### Contact for telephone discussion

Name	Position	Telephone
<b>Steve Barnes</b>	Deputy Director-General, Strategy, Policy and Legislation	section 9(2)(a)
<b>John McGrath</b>	Director, Priority Projects Strategy, Policy and Legislation	section 9(2)(a)

### Minister's office to complete:

- |                                               |                                    |                                              |
|-----------------------------------------------|------------------------------------|----------------------------------------------|
| <input type="checkbox"/> Approved             | <input type="checkbox"/> Decline   | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> Needs change         | <input type="checkbox"/> Seen      |                                              |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |                                              |

Comment:

# Briefing for decision

## Proposals for regulation of advertising in the Medical Products Bill

---

**Security level:** IN CONFIDENCE                      **Date:** 30 May 2025

---

**To:** Hon Casey Costello, Associate Minister of Health

---

### Purpose of report

1. This briefing provides you with proposals for the regulation of advertising in the Medical Products Bill, including advertising of prescription medicines and unapproved products.

### Summary

2. On 30 September 2024, Cabinet agreed to a Medical Products Bill [SOU-24-MIN-0115]. On 12 May 2025 you advised Cabinet that final policy approvals for the Medical Products Bill, including on advertising, would be obtained by the end of the third quarter 2025 and Cabinet agreed to a sequencing of decisions on the Bill [H2025066030].
3. In developing proposals, we have considered whether the current rules on advertising are operating effectively, feedback from stakeholders and a new review of literature on the harms of direct-to-consumer advertising of prescription medicines (Appendix 3). We have also considered the extent to which proposals are consistent with the rights and freedoms protected under the Bill of Rights Act 1990.
4. The proposed approach provides for:
  - a. a clearer definition of advertising than in the Medicines Act, with clear exclusions for activities such as news reporting, patient and family fundraising activities and advocacy whose primary purpose is not to advertise a specific medical product for the intention of financial gain. The definition of advertising should cover all promotional activities by, for example, online 'influencers'.
  - b. continuing to allow direct-to-consumer advertising of prescription medicines, as we do not consider that the evidence nationally and internationally supports an outright ban.
  - c. That the Bill include a regulation making power that could impose restrictions on specific types of advertising: for example, advertising of specific medicines (eg, sedatives) or advertisements targeting a specific audience or consumer group.
  - d. enabling exemptions to permit some advertising of unapproved medical products, for example to health practitioners attending trade shows [CAB-25-MIN-0097.01].
  - e. that the Medical Products Bill include high-level and universal standards for advertisements, such as not making false or misleading claims. More specific and detailed standards should be set in secondary legislation.
5. The current ban on advertising unapproved products is an important tool to protect consumers and the integrity of the medicine's approval system and should be retained.

Likewise, the Bill should enable controls – including prohibitions – on advertising a medical product for use outside its market authorisation (ie, 'off-label use').

6. Appendix 1 shows how different types of advertising would be regulated.
7. We recommend you discuss the proposals in this paper with Hon Simeon Brown, Minister of Health, and Hon David Seymour, Associate Minister of Health. We will then prepare a paper for you to take to Cabinet in July 2025.

## Recommendations

We recommend you:

- a) **Note** that Cabinet has invited you to report back on the Medical Products Bill's approach to advertising and decisions are required to finalise drafting of the Medical Products Bill **Noted**
- b) **Note** that in considering whether, and how, to regulate advertising we have applied the following principles (see further paragraph 17): **Noted**
  - i) regulation should be clear and workable
  - ii) the public and the media have a right to publicly share and receive information about medical products
  - iii) the exercise of patient autonomy and informed consent requires that the public can access accurate information about medical products
  - iv) advertising regulation should focus on activities which are intended to promote use and sales of the product, directly or via healthcare providers
  - v) health practitioners are generally better equipped than the public to assess the validity of advertising claims
- c) **Agree** that the Medical Products Bill should exclude from the definition of advertising (in primary legislation or via regulations):
  - i) public safety announcements, recall orders, public health campaign statements approved by the Chief Executive of the Ministry of Health, Pharmac's pharmaceutical schedule, any statement required by law, and any communication exempted via regulations **Yes / No**
  - ii) reporting of news or a matter of public concern, research, study or education, criticism or review, fundraising for a specific product for a specific person or people, and advocating for a change to Government policy **Yes / No**
  - iii) recruitment material for clinical trials, approved by a recognised ethics committee **Yes / No**
- d) **Note** that the Government has agreed to progress, via the Medicines Act Amendment Bill, an exemption for in-person promotion to practitioners, for educational purposes, who are allowed to supply or prescribe the product in New Zealand or another country [CAB-25-MIN-0097.01] **Noted**

- e) **Agree** that the Medical Products Bill will continue to enable trade show and medical conference exemptions generally consistent with approach adopted for the Medicines Amendment Bill **Yes / No**
- f) **Note** the Ministry commissioned a comprehensive literature review on direct-to-consumer advertising of prescription medicines (DTCA-PM) which concluded there is evidence of both benefits and risks from DTCA-PM, with neither outweighing the other **Noted**
- g) **Note** that the absence of compelling harm from DTCA-PM is a relevant factor in assessing whether a complete, outright ban on DTCA-PM would be consistent with the Bill of Rights Act 1990 **Noted**
- h) **Agree** that the Medical Products Bill will continue to allow DTCA of approved prescription medicines (subject to recommendation i)) **Yes / No**
- i) **Agree** to include a regulation making power to include controls on specific advertising practices, including forms of DTCA-PM **Yes / No**
- j) **Agree** that promotion of unapproved medical products (medicines and medical devices) will continue to be prohibited, except for:
- i) products which do not need an approval **Yes / No**
  - ii) promotion authorised by the Director-General of Health **Yes / No**
  - iii) in-person promotion to practitioners, for educational purposes, who are allowed to supply or prescribe the product in New Zealand or another country **Yes / No**
  - iv) promotion activities exempted via regulations, such as information relating to unapproved medicines supplied to defence personnel (eg, some vaccines) **Yes / No**
- k) **Agree** that advertising for off-label uses of medicines be treated in the same way as advertising for unapproved products, with the ability to create exemptions via regulations **Yes / No**
- l) **Agree** that the Medical Products Bill provide that no medical product advertisement may be false or misleading; contrary to, or inconsistent with the product's approval or any legal requirement; or claim that the product is infallible in preventing or treating any condition **Yes / No**
- m) **Discuss** the proposals in this paper with Hon Simeon Brown, Minister of Health, and Hon David Seymour, Associate Minister of Health **Yes / No**

*Steve Barnes*

Steve Barnes  
Acting Deputy Director-General  
**Strategy, Policy and Legislation**  
Date: 26/5/2025

Hon Casey Costello  
**Associate Minister of Health**  
Date:

# Proposals for regulation of advertising in the Medical Products Bill

## Background

8. On 30 September 2024, Cabinet agreed that the Medicines Act 1981 should be replaced with modern regulation of medicines and medical devices under a Medical Products Bill [SOU-24-MIN-0115]. Cabinet also invited you to report back on advertising provisions in the Medical Products Bill. On 12 May you provided an oral update to Cabinet, noting that decisions on advertising and other policy matters would be required by the end of September 2025 to enable the introduction of the Bill this parliamentary term. Following this meeting, you agreed a new timing for advice on the Bill [H2025066030].

## Current regulation of medical products advertising

9. Advertising of medical products under the Medicines Act 1981 and Regulations has four key features:
  - a. Medicines approved by Medsafe (except controlled drug medicines) under the Medicines Act, may be advertised to the general public. This is subject to general legal conditions such as not being misleading, not stating that the product is infallible or without risk, and the inclusion of various safety and other statements.
  - b. All Medsafe-approved medicines, including controlled drug medicines, may be advertised to health practitioners. This is subject to more limited conditions, including not being misleading.
  - c. No medicine which does not have Medsafe approval may be advertised to anyone in any circumstances.
  - d. All medical devices may be advertised to anyone, subject to legal conditions similar to those for medicines.
10. The current definition of advertisement in the Medicines Act is very broad and the Medicines Act does not include provisions enabling exceptions from the prohibition on advertising unapproved medicines [H2024040932]. This prohibition may be modified as a result of the Medicines Amendment Bill [CAB-25-MIN-0097.01].
11. Currently, advertising for medical products and services is generally subject to industry self-regulation through the Advertising Standards Authority. Regulatory bodies such as the Medical Council also have professional standards around advertising and promotion of products and services.

## Why does New Zealand regulate the advertising of medical products?

12. Unregulated advertising can result in the promotion and use of unproven, unapproved or off-label treatments, which may not be safe or effective. This can result in adverse health outcomes for patients and increased healthcare costs to patients and the Government due to complications or ineffective treatments.

13. Doctors and other healthcare providers rely on accurate information to prescribe treatments. Misleading advertisements hinder their ability to provide the best care, as patients might request specific treatments based on incomplete or biased information.
14. Certain groups, such as the elderly, children, and those with chronic illnesses, are particularly susceptible to the influence of advertising. They may be more likely to try new treatments without fully understanding the risks, leading to potential health hazards. There have been examples of this occurring in New Zealand, for example advertising of Vioxx (rofecoxib) was targeted at certain population groups. This medicine was later found to increase the likelihood of heart attacks and withdrawn from market.
15. A literature review commissioned by the Ministry in April 2025 (Appendix 3) found misleading advertisements can lead to increased healthcare costs due to unnecessary treatments and hospitalisations. This not only affects individuals but also places a burden on the healthcare system as a whole.
16. Analysis on the regulatory landscape in other jurisdictions and enforcement challenges can be found in Appendix 3.

### **What should be regulated as advertising?**

17. In considering the definition of advertising, and any restrictions on the practice, we have been guided by the following principles:
  - a. ensuring regulation is clear and workable (for example, taking into account the shift in advertising to online platforms, often not located in New Zealand)
  - b. the public and the media have a right to publicly discuss medical products, including through reporting, review, opinion, advocacy and fundraising
  - c. the exercise of patient autonomy and informed consent requires that the public can access accurate information about medical products, and to be protected from false or misleading claims about products
  - d. advertising regulation should focus on activities which are intended to promote use and sales of the product, directly or via healthcare providers
  - e. health practitioners are generally better equipped than the public to assess the validity of advertising claims; however it is not acceptable for any health product advertisement to be false or misleading.

### **Proposed definition of advertising**

18. It is essential that the Medical Products Bill includes a clear and consistent definition of advertising, which applies to medicines and medical devices, including approved and unapproved products. We recommend moving away from the existing definitions in the Medicines Act as these definitions are not consistent with each other and they have created uncertainty for industry, researchers and practitioners.
19. Medicines New Zealand has noted that the Australian Therapeutic Goods Act 1989 defines "advertise" as any statement or image "intended, whether directly or indirectly, to promote the use or supply" of a product. We agree that this definition is clearer and recommend aligning the definition in the Medical Products Bill. It also meets the request of industry for definitions to be aligned with those used in other countries. The exact wording will be finalised by the Parliamentary Counsel Office.

### **Some activities should be excluded from the definition of advertising**

20. The Therapeutic Products Act (the TPA) excluded the following from the definition of an advertisement:
  - a. public safety announcements
  - b. recall orders
  - c. public health campaign statements approved by the Chief Executive of the Ministry of Health
  - d. the pharmaceutical schedule published by Pharmac
  - e. any statement required by law
  - f. any communication exempted via regulations.
21. We recommend that these exclusions also be used in the Medical Products Bill. This will enable some public health campaigns which are currently not permitted, such as immunisation campaigns involving unapproved medicines.
22. In addition, we recommend that statements included in clinical trial participant recruitment materials be excluded from the definition of advertising, provided those materials have been approved by a recognised ethics committee.
23. We also recommend that the following should be excluded:
  - a. reporting of news or a matter of public concern
  - b. research, study or education
  - c. criticism or review
  - d. fundraising for a specific product for use by a specific person or specific people (eg, GoFundMe pages)
  - e. advocating for a change to Government policy, including public funding of medical products.
24. Excluding the activities listed above would respond to community concerns about the advertising restrictions in the Therapeutic Products Bill. The proposed exclusions will better ensure that advertising regulation does not inadvertently discourage patient advocacy and other non-commercial speech.

### **Direct-to-consumer advertising of prescription medicines (DTCA-PM)**

25. Along with the United States, New Zealand has some of the world's most permissive laws on direct-to-consumer advertising of prescription medicines (DTCA-PM). Advertising of opioids and other controlled drugs to the public is banned under the Misuse of Drugs Regulations, but advertising of other prescription medicines is allowed.

### **We recommend continuing to allow prescription medicine advertising**

26. We previously advised Parliament that there is no strong evidence that DTCA-PM has significant negative or positive effects (see appendix 2). A further review of new and existing evidence in April 2025 found no compelling evidence of harms or benefits to public health arising from DTCA-PM (appendix 3).

27. The key findings of this literature review are summarised below:
- a. DTCA-PM increases awareness and patient engagement, but often overemphasises benefits which can lead to further misconceptions. It prompts more prescription requests, but whether this has positive or negative net effects on health outcomes remains unclear.
  - b. DTCA-PM can enhance doctor-patient communication, but may also pressure prescribers to meet patient demands, which potentially undermines clinical judgement and the doctor-patient relationship.
  - c. DTCA-PM drives demand for newer, branded drugs, contributing to higher prescribing rates and increased healthcare costs, often at the expense of cheaper, potentially equally effective generic medication.
28. Findings also show that social media marketing of prescription medicines emphasise benefits over risks, similar to traditional forms of DTCA-PM. Some social media posts may also promote illegal online pharmacies. Subtle forms of advertising also exist, including through television dramas, which can raise ethical concerns. This supports the recommendation to regulate advertising, including in online forums. However, controls will need to be workable, feasible, and reflect New Zealand's limited jurisdiction over online activity on platforms and sites hosted abroad.
29. While possible benefits of DTCA-PM have been highlighted by industry, the 2025 literature review and a rapid review conducted in 2022 did not find the evidence compelling. However, in assessing whether to introduce an outright ban on DTCA-PM we have considered whether a ban would be consistent with the right to communicate and receive information. While rights can be limited, especially in the context of 'commercial speech', any limitations must be demonstrably justified, proportionate to the outcome sought, and the right should be impaired no more than is reasonably necessary to achieve that outcome.
30. An outright ban on DTCA-PM, with no exceptions is likely to go beyond what is reasonably necessary to achieve public health objectives. We note, for example, that many countries allow limited forms of DTCA-PM, such as 'disease awareness campaigns' (see Appendices 2 and 3). The inconclusive findings as to the harms of DTCA-PM also weakens the justification for an outright ban.
31. However, there are individual and public harms associated with inappropriate advertising that justify some controls. We therefore recommend a nuanced approach to DTCA-PM, enabling controls and limitations on specific advertising practices.
32. The Therapeutic Products Bill allowed for DTCA-PM to be limited via regulations. We recommend that the Medical Products Bill likewise enable regulations that can limit advertising of certain products (eg, sedatives, weight loss pills or antibiotics) in the interest of patient safety. While this will not satisfy some stakeholders who have called for a total ban, it could be an acceptable compromise between supporters and opponents of DTCA-PM. Any regulations made under the Medical Products Bill (ie, controls) will need to be agreed to by Cabinet and comply with the Bill of Rights Act.

## Promotion of unapproved products

33. Under the Medicines Act, it is unlawful to “advertise the availability” of a medicine which does not have Medsafe approval. There are no exceptions, and no ability to create exceptions via secondary legislation.
34. We understand that it is the Government’s intention to permit advertisement of unapproved products to healthcare professionals under set circumstances for medical education purposes [CAB-25-MIN-0097.01]. We propose that a functionally equivalent exemption would be accommodated for in the new regime. We also propose to allow a health practitioner to request information about an unapproved product from the product sponsor (but not to enable unsolicited, ‘cold-calls’ to practitioners from sponsors).
35. As noted above, we propose that other activities be excluded from the definition of advertising. This would enable public health campaigns, advocacy and fundraising by patients or their whānau and some other communications about unapproved products. Some organisations, such as the New Zealand Defence Force, may also require exemptions to enable information about, for example, unapproved medicines to be shared with defence personnel prior to deployment. These medicines are not unapproved because they are unsafe but because they treat or prevent diseases not present in New Zealand – and so there is no commercial incentive to seek approval here.
36. We also recommend that the Medical Products Bill enable the Director-General of Health to approve specific promotions involving unapproved products. This power would likely be used sparingly but would improve responsiveness in, for example, the roll out of vaccines during a public health emergency.
37. Products which are not required to have an approval (eg, exempt medical devices) could be promoted in the same way as approved products.
38. Promotion of unapproved products should be subject to all general advertising standards, other than those relating to the product approval. All promotional activity should be required to clearly disclose that the product does not have approval in New Zealand. Secondary legislation could also set specific requirements for promotion of unapproved products to practitioners.

## Off-label advertising

39. When medicines are approved under the Medicines Act, they are approved to treat specific conditions or symptoms. Approvals of prescription medicines can also include an age group, the number of doses, and other specifics. When the medicine is used differently, this is known as off-label use. We intend that this approach will continue in the Medical Products Bill.
40. Off-label use relates only to medicines approved by Medsafe, and so it is distinct from use of an unapproved medicine, discussed above.
41. Some off-label use is supported by good evidence, but some is experimental or has been shown to be ineffective or harmful. For this reason, we recommend that advertisements for off-label use be treated in the same way as advertisements for unapproved products (ie, tightly controlled). As well as ensuring that only approved uses are advertised, this will also encourage sponsors to ensure their product approval

reflects current evidence. The Director-General of Health could authorise off-label promotion in the same way as promotion of an unapproved product.

## Standards for advertising

42. General standards for medical product advertisements are currently set out in the Medicines Act and Regulations. Continuing to have legal requirements for medical products advertising will ensure a level playing field for responsible advertisers.
43. We recommend that advertising standards in the Medical Products Bill be limited to high-level requirements which are applicable to all modes of advertising and are unlikely to change over time. More detailed standards (eg, over the form of advertising and any required content) can be set in secondary legislation.
44. We recommend that the Medical Products Bill carry over the general rules for advertising in the Medicines Act. Specifically, the Bill should state that it is an offence for a medical product advertisement to include any statement or implication that:
  - a. is false or misleading
  - b. is contrary to, or inconsistent with:
    - i. the product's approval (if the product has one, and an exemption for off-label promotion has not been granted)
    - ii. any legal requirement
  - c. the product is infallible in preventing or treating any condition.
45. We also recommend that the above requirements should also apply to advertisements to practitioners and for medical products that do not require an approval.

## Equity

### DTCA-PM and health equity

46. Evidence from the April 2025 literature review suggests that DTCA-PM affects people differently depending on their health literacy, optimism bias, and health status.
47. Individuals with higher health literacy are more likely to seek further information, while those with optimism bias are less attentive to risks and less inclined to do so. Additionally, DTCA-PM appears to have a stronger impact on vulnerable populations, such as those with lower incomes, poorer health, and more severe conditions, who may be more responsive to medical advertising and more likely to act on it.
48. These groups appear to be more likely than the general population to make a medical appointment, or ask a doctor or pharmacist about a condition, after seeing DTCA-PM. Groups more likely to respond in this way included Māori, Indian and Chinese New Zealanders, people with lower education or income levels, poorer lifestyle choices, older people, and people with chronic illness or poor health.
49. It is not clear whether the evidence outlined above is evidence of harm or benefit, or simply evidence that people with higher health needs are more likely to seek health services and advice if prompted to do so.

## Medical products advertising and health equity

50. In relation to medical products advertising more generally, some groups are more vulnerable to misleading advertising. People with less education, people who are not fully fluent in English, and people with intellectual disabilities are likely to be particularly vulnerable. People with serious medical conditions may also be more vulnerable to advertising which promises 'miracle cures'.
51. Advertising standards in primary and secondary legislation, as well as continued industry self-regulation and professional regulation, will help prevent and respond to misleading and otherwise inappropriate advertising. Details of advertising standards will be developed following engagement with patient and consumer groups.

## Next steps

52. Once you have discussed the recommendations in this paper with Hon Ministers Brown and Seymour, your office will inform us of the outcome of those discussions. We will then draft a paper for you to take to Cabinet later in 2025.

PROACTIVELY RELEASED

## Appendix 1: How proposed regulation would apply

<b>Not regulated as advertising</b>	
Advocating for Pharmac to fund a medicine	Givealittle campaigns for unfunded medicines
Recruiting for registered clinical trials*	News reporting about medical products
Product reviews	Communicating scientific research
Public health campaigns involving an approved or unapproved product (if approved by DG)	Information about a medical condition if no product promoted
<b>Permitted advertising</b>	
Direct-to-consumer advertising of most approved medicines (except controlled drugs)	Promoting approved products to practitioners, including controlled drug medicines
Promoting specific unapproved or off-label products, if allowed via regulations	Advertising products which are not required to have an approval
Sponsor providing information about an unapproved product, in response to a practitioner request	Promoting unapproved products to practitioners at trade shows and conferences under strict criteria
<b>Unlawful advertising, unless otherwise permitted</b>	
Most advertising of unapproved products	Most advertising for off-label use
<b>Unlawful advertising</b>	
Any type of advertising banned via regulations	False or misleading claims
Direct-to-consumer advertising of controlled drug medicines (under Misuse of Drugs Act)	Claims that a product is infallible in treating or preventing any condition

\*The advertising of clinical trial participation will be regulated via the ethics approval process.

**Appendix 2: Rapid Literature Review: Impact of direct-to-consumer advertising of prescription medicines (2023)**

[Attached separately to maintain formatting]

PROACTIVELY RELEASED

**Appendix 3: Literature Review: Direct-to-consumer advertising of prescription medicines (2025)**

PROACTIVELY RELEASED

[Attached separately to maintain formatting]

ENDS.