Memorandum

Advertising of unapproved medicines

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Security level:	IN CONFIDENCE	**Health Report number:**	H2024042822
To:	Brian Watson, Private Secretary, Office of the Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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Action for Private Secretaries

N/A

Date dispatched to MO:

Advertising of unapproved medicines

Purpose

1. This report responds to Minister Costello's request for additional information on the rules about advertising unapproved medicines, particularly in the context of industry trade shows.

Background

2. On 21 May 2024, Minister Costello met with representatives of Business Events Industry Aotearoa (BEIA). They represent events centres, accommodation providers, and other organisations with an interest in trade shows, conferences, and similar events. We provided advice to the Minister on the current rules around advertising unapproved medicines in advance of this meeting (H2024040932).

3. At the meeting, BEIA advocated for a law change to allow promotion of unapproved medicines at trade shows and similar events for medical practitioners, which are not open to the general public. They also raised their concern that Medsafe's interpretation of the term 'advertising' is overly narrow and covers activities that – in their opinion – ought not to be considered advertising.

Advertising of unapproved medicines

4. The Medicines Act 1981 includes restrictions on what can be done with a medicine if it does not have Medsafe consent. Section 20(2) states that no person shall "advertise the availability of" any medicine which has not received consent (ie, an unapproved medicine). There are no exceptions, including for advertising to medical practitioners.

5. s 9(2)(h) [redacted]

6. In their letter to Hon Dr Shane Reti, the Minister of Health, BEIA state that section 20 of the Medicines Act "relates to the promotion and advertising of medicines to the consumer". This is not correct. Section 20 relates to all communications, not just communications to the public. There is nothing in the Act which would suggest the prohibition is limited in this way.

7. Medsafe state that companies may provide information about unapproved medicines to health care practitioners, to help the practitioner to make an informed decision.[1] However, the information may only be provided in response to a practitioner's inquiry. Product sponsors may not provide the information proactively or invite practitioners to make an inquiry.

[1] https://www.medsafe.govt.nz/compliance/Marketing.asp

Trade shows

8. There are no exceptions to the bar on "advertising the availability" of an unapproved medicine for trade shows or for presentations to specific audiences (eg, health practitioners). This applies even if the conference is restricted to registered medical practitioners.

9. BEIA state that trade shows are an important element of medical conferences, as the fees paid by trade show exhibitors help pay for the conference. This makes attendance at conferences more affordable for practitioners and their employers. BEIA also state that current restrictions on trade shows are depriving New Zealand of approximately $90 million in economic revenue.

Potential approaches

10. There is currently no leeway in the Medicines Act to allow companies to proactively supply information about an unapproved product, including to medical practitioners at a trade show. A change to primary legislation would be needed.

11. This means that either a change would be required to the Medicines Act, or for a different approach to be adopted in a future medical products bill.

Amending the Medicines Act

12. As we advised in our aide-memoire for the BEIA meeting (H2024040932), it is possible to amend the Medicines Act to enable unapproved medicines to be discussed at practitioner-only trade shows. For example, the equivalent Australian law has an express exemption for advertising to health practitioners (balanced against more restrictive approaches to allowing practitioners to prescribe unapproved medicines). The Therapeutic Products Act 2023 provided a general regulation making power to enable targeted exemptions; however, the Medicines Act has no equivalent regulation making power.

13. This is not a straightforward policy issue, and there is risk of unintended consequences. For example, there is risk that pharmaceutical companies would be less likely to seek approval for their medicine if they can promote it to prescribers (ie, health practitioners) without Medsafe approval.

14. Close engagement with key stakeholders would be required, particularly practitioner groups and industry, to ensure they understand the rationale and scope of any proposed change to the existing rules, and any limitations. s 9(2)(f)(iv) [redacted]

15. Developing a standalone amendment to the Medicines Act to create a new exemption would also divert resources from preparing a new, comprehensive medical products bill.

16. There may be a limited opportunity to align any work with the development of other Government legislation. For example, a targeted amendment to the advertising restrictions, for products approved by trusted overseas regulators, could be made as part of an upcoming government bill to enable verification of overseas medicine

approvals. The work on the verification pathway is being led by Minister Seymour. Minister Costello would need to discuss this issue with Minister Seymour.

Criteria for inclusion in short term improvements workstream

17. It is likely that you will receive numerous requests for 'short-term' improvements to the Medicines Act, and other elements of the current regulatory system. There is potential for these requests to divert resources away from higher priority longer term work. In order to effectively prioritise resources, we propose the following criteria:

    1) alignment with government priorities
    2) sufficient impact to justify potential diversion of time and resources
    3) quick implementation, relative to inclusion in a future medical products bill
    4) relatively low risk: for example, the changes are unlikely to be controversial; have cross-party support; are unlikely to create significant, unintended consequences; or do not require action by other government agencies (eg, Te Whatu Ora) or non-government entities (eg, Responsible Authorities).

18. Generally speaking, proposals that meet these criteria would only be simple changes that could take effect immediately. More complex changes would be more appropriate for a future medical products bill.

19. Implementing a targeted change to enable limited advertising at trade shows is likely to satisfy the first and second criteria, given the claimed economic benefits from bringing more conferences to New Zealand. s 9(2)(f)(iv) [redacted] As discussed above, the proposal does create a risk of unintended consequences, but these could be mitigated to some extent by creating a narrow exemption.

Next steps

20. We can provide the Minister with further advice at your request.

John McGrath
Director, Priority Projects
Strategy, Policy and Legislation
Date: