Briefing

Options to address DTCA-PM in the Therapeutic Products Bill

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To:	Hon Dr Ayesha Verrall, Minister of Health		
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Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Options to address DTCA-PM in the Therapeutic Products Bill

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To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. This briefing:

   a. responds to your request for additional information on the New Zealand Bill of Rights Act 1990 (BORA) implications of a total ban on direct-to-consumer advertising of prescription medicines (DTCA-PM)

   b. provides you with the requested options for how the Therapeutic Products Bill (the Bill) could enable a range of approaches to DTCA-PM, including a ban.

Summary

2. You have requested further advice around DTCA-PM under the Therapeutic Products Bill that notes the previous decisions made by Cabinet in this area, a range of options with respect to DTCA-PM (beyond just a full ban or not), and the potential Bill of Rights implications of those options.

3. To respond to this request for further advice, we first sought additional advice from the Ministry of Justice (MOJ) regarding the BORA implications of a full ban on DTCA-PM – as has been requested by various entities since the Bill's introduction. This advice on BORA has been supplied to your office as an appendix to this briefing.

4. The Ministry of Justice has reiterated that, as a starting point, under the New Zealand Bill of Rights Act 1990 (BORA), governments should not restrict freedom of expression unless the restriction 'can be demonstrably justified in a free and democratic society'. Courts may find secondary legislation which restricts rights to be invalid if the restriction is not explicitly enabled in primary legislation.

5. MOJ cannot provide legal advice on BORA except on request from the Attorney-General and in relation to a specific draft Bill or supplementary order paper (SOP). They have given policy advice that restricting or banning DTCA-PM would limit the right to freedom of expression affirmed in BORA.

6. They have also advised that whether the limit was reasonable would depend on the evidence justifying the limitation. To date, the evidence considered by the Ministry and the Health Committee on this issue is inconclusive. We have not been able to demonstrate through available evidence that the net harms of DTCA-PM would justify an outright prohibition in the context of the broader BORA considerations.

7. As currently drafted, the Therapeutic Products Bill (the Bill) currently enables regulations to restrict advertisements for therapeutic products; but does not explicitly enable

regulations that could prohibit DTCA-PM. s 9(2)(h) [redacted]

8. While the evidence to date does not conclusively establish that the harms of DTCA-PM would justify a total ban, examples provided by key stakeholders such as the Council of Medical Colleges has suggested that the potential for members of public to be inappropriately prescribed specific products (eg, opioids) due to the impacts of advertising may justify controls over advertising for such products.

9. Moreover, evidence may emerge that justifies a total ban on DTCA-PM in the future and as you know, the intent is to collect any such evidence more systemically after the Bill passes as well. At this stage of the Bill's progress, there are three options for how the Bill could be amended to address concerns about DTCA-PM:

    1. ***Do not amend the Bill*** prior to enactment (status quo), but review the operation of the advertising provisions within 2 years of commencement. Banning DTCA-PM would likely then require a subsequent Bill to amend the Therapeutic Products Act.
    2. ***Amend the Bill via a minor change to the existing SOP*** to explicitly enable regulations that could prohibit certain advertising practices (including DTCA-PM)
    3. ***Amend the Bill via a new supplementary order paper (SOP)***, moved during the Committee of the whole House debate, to completely ban DTCA-PM.

10. **[Legally privileged] Option 1** (status quo) creates the least risk of legal challenge under BORA, but does not enable a full ban on DTCA-PM. The current Bill allows for targeted restrictions on advertising, including controls on advertising particular products (eg opioids) or to a particular audience (eg children) s 9(2)(h) [redacted] If this status quo option is selected, a later decision to ban DTCA-PM outright would require a new Bill to be passed by a future Parliament.

11. **Option 2 (recommended option)** would provide greater certainty that regulations could prohibit certain advertising practices partially or in full, including DTCA-PM. This option allows time for a robust policy process that could ultimately result in a ban that takes effect when the Bill commences in 2026. This option reduces the risk that regulations could be successfully challenged on BORA grounds. This option would also allow BORA considerations and any new evidence of harms from DTCA-PM to be fully considered as part of the policy process. It would also allow for those potentially negatively impacted by a full ban to be consulted before this decision is reflected in the law. This option can be achieved without a new Cabinet decision.

12. **Option 3** would amend the Bill to entirely ban DTCA-PM. The ban would be effective from commencement of the Bill and would not require secondary legislating. Due to the limited time to prepare and consult on the necessary SOP, this option carries the greatest risk of unintended consequences, including incidentally capturing patient advocacy and fundraising activities that have recently been the subject of media and Parliamentary attention. There is also risk of the ban being declared inconsistent with BORA. Progressing this option would require a new decision from Cabinet. It is not possible at this point to amend the Bill to restrict DTCA-PM in a more nuanced way, such as a partial DTCA-PM ban.

13. Options which are more nuanced than the status quo or a total DTCA-PM can be enabled via option 2. These include enabling 'disease awareness' campaigns from pharmaceutical companies, but not permitting advertisements that reference a specific prescription medicine. This kind of nuanced option would be more complex to draft and is not possible under option 3 in the time available.

Recommendations

We recommend you:

a) **Note** that the Therapeutic Products Bill (the Bill) enables regulations restricting advertisements of therapeutic products, but does not explicitly enable a ban on direct-to-consumer advertising of prescription medicine (DTCA-PM) **Noted**

b) s 9(2)(h) [redacted] **Noted**

c) **Note** that amendments to the Bill to directly ban DTCA-PM at this stage in the Bill's development, without time to consult potentially impacted parties, risks unintended consequences, including capturing communications such as fundraising campaigns and vaccine promotion **Noted**

d) **Agree** to one of the options for how the Bill can address DTCA-PM:

1) Do not further amend the Bill at this point (status quo) **Yes / No**

2) Amend the Bill via the existing SOP to enable DTCA-PM, and other harmful advertising practices, to be banned via regulations **(recommended option)** **Yes / No**

3) Amend the Bill now via a new SOP to completely ban DTCA-PM **Yes / No**

e) **Note** that a nuanced approach to DTCA-PM is best enabled through option 2 **Noted**

f) **Note** that ***recommendation d(2)*** requires a minor change to the current SOP and will not require a new decision from Cabinet **Noted**

g) **Note** that ***recommendation d(3)*** will require taking an oral item to Cabinet on 17 July 2023, prior to introducing the SOP during the committee of the whole House debate (scheduled for 18-20 July). **Noted**

Steve Waldegrave
Associate Deputy Director-General of Health
Strategy, Policy and Legislation
Date: 6/07/2023

Hon Dr Ayesha Verrall
Minister of Health
Date:

Options to address DTCA-PM in the Therapeutic Products Bill

Background: Direct-to-consumer advertising of prescription medicines (DTCA-PM)

1. DTCA-PM is currently regulated in New Zealand under the Medicines Act 1981 (Medicines Act) and through self-regulation by the advertising industry. Complaints about advertising of medicines are investigated by Medsafe and by the Advertising Standards Authority.

2. Along with the United States, New Zealand has relatively permissive regulation of DTCA-PM. In other comparable countries, DTCA-PM is banned or only allowed in limited form. For example, advertisements for prescription medicines in Canada may state the medicine's brand name or the conditions that the medicine treats, but not both.

Stakeholder views on DTCA-PM

3. There is strong opposition to DTCA-PM from academics, consumer advocacy groups, health practitioner associations, healthcare providers and other health organisations, many of whom made submissions on this aspect of the Bill. They argue that DTCA-PM encourages inappropriate use of medicines, with harmful impacts on the public. They also consider that it creates additional costs on the public health system due to spending on unnecessary or inappropriate medicine.

4. Support for DTCA-PM comes primarily from the pharmaceutical and advertising industries, who argue that DTCA-PM is effectively regulated under the current system. Submitters in favour of DTCA-PM said that advertising can be an effective way to raise awareness of health conditions and available treatments.

How the Bill as currently drafted will regulate DTCA-PM

5. Under the Bill, advertisements for therapeutic products will be required to comply with the advertising requirements in clause 194, which include that the advertisement must:

    a. not contain any misleading information

    b. not contain information contrary to the product's market authorisation (if applicable)

    c. not promote the product for an off-label use

    d. comply with any standards set out in regulations.

6. In addition, regulations can impose 'distribution requirements' on advertisements. Distribution requirements can relate to:

    a. the form of an advertisement

    b. how an advertisement is distributed

    c. to whom an advertisement is distributed.

7. Detailed advertisement and distribution requirements will be developed as part of secondary legislation. We anticipate that, under the status quo wording of the Bill, advertising and distribution requirements, taken together, could be used to enable appropriate controls on certain advertising practices. For example, the requirements could, in practice, restrict advertising directed to a particular group (eg children), or of a particular type of product (eg opioids or sedatives), or through a particular form (eg TV before 7pm). There could also be very strict controls around advertising for types of product, for example weight loss products, or rules requiring disclosure of any funding.

Previous government decisions on DTCA-PM

8. Previous governments have considered whether to ban DTCA-PM. This includes a proposal to ban the practice during efforts to establish a joint Australia-New Zealand therapeutic regulator and – most recently – a proposal by former Minister of Health the Hon David Clark in 2018 to amend the Medicines Act to prohibit the practice. This last proposal did not ultimately proceed. When the draft Therapeutic Products Bill (the Bill) was released for public consultation in December 2018, it retained the status quo in relation to DTCA-PM.

9. In October 2021, Cabinet agreed [CBC-21-MIN-0117] to continue to allow DTCA-PM under the Bill, with other measures, such as advertising remediation orders and higher penalties, enabling enhanced controls over advertising. One of the grounds for this decision was that a total ban would be inconsistent with the New Zealand Bill of Rights Act 1990 (BORA).

A DTCA-PM ban would restrict freedoms under the Bill of Rights

10. Section 14 of BORA provides that 'Everyone has the right to freedom of expression, including the freedom to seek, receive, and impart information and opinions of any kind in any form.' Section 5 of BORA provides that rights may only be limited to the extent that 'can be demonstrably justified in a free and democratic society'.

11. The right includes freedom of commercial expression such as advertising, which is a form of expression involving imparting information. Legislation that regulates or prohibits the content of any publication, broadcast, display or promotion involves some level of interference with the right to freedom of expression. While there is a lower threshold to justify limitations on commercial expression (compared to political or artistic expression), those limitations do still need to be justified.

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

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

14. The BORA vetting team have also provided general policy advice on the test to be applied in assessing whether a limitation is justified. This includes considering whether:

    a. the objective is sufficiently important to justify the right. For example, the BORA vetting team's advice suggests that reducing poor-quality use of medicines is an important objective. s 9(2)(h) [redacted]

    b. there is a rational connection between the policy objective and the limit on the right (eg, is a ban on DTCA-PM logically connected with preventing harm to individual health or reducing poor-quality use of medicines).

    c. the limit on the right is no greater than reasonably necessary (ie, is there a less rights restrictive approach that can achieve the objective, such as more targeted restrictions or strengthened guidelines for prescribers?).

    d. the limit is in due proportion to the importance of the objective (eg, a total ban on DTCA-PM may not be justified if it is only addressing a minor risk).

The current evidence base may not be sufficient to justify a DTCA-PM ban

15. Manatū Hauora has considered the evidence found in literature reviews undertaken in 2021 and 2023, including examples of potential harms from inappropriately prescribed pharmaceuticals. We have however been unable to find evidence to date that demonstrate a strong link in New Zealand or overseas between DTCA-PM and inappropriate prescribing. Of course, we also recognise that it may be difficult to conclusively prove a link between advertising and ultimate harms from patients consuming medicines inappropriately.

16. However, even if a link between advertising of prescription medicines and ultimate harm to patients' health were to be found, it might be that the appropriate policy response would be to review prescribing practices and oversight first, rather than necessarily banning advertising, as the more effective policy response.

17. Consequently, on balance, Manatū Hauora has been unable to find sufficient evidence that the reported (potential future and/or overseas reported) harms of DTCA-PM justify a blanket prohibition in the Bill, and the consequential limitation on freedom of expression this would entail. In particular, we note that the literature review undertaken in March-April 2023 found that DTCA-PM is associated with more information-seeking behaviour and patient visits but concluded that this could have positive as well as negative effects.

18. DTCA-PM can be distinguished from situations where prohibitions on advertising can be fully justified under BORA due to the inherent harm associated with the activity. For example, a ban on tobacco advertising can be justified because smoking is inherently harmful and has no positive effects. By contrast, prescription medicines are necessary and usually beneficial if used appropriately. Prescribers also play an important role in reducing harms from and poor-quality uses of medicines.

19. The Ministry recognises that many of those who support DTCA-PM have a financial interest in the practice. In contrast, those opposed tend to represent health practitioners and academics with an interest in patient safety and efficient use of health resources. Motivations of stakeholders may influence the weight you give to evidence presented on

the benefits or harms associated with DTCA-PM. However, these motivations are not a determinative factor in justifying restrictions on freedoms affirmed under BoRA.

Options to address DTCA-PM

20. At this stage of the Bill's progress, there are three options for how you could address DTCA-PM:

    1) Do not further amend the Bill (status quo),

    2) Amend the Bill via a minor change to the existing SOP that would explicitly enable regulations to prohibit certain advertising practices, including DTCA-PM **(recommended option), OR**

    3) Amend the Bill via a new SOP to completely ban DTCA-PM.

21. These are the available options based on our understanding that you intend for the Bill to pass before the 2023 general election.

Option 1: Do not further amend the Bill (status quo)

22. The status quo includes the SOP Cabinet approved on 3 July 2023. Under this option, the Bill would not be amended further than the existing SOP proposes.

23. Clause 194 of the Bill currently allows for flexible controls to be imposed on the content of advertisements and how (and to whom) those advertisements are distributed. These provisions may not be sufficiently explicit to empower the making of regulations that, in practice or effect, result in a complete prohibition on a kind of advertising.

24. Chapter 14, Part 9 of the Legislation Design and Advisory Committee's *Legislation Guidelines* states that secondary legislation which is inconsistent with BoRA 'will generally be invalid' unless it is specifically enabled through an empowering provision in primary legislation. The current wording of clause 194 of the Bill is about how advertising is done, rather than whether it should be done at all.

25. This option would enable tight restrictions on some kinds of advertising in response to specific harms from promotion of specific types of medicine (eg, opioids and sedatives) or medical device (eg, a 'supply and use' restricted device). s 9(2)(h) [redacted]

26. This option is the most consistent with BORA but is unlikely to address the concerns of critics of DTCA-PM. This option does allow additional time for evidence to be collected and assessed on the harms associated with DTCA-PM and whether they justify a total ban. Cabinet has agreed to a report back from you on the advertising provisions in the Bill, including whether DTCA-PM should be banned, within two years of the Bill's commencement. This option preserves flexibility for future governments. However, should a future government seek to implement a more complete ban on DTCA-PM, it would need to amend the Therapeutic Products Act through a new Bill to clearly enable such as ban, as required by BORA.

Option 2: Amend the Bill via the existing SOP to enable DTCA-PM to be banned via regulations (recommended option)

27. Under this option, the existing SOP for the Bill would be amended to make it clear that advertising and distribution requirements set out in regulation can create, in practice, a prohibition on DTCA-PM or other advertising practices. This addresses the residual risk referred to in paragraph 22 above and is the basis for our recommendation.

28. The proposed change to the SOP would enable development of a robust policy on how DTCA-PM should be treated in secondary legislation, including consideration of a total ban. The change would also enable flexibility and help to future proof the Bill should future changes in context require different approaches to advertising. Taking the time to develop restrictions in secondary legislation will also minimise the risk of unintended consequences, for example on patient advocacy, fundraising and community public health and vaccination campaigns – especially those self-organised by marginalised communities. It would also allow time for consultation with those impacted by a ban prior to enacting it.

29. s 9(2)(h) This means the change does not require approval from Cabinet, although subsequent regulations will require Cabinet approval. Nonetheless, you may wish to discuss the change to the SOP with colleagues.

30. s 9(2)(f)(iv)

31. s 9(2)(h) While we recognise that the development of secondary legislation will create further opportunities for lobbying by industry, it also provides additional time to build a strong evidence base justifying a ban on DTCA-PM.

Option 3: Amend the Bill via a new SOP to completely ban DTCA-PM

32. It is possible to amend the Bill to completely ban DTCA-PM, via a new SOP. This SOP would be in addition to the one approved by Cabinet on 3 July 2023 and would be moved separately during the committee of the whole House debate.

33. PCO have advised that there is no longer time to draft an amendment providing for a more nuanced approach to DTCA-PM in the Bill (for example enabling advertising about a health condition without mention of a specific product). This approach would need to be enabled under regulations as per option 2.

34. s 9(2)(h)

s 9(2)(h) [redacted]

35. In addition, a total ban on DTCA-PM may unduly restrict or prevent desirable messaging, such as vaccine promotion. If there is only one vaccine available for a particular disease, for example, promotion of vaccination against that disease may be DTCA-PM even if it does not mention the product name.

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

37. This option also presents additional timing challenges. A DTCA-PM ban is new policy, so is not covered by Cabinet agreement to the existing SOP for the Bill. A new SOP and further agreement from Cabinet is therefore required for this option. Approval to introduce the SOP would need to be sought from Cabinet on 17 July 2023, one day before the anticipated start of the committee of the whole House debate.

38. This option carries high risk of legal challenge from pharmaceutical companies and others with financial interests in DTCA-PM, as they have not had the opportunity to make submissions on a potential ban. There would also not be time to reassess the available evidence for and against a ban. These factors significantly increase the risk of the ban being declared inconsistent with BORA (although a declaration would not overturn the provision in the Bill or any duly authorised regulations made under it).

39. Controls developed through the standard policy process, and set out in secondary legislation under option 2, are likely to avoid the problems outlined above. These regulations would also be subject to Cabinet approval and provide more time for further engagement with industry, academics and health practitioners.

Equity

40. Opponents of DTCA-PM argue that there is particular risk from DTCA-PM to groups which experience health inequities, particularly groups that are less able to critically assess advertisements due to language or education limitations. Stakeholders have told us that some marginalised groups have been specifically targeted for DTCA-PM, for example Pacific communities in relation to potentially harmful weight-loss medicines.

41. Amending the SOP to enable a ban via secondary legislation (option 2) would allow robust policy development, including taking into account the specific interests and needs of different population groups in Aotearoa New Zealand. This would include a strong focus on the impact of DTCA-PM on groups experiencing health inequities, and the extent to which restrictions or a ban could benefit those groups.

Next steps

42. If you agree to option 1, no further steps are required, and you may table the existing SOP in Parliament.

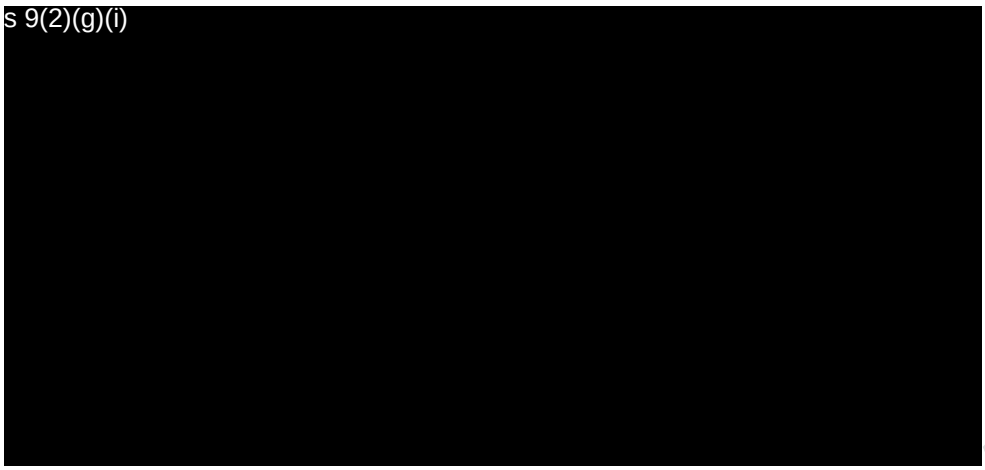
43. If you agree to option 2, PCO will make the minor amendment to the existing SOP to give effect to your decision. Once the existing SOP is tabled in Parliament it cannot be

further amended by PCO. We therefore recommend that you do not table the SOP in Parliament until the change to the existing SOP has been made and your office notified.

44. If you agree to option 3, we will ask PCO to draft a new SOP to give effect to your decision. Your office will need to seek agreement to take an oral item to Cabinet on 17 July, along with the new SOP, and the SOP would need to be tabled with Parliament immediately following Cabinet's approval for its introduction.

ENDS.

Appendix 1: Advice from Ministry of Justice Bill of Rights vetting team



Minister's Notes