

Briefing for decision

Medical Products Bill Cabinet paper on supporting exporters, pharmacy ownership, and other matters

Date due to MO:	7 July 2025	Action required by:	14 July 2025
Security level:	IN CONFIDENCE	Reference:	H2025066307
To:	Hon Casey Costello, Associate Minister of Health		
Consulted:	Health New Zealand: <input type="checkbox"/>		
Proactive release:	This title is proposed by the Ministry of Health for proactive release: <input type="checkbox"/>		

Contact for telephone discussion

Name	Position	Telephone
Geoff Short	Acting Deputy Director General Strategy, Policy and Legislation	section 9(2)(a)
Tim Vines	Manager, Therapeutics Strategy, Policy and Legislation	section 9(2)(a)

Author: Helen Robison, Principal Policy Analyst, Strategy Policy and Legislation

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 Withdrawn | |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

Medical Products Bill Cabinet paper on supporting exporters, pharmacy ownership, and other matters

Security level: IN CONFIDENCE **Date:** 7 July 2025

To: Hon Casey Costello, Associate Minister of Health

Purpose of report

1. This briefing provides you with a draft Cabinet paper for the Medical Products Bill (the Bill), covering supporting exporters, pharmacy ownership, statutory timeframes, and offences and penalties. It also provides you with a Regulatory Impact Statement (RIS) on pharmacy ownership.
2. This briefing seeks your decision on options for supporting exporters, which is necessary to finalise the Cabinet paper for departmental and Ministerial consultation.

Summary

3. In September 2024, Cabinet agreed to a Medical Products Bill, and invited you to report back on further policy proposals, including on supporting exporters, regulating pharmacies, statutory timeframes, and offences and penalties [SOU-24-MIN-0115]. The attached Cabinet paper and RIS support your report back.
4. You have agreed to policy settings on statutory timeframes [H2025060718] and offences and penalties [H2024054517]. The paper reflects those decisions.
5. You agreed to discuss community pharmacy ownership regulation with your Ministerial colleagues [H2024057299]. We have drafted the Cabinet paper on the understanding that you and your colleagues wish to remove all restrictions on who may own a community pharmacy. The RIS also states that this is your preferred option. If you wish to keep any of the restrictions, we will redraft the paper and update the RIS accordingly.
6. In relation to exporters, Cabinet agreed in September 2024 that the Bill should support exports “in a way that maintains New Zealand’s reputation as a producer of high-quality products” [SOU-24-MIN-0115]. Exporters can best be supported by avoiding unnecessary regulation, and by continuing to enable export certification.
7. There is scope for the Bill to protect New Zealand’s export reputation by requiring medical product exporters to register with Medsafe. This would make compliance action easier in response to dangerous or otherwise substandard exports, without imposing any significant regulatory burden on exporters.
8. The attached Cabinet paper includes paragraphs and a recommendation on registration of exporters. If you do not support the registration requirement, we will remove these parts of the Cabinet paper.
9. We recommend that you take the paper to the Cabinet Social Outcomes Committee (SOU) on 13 August 2025, and Cabinet on 18 August 2025. This would allow two weeks

simultaneous Ministerial and departmental consultation, running from around 16 July to 30 July (two weeks).

10. If you agree to the timeline above, we will organise departmental consultation. Your office will organise Ministerial consultation, with a revised paper if you do not support a requirement for medical product exporters to register.

Recommendations

We recommend you:

- a) **Note** that in September 2024, Cabinet invited you to report back on policy proposals for the Medical Products Bill, including on regulating pharmacies, supporting exporters, statutory timeframes, and offences and penalties **Noted**
- b) **Note** that the attached Cabinet paper reflects your prior decisions on statutory timeframes and offences and penalties **Noted**
- c) **Note** that the attached Cabinet paper and Regulatory Impact Statement are based on the understanding that you and your colleagues wish to remove the ownership restrictions on community pharmacy ownership **Noted**
- d) **Choose** one of the following options in relation to medical products exports:
- 1) a requirement for medical products exporters to register with Medsafe **Yes / No**
 - 2) no specific regulation of medical products exporters, in which case we will remove references to registration from the paper **Yes / No**
- e) **Agree** to a timeframe of two weeks simultaneous departmental and Ministerial consultation, from 16 to 30 July, then the paper going to SOU on 13 August 2025 and Cabinet on 18 August 2025. **Yes / No**

Geoff Short
Acting Deputy Director-General
Strategy, Policy and Legislation
Date: 7 July 2025

Hon Casey Costello
Associate Minister of Health
Date:

Medical Products Bill Cabinet paper on supporting exporters, pharmacy ownership, and other matters

11. In September 2024, Cabinet agreed to a Medical Products Bill (the Bill) to replace the Medicines Act [SOU-24-MIN-0115]. Cabinet invited you to report back on further policy proposals, including on regulating pharmacies, supporting exporters, statutory timeframes, and offences and penalties. The attached Cabinet paper supports your report back on those matters.

We need your decision on regulating exports

12. In September 2024, Cabinet agreed that the Bill would support exports “in a way that maintains New Zealand’s reputation as a producer of high-quality products” [SOU-24-MIN-0115]. Cabinet also agreed that the Bill “will not include any system of mandatory approval for medical products intended for export only”.
13. You were invited to report back to the Social Outcomes Committee (SOU) on how the Bill can support exporters.
14. Exporters are currently supported through official certification, which many countries require for medical product imports. Certification confirms matters including who the manufacturer is, and (where applicable) that the product can be legally supplied in New Zealand, that it meets any standards required in New Zealand, and/or that the manufacturer is licensed.
15. Medsafe currently provides certification on a cost-recovery basis, which aligns with Treasury guidance. We recommend that the Bill enable cost-recovery to continue.
16. Cabinet has agreed that the Bill will maintain New Zealand’s reputation as a producer of high-quality products. Some protection will be provided by carrying over elements of the Medicines Act 1981 that enable activities (including export) with a product to be prohibited, as well as by other elements of the Bill such as manufacturing licences.
17. We have considered whether New Zealand’s reputation can be further protected through a requirement that medical products exporters register with the regulator (eg, Medsafe). Registration would be a one-off process of notifying Medsafe; licensed manufacturers could also be automatically registered as exporters as part of their manufacturing licencing process. For exports, there would be no assessment of the exporter or ability to decline a registration.
18. A registration requirement would be very light touch and is unlikely to create a burden for exporters. In support of this view, the Ministry for Regulation has advised that a Regulatory Impact Statement for this option would not be required as the impacts are ‘minor or limited’. Registration would not involve any regulation of exported products. However, it would make it easier to place general duties on exporters, such as record-keeping, and to take action if an exported product was found to be dangerous.

19. We also considered a licensing system for exporters, but concluded that the costs to exporters and the Crown would likely outweigh the benefits.
20. The attached Cabinet paper includes a paragraph and a recommendation on a registration requirement. If you do not wish to require exporters to register, please advise us and we will provide you with a revised paper before consultation begins.

We understand you wish to deregulate pharmacy ownership

21. In February 2025, we provided you with advice on whether the three restrictions on community pharmacy ownership under the Medicines Act should be carried over into the Bill [H2024057299].
22. We noted that removing the ownership restrictions would align with the Government's focus on reducing regulation, but that some elements of deregulation will be opposed by the pharmacy sector. In particular, the sector is likely to oppose removing the requirement that pharmacists have majority ownership and effective control of companies which own pharmacies. There is no strong evidence on the positive or negative impacts of pharmacy ownership deregulation.
23. You agreed to discuss the matter with your Ministerial colleagues. We have drafted the attached Cabinet paper on the understanding that you and your colleagues wish to remove the three restrictions on pharmacy ownership. The attached RIS states that this is your preferred option.

The paper reflects your decisions on statutory timeframes

24. On 3 June 2025, we provided you with advice on statutory timeframes [H2025060718]. You agreed, and the attached Cabinet paper reflects that the Bill will:
 - a. carry over statutory timeframes from the Medicines Act and the Medicines Amendment Bill
 - b. enable regulations to be made under the Bill specifying timeframes
 - c. include timeframes for applicants, with an ability to lapse an application
 - d. include reporting requirements for the regulator
 - e. enable partial fee refunds (when appropriate) if statutory timeframes are not met.
25. Timeframes can be set after the regulator is established in its new form, and in consultation with industry, to ensure that they are practical and workable.

The paper reflects your decisions on offences and penalties

26. In September 2024, Cabinet agreed to carry over Part 8 of the Therapeutic Products Act (Enforcement), subject to a review of penalty provisions. We carried out that review, and provided you with advice in March 2025 [H2024054517].
27. You agreed to a Cabinet paper reflecting the approach set out in that paper, including:
 - a. tiered offences and penalties
 - b. civil pecuniary penalties for financially motivated offending
 - c. extending civil and criminal liability to the Crown for some contraventions

- d. a range of defences, including reasonable reliance on a third party
- e. a fit and proper person test, modified to reflect the Hon Shane Reti's Supplementary Order Paper on the Therapeutic Products Bill
- f. an offence of offering, or accepting, an improper inducement to a health practitioner to influence a clinical decision about a product.

Equity

- 28. We do not expect any of the policies in the Cabinet paper to have any significant equity impacts within New Zealand. Changes to pharmacy regulation are expected to reduce barriers to opening pharmacies in underserved areas and may have a positive impact on rural and non-urban Māori communities.
- 29. Allowing unregulated exports of medical products to countries without meaningful regulation may have inequitable impacts outside of New Zealand. Wealthy and well-governed countries will generally prevent substandard products from being imported, or will take effective post-market action. Less developed countries, including some Pacific Island countries, may be vulnerable to substandard imports from New Zealand. As well as harming consumers, unregulated exports could damage New Zealand's relationships with the importing countries.

Next steps

- 30. We recommend that you bring the paper to the Social Outcomes Committee on 13 August 2025, and Cabinet on 18 August 2025. This would allow two weeks simultaneous Ministerial and departmental consultation, running from around 16 July to 30 July.
- 31. If you agree to this timeline, we will organise departmental consultation. Your office will organise Ministerial consultation, with a revised paper if you do not support a requirement for medical product exporters to register.

ENDS.