In Confidence

Office of the Associate Minister of Health

Cabinet Social Outcomes Committee

Medical Products Bill: reducing regulation and other policy matters

Proposal

1 This paper seeks agreement to policy decisions for the Medical Products Bill (the Bill) on pharmacy ownership, advertising, statutory timeframes, supporting exporters, offences and penalties, and changes to Medsafe to enable it to administer the Bill.

Relation to government priorities

2 The Bill will support improved health outcomes for patients, and a more efficient health system. The proposals in this paper also contribute to the Government's priorities of supporting economic growth and reducing unnecessary regulation.

Executive Summary

3 In 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 (the Bill) [SOU-24-MIN-0115]. Cabinet made key policy decisions for the Bill and invited me to report back on policy matters necessary to finalise drafting.

4 My overall approach to policy for the Bill has been to retain the elements of the Medicines Act and Therapeutic Products Act 2023 which are fit-for-purpose, remove unnecessary regulation, improve clarity, and add safeguards where benefits will outweigh costs. Officials have consulted with industry on these proposals.

5 I recommend that we do not carry over current ownership restrictions for community pharmacy. These create unnecessary compliance costs for the sector and the Crown. Patient safety and professional standards can be better protected through safeguards in the Bill, such as the introduction of a supervisory pharmacist role.

6 Current regulation of medical products advertising mostly works well. I recommend that we continue to allow prescription medicines to be advertised directly to the public. The Bill should be clearer on what advertising is and is not allowed, by applying a consistent definition, with exclusions for activities such as fundraising, news reporting, and education. Promotion of unapproved products will be permitted in some circumstances, such as trade shows and medical conferences.

7 In order to support medical product exporters, Medsafe's ability to issue export certificates should be continued, and specifically provided for in the Bill. I also recommend that medical products exporters be required to register. This will help protect New Zealand's reputation as a producer of high-quality products, without imposing any significant burden on exporters. Registered exporters would be subject to general duties only, such as record keeping, and not undergo pre-approval.

8 Statutory timeframes for decisions provide certainty and encourage efficiency for both applicants and decision-makers. I recommend that the Bill carry over the approach in the current Medicines Amendment Bill of enabling timeframes to be set in secondary legislation. I also recommend that the Bill carry over a 45-day timeframe for clinical trial approvals. Where the decision-maker does not meet a statutory timeframe, I propose that the Bill enable a partial refund of fees, where appropriate.

9 I recommend that the Bill's offences and penalties framework provide that public and private healthcare providers be legally liable for contraventions in the same way, when they are providing the same kind of products and engaging in similar services. The Bill should also include a civil pecuniary regime, and an offence of improper inducement of a health practitioner to make a clinical decision about a medical product. There should be a fit and proper person test for licence holders and others.

10 I recommend that the Bill is drafted so that Medsafe can continue to be the medical products regulator and continue to be mostly cost-recovered, with an additional levy-setting power. I also recommend that Cabinet confirm its in-principle decision that regulatory functions be formally vested in an independent statutory officer supported by the Ministry of Health [SOU-24-MIN-0132]. The statutory officer would be appointed by the Director-General of Health and accountable to them for their general performance, and subject to general policy direction from the Minister of Health.

Background

11 In September 2024, Cabinet agreed that the Medicines Act should be replaced with modern regulation of medicines and medical devices under a Medical Products Bill [SOU-24-MIN-0115]. Cabinet also invited me to report back to the Cabinet Social Outcomes Committee with further policy proposals on topics including regulation of pharmacies, supporting exporters, statutory timeframes, advertising, and offences and penalties. Decisions on these matters will enable the Bill to be drafted.

Analysis:

Unnecessary regulation of pharmacy ownership should be removed

12 Under the Medicines Act, all pharmacies, and companies which own pharmacies, must be majority-owned by pharmacists, who must be in "effective control" of the company. In addition, no person or company may operate, or hold a majority interest in, more than five pharmacies, and prescribers may not own any interest in a pharmacy without Medsafe's consent.

13 These restrictions impede integrated services, such as practitioner-owned health clinics that include a pharmacy, and may deter pharmacists from becoming prescribers. Assessing pharmacy ownership is not a good use of taxpayer money. I recommend that we do not restrict pharmacy ownership in the Bill.

14 I have seen no evidence that ownership restrictions protect public safety or help to maintain standards. These aims are better met through more direct means, including professional regulation and standards, the pharmacy licensing system, and Health New Zealand's contracting processes.

15 It will be important for companies that own pharmacies to have clear lines of responsibility for compliance with pharmacy standards and legal requirements. I propose that the Bill create a supervisory pharmacist role, in addition to the current requirement that a pharmacist be physically present in every pharmacy. Any company that includes more than one pharmacy would be required to have a supervisory pharmacist, who would have formal responsibility for pharmacy standards and compliance of the company as a whole. This would be based on a similar role in the United Kingdom system, which does not have ownership restrictions.

16 The Bill will also require pharmacy licence holders to ensure pharmacists have adequate resources and make it an offence to encourage a pharmacist to act unprofessionally. Pharmacy activities such as dispensing will continue to be regulated and subject to professional standards.

Regulation of medical products advertising can be clarified and improved

17 Medical products advertising is regulated under the Medicines Act and subject to industry self-regulation through the Advertising Standards Authority. Occupational bodies such as the Medical Council, also have professional standards for promotion of products and services.

18 Many aspects of current regulation work well. Consumers can access information about medical products, while false or misleading claims are prohibited. While direct-to-consumer advertising of prescription medicines attracts criticism from some individuals and professional associations, I have not seen any evidence that it causes significant harm. I therefore recommend we continue to allow this form of advertising. I also recommend a regulation-making power to enable controls on specific harmful advertising practices, for example advertising to children or advertising of weight loss products.

19 The current system lacks clarity and consistency in some areas; for example the Medicines Act has two different meanings of ‘advertise’. I propose that the Bill include a clear definition of advertising that draws on the approach in the Australian Therapeutic Goods Act 1989 and applies to all medical products, unless exempted.

20 Public debate and information on medical products and public health is important and should be protected. I therefore recommend that the Bill does not treat the following as advertising:

20.1 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;

20.2 public safety announcements, recall orders, public health campaign statements approved by the Director-General of Health, the pharmaceutical schedule, any statement required by law, and any communication exempted via regulations;

20.3 clinical trial recruitment material approved by a recognised ethics committee.

21 The Medicines Act prohibits advertising of unapproved medicines, and advertising ‘off-label’, for a purpose a medicine is not approved for. In most cases this is necessary to protect consumers and support the product approval system, including

the incentive to seek approval. I recommend that the current approach continue for all product types that need an approval under the Bill, except:

21.1 at medical conferences and trade shows for health practitioners, as agreed by Cabinet as part of the Medicines Amendment Bill [CAB-25-MIN-0097.01];

21.2 where approved by the Director-General of Health, for example in relation to off-label use of a vaccine in a public health emergency.

22 Promotion of unapproved products should be subject to all general advertising standards (eg, accuracy) and professional standards, other than those requiring a product to have been approved.

Table 1: How proposed regulations would apply

Not regulated as advertising	
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 approved by the Director-General of Health	Information about a medical condition if no product promoted
Permitted advertising	
Direct-to-consumer advertising of most approved products (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
Providing information about an unapproved product, in response to a practitioner request	Promoting unapproved products to practitioners at trade shows and conferences
Unlawful advertising	
Most advertising of unapproved products	Most advertising for off-label use
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

Statutory timeframes will improve transparency and accountability

23 Statutory timeframes for regulatory decisions provide certainty for applicants and incentivises timely decision-making. The Medicines Amendment Bill will enable some decision timeframes to be set in secondary legislation. I recommend that the Medical Products Bill carry over this approach.

24 I also recommend that the existing timeframe for clinical trial approvals in the Medicines Act be carried over into the Medical Products Bill, along with any new timeframes added to the Medicines Act via the Medicines Amendment Bill.

25 Should statutory timeframes not be met, I recommend the Medical Products Bill enable (where appropriate) a partial refund of fees to the applicant. For example, if the applicant pays a priority processing fee, this could be refunded if the priority timeline

is not met. This will help build industry trust and confidence in the system. There will also be performance reporting requirements for decision-makers.

26 I also recommend that the Medical Products Bill include timeframes for applicants to provide any additional information requested by the regulator, for example an assessment report from a trusted overseas regulator. There should also be a power to lapse an application if that information is not provided on time. This will encourage applicants to engage with the system in a timely manner and prevent gaming of timeframes by applicants through deliberately incomplete or substandard applications.

The Bill will support medical products exporters

27 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".

28 The Bill can most directly support exporters by avoiding unnecessary regulation. Exporters can also be supported through official certification, which many countries require for medical product imports. Certification confirms matters such as who the manufacturer is, and (where applicable) that the product can be legally supplied in New Zealand, that it meets any required standards, and/or that the manufacturer is licensed. Medsafe currently provides certification on a cost-recovery basis. I recommend that the Bill specifically enable this to continue.

29 I propose that exporters be required to register with Medsafe. This would not involve any assessment of exporters, or the ability to decline a registration. There would not be any Customs compliance check required by Customs. Registered exporters would have only general legal duties, such as record keeping. While this is very minimal regulation, it will help to protect New Zealand's reputation as a producer of high-quality products.

The Bill will include a modern offences and penalties regime

30 In September 2024, Cabinet agreed that the Bill would draw on Part 8 of the Therapeutic Products Act, on enforcement, subject to a review of penalty provisions [SOU-24-MIN-0115]. I also noted that I would seek a new approval of other elements of the Bill's offence and penalty framework, such as Crown liability.

31 The offence and penalties framework in the Therapeutic Products Act was not controversial, except in relation to advertising and natural health products. Natural health products are not covered by the Bill and I consider that the framework in the Therapeutic Products Act can otherwise be carried over, with changes consistent with Cabinet's other decisions (eg, on advertising).

32 Penalties have been reviewed and will be proportional to the severity of the offence. They will take into account any harm to individuals or the public, and whether the action was intentional or reckless. Penalties will range from $1,000 fines for minor contraventions to imprisonment (up to five years) or a fine of $200,000 for an individual, and a fine of up to $1 million for an organisation. The highest penalties would only apply to the most serious conduct, which was intentional or reckless, and created a significant risk to personal or public health.

33 I also recommend that the Bill include a civil pecuniary regime, along the same lines as the Financial Markets Conduct Act 2013, the Food Act 2014, and the Gene Technology Bill. Civil pecuniary penalties are non-criminal monetary penalties imposed by a court after a civil trial, and deter financially motivated contraventions. Details of specific offences and penalties will be developed in consultation with the Ministry of Justice.

34 Public and private health providers have the same duties of care to their patients and customers. I recommend that, where the Crown provides health services involving a medical product, it should be liable in the same way as other health service providers. The Crown would not be liable for its regulatory activities, such as declining or approving a product approval or deciding whether or not to fund a specific product.

35 I recommend that the Bill include an offence of improper inducement of a health practitioner to make a clinical decision about a medical product, for example through financial incentives to prescribe a product. This will align New Zealand with countries such as United States and the United Kingdom. Improper inducement offences help prevent waste of taxpayer funds and harm to patients and the public, for example from misuse of antibiotics or controlled drug medicines.

36 In common with other regulatory regimes, I recommend that the Bill include a fit and proper person test to be applied as part of determining whether to issue a licence or other approval. The test will draw on the Hon Dr Shane Reti's Supplementary Order Paper for the Therapeutic Products Bill, which industry supported.

Medsafe should continue to be the medical products regulator

37 To support drafting of the Bill, I recommend that Medsafe continue to be responsible for medical product regulation. I also recommend that Cabinet confirm its October 2024 in-principle decision that regulatory functions be formally vested in a statutory officer supported by the Ministry of Health [SOU-24-MIN-0132]. The statutory officer would be a public servant appointed by the Director-General of Health.

38 I recommend that the objective of the statutory officer will be to operate the medical products regulatory regime independently, while being accountable to the Director-General of Health for the general performance of their functions and powers. They would also report publicly on their performance. The statutory officer would be subject to general policy directions issued by the Minister of Health in relation to medical products, and required to publish a regulatory strategy setting out their performance expectations and how they will perform their functions.

39 Medsafe is mostly cost-recovered and I propose that the Bill is drafted to enable this to continue, with a new power to set levies via regulations. Fees and levies would recover costs associated with product and licence approvals, accreditation and certification activities, audits, and issuing export certificates. Earlier Cabinet decisions, such as not requiring local evaluation for most medical devices [SOU-24-MIN-0115], will minimise cost to industry. A business case for a new digital platform for Medsafe is in development and would also enable more efficient workflow processes and more streamlined interactions with applicants.

40 In order to begin drafting promptly, I recommend drawing on the list of regulator functions in section 339 of the Therapeutic Products Act as well as the following subparts of Part 9 of the Therapeutic Products Act: subparts 2 (cost recovery), 3 (information), 4 (decision making and exercise of powers) and 6 (review of regulator's decisions), with modifications consistent with Cabinet's decisions. These provisions in the Therapeutic Products Act were largely uncontroversial and align with Treasury guidance on the use of cost-recovery.

Cost-of-living Implications

41 These proposals are unlikely to have significant cost-of-living implications.

Financial Implications

42 These proposals have no financial implications. Budget 2025 identified funding to implement the Bill, including delivering organisational change for Medsafe, to be funded through reprioritisation from Ministry of Health baselines.

Legislative Implications

43 These proposals will enable the Medical Products Bill to be drafted.

Impact Analysis

Regulatory Impact Statements

44 The Ministry of Health QA panel has reviewed the Impact Statement titled "Regulation of pharmacy ownership", produced by the Ministry of Health and dated June 2025. The panel considers that the Impact Statement **Meets** the quality assurance criteria. The Impact Statement is clear, concise, consulted, complete and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

45 A Regulatory Impact Statement on the medical products regulator was prepared and attached to the October Cabinet paper [SOU-24-MIN-0132]. It covered the form of the regulator and funding settings. A supplementary annex was developed in December 2024 [EXP-24-MIN-0077].

46 The Ministry for Regulation has determined that other proposals in this paper either do not trigger the Regulatory Impact Analysis requirements or are exempt from the requirement to provide a Regulatory Impact Statement. Appendix 2 lists proposals and exemption grounds.

Climate Implications of Policy Assessment

47 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to these policy proposals, as the threshold for significance is not met.

Population Implications

48 I do not expect the proposals in this paper to have significant impacts on any specific population groups.

Human Rights

49 These proposals are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Use of external Resources

50 No external resources were used to prepare the policy advice in this paper.

Consultation

51 The Ministry of Health consulted on this paper with the Public Service Commission; the Ministry of Foreign Affairs and Trade; the Ministry of Justice; the Ministry of Business, Innovation and Employment; the Ministry for Primary Industries; Te Puni Kōkiri; Customs; the Ministry for Regulation; ACC; the Office of the Privacy Commissioner; Health New Zealand; Pharmac; the New Zealand Blood and Organ Service; and the Commerce Commission. The Department of the Prime Minister and Cabinet was informed.

Communications

52 The Ministry of Health will inform stakeholders of Cabinet's decisions.

Proactive Release

53 This paper will be proactively released within 30 days of being considered by Cabinet, with redactions as appropriate under the Official Information Act 1982. The associated Regulatory Impact Statements will be published on the websites of the Ministry of Health and the Ministry for Regulation.

Recommendations

The Associate Minister of Health recommends that the Committee:

1 note that in September 2024, Cabinet agreed to modern regulation of medicines and medical devices under a Medical Products Bill (the Bill), and invited the Associate Minister of Health to report back to the Social Outcomes Committee on further policy proposals on topics including regulating pharmacies, advertising, supporting exporters, statutory timeframes, and offences and penalties [SOU-24-MIN-0115];

Pharmacy ownership

2 agree that the Medicines Act restrictions on the ownership of community pharmacies should not be carried over into the Bill;

3 agree to create a supervisory pharmacist role with formal responsibility for pharmacy standards and compliance in any company which includes more than one pharmacy;

Advertising

4 agree that the Bill will include a clear and consistent definition of advertising, drawing on the definition in the Australian Therapeutic Goods Act 1989, and applying to all medical products;

5 agree that the Bill not treat the following as advertising:

5.1 public safety announcements, recall orders, public health campaign statements approved by the Director-General of Health, the pharmaceutical schedule, any statement required by law, and any communication exempted via regulations;

5.2 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;

5.3 clinical trial recruitment material approved by a recognised ethics committee;

6 agree to continue to permit direct-to-consumer advertising of prescription medicines;

7 agree to a regulation-making power to enable controls on specific advertising practices;

8 agree to continue to prohibit promotion of unapproved medical products and off-label use of medicines, except for:

8.1 products which do not need an approval;

8.2 promotion authorised by the Director-General of Health;

8.3 promotion at trade shows and medical conferences;

Statutory timeframes

9 agree that the Bill will carry over all specific statutory timeframes from the Medicines Act, including any added via the current Medicines Amendment Bill, and enable the ability to set other decision timelines in secondary legislation;

10 agree that decision-makers will be required under the Bill to report annually on performance against statutory timeframes;

11 agree to enable a partial refund of fees if a decision has not been made within statutory timeframes;

12 agree that the Bill will include timeframes for applicants, and power to lapse applications if information is not provided in time;

Supporting exporters

13 agree that the Bill will provide for medical product exporters to be issued with certification needed by importing countries, and that this will be cost-recovered;

14 agree that the Bill will require medical products exporters to register, and that exporters will be subject only to general legal duties such as record-keeping;

Offences and penalties

15 agree that, where the Crown is carrying out activities in the same way as a private actor (eg, manufacturing a device) it will have the same legal liability;

16 agree that the Bill will include a civil pecuniary regime;

17 agree to an offence of improper inducement of a health practitioner to make a clinical decision about a medical product;

18 agree to a fit and proper person test to be applied as part of decision-making on a licence, permit, or other approval;

Enabling Medsafe to continue to carry out regulatory functions under the Medical Products Bill

19 agree regulatory functions being formally vested in a statutory officer supported by the Ministry of Health (in practice through Medsafe);

20 agree that the statutory officer must be a public servant (or be employed as a public servant on appointment), appointed by the Director-General of Health;

21 agree that Medsafe and the regulation of medical products will continue to be funded mostly through cost-recovery, with the addition of levies;

22 agree that the objective of the statutory officer will be to operate the medical products regulatory regime independently, while being:

22.1 accountable to the Director-General of Health for the general performance of their functions and powers;

22.2 subject to general policy directions issued by the Minister of Health in relation to medical products;

22.3 required to publish a regulatory strategy setting out their performance expectations and how they will perform their functions;

23 agree to draw on the list of regulator functions in section 339 of the Therapeutic Products Act 2023 as well as subparts 2 (cost recovery), 3 (information), 4 (decision making and exercise of powers) and 6 (review of Regulator's decisions) of Part 9 of the Therapeutic Products Act, with modifications consistent with Cabinet's decisions;

Drafting instructions and timing

24 authorise the Associate Minister of Health to issue drafting instructions to give effect to these decisions;

25 note that I intend to seek agreement from Cabinet to introduce the Bill to Parliament in 2026.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health

Appendix 1: Indicative offences to apply to the Crown

Provision	Extent of liability for Crown organisations
Product approval required to import or supply (where applicable)	Prosecution or infringement fine
Sponsor's consent required to import approved product	Prosecution or infringement fine
Authorisation required for controlled activity	Prosecution or infringement fine
Persons in supply chain must comply with regulations and/or rules	Prosecution or infringement fine
Activity with prohibited product without authorisation	Infringement fine only
Tampering with medical product	Prosecution or infringement fine
Supply of tampered-with medical product	Prosecution or infringement fine
Notifying of suspicion of tampering	Infringement fine only
Misrepresentation about medical product	Prosecution or infringement fine
Misleading information in records	Infringement fine only
Sponsor must notify of certain changes	Prosecution or infringement fine
Sponsor of approved product must ensure compliance with approval	Prosecution or infringement fine
Sponsor must ensure compliance with product standards	Prosecution or infringement fine
Sponsor must comply with regulations and/or rules	Prosecution or infringement fine
Licensee must ensure responsible person and/or health practitioner has authority and resources	Infringement fine only
Responsible person must comply with regulations and/or rules	Infringement fine only
Licensee must ensure only authorised persons carry on pharmacy activities	Infringement fine only
Compliance with directions order	Infringement fine only
Compliance with product prohibition order	Prosecution or infringement fine
Misleading information to regulator	Infringement fine only
Compliance with investigative requirements	Infringement fine only

Appendix 2: Grounds for Regulatory Impact Statement (RIS) exemptions

Proposal	Exemption ground	Supporting information
Advertising provisions Improved definition; enabling promotion of unapproved products in some situations	**Minor or limited impacts**	Will continue status quo from Medicines Act 1981 as modified by Medicines Amendment Bill
Crown liability The Crown to be held liable for contraventions in the same way as a non-Crown actor	**Duplication** A RIS was carried out for the Therapeutic Products Bill and the substantive policy and options have not changed	RIS: Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 1 (Civil Pecuniary Penalties and Crown Liability), 4 November 2022
Civil pecuniary penalty regime Enabling non-criminal monetary penalties imposed by a court after a civil trial	**Duplication** A RIS was carried out for the Therapeutic Products Bill and the substantive policy and options have not changed	RIS: Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 1 (Civil Pecuniary Penalties and Crown Liability), 4 November 2022
Fit and proper person test Enabling assessment of sponsors for new medicines or applicants for licences	**Minor or limited impacts** Consistent with existing frameworks	Medicines Regulations 1984, regulation 45
Attribution of liability Clarifying the liability of senior managers and corporations for actions of employees	**Minor or limited impacts** Consistent with existing frameworks	Medicines Act 1981, sections 79 and 82
Inducement of health practitioner offence Creating an offence of improper inducement of a health practitioner to make a clinical decision about a medical product	**Minor impact**	Medicines Act 1981, section 76A
Statutory timeframes for decision makers and applicants	**Maintains status quo; minor or limited impacts**	Medicines Act 1981, s30(4); Medicines Amendment Bill, clause 7
Enabling certification of exported medical products	**Maintains status quo**	Medsafe currently do this
Requiring medical products exporters to register	**Minor impact**	Registration will not involve any assessment, or ability to decline a registration