Briefing for decision

Offence and penalty proposals for the Medical Products Bill

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To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Simeon Brown, Minister of Health Hon David Seymour, Associate Minister of Health		
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Minister's office to complete:

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☐ See Minister's Notes	☐ Withdrawn	

Comment:

Briefing for decision

Offence and penalty proposals for the Medical Products Bill

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To:	Hon Casey Costello, Associate Minister of Health		

Purpose of report

1. This briefing provides you with proposals for offences and penalties in the Medical Products Bill.

Summary

2. In September 2024, Cabinet agreed to high-level policy settings for a new Medical Products Bill (the Bill), and invited you to report back on offences and penalties [CAB-24-MIN-0380].

3. This briefing seeks your decisions on five proposals for the Bill:
   - a modern offence and penalty framework, with regulatory offences and harm-based offences
   - a civil pecuniary penalty
   - extending liability to the Crown for some offences
   - defences, attribution of liability, and a fit and proper person test
   - deterring and preventing the improper inducement of a health practitioner.

4. The status quo for offences and penalties in the Medicines Act 1981 is out of step with modern legislation. There are very few non-criminal sanctions, limiting the ability to proportionately address non-compliance. In addition, financial penalties are too low to deter wrongful conduct, particularly if commercially motivated.

5. We propose a range of penalties for the Bill, with higher penalties for intentional and harmful conduct, including imprisonment for the most serious offences. If penalties are not sufficiently robust, or if the regulator does not have a range of enforcement tools, large companies may consider financial penalties a cost of doing business. Robust penalties also send an important signal of the seriousness of specific behaviours.

6. We also propose including:
   a. a civil pecuniary penalty regime for financially motivated wrongful conduct, enabling courts to impose a monetary penalty based on the potential 'gain' of the offence
   b. enforceable undertakings, which are a low-cost and legally binding enforcement tool for regulators, involving a promise to remedy bad practice.

7. Where the Crown provides health services, we propose that it be liable in the same way as other healthcare providers. This approach to Crown liability has been adopted in other areas where the Crown engages in similar activities to private companies (eg,

under building and workplace health and safety law). The Crown would not be liable for actions unique to Government, such as the allocation of resources or decisions to fund or not fund a particular medicine.

8. Recognising that the medical product supply chain is complex and involves many people, we propose that the Bill include defences for individuals who rely in good faith on other people in the supply chain. Likewise, defences should be available where a person takes reasonable steps to avoid harm. We propose that the Bill contain other defences as appropriate to ensure fairness to parties and enforcement officers.

9. Conversely, senior managers and those exercising control over their companies or organisations should not be able to escape liability through wilful blindness or negligence. As such, we recommend that the Bill include 'attribution of liability' provisions, and for senior managers and boards to be liable for the unlawful conduct of their employees where they fail to take reasonable steps to prevent the conduct occurring.

10. Finally, to ensure health practitioners continue to prioritise their patients' interests, and make decisions based on clinical need, we propose to make it an offence for a medical product sponsor or representative to offer an improper inducement to a practitioner. This offence would work alongside professional disciplinary processes.

11. Following your consultation with interested Ministers, the Ministry will prepare a Cabinet paper on the Bill's offence and penalty regime. We recommend you take this paper to Cabinet in April/May 2025.

Recommendations

We recommend you:

a) **Note** that this briefing proposes that the Medical Products Bill:

1) include a tiered approach to offences and penalties, with intentional and serious conduct punishable by fines and imprisonment, and lower-level breaches punishable by fines

2) include 'civil pecuniary penalties' for financially motivated offending

3) extend civil and criminal liability to the Crown for some contraventions

4) include a range of defences, including where a person reasonably relied on a statement made by a third party

5) include a fit and proper person test; and provisions allowing for the conduct of employees to be attributed 'upwards' to senior managers, where they failed take reasonable steps to prevent a breach of the law

6) include an offence of offering (or accepting) an improper inducement to a health practitioner to influence a clinical decision about a product

b) **Provide** your feedback on the proposals in this paper

c) **Share and discuss** this briefing with Hon Simeon Brown, Minister of Health and Hon David Seymour, Minister of Regulation **Yes / No**

d) **Agree** to the Ministry drafting a Cabinet paper on offences and penalties for the Medical Products Bill **Yes / No**

Maree Roberts
Deputy Director-General
Strategy, Policy and Legislation
Date: 27/03/2025

Hon Casey Costello
Associate Minister of Health
Date:

Offence and Penalty proposals for the Medical Products Bill

Background

12. In September 2024, Cabinet agreed to a high-level policy setting for a new Medical Products Bill (the Bill) [CAB-24-MIN-0380]. Offences and Penalties were identified as requiring a separate review and report back.

13. In developing these proposals, we have considered the status quo under the Medicines Act 1981, modern regulatory legislation in New Zealand and in comparable regimes, and feedback from stakeholders (including industry and Medsafe's compliance area) on the Therapeutic Products Bill and the proposed Medical Products Bill.

14. An effective compliance and enforcement regime, including appropriate offences and penalties, is a necessary part of a new medical products regulatory regime. There are various risks associated with the manufacture, storage and use of medicines and medical devices and the regulator will need appropriate tools to discourage and respond to unlawful or reckless conduct, or contraventions of regulatory requirements.

15. While many enforcement tools are reactive in nature (such as fines and licence suspensions) others, such as requiring applicants to be 'fit and proper persons', can reduce the chance of harms occurring in the first place. Likewise, enforceable undertaking can be used to prevent a harm repeatedly occurring and to shift workplace culture.[1]

16. This briefing will focus on five key proposals:

    a. including a modern offence and penalty framework in the Bill (relative to the Medicines Act 1981) – with regulatory offences and harm-based offences

    b. including a civil pecuniary penalty regime within the Bill

    c. extending liability to the Crown for certain contraventions of the Bill

    d. defences, attribution of liability and the inclusion of a fit and proper person test

    e. deterring and preventing the improper inducement of a health practitioner.

Proposals

17. The status quo under the Medicines Act for offences and penalties is out of step with modern legislation as there are very few non-criminal sanctions. This places patients at risk as Medsafe has few tools (other than prosecutions) to deter and punish harmful conduct. While criminal prosecutions may be necessary and justified in some instances, they are complex and costly for regulators – which reduces their use.

[1] **Enforceable undertakings are legally binding agreements outlining specific actions a party has offered to take to address issues of non-compliance with the law. If the party contravenes an enforceable undertaking, the regulator can seek to enforce it in Court, and a Court may also impose financial penalties for the non-compliance.**

18. Penalties that are sufficient to deter harmful conduct are an important measure in ensuring patient safety. The regime will offer outcomes that will ultimately serve to protect patients while promoting trust, confidence and the deterrence of harmful conduct. Moreover, not all offences deserve criminal prosecution, but patient welfare requires that action is taken to prevent the conduct occurring again. It may be helpful to have more options suited to different levels of offence. The offence and penalty framework must provide the regulator with appropriate tools to address the nature of offending, such as infringement notices and enforceable undertakings.

19. The following table provides an overview of different enforcement tools, when they may be used and what purpose they are intended to serve:

Table 1: Overview of enforcement tools and their rationale

Type of enforcement tool	**Common rationale for use**	**Purpose**
Criminal prosecution	To punish and denounce breaches of the law that are intentional, wilful or are reckless as to the possibility of harm. Prosecutions can deter repeat conduct by the defendant and deter others from acting the same way.	Punitive
Civil pecuniary penalties	To punish and deter breaches of the law that are financially motivated and do not justify a full criminal sanction.	Punitive
Enforceable undertakings	Where a negotiated agreement can achieve an overall better change to individual/ corporate behaviour to achieve an effective regulatory outcome.	Largely protective in nature – can become punitive if undertaking breached
Fines (infringement notices)	To punish and deter usually minor or technical breaches of the law.	Corrective-punitive
Administrative actions, eg, licence suspension/ cancellation, additional conditions, recall orders etc	Intended to protect individuals, the community or the proper functioning of the regulatory system. *Note: some administrative actions (eg, licence and product cancellation) can have as significant a commercial impact on an individual or corporation as a criminal or civil pecuniary penalty).*	Protective
Measures not discussed in this Briefing	Injunctions to stop or require certain conduct; 'name-and-shame' provisions.	

Modernising the offence and penalty framework

What we propose

20. We propose to include a tiered offence provision in the Bill. The status quo for offences and penalties in the Medicines Act is out of step with modern legislation as it adopts a one-size approach to punishing wrongful conduct. While some contraventions of the law may be minor and administrative in nature; others might be motivated by commercial gain, or result in real and serious harms to individuals and the public. Consistent with other modern regulatory laws, we recommend that the Medical Products Bill have a fit-for-purpose offence and penalty regime that can both respond to and deter wrongful conduct.

21. Specifically, we propose adopting a modern approach to offences and penalties in the new Medical Products Bill. This would include having different offences and penalties for:

    a. conduct that was intentionally undertaken and was reckless to the harm it could cause to people (the most serious offending), which could be punished through significant financial penalties or even imprisonment

    b. contraventions of an important regulatory rule, which may be accidental or the result of negligence (mid-level offences), which could be punished through financial penalties

    c. contraventions of minor, administrative or technical rules, which could be punished through a small fine or a warning letter (low-level offences).

22. This approach ensures that penalties are proportional to the severity of the offence, fair to individuals and organisations, and effective in deterring future breaches while encouraging compliance.

23. High maximum penalties, including possible imprisonment, would emphasise the seriousness of specific behaviours and prioritise protecting public health and safety. High penalties incentivise companies to comply with strict standards. It also discourages other organisations or individuals from committing similar offences or reoffending and provides a level of accountability to those who offend. Deliberate tampering with a medicine (for example adulterating or fraudulently diluting a product) can create serious risks to individual patients and wider public harms.

24. Mid-level offences include contraventions of a regulatory standard or rule. In common with similar legislation (such as the Food Act 2014), we propose that most of these offences be 'strict liability' offences. In a prosecution for a strict liability offence, the prosecution does not need to prove that the defendant intended to commit the offence. However, the Bill would include defences, for example that a person took reasonable steps to comply with the law, or reasonably relied on an assurance provided by another person in the supply chain (eg, a manufacturer).

What do stakeholders think?

25. Medsafe and its compliance area have argued that the current offence and penalty regime does not present a deterrence to large companies or financially motivated misconduct. Submitters on the Therapeutic Products Bill raised few concerns with the adoption of higher penalties and a strict liability regime. In general, consumer groups

favoured stronger penalties. Industry groups requested that offence provisions be worded clearly so that businesses knew what was expected. Our recent engagement with industry groups has emphasised that their interests are primarily in ensuring offence provisions are clearly worded.

26. Opposition from submitters on the Therapeutic Products Bill to high penalties (eg, imprisonment), was mostly in relation to natural health product-related offences. This concern no longer arises as the Government has already agreed to a standalone bill for NHPs and that this bill include its own offences and penalties.

27. Moreover, even if a high penalty is included in legislation, it is up to the courts to determine an appropriate sentence, considering all relevant factors.

28. The only other concerns about the offence and penalty provisions are related to the offences associated with advertising, given there is the potential for certain forms of speech and communication activities to be inadvertently captured. This briefing does not seek agreement to advertising offences or penalties, which will be included in a separate briefing on advertising regulation.

29. An indicative list of offences is set out in **Attachment 1**

We recommend including a civil pecuniary penalty regime in the Bill

What we propose

30. Civil pecuniary penalties are non-criminal monetary penalties imposed by a court after a trial and can be linked to the improper profit gained, commercial loss wrongly avoided or the turnover of a company. Reflecting the non-criminal nature of a pecuniary penalty, a trial is conducted under rules of civil procedure and evidence where liability is established on the civil standard of proof (the balance of probabilities), which is lower than the criminal standard of proof (beyond reasonable doubt). A penalty order is not a conviction, although it may be relevant to a fit and proper person assessment.

31. Civil pecuniary penalties broaden the range of compliance options for the regulator. Without the risk of substantial pecuniary penalties, large multinational entities may consider the benefits achieved through breaching regulations are an acceptable cost of business. International evidence suggests that enabling civil penalties is justified. For instance, a 2020 study in the United States found that, of the 26 largest pharmaceutical companies, 85% had financial penalties imposed on them for illegal activities between 2003-2016 – totalling USD33 billion.[2]

32. Civil pecuniary penalties are becoming more common in modern regulatory laws in New Zealand and abroad. They are available under the Commerce Act 1986, Telecommunications Act 2001, the Australian Therapeutic Goods Act 1989, and in the new Gene Technology Bill. The Food Act 2014 likewise allows a court to fix a penalty of up to three times the value of the commercial gain from the contravention, or – if not readily assessable – up to 10% of the defendant's combined turnover.

[2] **Arnold DG, Stewart OJ, Beck T. Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities. JAMA. 2020 Nov 17;324(19):1995-1997**

33. Including a civil pecuniary penalty regime in the Bill can make enforcement more efficient and effective by avoiding lengthy and expensive criminal litigation. It can also be more appropriate where behaviour or misconduct stems from corporate culture, and it is challenging or unreasonable to expect the regulator to identify a specific individual who possessed the necessary criminal intent.

34. Civil pecuniary penalties will not be suitable for all breaches of the law, especially where serious or direct harm was inflicted on a member of the public, or where the conduct was so egregious that it is appropriate to respond to it via a criminal trial and conviction. However, we recommend that the Bill include a civil pecuniary penalty regime as part of a full suite of enforcement tools.

What do stakeholders think?

35. General concerns over the use of civil pecuniary penalties include their lower burden of proof and the higher financial penalties that can be ordered against a defendant. While this may make them a more attractive option for the regulator, it raises issues of fairness to defendants, who will not have available the usual protections that accompany a criminal trial, conducted under the rules of criminal proceedings.

36. Nonetheless, similar provisions in the Therapeutic Products Bill did not attract adverse comments from submitters, nor from the Ministry of Justice's offence and penalty vetting team. Other aspects of the justice system (including rules of Court and the Evidence Act) provide important guarantees of fairness for a defendant. Industry stakeholders have not raised any concerns about civil pecuniary penalties with use during recent consultation on the Medical Products Bill.

Crown liability for certain contraventions of the new Bill

What we propose

37. In New Zealand, most healthcare is delivered in the publicly owned or funded sector. Public hospitals, for example, are significant actors in the procurement, supply and even manufacture of medical products. When people seek treatment, they rightfully expect that the quality of that treatment (including the products used on or in them), and accountability for conduct, is the same – regardless of whether it is a private or public organisation that provides the service.

38. In general, the Crown is not criminally liable for contraventions of the law unless a law explicitly says so. Without clarity over the liability of the Crown, it can also be difficult (if not impossible) to hold Crown employees to account for contraventions of the law. We propose that the Medical Products Bill provide for Crown liability in limited circumstances.

39. Under this proposal, Crown organisations (which includes departments and Crown entities) and their employees, senior managers and Boards would be liable for infringement fines and criminal penalties. Prosecutions against Crown organisations will be in accordance with the Crown Organisations (Criminal Liability) Act 2022. In addition, the regulator will be able to apply for injunctions against Crown organisations and enter into enforceable undertakings.

40. Extending liability to the Crown must be done explicitly in legislation. Crown liability was not common when the Medicines Act was first introduced. We now have an opportunity to make an active decision about extending liability in modern legislation.

41. In the Crown Organisation (Criminal Liability) Act 2002, there are only six laws where a criminal proceeding can be instituted against a Crown organisation.[3] Notably, most of these laws are ones where there would be a community expectation that a Crown Organisation would be treated the same as any other person or organisation, given the nature of the activities engaged in.

42. Crown liability can ensure better compliance with the Bill's requirements and clearly signal to the public that the Crown is held accountable for its actions. Given that the Crown is a significant player in the medical products supply chain, the Crown should be held equally liable as private actors. We consider it more likely that compliance action would be taken against an employee of a Crown organisation, rather than the organisation itself. For example, a practitioner who manufactures a medical device and uses it on patients contrary to the rules about medical device safety would be held liable for that contravention, regardless of whether they work for the Crown or in private practice.

43. Promoting trust and confidence in the new medical products regulatory regime is important, and not extending liability to the Crown risks creating cultures of impunity and practices that are harmful or detrimental to the long-term confidence of industry and the public, and which can undermine the regulatory regime.

What do stakeholders think?

44. As key health entities, we have circulated this briefing to Health New Zealand and Pharmac. We also considered feedback from Crown organisations on similar proposals in the Therapeutic Products Bill.

45. We note that criminal sanctions may not be the appropriate tool for discouraging behaviour from Crown organisations where such behaviour could be in response to funding and resource constraints. Budget decisions are a special Crown activity and are not traditionally subject to judicial questioning. This extends to decisions by Crown organisations (eg, Pharmac) over the allocation of limited funding to, for example, subsidise the cost of certain medicines.

46. In response to feedback from Crown organisations, we propose that Crown liability not extend to decisions of this nature; or to decisions made by the medical products regulator to approve or not approve a product. A decision to approve or not approve a product would, however, be subject to appeal and judicial review as an administrative decision.

47. Likewise, it should not be a criminal offence for Pharmac to make an urgent decision to substitute an unapproved medicine for an approved one in response to supply disruptions. Rather, the Bill will allow for this activity to be planned for and enabled via

[3] **Those laws are the Building Act 2004; Health and Safety at Work Act 2015; Resource Management Act 1991; Exclusive Economic Zone and continental Shelf (Environmental Effects) Act 2012; parts of the Children's Act 2014; and the Water Services Act 2021.**

secondary legislation, license or permits, or through work arrangements between the regulator and Pharmac. This appropriately manages risks associated with unapproved medicines.

48. Another potential objection to extending liability is that uncertainty over which provisions apply to Crown organisations could create a fear of liability and risk-averse cultures. Adopting a per-offence approach to extending liability, and including defences for good faith performance of duties, will help mitigate this concern. An indicative list of proposed offences for which the Crown could be liable is included in **Attachment 1**.

Defences, attribution of liability and the fit and proper person test

What we propose

49. In criminal and civil proceedings, a defendant may be able to rely on a **defence** to avoid liability. Defences ensure individuals or companies are not penalised for unintentional or unavoidable breaches. We recommend that the Bill include defences reflecting the practical realities of modern, global supply chains – where people at one end of the supply chain (eg, distributors and prescribers) have to rely on upstream actors (eg, manufacturers). For instance, we recommend that the Bill make it a defence that a contravention was due to a person's reliance on information given to them by another person and that reliance on that information was reasonable.

50. We also recommend that the Bill make it a defence that a person took all reasonable steps to prevent a contravention from occurring. This defence is particularly relevant when considering the responsibility of senior managers and 'attribution of liability'.

51. **Attribution of liability** refers to the process of determining who is legally responsible for harm, damage, or loss in civil or criminal matters. Where contraventions occur because of a negligent or criminal corrupt culture, or wilful blindness by senior managers, liability can be attributed 'up' from individual employees to a company's senior management. This ensures the right party is held to account. Attribution of liability would apply to private and public entities, including Health New Zealand.

52. Attribution of liability provisions are commonplace in comparable regulatory regimes, and already exist in the Medicines Act. For example, section 244 of the Food Act 2014 includes attribution of liability provisions that hold directors and managers liable where the company commits an offence. The Water Services Act 2021 also includes similar provisions for the liability of a company's directors and officers. We recommend that the Bill include provisions allowing for liability to be attributed upwards from individual employees to the senior managers and the employer. We also recommend that, where a company is convicted of an offence, the 'controlling minds' of the company (eg, CEO and board) can also be held liable for the contravention.

53. In both scenarios, it would be a defence that a person did not know, or could not reasonably have known, about the contravention; or that the person took all reasonable steps to prevent the contravention from occurring.

54. Finally, we recommend that the Bill include a **fit and proper person test** that would be applied by the regulator as part of determining whether to issue a market approval, licence or permit. A fit and proper person test is common to other regulatory regimes

and ensures individuals or entities involved in the supply, manufacture or regulation of medical products meet certain standards of integrity, competence, and reliability.

What do stakeholders think?

55. We have received feedback from stakeholders and have also considered Hon Dr Shane Reti's 2023 Supplementary Order Paper to amend the fit and proper person test in the Therapeutic Products Bill. The effect of Hon Dr Reti's amendment would have been to reduce the length of time that the regulator could take in assessing a person's fitness and clarifying that they could only consider the conduct of an applicant's senior managers if those managers were in New Zealand.

56. We propose to adopt these proposed changes in a new fit and proper person test in the Bill. This will ensure that the new Bill's enforcement regime is workable and balances the rights of the defendant with the ability of the regulator to take appropriate action to prevent individual and community harm.

We recommend including an offence of improper inducement of a health practitioner to make a favourable clinical decision about a medical product

Background to the need for an improper inducement offence

57. Prescribers, pharmacists, and procurers of medical products have a significant influence on the medical products used in the health system and by patients. A decision to recommend the use of a medicine, for example by prescribing or dispensing it, should be based on the clinical needs of a patient – and not on an ulterior or improper motive.

58. Evidence suggests that the relationship between industry and practitioners can influence clinical practice and drug prescribing. Globally, undisclosed commissions, 'kick-backs' and other forms of inducements to health practitioners have been shown to influence their prescribing behaviour. Partially in response to this, a number of pharmaceutical companies in New Zealand already release transparency reports, detailing the 'transfers of value' to healthcare professionals.[4] However, compliance with these guidelines is voluntary and a matter for industry self-regulation.

59. The existence of a single-payer system (Pharmac) may limit the scope for industry to influence prescribing decisions in terms of one brand over another. However, not all medicines are funded, and not all health care is publicly funded. There are also many medicines which continue to be prescribed by practitioners outside of Pharmac funding.

60. Improper inducement of health practitioners undermines the ability for patients to give informed consent to treatment and risks unnecessary (and potentially harmful) care. In addition to the risks to patient health, it can result in wider public health harms – such as the inappropriate use of antibiotics (contributing to resistance), drugs of addiction, or wastage of taxpayer funds.

61. Under the Medicines Act, there are no restrictions on inducement of a health practitioner by the sponsor of a medical product – although there is a narrow prohibition on pharmacists/pharmacy owners giving or offering commissions to authorised or

4 Medicines New Zealand Transparency Guidelines 15 October 2020.

delegated prescribers for prescriptions.[5] Comparable jurisdictions such as the US, EU and UK have controls in place to prevent or reduce improper inducement of health practitioners.

What do we propose?

62. We recommend that the Bill include an offence for offering a benefit to a health practitioner. Moving away from a purely self-regulatory approach and the limited prohibition in the Medicines Act, the new provision would prohibit:

    a. inducing a practitioner to make a favourable clinical decision about a therapeutic product in the interest of industry and not the patient; or

    b. rewarding a practitioner for making such a decision.

63. Including an offence of improper inducements would also provide an important safeguard for widening the scope of practitioners who can prescribe medicines, or supply unapproved medicines. Previous submissions on this in the Therapeutic Products Bill supported the inclusion of improper inducement.

64. However, having engaged with stakeholders on this proposal, and taking into account feedback on the Therapeutic Products Bill, we recommend that the provision:

    a. provide greater recognition of existing industry disclosure guidelines and practices

    b. make non-compliance by a health practitioner a professional disciplinary matter rather than a criminal matter.

65. We acknowledge that industry and professional groups are already engaged in some activity in this area but believe that legislation can support and strengthen those efforts. For example, the Bill could extend the application of codes of conducts to all individuals and companies engaged in a relevant activity (and not merely members of a professional or industry group). While the Bill could set clear examples of improper conduct, guidelines would provide for more nuanced rules and operational matters.

66. In relation to practitioner conduct (ie, accepting an improper inducement), we recommend that the regulator can use existing mechanisms, and refer a suspected contravention to the relevant Responsible Authority. The Responsible Authority would then be responsible for determining whether the practitioner's conduct amounted to professional misconduct and if so, the appropriate penalty.

67. For example, in extreme cases a medical practitioner could have their license suspended or revoked. There are already mechanisms for protecting patients against violations of professional conduct. There is no responsible authority equivalent that applies to pharmaceutical companies, the benefactors. A similar referral-power operates under the End-of-Life Choices Act.

[5] **Under the Medicines Act it is an offence for a pharmacist, person licensed to operate a pharmacy, or operator or manager of a pharmacy to give, offer, or agree to give to any authorised prescriber or to any delegated prescriber or to any other person any money or other consideration as a commission on prescriptions.**

What do stakeholders think?

68. Medicines New Zealand already operate a disclosure regime through 'Transfer of Value' reporting for medical practitioners that provides a useful model for any future regime. The Medical Technology Association of New Zealand (MTANZ), which represents medical device manufacturers and importers, likewise believe improper inducement is an issue that needs to be addressed.

69. MTANZ and Medicines New Zealand caution that any offence provision should be clearly worded so that industry understands what is required of them. They also do not support disclosure regimes that create onerous reporting duties or centralised reporting (ie, to the regulator). However, we believe that a proposal that builds off the existing voluntary disclosure regime led by industry will meet the expectations of the community and not create obligations that differ from those expected in other countries that operate disclosure regimes. Specifically, we are not proposing a centralised reporting regime.

70. The approach we propose would see a clearly worded inducement offence provision and respond to industry concerns. Initially, improper inducement by a sponsor would be an offence but, eventually, the regulator, industry and practitioners could agree to guidelines to further clarify the operation of the provision.

71. We note that while industry might have reservations about this provision, its inclusion in the Therapeutic Products Act was generally supported by patient groups.

Equity

72. An effective offence and penalty regime ensures there is fairness, proportionality and consistency in how penalties are applied for the protection of New Zealand citizens in general. The proposal to extend liability to the Crown signals that all actors within the sector (whether public or private) can and will be held to account through a robust enforcement regime.

Next steps and timing

73. We recommend that you discuss the proposals in this paper with officials before circulating a copy to Hon Simeon Brown (Minister of Health) and Hon David Seymour (Minister for Regulation; Associate Minister of Health).

74. Once Ministers have provided feedback about the matters covered in this paper, we will draft a Cabinet paper and Regulatory Impact Statements for your consideration.

75. We are aiming to have the offence and penalty decisions sent to Cabinet by the end of Quarter 2 2025 [see briefing H2024057261].

ENDS.

Appendix 1 – Indicative list of offences and penalties

Provision	Criminal offence	Infringement offence	Civil pecuniary penalty	Crown liability
Product approval required to import or supply	Yes	Yes	Yes	Prosecution or infringement fine
Sponsor's consent required to import approved product	Yes	Yes	Yes	Prosecution or infringement fine
Authorisation required for controlled activity	Yes	Yes	Yes	Prosecution or infringement fine
Authorisation required for non-wholesale supply of prescription medicine	Yes	No	No	Prosecution or infringement fine
Persons in supply chain must comply with regulations	Yes	Yes	Yes	Prosecution or infringement fine
Supplying etc… a prohibited product without authorisation	Yes	No	No	Infringement fine only
Tampering with therapeutic products	Yes	No	No	Prosecution or infringement fine
Supply of tampered-with therapeutic products	Yes	No	No	Prosecution or infringement fine
Notifying regulator of suspicion of tampering	Yes	Yes	Yes	Infringement fine only
Misrepresentation about therapeutic product	Yes	Yes	Yes	Prosecution or infringement fine
Holding out misrepresentation	Yes	No	Yes	No
Agreeing or offering to carry on supply chain activity unlawfully	Yes	Yes	No	No
Obtaining therapeutic product when supply is unlawful	Yes	Yes	No	No
Misleading information in records	Yes	Yes	Yes	Infringement fine only

Provision	Criminal offence	Infringement offence	Civil pecuniary penalty	Crown liability
Sponsor must notify Regulator of certain minor changes	Yes	Yes	No	Prosecution or infringement fine
Sponsor of approved product must ensure compliance with approval	Yes	Yes	Yes	Prosecution or infringement fine
Sponsor must ensure compliance with product standards	Yes	Yes	Yes	Prosecution or infringement fine
Sponsor must comply with regulations	Yes	Yes	Yes	Prosecution or infringement fine
Licensee must ensure responsible person has authority and resources	Yes	No	Yes	Infringement fine only
Licensee must ensure health practitioner has authority and resources	Yes	Yes	Yes	Infringement fine only
Licensee or manager must not induce health practitioner to act unprofessionally	Yes	Yes	Yes	No
Responsible person must report non-compliance	No	Yes	No	No
Protection of responsible person from retaliation	Yes	No	Yes	No
Responsible person must comply with regulations	Yes	Yes	No	Infringement fine only
Licensee must ensure only authorised persons carry on pharmacy activities	Yes	Yes	Yes	Infringement fine only
Compliance with recall order	Yes	No	Yes	No
Compliance with premises restriction order	Yes	Yes	Yes	No

Provision	Criminal offence	Infringement offence	Civil pecuniary penalty	Crown liability
Compliance with directions order	Yes	No	No	Infringement fine only
Compliance with product prohibition order	Yes	No	No	Prosecution or infringement fine
Misleading information to regulator	Yes	Yes	Yes	Infringement fine only
Compliance with investigative requirements	Yes	Yes	No	Infringement fine only
Obstructing regulator	Yes	No	No	No
Compliance with enforceable undertaking	Yes	No	No	No