Regulatory Impact Statement: Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No 1.

Coversheet

Purpose of Document	
Decision sought:	Supplementary analysis produced to support Cabinet's decision to introduce the Therapeutic Products Bill to Parliament in 2022
Advising agencies:	Ministry of Health
Proposing Ministers:	Ministry of Health
Date finalised:	04/11/2022

Problem Definition

The Therapeutic Products Bill (the Bill) will replace the current Medicines Act 1981 (Medicines Act), and the Dietary Supplements Regulations 1985 under the Food Act 2014 (the DSR) to provide comprehensive regulation of therapeutic products (medicines, medical devices and natural health). It will also control a range of activities, including pharmacy businesses, manufacturing, and clinical trials.

The problems with the current Medicines Act are longstanding and have been examined in a previous regulatory impact statement (RIS) prepared in 2015 and 2016.[1] The DSR also have longstanding issues and were examined in a RIS in 2021.[2]

This RIS addresses two issues not previously examined.

Sanctions

The Bill does not include lower-level sanctions to address conduct that may not reach the level of criminal offending. It is important to have a suite of instruments that can respond to lower-level behaviours and practices before they escalate or cause compliance costs for all operators.

Crown Liability

The Crown is currently not criminally liable for breaches of the Medicines Act.

The Crown is a large user of therapeutic products, through entities such as hospitals and service providers. Crown organisations may also engage in supply chain and controlled activities such as importing, exporting, manufacturing, conducting clinical trials, compounding, dispensing and non-wholesale supply of therapeutic products.

In law, the convention is that the Crown is not held to be criminally liable unless the law specifically provides that it is. Given the large role the Crown plays in the health system in

[1] Available on the Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

[2] Available on the Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

New Zealand, it is useful to consider what the Crown's liability should be under the new Therapeutic Products Act (if any).

Executive Summary

Therapeutic products, which are medicines, medical devices and natural health products[3] are used by all New Zealanders in their everyday lives and in all parts of the health system. Because of the potential for serious harm from the use (and misuse) of therapeutic products and inequalities of power and information between all actors in the system, strict government oversight and regulation is appropriate.

Currently medicines are regulated under the Medicines Act. It has not kept pace with rapid advances in health technologies or developments in best practice regulation. For example, that Act provides little oversight of the increasing medical device and biologic medicines sectors (i.e., material taken from natural sources in scientifically advanced ways such as gene and tissue therapies).

In 2015, Cabinet agreed to repeal and replace the Medicines Act with a new Therapeutic Products Bill (the Bill) [SOC-15-MIN-0049] and regulatory regime. In March 2016, Cabinet also agreed that the Bill include a hierarchy of enforcement tools to support a new offence and penalty framework. In July 2021, Cabinet agreed to include natural health products in the Bill.

This supplementary RIS examines options to address issues that were not explored in the previous RIS, specifically the inclusion of a civil pecuniary penalty regime and extending civil and criminal liability to the Crown.

The regulator will need a range of tools to effectively ensure compliance by actors throughout the therapeutic product's lifecycle.

Civil pecuniary penalties are non-criminal monetary penalties imposed by a court after a trial. They may be an appropriate enforcement tool where the conduct engaged in is in breach of the law but does not reach the level of requiring a criminal law response. Like criminal penalties, they can have a deterrent function.

Civil pecuniary penalties broaden the range of compliance options for the regulator to address non-criminal breaches of regulation. These are particularly important for ensuring accountabilities for all and provide for a safe and competitive market for all operators to engage within.

Of the options considered, our preferred option is to include Civil pecuniary penalties in the Bill.

The Crown has an extensive and, in some areas (e.g., the provision of acute care), dominant role in providing healthcare in New Zealand. It is logical and reasonable to extend criminal and civil liability to the Crown organisations responsible for healthcare delivery.

Out of the options regarding liability of the Crown, our preferred option is to extend criminal and civil liability to Crown organisations for contraventions of the Therapeutic Products Bill and its future regulations.

[3] Natural health products include dietary supplements, preparations used in complementary and traditional medicines such as rongoā Māori, long-established practices such as Chinese medicine, and western practices such as aromatherapy and homeopathy.

Limitations and Constraints on Analysis

Policy constraints

This supplementary analysis is limited in scope to new policy decisions regarding the Bill's content, and it builds upon previous work and Cabinet decisions. Relevant Cabinet decisions include:

- Cabinet's 2015 agreement to repeal and replace the Medicines Act with a new Therapeutic Products Bill (the Bill) [SOC-15-MIN-0049] and regulatory regime, with the following objectives:
    - [Safe] - meet expectations of risk management and assurance of safety
    - [Efficient] - result in efficient and cost-effective regulation
    - [Flexible] - be flexible, durable, up-to-date, and easy to use
    - [Quality decisions] - ensure high-quality, robust and accountable decision-making
    - [Capacity] - foster sustainable regulatory capacity
    - [Economy] - support New Zealand trade and economic objectives
    - [Trust] - be trusted and respected
    - [Access] - support consumer access and individual responsibility for care.
- Cabinet's 2015 agreement that the objectives for the regulatory regime be best met by (SOC-15-MIN-0050 and SOC-15-MIN-0049):
    - an enabling legislative framework
    - regulatory requirements that reflect international norms, standards and frameworks
    - a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable, and able to engage internationally.
- Cabinet's decision in July 2021 to include regulation of natural health products as part of the Bill [SWC-21-MIN-0109].
- Cabinet's decision in October 2021 to include a civil pecuniary penalty regime in the Bill [CBC-21-MIN-0117].
- Cabinet's decision in February 2022 to extend criminal and civil liability to Crown organisations [CAB-22-MIN-0039].

This analysis has been conducted in the context of the provisions of the 2018 exposure draft Bill.

Prior public consultation on the Bill

Public consultation on an exposure draft of the Bill and accompanying consultation document was undertaken between December 2018 and April 2019, and 442 submissions were received. That consultation did not address the proposals in this RIS, although the consultation document identified that the Ministry was considering this option (at [191]).

A summary of that feedback is available on the Ministry's website: https://www.health.govt.nz/system/files/documents/publications/submissions_on_the_therapeuticproducts_bill-keythemes_0.docx.

Consultation on civil pecuniary penalties and extending criminal and civil liability to the Crown

Cross-government consultation was separately undertaken on the specific proposal to include civil pecuniary penalties. The Ministry considered feedback from the Ministry of Justice, the Parliamentary Counsel's Office (PCO), the Legislation Design and Advisory Committee (LDAC) and the Public Service Commission. The application of civil pecuniary penalties to Crown organisations was also considered as part of that work.

Cross-government consultation was undertaken on the proposal to extend liability to Crown organisations. This included consultation with Crown Law, the Ministry of Justice, PCO, LDAC and the Public Service Commission on constitutional and policy issues associated with the proposal to extend criminal liability to Crown organisations.

In addition, the Ministry sought feedback from Crown organisations most likely to be affected by the proposals. To that end, the Ministry engaged with New Zealand Blood Service, interim Health New Zealand and the Māori Health Authority, Pharmac, the Health Research Council, ACC and the Transition Unit. Consultation with these agencies focused on associated implementation issues and ways to mitigate unintended consequences (such as risk aversion for governance created by potential liability).

The public was not included in the consultation process for these two proposals. However, the public will not be directly affected by Crown liability, as regulated parties will be Crown organisations.

Timing

The Government has expressed its intention to table the Bill in Parliament in late 2022.

Responsible Manager(s) (completed by relevant manager)
Tim Vines Manager, Therapeutics Policy Strategy, Policy and Legislation Ministry of Health 7 November 2022

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health, Papers and Regulatory Committee
Panel Assessment & Comment:	The Ministry of Health's Papers and Regulatory Committee has reviewed the supplementary analysis on civil pecuniary penalties and Crown liability which meets the quality assurance criteria, and the analysis was clear and concise, and the analysis convincing.

Civil Pecuniary Penalties

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo and context expected to develop?

1. The compliance regime in the Medicines Act 1981 is:
    a. outdated
    b. inflexible, unresponsive and not proportionate enough for the modern environment
    c. Has penalty levels that do not align with similar product regulation regimes (e.g., the Food Act 2014) and other public safety legislation (e.g., the Water Services Act 2021 and the Hazardous Substances and New Organisms Act 1996).
2. In 2015, Cabinet agreed to repeal and replace the Medicines Act with a new therapeutic products regime that meets the needs of the health sector now and into the foreseeable future. It is aligned with international regulatory and market settings (and New Zealand's small market), and the Government's expectations for regulatory regimes.
3. In March 2016, Cabinet agreed that the Bill include a hierarchy of enforcement tools to support a new offence and penalty framework. Cabinet also requested the Ministry to consider and report back on the inclusion of a civil pecuniary penalty regime in the future Bill.

<u>Civil pecuniary penalties as an additional enforcement tool to support a new offence and penalty framework</u>

4. The offences and penalties framework of the Bill must provide the Regulator with appropriate tools to address the level of offending. This includes providing a deterrent to all operators in the therapeutic products sector (including large, multinational companies) from engaging in unlawful conduct. Sanctions under the new regime must have a meaningful deterrent effect.

<u>The Crown's involvement in the therapeutic products supply chain and its continuation under the status quo</u>

5. In New Zealand, 'the Crown' (as represented by Crown organisations, including Crown entities, Departments, public servants, and publicly-funded health facilities) currently plays a central role in the delivery of healthcare. System-level activities engaged in by the Crown include procuring, importing and funding therapeutic products, supplying products to patients, health practitioners and hospitals and designing and operating some laboratory and testing facilities – for example, the wastewater and COVID-19 testing services operated by ESR.
6. In addition, a range of health care activities that involve therapeutic products are conducted in, or by, publicly-owned facilities (such as hospitals). These include, surgeries, in-patient and out-patient hospital services (such as chemotherapy), some pharmacy and laboratory services and clinical trials.
7. The role of the Crown in the therapeutic products supply chain is expected to continue under the new therapeutic products regulatory regime. It will have additional responsibilities and wider regulatory instruments to reflect a wider regime. The Crown

will act as both the regulator as well as an actor(s) within the therapeutic products supply chain.

8. For the Crown to be criminally liable, the courts have held that *"it is necessary for the Act to include very clear wording to that effect. It is not enough for the Act to be generally stated as binding the Crown"* (Cabinet Office circular CO(02)4).

9. Under the Medicines Act, the Crown could not be subject to enforcement measures for any contraventions to the Act and regulations.

10. Clause 6 (of the exposure draft) of the draft Therapeutic Products Bill provides that "this Act binds the Crown". Unless the Bill is amended, enforcement options against Crown organisations will continue to be limited.

11. The status quo does provide for a number of non-criminal accountability options, including internal review and the availability of judicial review. Existing, system-level accountability mechanisms also include:

    a. parliamentary oversight of Crown organisations, including select committees and petitions

    b. reviews by the Ombudsman and transparency via the Official Information Act

    c. measures under the Health Practitioners Competence Assurance Act 2003

    d. investigation by the Health and Disability Commissioner on any healthcare provider breaches to support consumer rights

    e. measures by Te Aka Whai Ora – the Māori Health Authority.

What is the policy problem or opportunity?

Civil pecuniary penalties

12. The regulator will need a range of tools to effectively ensure compliance by actors throughout the therapeutic product's lifecycle. To ensure the regime remains credible and that patient and public safety is (above all considerations) maintained, the regulator will need to be able to take appropriate and meaningful enforcement actions against all actors regardless of their interest or size.

13. One example of a gap in the enforcement tools contained in the exposure draft Bill was responses to lower-level offending.

14. There is an opportunity to refine the offences and penalties framework of the draft exposure Bill prior to its introduction to Parliament.

Extending civil and criminal liability to the Crown

15. The Crown will continue to play a significant (if not leading) role in the delivery of health care. It is likely that an adverse health care outcome consumers may experience in a healthcare context will in some way have a relationship or connection to the Crown.

16. These adverse events extend beyond treatment injuries (most of which are covered by the Accident Compensation Corporation) and can include those that involve the inappropriate use of therapeutic products, whether under the current Medicines Act or (hypothetically) under the proposed Therapeutic Products Bill.

17. Given the extensive role of the Crown in providing healthcare, not extending criminal and civil liability to the Crown organisations would be illogical and could even have

perverse outcomes such as diminished accountability from some actors towards patients and consumers of health technologies.

18. For example, scenarios where a Crown organisation may hypothetically contravene the future Therapeutic Products Act (the Act), include:

    a. A public hospital imports and stockpiles a therapeutic product that does not have market authorisation

    b. As a 'cost saving' activity, a Crown organisation directs its employees to sterilise and re-use medical devices that are approved only as 'single-use' devices (which constitutes an act of manufacturing)

    c. A Crown organisation manufactures in-vitro diagnostic testing devices (type of medical devices) for patients in accordance with a limited exemption under the Act. It then decides to supply excess devices 'at cost' to GP clinics. This activity is beyond the scope of the exemption and contravenes the requirements in the Act for medical devices to be approved prior to being supplied.

    d. A hospital conducts a 'pharmacy business' without a proper licence or undertakes pharmacy activities not in accordance with the conditions of its licence (e.g., it fails to properly report to the regulator or store medicines in accordance with relevant standards)

    e. The New Zealand Blood and Organ Service breaches a licence condition by failing to process and store blood products (e.g., plasma and platelets) in accordance with the appropriate standards.

Under the auspices of their Crown employer, medical practitioners conduct a clinical trial without first obtaining ethics approval or a waiver.What objectives are sought in relation to the policy problem?

19. Cabinet has previously agreed [SOC-15-MIN-0049 & SOC-15-MIN-0050] to the high-level objectives for the new therapeutic products regulatory system:

    a. Safe - meets expectations of risk management and assurance of safety

    b. Efficient - results in efficient and cost-effective regulation

    c. Flexible - be flexible, durable, up-to-date, and easy to use

    d. Quality decisions - ensure high-quality, robust and accountable decision-making

    e. Capacity - fosters sustainable regulatory capacity

    f. Economy - supports New Zealand trade and economic objectives

    g. Trust - be trusted and respected

    h. Access - supports consumer access and individual responsibility for care.

20. Cabinet also agreed that these objectives are to be realised through:

    a. an enabling legislative framework

    b. regulatory requirements that reflect international norms, standards and frameworks

    c. a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable, and able to engage internationally.

21. These objectives for the therapeutics regulatory scheme apply to all proposals considered in this supplementary RIS regarding the offence and penalty regime. The

objectives informed the development of the specific criteria that were applied in the assessment of different options for civil pecuniary penalties and Crown liability.

22. A robust enforcement regime will ensure all actors within the therapeutics sector can be held to account and help to deliver a modern and comprehensive regulatory scheme that provides equitable access to safe and effective therapeutic products.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

23. The following criteria have been applied to compare different options for including (or not) a civil pecuniary penalty regime and extending liability to the Crown (or not). These principles are derived from Cabinet's objectives for the regime (see discussion above) and have been applied generally to the review of the offence and penalty regime in the Bill. The criteria are:

    a. **Effectiveness** – the Regulator can bring the right type of action, against the right party that achieves an appropriate regulatory or criminological outcome (protection, correction of defective performance, deterrence, denunciation, restoration) and secure the integrity of the therapeutics regulatory regime

    b. **Justice** – reflects concepts of 'natural' justice (procedural justice, clarity of the penalty, knowability and certainty of the law), and ensuring fair treatment and fair outcomes for parties (including injured parties, the Regulator)

    c. **Responsiveness and efficiency**– the Regulator can exercise an appropriate degree of discretion in how it responds to alleged contraventions of the law, ensuring it is proportionate to the level of infraction including the circumstances of the conduct and the offender, and is actively able to monitor this

    d. **Clarity and certainty** – actors in the sector have confidence that like-cases will (generally) be treated alike and that the regulatory requirements are clear and knowable.

24. These qualitative criteria were applied through an unweighted quantitative Multi-Criteria Analysis.

What scope will options be considered within?

25. The scope of options has been influenced by a range of factors:

    a. Previous policy decisions –

        i. Cabinet has already set the high-level objectives for the new therapeutic products regulatory regime

        ii. Cabinet has already agreed to include a civil pecuniary penalty regime in the Bill (CBC-21-MIN-0117).

    b. Advice from the Ministry of Justice, PCO and LDAC.

    c. How the offences and penalties framework in the draft Bill will operate as a whole. The scope of the Bill extends from very major players in the pharmaceutical industry through to individual consumers seeking to import a health product for personal use. The Bill needs to support a 'responsive enforcement' approach with proportionate responses possible depending on the

compliance context and the nature of the conduct and the potential consequences

26. Options will also take into account current trends in regulatory design. Pecuniary penalties are increasingly common in regulatory regimes targeting commercial behaviour, as civil enforcement is more appropriate than criminal enforcement in most cases of non-compliance with the regulations. They were introduced in New Zealand in the Commerce Act 1986 and have been used in legislation such as the Biosecurity Act 1993, the Anti-Money Laundering and Countering Financing of Terrorism Act 2009 and the Financial Markets Conduct Act 2013.

27. Options for Crown liability will be limited by constitutional convention, legal precedence and other legislation that provides for Crown liability (Health and Safety at Work Act 2015, Building Act 2004, Water Services Act 2021). Extending criminal and civil liability to the Crown is uncommon and requires a strong case for the regulatory regime.

28. Further discussion of the scope of options on other aspects of the proposed regime are set out in the 2015 and 2016 regulatory impact statements available on Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

What options are being considered?

Civil pecuniary penalties

Option One – No inclusion of the civil pecuniary penalties in the offences and penalties regime already developed for the Bill

29. The draft Bill offences and penalties framework provides a hierarchy of compliance and enforcement instruments compared to the Medicines Act. It reconsiders the offence and penalty structure as a whole, aligning it with similar recent legislation, providing for tiered offences and penalties allowing a proportionate response to varying seriousness of offending.

30. A tier of enforcement tools is proposed:

    a. **Tiered criminal offences**, generally in two levels. Higher penalties will be associated with intentional or reckless conduct that creates or increases a risk of public or individual harm. Strict liability provisions provide for generally lower penalties and apply to breaches of the Act that are not intentional or reckless as to the risk of public or individual harm.
    b. **Infringement notices**, which will allow fines for low-level contraventions of the Act.
    c. Enforceable undertakings, which allow the regulator to accept an undertaking from a license-holder, in lieu of more severe enforcement action. Such undertakings are then enforceable in the Courts and offer an interim step before suspension or cancellation of licenses, or even criminal charges.

Option Two – Include civil pecuniary penalties in the offences and penalties regime

31. This option proposes to include civil pecuniary penalties in the offences and penalties regime already developed for the Bill.

32. Civil pecuniary penalties are non-criminal monetary penalties imposed by a court after a trial. They may be an appropriate enforcement tool where the conduct engaged in is in breach of the law and should be deterred but does not warrant a criminal conviction. As with criminal provisions, a pecuniary penalty can serve as deterrence.

33. The monetary penalty, which can be incurred by both individuals and corporate bodies, is a debt owed to the Crown and can be large — potentially higher than the fines

available for many criminal offences. The penalties are intended to punish and to deter contraventions and can involve large sums of money paid to the Crown.

34. Civil pecuniary penalties can make enforcement of commercial regulation 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.

35. Likewise, if the value of the pecuniary penalty is set high enough it can also diminish any perverse incentive for any operator to consider penalties as a 'cost of doing business'.

36. 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.

37. Conversely, civil pecuniary penalties will not be suitable for all breaches of the law. Some breaches may be so flagrant or result in such harm that a criminal prosecution is the only justified course of action. Other breaches will be minor and of a technical or administrative nature. A regulator should be able to deal with these lower-level breaches according to an appropriate enforcement model (e.g., a responsive regulation approach or the 'Engage, Encourage, Educate, and Enforce' model adopted by Police during COVID-19 alert levels and consistent with modern regulatory best practice).

Extending liability to the Crown

Option One – consistent with the current Medicines Act and the 2018 exposure draft of the Therapeutic Products Bill, liability is not extended to the Crown (status quo)

38. The Crown is bound by Medicines Act but cannot be prosecuted for contraventions. The regulator cannot seek injunctions against Crown organisations nor enter into enforceable undertakings with them. There is a general expectation and a duty that the Crown does indeed comply with the Medicines Act, and future therapeutic products regime.

39. The Therapeutic Products Bill as drafted in 2018 carries over the status quo. Clause 6 provides that "this Act binds the Crown", but without wording to specify criminal liability, the Crown cannot be prosecuted (Cabinet Office circular CO(02)4).

40. The Crown will be subject to the same general rules as citizens and private corporate actors. Fear of criminal liability will not have the same negative consequences, such as risk-averse behaviour, for Crown actors in the supply chain. Where boundaries of permitted conduct are unclear, or where state actors need to act in response to an emergency situation (e.g., a global pandemic or health crisis), the Crown will not be limited by potential liability.

41. Non-criminal oversight and accountability mechanisms exist for Crown actors, such as the Health Practitioners Competence Assurance Act 2003 and Parliamentary oversight of Crown organisations. Civil enforcement actions are also available such as prohibitory injunctions and enforceable undertakings.

42. Victims of any harmful misconduct by the Crown can obtain justice through non-criminal procedures, including complaints to the Responsible Authorities, to the Ombudsman or Health and Disability Commissioner, or petitions to Parliament and MPs.

Option Two – extend civil and criminal liability to Crown organisations

43. The Bill could specify that Crown organisations can be held liable for some or all of the Bills offence provisions. This recognises the significance of the Crown's involvement in

the therapeutic products supply chain, and the implications if a Crown organisation fails to comply with the Bill.

44. The proceedings would be in accordance with the Crown Organisations (Criminal Liability) Act 2002 which enables Crown liability, except for acts in the performance of its functions or exercise of its powers (as the Regulator, or Pharmac in funding decisions), and in good faith.

45. Engagement with the Ministry of Justice and Crown Law has not identified any fundamental constitutional risks associated with the proposal to extend liability under the Bill.

46. 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 supply chain, recently demonstrated by the roll-out of the COVID-19 vaccine, the Crown should be held equally liable as private actors.

47. Promoting trust and confidence in the new therapeutic products regulatory regime is vital, 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 which can undermine the regulatory regime.

48. Considering the significant role of Crown organisations in the delivery of healthcare, and the principle of equality before the law, extending liability enables greater justice to those harmed through malfeasance. It would ensure a level playing field for state and non-state actors in the regulatory regime where they are engaged in similar activities. Distributive justice outcomes are more neutral, as an injured party may benefit from a successful prosecution of a Crown organisation, but the costs of penalties will fall on the community overall.

49. This option would need to include appropriate safeguards to protect the Crown's unique functions. Careful drafting of enabling legislation (e.g., ensuring there are emergency market authorisation pathways and special Ministerial discretion) can eliminate the need to rely on Crown immunity, and maintains confidence in the rule of law. Moreover, limiting liability to Crown conduct that is similar to non-state actors will reduce the risk that the unique activities of the Crown will be constrained by liability. Indemnity can be given if the Crown organisation or individual acts in good faith.

50. Crown organisations, which have not been previously held liable under the Medicines Act may be unsure of what is expected to comply with the new regime. Communicating specific requirements upfront with Crown organisations e.g., for the market authorisation framework, could mitigate this and provide best practice guidance.

Option Three – the Crown is not liable for a penalty, but a declaration could be made that the Crown has contravened the Act

51. Under this Option, the Regulator could take legal action against a Crown organisation for contraventions of the Act but a successful prosecution would not result in a financial penalty being imposed on the organisation.

52. The Bill could specify that, if the Crown contravenes the Bill (or rules or regulations made under the Bill) which constitutes an offence, a declaration can be made by the High Court to that effect.

53. A public declaration that the Crown has contravened the Bill is likely to have political and reputational consequences. It can send a message to the public that Crown actors are equally accountable as private actors to the regime and can provide an incentive for the Crown organisation to comply with the Bill.

54. The penalty may not be equal or proportionate to one incurred by a private party for a similar breach, and a declaration alone may not ensure redress for any victims of Crown malfeasance. Personal injuries can be separately compensated for under the

Accident Compensation Act 2001 regime, but an injured party will not have “their day in Court” to be heard.

55. It is assumed for this option that a declaration of contravention could only be made if a Court found (to the criminal standard of beyond a reasonable doubt) that a Crown organisation had contravened a provision of the Act (or the Crown organisation pleaded guilty). However, without the threat of a fine or conviction, it may be appropriate for a lower standard of proof to apply, e.g., the civil law standard of ‘on the balance of probabilities’. A lower standard of proof, however, may create potential overlaps with actions for negligence or judicial review of conduct engaged in by Crown organisations.

How do the options compare to the status quo?

0/neutral = no change; + = improvement; - = less than status quo

Civil pecuniary penalties Note: As the regulator will retain a discretion over which enforcement action to adopt (including taking no action), these options are not mutually exclusive. Therefore, the analysis conducted below considers the additional benefit (or costs) of including a CPP regime.

	Option One – *Offences and penalties framework in 2018 exposure draft Bill*	**Option Two – *Inclusion of civil pecuniary penalties in addition to offence and penalty framework in 2018 exposure draft Bill***
Effectiveness	**+** The regulator will have additional non-criminal sanctions that can act as deterrents and avoids any unintended, stigmatising effects that flow from a criminal conviction.	**++** Provides an additional enforcement tool that is especially valuable against well-resourced actors and corporate entities, who may see infringement fines as a 'cost of doing business'.
Justice	**+** The range of enforcement options can protect the community from wider harms.	**++** CPP orders are specifically tailored to match and defeat the profit or avoidance of loss that motivated the offending conduct. They are therefore a particularly just remedy.
Responsiveness & efficiency	**+** The regulator will have a hierarchy of options to deal with contraventions of the Act in a manner that the circumstances warrant.	**+++** The regulator will have additional options that can result in significant fines but without the costs associated with a criminal trial. The regulator is less likely to have to choose between a potentially insufficient response (infringement fee) or something disproportionate to the contravention (criminal prosecution).
Clarity and certainty	**+** Provides the Judiciary with criteria for sentencing offenders where commercial gain is a relevant factor. Regulated parties know what penalty they might face if they engage in particular conduct.	**-** Additional remedy may make it harder for the public and regulated parties to know what penalty they face if they engage in particular conduct.
Overall assessment	**4**	**6**

0/neutral = no change; + = improvement; - = less than status quo

Extending liability to the Crown

	Status quo – *the Crown is not liable under the Medicines Act and Therapeutic Products Bill*	Option Two – *Extend civil and criminal liability to the Crown*	Option Three – *The Crown is not liable, but a declaration could be made that the Crown has contravened the Act*
Effectiveness	0	**+**	**neutral** It is unclear to what extent this would deter bad actors compared to criminal sanctions and other remedies that may be more stigmatising or costly.
Justice	0	**++** (where Crown and non-state actors are engaged in similar activities) Promotes equality of supply chain actors before the law and provides for the vindication of victims' rights.	**+** A declaration alone may not ensure redress for any victims of Crown actions but a public sanction is an improvement over the status quo.
Responsiveness & efficiency	0	**++** This option would avoid or limit cultures of impunity and practices which can undermine the regulatory regime Limiting liability to Crown conduct that is similar to non-state actors will reduce the risk that the unique activities of the Crown will be constrained.	**+** The Regulator can seek a declaration of contravention
Clarity and certainty	0	**0** Communicating specific requirements upfront with Crown organisations can provide best practice guidance.	**neutral** It is uncertain the level and nature of misconduct that would justify a declaration of Contravention.
Overall assessment	0	**5**	**2**

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Civil pecuniary penalties

56. The analysis of the benefits of including civil pecuniary penalties in the offences and protection regime in the draft Bill over the status quo and the sticking with the draft Bill offences and penalties regime is set out in the table above.

57. The status quo for offences does not align with the criteria for efficient and effective enforcement tools. It is out of step with modern legislation, too specific for primary legislation, and has no non-criminal sanctions limiting the offences and penalties tools.

58. The status quo also does not support the objectives of having flexible and enabling regulation. Actors in the sector have reported that the provisions in the Act are confusing and, for the regulator difficult to apply in response to certain conduct which does not meet the criteria for clarity and responsiveness.

59. Under option 2 the existing offences and penalties criminal and civil instruments, enforceable undertakings, injunctions, and infringement scheme is good but not adequate to address conduct driven by big profit or market share motive when scale is significant.

60. The analysis supports the inclusion of a civil pecuniary penalty regime in the Bill. By including civil pecuniary penalties, the regulator will have additional non-criminal sanctions in the offences and penalties framework that will:

    a. deal with contraventions of the Act that can result in significant fines but without the costs associated with a criminal trial. If successful, costs can be awarded to the Regulator to cover the costs associated with bringing the proceedings.

    b. act as deterrents that is especially valuable against well-resourced actors and corporate entities, who may see infringement fines as a ‘cost of doing business’.

    c. avoid any unintended, stigmatising effects that flow from a criminal conviction.

    d. promote overall enforcement ‘fairness’ by minimising the extent to which material wealth dictates the practical impact of punishment (i.e., a small fine can have a big effect on an individual but little to no impact on a large corporate. Even a criminal penalty may not deter the largest corporate actors).

61. Some risks include:

    a. Providing the regulator with an additional remedy may make it harder for the public and regulated parties to know what penalty they face if they engage in particular conduct. However, careful drafting of the Bill and the development and publication of a sound regulatory and enforcement strategy can help mitigate this risk.

    b. If used appropriately, the human rights impact of civil pecuniary penalties can be mitigated. Civil rules of evidence and standards of proof provide robust protections for rights and orders are determined by the independent judiciary. CPPs are more likely to be brought against corporate entities, further limiting their potential impact on human rights. Risks can be mitigated through careful drafting of the Bill and the development of a sound regulatory and enforcement strategy.

62. With the inclusion of a civil pecuniary penalty regime in the Bill, an analysis of the model is required. Determining the scope of the civil pecuniary penalty regime, requires an application of the criteria set out earlier. Applying these criteria supports a limited

civil pecuniary penalty regime that extends to conduct that is a contravention of the Act and:

a. is undertaken ‘in the course of business’

b. is not of minor administrative or regulatory nature (where a warning or infringement fee may be more appropriate)

c. involves a moderate-to-high level of financial materiality – e.g., seeking to gain or avoid a profit/loss in excess of a defined material threshold

d. does not warrant the full denunciatory, stigmatising or incapacitory effects of the criminal law, e.g., conduct that has resulted in serious harm to individuals or the community.

Extending liability to the Crown

63. The preferred option on the issue of Crown liability, is to extend criminal and civil liability to Crown organisations for contraventions of the Therapeutic Products Bill and its future regulations. This recognises the role of the Crown in the therapeutic products supply chain, ensuring equal treatment of actors where they are engaged in similar activities, and ensuring patient-safety and the victim’s interests. The scope of liability is determined with the same principles used for the analysis of options.

64. The Crown plays a unique role in the health sector, and secures, approves and funds therapeutic products, and delivers publicly funded healthcare. Where Crown organisations participate in activities which are not similar to private actors in the supply chain, and are specific to the role of Government (for example, Pharmac’s funding decisions) or act in good faith, they should not attract criminal or civil liability.

65. In terms of enforcement remedies, Crown organisations should not be liable for civil pecuniary penalties due to an absence of profit-motive and negative distributional impacts of penalties borne out of public funds.

What are the marginal costs and benefits of the option?

Civil pecuniary penalties

Affected groups *(identify)*	**Comment** *nature of cost or benefit (e.g., ongoing, one-off), evidence and assumption (e.g., compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Regulated groups – industry (contravening)	Will incur significant penalties for non-criminal law breaches.	High	Medium *The language of the Bill provides for high monetary fines. However, it is difficult to determine the extent of non-compliance in the sector that will be detected and successful prosecuted.*
Regulated groups – industry (law-abiding)	The lower legal threshold for the Crown to secure a significant penalty order may result in a chilling effect on regulated parties engaged in lawful activities.	Low	Low *It is difficult to determine the extent to which the existence of civil pecuniary penalties influenced any particular choice of action by a regulated party. However, we have assumed businesses will act in an economically rational manner.* *Any 'loss' resulting from a regulatory chilling effect, is difficult to determine prior to the introduction of the regime (as it is difficult to know how much borderline activity is being engaged in and how rational the actors in the system are) but may be measurable as part of a later review and evaluation.*
Regulator	Will still require bringing legal proceedings, although costs can be reimbursed as part of a civil pecuniary order.	Medium	Medium *Future legal costs are difficult to quantify but the analysis assumes some unsuccessful proceedings (resulting in unrecoverable legal fees and potentially, cost orders against the Crown).*
Others - wider govt, consumers, etc.	Potential cost to the public through tax for Court and enforcement fees.	Low	Medium *Civil pecuniary penalty proceedings are conducted within ordinary Court processes.*

Extending liability to the Crown

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the proposed approach compared to taking no action			
Crown organisations fined or charged with contravening the Act or regulations	Will be liable to pay infringement fees (generally low monetary value)	Low (small increase on status quo)	High *The Bill will provide how and what Crown organisations can be fined.*
	Will be liable to pay criminal penalties and associated costs with a criminal proceeding (generally high monetary value)	High (significant increase on status quo)	High *The Bill will provide how and what Crown organisations can be fined.*
	Will be liable for costs incurred in defending proceeding (even if pleading guilty at early stage)	High (significant increase on status quo)	High
Regulator	Cost of bringing criminal proceeding (general costs from unsuccessful defendant are not recoverable)	No additional cost over status quo as overall enforcement budget likely to remain the same	High
Others – Government; the public	Costs of proceedings for both parties (prosecution and defence) are borne by	Medium (moderate increase on status quo)	Medium *Civil pecuniary penalty proceedings are conducted within ordinary court processes and do not demand additional resources. However, costs expended on criminal and*

	public, in addition to court costs		*civil proceedings represent an opportunity cost to the Crown which are difficult to quantify.*
Additional benefits of the proposed approach compared to taking no action			
Crown organisations	Removing existing immunities from financial penalties internalises previously externalised costs, creating an incentive for improvements in behaviour	Medium	Low *It is difficult to determine prior to the introduction of the regime how much borderline activity is being engaged in and how rational the actors in the system are. The impact of the reforms may be measurable as part of a later review and evaluation.*

Section 3: Delivering an option

How will the new arrangements be implemented?

66. Implementation of the proposals in this supplementary analysis is tied to the development and implementation of the new Therapeutic Products Bill, which will replace the current Medicines Act and its regulations. The Ministry of Health (including staff from Medsafe) will be responsible for leading the implementation of the Bill, which will include developing guidance on civil pecuniary penalties and prosecutions of Crown organisations.

67. The draft Bill currently includes a hierarchy of enforcement tools that include tiered criminal offences. This Bill will be revised to incorporate the preferred options of including civil pecuniary penalties and extending civil and criminal liability to Crown organisations.

68. Existing models for civil pecuniary penalties and Crown criminal liability with inform legislative design choices. The Crown Organisations (Criminal Liability) Act 2002 could provide the overarching legal mechanism for brining proceedings against Crown organisations. To permit injunctions against a Crown organisation, the application of the Crown Proceedings Act 1950 to the Bill will be modified.

How will the new arrangements be monitored, evaluated, and reviewed?

Formal review of Bill and regulatory regime

69. The regulatory regime will not be fully operational until later this decade. This reflects the current timetable for further policy development, the legislative process, and the proposed transitional arrangements.

70. Section 268 of the Bill requires the Minister of Health to review the policy and operation of the Therapeutic Products Act five years after it comes into force, and every five years thereafter. The Minister of Health must report on each review within 12 months and present the report to the House of Representatives as soon as practicable after it is completed. It is proposed that the offence and penalty framework, including the application of civil and criminal liability to Crown organisations be reviewed in the initial review.

Opportunities for review and evaluation during the design of the regulatory regime

71. Following the passage of the Bill, there will be substantial work required to prepare the necessary secondary legislation – regulations, rules and regulator's notices – to support the therapeutic products and natural health products regulatory regime. This work will be led by the Ministry of Health, including staff from Medsafe and – eventually – the new regulator. The development of the regime will provide significant opportunities to review and evaluate different options, and to engage with stakeholders within and outside government.

72. Consultation is further protected by a specific provision of the Bill which imposes a duty on the Minister of Health administering the Act and the regulator to consult persons and organisations that the Minister or regulator considers appropriate, having regard to the subject matter of the proposed secondary legislation. This consultation must occur prior to making the secondary legislation.

73. Legislated consultation requirements will be supported by formal parliamentary accountability mechanisms and health system performance oversight provided by the Ministry of Health and the Māori Health Authority. Stakeholders will be able to contribute to the development of the Bill during the Select Committee stage.

Stewardship expectations

74. The Government has signalled its core expectations for regulatory stewardship to agencies involved in designing and administering regulation. As the regulator will sit

within the Ministry of Health – and the regulator will be accountable for their performance to the Director-General of Health – the regulatory regime will be subject to the Ministry of Health's ongoing responsibility to:

a. actively monitor and periodically assess the performance and condition of the regulatory regimes it administers, and to use that information to advise or act on problems, vulnerabilities and opportunities for improvement

b. adopt best practice compliance strategies, as part of a cross-government forum designed to share experiences and promote greater consistency between regulators

c. report publicly on its regulatory management strategy, the state of the regulatory stock, and plans for improvement, including engaging actively with stakeholders and other regulatory agencies, and undertaking rigorous organisational self-review.

75. These requirements will impact on the stewardship of the new regime (i.e., the design will need to enable and be compatible with effective stewardship).