

In Confidence

Office of the Minister of Health

Cabinet Social Wellbeing Committee

Crown liability under the Therapeutic Products Bill and other offence and penalty matters

Proposal

- 1 This paper seeks agreement to the following changes to an exposure draft of the Therapeutic Products Bill:
 - 1.1 reworking the offence and penalty framework consistent with policy decisions previously made by Cabinet
 - 1.2 extending civil and criminal liability to Crown organisations for contraventions of the Act and secondary legislation (Crown liability).

Relation to government priorities

- 2 This proposal helps to deliver the Government's plan to develop a modern and comprehensive regulatory scheme for therapeutic products and natural health products by ensuring all actors within the sector can be held to account through a robust enforcement regime. As equitable access to safe and effective therapeutic products are a core part of our health system, this proposal contributes to the Government's commitment to build a stronger, accountable and sustainable health and disability system that delivers for all New Zealanders.

Executive Summary

- 3 The Ministry of Health has recently finalised drafting instructions to support the Parliamentary Counsel Office (PCO) revisions of a 2018 exposure draft of the Bill. These drafting instructions will give effect to decisions of Cabinet in July and October 2021 (SWC-21-MIN-0109 and CBC-21-MIN-0117), stakeholder feedback received during a period of public consultation (December 2018 – April 2019), advancements in health technologies and lessons from COVID-19.
- 4 Revisions to the draft Bill include a reworking of the offence and penalty framework consistent with Cabinet's decisions, and to address feedback from the Legislation Design and Advisory Committee s 9(2)(h) on the earlier draft of the Bill. This paper seeks confirmation of the reworked offence and penalty framework, which includes:
 - 4.1 a civil pecuniary penalty regime

- 4.2 a simplified penalty regime, with higher-level penalties for deliberate or reckless conduct
- 4.3 an improved infringement notice regime
- 4.4 revisions to defences and miscellaneous matters.
- 5 The Crown will play a significant role in the therapeutic products supply chain under the new therapeutic products and natural health products regulatory regime.¹ Given this large and ongoing role, this paper also seeks agreement on the liability of Crown organisations under the Act, including whether Crown organisations should be criminally liable for contraventions of the Act and, if so, the penalties that should apply.
- 6 Extending liability to the Crown raises competing and fundamental constitutional and policy issues, touching on the distinctive role of the Crown in the delivery of healthcare and equality before the law.
- 7 I propose to revise the Bill to extend liability to the Crown for breaches of the Act. Under my 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 2002. In addition, the regulator will be able to apply for injunctions against Crown organisations and enter into enforceable undertakings.
- 8 Promoting trust and confidence in the new regulatory environment, supporting positive organisation culture and ensuring justice to individuals harmed through malfeasance are critical factors to my decision. Carefully limiting the scope of offences that apply to the Crown, how liability is attributed, and the remedies available, will protect the unique functions of the Crown and address specific concerns raised by affected entities, including the new Health New Zealand.
- 9 Crown organisations that are most likely to be affected by this decision include Health New Zealand and the New Zealand Blood Service. It is less likely, but still possible, that the Ministry of Health (including the regulator itself), the Māori Health Authority and Pharmac, could also engage in conduct that would be the subject of the regime.
- 10 The Bill currently allows for corporate liability to be ‘attributed’ to senior managers. Extending criminal liability may therefore create additional governance risks for individuals appointed to the boards of Crown organisations. I believe that, with appropriate revisions to the defences available under the Bill, proactive engagement by the regulator and adoption by regulated parties of good governance practices, these risks are manageable and appropriate.

¹ Scenarios where a Crown organisation may contravene the Act are set out in **Appendix 1**.

- 11 The effectiveness and appropriateness of the Act's offence and penalty framework will be considered in the first legislated review of the Act, which will take place five years after the Act commences.

Background

Development of a new regulatory regime for therapeutic products and natural health products

- 12 Therapeutic products are medicines and medical devices and are currently regulated under the Medicines Act 1981 (Medicines Act), which is outdated. The regulation of natural health products (NHPs), which are a broad group of traditional and complementary products that support health and wellbeing, is also not fit for purpose.
- 13 In 2015, Cabinet agreed to repeal and replace the Medicines Act 1981 with a new Therapeutic Products Bill [SOC-15-MIN-0049]. In July 2021, Cabinet also agreed to include regulation of natural health products as part of the Bill [SWC-21-MIN-0109].
- 14 In March 2016, Cabinet agreed that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings and infringement notices [SOC-16-MIN-0025] and, in October 2021, agreed to include a civil pecuniary penalty regime as an additional enforcement tool [CBC-21-MIN-0117].
- 15 Since then, officials have prepared drafting instructions for PCO to revise a 2018 exposure draft of the Bill and it is my intention to introduce a Bill to Parliament in 2022. Prior to the finalisation of drafting instructions, I am seeking Cabinet's confirmation to a reworking of the Bill's offence and penalty framework and agreement to extend liability to Crown organisations.

Reworking of offence and penalty framework

- 16 Reworking the offence and penalty framework includes adding a civil pecuniary penalty regime (agreed by Cabinet in CBC-21-MIN-0117) and addressing feedback from the Legislation Design and Advisory Committee s 9(2)(h) on the earlier draft of the Bill.
- 17 The reworked provisions fall within existing Cabinet mandates [SOC-16-MIN-0025 and CBC-21-MIN-0117] but, because of the size and nature of the revisions and the passage of time since the original Cabinet mandate (2015 2016, SOC-16-MIN-0025), I am seeking Cabinet confirmation. The reworked provisions include:

Change	Explanation of proposed revision
Inclusion of a civil pecuniary penalty regime	The regulator will be able to seek civil pecuniary penalty orders for contraventions of civil liability provisions. These provisions will primarily relate to conduct that occurs 'in the course of business' and for financial or market-share purposes. An order would include a declaration that an

	individual had contravened a civil liability provision and, in most cases, a pecuniary penalty order. Civil liability provisions are proved at the lower, civil standard of proof (balance of probabilities). The rationale for civil pecuniary penalties was set out in CBC-21-SUB-0117.
Simplifying criminal offence provisions	Reworking criminal offence provisions will make them easier to read and understand. A clearer link will be drawn between the penalty level and the contravening conduct, level of intent (knowledge, recklessness, negligence), and the real or potential harm that could or does result from the conduct.
Strict liability offences, where it is not necessary to prove intent	In a strict liability offence, the prosecution is not required to prove <i>mens rea</i> (intent), but the defendant can escape liability if he or she can show the existence of a defence or an absence of fault. Strict liability offences are often used to enforce requirements of regulatory regimes and carry a lower penalty level than offences where intent must be proven. The inclusion of strict liability offences has been undertaken in accordance with the <i>Legislation Guidelines 2021</i> and defences are available under the Bill. These include that the contravention was due to the defendant's reasonable reliance on information given to the defendant by another person.
An improved infringement notice regime	s 9(2)(h) [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Infringement notices will be able to be issued for many of the offences under the Act and offences against future regulations.
Revisions to defences, evidentiary matters and surveillance powers to bring them up to date with current best practice	Minor administrative and technical changes have also been made to the sections of the Bill that set out available defences, evidentiary matters and the regulator's investigative powers. These changes include aligning the Bill's investigative powers with the Search and Surveillance Act 2012.

- 18 Further analysis of the offences and penalty regime will be undertaken as part of the formal Bill of Rights Act 1990 assessment prior to the final Bill being submitted to the Legislation Committee of Cabinet in 2022.

Analysis – Crown Liability

- 19 Extending liability to the Crown (especially criminal liability) raises competing and fundamental constitutional and policy issues. There are conceptual problems in the Crown punishing itself, although these have been partially resolved through mechanisms such as the Crown Organisations (Criminal Liability) Act 2002.
- 20 The Crown also performs many functions that are distinct from those engaged in by non-state actors and which are arguably more appropriately subject to

different forms of accountability (such Parliamentary, Ministerial and judicial oversight).² These include budget setting and allocation, Pharmac's funding decisions, and system performance monitoring by the Ministry and, in the future, the Māori Health Authority. The 'public good' and non-commercial basis for much Crown activity are further arguments against extending criminal and civil liability.³

- 21 As exposing the Crown to criminal liability is not common in legislation, I consider a positive case for extending criminal liability must be made out.

Arguments for extending liability to the Crown (including criminal liability)

- 22 Weighing in favour of extending criminal liability are 'rule of law' principles, equity considerations, and international law conceptions of non-discrimination in trade. Many of the recognised purposes of sentencing also apply in the context of misconduct by a Crown organisation, including holding the defendant to account, promoting a sense of responsibility, general and specific deterrence and providing for the interests of the victim(s).⁴

- 23 Everyone is equal before the law, including the Crown (and, by extension, her Government and public service). Modern democracies now have mechanisms to hold the Crown to account in both civil and, in rarer cases, criminal proceedings. For example, it may be appropriate to limit immunity from civil proceedings where the Crown acts in the course of business, trade or in the delivery of services. To give effect to this in New Zealand, the Crown Proceedings Act 1950 allows the Crown to be sued for most causes of action.

- 24 Examples of where criminal liability has been extended to the Crown include workplace health and safety and building safety legislation extends criminal liability to the Crown. This has been justified based on the similarities between the Crown and private employers and operators. These proceedings are facilitated by the Crown Organisations (Criminal Liability) Act 2002 which provides that proceedings are brought against a Crown organisation in its own name and not in the name of the Crown.

- 25 Ensuring confidence in the integrity of the regulatory regime is a foremost consideration in whether to extend liability to the Crown. The real or perceived failure by a regulator to hold individuals and organisations to account for contraventions of the law has a corrosive effect on trust, whether that is the trust of the public, other regulated parties or international regulators. Where, as here, the Crown is a large – if not the largest – actor in a sector, the argument to treat them the same as non-state actors is stronger and its exclusion from all liability seems anomalous. That does not mean that appropriate and targeted protections are never justified.

² For example, transparency requirements under the Official Information Act 1982, Judicial Review by the Courts of administrative decision making and oversight by the Ombudsman.

³ For example, it may be inappropriate for a court to grant an injunction against a Crown organisation where the effect of that injunction would be to require expenditure of public funds over and above that appropriated by Parliament.

⁴ Sentencing Act 2002, section 7.

- 26 Extending liability to the Crown and its employees and agents may encourage positive changes in organisational culture that support this vision. Cultural change, even more so than structural change, is integral to the delivery of the Government's vision of Pae Ora and a transformed health system.⁵
- 27 Fairness and the vindication of individual rights and interests also weigh in favour of extending criminal liability to the Crown. This is particularly important in areas where the Crown operates as the sole or main provider of health services, e.g., acute health interventions, surgeries and in-patient treatments delivered in public hospitals. Protecting the Crown from liability for breaches of the law, may deny victims a sense of justice and not encourage the organisation to improve their practices.
- 28 Finally, while not a specific basis for extending Crown liability, holding the Crown liable for contraventions of the law may provide a tangible means to recognise the principles of Te Tiriti o Waitangi. Prosecuting a Crown organisation for a criminal breach of a law intended to protect patient safety can further the Treaty principle of 'active protection'. Likewise, treating a Crown health organisation the same as an iwi-led health provider furthers the principles of equity or options, in an analogous manner to the protection afforded to multi-national businesses under the international trade law concept of non-discrimination.

Arguments against extending liability to the Crown (including criminal liability)

- 29 Notwithstanding the above points, Crown criminal liability remains uncommon in New Zealand. The Crown Organisations (Criminal Liability) Act 2002 lists only five laws under which a criminal proceeding can be instituted against a Crown organisation, although other laws may directly extend criminal liability to the Crown independently of the Crown Organisations (Criminal Liability) Act 2002, for example the Water Services Act 2021.
- 30 First, there are historical and constitutional arguments against extending liability to the Crown. Some protection from criminal liability and even Judicial Review can be justified on the grounds that the 'separation of powers', requires each branch of government to recognise and respect each other's 'sphere of influence'.⁶
- 31 Pragmatic and political factors also caution against extending liability to Crown organisations. For instance, criminal sanctions may not be the appropriate tool for discouraging behaviour from Crown organisations where such behaviour is (argued to be) in response to funding and resource constraints. Budgetary decisions are a unique Crown activity and are not traditionally subject to judicial questioning. This extends to decisions by Crown organisations (e.g., Pharmac) over the allocation of limited funding to, for example, subsidise the cost of certain medicines.

⁵ See discussion on importance of organisational culture as a mediator for change in Shane L. Scahill, "The way things are around here": organisational culture is a concept missing from New Zealand healthcare policy, development, implementation, and research' (2012) 125 (1348) *New Zealand Medical Journal* 79.

⁶ See the definition of 'comity' in the Parliamentary Privilege Act 2014, section 4(1)(b).

- 32 Another objection to extending liability is the public-good motivation for many of the Crown’s activities and fear of liability may create risk-averse cultures. Indeed, the draft Bill already provides protection (or indemnity) to the regulator and the Crown from civil or criminal proceedings for certain decisions. These include making a ‘public safety announcement’ (clause 161) or making a statement about an ‘oversupplied person’ (clause 175). In both cases, the indemnity applies only if the regulator, Crown or person acts in good faith. Similar provisions are present in a number of Acts and protect public servants and others engaged in public duties from liability for the good faith performance of those duties.
- 33 Even if liability were extended to Crown organisations, careful drafting would be required to ensure liability fell on the right party (e.g., an employee, senior manager, Board or the Crown organisation itself) to support the development of appropriate governance and due diligence processes, and to reduce the risk of unintended consequences. This is a relevant consideration as the draft Bill includes provisions that allow for the ‘upwards’ (i.e., from employee to senior manager or corporate entity) and ‘downwards’ attribution of liability for contraventions (i.e., from the corporate entity itself to its Board or senior managers).
- 34 Further, the regulator will have limited resources and will need to prioritise enforcement action, notwithstanding that the Bill will support more effective enforcement. Investigating and prosecuting low and medium level offences by Crown organisations may divert resources away from equally important action against private actors (who are not subject to other accountability mechanisms). However, where the option exists for the regulator to initiate action against the Crown, a private sector defendant may highlight the perceived ‘unfairness’ of the regulator ‘protecting its own’ if the regulator adopts a different enforcement strategy against Crown organisations. This risk can be mitigated through the adoption of a clear enforcement strategy at an operational level, which focuses on the consequences of contraventions (including harm) as opposed to the nature of the defendant.
- 35 Another argument against extending criminal liability is that any fine or penalty imposed by a court will be paid, ultimately, out of public funds. This not only raises issues of the effective use of public funds, but also the deterrence effect of any criminal fine or pecuniary penalty. While the threat of a (potentially large) financial penalty may prove an effective deterrent to a private sector company or individual, when the costs fall on others (i.e., the public) that additional gain in deterrence effect may be marginal over a ‘name and shame’ approach that is adopted in tandem with existing non-criminal accountability mechanisms (e.g., Ministerial and Parliamentary oversight).
- 36 Finally, not extending criminal liability may be justified because of other oversight and accountability mechanisms, including:
- 36.1 Parliamentary oversight of Crown organisations, including review of primary and secondary legislation and select committees and petitions

- 36.2 Judicial Review of administrative decision-making, including declarations of inconsistency under the Bill of Rights Act 1990
- 36.3 reviews by the Ombudsman and the use of the Official Information Act 1982
- 36.4 the Health Practitioners Competence Assurance Act 2003, which allows criminal and disciplinary sanctions against regulated health professionals
- 36.5 the Health and Disability Commissioner may investigate any healthcare provider breaches to support consumer rights.

Alternatives to extending liability to the Crown (including criminal liability)

- 37 Even if criminal liability is not extended to the Crown, other enforcement actions could be available, including prohibitory injunctions, improvement notices and enforceable undertakings.
- 38 Finally, the question of Crown liability could be a specific term of reference for the first review of the Act. Clause 268 of the Bill currently provides that the Minister responsible for the Act must conduct a review of the policy and operation of this Act after the expiry of five years from the commencement of the Act.

I propose extending criminal liability to the Crown for certain breaches of the Therapeutic Products Act

- 39 Having weighed the arguments in favour and against, I propose extending criminal liability to Crown organisations involved in the therapeutic products and natural health products supply chain. Depending on the conduct, liability could fall on the organisation itself, its board or senior management, or individual employees and agents of the organisation when acting with the knowledge of the organisation.
- 40 Promoting trust and confidence in the new regulatory regime, supporting positive organisational culture and ensuring justice to individuals harmed through malfeasance, are critical factors to my decision. While recognising that Crown organisations deliver healthcare without a profit motivation, I also believe that it is appropriate to create a level playing field where state and non-state actors are engaged in similar activities, as it is reasonable to hold all to the same standards of care and diligence.
- 41 Carefully limiting the scope of offences that apply to the Crown and its employees, and the remedies available, will protect the unique functions of the Crown and mitigate unintended consequences.⁷ For example, although the regulator (as an independent statutory officer within a branded business unit of the Ministry of Health) will be subject to liability under the Act as a Crown organisation, it is not intended that its regulatory decisions could be the

⁷ This includes maintaining a good-faith immunity for the new therapeutic products and natural health products regulator, who will be an independent statutory officer within the Ministry of Health.

subject of criminal proceedings.⁸ Likewise, the Ministry of Health will work with relevant Crown organisations to identify and – where appropriate – address any unintended consequences of this proposal and support the development of guidance to Crown organisation and their boards on their responsibilities. This will be an ongoing project as the Bill progresses and the wider regulatory regime develops.

- 42 I also propose revising the Bill to allow the regulator to seek injunctions against Crown organisations, to enter into enforceable undertakings with Crown organisations and to issue infringement notices against Crown organisations (including, as appropriate, its board, management or employees).
- 43 Specifically, I propose that the Bill be revised to include a clause similar to section 6 of the Health and Safety at Work Act 2015, and section 20 of the Water Services Act 2021, which set out explicitly what enforcement action can be taken against Crown organisations. Criminal proceedings against Crown organisations will be in accordance with the Crown Organisations (Criminal Liability) Act 2002.
- 44 However, recognising the unique role the Crown plays in securing, approving and funding therapeutic products, as well as the non-commercial basis on which publicly funded healthcare is delivered by the Crown, I propose that liability only extend to those offences under the Act where a Crown organisation is directly acting in the therapeutic product and natural health product supply chain (as opposed to approving products for supply). Likewise, Crown organisations and their boards and management will not be liable for civil pecuniary penalties.
- 45 An indicative list of offences is set out in **Appendix 2**. I seek Cabinet's authority to amend the list following engagement with the Ministry of Justice and PCO during drafting, including by:
- 45.1 narrowing the offences the Crown can be prosecuted for and the maximum penalty available if a contravention is proved
 - 45.2 creating specific exemptions or defences for Crown organisations (including modifying existing defences in the Bill)
 - 45.3 determining good-faith exemptions or other criteria to be satisfied before a prosecution or application for an injunction or enforceable undertaking is brought against a Crown organisation, its board or management, or employees
 - 45.4 modifying the way liability of senior managers, workers and agents can be attributed upwards and, likewise, how liability can be attributed downwards from a Crown organisation to senior managers, including Board members

⁸ The Bill currently provides for certain 'reviewable decisions' of the regulator to be appealed through internal and external administrative review processes. This remains unaffected by the proposals in this paper.

45.5 making other technical and minor changes.

46 I have also considered what remedies should be available, should a criminal prosecution against Crown organisations be successful. I would allow the Court to convict the Crown organisation and impose an infringement fine or fee, or criminal penalty on the organisation.

47 I considered permitting a court to issue a declaration that the Crown organisation has contravened the Act but not otherwise allowing a fine or financial penalty to be imposed. I do not consider this acceptable on the basis that such a model would not satisfy the purposes of sentencing, ensure justice for any victims of Crown malfeasance and is inconsistent with the precedent of the Health and Safety at Work Act 2015, Building Act 2004 and the Water Services Act 2021.

Financial Implications

48 There are no specific financial implications with this paper, as it seeks authority to issue drafting instructions to PCO to extend criminal liability to the Crown for breaches of the Bill.

49 If Cabinet agrees to extend criminal liability to the Crown, then there may be costs incurred by a Crown organisation for future contraventions of the Act and regulations, for example fines. There will be costs associated with defending any charge (even if the Crown organisation pleads guilty at an early stage). These costs cannot be quantified in advance but would, in any event, be met from the operating budget of the relevant Crown organisation.

50 The costs to the Crown of bringing a prosecution against a Crown organisation will be part of the ordinary funding request for Vote Health.

Legislative Implications

51 Legislation is required to extend criminal liability to the Crown. If Cabinet agrees to my proposal, I will issue drafting instructions to PCO to revise the Bill to give effect to Cabinet's decision.

52 Subject to advice from PCO, revisions to the Bill will include a consequential amendment to the Crown Organisations (Criminal Liability) Act 2002 and a specific provision within the Bill setting out how the Act can be enforced against the Crown.

53 Drafting instructions on all other matters related to the Bill have already been finalised. It is my intention that the Bill, including Crown criminal liability, will be introduced to Parliament in 2022. I will bring a future paper to the Cabinet Legislation Committee seeking approval to introduce the Bill.

Impact Analysis

Regulatory Impact Statement

- 54 Cabinet's impact analysis requirements apply to the proposals relating to the proposal to extend liability to the Crown, but there is no accompanying Regulatory Impact Statement, and the Treasury has not exempted the proposals from the impact analysis requirements. Therefore, it does not meet Cabinet's requirements for regulatory proposals. The Papers and Regulatory Committee at the Ministry of Health has agreed that a supplementary analysis will be provided before the Cabinet Legislation Committee considers approving introduction of the Bill in 2022.

Climate Implications of Policy Assessment

- 55 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

Population Implications

- 56 The proposals in this paper do not raise different implications for different populations. The equity and Te Tiriti o Waitangi implications of extending criminal liability to the Crown are explored in paragraph 28.

Human Rights

- 57 The proposals in this paper are consistent with the rights affirmed in the New Zealand Bill of Rights Act 1990. Extending civil and criminal liability to the Crown furthers the right to justice, recognised in section 27 of the New Zealand Bill of Rights Act 1990.

Consultation

- 58 I have consulted with the Ministry of Justice and PCO on the proposals in this paper and in the revision to other elements of the offence and penalty framework. The Ministry of Justice had no specific feedback on the proposals in this paper and PCO has indicated the proposals are workable and will continue to work with the Ministry to revise the draft Bill.
- 59 I have also consulted with the Public Service Commission (PSC) on the proposal to extend criminal liability to Crown organisations. PSC were not opposed to the proposal to extend criminal liability to Crown organisations, nor the proposed model for available remedies. Nonetheless, PSC did suggest that sufficient deterrence and regulatory compliance could be achieved with a declaration of breach by the Crown, i.e., without imposing a financial penalty on the Crown.
- 60 Within the Health portfolio, feedback was sought from Medsafe, Pharmac, the New Zealand Blood Service, the Health Research Council and the interim Chief Executives of Health New Zealand and the Māori Health Authority.

- 61 Following discussions with Ministry of Health officials, the New Zealand Blood Service and the Health Research Council were not opposed to the proposals and will work with the Ministry to support the development of the wider regulatory regime. Highlighting its unique role and reliance on exemptions under the current Medicines Act, Pharmac requested that officials consider Pharmac's functions in the design of the criminal liability provisions. Health officials advise that the Bill already provides for Pharmac's operational role.
- 62 Medsafe had no specific feedback on the proposals in this paper.
- 63 The Transition Unit and officials supporting the interim Health New Zealand raised concerns about the potential risks the proposals might create for the Health New Zealand Board. Attention was drawn to the need to avoid unintended consequences and to ensure that the Bill's upwards and downwards attribution of liability clauses were appropriate, given the role, scale, and dispersed nature of Health New Zealand operations.
- 64 I have carefully considered the feedback and consider the risks identified are manageable through carefully drafted provisions, proactive and early engagement by the future regulator and by Health New Zealand and all other regulated parties, adopting appropriate good governance and operational practices.
- 65 I will direct officials to work with PCO to review and, if necessary, revise existing clauses in the Bill related to attribution of liability to ensure they work appropriately for Crown organisations. As part of their work to develop the regulatory regime, Ministry officials will also develop material to support Crown organisations understand their obligations under the Bill and secondary legislation.
- 66 The interim Māori Health Authority had no specific concerns with the proposal to extend liability to Crown organisations. Likewise, discussions with ACC confirmed that it is not likely that Crown liability proposals would have a material impact on ACC given their purchasing and funding roles.
- 67 Because the Bill will commence after the planned disestablishment of district health boards, these entities were not consulted.

Communications

- 68 No specific communication activities are planned in relation to this paper or the enforcement regime. I intend to make a public announcement later in 2022 about the Bill generally when it is tabled in Parliament.

Proactive Release

- 69 I intend to proactively release this Cabinet paper as part of a wider package of information to be released when the Bill is tabled in Parliament. As such, this paper will not be proactively released within the standard 30 business days.
- 70 Redactions will be made to this paper pursuant to the Official Information Act.

Recommendations

The Minister for Health recommends that the Committee:

- 1 note that the Ministry of Health (Ministry) is finalising drafting instructions to revise the 2018 exposure draft of the Therapeutic Products Bill (the Bill) to:
 - 1.1 give effect to Cabinet's decision to regulate natural health products under the Bill (SWC-21-MIN-0109)
 - 1.2 give effect to Cabinet's decision to include a civil pecuniary penalty regime in the Bill (CBC-21-MIN-0117)
 - 1.3 address feedback from stakeholders received during public consultation in 2019, advancements in health technologies and lessons from COVID-19.

Reworked offence and penalty framework

- 2 note that, in response to feedback from the Ministry of Justice, the Legislation Design and Advisory Committee s 9(2)(h), I intend to authorise the Ministry to issue drafting instructions to rework the Bill's offence and penalty framework to include:
 - 2.1 allowing the regulator to seek civil pecuniary penalty orders for contraventions of a civil liability provision (generally for conduct that occurs 'in the course of business' or for financial or market-share purposes), with the court able to issue a declaration of contravention and impose a civil pecuniary penalty on the individual
 - 2.2 simplified criminal offence provisions, with higher-level penalties tied to a defendant's level of intent (i.e., knowledge or recklessness) and the actual or potential consequences of their actions
 - 2.3 strict liability offences
 - 2.4 an improved infringement notice regime
 - 2.5 revisions to defences, evidentiary matters and investigative powers to bring them up to date with current best practice
- 3 note that revisions identified in 2.1-2.5 fall within existing Cabinet mandates (SOC-16-MIN-0025 and CBC-21-MIN-0117)

Extending liability, including criminal liability, to Crown organisations

- 4 note that the Crown (as represented by Crown organisations, boards and management, public servants and other employees) plays an important role at a number of points in the therapeutic product and natural health product supply chain

- 5 note that the Crown Proceedings Act 1950 provides for a mechanism for civil actions to be brought against the Crown and Crown organisations and that the Crown Organisations (Criminal Liability) Act 2002 provides a mechanism for bringing prosecutions against Crown organisations in their own name
- 6 note that rule of law and equity considerations, as well as patient-safety and victim's interests support extending liability, including criminal liability, to Crown organisations, especially where those organisations are engaging in similar activities as private-sector actors
- 7 agree to extend civil liability and criminal liability to Crown organisations for contraventions of the Act and future regulations, including permitting:
 - 7.1 criminal proceedings to be brought against Crown organisations in accordance with the Crown Organisations (Criminal Liability) Act 2002, and with a Crown organisation liable to be convicted and fined
 - 7.2 the regulator to issue infringement fines and fees against Crown organisations and its employees
 - 7.3 the regulator to enter into enforceable undertakings with Crown organisations
 - 7.4 the regulator to seek and obtain injunctions against a Crown organisation (noting this will require modifying the application of the Crown Proceedings Act 1950)
- 8 note that criminal liability for Crown organisations is proposed to be limited to conduct where the Crown is acting directly in the therapeutic products and natural health products supply chain in a manner similar to that of a non-state actor
- 9 authorise the Minister of Health to issue drafting instructions to give effect to Cabinet's decision to extend civil and criminal liability to Crown organisations, with civil remedies including injunctions and enforceable undertakings, but not civil pecuniary penalty orders
- 10 agree that the Minister for Health may, following engagement with the Ministry of Justice and PCO, revise the list of offences, including by:
 - 10.1 narrowing the offences the Crown can be prosecuted for or the maximum penalty that can be imposed
 - 10.2 creating specific exemptions or defences for Crown organisations (including modifying existing defences in the Bill)
 - 10.3 determining good-faith exemptions or other criteria to be satisfied before a prosecution or civil proceeding is brought against a Crown organisation, including its board or management or employees (jointly or separately)

IN CONFIDENCE

- 10.4 modifying the way liability of senior managers, workers and agents can be attributed upwards and, likewise, how liability can be attributed downward from a Crown organisation to senior managers, including Board members
- 10.5 making other technical and minor changes
- 11 note that the Crown organisations most likely to be affected by this change will be: Health New Zealand (including public hospitals), the New Zealand Blood Service and (less likely) the Ministry of Health, the Māori Health Authority, and Pharmac
- 12 authorise me to make minor and technical changes (within the scope of Cabinet's decision) identified during drafting to resolve any unintended consequences that are associated with the extension of criminal liability to Crown organisations
- 13 note that this paper will not be proactively released within 30 days but will be proactively released, with redactions, as part of a general release of papers to accompany the introduction of the Bill to Parliament.

Authorised for lodgement

Hon Andrew Little

Minister for Health

PROACTIVELY RELEASED

Appendices

PROACTIVELY RELEASED

Appendix 1 – Scenarios where Crown acts directly in therapeutic product and natural health product supply chain

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

Potential breach of clause 51 of the Therapeutic Products Bill

2. As a 'cost saving' activity, a Crown organisation directs its employees to sterilize and re-use medical devices that are approved only as 'single-use' devices

Potential breach of clause 53(1) of the Therapeutic Products Bill. The Crown organisation may also be acting as a 'remanufacturer', and the now reusable product may require market authorisation before it can be lawfully supplied or used

3. A Crown organisation manufactures in-vitro diagnostic devices (i.e., 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

Potential breach of clauses 51, 53 and 55 of the Therapeutic Products Bill

4. A hospital conducts a 'pharmacy business' without a proper licence and undertakes unauthorised pharmacy activity and other activities not in accordance with the conditions of its licence

Potential breach of clauses 55, 158 and 159 of the Therapeutic Products Bill

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

Potential breach of clauses 55 and 117 of the Therapeutic Products Bill

6. Under the auspices of their Crown employer, health practitioners conduct a clinical trial without first obtaining ethics approval or a waiver

Potential breach of clause 55 of the Therapeutic Products Bill

Appendix 2 – Indicative offences to apply to the Crown

Clause in Bill (exposure draft 2018)	Provision	Extent of criminal liability for Crown organisations
51	Product approval required to import or supply	Prosecution or infringement fine
52	Sponsor's consent required to import approved product	Prosecution or infringement fine
53	Authorisation required for controlled activity	Prosecution or infringement fine
54	Authorisation required for non-wholesale supply of category 1 medicine	Prosecution or infringement fine
55	Persons in supply chain must comply with regulations	Prosecution or infringement fine
81	Prohibited product without authorisation	Infringement fine only
85	Tampering with therapeutic products	Prosecution or infringement fine
86	Supply of tampered-with therapeutic products	Prosecution or infringement fine
87	Notifying regulator of suspicion of tampering	Infringement fine only
88	Misrepresentation about therapeutic product	Prosecution or infringement fine
92	Misleading information in records	Infringement fine only
101	Sponsor must notify Regulator of certain minor changes	Prosecution or infringement fine
116	Sponsor of approved product must ensure compliance with approval	Prosecution or infringement fine
117	Sponsor must ensure compliance with product standards	Prosecution or infringement fine
118	Sponsor must comply with regulations	Prosecution or infringement fine

IN CONFIDENCE

153	Licensee must ensure responsible person has authority and resources	Infringement fine only
154	Licensee must ensure health practitioner has authority and resources	Infringement fine only
158	Responsible person must comply with regulations	Infringement fine only
159	Licensee must ensure only authorised persons carry on pharmacy activities	Infringement fine only
169	Compliance with directions order	Infringement fine only
171	Compliance with product prohibition order	Prosecution or infringement fine
197	Misleading information to regulator	Infringement fine only
198	Compliance with investigative requirements	Infringement fine only

PROACTIVELY RELEASED