MINISTRY OF JUSTICE
Tāhū o te Ture

LEGAL ADVICE

LPA 01 01 24

21 November 2022

Hon David Parker, Attorney-General

Consistency with the New Zealand Bill of Rights Act 1990: Therapeutic Products Bill

Purpose

1. We have considered whether the Therapeutic Products Bill (the Bill) is consistent with the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990 (the Bill of Rights Act).

2. We have not yet received a final version of the Bill. This advice has been prepared in relation to the latest version of the Bill (PCO 19563/45.2) received on 18 November 2022. We will provide you with further advice if the final version includes amendments that affect the conclusions in this advice.

Summary

3. The Bill is intended to replace the current Medicines Act 1981 and Dietary Supplements Regulations 1985 to provide for the comprehensive, risk-proportionate regulation of therapeutic products.

4. Therapeutic products are medicines, medical devices, Natural Health Products (NHPs)[1], and active pharmaceutical ingredients (APIS). They include:

    a. Medicines made from biological components, gene therapies, and advanced cell and tissue therapies;

    b. Medical devices that are software, production systems, whole organs and tissue grafts; and

    c. NHPs that are traditional and herbal medicines, and vitamin and mineral supplements.

5. Therapeutic products are used by all New Zealanders in their everyday lives and in all parts of the health system.

6. We have concluded that the Bill appears to be consistent with the rights and freedoms affirmed in the Bill of Rights Act. In reaching that conclusion, we have considered the consistency of the Bill with:

    a. section 14 (freedom of expression);

[1] NHPs are traditional and herbal medicines, and vitamin and mineral supplements. Examples include rongoā Māori (traditional Māori remedies) and traditional Chinese medicine, as well as low concentration NHPs.

b. section 20 (rights of minorities);

c. section 21 (unreasonable search and seizure);

d. section 25(c) (the right to be presumed innocent until proven guilty); and

e. section 26(2) (double jeopardy).

7. Our analysis is set out below.

The Bill

8. The purpose of the Bill is to protect, promote, and improve the health of all New Zealanders by providing for the —

a. acceptable safety, quality, and efficacy of medicines and APIs across their life cycle; and

b. acceptable safety, quality, and performance of medical devices across their life cycle; and

c. acceptable safety and quality of NHPs across their life cycle.

9. A therapeutic product is one that is intended to be used by humans for a therapeutic purpose. This includes: preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury; testing the susceptibility of humans to a disease or an ailment; investigating, replacing, modifying, or supporting part of a human's anatomy; disinfecting medical devices; and maintaining health and providing for human nutritional supplementation.

10. While therapeutic products can provide enormous benefits, they are not risk-free. The ingredients used in a product may be inherently risky (for example, many chemotherapies), harmful in large amounts (for example, many pain relievers) or present unique risks to different groups (for example, pregnant people, infants, or those taking other medicines). Risk can also arise during a product's manufacture, such as contamination or counterfeiting. The effectiveness or safety of products can be affected by improper handling and transportation, inappropriate supply, or administration or use by unqualified people. A guiding principle for regulating therapeutic products is that the likely benefits should outweigh the likely risks and their regulation should be proportionate to those benefits and risks.

11. Other guiding principles important in helping achieve the Bill's aim are that regulation of therapeutic products should support timely access to products, open and well-functioning markets, and innovation. Regulation should also support choice of, and equity of access to, therapeutic products. There should be co-operation with overseas regulators and, if appropriate, alignment with international standards and practice.

12. The Bill's aim and guiding principles mean therapeutic products will be regulated across their life cycle with obligations being imposed on people involved in a product's supply chain.

13. The regulatory scheme consists of two broad components:

a. market authorisation requirements, which regulate which therapeutic products may be imported into, supplied in, or exported from New Zealand; and

b. controlled activity and supply chain activity requirements, which regulate how those therapeutic products can be dealt with and by whom.

14. The Bill also establishes a Therapeutic Products Regulator to administer the regulatory scheme. The Regulator will be responsible for ensuring the safety, quality and efficacy or performance of regulated products across their life cycle.

15. The Bill provides the Regulator with a range of compliance and enforcement powers backed up by a comprehensive offence and civil penalty regime.

Consistency of the Bill with the Bill of Rights Act

Section 14 – Freedom of expression

16. Section 14 of the Bill of Rights Act affirms the right to freedom of expression, including the freedom to seek, receive, and impart information and opinions of any kind in any form. The right to freedom of expression has also been interpreted as including the right not to be compelled to say certain things or to provide certain information.[2]

17. There are a vast number of provisions in the Bill which *prima facie* engage the right to freedom of expression. Some of these provisions are prescriptive, describing in detail what is required and by whom, while others set out more generic requirements that may be drawn upon further in any regulations (noting secondary legislation is also subject to the Bill of Rights Act).

18. These provisions can be broadly split into the following categories:

a. **Requirement to provide information:** There are a number of clauses that require the sponsor (that is, a holder of a market authorisation) of certain products to notify the Regulator of certain things. For example, clause 145 requires a sponsor to notify the Regulator of likely shortages if they have reasonable grounds to believe that demand in New Zealand for a reportable product is likely to exceed supply at any time in the next 6 months. Clause 206 states that an inspector may, by written notice, require a specified person to give the Regulator any information that they reasonably need for regulatory purposes. Clause 365 states that in assessing an application, the Regulator may obtain any other information they consider appropriate from any source.

b. **Notification of misconduct:** There are a number of clauses that require people to notify the Regulator if there are issues of misconduct. For example, clause 183 states that if a responsible person for a licence has reason to believe that a relevant person has contravened a provision of the Bill or has attempted or intends to do so (amongst other things) the responsible person must promptly notify the licensee of their belief and the reasons for it. Clause 189 requires a sponsor or person in the supply chain to notify the Regulator of known or suspected tampering or a risk of tampering.

[2] See, for example, *Slaight Communications v Davidson* 59 DLR (4th) 416; *Wooley v Maynard* 430 US 705 (1977).

c. **Labelling:** There are a number of clauses that require people to comply with certain labelling requirements. For example, clause 187 prohibits a person from tampering with a therapeutic product, threatening to do so, or claiming to have done so. The meaning of "tamper with" includes to interfere with its identification or labelling, its package, or its product information or consumer information in a way that adversely affects or might reasonably be expected to affect the product in specified ways. Clause 326 allows the court to make any orders it thinks appropriate in relation to the defendant's future use of identification, labelling, packages, or advertisements for therapeutic products if the defendant has contravened provisions relating to these matters.

d. **Advertising:** There are a number of clauses that require people to comply with certain advertising requirements. For example, clause 194 prohibits a person from advertising a therapeutic product unless it has appropriate authorisation and complies with the advertising and distribution requirements. This includes that the advertisement must include the name of the person using the advertisement to promote the product and if it is an advertisement for an NHP, it must not make a health benefit claim that is not a permitted health benefit claim for the NHP. In addition, the Regulator may make an advertising remediation order (such as directing the advertiser to distribute a correction) if satisfied on reasonable grounds that the advertiser has distributed, or caused the distribution of, an advertisement for a therapeutic product in contravention of clause 194 (see clause 218).

e. **Impermissible health benefit claims:** Clause 192 prohibits the sponsor of an NHP with a market authorisation from making a health benefit claim about the NHP unless it is a permitted health benefit claim or is made in accordance with the rules about how health benefit claims may be made.

f. **Prohibition on asking for benefit**: Clause 195 prohibits the sponsor or a supplier of a therapeutic product from giving a benefit to a health practitioner or veterinarian with the intention of inducing them to make favourable clinical decisions about the product. It also prohibits a health practitioner or veterinarian from accepting or asking for such a benefit.

19. A limit on a right may nonetheless be consistent with the Bill of Rights Act if the limit is justified under s 5 of that Act. The s 5 inquiry asks:

    a. does the provision serve an objective sufficiently important to justify some limitation of the right or freedom?

    b. if so, then:

        i. is the limit rationally connected with the objective?

        ii. does the limit impair the right or freedom no more than is reasonably necessary for sufficient achievement of the objective?

        iii. is the limit in due proportion to the importance of the objective?[3]

20. We consider that any limits on the freedom of expression contained within the Bill are justified under s 5 of the Bill of Rights Act because:

[3] *Hansen v R* [2007] NZSC 7, [2007] 3 NZLR 1.

a. The overall objective of the Bill, which is to provide for the comprehensive, risk-proportionate regulation of therapeutic products is sufficiently important to justify some limit on s 14. The objective of many of these provisions is to ensure compliance with the regulatory regime. For example, they enable the Regulator to assess an application for an NHP or require a sponsor or person in the supply chain to provide information to enable the Regulator to determine whether the Bill is being complied with. The objective of other provisions is to support public health, such as by regulating advertising and the kinds of claims that can be made about NHPs and prohibiting health practitioners from asking sponsors or suppliers of therapeutic products for benefits. Requiring parties to provide information to the Regulator and prohibiting certain claims and requests go to the heart of the regulatory regime and, as such, we consider it reasonable for persons to be required to comply with these requirements.

b. The requirements imposed on people to provide certain information in specific circumstances are rationally connected to this objective. Ensuring that relevant information is provided in the prescribed manner to all necessary parties is fundamental for achieving the Bill's regulatory and public health objectives.

c. The requirements in the Bill limit freedom of expression no more than reasonably necessary for the regime to operate efficiently and are proportionate to the importance of the Bill's objectives. We note in particular that many of these provisions involve factual information and contain limited expressive value, and that people will choose to be part of the regulatory regime in the course of business. Under clause 365, people who have not chosen to be part of the regulatory regime may be requested by the Regulator to provide information. However, there is a public interest in there being a sufficient ability for the Regulator to obtain relevant information.

21. Accordingly, any limits to s 14 are justified under s 5 of the Bill of Rights Act.

Section 20 – Rights of minorities

22. Section 20 of the Bill of Rights affirms that individuals who belong to an ethnic, religious, or linguistic minority in New Zealand shall not be denied the right, in community with other members of that minority, to enjoy the culture, to profess and practice the religion, or to use the language, of their minority.

23. The Bill appears to limit this freedom under the Bill of Rights Act by regulating NHPs, which includes rongoā Māori and Traditional Chinese Medicine, in so far as it restricts an individual's right to import, supply, export, and provide information about such NHPs in the course of business.

Market authorisation and controlled activities

24. Clause 67 prohibits a person from importing, supplying, or exporting an NHP in the course of a business or undertaking, unless the product has requisite authorisation. "Business or undertaking" means a business, professional practice, or other undertaking, whether or not carried on for gain or reward.[4]

[4] See clause 14 of the Bill. We have been informed that this Bill is not intended to regulate individuals' personal or domestic affairs.

25. Clauses 122 to 125 provide for the issue of market authorisations for NHPs. They differ from the provisions relating to medicines to reflect the fact that the risks associated with NHPs are generally less than the risk associated with medicines. For example, there is no requirement to establish the efficacy of the product (like the requirement for medicines).

26. Clause 69 provides a person must not carry out a controlled activity unless they have a licence, permit, or are allowed by a provision of subpart 3 of Part 3. Controlled activities in relation to NHPs means manufacturing or exporting an NHP, or importing a low concentration NHP, in the course of business. The criteria for granting a licence (clause 158) or permit for controlled activities (clause 165) include criteria relating to ensuring adequate management of the risks with carrying on the controlled activity.

27. The Bill contains carve outs for NHPs from the requirements regarding market authorisation and controlled activities in some circumstances, including the following:

    a. Clause 111 provides an exception to the requirements of clause 69 as outlined above and allows the sponsor of an NHP with market authorisation to manufacture or export it without needing a licence.

    b. Clause 112 provides an exception to the requirements in clause 67 and 69 outlined above and allows an NHP practitioner to manufacture, supply or export an NHP without authorisation if they meet the specified criteria.[5]

    c. Clause 67(2) provides an exception to the requirements in clause 67, as outlined above, where the product is a low concentration NHP.

Impermissible health benefit claims

28. Clause 192 prohibits the sponsor of an NHP with a market authorisation from making a health benefit claim about the NHP unless it is a permitted health benefit claim or is made in accordance with the rules about how health benefit claims may be made. However, clause 61 states that a health benefit claim about an NHP may be substantiated by scientific evidence, evidence of traditional use, or both. It also states that information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is *prima facie* evidence of that use.

Discussion

29. We have considered if the limit on the right is consistent with the Bill of Rights Act in accordance with the test at paragraph 19 above.

30. On balance, we are satisfied that some limitation on the right to s 20 of the Bill of Rights Act is justifiable given the important public health objectives of the regulatory scheme. In coming to this view, we note that these provisions aim to provide for the acceptable safety and quality of NHPs across their life cycle, and to adequately regulate health benefit claims made about NHPs. Regulating the import, supply, export, and provision of information about NHPs in the course of business is rationally connected with these

[5] Clause 112 allows an NHP practitioner to manufacture and supply an NHP that does not have market authorisation if it is manufactured for a specific client after the practitioner has determined that it is appropriate for the client and the other criteria in the clause are met. If the client is overseas, but ordinarily in New Zealand, the NHP practitioner can export it to the client.

objectives. The limit is no greater than reasonably necessary and proportionate to the objectives as the Bill only regulates those who are acting in the course of business or undertaking, and not those acting in a personal or domestic capacity. In addition, there are less stringent requirements for NHPs than there are for medicines to reflect their lower risk as well as carve outs of the regulatory scheme for NHPs (as outlined above).

Section 21 – Unreasonable search and seizure

31. Section 21 of the Bill of Rights Act affirms that everyone has the right to be secure against unreasonable search or seizure, whether of the person, property, correspondence or otherwise. The right protects a number of values, including personal property, dignity, and privacy.[6]

32. Ordinarily, a provision found to limit a particular right or freedom may be consistent with the Bill of Rights Act if it can be considered reasonably justified in terms of s 5 of that Act. However, the Supreme Court has held that an unreasonable search logically cannot be demonstrably justified and therefore the inquiry does not need to be undertaken.[7] Rather, s 21 is self-limiting in that the assessment to be undertaken is whether the search power is reasonable. The reasonableness of a search and seizure can be assessed with reference to the purpose of the search and seizure and the degree of intrusion on the values which the right seeks to protect.

Regulatory powers

33. Subpart 2 of Part 7 provides regulatory powers to enable the Regulator to perform their surveillance, response and compliance monitoring functions. The powers are exercisable by appointed inspectors and the Regulator (who is, by definition, also an inspector). Clause 355 also provides that the Regulator may exercise any of their powers under this subpart to obtain information or things at the request of an overseas regulator.

34. The Bill provides the Regulator with a number of regulatory powers that engage s 21, for example:

    a. The requirement for a sponsor, licensee or permit holder, person in the supply chain, or other person listed in the Bill to give the Regulator any information the Regulator reasonably needs for regulatory purposes (clause 206).

    b. The power for an inspector to require the sponsor of a therapeutic product to take samples and test products and devices, or give the Regulator a sample or a sample of a device's output, for testing (clause 207).

    c. The power to enter a place (clause 208) where a supply chain activity or an activity that a licence or permit allows to be done, is being carried out. Upon entry the inspector may (see clause 210):

        i. inspect or examine the place and anything found there that relates to a supply chain activity, an activity related to a licence or permit, or a therapeutic product;

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[6] See, for example, *Hamed v R* [2011] NZSC 101, [2012] 2 NZLR 305 at [161] per Blanchard J.

[7] *Hansen v R* [2007] NZSC 7, [2007] 3 NZLR 1 (SC) per Blanchard J.

ii. test any equipment, process or procedure;

iii. take samples;

iv. make records or recordings of things done at the place;

v. take copies of documents or information produced; and

vi. use any equipment they reasonably need.

35. Subpart 3 of Part 7 also allows the Regulator to make a recall order for a therapeutic product if satisfied that the continued availability of the product poses a risk to health. A recall order may also impose requirements on people in the supply chain to, for example, return or dispose of the product. The Regulator may also seize or require the destruction of a prohibited product or product that has been misrepresented as a therapeutic product (clause 224).

36. The Bill provides that a person who impedes the Regulator or an inspector in these activities commits an offence and may be subject to a fine on conviction.

37. Overall, we consider that the *prima facie* limits to the right under s 21 are reasonable in the circumstances. In particular:

a. A person may only be required to obtain or compile information for the purposes of giving it to the Regulator, where the inspector is satisfied on reasonable grounds that it is reasonable to require the person to do so. Personal information is generally excluded unless the information could not reasonably be obtained without the personal information being disclosed.

b. Persons must be given a reasonable timeframe within which to comply with the notice to provide information or samples or undertake testing.

c. The power of the Regulator to either require a sponsor to take samples or provide information is limited to persons described in the Bill, all of whom voluntarily participate in the regulatory regime knowing that they will be subject to regulatory requirements.

d. Any sample taken or required to be tested must be no more than the smallest sample reasonably needed for the purpose for which it is required.

e. Although the degree of intrusiveness is high as the inspector may enter property that is private, without providing any prior notice, entry to a home, a marae or associated building, or a consultation treatment room that is in use, may only be made with consent of the occupier or in accordance with a warrant issued under the Search and Surveillance Act 2012.

f. The expectation of privacy in a public welfare regulatory context is lower than in other contexts. The power of entry and inspection may only be used in places where a supply chain activity or an activity that a licence or permit allows to be done, is being carried out.

g. On entering a place, the inspector's powers to inspect, examine, and test any equipment, process or procedure is limited to anything found there that relates to a supply chain activity carried on at that place, an activity that a licence or permit

allows to be carried on at the place, and therapeutic products that are or were at the place.

h. The inspector is not permitted to access or require anyone to give them access to any computer system, or data storage device that is not part of a therapeutic product.

i. When entering a place an inspector must take reasonable steps to find the person in charge of the place, identify themselves and inform them of the purpose of entry.

j. Section 60 of the Evidence Act 2006 applies to this subpart, which means a person can refuse to provide information to the inspector if the information would likely incriminate the person for an offence.

k. Recall orders may only be made by the Regulator if they are satisfied, on reasonable grounds, that the continued availability of the product directly or indirectly creates or increases a significant risk to personal or public health.

l. The requirement to destroy or give the Regulator a prohibited product relates to a product that exposes an individual to a risk of death, serious injury or serious illness and the risk cannot be adequately managed by the Regulator's powers.

38. In so far as the Bill allows these powers to be exercised at the request of an overseas regulator (clause 355), they may be exercised at the discretion of the Regulator and only where the Regulator is satisfied that it is appropriate to do so. The powers are also rationally connected with the functions of the Regulator which include engaging and cooperating with overseas regulators and organisations, which in turn facilitates the Regulator being able to rely on reports, assessments, decisions or information received from overseas regulators.

39. We have concluded that these regulatory powers contain sufficient safeguards to ensure that they are reasonable under s 21 of the Bill of Rights Act, taking into account the public health rationale for which these powers are being exercised and the safeguards around the use of these powers.

Investigative powers

40. Subpart 1 of Part 8 sets out investigative powers to enable the Regulator to investigate and obtain evidence of noncompliance with the Bill and perform their investigative functions. A number of these powers engage s 21 with associated offences for non-compliance under this subpart.

41. For example, clause 240 allows the Regulator to authorise an inspector to enter and search a specific place if the Regulator reasonably suspects that a provision of the Bill has, is being, or will be, contravened and that the search will find evidential material relating to that contravention. The inspector may enter and search the place with the consent of the occupier or under a search warrant. The provisions of the Search and Surveillance Act 2012 relating to search, surveillance, and inspection powers and production orders apply to a search under this part. On entering, the inspector has the same search powers for enforcement purposes as they would for regulatory purposes.

42. The Bill also allows an inspector who is exercising a regulatory power of entry, and finds evidence of a contravention of the Bill, to carry on exercising that power. This means

that an inspector who has entered a place for regulatory purposes and finds evidence of an offence does not have to leave the place and get a search warrant before continuing the search. They can remain at the place and continue exercising that power for enforcement purposes.

43. Although this permits a departure from the original purpose of the search, we consider that this expansion is reasonable. To require the inspector to leave the premises and apply for a search warrant would enable evidence of non-compliance to be removed or destroyed, having the effect of undermining the Bill's objective to protect public health and the Regulator's enforcement powers.

44. This subpart also provides for the destruction of things seized under this subpart. Given the safeguards in the Search and Surveillance Act that apply to searches under this subpart and the importance of removing products from circulation that pose a risk to public safety, we consider that these seizure powers are reasonable.

45. An inspector who finds a person contravening the Bill, or reasonably suspects that the person has done so, may require that person to give their name and address. It is an infringement offence to fail to provide this information. This information is necessary to be able to take any kind of enforcement action against that person.

46. Clause 327 also enables a court to make orders about forfeiture or disposal of therapeutic products that are the subject of proceedings and things related to them. This also *prima facie* engages s 21. However, we consider this seizure power is reasonable, as its purpose is to remove from circulation certain products (including ingredients or packaging) which may be harmful to public health.

47. Although the intrusion on privacy is high, we consider that there are sufficient safeguards to ensure that the intrusion is no greater than necessary in order to enable the Regulator to enforce the provisions of the Bill. The ability of the Regulator to take enforcement action is dependent on their ability to gather evidence of any contravention. We therefore consider that the search powers are necessary and reasonable in these circumstances.

Conclusion

48. We have concluded that in so far as the regulatory, investigative and enforcement powers contained in the Bill constitute search and seizure and engage s 21, they are reasonable when viewed in light of the Bill's objectives of protecting public health and safety, and the purpose of the Regulator's powers to monitor compliance with the regulatory regime and to enforce the provisions of the Bill.

Section 25(c) – Right to be presumed innocent until proven guilty

49. Section 25(c) of the Bill of Rights Act affirms the right of everyone charged with an offence to be presumed innocent until proven guilty according to law. The right to be presumed innocent requires the Crown to prove an accused person's guilt beyond reasonable doubt.

50. Strict liability offences *prima facie* limit s 25(c) of the Bill of Rights Act. This is because a strict liability offence may be proved by a finding that certain facts occurred without proof of *mens rea*. The accused is required to prove a defence (on the balance of probabilities), or disprove a presumption, to avoid liability. This means that, where the accused is unable to prove a defence, they could be convicted even where reasonable doubt about their guilt exists.

51. Strict liability offences may nevertheless be justifiable limits on rights under s 5 of the Bill of Rights Act. They have been found to be more likely to be justifiable where:

    a. The offences are regulatory in nature and apply to persons participating in a highly regulated industry;

    b. The defendant will be in the best position to justify their apparent failure to comply with the law, rather than requiring the Crown to prove the opposite; and

    c. The penalty for the offence is proportionate to the importance of the Bill's objective.

52. The Bill contains numerous strict liability offences for contravention of provisions under the Bill (refer subpart 3 of Part 8), which give rise to a *prima facie* issue of inconsistency with s 25(c).

53. We have concluded that the strict liability offences are justified for the following reasons:

    a. The offences serve the important objective of promoting compliance with the Bill in order to protect public health.

    b. We consider that the fines are reasonable, likely to be commensurate with the entities' or individuals' ability to pay and necessary to ensure compliance with the Bill. The maximum penalty for a strict liability offence is a fine of an amount set out in the offence provision, but ranges from between $30,000 and $100,000 for individuals, and otherwise between $170,000 and $500,000.

    c. The court maintains the discretion to impose a lesser penalty.

    d. Because there is no requirement to prove a state of mind, the fines are considerably less than those for fault-based offences.

    e. Subpart 10 of Part 8 of the Bill provides a defence if the defendant took all reasonable steps to ensure that the conduct constituting the contravention did not occur and to mitigate any effect the conduct had in creating or increasing a significant risk to personal health or public health. Common law defences of absence of fault are also available to the defendant. The defendant will be best placed to demonstrate that they took reasonable steps or there was a total absence of fault.

54. Clauses 318 and 319 include certain presumptions regarding labels and samples relating to any proceedings under the Bill, unless the contrary is proved. This places the burden of proof on the defendant to prove otherwise. We consider that the presumption with respect to samples is reasonably justified as it would be impractical to require the Regulator to test every product from an identified quantity of therapeutic products. With respect to labelling, it is reasonable to presume that the package conforms with that description and that the person identified on the label carried out a supply chain activity. In both cases, in any proceedings under the Bill the defendant is best placed to be able to show that the presumption is incorrect.

55. The Bill also contains a number of infringement offences resulting in the requirement to pay an infringement fee or fine. The quantum is to be set out in regulations but will be at the lower end of the penalty scale. The Bill provides that an infringement fee must not be more than 5% of the strict liability penalty (or if there is no strict liability offence,

$1,000) and a fine must not be more than the strict liability penalty (or if there is no strict liability offence, $5,000). A person issued with an infringement offence may either pay the infringement fee or elect for the matter to go to court, and the matter will generally dealt with in accordance with the Criminal Procedure Act for a category 1 offence. However, if they are found to have committed the contravention, that is not a conviction.

56. The context for these strict liability and infringement offences is within a highly regulated environment designed to protect public health. They apply to individuals engaged within that regulated environment and in contexts where defendants have an opportunity to provide a defence. Fines are also set at a level that accounts for no-fault-based offences. Bearing all these factors in mind, these offences appear to be justifiable limits to the right to be presumed innocent.

Section 26(2) – Double jeopardy

57. For completeness, we have considered whether the offence provisions engage the right in s 26(2) of the Bill of Rights Act to be protected from double jeopardy. While subpart 6 of Part 8 of the Bill expressly prevents a person who contravenes a provision of the Bill being subject to both a civil penalty order and liability for an offence, the Bill does not specifically address the situation where a person's conduct constitutes 2 or more offences (whether knowledge based, strict liability or infringement offences).

58. We consider that the Bill can be read consistently with the Bill of Rights Act in this respect, because the criminal rule of double jeopardy would apply to ensure that a person cannot be held criminally liable twice for the same conduct. Therefore, although the Bill gives the Regulator a range of options for enforcing compliance with the Bill, only one of those options can be used with respect to the same conduct. Section 26(2) of the Act is therefore not engaged.

Conclusion

59. We have concluded that the Bill appears to be consistent with the rights and freedoms affirmed in the Bill of Rights Act.

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