6 December 2006

ATTORNEY-GENERAL

LEGAL ADVICE
CONSISTENCY WITH THE NEW ZEALAND BILL OF RIGHTS ACT 1990:
THERAPEUTIC PRODUCTS AND MEDICINES BILL 2006

1. We have considered whether the Therapeutic Products and Medicines Bill 5277/29 is consistent with the New Zealand Bill of Rights Act 1990 ("the Bill of Rights Act"). We understand that the Bill was considered by Cabinet on 4 December 2006 and was introduced on 5 December 2006.

2. We have concluded that the Bill appears to be consistent with the Bill of Rights Act. In reaching this conclusion, we considered potential issues of consistency with sections 14, 21 and 25(c) of the Bill of Rights Act. Our analysis of these potential issues is set out below.

3. We are advised that the Bill will be divided into a Therapeutic Products Bill and a Medicines Bill at the conclusion of the Committee of the Whole House stage of the legislative process, resulting in two Acts of Parliament. Accordingly, for ease of reference, we have divided our advice, under the different sections of the Bill of Rights where an issue of consistency appears to be raised, into two headings reflecting the two distinct parts of the Bill.

SUMMARY OF THE BILL OF RIGHTS ACT ISSUES

4. The following summary provides you with:

   - A brief overview of the contents of the Bill;
   - A note of the provisions of the Bill which appear to raise issues under one of the sections of the Bill of Rights Act; and.
   - Our conclusion as to the Bill's consistency with the Bill of Rights Act.

5. This summary is followed by a fuller analysis which discusses each of the issues raised under the Bill of Rights Act noting where relevant the justificatory material in each instance.

6. The purpose of the Bill is to establish a new trans-Tasman regulatory scheme for the regulation of therapeutic products. The joint regulatory scheme will cover all of the pre-market controls required to help ensure the safety, quality and efficacy or performance of medicines and medical devices, along with some post-market monitoring and surveillance activities. The Bill disestablishes the New Zealand Medicines and Medical Devices Safety Authority, and establishes the Australia New Zealand Therapeutic Products Authority in its place.

7. In addition, the Bill repeals and replaces the Medicines Act 1981 (and regulations made under that Act) with updated legislation for controls on medicines after they have been approved for the market and are in the domestic supply and distribution chain in New Zealand.

8. Several clauses in the Bill require people to provide information and documents to authorities and to the Finance Minister. These clauses give rise to an issue under section 14 of the Bill of Rights Act (right to freedom of expression) because they compel an individual to provide information. We consider that any potential issues of inconsistency are justifiable as the information will be used to ensure compliance with the regulatory regime and detecting and prosecuting breaches of the Act.

9. The Bill contains a number of provisions that empower searches for and seizures of documents, therapeutic products and medicines. These clauses give rise to issues under section 21 of the Bill of Rights Act which provides protection against unreasonable search and seizure. Given the public safety reasons for the searches and the safeguards that are included, we consider that the search powers are reasonable

10. We have also considered whether the reverse onus and strict liability offences and presumptions in the Bill are consistent with the right to presumption of innocence under section 25(c) of the Bill of Rights Act. We consider that the offences are justifiable in light of the nature and degree of offending that could occur under the Bill.

11. We have concluded that the Bill does not appear to be inconsistent with the Bill of Rights Act.

BILL OF RIGHTS ACT ISSUES

SECTION 14 FREEDOM OF EXPRESSION

12. Section 14 of the Bill of Rights Act protects the right to "freedom of expression, including the freedom to seek, receive and impart information and opinions of any kind and any form." The right to freedom of expression includes the right to say nothing or the right not to say certain things.[1]

Therapeutic Products Bill

<u>Providing information about therapeutic products</u>

13. Clause 78 (Applicants, holders, and former holders failing to comply with information requirement notice) and clause 80 (Persons exempt from requirement

[1] *RJR MacDonald v Attorney-General of Canada* (1995) 127 DLR (4th)1.

to hold product licence failing to comply with information requirement notice) create the offence of failure to provide information with respect to a therapeutic product where a person is given a notice under the Rules requiring her or him to do so.

14. Clause 81(1) provides that a person is not excused from giving this information on the grounds that the information would tend to incriminate the person or expose the person to penalty. Clause 81(2) further states that this rule applies 'despite anything to the contrary in any enactment, including the Bill of Rights Act, or the rule of law.' However, clause 81(3) provides that information provided under these provisions cannot be used in civil penalty or criminal proceedings against that person unless the information is false or misleading (clauses 79 and 82).

15. We consider that the requirements of clauses 78, 79, 80, 81(1) and (2) and 82 amount to compulsion to provide information and therefore are prima facie inconsistent with section 14 of the Bill of Rights Act.

16. Where a provision is found to be prima facie inconsistent with a particular right or freedom, it may nevertheless be consistent with the Bill of Rights Act if it can be considered a reasonable limit that is justifiable in terms of section 5 of that Act. The section 5 inquiry is essentially two-fold: whether the provision serves an important and significant objective; and whether there is a rational and proportionate connection between the provision and the objective.

17. The objective of these provisions is to ensure compliance with the regulatory regime by requiring persons such as manufacturers to provide information which will enable the authorities to determine whether licensing and conformity assessment procedures are being complied with. Requiring those involved in the manufacture of therapeutic products to provide information to regulators goes to the heart of the regulatory regime, and as such we consider to reasonable for persons to be required to provide this information.

18. We note that, while purporting to oust the protection of the Bill of Rights Act and the common law, clause 81(3) generally provides protection against the use of the information in any subsequent proceedings against the individual who provides it. The only proceedings in which this information can be used is for the offence of giving false information. Given this safeguard, we consider that any limit that these provisions place upon the freedom of expression is justifiable.

<u>Providing information to Finance Minister</u>

19. Clause 248 (Requirement to provide information in connection with criminal proceedings) and clause 254 (Requirement to provide information in connection with civil penalty proceedings) empower the Finance Minister to require a person to give all reasonable assistance in connection with criminal and civil proceedings

relating to the failure of a senior officer (board members and senior managers) to comply with their duties under clause 247 (criminal) and clause 250 (civil). We consider that these requirements amount to compelled expression, which gives rise to *prima facie* inconsistency with section 14 of the Bill of Rights Act.

20. The objective of clause 247 is to ensure that senior officers act in a manner consistent with the spirit of service to the public, in good faith, and for a proper purpose. Empowering the Finance Minister to require information from a person under clause 248 is essential as a means of detecting and prosecuting breaches of senior officers' duties.

21. Turning to the issue of proportionality, we note that under clause 248 the Finance Minister can only exercise this power where she or he believes on reasonable grounds that the person has information that is relevant to the proceedings and the information cannot readily be obtained from any other person. In addition, no information provided pursuant to such a requirement may be used in any civil penalty or criminal proceedings as evidence against the person who provided the information. The class of persons from whom information may be required excludes:
    - a defendant in any criminal proceedings under clause 247;
    - an employee, agent (including banker or auditor), or business partner of a person who is, or is likely to be, a defendant in the proceedings; and
    - a lawyer who has acted for the defendant, or likely defendant, in any current or previous criminal or civil proceedings under this Part.

22. Under clause 254, the Finance Minister can only exercise this power in anticipation of civil penalty proceedings (under clause 250), where the Finance Minister suspects or believes that the person is required to assist can give information relevant to the application; and the person is not, and has not been, a lawyer for the person in respect of whom the application is made.

23. Given these restrictions and safeguards on use of this power, we conclude that the limitation these clauses place on the right to freedom of expression is justified.

SECTION 21 SECURITY AGAINST UNREASONABLE SEARCH AND SEIZURE

24. Section 21 provides the right to be secure against unreasonable search and seizure. There are two limits to the section 21 right. First, section 21 is applicable only in respect of those activities that constitute a "search or seizure". Second, where certain actions do constitute a search or seizure, section 21 protects only against those searches or seizures that are "unreasonable" in the circumstances.

Therapeutic Products Bill

<u>Searches for monitoring purposes</u>

25. Clause 101 of the Bill provides that an authorised officer[2] may enter a place at a reasonable time, in order to monitor compliance with the regulatory regime. The powers of the authorised officer include inspecting and examining anything at that place that relates to therapeutic products, inspecting documents and seizing evidential material. We consider that clause 101 constitutes a power of search and seizure for the purposes of section 21 of the Bill of Rights Act.

26. There is a general presumption that searches should only be undertaken under the authority of a search warrant. However, in certain circumstances this presumption can be overridden. The provisions of the Act (including the Rules and Orders) apply to people involved in an activity that poses potential harm to individual and public safety. The expectation of privacy by an individual is greatly reduced in this context due to the highly regulated nature of the activity.

27. In our view, the search and seizure powers are reasonable in terms of section 21 of the Bill of Rights Act. The requirements of the Act exist for public safety reasons by ensuring that strict controls are in place around the quality and safety of therapeutic products and their manufacture and import and export. An ability to investigate potential failures to meet the specified requirements will enhance public safety, and accordingly the powers provide a necessary enforcement tool to ensure that all requirements of the Act are being strictly adhered to at all times, and to take further action where requirements are not being met. Failure to address potential and identified deficiencies will impact on the safe manufacturing and supply of therapeutic products.

28. When carrying out these duties, authorised officers may observe matters that allow them to form a belief on reasonable grounds than an offence against the Act has been or is being committed. If such a situation arose it might be necessary for the officer to secure evidence and mitigate any risks to public health.

29. We consider that the powers are a proportionate means of achieving the policy objective. In forming this view we have taken into account the following:

    - Dwellinghouses and marae (where there is a greater expectation of privacy than commercial premises) may not be searched under this provision (clause 101(1)).

    - The manner in which the search must be executed include:
        - The authorised officers are required to produce identification on entry and at any subsequent time when asked (clause 107);
        - The occupier is entitled to observe the search (clause 110);
        - If a document is to be seized a copy must be made and the left at the place (clause 112).

[2] Under clause 99 the Managing Director of may appoint authorised officers for all or specified purposed under Parts 1 to 5 of the Bill.

- Other safeguards to ensure that the powers are exercised reasonably include:
  - An authorised officer may only enter at a reasonable time (clause 101(1));
  - If the authorised officer fails to produce identification their authority to enter ceases (clause 107(2));
  - If documents are seized a receipt must be issued (clause 113).

30. We also note that clause 117 (Samples for testing or analysis) outlines the requirements that authorised officers who obtain samples for testing without a search warrant must comply with. These include informing the person that the sample may be submitted for testing or analysis. Furthermore, if the results of any testing or analysis of the article or thing may not be used in any proceedings for an offence or civil penalty under Parts 1 to 5 of the Bill, and if a sample is not submitted for testing or analysis, it must be treated in the same way as any other thing that is seized.

Search on serious public health grounds

31. Clause 102 of the Bill deals with situations posing a serious risk to public health. An authorised officer or a member of the police may enter and search any place and seize items if they reasonably believe that: provisions of Parts 1 - 5 of the Bill have not been complied with; it is necessary to exercise the powers in order to avoid an imminent risk of death, serious illness or serious injury; and it is not practicable to obtain a search warrant.

32. The objective of the clause is to ensure that authorised officers and members of the police have the necessary authority and powers to intervene in a situation where there is a significant risk to an individual's safety or to public safety.

33. As noted above, the presumption of searches being undertaken under the authority of a search warrant can be displaced in certain circumstances, including saving human life or serious public health issues. We have compared clause 102 with a similar provision in the Law Reform (Epidemic Preparedness) Bill. In that Bill it is proposed that police officers have the authority to enter into or on any land or building in order to assist Medical Officers of Health in dealing with the outbreak of infectious disease.

34. On balance and in light of the significant public harm that could occur in relation to activities regulated by the Bill, we consider that the powers under clause 102 are reasonable in terms of section 21 of the Bill of Rights Act. We note that requiring an officer to obtain a search warrant in this situation may delay any action being taken by the officer and could result in risk to public health and safety if medicines are inappropriately handled or distributed in the time it takes to obtain the warrant. In addition, we have taken into account the following checks and balances:

- The purpose of the entry and search power is to allow authorised officers to enter a place and exercise search and seizure powers in a situation where it is

necessary to do so to avoid an imminent risk of death, serious illness or serious injury (clause 102(1)(b)).

- The premises that can be searched exclude dwellinghouses and marae, where there is a greater expectation of privacy (clause 102(1)).

- The authorised officer must produce his or her identification card for inspection on entry and at any later time when requested (clause 107(1)).

- Safeguards include that authorised officer or member of the police must hold a reasonable belief that the situation exists (clause 102(1); and a search can only be executed where it is not practicable to obtain a search warrant (clause 102(1)(c)).

Powers under search warrant

35. Clauses 104 (Search warrant to seize evidential material) and 105 (Powers under search warrant) provide for powers of entry with search warrants. The powers include questioning the occupier and requiring the production of documents. We consider that these clauses create a power of search and seizure for the purposes of section 21 of the Bill of Rights Act.

36. We are of the view that the powers of entry and inspection are reasonable and therefore consistent with section 21 of the Bill of Rights Act. In forming this view, we note that the objective behind these clauses is to enable authorised officers to seize evidential material[3] where they reasonably believe that a person is or has not complied with the requirements of the Bill. We are advised that these powers are essential to ensure that persons who supply medicines to consumers comply with the regulatory regime.

37. We also note that these search and seizure powers are subject to the following checks and balances:

- There must be reasonable grounds for believing that there is evidential material at the place to be searched in order for a warrant to be issued (clause 104(1)).

- The requirements for exercising the search power include:
  - Generally, before entering a place the authorised officer or member of the police must announce that they are authorised to enter the premises (clause 108);
  - Giving copy of the warrant to the occupier (clause 109);
  - Allowing the occupier to observe the search (clause 110);

[3] Evidential material is defined in clause 98 as anything that there are reasonable grounds for believing is or may be evidence of an offence under Part 3, an attempt to commit an offence under Part 3 or the contravention of a civil penalty provision.

- If a document is to be seized, requiring a copy to be made and left at the place (clause 112).

- Safeguards against the search and seizure powers being exercised unreasonably include:
  - When items are seized from the premises, a receipt for the items must be provided to the occupier (clause 113(1));
  - The occupiers of the premises are protected against giving incriminating statements (clause 105(3)).

Searches at request of manufacturer

38. Clause 103 provides that a person may request that an authorised officer inspect any place and any specified processes for the purposes of paragraph 2 of Article 3 of the Mutual Recognition Convention[4] which relates to voluntary inspection of products to be exported to countries outside of Australia and New Zealand.

39. As the search is conducted at the request of the occupier, we consider that it is reasonable for the purposes of section 21 of the Bill of Right Act. We note that the authorised officer is required to carry out the search in accordance with the request (clause 103(2)).

Customs controlled areas

40. Clauses 123 (Right to inspect therapeutic products imported or for export), 124 (Non-compliant therapeutic products held at customs controlled area) and 125 (Special provisions relating to consignments) empower authorised officers to inspect and sample any therapeutic product and inspect any documents associated with the import or export of the therapeutic product, if the therapeutic product is in a customs controlled area. This process seeks to ensure that the rules relating to the import or export of the therapeutic product are being complied with; and thereby allows for the seizure of non-compliant products.

41. Given the objective of protecting public health and safety by ensuring that imported products comply with the regulatory regime, we consider that these search and seizure powers are reasonable. In forming this view we note that clause 124 requires the authorised officer to act in a manner that avoids or minimises the loss to the importer or exporter of any therapeutic products that are seized; and provides that the authorised officer may arrange for the products to be retained pending satisfaction of the requirements that will permit the products to be imported into, or exported from, New Zealand. Clause 125 requires the authorised officer to notify the importer or exporter where a sample has been taken, and serve notice on the importer or exporter that the products have been seized.

[4] Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products, opened for signature Geneva, 8 October 1970, entered into force 26 May 1971.

Medicines Bill

Powers of entry to inspect compliance

42. Clause 447 (Powers of entry to inspect compliance) provides that where a medicines control officer[5] has a reasonable belief that an activity regulated under Parts 6 and 7 of the Bill is being carried out at a particular premises, he or she may enter at any reasonable time those premises (except a dwellinghouse or marae). The medicines control officer, amongst other powers, may question the occupier, require the production of documents, and seize evidential material. We consider that clause 447 constitutes a power of search and seizure for the purposes of section 21 of the Bill of Rights Act.

43. The objective behind this clause is to ensure compliance with the provisions relating to the distribution and supply of medicines to consumers.

44. For the same reasons as set out above in paragraphs 27 to 29 regarding clause 101, we consider that the entry and inspection powers under clause 447 are reasonable in terms of section 21 of the Bill of Rights Act. In addition, we note that an occupier is protected from self-incrimination under clause 447(6).

Search where serious risk to public health

45. Clause 448 (Entry on serious risk to public health ground) of the Bill deals with situations posing a serous risk to public health. A medicines control officer or a member of the police may enter any place (other than a dwellinghouse or marae) if they reasonably believe that: provisions of Parts 6 & 7 have not been complied with; it is necessary to in the interests of public health to exercise the powers under this clause in order to avoid an imminent risk of death, serious illness or serious injury; and it is not practicable to obtain a search warrant. We consider that clause 448 constitutes a power of search and seizure for the purposes of section 21 of the Bill of Rights Act.

46. For the same reasons as set out above regarding clause 102 we consider that the search powers under clause 448 of the Bill are reasonable in terms of section 21 of the Bill of Rights Act.

Powers of entry with search warrant

47. Clauses 449 (Issue of search warrants) and 450 (Powers of entry with search warrant) provide for powers of entry with search warrants. The powers include

[5] Under clause the Director-General is required to appoint medical control officers to enforce Parts 6 and 7 of the Bill.

questioning the occupier and requiring the production of documents. We consider that clause 450 constitutes a power of search and seizure for the purposes of section 21 of the Bill of Rights Act.

48. For the same reasons set out above, regarding clause 105, we are of the view that the powers of entry and inspection under clause 450 of the Bill are reasonable and therefore consistent with section 21 of the Bill of Rights Act.

Producing documents and records

49. Clause 462(2) (Director-General or Medical Officer of Health may require documents or records) enables the Director-General or a Medical Officer of Health to exercise certain seizure powers if they reasonably suspect that a person is in possession of a medicine for supply or a related article in breach of Parts 6 or 7. Where subsection (1) is satisfied the Director-General or a Medical Officer of Health may require a person to produce any document or record that relates to the matters in that subsection. A statutory requirement to produce documents constitutes a search for the purposes of section 21 of the Bill of Rights Act.

50. This clause is intended to allow the Director-General or a Medical Officer of Health to investigate reasonably held suspicions in order obtain further information to enable a better assessment to be made as to whether there is a potential breach of Part 6 or 7. Accordingly, clause 462(2) provides low-level investigatory powers to enable this information to be accessed at an early stage.

51. We have been advised by the Ministry of Health that if after that initial low-level investigation the Director-General or a Medical Officer of Health form a reasonable belief that the Act is not being complied with, the powers under the search provisions (clauses 447 and 450) would then be used.

52. We consider that this power is reasonable in terms of section 21 of the Bill of Rights Act. In reaching this view, we note that these requirements exist for public safety reasons by ensuring that strict controls are in place around the distribution and supply of medicines. Because of the risk that those with access to medicines pose to public safety it is important to have an effective system which allows preliminary investigations, including accessing relevant information, to be undertaken in order to determine whether there is a problem and if so, who is involved.

SECTION 25(C) PRESUMPTION OF INNOCENCE

53. Section 25(c) provides:

> Everyone who is charged with an offence has, in relation to the determination of the charge, the right to be presumed innocent until proved guilty according to law.

54. This means that an individual must not be convicted where reasonable doubt as to her or his guilt exists, meaning the prosecution in criminal proceedings must prove, beyond reasonable doubt, that the defendant is guilty. Reverse onus offences and presumptions give rise to an issue of inconsistency with section 25(c) because the defendant is required to prove (on the balance of probabilities) the defence or disprove a presumption to escape liability; whereas in other criminal proceedings a defendant must merely raise a defence in an effort to create reasonable doubt. Where a defendant is unable to prove the defence (or disprove a presumption), then she or he could be convicted even though reasonable doubt exists as to her or his guilt.

55. We note the comment of the Supreme Court of Canada in *R v Oakes*[6] that the right to be presumed innocent until proven guilty requires that guilt must be proven beyond reasonable doubt, and that it is the State which must bear the burden of proof. In general, a provision which requires an accused person to disprove (on the balance of probabilities) the existence of a presumed fact, that fact being an important element of the offence in question, would be inconsistent with the presumption of innocence.

56. In *R v Downey,*[7] the Supreme Court of Canada held that mandatory presumptions requiring the accused to provide evidence raising reasonable doubt as to the existence of a fact may give rise to issues of consistency with the presumption of innocence. The Court said in *Downey* that such presumptions may, in situations where the defendant is unable to adduce sufficient evidence to rebut the presumption, lead to the conviction of a person even though reasonable doubt exists as to their guilt.

57. We have considered whether the following clauses can be considered a reasonable limit on the right to be presumed innocent until proven guilty by law in terms of section 5 of the Bill of Rights Act. In our view, justification for strict liability provisions and offences containing presumptions can occur where: the offence relates to a public welfare regulatory regime rather than truly criminal behaviour; the information sought is 'peculiarly within the realm of the defendant'; and the penalty for breach is at the lower end of the scale.

Medicines Bill

Reverse onus offences

[6] (1986) 26 DLR (4th) 200 (SCC).
[7] R *v Downey* [1992] 2 SCR 10

58. Two clauses in the Bill contain reverse onus offences:

- Clause 382 (possessing prescription medicines: controlled activity) provides that it is an offence to possess a prescription medicine without a reasonable excuse.

- Clause 460(3) (Offence of wilfully obstructing) provides that it is an offence for a person to refuse, without reasonable excuse, to provide a sample for the purpose of testing or analysis; produce, reproduce or assist in reproducing a document; or to answer any questions when required to do so by a medicines control officer or a member of the police who is exercising a search and seizure power under clause 447 or 450 of the Bill.

59. The objective of these provisions is to ensure that scheduled medicines, which may be harmful if not used as intended or prescribed, are kept secure, and are correctly supplied only to those persons who for which they have been prescribed. We consider that this is a significant and important objective.

60. Given that these offences are regulatory in nature, we consider it rational that the defendant be required to prove a reasonable excuse, as the defendant is best placed to adduce evidence as to the reasons for failure to comply with these requirements. While the penalties for these offences relatively high (up to 3 months imprisonment and / or a fine up to $ 40,000 for an individual, and a fine of up to $100,000 for a body corporate under clause 382; and a fine up to $20,000 for clause 460), they are broadly consistent with other strict liability regulatory offences aimed at protecting the public from significant harm, such as those under the Gambling Act 2003 and Films, Videos, and Publications Classification Act 1993.

61. In light of the nature and degree of offending which could occur under the Medicines Bill, we consider that the limit that these provisions place on the right to be presumed innocent is justifiable in terms of section 5 of the Bill of Rights Act.

Strict liability offences

<u>Offences related to handling medicines</u>

62. Clause 472(1) (strict liability) provides that a number of offences under the Bill are strict liability offences. A defendant can escape liability where she or he proves an absence of intention to commit the offence or that that all reasonable steps were taken to ensure that ‘anything required to be done was done’ or ‘anything prohibited from being done was not done’. The penalty for these offences is a fine of up to $5,000 for an individual and up to $40,000 for a body corporate. The offences are:

- clause 431 (security of medicines in pharmacies)
- clause 432 (storage of scheduled medicine in person’s possession or charge)

- clause 435 (containers and packages when supplying and transporting medicine)
- clause 436 (container for medicine in person's possession or charge)
- clause 437 (packing and preparing medicines for use)
- clause 438 (delivering medicines)
- clause 439 (disposal of medicines)

Are these justified limitations under section 5?

63. The purpose of these provisions is to ensure that scheduled medicines (which have the potential to cause significant public harm if not used as intended or prescribed) are correctly secured, stored and delivered, and properly prepared, packaged, and disposed of by a pharmacy or person who has a scheduled medicine in his or her possession or is transporting it in the course of business.

64. Many of those persons who store and supply scheduled medicines will do so under a statutory licensing regime, and will be expected to maintain high standards of control over the scheduled medicines. Understanding and maintaining those professional requirements is an accepted part of the licensing regime, and where there is evidence that a licence holder has failed to meet the required standards of storage or handling of scheduled medicines, it is reasonable to require that person to prove that there were exceptional circumstances in order to avoid liability. The defences that are available under clause 472(3) ensure that there is sufficient opportunity for a defendant to exonerate him or herself.

65. As stated in paragraph 60 above, the levels of fine are relatively high but justifiable in view of the nature of the offences. Considering the regulatory character of these offences and their purpose of protecting public health and safety, it is our view that these provisions constitute justified limitations on the right to be presumed innocent as affirmed by section 25(c) of the Bill of Rights Act.

<u>Licensing offences</u>

66. Clause 413 (producing a license to court) is also a strict liability offence. Under this provision, it is an offence if a license holder fails to produce the licence in the time and manner directed by the court.[8] The penalty for this offence is the same as for the other strict liability provisions under clause 472.

Is this a justified limitation under section 5?

[8] A court may require a license holder to produce their licence if it decides under clause 412(2) to cancel or endorse a licence, or disqualify the licence holder from holding any kind of licence.

67. The purpose of the provision is to prevent the licence holder from selling medicines after a court has cancelled or endorsed a licence or has otherwise disqualified the licence holder. In so doing, the provision aims to prevent the licence holder from acting in a manner which may be harmful to the public.

68. The Ministry of Health advises that the offence is also intended to encourage those responsible for medicines to meet a high standard of care. For the purposes of protecting public health and safety, a higher standard of care is required than absence of recklessness when dealing with scheduled medicines. It would not further the objective of the provision if the prosecution was required to prove either recklessness or intention to breach the requirements of the Act. The information required to exonerate the defendant (that he or she took all reasonable steps not to commit the offence) is information that is peculiarly in the realm of the defendant.

69. Taking into account the regulatory nature of the offence, its purpose of protecting public health and safety, and the level of the penalty (see paragraph 61), we consider it reasonable that the defendant be put to the proof when charged with this offence. Accordingly, we consider that the limit that this provision places on the right to be presumed innocent is justifiable in terms of section 5 of the Bill of Rights Act.

Documents and other records

70. The Bill also contains strict liability offences relating to keeping and producing documents and other records:

- clause 440 (keeping records relating to supplying medicine)
- clause 463 (offence not to comply with the requirement in clause 462(2) to produce documents or records)

71. Clause 440 makes it an offence for suppliers of medicines to fail to keep and retain appropriate records. Clause 462 empowers the Director-General of Health or a Medical Officer of Health to require a person to produce documents and records relating to the supply and dispensing of medicines where she or he reasonably suspects that a person is in possession of medicines or other items in breach of Parts 6 and 7 of the Bill or the associated regulations and makes it an offence to fail to produce these items.

72. The purpose of these provisions is to ensure that persons involved with supply of medicines keep and produce proper records. Appropriate records help ensure that any issues of concern for public health and safety can be properly and effectively investigated. These records are important as they provide investigators with the ability to trace back actions and activities involving the movements of medicines, particularly medicines that are harmful to public health.

73. It would not further the objective of these provisions if the prosecution was required to prove either recklessness or intention to breach the requirements of the Act. A

defendant is best placed to prove that he or she took all reasonable steps not to commit the offence.

74. Taking these factors into account, as well as the regulatory nature of the offence, its purpose of protecting public health and safety, and the level of the penalty, we consider the limitation that these strict liability offences place on the presumption of innocence is justifiable under section 5 of the Bill of Rights Act.

Presumptions

75. Clause 467 (Contents of container presumed in proceedings) establishes a presumption that the contents of a container are the same as the description of its contents set out on the label of the container. This presumption applies to proceedings under Parts 6 and 7 of the Bill or under the regulations.

76. We consider that this presumption is justifiable. Without the presumption, the prosecution would be required to test the contents of each single container involved. The information needed to rebut the presumption is clearly in the realm of the defendant. That is, the defendant can escape liability by proving on the balance of probabilities that that the contents of a container are not the same as the description of its content on the label.

Therapeutic Products Bill

77. The Bill contains several strict liability offences and presumptions that a defendant must rebut to escape liability.

Strict liability offences – defence of mistake of fact on reasonable grounds

78. The following clauses contain strict liability offences. The defendant can exonerate herself by way of raising a defence of belief on reasonable grounds in the existence of facts that, if true, would have meant that the defendant's conduct did not constitute an offence:

- 50(9) (Manufacture without manufacturing license or correct manufacturing license)
- 51(7) (Breaching conditions of manufacturing license)
- 52(11) (Manufacture, import, export, or supply without product license or correct product license)
- 53(7) (Breaching conditions of product license)
- 54(8) (Breaching conditions of special purpose approval or exemption or requirements of exemption)
- 55(8) (Import, export or supply of product that does not conform to applicable standards)
- 56(8) (Breaching conditions of authorisation not to conform to applicable standards)

- 58(9) (Manufacturer supplying or exporting therapeutic product to which conformity assessment procedures not applied)
- 62(6) (Publishing or broadcasting proscribed advertisements)
- 63(5) (Advertising for which approval is required)
- 65(4) (Advertising in breach of direction by Authority)
- 78(2) (Applicants, holders, and former holders failing to comply with information requirement notice)
- 85(8) (Failing to comply with recovery notice).

79. Additionally, clause 63(7) (Advertisements for which approval required) provides specific alternative defences. A defendant can escape liability where she or he proves:
    - that she or he 'received the advertisement for publication or broadcast in the ordinary course of business;' or
    - that the advertisement which was published or broadcast differed from the one approved only in respect of certain factors

Are these justified limitations under section 5?

80. The purpose of these provisions is to give effect to the objective of safeguarding public health and safety with regard to the manufacture, supply, import and export of therapeutic products. The Bill creates various offences to give effect to this objective. We consider that this is a significant and important objective.

81. We note that these offences have been cast as strict liability to ensure that the onus is on the individual to comply with the regulatory requirements established under the Bill. We are advised that these offences are necessary to avoid harm arising from improper manufacture, import, export, supply or advertising of therapeutic products.

82. In our view, it would be difficult for the Authority to prove the intention that lead to the defendant's failure to comply with obligations such as ensuring that they have the correct license to manufacture products. The information required to exonerate the defendant (a belief on reasonable grounds in the existence of facts that, if true, would have meant that the defendant's conduct did not constitute an offence) is information that is peculiarly within the realm of the defendant's knowledge.

83. However, the penalties for these offence are not at the lower end of the scale: they include fines of up to,$220,000 for individuals and up to $1,100,000 for a body corporate in respect of all offences except those in clauses 54, 56, 62, 63, 65 (up to $110,000 for an individual and up to $550,000 for a body corporate) and clause 78 (up to $55,000 for an individual or $275,000 for a body corporate).

84. In assessing the proportionality of these penalties, we have had regard to other strict liability regulatory offences aimed at protecting the public from significant harm (such as in the Gambling Act and Films, Videos, and Publications Classification Act). In light of the nature and degree of offending which could

occur, we consider that having the potential of a high penalty is justifiable. We have also taken into account the Ministry of Health's explanation that the penalties have been set at this level in order to ensure that the penalties are similar to Australia's in order to avoid regulatory arbitrage.

85. On balance, we consider that these strict liability offences constitute justified limitations on the right to be presumed innocent.

Reverse onus offence: 'without reasonable excuse'

86. Clause 10(1)(c) of Schedule 2 of the Bill (Contempt of Review Tribunal) provides that it is an offence to 'intentionally and without lawful excuse disobey an order or direction of a member of the Review Tribunal in the course of any proceedings before the Review Tribunal. While the prosecution has to prove intention on the part of a defendant, the defendant can escape liability if she or he proves a reasonable excuse for her or his actions.

87. We consider that this requirement is a reasonable limit on the presumption of innocence, as the defendant would be best placed to adduce evidence as to the reasons for their actions. In addition, the penalty (a fine of up to $1000) is at the lower end of the scale.

Presumptions

88. Several clauses in the Bill establish a presumption of causation between the defendant's conduct and harm occurring as a result of use of a therapeutic product, or presume other facts which are elements of the relevant offence. The Bill contains two types of presumptions:

- Presumptions where there is an *evidential burden* on the defendant to rebut the presumption and thereby put the burden of proof back on the prosecution. Such presumptions work on the basis that proof of the existence of one fact is proof of the existence of an element of the offence, unless the accused is able to raise evidence to the contrary.

- Presumptions which impose a *persuasive burden* (burden of proof) on the defendant to displace the presumption. A persuasive burden is similar to an evidential burden, except that the evidential fact must be *disproved* on a balance of probabilities instead of by the mere raising of evidence to the contrary.

89. Provisions requiring a defendant to simply provide evidence (evidential onus) in reply to the prosecution case rather than actually prove a fact or defence (a persuasive onus) will be easier to justify. This is because it will be easier for the defendant to discharge the requirement in the first instance. However, such a provision may still be inconsistent with s25(c) if the effect of it is that, in the absence of any evidence from the defendant, they can be convicted without the Crown proving all elements of the offence in the usual way. This is particularly so

when the presumption leads to acceptance of a fact that is an element of the offence.

90. The Bill generally provides for three tiers of offences commensurate with the level of the defendant's culpability. The following offences where presumptions apply can be tried either indictably, or summarily as strict liability offences. The indictable offences have a higher degree of moral fault associated with the *mens rea.* In this sense these offences can be described as truly criminal in nature, which means that the limit that the provisions place on the presumption of innocence under section 25(c) of the Bill of Rights Act is more difficult to justify.

Presumptions – persuasive onus

Presumed causal link between actus reus and harm

91. Clauses 50(6) and (9) (Manufacture without manufacturing license or correct manufacturing license) establish a presumed causal link between carrying out a step in the manufacture of a therapeutic product or kind of a therapeutic product where the defendant does not comply with manufacturing licence requirements; and use of the therapeutic product harms a person or there is likely harm or serious risk of harm.

92. Clauses 58(6) and 9) (Manufacturer supplying or exporting therapeutic product to which conformity assessment procedures not applied) establish a presumption of a causal link between the defendant's conduct and harm or risk or likelihood of harm as a result of use of the therapeutic product.

93. The presumptions in both clauses 50 and 58 apply in respect of both indictable and strict liability offences: however, in respect of the indictable offences, the prosecution must prove intention or recklessness as to whether harm or a serious risk of harm will result from the use of the therapeutic product (clause 50(8)); or whether the specified conformity assessment procedures had not been applied to the therapeutic product (58(8)).

94. In order to escape liability, the defendant must rebut the presumption of causation by proving on the balance of probabilities[9] that the harm, serious risk of harm, or likelihood of harm (as the case may be) was not a result of a step carried out by the defendant in the manufacture of the therapeutic product (clause 50) or as a result of failure to apply the specified conformity assessment procedures to the therapeutic product (58).

Are these presumptions justified limitations under section 5?

95. The purpose of these provisions is to protect the public from risk of harm resulting from use of therapeutic products, by creating offences designed to ensure

[9] With regard to the standard of proof, see, for example, *R v Perry & Pledger* [1920] NZLR 21 (CA).

compliance with the regulatory regime. We note that these offences are designed to prevent the compliance problems that have occurred in Australia, which have resulted in harm to consumers of therapeutic products. We agree that this is a significant and important objective.

96. Turning to the issue of proportionality, we have taken into account the Ministry of Health's advice that it would be not be feasible for the prosecution to prove the causal link between the regulatory breach and the harm to the user of the product. Moreover, the defendant is best placed to adduce evidence about the safety of the product and what happened during the manufacturing process. In respect of the indictable offence, the prosecution additionally must prove intention or recklessness with respect to the actus reus and accordingly the defendant can raise a defence of absence of mens rea. With regard to the strict liability offence, the defendant can also raise the general defence of mistake of fact on reasonable grounds, and can in addition adduce evidence to show why they were not at fault.

97. In assessing the proportionality of the limitation that these clauses place on this right, we have also taken into account the penalty for these offences. As we noted above, as a general principle, offences containing presumptions or strict liability should carry penalties at the lower end of the scale for that type of offence. As imprisonment over 1 year is usually a penalty associated with indictable offences, offences with terms of imprisonment for longer periods are generally considered to require the prosecution to prove all the elements of the offence beyond reasonable doubt.[10]

98. The Canadian Supreme Court in *R v Wholesale Travel Group*[11] has stated that imprisonment for a regulatory offence is justifiable as the stigma associated with imprisonment for a regulatory offence is less than that for a truly criminal offence. However, while an offence that infringes on the presumption of innocence and contains a penalty of a term of imprisonment may, in limited situations, be justifiable, the penalty must be clearly associated with the seriousness of the offence and the importance of the objective to which the offence is aimed.

99. The penalty for clause 50 is up to five years imprisonment for an individual and/or a fine of $440,000 in respect of the indictable offence, and a fine of up to $2,200,000 for a body corporate. Under clause 58 in respect of the indictable offence, an individual is liable on conviction for a imprisonment for not more than five years and/or a fine of $440,000. A body corporate is liable to a fine of up to $2,200,000. With respect to the strict liability offences, the penalties are a fine of up to $220,000 for an individual and a fine of up to $1,100,000 for a body corporate for clauses 50 and 58.

100. The penalties associated with these offences recognise that the high potential for harm resulting from use of therapeutic products where correct procedures are not

[10] REF
[11] *R v Wholesale Travel Group* (1992) 84 DLR (4th) at 219.

followed. We have also had regard to clause 31 (Sentencing guidelines for offences involving harm). This clause directs the sentencing Judge to take into account a number of factors, including the likelihood of harm caused by the offender, the number of people at risk of harm, whether harm in fact occurred, and the seriousness of the harm or likely harm. For these reasons we consider that the penalties for breach of these two offences, while at the upper end of the scale for regulatory regimes, are proportionate to the seriousness of the offence and the objective to which the offence is aimed.

101. On balance, we consider that the limit that these clauses place on the right to the presumption of innocence is justifiable.

Presumption relating to other elements of the actus reus

102. Clause 55 (Import, export or supply of product that does not conform to applicable product standards) establishes a presumption that breach of applicable standards for therapeutic products relates to a substantive standard relating to the product itself. The presumption applies in respect of both indictable and strict liability offences under clause 55. A defendant can escape liability if they can prove that the standard to which the therapeutic product did not conform is a standard that relates only to labelling or packaging (for importing), labelling (for exporting) or where the defendant can prove that she or he has an exemption from these requirements. .

103. Clause 59 (Other persons supplying or exporting products to which conformity assessment procedures not applied), is an indictable offence. It establishes a presumption that a person who exports or supplies a therapeutic product is the sponsor (manufacturer, importer, exporter or supplier) of the therapeutic product at the time of its export or supply, rather than an agent of the sponsor. To escape liability the defendant must prove that she or he was not the sponsor at the time of the regulatory breach.

104. Like the indictable offences in clauses 50 and 58 the penalty on conviction of an indictable offence under clauses 55 and 59 is imprisonment for not more than five years and/or a fine of $440,000. A body corporate is liable to a fine of up to $2,200,000. The penalty for conviction of a strict liability offence under clause 55 is fine of up to $220,000 for an individual and a fine of up to $1,100,000 for a body corporate.

Are these justified limitations under section 5?

105. The purpose of this provision is to ensure that manufacturers of therapeutic products comply with product standards and conformity assessment procedures. Again, due to the potential for harm to arise as the result of use of these products, we agree that this is a significant and important objective.

106. We consider that this presumption is reasonable. The Ministry of Health advises that it is not feasible for the prosecutor to prove in each case that the defendant was the sponsor, because the principal-agent relationship can only be ascertained conclusively through confidential commercial arrangements known only to the parties concerned. Evidence about the agency relationship is, therefore, peculiarly within the defendant's knowledge and is information which the prosecution will not have access to. We also note that the prosecution is required to prove that the failure to apply the specified conformity assessment procedures caused harm or risk or harm, and well as the requisite mens rea.

107. We therefore consider that the limit that these clauses place on the right to the presumption of innocence is justifiable.

Presumptions – evidential onus

108. Clause 52(7) (Manufacture, import, export, or supply without product license or correct product license) establishes, for an indictable offence, a presumed causal link between breach of product license requirements; and harm or serious risk of harm to a person resulting from the use of the product.

109. Under this clause, the prosecution must also prove a mens rea element of intention or recklessness. The defendant can rebut the presumption by raising evidence that the harm or risk of harm was not caused by the quality or efficacy of the therapeutic product or of a matter relating to its labelling or packaging, or was directly caused by improper use of the therapeutic product.

110. The purpose of this clause is to ensure that those involved in the production and distribution of therapeutic products hold the correct product license. The Ministry of Health has advised that where harm or risk of harm occurs, without the relevant chemical or other data about the product it would not be feasible for the prosecution to prove the causal link between the defendant's conduct and the harm suffered by the product user. In the Ministry's opinion, the information is peculiarly within the realm of the defendant, who is best placed to adduce evidence as to their actions.

111. As noted in para 89 above, a requirement to raise an evidential onus is easier to justify than a persuasive onus. This is because it will be easier for the defendant to discharge the requirement in the first instance.

112. The penalties for the indictable offence in clause 52 are the same as the penalties under clauses 50, 55, 58 and 59; a level of penalty normally associated with a requirement that the prosecution to prove all the elements of the offence beyond reasonable doubt. However, as we noted in paragraph 83 the penalties are broadly comparable to other regulatory regimes which aim to protect the public from significant harm.

113. On balance, we consider that the limit that these clauses place on the right to the presumption of innocence is justifiable.

Civil penalties

114. For completeness, we also note that the Bill establishes a civil penalty regime for lower level offending. While section 25(c) of the Bill of Rights Act is generally considered to apply only to criminal proceedings, overseas case law suggests that in proceedings that result in the imposition of civil penalties, the respondent has the protection of the various fair trial rights if that penalty has a 'punitive element'.[12] It is possible to argue that the fines imposed for the civil penalty offences in the Bill have a punitive character and, thus, the right set out in section 25(c) of the Bill of Rights could apply. We note, however, that this issue has yet to be determined in New Zealand and it is unclear whether the courts would agree that individuals facing sanctions under a civil penalty regime have the protections provided for in section 25(c) of the Bill of Rights Act.

115. Irrespective of the debate as to whether section 25(c) of the Bill of Rights Act applies to civil penalty regimes, we consider that these offences would amount to a reasonable limit on the right to be presumed innocent in terms of section 5 of that Act. The aim of the relevant provisions in the Bill is to protect the public from harm arising from the consumption of therapeutic products. The Ministry of Health has indicated that these civil penalty provisions are necessary to expediently address instances of lower-level offending.

116. For these reasons we have concludes that the limit that the civil penalty provisions place on the right to be presumed innocent are justifiable.

CONCLUSION

117. We have concluded that the Bill is consistent with the rights and freedoms contained in the Bill of Rights Act.

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[12] See *Benham v the United Kingdom* (1996) 22 EHRR 293, para 56, and *Lauko v Slovakia* (1998) 33 EHRR 994, para 58

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