

## Privacy Commissioner's submission to the Health Committee on the Therapeutic Products Bill [204-1]

1. I am pleased to provide a submission on the Therapeutic Products Bill (the Bill).
2. The Privacy Act 2020 is New Zealand's main privacy statute. One of the Privacy Commissioner's functions under the Privacy Act is to examine proposed legislation that may affect the privacy of individuals.

### Executive summary

3. The Bill will replace the current Medicines Act 1981 and Dietary Supplements Regulations 1985 to provide for the comprehensive, risk-proportionate regulation of therapeutic products. I support the purpose of the Bill to protect, promote and improve the health of all New Zealanders by providing for the acceptable safety, quality and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients, and the acceptable safety and quality of natural health products.
4. This Bill establishes a new Therapeutics Products Regulator ('Regulator') with a range of compliance and enforcement powers. While I consider it is appropriate that the new Regulator be suitably equipped to achieve the objectives of the Bill, there are some provisions in this Bill which I consider are unnecessarily broad overrides to the Privacy Act 2020.
5. I understand from officials that most of the information collected under the Bill will be about regulated entities (and therefore less likely to be personal information, as it will likely pertain to companies rather than identifiable individuals). My understanding is that there will be personal information collected under the Bill, for example in relation to oversupplied persons or information about employees of regulated entities, or registered practitioners.
6. My submission is limited to three parts of the Bill that I consider warrant additional work to ensure that the Privacy Act is only overridden where it is necessary and justified. I am particularly concerned about the breadth of clause 343 of the Bill.

### Statements about oversupplied persons

7. Cl 229 provides that the Regulator may make a statement about an oversupplied individual for the purposes of limiting the supply of prescription or pharmacist medicines to the person or assisting in the treatment of the individual's addiction or habit. Cl 229 is an updated version of s 49A of the Medicines Act 1981, which was introduced in a 1987 amendment bill, prior to the enactment of the Privacy Act.
8. Making a statement that an individual is an oversupplied individual is likely to involve the disclosure of particularly sensitive information which could result in serious adverse impacts for individuals if appropriate protections are not in place to ensure that information is only shared when necessary to achieve the objectives in cl 229(1). Given the potential sensitivity of the information that is likely to be disclosed, and the adverse impacts if the disclosure is inappropriate, I consider that the current threshold for disclosure (which requires "that the Regulator be satisfied on reasonable grounds that the disclosure is necessary *or desirable* for the purposes" set out in subclause (1)) does

not sufficiently recognise the privacy interest in the information that I consider will be likely be disclosed under this clause.

9. To that end, I **recommend** removing the phrase 'or desirable' in cl 229(2) and (3). This would mean that the Regulator (and any notifiable persons who receive a statement from the Regulator) can only disclose information that is necessary for the stated purposes. It is appropriate that those disclosing such sensitive information be required to consider whether it is necessary, rather than desirable.

### **Complaints from individuals who are the subject of a statement about an oversupplied person**

10. Cl 229(6) provides that an individual in respect of whom a statement is made can complain to my Office as if the definition of an interference with the privacy of an individual in section 69 of the Act included a breach of subclauses (3) and (4). I support this complaint provision in the Bill. Cl 229(7) otherwise provides an immunity against proceedings, except for judicial review.
11. Privacy complaints can proceed to the Human Rights Review Tribunal, either via the Director of Human Rights Proceedings (on referral by the Privacy Commissioner) or initiated directly by the complainant, following the issuance of a certification of investigation by my Office. The Tribunal is an appropriate forum to escalate complaints that my Office has been unable to satisfactorily resolve, and it is appropriate that the Bill clarify that this avenue is not extinguished by cl 229(7). I **recommend** the drafting be clarified to ensure that cl 229(7) does not limit an individual's ability to pursue proceedings at the Human Rights Review Tribunal for an interference with their privacy under the Privacy Act 2020.

### **Sharing information with regulatory entities**

12. Cl 343 introduces an ability for the Regulator to share information with regulatory entities, overseas regulators and overseas organisations for the purpose of assisting the recipient in performing their functions or exercising their powers. Cl 343 is a very broad override to the Privacy Act and I have not yet seen any evidence it is necessary.
13. 'Regulatory entity' for these purposes includes many entities, plus departments responsible for the administration of a relevant law as defined in section 60, as well as an entity with regulatory functions under an Act that the regulations say is a regulatory entity.
14. For overseas regulators and organisations, the Regulator must not share personal information unless satisfied on reasonable grounds that appropriate protections will be in place to maintain the privacy of the person to whom the information relates (cl 343(5)).
15. The same requirement does not exist for sharing with New Zealand regulatory entities, and I understand that this is because New Zealand regulatory entities are subject to the Privacy Act.
16. I understand from officials that information shared under this section is most likely to involve sharing of commercial information rather than personal information, although the reference to personal information in cl 343(5) anticipates that personal information *can* be shared under cl 343.

17. The effect of this clause is that the Regulator could share personal information with a large list of regulatory entities to assist those entities in performing their functions or exercising their powers. It is not restricted to the performance of functions or powers under this Bill, nor the purposes and objectives of this Bill.
18. Should personal information need to be shared with other entities, the Regulator could already do so under the existing provisions of the Privacy Act, which allows for the disclosure of information in flexible circumstances, including where reasonably necessary for the protection, prevention, detection and investigation of offending; where the disclosure is one of the purposes for which the information was collected or a directly related purpose; and to lessen or prevent a serious threat to public health or public safety or the life or health of an individual.
19. I **recommend** amending the provision so that personal information cannot be shared solely based on cl 343. This could be achieved adding a subclause which notes that the section is subject to the Privacy Act 2020.

### **Rule-making power**

20. Cl 377 provides that the Regulator can make rules for anything that the Bill says may or must be provided for in rules, this can include (inter alia) record-keeping, auditing and giving information or samples to the Regulator. I understand from engagement with officials that information requested under the rules is likely to relate to regulated products or activities, but it may also include personal information. I **recommend** that where the rules may be drafted to override the Privacy Act, that the Regulator be required to consult with my Office.

### **Conclusion**

21. I trust my comments are of use to the Committee. I do not seek to be heard on my submission but am happy to appear before the Committee if that would be of assistance. I am happy to provide further comment and advice to the Committee as they consider the privacy implications of the Bill.



Michael Webster  
**Privacy Commissioner**

3 March 2022