

19 May 2021

Hon David Parker, Attorney-General

Consistency with the New Zealand Bill of Rights Act 1990: Medicines Amendment Bill

Purpose

1. We have considered whether the Medicines Amendment 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 23826/3.1). This advice has been prepared in an extremely short timeframe due to late receipt of the Bill that was not in compliance with Cabinet Office Guidance. We will provide you with further advice if the final version includes amendments that affect the conclusions in this advice.
3. 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 s 10 (right not to be subjected to medical or scientific experimentation) and s 27 (right to justice). Our analysis is set out below.

The Bill

4. The Bill amends the Medicines Act 1981 (the Principal Act). The Principal Act provides for the sale, supply and use of new medicines, setting out restrictions, application, procedure and conditions for consent and provisional consent.
5. Section 23 of the Principal Act provides that the Minister may give provisional consent to the sale or supply or use of a new medicine on a restricted basis for the treatment of a limited number of persons. It also allows setting of conditions on the provisional approval.
6. Several medicines have been approved under section 23 including the Pfizer COVID-19 vaccine. An issue has arisen as to whether these consents have been validly issued.
7. The Bill amends the Principal Act to:
 - a. remove the requirement that provisional consent under section 23 be on a restricted basis for the treatment of a limited number of persons; and
 - b. retrospectively validate certain existing provisional consents that have been granted under section 23 of the Medicines Act, including consent for the Pfizer vaccine.
8. The amendment to section 23 does not affect existing requirements related to the safety, quality and efficacy of the medicines and an assessment of the therapeutic benefits and risks, as set out under sections 21 and 22 of the Principal Act. It also does not affect the ability to impose conditions on the use of the medicine.

Consistency of the Bill with the Bill of Rights Act

Section 10 - Right not to be subjected to medical or scientific experimentation

9. Section 10 of the Bill of Rights Act affirms that every person has the right not to be subjected to medical or scientific experimentation without that person's consent.
10. The Bill allows new medicines to have provisional consent without any requirement that it be for a limited number of people. This could potentially include new medicines that could be considered "experimental".
11. However, we do not think that potentially exposing a wider range of people to "experimental" medicine engages section 10.
12. The fact that medicine is "experimental" does not make it "experimentation", if, for example, there is no plan to "gather any new or additional information about the effect of the thing on people for general scientific purposes".¹
13. Further, the Bill does not affect requirements to ensure that any medical experiments are conducted in a way that is consistent with the Bill of Rights Act, for example, by requiring informed consent.

Section 27(2) - Right to justice

14. Section 27(2) of the Bill of Rights Act protects the right of every person whose rights, obligations, or interests protected or recognised by law have been affected by a determination of any tribunal or other public authority to apply, in accordance with law, for judicial review of that determination.
15. The Bill retrospectively validates a number of provisional consents that were given under section 23. It does this by providing that the consents are to be treated as having been given under section 23 as amended by the Bill.
16. One of the provisional consents validated by the Bill has been the subject of a judicial review application. One effect of the retrospective validation could be to pre-empt or override the outcome of that case. This raises the issue of whether the retrospective validation could be seen as limiting the right to judicial review.
17. In our view, the retrospective validation of the provisional consents does not engage section 27(2). In *Mangawhai Ratepayers and Residents Association Inc v Kaipara District Council* the appellants argued that Parliament's decision to override extant judicial review proceedings by retrospective validation was a violation of its rights to challenge the Kaipara District Council's decision (about rates) by way of judicial review. The majority of the Court of Appeal held that it cannot be properly argued that validating legislation results in a deprivation of rights in a section 27(2) sense.²
18. Further, the majority agreed with the Attorney-General's submission that:

¹ Andrew Butler and Petra Butler, *The New Zealand Bill of Rights Act: A Commentary* (2ed) (LexisNexis NZ Limited, 2015) at [11.7.22] citing *Taunoa v Attorney-General* (2004) 7 HRNZ 379 (HC) at [302].

² *Mangawhai Ratepayers and Residents Association Inc v Kaipara District Council* [2016] 2 NZLR 437 at [204].

nothing in s 27(2) of BORA affirms as a general proposition a right to have the existing law preserved against retrospective amendment. As he put it, acceding to the MRA's argument would incorporate into s 27(2) whatever substantive entitlements happen to exist under the general law from time to time and require justification for their change under s 5 of BORA. We accept his submission that there is nothing in BORA that requires the court to proceed in that way.³

19. For these reasons, we do not consider that the Bill engages section 27(2).

Conclusion

20. 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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³ *Mangawhai Ratepayers and Residents Association Inc v Kaipara District Council* [2016] 2 NZLR 437 at [206].