

1 June 2022

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. 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 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 24788/10.0). 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 section 19 (freedom from discrimination). Our analysis is set out below.

The Bill

4. The Bill amends the Medicines Act 1981 (the principal Act).
5. It inserts a new section 24H into the principal Act to enable the Director-General of Health to authorise by notice the administration of a consented COVID-19 vaccine, without a prescription, otherwise than in accordance with the approved data sheet for that vaccine. The notice may specify matters in relation to the administration of the vaccine including:
 - a. who it may be administered to;
 - b. the recommended dosage and frequency;
 - c. the recommended manner of administration; and
 - d. the circumstances in which it may be administered.
6. Before issuing a notice, the Director-General must have regard to the therapeutic benefit of the proposed use of the vaccine and the risk (if any) that the proposed use may injuriously affect health. The Director-General must also be satisfied that it is an

appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

7. The practical effect of the amendment is that the Director-General will be able to authorise the use of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine.
8. We understand that this power is likely to be used to enable “off-label” fourth doses of the Pfizer/BioNTech COVID-19 vaccine (Pfizer vaccine) to be administered without a prescription. However, this power may also be used in potential future scenarios that require, for example, further vaccine doses, changes to dose intervals, or targeting different population groups in response to future variants, where scientific evidence supports this.

Consistency of the Bill with the Bill of Rights Act

Section 19 – Freedom from discrimination

9. Section 19(1) of the Bill of Rights Act affirms the right to freedom from discrimination on the prohibited grounds listed in section 21 of the Human Rights Act 1993 (HRA).
10. Discrimination under section 19 of the Bill of Rights Act arises where:¹
 - a. there is differential treatment or effects as between persons or groups in analogous or comparable situations on the basis of a prohibited ground of discrimination; and
 - b. that treatment has a discriminatory impact (i.e. it imposes a material disadvantage on the person or group differentiated against).
11. The Bill provides a method for authorising uses of a COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine without the requirement for a prescription. This does not, in itself, engage section 19.
12. International evidence has shown immunity after third doses wanes at a similar rate as it does after completion of a primary course of COVID-19 vaccination, and waning occurs more quickly for those in vulnerable population groups. These population groups are also the most likely to be significantly affected by COVID-19 infection.
13. There is a strong public health rationale in ensuring that the most vulnerable population groups are afforded additional protection from COVID-19. As such, a notice issued by the Director-General, as provided for by the Bill, may lead to differential treatment based on prohibited grounds of discrimination, such as age and ethnicity. This is a form of positive discrimination that allows for the protection of the most vulnerable populations.
14. Further, the Director-General may only issue a notice when satisfied that it is an appropriate measure to manage the risks associated with the outbreak or spread of

¹ *Ministry of Health v Atkinson* [2012] NZCA 184, [2012] 3 NZLR 456 CA at [55].

COVID-19 and after having regard to the therapeutic benefit of the proposed use of the vaccine and the risk (if any) that the proposed use may injuriously affect health. Any such notice would also have to be in compliance with the Bill of Rights Act.

15. As such, we consider that any restriction on the right to be free from discrimination arising from notices issued under the Bill would be clearly justified in terms of section 5 of the Bill of Rights Act.

Conclusion

16. 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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