Departmental Disclosure Statement

Medicines Amendment Bill (No 2)

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry of Health.

The Ministry of Health certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

3 June 2022

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Part One: General Policy Statement

The purpose of this Bill is to amend the Medicines Act 1981 to provide population protection against COVID-9 via vaccination by providing for:

- the lawful administration of fourth doses of COVID-19 vaccines beyond use on prescription via an authorised prescriber other than in accordance with the data sheet (off-label use);

- a long term solution for the provision of the third (booster) dose at the 3-month dose interval;

- any future doses of COVID-19 vaccines to be administered if scientific evidence demonstrates this is recommended.

The Bill meets these objectives by creating a new provision (*section 34A*) that enables the Director-General of Health (the Director General) to authorise, by notice, the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine.

This is consistent with the policy intent of the COVID-19 vaccination programme to provide ongoing population protection against COVID-19, and to continue to adapt and respond as the pandemic evolves.

The amendment will enable the Director-General to specify by notice who the vaccine may be administered to, the recommended number of doses and frequency of doses, the recommended manner of administration, and any circumstances in which the vaccine may be administered.

The Director-General must be satisfied that doing so is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19, having regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and the risk (if any) that any proposed administration of the vaccine may injuriously affect the health of any person.

The amendment will only enable the Director-General to use this power in relation to COVID-19 vaccines that have consent or provisional consent under section 20 or 23 of the Act. The amendment does not affect the usual consenting process under the Act.

Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?	NO

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	NO

2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty?	NO

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	YES
The Treasury's Regulatory Impact Analysis team has determined that the proposal for the Bill to enable a fourth dose of COVID-19 vaccinations over the winter period is exempt from the requirement to provide a full Regulatory Impact Statement (RIS). The exemption is on the grounds that the proposal is intended to mitigate the short-term impacts of the COVID-19 emergency and it is required urgently to be effective. However, the exemption is conditional on the Ministry of Health completing a streamlined RIS, which has not been formally quality assured as per the usual RIA requirements, given the time constraints. The link to the streamlined RIS can be found in Appendix One.	

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	NO
As above the exemption is conditional on the Ministry of Health completing a streamlined RIS, which has not been formally quality assured as per the usual RIA requirements, given the time constraints.	

2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?	NO

Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?	**NO**

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	**NO**
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	**NO**

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	**NO**
(b) the nature and level of regulator effort put into encouraging or securing compliance?	**NO**

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?
The Bill does not affect New Zealand's international obligations.

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?
The Bill is consistent with the principles of the Treaty of Waitangi. Consideration has been given to the impact the Bill will have on Māori interests protected by the Treaty. The Bill may help to facilitate the roll out of fourth doses of COVID-19 vaccines in a more equitable and accessible way. It will also provide for any future COVID-19 doses the general population, or targeted groups may require. The initial focus is fourth doses, and how their provision will be consistent with the principles of the Treaty of Waitangi. In this context the Bill will: a. enhance Tino rangatiratanga – by providing broad access to fourth doses, including via Māori health providers, which will help Māori to self-determine their collective and individual health response to COVID-19 b. assist the Crown to work in partnership with iwi and Māori health stakeholders to improve vaccine uptake for Māori c. help minimise and address existing inequities in the recommended groups, including targeting Māori over 50 years of age. This will support health system resilience and help to reduce the impacts of the Omicron outbreak on Māori. This is consistent with Te Tiriti principle of active protection d. contribute to achieving equitable outcomes for Māori by leveraging existing gains made to achieve equitable vaccine uptake for Māori and targeting Māori over 50 years.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	**YES**
The Ministry of Justice will provide advice to the Attorney-General. This is generally expected to be available on the Ministry of Justice's website upon introduction of a Bill. Such advice, or reports, will be accessible on the Ministry's website at http://www.justice.govt.nz/policy/constitutional-law-and-human-rights/human-rights/bill-of-rights/	

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	**NO**
(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	**NO**

3.4.1. Was the Ministry of Justice consulted about these provisions?	**NO**
N/A	

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	**NO**

3.5.1. Was the Privacy Commissioner consulted about these provisions?	**NO**

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	**NO**

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?	**YES**
The proposals have been developed in consultation with the Department of the Prime Minister and Cabinet, Ministry of Justice, Crown Law and the Parliamentary Counsel Office	

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	**NO**

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	**NO**

Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	**NO**

Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	**NO**
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	**NO**

Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	**NO**

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	**NO**

Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	YES
The new section [34A] gives the Director-General of Health the ability to authorise, by notice, the administration of a consented COVID-19 vaccine otherwise than in accordance with the approved data sheet for that vaccine. The power is constrained by including criteria that the Director-General must be satisfied that doing so is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19 and having regard to the likely therapeutic value of the proposed administration of the COVID-19 vaccine and its risk (if any) of injuriously affecting the health of any person. The amendment will only enable the Director-General to use this power in relation to COVID-19 vaccines that have consent or provisional consent under section 20 or 23 of the Act. The amendment does not affect the usual consenting process under the Act. The power is necessary to support the COVID-19 vaccination programme to provide ongoing population protection population against COVID-19, and to continue to adapt and respond as the pandemic evolves.	

4.8. Does this Bill create or amend any other powers to make delegated legislation?	NO

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	NO

Appendix One: Further Information Relating to Part Two

Regulatory impact statement:

https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/amending-medicines-act-1981-allow-label-use-covid-19-vaccinations