Medicines Amendment Bill (No 2)

Government Bill

Explanatory note

General policy statement

The purpose of this Bill is to amend the Medicines Act 1981 to provide population protection against COVID-19 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 that is recommended.

The Bill meets these objectives by creating a new provision (*new 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.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2022&no=138

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 30 May 2022 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

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

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 provides that the Bill, when enacted, comes into force on the day after the date on which it receives Royal assent.

Clause 3 provides that the Bill amends the Medicines Act 1981.

Clause 4 inserts *new section 34A* into Part 2 of the Act (which provides for dealings with medicines and medical devices). In summary, *new section 34A*—

- enables the Director-General, by notice, to authorise the administration of a COVID-19 vaccine other than in accordance with the data sheet (**off-label administration**) if the vaccine has consent or provisional consent under section 20 or 23 of the Act:
- enables the Director-General to specify in the notice who the vaccine may be administered to, the recommended number and frequency of doses, the recommended manner of administration, and any circumstances in which the vaccine may be administered:
- requires the Director-General, before making a notice, to be satisfied that the proposed administration of the vaccine 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) of injuriously affecting the health of any person:

- provides that neither the off-label administration nor the authorisation of the off-label administration of a COVID-19 vaccine makes the vaccine a new medicine for the purpose of section 20:
- provides that any person or class of persons permitted by the Act or regulations to administer a COVID-19 vaccine may administer a dose of the vaccine in accordance with a notice made under *new section 34A*:
- provides that a notice made under *new section 34A* does not limit section 24 (which relates to the distribution of a medicine if a material change is made to the medicine by its manufacturer).

Clause 5 revokes the Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022.

Hon Andrew Little

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Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Medicines Amendment Act **2022**.

2 Commencement

This Act comes into force on the day after the date of Royal assent.

3 Principal Act

This Act amends the Medicines Act 1981.

4 New section 34A inserted (Director-General may authorise off-label administration of COVID-19 vaccines)

After section 34, insert:

COVID-19 vaccines

34A Director-General may authorise off-label administration of COVID-19 vaccines

(1) This section applies if—

(a) the Minister has given consent or provisional consent to a COVID-19 vaccine; and

(b) a data sheet is approved for the vaccine under the regulations.

Notice

(2) The Director-General may, by notice, authorise the administration of the vaccine other than in accordance with the data sheet.

(3) The notice may specify any 1 or more of the following matters in relation to the administration of the vaccine:

(a) who it may be administered to:

(b) the recommended number and frequency of doses:

(c) the recommended manner of administration:

(d) any circumstances in which it may be administered.

(4) Before issuing a notice under this section, the Director-General must—

(a) have regard to the likely therapeutic value of the proposed administration of the vaccine and the risk (if any) that the proposed administration of the vaccine may injuriously affect the health of any person; and

(b) be satisfied that the proposed administration of the vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

Effect of notice

(5) A COVID-19 vaccine is not a new medicine for the purpose of section 20 by reason only of—

(a) a notice made under this section in relation to the vaccine; or

(b) administration of the vaccine in accordance with the notice.

(6) Any person or class of persons permitted by the Act or by regulations to administer the vaccine may administer the vaccine in accordance with the notice.

(7) Nothing in this section limits section 24.

Status of notice

(8) A notice made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Revocation

5 Order revoked

The Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022 (SL 2022/7) is revoked.

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