



Medicines Amendment Act 2022

Public Act 2022 No 31
Date of assent 22 June 2022
Commencement see section 2

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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).

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	The maker must publish it in accordance with the Legislation (Publication) Regulations 2021	LA19 s 74(1)(aa)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

*Revocation***5 Order revoked**

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

Legislative history

7 June 2022	Introduction (Bill 138–1), first reading and referral to Health Committee
20 June 2022	Reported from Health Committee
21 June 2022	Second reading, committee of the whole House, third reading
22 June 2022	Royal assent

This Act is administered by the Ministry of Health.