



Medicines Amendment Act 2021

Public Act 2021 No 16
Date of assent 24 May 2021
Commencement see section 2

Contents

	Page
1 Title	1
2 Commencement	1
3 Principal Act	2
Part 1	
Amendment to provisional consenting provision	
4 Section 23 amended (Minister may give provisional consent)	2
Part 2	
Validations	
5 New section 5C inserted (Transitional, savings, and related provisions)	2
5C Transitional, savings, and related provisions	2
6 New Schedule 1AA inserted	2
Schedule	
New Schedule 1AA inserted	
	3

The Parliament of New Zealand enacts as follows:

- Title**
This Act is the Medicines Amendment Act 2021.
- Commencement**
This Act comes into force on the day after the date on which it receives the Royal assent.

3 Principal Act

This Act amends the Medicines Act 1981.

Part 1

Amendment to provisional consenting provision

4 Section 23 amended (Minister may give provisional consent)

Replace section 23(1) with:

- (1) Notwithstanding sections 20 to 22, the Minister may, by notice in the *Gazette*, in accordance with this section, give provisional consent to the sale or supply or use of a new medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used.

Part 2

Validations

5 New section 5C inserted (Transitional, savings, and related provisions)

After section 5B, insert:

5C Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in Schedule 1AA have effect according to their terms.

6 New Schedule 1AA inserted

Insert the Schedule 1AA set out in the Schedule of this Act as the first schedule to appear after the last section of the principal Act.

Schedule
New Schedule 1AA inserted

s 6

Schedule 1AA
Transitional, savings, and related provisions

s 5C

Part 1
Provisions relating to Medicines Amendment Act 2021

1 Validation of certain provisional consents

- (1) The following provisional consents must be treated as having been given under section 23 as amended by the Medicines Amendment Act 2021:
- (a) the provisional consent for Comirnaty (COVID-19 mRNA vaccine) (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2021-go338));
 - (b) the provisional consent for Necon 0.5/35 (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go2377));
 - (c) the provisional consent for 0.9% Sodium Chloride Injection (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go3009));
 - (d) the provisional consent for the Panvax vaccine (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2018-go6374));
 - (e) the provisional consent for Brevinor 28 Day (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2020-go1987));
 - (f) the provisional consent for H5N1 Influenza Vaccine (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2018-go576)).
- (2) For the purposes of subclause (1),—
- (a) the Medicines Amendment Act 2021 must be treated as having been in force when the provisional consents were given; and
 - (b) a reference to a provisional consent includes any renewal of the provisional consent or subsequent provisional consent for the same product; and
 - (c) a reference to a notice in the *Gazette* includes any notice that amends or replaces that notice.

Legislative history

19 May 2021

Introduction (Bill 41–1), first reading, second reading,
committee of the whole House, third reading

24 May 2021

Royal assent

This Act is administered by the Ministry of Health.