



Medicines Amendment Regulations 2023

Cindy Kiro, Governor-General

Order in Council

At Wellington this 12th day of June 2023

Present:

Her Excellency the Governor-General in Council

These regulations are made under section 105 of the Medicines Act 1981—

- (a) on the advice and with the consent of the Executive Council; and
- (b) on the advice of the Minister of Health given after complying with that section.

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New Schedule 1AA inserted	

Regulations

1 Title

These regulations are the Medicines Amendment Regulations 2023.

2 Commencement

These regulations come into force on 16 June 2023.

3 Principal regulations

These regulations amend the Medicines Regulations 1984.

4 New regulation 2A inserted (Transitional, savings, and related provisions)

After regulation 2, insert:

2A Transitional, savings, and related provisions

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

5 Regulation 65A revoked (Transitional provision arising from enactment of Medicines Amendment Regulations 2011)

Revoke regulation 65A.

6 New Schedule 1AA inserted

Insert the Schedule 1AA set out in the Schedule of these regulations as the first schedule to appear after the last regulation of the principal regulations.

Schedule New Schedule 1AA inserted

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Schedule 1AA Transitional, savings, and related provisions

r 2A

Part 1 Provisions relating to Medicines Amendment Regulations 2023

- 1 Exemption from requirement in regulation 13(1)(f) for zopiclone and zolpidem supplied before 1 July 2023**

The requirement in regulation 13(1)(f) does not apply in respect of zopiclone or zolpidem supplied by a retailer, manufacturer, or wholesaler before 1 July 2023.
- 2 Exemption from requirement in regulation 13(1)(f) for tramadol supplied before 1 October 2023**

The requirement in regulation 13(1)(f) does not apply in respect of tramadol supplied by a retailer, manufacturer, or wholesaler before 1 October 2023.

Rachel Hayward,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 16 June 2023, amend the Medicines Regulations 1984 to provide exemptions from labelling requirements in respect of specified prescribed medicines.

On 1 July 2023, the prescribed medicines zopiclone and zolpidem become class C5 controlled drugs. On 1 October 2023, the prescribed medicine tramadol becomes a class C2 controlled drug (*see* the Misuse of Drugs (Classification and Presumption of Supply) Order 2022). The exemptions in *new Schedule 1AA* permit a retailer, manufacturer, or wholesaler to supply those prescribed medicines with labelling updated to reflect their new designations in advance of 1 July and 1 October 2023 respectively.

Regulatory impact statement

A regulatory impact statement is not required for these regulations.

Issued under the authority of the Legislation Act 2019.

Date of notification in *Gazette*: 15 June 2023.

These regulations are administered by the Ministry of Health.