Medicines Amendment Act 2025

Public Act	2025 No 66
Date of assent	18 November 2025
Commencement	see section 2

Contents

		Page
1	Title	2
2	Commencement	2
3	Principal Act	2
	Part 1 **Consent to distribute medicines by verification**	
4	Section 2 amended (Interpretation)	2
5	Section 20 amended (Restrictions on sale or supply of new medicines)	2
6	Section 21 amended (Applications for Minister's consent)	3
7	New sections 22A to 22F inserted	3
	22A Interpretation	3
	22B Recognised regulatory authorities	4
	22C Application for Minister's consent by verification	4
	22D Minister's consent by verification	5
	22E Rules for Minister's consent by verification	6
	22F Powers of Minister after grant of consent	7
8	Section 23A amended (Interpretation)	7
9	New section 23BA inserted (Protection of confidential supporting information supplied in application for consent by verification)	7
	23BA Protection of confidential supporting information supplied in application for consent by verification	8
10	Section 23C amended (Circumstances where protection under section 23B does not apply)	8

Part 2
Other amendments

11	Section 29 amended (Exemption for medicine required by medical practitioner)	8
12	New sections 29A and 29B inserted	9
	29A Exemption for funded alternative medicine	9
	29B Reporting sale or supply of new medicine exempted under section 29 or 29A	9
13	New section 34AA inserted (Exemption for advertising medicines at medical conferences)	10
	34AA Exemption for advertising medicines at medical conferences	10
14	Section 42C repealed (Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies)	10
15	Consequential and other amendments to principal Act	10
	Schedule	11
	Consequential and other amendments to principal Act	

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Medicines Amendment Act 2025.

2 Commencement

This Act comes into force on 19 November 2025.

Section 2: editorial change made by the PCO, on 2 December 2025, under sections 86(1) and 87(m) of the Legislation Act 2019 (2019 No 58).

3 Principal Act

This Act amends the Medicines Act 1981.

Part 1
Consent to distribute medicines by verification

4 Section 2 amended (Interpretation)

In section 2(1), insert in its appropriate alphabetical order:

consent by verification means consent granted under section 22D allowing the sale, distribution, and advertising of a new medicine

5 Section 20 amended (Restrictions on sale or supply of new medicines)

(1) In section 20(2), replace "consent or provisional consent" with "consent, consent by verification, or provisional consent" in each place.

(2) In section 20(6A), replace "consent or provisional consent" with "consent, consent by verification, or provisional consent" in each place.

6 Section 21 amended (Applications for Minister's consent)

Replace section 21(2) with:

(2) The following particulars are required:

(a) the business address of the person in whose name the application is made:

(b) the name under which the medicine will be distributed:

(c) details of the method of manufacture of the medicine:

(d) qualitative and quantitative particulars of all ingredients of the medicine named by the descriptive or non-proprietary names of the ingredients:

(e) a description of the quality of the raw materials used in the manufacture of the medicine:

(f) a description of the form or forms of the medicine, the dosage, and the method and route of administration:

(g) the indications for which the medicine may be administered:

(h) reports of toxicological, pharmacological, and clinical studies that support the application:

(i) reports of any tests made to control or monitor the quality of the medicine, including any tests that relate to its stability:

(j) a translation into English, authenticated in a manner required in writing by the Director-General, of any report referred to in paragraph (h) or (i) that is not in English:

(k) any evidence to show that the distribution in any country other than New Zealand of the medicine in the form and for the purposes that it is proposed to be distributed in New Zealand has been approved or consented to by the appropriate authorities in that country:

(l) an accurate copy of every label and other descriptive matter proposed to be used on or included in, or to accompany, packages or containers containing the medicine:

(m) the name and address of the place or places where the manufacture, preparation, or packing is intended to be carried out.

7 New sections 22A to 22F inserted

After section 22, insert:

22A Interpretation

In this section and in sections 22C to 22F, unless the context otherwise requires,—

full evaluation does not include an evaluation that is abbreviated, abridged, made in reliance on another evaluation, or simplified in any way

full marketing authorisation—

(a) means an authorisation that permits the sale, distribution, and advertising of a medicine that is based on a full evaluation of the medicine by a recognised regulatory authority; but

(b) does not include a provisional, conditional marketing, emergency, or export-only authorisation

recognised regulatory authority means a person or body declared to be a recognised regulatory authority by notice given in accordance with section 22B

rules means rules made by the Minister under section 22E.

22B Recognised regulatory authorities

(1) The Minister may, by notice in the *Gazette*, declare a person or body (whether in New Zealand or overseas) to be a recognised regulatory authority if the Minister is satisfied that the person or body—

(a) is a regulator of medicines; and

(b) operates in a regulatory framework similar to that provided under this Act and other legislation relevant to—

(i) the matters that they must take into account in making decisions as a regulator; and

(ii) the decision-making process; and

(c) has a formal framework for co-operation with the Director-General; and

(d) uses international guidelines and standards in relation to medicines consistent with those used under this Act; and

(e) conducts their business and releases reports in English.

(2) The Minister may revoke a declaration under subsection (1) if the Minister is satisfied that the recognised regulatory authority no longer meets 1 or more of the criteria in subsection (1).

22C Application for Minister's consent by verification

(1) A person may apply for consent by verification by lodging the application with the Director-General.

(2) Before the Minister considers an application under section 22D, the Director-General must decide within the period specified in the rules whether an application for consent by verification complies with subsection (3).

(3) An application must contain all the particulars and be in the form required by—

(a) section 21(2); and

(b) the rules.

(4) The Director-General may issue the applicant with 1 or more invoices for any fee payable under regulations in respect of the application.

22D Minister's consent by verification

(1) Despite section 22, the Minister may, by notice, consent to the sale, distribution, and advertising of a new medicine if the Minister is satisfied that—

(a) any fee payable under regulations in respect of the application has been paid; and

(b) the new medicine—

(i) has a full marketing authorisation granted by 2 or more recognised regulatory authorities; and

(ii) is identical in all material respects to the medicine that has full marketing authorisation granted by 2 or more recognised regulatory authorities; and

(iii) meets the requirements for consent by verification set out in the rules; and

(iv) meets the relevant requirements of the Medicines Regulations 1984; and

(v) does not require independent assessment by the Director-General to contextualise the benefit-risk profile of the medicine due to local disease epidemiology, public health considerations, or New Zealand specific health risks; and

(vi) is not pending deferral of full marketing authorisation, or has not had full marketing authorisation rejected or withdrawn, by a recognised regulatory authority for quality, safety, or efficacy reasons; and

(vii) has not been subject to any regulatory action that may result or has resulted in a suspension or revocation of the market authorisation by a recognised regulatory authority.

(2) A decision under subsection (1) may grant consent, refuse consent, or withdraw the application for resubmission as an assessment under section 22 or 23.

(3) A decision under subsection (1) may be made subject to any conditions that the Minister considers appropriate in the circumstances.

(4) The Minister must make a decision under subsection (1) within the time period specified in the rules, which begins on the date the fee payable under regulations in respect of the application is paid.

(5) The Minister may request an applicant to provide further information or to amend an application (or both) if the Minister considers that—

(a) further information is required to assess the new medicine under subsection (1); or

(b) the information provided indicates that the medicine may not be suitable for use in New Zealand.

(6) If the Minister makes a request under subsection (5), the time period specified for decision making in the rules ceases to run from the date the request is made until the date on which the applicant complies with the request.

(7) A consent given under this section does not warrant the safety or efficacy of the medicine to which the consent relates.

(8) A notice 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[The Ministry of Foreign Affairs and Trade considers that the secondary legislation may have international transparency obligations under the CPTPP. As a result the maker may also have to comply with s 75 of the Legislation Act 2019]	LA19 s 74(1)(aa)LA19 ss 74(2), 75
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.

22E Rules for Minister's consent by verification

(1) The Minister may make rules setting out requirements—

(a) relating to applications for consent by verification; and

(b) relating to medicines for which consent by verification is sought; and

(c) for lodging an application for consent by verification; and

(d) for processing an application for consent by verification.

(2) Before making rules under this section, the Minister must consult the organisations or bodies that the Minister considers to be representative of persons likely to be substantially affected by the rules during a period of at least 8 weeks.

(3) Subsection (2) does not apply if the Minister is satisfied that the rules make an amendment that is minor in effect or corrects a minor or technical error.

(4) Rules made under this section are 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.

22F Powers of Minister after grant of consent

(1) The Minister may request the holder of a consent by verification to provide further information in relation to that consent within a time frame specified in the request if the Minister has reason to believe that the medicine did not or may no longer meet the requirements in section 22D(1).

(2) If the Minister has requested further information in relation to a consent, the Minister may suspend that consent for the period—

(a) starting on the date of the request; and

(b) ending no later than the close of the day on which the Minister decides whether to act under subsection (3).

(3) The Minister may revoke the consent or impose conditions on the consent if,—

(a) having considered the further information provided by the holder of the consent, the Minister considers that there is reasonable doubt as to whether the medicine meets the requirements in section 22D(1); or

(b) the holder of the consent has not provided the information requested within the specified time frame.

(4) The Minister may impose conditions on a consent by verification that the Minister considers appropriate in the circumstances at any time.

8 Section 23A amended (Interpretation)

(1) In section 23A, insert in their appropriate alphabetical order:

application for consent by verification means an application for consent to be granted under section 22D allowing the sale, distribution, and advertising of a new medicine

verification protected period means, in relation to confidential supporting information relating to an application for consent by verification, a period—

(a) commencing on the date that information was received by the Minister; and

(b) ending on the date 5 years after the date of—

(i) notification of consent; or

(ii) refusal of consent

(2) In section 23A, definition of **confidential supporting information**, paragraph (b), after "application", insert "or an application for consent by verification".

9 New section 23BA inserted (Protection of confidential supporting information supplied in application for consent by verification)

After section 23B, insert:

23BA Protection of confidential supporting information supplied in application for consent by verification

If the Minister receives an application for consent by verification and confidential supporting information, the Minister must, during the verification protected period in relation to that confidential supporting information,—

(a) take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and

(b) not use that confidential supporting information for the purposes of determining whether to grant any other application.

10 Section 23C amended (Circumstances where protection under section 23B does not apply)

(1) In the heading to section 23C, after "**section 23B**", insert "**or 23BA**".

(2) In section 23C(1), replace "Notwithstanding section 23B" with "Despite sections 23B and 23BA".

(3) In section 23C(1), after "protected period", insert "or verification protected period".

Part 2
Other amendments

11 Section 29 amended (Exemption for medicine required by medical practitioner)

(1) In the heading to section 29, replace "**medical practitioner**" with "**specified practitioners**".

(2) Replace section 29(1) to (3) with:

(1) Sections 20 and 24 do not prevent—

(a) a person supplying to a specified practitioner, on the request of the specified practitioner, any medicine that the specified practitioner requires for the treatment of a patient currently under their care; or

(b) a person supplying to a pharmacy practice a medicine described in paragraph (a) for dispensing by the pharmacy practice to the patient; or

(c) a specified practitioner administering a medicine described in paragraph (a) to the patient.

(2) In this section,—

pharmacist prescriber means a pharmacist who is a designated prescriber under the Medicines (Designated Pharmacist Prescribers) Regulations 2013

specified practitioner means—

(a) a medical practitioner; or

(b) a nurse practitioner; or

(c) a pharmacist prescriber.

12 New sections 29A and 29B inserted

After section 29, insert:

29A Exemption for funded alternative medicine

(1) Sections 20 and 24 do not prevent—

(a) a person supplying to an authorised prescriber, on the authorised prescriber's request, a funded alternative medicine required by that authorised prescriber for the treatment of a particular patient currently under that authorised prescriber's care; or

(b) a person supplying to a pharmacy practice a medicine described in paragraph (a) for dispensing to the patient; or

(c) an authorised prescriber administering the funded alternative medicine to the patient.

(2) In this section,—

funded alternative medicine means a new medicine—

(a) that has not been granted consent by the Minister under section 20, 22D, or 23 of this Act; and

(b) that is listed in the pharmaceutical schedule by Pharmac as an alternative to a medicine that has been granted consent by the Minister under those provisions, because the consented medicine is in short supply

Pharmac has the meaning given in section 4 of the Pae Ora (Healthy Futures) Act 2022

pharmaceutical schedule has the meaning given in section 4 of the Pae Ora (Healthy Futures) Act 2022.

29B Reporting sale or supply of new medicine exempted under section 29 or 29A

(1) Subsections (2) and (3) apply to an importer or manufacturer who, for the purposes of section 29(1) or 29A(1), sells or supplies any medicine that is a new medicine by virtue of paragraph (a) of the definition of new medicine in section 3(3) before the notice of consent of the Minister to the distribution of that medicine has been published under the Legislation Act 2019.

(2) The importer or manufacturer must, as soon as practicable after the end of every month in which they have sold or supplied the medicine, provide the following details to the Director-General in writing:

(a) the trade name and generic name of the medicine:

(b) the dose form:

(c) the strength:

(d) the pack size:

(e) the month and year of supply:

(f) the quantity sold or supplied.

(3) The importer or manufacturer must—

(a) keep a record of the name of the authorised prescriber who requested the medicine, the name of the patient, and the place of supply; and

(b) provide the names and the place of supply to the Director-General on request.

13 New section 34AA inserted (Exemption for advertising medicines at medical conferences)

After section 34, insert:

34AA Exemption for advertising medicines at medical conferences

(1) This section applies if the organiser of a medical conference notifies the Director-General at least 30 working days before the opening of the conference of the following:

(a) that 1 or more medicines that are not approved under section 20, 22D, or 23 will be advertised at the medical conference:

(b) the dates on which the medical conference will open and close:

(c) the location of the medical conference:

(d) whether the medicines have been approved by a recognised regulatory authority:

(e) whether applications for approval of the medicines under section 20, 22D, or 23 have been submitted to the Director-General.

(2) Section 20(2)(c) does not apply to a person who advertises at the medical conference the availability of the medicines.

(3) In this section, **medical conference** means any conference, including an associated trade show, where the intended audience are health practitioners regulated under the Health Practitioners Competence Assurance Act 2003.

14 Section 42C repealed (Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies)

Repeal section 42C.

15 Consequential and other amendments to principal Act

Amend the principal Act as set out in the Schedule.

Schedule
Consequential and other amendments to principal Act

s 15

Section 9

Replace section 9(3) with:

(3) The Minister must appoint at least 7 members to the Committee.

(3A) The Minister must not appoint a person to the Committee unless they are satisfied that the person is suitably qualified to be a member.

Replace section 9(4) with:

(4) The members of the Committee hold office for a term of 3 years, subject to subsection (5), but any member may be reappointed for 1 further term.

Replace section 9(6) to (9) with:

(6) The quorum for a meeting of the Committee is half of the membership of the Committee plus 1, rounded down to the nearest whole number.

Section 22

In section 22(4), replace “28 days” with “20 working days”.

Section 23

In section 23(2)(c), replace “paragraphs (a) to (h)” with “paragraphs (a) to (g) and (i)”.

Section 24

In section 24(3), replace “90 days” with “64 working days”.

In section 24(4), replace “45 days” with “32 working days”.

Section 30

In section 30(4), replace “45 days” with “32 working days”.

Section 35

In section 35(1), replace “or suspend for such period as he may determine, any consent given under section 20 or section 23, if he is of the opinion that” with “or suspend for such period as they may determine, any consent given under section 20, 22D, or 23, if they are of the opinion that”.

Section 89

In section 89(1)(a), after “20,”, insert “22D,”.

Legislative history

31 March 2025	Introduction (Bill 134–1)
10 April 2025	First reading and referral to Health Committee
31 July 2025	Reported from Health Committee (Bill 134–2)
21 October 2025	Second reading
4 November 2025	Committee of the whole House (Bill 134–3)
11 November 2025	Third reading
18 November 2025	Royal assent

This Act is administered by the Ministry of Health.

Wellington, New Zealand:
Published under the authority of the New Zealand Government—2025