Medicines Amendment Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

The Health Committee has examined the Medicines Amendment Bill and recommends that it be passed. We recommend all amendments unanimously.

Introduction

The Medicines Amendment Bill seeks to expedite the approval of medicines. It would amend the Medicines Act 1981 to introduce a new verification pathway. The bill would allow medicines to be approved for distribution in New Zealand if they have been approved by two recognised overseas jurisdictions. An increasing number of overseas medicine regulators now rely partly on assessments made by counterparts in other jurisdictions.

The bill would also expand prescribing rights by allowing nurse practitioners to prescribe medicines under section 29 of the Medicines Act, in the way medical practitioners may currently. In addition, all authorised prescribers would be able to prescribe unapproved medicines, if they are funded by Pharmac, to address a shortage of approved medicines.[1]

Lastly, the bill proposes changes to the requirements for the membership of the Medicines Classification Committee.

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[1] The Medicines Act 1981 allows unapproved medicines to be obtained by an authorised prescriber or a medical practitioner for a known patient under their care. Under section 29, a medical practitioner (only) may prescribe unapproved medicines. Certain conditions apply.

Legislative scrutiny

As part of our consideration of the bill, we have examined its consistency with principles of legislative quality. We have no issues regarding the legislation's design to bring to the attention of the House.

Proposed amendments

This commentary covers the main amendments we recommend to the bill as introduced. We do not discuss minor or technical amendments.

New verification pathway

List of recognised overseas regulators

Clause 7 of the bill would insert new sections 22A to 22E into the Medicines Act. Proposed section 22A lists the recognised regulatory authorities for the purposes of the new verification pathway. They are the medicines regulators of the European Union, Australia, Canada, the United States, the United Kingdom, Singapore, and Switzerland.

We are aware of concern that the bill as introduced would lack the flexibility needed to adapt to a rapidly changing global context. The bill would not allow for an overseas regulator to be removed if it was no longer deemed reputable, or a new regulator to be added to the list. Varying the list of recognised regulatory authorities could only be achieved by amending the primary legislation.

Instead, we recommend that recognised regulatory authorities be declared by the Minister, by notice in the *Gazette*. Our proposed new section 22AA would require the Minister to be satisfied that the person or body:

- is a regulator of medicines
- operates in a regulatory framework similar to that provided under the Medicines Act and other legislation in relation both to the matters that they must take into account in making decisions as a regulator and to the decision-making process
- has a formal framework for co-operation with the Director-General
- uses international guidelines and standards in relation to medicines consistent with those used under the Medicines Act
- conducts their business and releases reports in English.

Subsection (2) would allow the Minister to revoke a declaration if they are no longer satisfied that a recognised regulatory authority meets all the criteria listed above.

Time frames counted in "working days"

The Schedule of the bill would make several amendments to the Medicines Act to replace "days" with "working days" in relation to certain statutory time frames. We understand that this change is intended to ensure that time frames are measured con-

sistently with other jurisdictions, such as Australia, where time frames are measured in working days.

The bill as introduced would replace the number of "days" with "working days", without changing the number of days. We agree with concerns that this amendment would have the unintended consequence of lengthening statutory time frames for existing evaluation pathways. We therefore recommend amending the Schedule so that the bill would replace the number of calendar days with the equivalent number of working days. This would affect sections 22(4), 24(3)–(4), and 30(4).

Subsection (5) of new section 22C would allow the Minister to request that an applicant provide further information or amend their application as part of the verification process. Under subsection (6), the time frame for decision making, to be specified in the rules, would cease to run from the date the request is made until the applicant complies with the request. We heard concerns from submitters that the verification process could be unduly delayed as a result. However, we are satisfied that the bill would provide the flexibility needed for Medsafe to process applications effectively. We understand that this provision is not intended to be used to extend the time frames set in the rules.

Prescription of unapproved medicines by pharmacist prescribers

Under the Medicines Act, medicines cannot be advertised, sold, or distributed without the approval of the Minister of Health (delegated to Medsafe). However, section 29 of the Act provides an exemption for medical practitioners, who may prescribe an unapproved medicine for the treatment of a specific patient. Prescribing unapproved medicines has become more common due to frequent shortages in global supplies.

Currently, authorised prescribers other than medical practitioners (doctors) are not allowed to prescribe unapproved medicines. The bill proposes to expand these prescribing rights to nurse practitioners, to avoid delays for patients and workload pressures on medical practitioners. We agree with this change, which recognises that nurse practitioners are highly trained and skilled. Their required qualifications include at least four years' experience, completion of an approved clinical Master's degree programme entailing at least 300 hours of clinical learning, and passing an assessment against competencies set by the Nursing Council of New Zealand.

We consider that pharmacist prescribers are equally qualified to prescribe unapproved medicines in specific circumstances. Pharmacist prescribers receive substantial training in applied pharmacotherapy and have experience working in a clinical setting such as general practice or a hospital. To become a designated pharmacist prescriber, candidates must hold qualifications prescribed by the Pharmacy Council. Required course content includes pharmaceutics, physical assessment and diagnostic skills, the "mechanics" of prescribing, pharmacoeconomic considerations, and completion of a practicum with a medical practitioner or nurse practitioner. The practicum must demonstrate knowledge to safely prescribe specified prescription medicines and knowledge of the regulatory framework for prescribing. We understand that no other professional training includes the discipline of pharmaceutics.

We recommend classifying those who would be able to prescribe unapproved medicines (medical practitioners, nurse practitioners, and pharmacist prescribers) as "specified practitioners", and propose amending clause 11 of the bill accordingly.

Clarification of reporting requirement

Proposed new section 29B sets out requirements for reporting by importers or manufacturers of unapproved medicines. Subsection (3)(a) would require the importer or manufacturer to keep a record of the name of the medical practitioner or nurse practitioner who requested the medicine, the name of the patient, and the place of supply. The class of prescriber to be recorded is broader than just "medical practitioner or nurse practitioner". We recommend that these terms be replaced with "authorised prescriber".

Quorum of the Medicines Classification Committee

The Schedule would amend section 9 of the Act to make changes to the membership requirements for the Medicines Classification Committee. We recommend a minor amendment to new section 9(6) to clarify that the quorum for the Medicines Classification Committee would be half the Committee plus 1, rounded down to the nearest whole number. This is intended to address situations where the membership of the committee was an odd number.

Appendix

Committee process

The Medicines Amendment Bill was referred to this committee on 10 April 2025. The House instructed us to report the bill back no later than 11 August 2025. We invited the Associate Minister of Health (Pharmac), Hon David Seymour, to provide an oral submission on the bill. He did so on 21 May 2025.

We called for submissions on the bill with a closing date of 19 May 2025. We received and considered submissions from 185 interested groups and individuals. We heard oral evidence from 32 submitters.

Advice on the bill was provided by the Ministry of Health. The Office of the Clerk provided advice on the bill's legislative quality. The Parliamentary Counsel Office assisted with legal drafting. The Regulations Review Committee reported to us on the powers contained in clause 7.

Committee membership

Sam Uffindell (Chairperson)

Dr Hamish Campbell

Dr Carlos Cheung

Ingrid Leary

Cameron Luxton

Hūhana Lyndon

Jenny Marcroft

Debbie Ngarewa-Packer

Hon Dr Ayesha Verrall

Related resources

The documents we received as advice and evidence are available on the Parliament website.

Key to symbols used in reprinted bill

As reported from a select committee

text inserted unanimously

~~text deleted unanimously~~

Hon David Seymour

Medicines Amendment Bill

Government Bill

Contents

Part 2
Other amendments

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 the day after Royal assent.

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 22C** 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 22E inserted

After section 22, insert:

22A Interpretation

In this section and in **sections 22B to 22E**, 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 any of the following:~~

~~(a) European Medicines Agency:~~

~~(b) Therapeutic Goods Administration (Australia):~~

~~(c) Health Canada:~~

~~(d) Centre for Drug Evaluation and Research (US Food and Drug Administration):~~

~~(e) Medicines and Healthcare products Regulatory Agency (UK):~~

~~(f) Health Sciences Authority (Singapore):~~

~~(g) Swiss Agency for Therapeutic Products (Swissmedic)~~

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

rules means rules made by the Minister under **section 22D**.

22AA 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)**.

22B 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 22C**, 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.

22C 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).

22D 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).

22E 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 22C(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 22C(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 22C** 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, ~~after~~ replace "**medical practitioner**"~~, insert~~ with "~~**or nurse practitioners**~~**specified practitioners**".

(1A) 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.

~~(2) In section 29(1), replace "medical practitioner" with "medical practitioner or nurse practitioner" in each place.~~

~~(3) In section 29(1), replace "medical practitioner's" with "medical practitioner's or nurse practitioner's" in each place.~~

~~(4) After section 29(1)(a), insert:~~

~~(aa) the supply by a person to a pharmacy of a medicine described in paragraph (a) for dispensing to the patient; or~~

~~(5) Repeal section 29(2) and (3).~~

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, **22C**, 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 ~~medical practitioner or nurse practitioner~~ 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 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 13

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 "~~28~~ 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 "~~90~~ 64 working days".

In section 24(4), replace "45 days" with "~~45~~ 32 working days".

Section 30

In section 30(4), replace "45 days" with "~~45~~ 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, **22C**, or 23, if they are of the opinion that".

Section 89

In section 89(1)(a), after "20,", insert "**22C**,".

Legislative history

31 March 2025	Introduction (Bill 134–1)
10 April 2025	First reading and referral to Health Committee

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