

# Medicines Amendment Act 2003

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**The Parliament of New Zealand enacts as follows:**

**1 Title**

- (1) This Act is the Medicines Amendment Act 2003.
- (2) In this Act, the Medicines Act 1981 is called “the principal Act”.

## 2 Commencement

This Act comes into force on the day that is 1 year after the date on which this Act receives the Royal assent.

## 3 Interpretation

- (1) Section 2(1) of the principal Act is amended by inserting, after the definition of **approved laboratory**, the following definition:

**authorised prescriber** means a practitioner, registered midwife, or designated prescriber.

- (2) Section 2(1) of the principal Act is amended by inserting, after the definition of **disease**, the following definition:

**dispensing**, in relation to a medicine, includes, without limitation,—

- (a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and
- (b) the packaging, labelling, recording, and delivery of that medicine.

- (3) Section 2(1) of the principal Act is amended by repealing the definitions of **dentist**, **licensing authority**, **medical practitioner**, **optician**, **pharmacist**, **pharmacy**, **registered health professional**, and **registered midwife**, and substituting, in their appropriate alphabetical order, the following definitions:

**dentist** means a health practitioner who is, or is deemed to be, registered with the Dental Council of New Zealand established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of dentistry

**licensing authority** —

- “(a) means the Director-General; and
- “(b) to avoid doubt, includes any person or persons acting as the Director-General’s delegate as a consequence of a delegation under section 41 of the State Sector Act 1988”

**medical practitioner** means a health practitioner who is, or is deemed to be, registered with the Medical Council of New Zealand continued by the Health Practitioners Competence

Assurance Act 2003 as a practitioner of the profession of medicine

**pharmacist** means a health practitioner who is, or is deemed to be, registered with the Pharmacy Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of pharmacy

**pharmacy** means a place where pharmacy practice is carried on

**registered health professional** means a health practitioner who is, or is deemed to be, registered with an authority established or continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of a particular health profession

**registered midwife** means a health practitioner who is, or is deemed to be, registered with the Midwifery Council established by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of midwifery.

- (4) Section 2(1) of the principal Act is amended by inserting, after the definition of **pharmacy**, the following definition:

**pharmacy practice** includes, without limitation, the following

- (a) the compounding and dispensing of prescription medicines, restricted medicines, or pharmacy-only medicines:
- (b) the supply of a medicine by a pharmacist to suit the needs of a particular person:
- (c) the sale of prescription medicines, restricted medicines, or pharmacy-only medicines.

#### 4 New sections 5A and 5B inserted

The principal Act is amended by inserting, after section 5, the following sections:

##### “5A Meaning of holding an interest in a pharmacy

- “(1) For the purposes of this Act, a person holds an interest in a pharmacy if the person has, or acquires, any direct or indirect estate or interest in the pharmacy (whether by way of shares in a company or by way of charge, loan, guarantee, indemnity, or

otherwise) that affects the ownership, management, or control of the pharmacy practice carried on in the pharmacy.

- “(2) For the purposes of subsection (1), a person acquires a direct or indirect estate or interest in a pharmacy if the acquisition is made in the person’s name, or in the name of a nominee, or the acquisition is made by the person by means of any device or arrangement.
- “(3) Despite subsections (1) and (2),—
- “(a) a person does not hold an interest in a pharmacy merely by—
- “(i) making, in good faith and in the ordinary course of business to facilitate the carrying on of the pharmacy, any loan of money; or
- “(ii) holding any security for repayment of that loan:
- “(b) a person does not hold an interest in a pharmacy that is being carried on by an administrator of the estate of a deceased pharmacist, or by an administrator of the estate of a deceased operator of a pharmacy, merely by holding an interest in that estate.
- “(4) Despite subsection (3), any covenant, condition, or stipulation, expressed or implied in any contract or agreement restricting the operator of a pharmacy in the purchase of pharmaceutical requirements or other stock in trade is to be treated, for the purposes of this Act, as a device or arrangement affecting the management and control of the pharmacy practice carried on in that pharmacy.

“**5B Meaning of operating a pharmacy**

For the purposes of this Act, a person operates a pharmacy if the person—

- “(a) establishes, or carries on business in, a pharmacy; or
- “(b) establishes, owns, or is responsible for the management or control of a hospital in which there is a pharmacy; or
- “(c) establishes, or is responsible for the management or control of a pharmacy carried on, on a not for profit basis.”

Compare: 1970 No 143 s 2(2)-(4)

## **5 Manufacturers, wholesalers, and packers of medicines to be licensed**

- (1) The heading to section 17 of the principal Act is amended by omitting the words “and packers of medicines”, and substituting the words “packers of medicines, and operators of pharmacies”.
- (2) Section 17(1) of the principal Act is amended by omitting paragraph (c), and substituting the following paragraphs:
  - “(c) pack or label any medicine; or
  - “(d) operate any pharmacy,—”
- (3) Section 17 of the principal Act is amended by repealing subsection (2), and substituting the following subsection:
  - “(2) Every person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine not exceeding \$40,000.”

## **6 Sale of medicines by retail**

- (1) Section 18(1) of the principal Act is amended by omitting paragraphs (a), (aa), and (b), and substituting the following paragraphs:
  - “(a) any prescription medicine unless—
    - “(i) the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or
    - “(ii) the medicine is supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order; or
  - “(b) any restricted medicine unless the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or
  - “(c) any pharmacy-only medicine unless the medicine is sold, supplied, or distributed by—
    - “(i) a person under the supervision of a pharmacist in a pharmacy or a hospital; or
    - “(ii) a person who sells, supplies, or distributes the medicine in any shop described in section 51(2) and in accordance with a licence issued under Part 3.”
- (2) Section 18(5) of the principal Act is amended by omitting the expression “\$1,000”, and substituting the expression “\$40,000”.

- 7 Administering prescription medicines**  
Section 19 of the principal Act is amended by repealing subsection (4).
- 8 Exemptions for practitioners and others**  
Section 25 of the principal Act is amended by repealing subsection (4).
- 9 Exemptions for veterinarians and opticians**
- (1) The heading to section 27 of the principal Act is amended by omitting the word “opticians”, and substituting the words “certain registered health practitioners”.
- (2) Section 27 of the principal Act is amended by repealing paragraph (b), and substituting the following paragraph:
- “(b) any person registered with the Optometrists and Dispensing Opticians Board continued under section 114(1) of the Health Practitioners Competence Assurance Act 2003, and having the appropriate scope of practice as defined by the Board under that Act, may:
- “(i) sell or supply a medicine for use in cleaning, soaking, or lubricating contact lenses if the medicine is suitable for that purpose; and
- “(ii) pack or label the medicine for the purposes of any sale or supply.”
- (3) Section 27 of the principal Act is amended by repealing paragraph (c)(ii), and substituting the following subparagraph:
- “(ii) to any person referred to in paragraph (b), any medicine referred to in subparagraph (i) and (ii) of that paragraph.”
- 10 Exemptions for agents and employees**  
Section 31 of the principal Act is amended by adding the following subsection:
- “(4) Subsection (3)(a) does not apply in respect of any authority conferred by section 26 on a pharmacist or on a pharmacist employed or engaged by a person who is not a pharmacist but who holds a licence to operate a pharmacy.”

**11 New heading and sections 42A to 42C inserted**

The principal Act is amended by inserting, after section 42, the following heading and sections:

*“Restrictions on operation of pharmacies*

**“42A Every pharmacy must be under supervision of pharmacist**

No person may operate any pharmacy that is not for the time being under the immediate supervision and control of a pharmacist.

**“42B Security of pharmacies**

- “(1) Every person who operates a pharmacy must ensure that every prescription medicine or restricted medicine in the pharmacy is at all times secured in a way that prevents the public gaining ready access to the medicine.
- “(2) Every person who operates a pharmacy must ensure that all medicines held in storage for the purposes of the pharmacy are secured in a way that prevents the public gaining access to the medicines.
- “(3) Subsections (1) and (2) do not prevent a pharmacist engaged at the pharmacy or another person authorised by a pharmacist engaged at the pharmacy, from supplying any medicine to a member of the public.
- “(4) The requirements imposed by subsections (1) and (2) are in addition to the requirements imposed by section 47 or any regulations made under this Act.

**“42C Restriction on authorised prescribers holding interest in pharmacies**

- “(1) No authorised prescriber may hold an interest in a pharmacy other than a pharmacy for which the person holds a licence to operate, except with the consent of the licensing authority and in accordance with any conditions or restrictions imposed by that authority.
- “(2) No person who has an interest in a pharmacy may permit or enable any authorised prescriber to hold or acquire that or any other interest in the pharmacy contrary to subsection (1).
- “(3) The licensing authority may not give its consent under subsection (1) unless it is satisfied that there are sufficient safeguards



to prevent the issue of prescriptions, the manner in which prescriptions are issued, or the other provision of health care by the authorised prescriber from being influenced by the commercial or financial interests of the authorised prescriber or any other person holding an interest in the pharmacy.”

Compare: 1970 No 143 s 41

## **12 Powers of Minister to prohibit prescribing, etc**

- (1) Section 48(2)(c) of the principal Act is amended by omitting the words “Council of the Pharmaceutical Society of New Zealand”, and substituting the words “Pharmacy Council”.
- (2) Section 48(2)(d) of the principal Act is amended by inserting, after the words “on the recommendation of”, the words “the Midwifery Council or”.
- (3) Section 48(2)(f) of the principal Act is amended by omitting the words “Council or Board”, and substituting the words “authority under the Health Practitioners Competence Assurance Act 2003”.

## **13 Applications for licences**

- (1) Section 50 of the principal Act is amended by repealing subsection (1), and substituting the following subsection:
  - “(1) Every application for a licence must be made in the prescribed form to the Director-General or to any person designated for the purpose by the Director-General by notice in the *Gazette*.”
- (2) Section 50 of the principal Act is amended by repealing subsections (4) and (5), and substituting the following subsections:
  - “(4) An application may be made either by an individual who is a New Zealand resident on the person’s own behalf or by an appropriate officer of a body corporate that is incorporated in New Zealand on behalf of that body corporate.
  - “(5) If a person authorised to receive an application under subsection (1) is satisfied that an application complies with the requirements of this section and of any regulations made under this Act that are applicable to the application, the person must refer the application to the licensing authority.”

**14 Grant of licences**

- (1) Section 51(1) of the principal Act is amended by omitting the words “section 52 of this Act”, and substituting the words “sections 52, 55A, and 55B”.
- (2) Section 51(1)(f) of the principal Act is amended by adding the words “or, in the case of an application for a licence to operate a pharmacy, in respect of medicines that are manufactured, stored, packed, labelled, or sold on the premises or in any other place for which the licence to operate is sought”.
- (3) Section 51(2) of the principal Act is amended by adding the words “in respect of which a licence to operate has been, or is deemed to have been, issued”.
- (4) Section 51 of the principal Act is amended by inserting, after subsection (6), the following subsections:
  - “(6A) If the licensing authority is satisfied that the holder of a licence to operate a pharmacy has failed to comply with any conditions affecting the licence, the licensing authority may, instead of or as well as exercising the powers conferred by subsection (6),—
    - “(a) impose on the holder of the licence a penalty not exceeding \$40,000:
    - “(b) forbid the licence holder or any person with an interest in the pharmacy from holding any interest in or operating a pharmacy for a period, not exceeding 5 years, specified by the licensing authority.
  - “(6B) A penalty imposed under subsection (6A) may be recovered in a court of competent jurisdiction as a debt due to the licensing authority.”
- (5) Section 51(7) of the principal Act is amended by inserting, after the words “cancels a licence”, the words “under this section or under section 55A”.

**15 Effect of licences**

- (1) Section 52(1) of the principal Act is amended by adding the following paragraph:
  - “(e) a licence to operate a pharmacy authorises the establishment of the pharmacy and the carrying on of pharmacy practice in the pharmacy.”

- (2) Section 52(3) of the principal Act is amended by adding the words “(including, without limitation, any conditions that restrict or prohibit the licence holder from undertaking any specified activity or using any specified process)”.

#### **16 Duration of licence**

Section 53 of the principal Act is amended by repealing subsection (1), and substituting the following subsection:

- “(1) Subject to subsections (2) and (3) and to section 55G, every licence, unless sooner cancelled under section 55A(3) or section 83, continues in force for a period of 1 year and then expires.”

#### **17 New sections 55A to 55G inserted**

The principal Act is amended by inserting, after section 55, the following sections:

##### **“55A Additional criteria to be satisfied by pharmacy operators**

- “(1) The licensing authority must not grant an application for a licence to operate a pharmacy unless the authority is satisfied that, in addition to satisfying the criteria set out in section 51(1),—
- “(a) the applicant is a person who is qualified under any of sections 55D, 55E, or 55G, to be granted a licence to operate a pharmacy; and
  - “(b) the applicant is a person who is able to satisfy the condition set out in section 55C.
- “(2) If the licensing authority has reasonable grounds to believe that the holder of a licence to operate a pharmacy has ceased to be a person who satisfies each of the criteria set out in subsection (1), the licensing authority may suspend the licence for a reasonable period to enable the authority to consider the case.
- “(3) If, after giving the holder of a licence to operate a pharmacy whose licence is suspended under subsection (2) a reasonable opportunity to be heard and after considering any evidence adduced or submissions made by the licensee, the licensing authority is not satisfied that the holder satisfies all of the criteria set out in subsection (1), the licensing authority may cancel the licence.

“(4) If, after giving the holder of a licence to operate a pharmacy whose licence is suspended under subsection (2) a reasonable opportunity to be heard and after considering any evidence adduced or submissions made by the licensee, the licensing authority is satisfied that the holder satisfies all of the criteria set out in subsection (1), the licensing authority must reinstate the licence.

**“55B Licensing authority may require further information**

“(1) The licensing authority, may for one or more of the purposes set out in subsection (2), require an applicant for a licence to operate a pharmacy to supply information additional to that contained in the application.

“(2) The purposes referred to in subsection (1) are—

“(a) the determination of the nature of the interest held by any person in the pharmacy:

“(b) the assessment required by section 51(1)(b) (which requires an applicant who is an individual to be a fit and proper person and an applicant who is a body corporate to be of good repute):

“(c) the assessment required by section 55A(1).

“(3) If the applicant fails to supply the information requested within 30 days of the date of the request, or within any further time allowed by the licensing authority, the application lapses.

**“55C Mandatory condition of licence to operate pharmacy.**

It is a condition of every licence to operate a pharmacy that the holder of the licence must not request or require any pharmacist who is employed or engaged in duties at a pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice.

*“Restrictions on persons allowed to operate pharmacies*

**“55D Restriction on companies operating pharmacies**

“(1) No company may be granted a licence to operate a pharmacy unless any of paragraphs (a) to (e) of subsection (2) apply.

- “(2) A company may be granted a licence to operate a pharmacy if—
- “(a) at all times more than 50% of the share capital of the company is owned by a pharmacist or pharmacists, and effective control of the company is vested in that pharmacist or those pharmacists; or
  - “(b) it is exempt from the requirements set out in paragraph (a) under an Order in Council made under section 105C or complies with any modification of those requirements authorised by an Order in Council made under that section; or
  - “(c) it is deemed to have been issued with a licence under section 114A(2); or
  - “(d) the pharmacy is in a hospital owned or operated by the company; or
  - “(e) it is a company that, at the commencement of this section, was lawfully operating a pharmacy.
- “(3) Subsection (2)(e) ceases to apply to a company if there is or are a change or changes in the ownership of shares representing 25% of the share capital of the company after the commencement of this section.
- “(4) For the purposes of subsection (2), pharmacist includes an administrator of the estate of a deceased pharmacist, and an assignee within the meaning of the Insolvency Act 1967 of the estate of a pharmacist, until—
- “(a) the expiry of the period of 1 year after the date of the death of the deceased pharmacist, or the date on which the pharmacist was adjudicated bankrupt, has expired; or
  - “(b) subject to any conditions that the licensing authority proposes, the expiry of any extended period or periods permitted by the licensing authority.
- “Compare: 1970 No 143 s 42

**“55E Restriction on individuals operating or holding majority interest in pharmacies**

- “(1) No person, either alone or in partnership, may be granted a licence to operate a pharmacy, or hold a majority interest, in a pharmacy unless

- “(a) the person is a pharmacist; or
  - “(b) the person is exempt from the requirements set out in paragraph (a) under an Order in Council made under section 105C or complies with any modification of those requirements authorised by that Order in Council; or
  - “(c) the person is deemed to have been issued with a licence under section 114A(2); or
  - “(d) the pharmacy is in a hospital owned or operated by the person; or
  - “(e) the person, at the commencement of this section, was lawfully operating a pharmacy.
- “(2) For the purposes of subsection (1), a person does not hold an interest in a pharmacy merely by reason of the person’s membership of a company, or of any other body of persons (whether corporate or unincorporate) other than a partnership, that is lawfully carrying on business in a pharmacy.
- “(3) For the purposes of subsection (1),—
- “**person** does not include a company
  - “**pharmacist** includes the following persons
    - “(a) an administrator of the estate of a deceased pharmacist:
    - “(b) an assignee, within the meaning of the Insolvency Act 1967, carrying on a pharmacy in his or her capacity as assignee of the estate of a pharmacist:
    - “(c) a liquidator carrying on a pharmacy under the authority of section 260 and Schedule 6 of the Companies Act 1993:
    - “(d) a receiver or manager of the property of a company carrying on, subject to the Receiverships Act 1993, a pharmacy comprised in that property.
- “(4) Subsection (3) does not entitle any person to carry on business in a pharmacy after—
- “(a) the expiry of 1 year after the date of the death of the deceased pharmacist, or the date on which the pharmacist was adjudicated bankrupt, or the date of the first appointment of a liquidator, receiver, or manager, in respect of a company that has carried on a pharmacy; or

“(b) subject to any conditions that the licensing authority imposes, the expiry of any extended period or periods permitted by the licensing authority.

“(5) In this section and in section 55F, majority interest, in relation to a pharmacy, means an interest in the pharmacy of more than 50% of the value of the business or businesses undertaken in the pharmacy.

“Compare: 1970 No 143 s 43

**“55F Prohibition on operating or holding of majority interest in more than 5 pharmacies**

“(1) Despite sections 55D and 55E, and unless subsection (2) or subsection (3) applies,—

“(a) no company may operate more than 5 pharmacies:

“(b) no person referred to in section 55E(3) may operate or hold a majority interest in more than 5 pharmacies.

“(2) Subsection (1) does not apply to any person referred to in section 55E(3), to the extent that 1 or more pharmacies, or interests in 1 or more pharmacies, are lawfully included in the estate or property that the person is administering, unless section 55E(4) applies.

“(3) Subsection (1) does not apply to any person who, while attempting to sell 1 pharmacy of which the person is the operator, carries on business in no more than 5 other pharmacies for a period not exceeding 3 months, or, subject to any conditions that the licensing authority imposes, any extended period or periods permitted by the authority.

“(4) Subsection (3) is subject to sections 55D and 55E.

“Compare: 1970 No 143 s 45

**“55G Exemption for mortgagees in possession**

“(1) Despite sections 55D and 55E, a mortgagee in possession of a pharmacy may be granted a licence to operate that pharmacy for a period of 3 months or, subject to any conditions that the licensing authority imposes, for any extended period or periods permitted by the licensing authority.

“(2) In this section, mortgagee in possession has the same meaning as in section 2 of the Property Law Act 1952.

“Compare: 1970 No 143 s 47.”

**18 New section 76A inserted**

The principal Act is amended by inserting, after section 76, the following section:

**“76A Offences in relation to authorised prescribers**

Every pharmacist, person licensed to operate a pharmacy, or operator or manager of a pharmacy commits an offence against this Act who gives, offers, or agrees to give to any authorised prescriber or to any other person any money or other consideration as a commission on prescriptions.

“Compare: 1970 No 143 s 49(1)(a).”

**19 Regulations relating to practitioners, veterinarians, and registered midwives**

Section 105A(2)(a) of the principal Act is amended by omitting the words “Council or Board”, and substituting the words “authority under the Health Practitioners Competence Assurance Act 2003”.

**20 Regulations relating to designated prescribers**

Section 105B(2) of the principal Act is amended by omitting the words “Council or Board”, and substituting the words “authority under the Health Practitioners Competence Assurance Act 2003”.

**21 New section 105C inserted**

The principal Act is amended by inserting, after section 105B, the following section:

**“105C Orders in Council providing for exemption from, or modifications of, restrictions on pharmacy ownership and operation**

“(1) The Governor-General may, by Order in Council made on the recommendation of the Minister,—

“(a) exempt any person or class of person from any of the requirements of section 55D(2)(a) or section 55E(1)(a):



- “(b) modify the application of the provisions of section 55D(2)(a) or section 55E(1)(a) in respect of any person or class of person.
- “(2) The Minister must not recommend the making of any Order in Council under subsection (1) unless in the opinion of the Minister—
  - “(a) health services or access to those services will be improved by the making of that Order in Council; and
  - “(b) the making of that Order in Council is necessary to meet the needs of the community in the particular location of the pharmacy or proposed pharmacy.
- “(3) The Minister’s reasons for making the recommendation must be included in, or appended to, the Order in Council.”

## **22 New sections 114A and 114B inserted**

The principal Act is amended by inserting, after section 114, the following sections:

### **“114A Certain persons deemed to have licence to operate pharmacy**

- “(1) Every person who, immediately before the commencement of this section, was entitled under the Pharmacy Act 1970 to establish or to carry on a business in a pharmacy, and had established or was carrying on a business in a pharmacy, is deemed, on the commencement of this section, to have been issued under section 51 with a licence to operate that pharmacy that is subject to—
  - “(a) any conditions relating to the establishment or carrying on of business in that pharmacy imposed by the pharmacy authority and in force immediately before the commencement of this section; and
  - “(b) the condition set out in section 55C.
- “(2) Every person who, immediately before the commencement of this section, owned or was responsible for the management of a hospital or other place in which pharmacy practice was undertaken in reliance on any authority conferred by this Act or any other enactment or regulations is deemed, on the commencement of this section, to have been issued with a licence to operate the pharmacy, subject to the condition set out in section 55C.

- “(3) The licensing authority must, as soon as is reasonably practicable after the commencement of this section, send to every person to whom a licence is deemed to have been issued under subsection (1) or subsection (2) a copy of that licence, that includes—
- “(a) the conditions referred to in subsection (1)(a) and (b) or, as the case requires, the condition referred to in subsection (2); and
  - “(b) notice of the revocation or variation of any of those conditions under subsection (4)(a); and
  - “(c) any conditions imposed by the licensing authority under subsection (4)(b).
- “(4) Despite subsections (1) to (3), the licensing authority may, in respect of any licence that is deemed to be issued under subsection (1) or subsection (2),—
- “(a) vary or revoke any condition referred to in subsection (1)(a); and
  - “(b) impose any other condition that it considers appropriate.

“**114B Expiry of section 114A**

Section 114A expires 1 year after the date of its commencement.”

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**Legislative history**

28 August 2003

Divided from Health Practitioners Competence Assurance Bill (230-2) as Bill 230-3B

11 September 2003

Third reading

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