



# Medicines Amendment Regulations 2004

Silvia Cartwright, Governor-General

## Order in Council

At Wellington this 6th day of September 2004

Present:

Her Excellency the Governor-General in Council

Pursuant to section 105 of the Medicines Act 1981, Her Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representatives of persons likely to be substantially affected, and by and with the advice and consent of the Executive Council, makes the following regulations.

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principal regulations

## Regulations

### 1 Title

- (1) These regulations are the Medicines Amendment Regulations 2004.
- (2) In these regulations, the Medicines Regulations 1984<sup>1</sup> are called “the principal regulations”.

<sup>1</sup> SR 1984/143

### 2 Commencement

These regulations come into force on 18 September 2004.

### 3 New Part 7B inserted

The principal regulations are amended by inserting, after regulation 44C, the following Part:

#### “Part 7B

#### “Supply of restricted medicine and pharmacy-only medicine

##### “44D Supply of restricted medicine and pharmacy-only medicine

- “(1) A person may, in the course of any business carried on by that person, supply a restricted medicine or pharmacy-only medicine if he or she—
  - “(a) is authorised to supply the medicine in accordance with a standing order; and
  - “(b) supplies that medicine in accordance with that standing order.
- “(2) The circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under subclause (1) are in addition to the circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under section 18(1)(b) or (c) of the Medicines Act 1981.”

### 4 New regulations 45 and 45A substituted

The principal regulations are amended by revoking regulation 45, and substituting the following regulations:

- “45 Application for licence to manufacture, hawk, sell, or pack medicine**
- “(1) Every application for a licence to manufacture, hawk, sell, or pack medicine must—
- “(a) be made in form 1 of Schedule 2:
  - “(b) be accompanied by the appropriate fee:
  - “(c) specify—
    - “(i) the premises the applicant intends to use for the activity to which the application relates; or
    - “(ii) in the case of an application for a licence to hawk medicines, the area in which the applicant intends to operate:
  - “(d) specify the medicines, or the descriptions or classes of medicines, that the applicant proposes to manufacture, hawk, sell, or pack:
  - “(e) specify—
    - “(i) the applicant’s qualifications; or
    - “(ii) if the applicant is a body corporate, the qualifications of every person who will, if the application is successful, be a responsible person for the purposes of the licence to which the application relates:
  - “(f) in the case of an application for a licence to sell any medicine by retail or to hawk any medicine, be accompanied by a certificate of character that states that the applicant—
    - “(i) is well known to the person giving the certificate; and
    - “(ii) is of good character; and
    - “(iii) is considered by the person giving the certificate to be a fit and proper person to be licensed to sell or hawk medicine.
- “(2) A licence to undertake an activity referred to in subclause (1) may only be granted in respect of 1 place of business.
- “(3) Despite subclause (2), the licensing authority may grant a licence that allows for the manufacture of medicine, or a description or class of medicines, at more than 1 place of business if—
- “(a) the application to which the licence relates is made by a body corporate; and

- “(b) the licensing authority is satisfied that the body corporate has taken steps to ensure appropriate supervision of the manufacture of the product at each of the places of business.
- “(4) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:
- “(a) further information:
- “(b) an opportunity to inspect the applicant’s premises and equipment.
- “(5) The licensing authority may, in order to determine if a person to whom section 51(1)(d) of the Act applies has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines to which a licence to manufacture, hawk, sell, or pack medicine relates, require that person to undertake and pass any oral, written, or practical tests that the licensing authority considers reasonably necessary in the particular case.

**“45A Application for licence to operate pharmacy**

- “(1) Every application for a licence to operate a pharmacy must—
- “(a) be made,—
- “(i) in the case of a company, in form 1A of Schedule 2; and
- “(ii) in the case of a person (including a body corporate that is not a company), in form 1B of Schedule 2; and
- “(b) be accompanied by—
- “(i) the fee set out in regulation 61(1)(g); and
- “(ii) a completed statutory declaration (as set out in the relevant form).
- “(2) A licence to operate a pharmacy may only be granted in respect of 1 place of business.
- “(3) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:
- “(a) further information:
- “(b) an opportunity to inspect the applicant’s premises and equipment.

- “(4) The licensing authority may, in order to determine if a person to whom section 51(1)(d) of the Act applies has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines to which a licence to operate a pharmacy relates, require that person to undertake and pass any oral, written, or practical tests that the licensing authority considers reasonably necessary in the particular case.”

## 5 Form and conditions of licence

Regulation 46 of the principal regulations is amended by revoking subclause (1), and substituting the following subclause:

- “(1) The following licences must be in the following forms:
- “(a) a licence to manufacture medicines must be in form 2 of Schedule 2:
  - “(b) a licence to hawk medicines must be in form 3 of Schedule 2:
  - “(c) a licence to sell medicines by wholesale must be in form 4 of Schedule 2:
  - “(d) a licence to sell medicines by retail must be in form 5 of Schedule 2:
  - “(e) a licence to pack medicines must be in form 6 of Schedule 2:
  - “(f) a licence to operate a pharmacy must be in form 7 of Schedule 2.”

## 6 New regulation 48A inserted

The principal regulations are amended by inserting, after regulation 48, the following regulation:

### “48A Licensing authority to be advised of change in particulars relating to operating pharmacy

- “(1) A company or person who is granted a licence to operate a pharmacy must advise the licensing authority as soon as practicable of any change in the details that relate to the application for that licence (including, without limitation, changes in the details of any additional information required by the licensing authority).
- “(2) A company that is granted a licence to operate a pharmacy under section 55D(2)(a) of the Act must immediately advise the licensing authority if there is a change or are changes in the ownership of the share capital of the company that means

that more than 50% of the share capital is no longer owned by a pharmacist or pharmacists.

- “(3) The requirement imposed by subclause (2) is in addition to the requirement imposed by subclause (1).”

## **7 Surrender of licence**

- (1) Regulation 49 of the principal regulations is amended by revoking subclause (1), and substituting the following subclauses:

“(1) Subclause (1A) applies if a licensee ceases to—

“(a) manufacture, hawk, sell, or pack any medicine; or

“(b) operate a pharmacy.

“(1A) If this subclause applies, the licensee must, within 7 days of ceasing to undertake the activity to which the licence relates, surrender that licence to the licensing authority.”

- (2) Regulation 49(2) of the principal regulations is amended by omitting the expression “subclause (1)”, and substituting the expression “subclause (1A)”.
- (3) Regulation 49(3) of the principal regulations is amended by omitting the expression “subclause (1)”, and substituting the expression “subclause (1A)”.

## **8 Fees**

Regulation 61(1) of the principal regulations is amended by adding the following paragraph:

“(g) licence to operate a pharmacy \$950”.

## **9 Schedule 2 amended**

- (1) Form 1 of Schedule 2 of the principal regulations is amended—

(a) by revoking the heading, and substituting the heading “Application for licence to manufacture, hawk, sell, or pack medicine”; and

(b) by inserting in Part 1, below the words “Name of applicant”, the words “I am a New Zealand resident **Yes/No**”; and

(c) by inserting in Part 2, below the words “Name of body corporate:”, the words “The body corporate is incorporated in New Zealand **Yes/No**”.

- (2) Form 2 of Schedule 2 of the principal regulations is amended—
- (a) by omitting the words “*Further conditions imposed by the Director-General*”, and substituting the words “*Further conditions imposed by the licensing authority*”; and
  - (b) by omitting from the signature block the words “Director-General of Health”, and substituting the words “Licensing authority”.
- (3) Forms 3 to 6 of Schedule 2 of the principal regulations are amended—
- (a) by omitting the words “*Further conditions imposed by the Medical Officer of Health*”, and substituting the words “*Further conditions imposed by the licensing authority*”; and
  - (b) by omitting from the signature block the words “Medical Officer of Health”, and substituting the words “Licensing authority”.

#### **10 New forms 1A and 1B inserted in Schedule 2**

Schedule 2 of the principal regulations is amended by inserting, after form 1, the forms set out in Schedule 1 of these regulations.

#### **11 New form 7 added to Schedule 2**

Schedule 2 of the principal regulations is amended by inserting, after form 6, the form set out in Schedule 2 of these regulations.

#### **12 Transitional provision**

Nothing in these regulations requires a person who has been issued a licence to manufacture, hawk, sell, or pack medicine before 18 September 2004 (being the date on which these regulations come into force) to reapply for a licence to carry out that activity before his or her existing licence expires.

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r 10

## Schedule 1

### New forms 1A and 1B inserted in Schedule 2 of principal regulations

r 45A(1)(a)(i)

#### Form 1A

Application for licence to operate pharmacy made (by employee or agent) on behalf of company

#### Important information

Before filling out this application please note the following important information:

- this form may be used by an employee or agent who is making an application on behalf of a company:
- you must make yourself familiar with the provisions of the Medicines Act 1981 and the Medicines Regulations 1984, in particular those provisions relating to licensing and operating pharmacies:
- the following **must** accompany this application:
  - the prescribed fee:
  - a completed statutory declaration:
- it is an offence to make a false statutory declaration:
- the licensing authority may require you to supply additional information at a later date (*see* section 55B of the Medicines Act 1981). If you do not supply that information within 30 days of the request, this application will lapse.

Please complete the following:

#### **Applicant and company**

I, [full name of employee or agent of company], [specify position in company], make this application for a licence to operate a pharmacy on behalf of [name of company], which—

- (a) was incorporated in New Zealand on [specify date of incorporation]; and
- (b) has the following board members:  
[specify the full names of all board members].

The address of the company is [specify address].

The following persons are nominated to be responsible persons for the purposes of the licence under the Medicines Act 1981:

[specify full names, dates of birth, and positions held].



Form 1A—*continued***Street address and description of pharmacy**

The street address of the pharmacy to which this application relates is [*specify street address*].

The pharmacy will comprise the following part or parts of that street address: [*specify the part or parts of the street address that are to be a pharmacy or attach a line drawing showing the part or parts*].

**Interests held in pharmacy**

(Note: *Before filling out this part of the form please read section 5A of the Medicines Act 1981, which sets out the meaning of **holding an interest in a pharmacy**.*)

The following person(s) or company (*or companies*) hold an interest in the pharmacy (as defined in section 5A of the Medicines Act 1981) to which this application relates: [*specify name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or specify “none” if applicable)*].

The following person(s) who hold an interest in the pharmacy to which this application relates is a (*or are*) practitioner(s) (*or registered midwife (midwives)*) (*or designated prescriber(s)*): [*specify the name of the interest holder(s) and his or her relevant position (or specify “none” if applicable)*].

**Eligibility to hold licence**

\*The share capital of the company is more than 50% owned by [*specify full name of pharmacist*] who is a pharmacist† (*or [specify full names of pharmacists] who are pharmacists*) and effective control of the company is vested in the above-named pharmacist (*or pharmacists*).

†In this context, a **pharmacist**—

- (a) 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; and
- (b) 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—
  - (i) 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; or
  - (ii) subject to any conditions that the licensing authority proposes, the extended period or periods permitted by the licensing authority.

Form 1A—*continued*

*or*

\*The pharmacy to which this application relates is in a hospital owned or operated by the company. [*Specify details.*]

*or*

\*[*Specify other ground in section 55D(2) of the Medicines Act 1981 that makes the company eligible to hold a licence.*]

\*Delete if inapplicable.

**Practices and procedures for pharmacists working in pharmacy**

The following practices and procedures will be in place to ensure that any pharmacist\* who is employed or engaged in duties in the pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice: [*specify relevant practices and procedures*].

\*In this context, a **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.

**Other pharmacies**

The company operates the following pharmacy (*or* pharmacies): [*specify name(s) and address(es) of pharmacy (or pharmacies) (or specify "none" if applicable)*].

[*Specify number, or specify "none" if applicable*] of those pharmacies are (*or* is) currently for sale.

**\*Mortgagee in possession**

The company is a mortgagee in possession† of the pharmacy to which this application relates.

\*Delete if inapplicable.

†For the purposes of this application a **mortgagee in possession** has the same meaning as in section 2 of the Property Law Act 1952.

.....  
Signature of applicant

Form 1A—*continued*

**Declaration**

I, [*full name of agent or employee of the company*], of [*place*], [*occupation*], solemnly and sincerely declare that the statements made in the above application are true and correct.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Declared at            this            day of            20            , before me:

.....  
Justice of the Peace (*or* other  
person authorised to take a  
statutory declaration)

r 45A(1)(a)(ii)

## Form 1B

Application for licence to operate pharmacy made by person who is individual (*or* employee or agent of body corporate that is not company)

**Important information**

Before filling out this application please note the following important information:

- this form may be used by—
  - an individual who is applying for a licence to operate a pharmacy; or
  - an employee or agent of a body corporate (other than a company) who is applying for a licence to operate a pharmacy on behalf of that body corporate (for example, an application made on behalf of a partnership or friendly society):
- you must make yourself familiar with the provisions of the Medicines Act 1981 and the Medicines Regulations 1984, in particular those provisions relating to licensing and operating pharmacies:
- the following **must** accompany this application:
  - the prescribed fee:
  - a completed statutory declaration:
- it is an offence to make a false statutory declaration:
- the licensing authority may require you to supply additional information at a later date (*see* section 55B of the Medicines Act 1981). If you do not supply that information within 30 days of the request, this application will lapse.

Please complete the following:

**Applicant (*and* body corporate)**

I, [full name], of [address], being a resident of New Zealand, apply for a licence to operate a pharmacy on—

\*my own behalf.

\*on behalf of the body corporate called [name of body corporate], which—

(a) is not a company, but is a [specify the type of body corporate];  
and

Form 1B—*continued*

- (b) was incorporated in New Zealand on [*specify date*]; and  
(c) has the following board members (*or trustees*) (*or partners*):  
[*specify full names of board members (or trustees) (or partners)*].

\*Delete if inapplicable.

My address (*or The address of the body corporate*) is [*specify address*].

\*I was born on [*date*].

*or*

\*I hold the office of [*specify office held*] within the above-named body corporate. The following persons are nominated to be responsible persons under the Medicines Act 1981:

[*specify full names, dates of birth, and positions held*].

\*Delete if inapplicable.

**Street address and description of pharmacy**

The street address of the pharmacy to which this application relates is [*specify street address*].

The pharmacy will comprise the following part or parts of that street address: [*specify the part or parts of the street address that are to be a pharmacy or attach a line drawing showing the part or parts*].

**Interests held in pharmacy**

(Note: *Before filling out this part of the form please read section 5A of the Medicines Act 1981, which sets out the meaning of **holding an interest in a pharmacy**.*)

The following person(s) or company (*or companies*) hold an interest in the pharmacy (as defined in section 5A of the Medicines Act 1981) to which this application relates: [*specify name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or specify "none" if applicable)*].

The following person(s) who hold an interest in the pharmacy to which this application relates is a (*or are*) practitioner(s) (*or registered midwife (midwives)*) (*or designated prescriber(s)*): [*specify the name of the interest holder(s) and his or her relevant position (or specify "none" if applicable)*].

Form 1B—*continued***Eligibility to hold licence**

\*I am (*or* [*Name of person in body corporate who has the majority interest*]) is a pharmacist for the purposes of this application because I am (*or* he or she is) 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.

*or*

\*I am (*or* The body corporate is) a pharmacist because [*specify part of the definition of **pharmacist** in section 55E(3) of the Medicines Act 1981*] applies.

*or*

\*The pharmacy I am (*or* the body corporate is) applying to operate is in a hospital owned or operated by me (*or* the body corporate). [*Specify details.*]

*or*

\*I am (*or* The body corporate is) eligible to operate a pharmacy because [*specify other ground in section 55E(1) of the Medicines Act 1981 that makes person or body corporate eligible to hold a licence*].

\*Delete if inapplicable.

**Practices and procedure for pharmacists working in pharmacy**

The following practices and procedures will be in place to ensure that any pharmacist\* who is employed or engaged in duties in the pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice: [*specify practices and procedures*].

\*In this context, a **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.

**Other pharmacies**

I operate (*or* have a majority interest in) (*or* The body corporate operates) the following pharmacy (*or* pharmacies): [*specify the*

Form 1B—*continued*

*name(s) and address(es) of the pharmacy (or pharmacies) (or specify “none” if applicable).*]

[Specify number, or specify “none” if applicable] of those pharmacies are (or is) currently for sale.

**\*Mortgagee in possession**

I am (or The body corporate is) the mortgagee in possession† of the pharmacy to which this application relates.

\*Delete if inapplicable.

†For the purposes of this application a **mortgagee in possession** has the same meaning as in section 2 of the Property Law Act 1952.

.....  
Signature of applicant

**Declaration**

I [*full name of applicant*], of [*place*], [*occupation*], solemnly and sincerely declare that the statements made in the above application are true and correct.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Declared at                    this                    day of                    20                    , before me:

.....  
Justice of the Peace (or other person authorised to take a statutory declaration)



r 11

**Schedule 2**  
**New form 7 added to Schedule 2 of**  
**principal regulations**

r 46(1)(f)

**Form 7**  
**Licence to operate pharmacy**  
*Section 51, Medicines Act 1981*

Licence No:.....

This licence to operate a pharmacy is granted to *[full name of person or body corporate]* of *[address]* and authorises—

- the establishment of a pharmacy at *[location]* (or in the following part or parts of *[location]*: *[specify relevant part or parts]*); and
- the carrying on of pharmacy practice in that pharmacy.

\*Names of responsible persons for body corporate:

.....

.....

.....

.....

.....

\*Delete if inapplicable.

The pharmacy must be operated in accordance with the duties and obligations in the Medicines Act 1981.

This licence is subject to the following conditions:

- (a) the holder of this licence must not request or require any pharmacist who is employed or engaged in duties at the above-named pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice:
- (b) *[specify any other conditions]*.

This licence expires on *[specify date]*.

.....  
Licensing authority



Martin Bell,  
Acting for Clerk of the Executive Council.

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### 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 18 September 2004, make amendments to the Medicines Regulations 1984 (“the principal regulations”). All of the amendments, except the insertion of *new Part 7B*, are consequential on amendments made to the Medicines Act 1981 by the Medicines Amendment Act 2003.

The Medicines Amendment Act 2003 (which also comes into force on 18 September 2004) provides for a new licensing regime for operating pharmacies. The majority of amendments made to the principal regulations by these regulations relate to that new regime and include—

- an application form for a licence to operate a pharmacy (*new regulation 45A*);
- the fee for making an application for a licence to operate a pharmacy (*new regulation 61(1)(g)*);
- the form of a licence to operate a pharmacy (*new form 7 added to Schedule 2*).

*New regulation 45* recasts the existing regulation 45 of the principal regulations in light of *new regulation 45A*, which provides specifically for an application for a licence to operate a pharmacy. Regulation 45 could no longer refer broadly to applications for licences under the Medicines Act 1981, rather it must only refer to applications for licences to manufacture, hawk, sell, or pack medicines. *Regulation 12* of these regulations clarifies that if a person holds a licence to manufacture, hawk, sell, or pack medicine before the commencement of these regulations, he or she need not reapply for a licence before that existing licence expires.

*New Part 7B* (inserted into the principal regulations by *regulation 3*), provides that a person may, in the course of business carried on by that person, supply a restricted medicine or a pharmacy-only

medicine if he or she is authorised to supply that medicine in accordance with a standing order and supplies the medicine in accordance with that standing order. *New regulation 44D—*

- reflects 1 of the amendments made to the definition of **standing order** in section 2(1) of Medicines Act 1981 by section 3 of the Medicines Amendment Act (No 3) 2003. That amendment inserted a new paragraph (c) into the definition of standing order which enabled standing orders to be issued in relation to restricted medicine and pharmacy-only medicine. Previously, standing orders were only able to be issued in relation to prescription medicine; and
- supplements (as *new regulation 44D(2)* provides) the circumstances set out in section 18(1)(b) and (c) of the Medicines Act 1981 in which a person may supply a restricted medicine or pharmacy-only medicine; and
- mirrors section 18(1)(a)(ii) of the Medicines Act 1981, which provides that a prescription medicine may be supplied in accordance with a standing order.

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Issued under the authority of the Acts and Regulations Publication Act 1989.  
Date of notification in *Gazette*: 9 September 2004.  
These regulations are administered in the Ministry of Health.

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