

Reprint  
as at 11 November 2020



## Medicines Regulations 1984 (SR 1984/143)

David Beattie, Governor-General

### Order in Council

At the Government House at Wellington this 5th day of June 1984

Present:

His Excellency the Governor-General in Council

Pursuant to section 105 of the Medicines Act 1981, and, in the case of Part 3 of the regulations, to section 62 of that Act, His 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, hereby makes the following regulations.

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#### Note

Changes authorised by subpart 2 of Part 2 of the Legislation Act 2012 have been made in this official reprint.  
Note 4 at the end of this reprint provides a list of the amendments incorporated.

**These regulations are administered by the Ministry of Health.**

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## Regulations

### 1 Title and commencement

- (1) These regulations may be cited as the Medicines Regulations 1984.
- (2) These regulations shall come into force on 1 August 1984.

### 2 Interpretation

- (1) In these regulations, unless the context otherwise requires,—

**Act** means the Medicines Act 1981

**appropriate designation**, in relation to a medicine, or an ingredient of a medicine, or a related product, or an active ingredient of a related product, has the following meaning in each of the cases specified:

- (a) where the medicine, related product, or ingredient is named or described in a monograph contained in the current edition of a specified publication, the term means the name or one of the synonyms used in that specified publication for that medicine, related product, or ingredient:
- (b) where the medicine, related product, or ingredient—
  - (i) is not named or described in a monograph contained in the current edition of any specified publication but was named or described in a monograph contained in an earlier edition; and
  - (ii) is not sold under any name or description except the name or one of the synonyms used in that earlier edition for that medicine, related product, or ingredient,—

the term means the name or one of the synonyms so used in that earlier edition followed immediately by a reference to that earlier edition:

- (c) where neither paragraph (a) nor paragraph (b) applies, the term means—

- (i) the international non-proprietary name of the medicine, related product, or ingredient; or
- (ii) if it has no international non-proprietary name, the name appearing in a list published in the United Kingdom on the recommendation of the Medicines Commission pursuant to section 100 of the Medicines Act 1968 (UK); or
- (iii) if the medicine, related product, or ingredient has neither an international non-proprietary name nor a name appearing in a list referred to in subparagraph (ii), its accepted scientific name or some other name descriptive of the true nature of the medicine, related product, or ingredient

**appropriate quantitative particulars**, in relation to any active ingredients of a medicine or of a related product,—

- (a) where the medicine or related product consists of or comprises tablets, capsules, or other separate portions, means the quantity (expressed by weight or volume) of each of the ingredients contained in each portion; or
- (b) in any other case, means the percentage of each of those ingredients contained in the medicine or related product, or the quantity of each of those ingredients contained in a stated quantity of the medicine or related product

**approved immunisation programme** means a vaccination programme—

- (a) pursuant to the National Immunisation Schedule administered by Pharmac; or
- (b) approved by the Director-General or a Medical Officer of Health

**biochemical preparation** includes—

- (a) an antigen; and
- (b) an antitoxin; and
- (c) a toxin; and
- (d) a blood fractionation preparation; and
- (e) an insulin; and
- (f) a preparation from a mammalian gland; and
- (g) a serum; and
- (h) a vaccine; and
- (i) any other substance or preparation that is similar in nature to any of those specified in paragraphs (a) to (h),—

whether natural or synthetic, that is intended for diagnostic, prophylactic, or therapeutic purposes

**consent to distribute**, in relation to any medicine or related product, means a consent to the distribution of that medicine or related product given by the Minister under section 20 of the Act; and includes a provisional consent given under section 23 of the Act

**controlled drug** has the same meaning as in the Misuse of Drugs Act 1975

**described**, in relation to any medicine, related product, or medical device, means represented or held out (whether in writing or otherwise) by the manufacturer, seller, or supplier of the medicine, related product, or medical device

**dispensary technician** means a person who holds a certificate issued by the Pharmaceutical Society of New Zealand before 18 September 2004 that—

- (a) classifies the holder as a dispensary assistant; or
- (b) records that the person has completed the requirements of the Pharmacy Technicians Certificate

**for external use**, in relation to any medicine or related product, means for application to the anal canal, ear, eye, mucosa of the mouth, nose, skin, teeth, throat, or vagina, where local action only is required and where extensive systemic absorption will not occur; but nothing in these regulations relating to medicines or related products intended for external use shall apply to nasal drops, nasal inhalations, nasal sprays, teething applications, throat lozenges, throat pastilles, throat sprays, or throat tablets

**general sale medicine** has the meaning given to it by section 99(2) of the Act

**Pharmac** means the Pharmaceutical Management Agency established by section 46 of the New Zealand Public Health and Disability Act 2000

**Pharmacy Council** means the Pharmacy Council established by section 114(5) of the Health Practitioners Competence Assurance Act 2003

**pharmacy graduate** means a person who is not a pharmacist, but who—

- (a) has 1 or more of the qualifications prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003 for registration as a pharmacist; and
- (b) is actively taking steps towards registration as a pharmacist

**pharmacy student** means a person who is undertaking, but has not yet completed, the course and examinations leading to a qualification of a kind prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003

**pharmacy technician** means any person who has a National Certificate in Pharmacy (Technician)

**pharmacy technician student** means a person who is undertaking, but who has not yet completed, training and examinations leading to a National Certificate in Pharmacy (Technician)

**poison bottle** means a container that is made of glass, plastic, or other like material, and that either—

- (a) has embossed on at least one-third of its outer surface narrow flutings, ribs, nettings, or points, or other similar surface impressions readily recognisable by touch; or
- (b) has clearly embossed on 2 opposite sides of the shoulder of the container the word “POISON” in capital letters, the height of the letters being not less than half the width of that shoulder

**principal display panel** means the part of a label that is most likely to be displayed, presented, shown, or examined under ordinary or customary conditions of display; and, if such likelihood is equal in respect of 2 or more panels, means every such panel

**printed** includes written, typewritten, engraved, lithographed, or otherwise traced or copied

**registered midwife** means a health practitioner who is, or is deemed to be, registered with the Midwifery Council established by section 114(3) of the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of midwifery

**safety container** means a container, whether or not part of a strip of containers, that—

- (a) encloses a single tablet or other single item of a medicine that is a solid or a class of medicines that are solids (including a medicine or class of medicines in powder form); and
- (b) is made of aluminium foil or laminated plastic, or such other material as may be approved by the Director-General in relation to the packaging of any solid medicine to which regulation 37 applies, either by notice in the *Gazette* or in writing addressed to a particular manufacturer, packer, importer, or seller of medicines; and
- (c) is reasonably resistant to attempts by young children to open it

**specified publication** means a publication named in section 108(1) of the Act

**student** means a pharmacy student or a pharmacy technician student.

- (2) In these regulations, unless the context otherwise requires, all references to proportions in a medicine (whether as percentages, parts per million, or otherwise) shall be references to—
  - (a) proportions by weight, where the medicine is a solid; or
  - (b) proportions by volume, where the medicine is a liquid at ambient temperatures.

Regulation 2(1) **approved immunisation programme**: inserted, on 17 April 1992, by regulation 2 of the Medicines Regulations 1984, Amendment No 5 (SR 1992/43).

Regulation 2(1) **approved immunisation programme** paragraph (a): amended, on 29 November 2012, by regulation 4(1) of the Medicines Amendment Regulations 2012 (SR 2012/329).



Regulation 2(1) **approved school**: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **colouring substance**: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **designated prescriber nurse**: revoked, on 1 October 2005, by regulation 3 of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 2(1) **Dispensary Assistant's Certificate**: revoked, on 1 August 2011, by regulation 4(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **dispensary technician**: substituted, on 1 August 2011, by regulation 4(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **general sale medicine**: inserted, on 1 August 2011, by regulation 4(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **Pharmac**: inserted, on 29 November 2012, by regulation 4(2) of the Medicines Amendment Regulations 2012 (SR 2012/329).

Regulation 2(1) **Pharmacy Council**: inserted, on 1 August 2011, by regulation 4(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **pharmacy graduate**: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **pharmacy student**: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **pharmacy technician**: substituted, on 1 August 2011, by regulation 4(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 2(1) **pharmacy technician student**: inserted, on 19 December 2002, by regulation 3(3) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

Regulation 2(1) **registered midwife**: substituted, on 18 September 2004, by section 175(3) of the Health Practitioners Competence Assurance Act 2003 (2003 No 48).

Regulation 2(1) **safety container** paragraph (b): amended, on 1 January 1995, by regulation 2 of the Medicines Regulations 1984, Amendment No 6 (SR 1994/299).

Regulation 2(1) **student**: added, on 19 December 2002, by regulation 3(4) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

## Part 1

### Classification of medicines

#### 3 Classification of medicines

- (1) All medicines and classes of medicines specified in Part 1 of Schedule 1 are hereby declared to be prescription medicines.
  - (1A) *[Revoked]*
  - (1B) *[Revoked]*
- (2) All medicines and classes of medicines specified in Part 2 of Schedule 1 are hereby declared to be restricted medicines.
- (3) Subject to subclause (4), all medicines and classes of medicines specified in Part 3 of Schedule 1 are hereby declared to be pharmacy-only medicines.
- (4) Nothing in subclause (3) shall apply to a remedy that is, and is described as, homoeopathic.

Regulation 3(1A): revoked, on 1 November 2005, by regulation 12(2)(a) of the Medicines (Designated Prescriber: Nurse Practitioners) Regulations 2005 (SR 2005/266).

Regulation 3(1B): revoked, on 1 November 2005, by regulation 12(2)(a) of the Medicines (Designated Prescriber: Nurse Practitioners) Regulations 2005 (SR 2005/266).

## **Part 2**

### **Standards**

#### **4 Standards for medicines, related products, medical devices, cosmetics, and surgical dressings**

- (1) Any medicine or related product, other than a medicine or related product for which a standard is otherwise prescribed in these regulations, shall, where it is described as conforming to a monograph in a specified publication, conform to the description and tests set out in that publication for that medicine or related product.
- (2) Every medicine, related product, or cosmetic used or represented as suitable for application into the eye shall conform to the tests for sterility set out in a specified publication.
- (3) Every medicine, related product, or cosmetic that is a dusting powder for use on the skin of a baby, or on any inflamed, abraded, or broken skin, shall be free of pathogenic organisms.
- (4) No medicine, related product, cosmetic, or dentifrice intended for sale shall contain or have attached to it or enclosed with it any extraneous thing that is harmful, dangerous, or offensive.
- (5) A surgical dressing that is described as conforming to a monograph in a specified publication shall conform to the description and tests set out in that publication for that surgical dressing.
- (6) A medical device that is described as conforming to a particular description shall conform to that description.

#### **4A Standard for CBD products**

- (1) The minimum quality standard imposed by Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 applies to a CBD product as if it were both a cannabis-based ingredient and a medicinal cannabis product under those regulations.
- (2) However, the minimum quality standard does not apply to a CBD product that is imported by—
  - (a) a medical practitioner whose purpose is to prescribe, supply, or administer it for the treatment of a particular patient under their care; or
  - (b) a pharmacist for a prescription to which paragraph (a) applies.

- (3) Subclause (4) applies to a CBD product of a type that, at the commencement of this regulation, has been imported into New Zealand by the holder of a licence issued under the Medicines Act 1981.
- (4) The minimum quality standard does not apply to any of that product of the licence holder until 1 April 2021.
- (5) In this regulation, **CBD product** has the meaning given by section 2A of the Misuse of Drugs Act 1975.

Regulation 4A: inserted, on 1 April 2020, by regulation 84 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (LI 2019/321).

Regulation 4A(4): amended, on 30 September 2020, by regulation 4 of the Medicines Amendment Regulations 2020 (LI 2020/262).

## 5 **Pharmacist may dilute medicine in particular case**

Where any liquid medicine in respect of which a standard is prescribed by any of the provisions of these regulations is to be supplied by a pharmacist pursuant to a prescription issued for a particular patient, the pharmacist may add a compatible diluent to the medicine if he is satisfied that—

- (a) such dilution is necessary to adjust the dose to a quantity easily measurable by the patient or by any other person on behalf of the patient; and
- (b) the addition of that diluent will not affect injuriously the composition of the medicine.

## 6 **Colouring substances**

*[Revoked]*

Regulation 6: revoked, on 1 August 2011, by regulation 5 of the Medicines Amendment Regulations 2011 (SR 2011/245).

# Part 3

## Advertisements

### 7 **Advertisements not to claim official approval**

No advertisement relating to any medicine, related product, or medical device shall contain a statement to the effect that an advisory or technical committee established under section 8 of the Act, or any member of such a committee, or any officer in the service of the Government, has approved, or has refrained from disapproving, the advertisement or any of the claims or statements made in it.

### 8 **Advertisements for medicines**

- (1) Every advertisement for a prescription medicine must include—
  - (a) the words “Prescription medicine” or words of a similar meaning; and
  - (b) the name of each active ingredient; and

- (c) the appropriate quantitative particulars of each active ingredient; and
  - (d) a statement of the purpose for which the medicine is intended to be used; and
  - (e) a statement that the medicine has risks and benefits; and
  - (f) a statement about how to find further information on the risks and benefits of the medicine.
- (2) Every advertisement for a restricted medicine must include—
- (a) the following statements, or statements with a similar meaning:
    - (i) “Available only from your pharmacist.”; and
    - (ii) “If symptoms persist, see your doctor or health professional.”; and
    - (iii) “Use only as directed.”; and
  - (b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:  
“Always read the label.”; and
  - (c) a statement of the purpose for which the medicine is intended to be used; and
  - (d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.
- (3) Every advertisement for a pharmacy-only medicine or a general sale medicine must include—
- (a) the following statements, or statements with a similar meaning:
    - (i) “If symptoms persist, see your doctor or health professional.”; and
    - (ii) “Use only as directed.”; and
  - (b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:  
“Always read the label.”; and
  - (c) a statement of the purpose for which the medicine is intended to be used; and
  - (d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.
- (4) Every advertisement for a medicine to be supplied by mail order, direct marketing, or via the Internet must—
- (a) include the name of each active ingredient; and
  - (b) include the appropriate quantitative particulars of each active ingredient; and
  - (c) comply with the following, to the extent they are applicable:
    - (i) subclause (1)(a), and (d) to (f):

- (ii) subclause (2)(a), (c), and (d):
  - (iii) subclause (3)(a), (c), and (d).
- (5) A statement required by this regulation must be—
- (a) clearly printed; or
  - (b) clearly spoken.
- (6) A statement that is required by this regulation may be both clearly printed and clearly spoken.
- (7) This regulation does not apply to—
- (a) an advertisement for a medicine that does not refer to a therapeutic purpose:
  - (b) an advertisement (not being an advertisement of the kind described in subclause (4)) that is—
    - (i) located at the point of sale; and
    - (ii) positioned immediately above, below, or next to the medicine to which it relates:
  - (c) labels:
  - (d) price lists.
- (8) An advertisement for a prescription, restricted, pharmacy-only, or general sale medicine that is subsequently reclassified must be treated as compliant with this regulation if—
- (a) the advertisement was compliant with every applicable requirement in this regulation immediately before the medicine was reclassified; and
  - (b) not more than 3 months have elapsed since the medicine was reclassified.
- (9) In any proceedings for an offence against section 57 of the Act, it is for the defendant to prove that subclause (8) applies.

Regulation 8: substituted, on 1 August 2011, by regulation 6 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **9 Advertisements for related products**

- (1) Every advertisement for a related product, other than a label or a price list, shall include a statement of the uses of the related product.
- (2) Every advertisement that refers to an active ingredient of a related product by name shall state the appropriate designation of the ingredient.

## **10 Advertisements for medical devices**

Every advertisement for a medical device, other than a label or a price list, shall include, where appropriate, the following:

- (a) an accurate description of the medical device:

- (b) a statement of the uses of the medical device:
- (c) a statement of the appropriate precautions to be taken in the use of the medical device:
- (d) a statement of any contraindications to the use of the medical device.

## **11 Advertisements intended for health professions**

- (1) This regulation applies—
  - (a) to advertisements intended for members of the medical, dental, pharmaceutical, and related professions; and
  - (b) in addition to the requirements in regulations 7, 9, and 10 (but not regulation 8).
- (2) Every advertisement for a medicine must—
  - (a) include—
    - (i) the classification of the medicine; and
    - (ii) the name of each active ingredient; and
    - (iii) the appropriate quantitative particulars of each active ingredient; and
    - (iv) a statement of the purpose for which the medicine is intended to be used; and
    - (v) a statement of the appropriate precautions to be taken in the use of the medicine; and
    - (vi) information on the effectiveness and limitations of the medicine; and
    - (vii) a statement of any restriction imposed on distribution; and
    - (viii) the dosage regime and mode of administration, or method of use, of the medicine; and
    - (ix) a statement of any contraindications to the use of the medicine; and
    - (x) information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences; and
    - (xi) a statement of the known or likely poisonous effects of, or adverse reactions to, the medicine; but
  - (b) not include—
    - (i) a statement (based on the citation of a report) relating to the effectiveness or safety of the medicine that omits relevant parts of the report, or quotes from the report in such a way that another meaning to that intended by the report is conveyed; or
    - (ii) an unsubstantiated comparison with other medicines; or

- (iii) data, previously considered valid, but made obsolete or false by subsequent findings; or
  - (iv) a statement of the use of the medicine, or the dosage of the medicine, that contravenes any condition of a consent given under section 20, 23, or 24 of the Act.
- (3) Nothing in subclause (2)(a)(iii) or (vi) to (xi) applies to an advertisement that—
  - (a) is intended to provide a practitioner with details of—
    - (i) a major therapeutic indication of a medicine; or
    - (ii) the listing of a medicine in the pharmaceutical schedule (within the meaning of section 6(1) of the New Zealand Public Health and Disability Act 2000); or
    - (iii) a new or changed strength of a medicine; and
  - (b) does not enable the practitioner to reach a prescribing decision.
- (4) Every advertisement for a related product or medical device must include—
  - (a) a statement of any restriction imposed on distribution; and
  - (b) the dosage regime and mode of administration, or method of use, of the related product or medical device; and
  - (c) information on the effectiveness and limitations of the related product or medical device.

Regulation 11: substituted, on 1 August 2011, by regulation 7 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **Part 4**

### **Labelling**

#### **12 Medicines, related products, and medical devices not to be sold unless properly labelled**

- (1) No person shall sell any medicine or related product in a container if the container—
  - (a) does not bear a label containing all the particulars required by these regulations to be on a label relating to such a container; or
  - (b) bears a label containing anything that is prohibited by these regulations from appearing on a label relating to such a container; or
  - (c) bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to such a container.
- (2) No person shall sell a package containing a single container of any medicine or related product unless that package is labelled in a manner similar to that in which the container is labelled.

- (3) No person shall sell any medicine in a poison bottle bearing any label that obscures any flutings, ribs, nettings, points, embossed words, or similar markings on the bottle.
- (4) No person shall sell any medical device that does not bear the name of the manufacturer of the medical device or the name of the manufacturer's distributor in New Zealand.
- (5) Notwithstanding anything in the foregoing provisions of this regulation, the Director-General may, by notice in writing to the manufacturer or importer of any medicine, exempt from the labelling requirements of these regulations the sale of that medicine in a container of a specified type.

### **13 Labelling of medicines**

- (1) Every container of a medicine must, unless otherwise provided by these regulations, bear a label containing the following information:
  - (a) the trade name of the medicine or, if there is no trade name, the appropriate designation of the medicine:
  - (b) the name of each active ingredient:
  - (c) the appropriate quantitative particulars of each active ingredient:
  - (d) a description of the medicine, including dose form, or presentation, that indicates the true nature of the medicine:
  - (e) a statement of the net weight or volume or number of the contents of the container, as the case may require:
  - (f) in the case of a prescription medicine,—
    - (i) the words "PRESCRIPTION MEDICINE" or words of a similar meaning; or
    - (ii) the words "PRESCRIPTION-ONLY MEDICINE" or words of a similar meaning; or
    - (iii) the acronym "POM":
  - (g) in the case of a restricted medicine,—
    - (i) the words "RESTRICTED MEDICINE"; or
    - (ii) the words "PHARMACIST-ONLY MEDICINE":
  - (h) in the case of a pharmacy-only medicine,—
    - (i) the words "PHARMACY-ONLY MEDICINE" or words of a similar meaning; or
    - (ii) the words "PHARMACY MEDICINE" or words of a similar meaning:
  - (i) any warning statement required by these regulations for the medicine:
  - (j) in the case of a medicine other than a prescription medicine, a statement of the purpose for which the medicine is intended to be used:



- (k) in the case of a medicine sold, or intended for sale, for external use,—
    - (i) a statement of directions for use and frequency of use; and
    - (ii) the words “Caution: not to be taken”, or “For external use only”, or words of a similar meaning:
  - (l) in the case of a medicine sold, or intended for sale, for internal use,—
    - (i) the dose recommended; and
    - (ii) the frequency of that dose:
  - (m) the words “Batch Number” or “Lot Number”, or the word “Batch” or “Lot”, or the letter “B” (either alone or inside a circle) followed by the batch or lot number of the medicine:
  - (n) the words “Use by” or “Use before”, or words of a similar meaning, followed by the expiry date (being in no case later than 5 years after the date of manufacture of the medicine) appropriate to the stability of the medicine:
  - (o) where appropriate, a statement of the recommended storage conditions:
  - (p) the name and address of—
    - (i) the manufacturer or seller of the medicine; or
    - (ii) the owner of the rights of manufacture; or
    - (iii) the agent of any person who comes within subparagraph (i) or (ii).
- (2) For the purposes of subclause (1)(p),—
- (a) an address at a post office is not sufficient:
  - (b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the medicine is wholly manufactured and packed outside New Zealand:
  - (c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.
- (3) In the case of a medicine intended for administration only in accordance with the directions of a practitioner, it is sufficient compliance with subclause (1)(l) to indicate the dose by a range if the container is accompanied by a more specific statement relating to each usage.
- (4) In the case of a prescription medicine, compliance with the requirements of subclause (1)(k) or (l) is required only at the time at which that medicine—
- (a) is sold by retail; or
  - (b) is supplied in circumstances corresponding to retail sale; or
  - (c) is supplied by way of gift or sample for the purpose of promoting a sale.

- (5) Subclause (1)(l) does not apply in the case of a medicine intended to be administered by or under the supervision of a practitioner, in circumstances where the dosage is to be dependent on concurrent skilled observation.
- (6) Every container of a medicine that is prepared for injection into the human body and that contains an antiseptic or preservative must be labelled with a statement of the nature and amount of the antiseptic or preservative.
- (7) Every container of a medicine that is a biochemical preparation must, in addition to the other requirements in this regulation, bear a label containing the following:
  - (a) a statement of the potency of the preparation; and
  - (b) a statement of the nature and amount of every antiseptic or preservative (if any) used in the medicine.
- (8) Where it is impractical to put all of the information required by this regulation on a label because the container is too small, it is sufficient compliance with this regulation to print the information required by subclause (1)(i), (j), and (o) on a separate information sheet, in the same manner as that information would be required by these regulations to be printed on a label, and to supply that sheet to the customer with the medicine.
- (9) This regulation is subject to regulations 15 and 23.

Regulation 13: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### **14 Labelling of related products**

- (1) Every container of a related product must, unless otherwise provided by these regulations, bear a label containing the following information:
  - (a) the trade name of the related product or, if there is no trade name, the appropriate designation of the related product:
  - (b) the name of each active ingredient:
  - (c) the appropriate quantitative particulars of each active ingredient:
  - (d) a description of the related product that indicates the true nature of the related product:
  - (e) a statement of the net weight or volume or number of the contents of the container, as the case may require:
  - (f) any warning statement required by these regulations for the related product:
  - (g) in the case of a related product sold, or intended for sale, for external use,—
    - (i) a statement of directions for use and frequency of use; and
    - (ii) the words “Caution: not to be taken”, or “For external use only”, or words of a similar meaning:

- (h) in the case of a related product sold, or intended for sale, for internal use,—
    - (i) the dose recommended; and
    - (ii) the frequency of that dose:
  - (i) the words “Batch Number” or “Lot Number”, or the word “Batch” or “Lot”, or the letter “B” (either alone or inside a circle) followed by the batch or lot number of the related product:
  - (j) where appropriate, an expiry date:
  - (k) the name and address of—
    - (i) the manufacturer or seller of the related product; or
    - (ii) the owner of the rights of manufacture; or
    - (iii) the agent of any person who comes within subparagraph (i) or (ii).
- (2) For the purposes of subclause (1)(k),—
- (a) an address at a post office is not sufficient:
  - (b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the related product is wholly manufactured and packed outside New Zealand:
  - (c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.

Regulation 14: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **15 Exemptions from regulations 13 and 14**

- (1) Nothing in regulation 13 (except subclause (1)(a), (b), (c), (m), and (n)) and nothing in regulation 14 (except subclause (1)(a), (b), (c), (i), and (j)) applies to—
- (a) a container that—
    - (i) contains a single dose of a medicine or related product; and
    - (ii) is made of sheet material; and
    - (iii) is not attached to another container; and
    - (iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
    - (v) is not intended for sale other than in that package:
  - (b) a container that—
    - (i) contains a single dose of a medicine or related product; and
    - (ii) is not made of sheet material; and
    - (iii) has a volume of 20 millilitres or less; and

- (iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
    - (v) is not intended for sale other than in that package:
  - (c) a container (other than an aerosol container) that—
    - (i) contains a medicine or related product that is a gas; and
    - (ii) is of a kind commonly used for storing or transporting gases in compressed, liquefied, or dissolved form; and
    - (iii) has a capacity not exceeding 250 litres water capacity:
  - (d) a container of a remedy that is, or is described as, homeopathic.
- (2) Nothing in regulation 13 or 14 applies to a strip of containers that—
  - (a) is made of sheet material; and
  - (b) bears the information required by—
    - (i) regulation 13(1)(m) and (n) or regulation 14(1)(i) and (j) (as the case requires) at least once on the strip; and
    - (ii) regulation 13(1)(a), (b), and (c) or regulation 14(1)(a), (b), and (c) (as the case requires)—
      - (A) at least once in relation to every 2 containers, if the containers are easily detached from the strip; and
      - (B) at least once on the strip in any other case; and
  - (c) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
  - (d) is not intended for sale other than in that package.
- (3) In this regulation, **strip of containers** means a series of containers that each contain a single dose of a medicine or related product and that together form a strip.
- (4) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only medicine, held for sale by a manufacturer or wholesaler, for the period of 3 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the manufacturer or wholesaler.
- (5) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only medicine, held for sale by a retailer, for the period of 6 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the retailer.
- (6) For the purposes of subclauses (4) and (5), any goods purchased before the date on which a substance becomes a prescription medicine, restricted medicine, or

pharmacy-only medicine (as the case may be) for importation into New Zealand are deemed to be part of the purchaser's stock-in-trade in New Zealand.

- (7) In any proceedings for an offence against section 44 of the Act in respect of any container that does not comply with regulation 13(1)(f), (g), or (h), the onus is on the defendant to prove that the relevant paragraph does not apply by virtue of subclause (4) or (5) of this regulation.

Regulation 15: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **16 Principal display panel**

- (1) The principal display panel of the label of a medicine must contain—
- (a) the information required by regulation 13(1)(a), (d), and (e); and
  - (b) the information required by regulation 13(1)(b) and (c), but only if the medicine contains 3 or fewer active ingredients.
- (2) Subclause (1) is subject to regulation 23.
- (3) The principal display panel of the label of a related product must contain—
- (a) the information required by regulation 14(1)(a), (d), and (e); and
  - (b) the information required by regulation 14(1)(b) and (c), but only if the related product contains 3 or fewer active ingredients.
- (4) Nothing in subclause (1) or (3) prevents the inclusion in the principal display panel of any other matters required by these regulations to appear on a label of any medicine or related product.
- (5) Subclause (4) is subject to regulation 19.

Regulation 16: substituted, on 1 August 2011, by regulation 8 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **17 Form and manner of labelling**

- (1) Subject to subclause (4), every label that is required by these regulations to be borne on a container shall—
- (a) be conspicuously written in English and, for each statement separately required, be in a colour or colours contrasting strongly with the statement's background; and
  - (b) be legibly and durably marked either on the material of the container or on material firmly and securely attached to the container; and
  - (c) be of such nature and material that it will not fade to the extent of becoming illegible, or become detached, by the influence of—
    - (i) light; or
    - (ii) atmospheric humidity or dryness; or
    - (iii) normal atmospheric temperatures; or
    - (iv) recommended storage temperatures; or

- (v) the contents of the container; and
  - (d) be of such a nature and in such a position that it will not readily be defaced in the course of normal handling and use; and
  - (e) be in such a position that it is not damaged, defaced, destroyed, or removed when the container is opened; and
  - (f) not be obscured by any other label, folder, or pamphlet.
  - (g) *[Revoked]*
- (2) The lettering of the words required by these regulations shall be clear, distinct, and legible, with no decoration, embellishment, or distortion that could interfere with the legibility of the words.
- (3) Every label that is required by these regulations to appear on a container shall, if the medicine or related product is sold otherwise than in a container, appear on the medicine or related product.
- (4) It shall be sufficient compliance with subclause (1) if the particulars required by paragraphs (d) and (e) of regulation 13(1) are embossed conspicuously on the container of the medicine.

Regulation 17(1)(a): amended, on 30 November 2000, by regulation 7(1) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 17(1)(g): revoked, on 30 November 2000, by regulation 7(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

## **18 Size of letters**

- (1) A minimum size of lettering used on labels that is prescribed by these regulations refers to the height of capital letters, or lower case letters with an ascender or descender, in the typeface used.
- (2) *[Revoked]*
- (3) *[Revoked]*
- (4) *[Revoked]*
- (5) Subject to subclause (6) and except as otherwise expressly permitted by any of the provisions of these regulations, the lettering of words required by these regulations to appear on labels shall be not less than 1.5 millimetres in height.
- (6) Where words are required by these regulations to appear on labels in letters of a specified size, and the container to be labelled is so small as to prevent the use of letters of that size, letters of a smaller size may be used if they are of the largest size practicable in the circumstances and are in any event no smaller than 0.75 millimetres.
- (7) *[Revoked]*

Regulation 18(1): substituted, on 30 November 2000, by regulation 8(1) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 18(2): revoked, on 30 November 2000, by regulation 8(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 18(3): revoked, on 30 November 2000, by regulation 8(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 18(4): revoked, on 30 November 2000, by regulation 8(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 18(7): revoked, on 30 November 2000, by regulation 8(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

## **19 Labelling of prescription medicines, restricted medicines, and pharmacy-only medicines**

Where a label on a container is required by these regulations to bear—

- (a) the words “PRESCRIPTION MEDICINE” or words of a similar meaning; or
- (b) the words “PRESCRIPTION ONLY MEDICINE” or words of a similar meaning; or
- (c) the acronym “POM”; or
- (d) the words “RESTRICTED MEDICINE”; or
- (e) the words “PHARMACIST ONLY MEDICINE”; or
- (f) the words “PHARMACY-ONLY MEDICINE” or words of a similar meaning; or
- (g) the words “PHARMACY MEDICINE” or words of a similar meaning,—

the words or acronym, as the case may require, shall be placed prominently and legibly on the label.

Regulation 19: substituted, on 1 January 1995, by regulation 5 of the Medicines Regulations 1984, Amendment No 6 (SR 1994/299).

Regulation 19: amended, on 1 August 2011, by regulation 9 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **20 Consumer information panel**

*[Revoked]*

Regulation 20: revoked, on 1 August 2011, by regulation 10 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **21 Labels on containers of medicines or related products containing vitamins**

The quantitative declaration of every vitamin in any medicine or related product shall be expressed in milligrams or micrograms.

## **22 Warning statements for medicines and related products**

- (1) Every container of a medicine or related product must include on its label any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.
- (2) A warning statement is additional to any other statement or information that is required by these regulations to be shown on a label.

- (3) Subclause (1) is subject to regulation 23.

Regulation 22: substituted, on 1 August 2011, by regulation 11 of the Medicines Amendment Regulations 2011 (SR 2011/245).

### **23 Labels on containers of medicines sold by authorised prescribers or pharmacists**

It shall not be necessary to comply with the requirements of regulation 13 or regulation 16(1) or regulation 22 in respect of any label on a container of a medicine that is packed, supplied, or sold by an authorised prescriber or a pharmacist with reference to the needs of a particular patient or (as the case may be) a particular customer, if the label contains the following:

- (a) the name of, or a description of the nature of, the contents; and
- (b) the name of the patient; and
- (c) the name and address of the seller; and
- (d) in the case of a medicine for internal use, the dose and frequency of dose; and
- (e) in the case of a medicine for external use, a statement of the directions for use and frequency of use, and one or other of the following statements, or words of similar meaning:  
“Caution: Not To Be Taken”, or “For External Use Only”; and
- (f) a unique identifying number or code for the prescription or record of supply; and
- (g) the date on which the medicine was packed, sold, or supplied.

Regulation 23 heading: substituted, on 11 October 2001, by regulation 7(1) of the Medicines Amendment Regulations 2001 (SR 2001/232).

Regulation 23 heading: amended, on 1 October 2005, by regulation 5(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 23: amended, on 1 August 2011, by regulation 12(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23: amended, on 1 October 2005, by regulation 5(2) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 23(a): substituted, on 1 August 2011, by regulation 12(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(e): amended, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(f): added, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 23(g): added, on 1 August 2011, by regulation 12(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

### **24 Labels on containers of hair dyes**

- (1) This regulation applies to labels on containers of related products and cosmetics that are intended for dyeing hair and consist of or contain—



- (a) phenylenediamine, or its salts; or
  - (b) toluenediamine, or its salts; or
  - (c) other aromatic amines intended for dyeing hair, or their salts; or
  - (d) any derivative of any substance to which paragraph (a) or paragraph (b) or paragraph (c) applies.
- (2) Every label to which this regulation applies shall include the following:
- (a) the name or description of the dye substance:
  - (b) the name and address of the manufacturer or (as the case may be) the packer or seller of the related product or cosmetic:
  - (c) directions for the use of the related product or cosmetic:
  - (d) one or other of the following statements, or words of similar meaning:  
“Not To Be Taken”, or “For External Use Only”:
  - (e) the following statement, or words of similar meaning:  
“May cause serious inflammation of the skin. Do not use on eyelashes”.

## **25 Misleading statements**

- (1) No written, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any medicine or medical device shall include any comment on, reference to, or explanation of any statement or label required by these regulations to be borne on any medicine or medical device if that comment, reference, or explanation either directly or by implication contradicts, qualifies, or modifies that statement or the contents of that label.
- (2) No written, pictorial, or other descriptive matter supplied or displayed with any medicine or medical device shall include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the medicine or medical device or any ingredients of the medicine or components of the medical device.

## **Part 5**

### **Manufacture, packing, storage, and handling**

#### **26 Persons handling medicines, related products, and cosmetics**

- (1) Every person who—
- (a) is engaged or employed in the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale; and
  - (b) in the course of his engagement or employment in that activity comes into direct contact with—
    - (i) any medicine, related product, or cosmetic; or

- (ii) the interior part of any container containing any medicine, related product, or cosmetic; or
  - (iii) a wrapper for any medicine, related product, or cosmetic—
- shall, at all times while so engaged or employed, maintain his clothing and his person in a state of cleanliness.
- (2) No person who is engaged or employed in the sale of any medicine, related product, or cosmetic, or in the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale, shall do any act or make any default or omission whereby that medicine, related product, or cosmetic becomes or is liable to become contaminated, polluted, or tainted.

### **27 Infected persons**

No person who is suffering from a communicable disease (within the meaning of the Health Act 1956), or is a carrier (within the meaning of that Act), or is suffering from a condition causing a discharge of pus or exudate, shall engage or be employed in the sale, or the manufacture, packing, labelling, storage, or supply, for sale, of—

- (a) any medicine, related product, or cosmetic; or
- (b) any material or article used or likely to be used as a wrapper or container for any medicine, related product, or cosmetic.

### **28 Persons in contact with infected persons**

- (1) The Medical Officer of Health may, by notice in writing served on a person who has been in recent contact with any person to whom regulation 27 applies, prohibit the person so served from engaging or being employed in the sale of any medicine, related product, or cosmetic, or the manufacture, packing, labelling, storage, or supply of any medicine, related product, or cosmetic for sale.
- (2) Where, in the opinion of the Medical Officer of Health, there is no longer any risk of any medicine, related product, or cosmetic becoming infected by a person on whom any such notice has been served, the Medical Officer of Health shall revoke the notice, and shall notify the person in writing of the revocation.
- (3) No person shall—
  - (a) engage or undertake employment in any activity in contravention of a notice served on him under this regulation; or
  - (b) knowingly employ any other person in contravention of a notice served on that other person under this regulation.

### **29 Places of manufacture, storage, and sale**

No person shall use any place or permit any place to be used for or in connection with the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, unless the place complies with the following requirements:

- (a) the place shall be kept adequately lighted by daylight or artificial light, as the circumstances require, at all times when any work is being carried out there:
- (b) the place shall be kept appropriately ventilated at all times while any medicine, related product, or cosmetic, or any container or material for the packing of any medicine, related product, or cosmetic, is present there:
- (c) if a waste liquid is produced there, the place shall be provided with a means of drainage that is sufficient for the removal of the waste liquid, and that is kept in good, clean, working order and condition:
- (d) the place shall be kept, so far as is practicable, clean and free from foul odours and free from dust and creatures likely to contaminate the medicine, related product, or cosmetic:
- (e) the walls, floors, ceilings, and roofs shall be properly constructed and kept in good repair, and shall be easy to clean:
- (f) the place shall not be used for any purpose (other than the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale) that might affect the quality of the medicine, related product, or cosmetic:
- (g) the place shall be provided with sinks and other sanitary fittings reasonably necessary for cleansing appliances used there, and all such sinks and other sanitary fittings shall be maintained in good, clean working order and condition:
- (h) the place shall be provided with an adequate supply of hot and cold water, and soap or other detergent:
- (i) the place shall be provided adequately with wash basins and toilets for the use of persons engaged or employed in or about the premises, and all such wash basins and toilets shall be maintained in good, clean working order and condition, and shall be provided with an adequate supply of hot and cold water, soap or other detergent, nail brushes, and towels or other drying equipment.

**30 Dwellinghouses prohibited for manufacture and packing**

No person shall use any dwellinghouse, or permit any dwellinghouse to be used, for or in connection with the manufacture or packing of any medicine, related product, or cosmetic for sale if the use of the dwellinghouse is likely to result in the contamination of the medicine, related product, or cosmetic, or to affect injuriously its cleanliness.

**31 Powers of Medical Officer of Health in respect of premises**

- (1) This regulation shall apply to premises that are, in the opinion of the Medical Officer of Health, by reason of their construction or disrepair, or by reason of

the use or character of any neighbouring premises, in such a condition that any medicine, related product, or cosmetic in the first premises may be exposed to contamination or taint, or may deteriorate or become dirty.

- (2) Subject to subclause (6), the Medical Officer of Health may serve a notice in writing on any owner or occupier of any premises to which this regulation applies, prohibiting the use of the premises for or in connection with the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale.
- (3) Every such notice shall—
  - (a) specify the premises to which it relates:
  - (b) state the reason for the prohibition:
  - (c) specify a date on which the prohibition is to come into force.
- (4) Subject to subclause (6), where in the opinion of the Medical Officer of Health the reason for which any such notice was served has ceased to exist, he shall revoke the notice, and shall notify in writing the owner or occupier of the premises concerned, and every other person on whom a copy of the notice has been served, of the revocation.
- (5) While any such notice remains in force,—
  - (a) no person on whom it has been served shall use or permit the use of the premises specified in the notice for or in connection with the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale; and
  - (b) no person on whom a copy of the notice has been served or who knows the contents of the notice shall use those premises for any such purpose.
- (6) No notice shall be served by a Medical Officer of Health pursuant to subclause (2) or subclause (4) unless approval to serve the notice has first been obtained from the Director-General.

### **32 Storage of medicines, etc**

- (1) Every person in possession or control of any medicine, related product, or cosmetic for sale, or of any container or appliance used for or in connection with the sale of any medicine, related product, or cosmetic, or the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, shall at all times—
  - (a) keep the medicine, related product, cosmetic, container, or appliance clean and free from contamination by moisture, foul odours, or dust; and
  - (b) protect the medicine, related product, cosmetic, container, or appliance from access by creatures likely to contaminate it.
- (2) Every person in possession of any medicine, related product, or cosmetic for sale shall at all times store and keep it packed in such manner as to minimise its deterioration, and shall comply with all requirements for storage stated on the

label or contained in a specified publication in respect of that medicine, related product, or cosmetic.

### **33 Construction and use of containers, etc**

- (1) No person shall use, or permit to be used, any container, appliance, or vehicle for or in connection with the manufacture, storage, packing, or supply of any medicine, related product, or cosmetic for sale unless that container, appliance, or vehicle is constructed of such material and in such manner as to allow for easy cleaning, and is kept clean.
- (2) No person shall use, or permit to be used, in the supply of any medicine, related product, or cosmetic for sale any container, appliance, or vehicle that is also used for the carriage of any matter that endangers or could endanger the cleanliness or freedom from contamination of the medicine, related product, or cosmetic.
- (3) No person shall use, or permit to be used, for the manufacture, storage, or packing of any medicine, related product, or cosmetic for sale, any container that has been used for any purpose that may contaminate or taint the medicine, related product, or cosmetic, unless the container has been thoroughly cleaned.

### **34 Exposure to toxic substances prohibited**

Except as otherwise provided in these regulations, no person shall, in the course of the manufacture, storage, packing, or supply of any medicine, related product, or cosmetic for sale, keep, carry, spread, or use, or permit to be kept, carried, spread, or used, any toxic or noxious substance so as to expose the medicine, related product, or cosmetic to the risk of contamination by that substance at any time.

### **35 Containers for medicines, related products, and cosmetics**

- (1) A person must not pack, store, or sell a prescription medicine, restricted medicine, or pharmacy-only medicine in a container made of paper; but nothing in this subclause prevents the person from packing, storing, or selling the medicine in a container made of cardboard.
- (2) *[Revoked]*
- (3) No person shall use, or permit to be used, in the storage, packing, or supply of any medicine, related product, or cosmetic for sale, a container that yields, or could yield, to its contents a toxic, injurious, or tainting substance.
- (4) Every container used in the packing of a medicine and made of glass or plastic shall comply with the tests for that type of container (if any) specified in the *United States Pharmacopeia*.
- (5) Every container used in the packing of a medicine and made of metal shall be impermeable to moisture.

- (6) Every container used in the packing of a medicine and made of metal or plastic shall be made of a material that will not adversely react with the contents of the container.
- (7) Except as provided in subclause (8), no person shall store, pack, or sell in a container of a capacity of not less than 15 millilitres and not more than 2.5 litres any medicine, related product, or cosmetic that—
- (a) is in liquid form; and
  - (b) is intended for external use; and
  - (c) has poisonous properties,—
- unless the container is a poison bottle.
- (8) It shall not be necessary to pack in a poison bottle any medicine, related product, or cosmetic to which subclause (7) applies if that medicine, related product, or cosmetic is—
- (a) supplied to or held for use in educational establishments, or in scientific or industrial laboratories; or
  - (b) supplied to or held by analysts, pharmacists, authorised prescribers, or veterinary surgeons; or
  - (c) supplied to or held by persons engaged as suppliers to any of the establishments, laboratories, or classes of persons mentioned in paragraphs (a) and (b); or
  - (d) a hair dye to which regulation 24 applies.
- (9) No person shall have in his possession or charge (whether for the purposes of sale or otherwise) in an open container, any medicine, related product, or cosmetic that has poisonous properties, except while the container is being filled or the medicine, related product, or cosmetic in the container is being used.
- (10) No person in possession or charge of any medicine, related product, or cosmetic shall keep it, whether temporarily or permanently, in any bottle, jar, can, tinsplate container, culinary utensil, or other container of a type that—
- (a) bears any brand, mark, statement, or picture that indicates the presence in the container of any food, drink, or condiment; or
  - (b) is of a distinctive type in which any food, drink, or condiment, has been commonly or is being currently sold, whether or not the container bears any brand, mark, statement, or picture.

Regulation 35(1): substituted, on 24 July 2006, by regulation 6 of the Medicines Amendment Regulations 2006 (SR 2006/158).

Regulation 35(2): revoked, on 24 July 2006, by regulation 6 of the Medicines Amendment Regulations 2006 (SR 2006/158).

Regulation 35(8)(b): amended, on 1 October 2005, by regulation 6 of the Medicines Amendment Regulations 2005 (SR 2005/255).

**36 Storage to be separate**

No person shall store or keep for ready use any medicine, related product, or cosmetic in such manner that a food or drink may be contaminated by the escape or leakage of the medicine, related product, or cosmetic, or by the release of vapours from the medicine, related product, or cosmetic.

**37 Safety containers**

- (1) No person shall sell any tablet, or other single item in solid form that is intended to be taken orally, being or comprising a medicine or belonging to a class of medicines to which this regulation applies, unless the tablet or item is enclosed in a safety container.
- (2) Subclause (1) shall not apply—
  - (a) where an authorised prescriber directs, either on the prescription or otherwise,—
    - (i) that a medicine is not to be sold enclosed in a safety container; or
    - (ii) that he or she does not wish the name of the medicine to appear on the label; or
  - (b) where a pharmacist is of the opinion that, because of the age or infirmity of a particular person, a medicine to be used by that person should not be enclosed in a safety container; or
  - (c) in the case of capsules, pills, powder, or other solid dose forms, prepared in a pharmacy with reference to the particular needs of a patient.
- (3) *[Revoked]*
- (4) This regulation applies to the following medicines:  
aspirin, and its salts; and medicines containing aspirin or its salts:  
iron, in medicines for human use containing more than 24 milligrams of elemental iron per dose:  
paracetamol; and medicines containing paracetamol.
- (5) This regulation applies to the following classes of medicines:  
barbiturates:  
phenothiazine, and derivatives of phenothiazine and their salts, except dimethothiazine, methdilazine, promethazine, and trimeprazine, and their salts and molecular compounds:  
tricyclic, tetracyclic, and analogous antidepressants.  
Regulation 37(2)(a): amended, on 1 October 2005, by regulation 7 of the Medicines Amendment Regulations 2005 (SR 2005/255).  
Regulation 37(2)(a)(ii): amended, on 11 October 2001, by regulation 9(b) of the Medicines Amendment Regulations 2001 (SR 2001/232).  
Regulation 37(3): revoked, on 1 August 2011, by regulation 13 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **Part 6**

### **Importation and transport**

#### **38 Containers**

- (1) Every medicine imported into, or packed or consigned for transport in, New Zealand shall be securely packed in a container that is sufficiently strong to withstand, and to protect the contents from damage arising in, the ordinary course of transport.
- (2) No person shall import into, or transport or cause to be transported in, New Zealand any medicine that is not packed in compliance with subclause (1).
- (3) Every related product packed or consigned for transport in New Zealand shall be securely packed in a container that is sufficiently strong to withstand, and to protect the contents from damage arising in, the ordinary course of transport.
- (4) No person shall transport or cause to be transported in New Zealand any related product that is not packed in compliance with subclause (3).

## **Part 7**

### **Prescriptions**

#### **39 Conditions under which authorised prescribers and veterinarians may prescribe prescription medicines**

- (1) An authorised prescriber (including a designated prescriber) may only prescribe a prescription medicine if the authorised prescriber—
  - (a) is prescribing the prescription medicine—
    - (i) for the treatment of a patient under the authorised prescriber's care; and
    - (ii) within, and in accordance with all conditions (if any) stated in, the authorised prescriber's scope of practice, as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003 by the authority responsible for the registration of the authorised prescriber; and
  - (b) is not prohibited by a notice under section 48(1) of the Act from prescribing that prescription medicine or any prescription medicines of a class or description that includes that prescription medicine.
- (2) An authorised prescriber who is a designated prescriber may only prescribe a prescription medicine if—
  - (a) the prescription medicine is of a class or description that the designated prescriber is authorised to prescribe by regulations made under the Act; and



- (b) the requirements specified in or imposed under those regulations are satisfied.
- (3) A veterinarian may only prescribe a prescription medicine that is for the treatment of an animal under the veterinarian's care.
- (4) Subclause (1) does not apply to an authorised prescriber who is acting in the course of his or her employment by the Crown.

Regulation 39: substituted, on 1 December 2011, by regulation 14 of the Medicines Amendment Regulations 2011 (SR 2011/245).

### **39A Limit on period of supply of prescription medicines**

- (1) An authorised prescriber may not on any occasion prescribe for any patient a quantity of any prescription medicine that exceeds—
  - (a) 6 months' supply in the case of an oral contraceptive; or
  - (b) 3 months' supply in any other case.
- (2) However, the Director-General may, at his or her discretion, authorise—
  - (a) an authorised prescriber to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b):
  - (b) a class of authorised prescribers to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b).

Regulation 39A: inserted, on 1 December 2011, by regulation 15 of the Medicines Amendment Regulations 2011 (SR 2011/245).

### **40 Prescriptions to comply with regulations**

- (1) Except as provided in regulation 40A, every authorised prescriber or veterinarian who issues a prescription to a person must comply with regulation 41.
- (2) Subclause (1) applies to a prescription for any medicine (whether a prescription medicine or not).
- (3) Subclause (2) does not prevent the sale by retail, or the supply in circumstances corresponding to retail sale, or the dispensing, of a medicine (other than a prescription medicine) without a prescription.

Regulation 40: substituted, on 11 October 2001, by regulation 11 of the Medicines Amendment Regulations 2001 (SR 2001/232).

Regulation 40(1): amended, on 1 August 2011, by regulation 16 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 40(1): amended, on 1 October 2005, by regulation 9 of the Medicines Amendment Regulations 2005 (SR 2005/255).

### **40A Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing**

- (1) Where an authorised prescriber or veterinarian finds it necessary to do so, he or she may communicate orally to a pharmacist to whom he or she is known per-

sonally (whether in the pharmacist's presence or by speaking to the pharmacist on the telephone) a prescription relating to a prescription medicine that the authorised prescriber or veterinarian requires urgently.

- (2) Within 7 days after a communication made by an authorised prescriber or veterinarian to a pharmacist under subclause (1), the authorised prescriber or veterinarian must forward to the pharmacist a written prescription confirming the oral communication.

Regulation 40A: inserted, on 11 October 2001, by regulation 11 of the Medicines Amendment Regulations 2001 (SR 2001/232).

Regulation 40A(1): amended, on 1 August 2011, by regulation 17 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 40A(1): amended, on 1 October 2005, by regulation 10(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 40A(1): amended, on 1 October 2005, by regulation 10(2) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 40A(2): amended, on 1 August 2011, by regulation 17 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 40A(2): amended, on 1 October 2005, by regulation 10(3) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 40A(2): amended, on 1 October 2005, by regulation 10(4) of the Medicines Amendment Regulations 2005 (SR 2005/255).

#### **41 Form of prescription**

Every prescription given under these regulations shall—

- (a) be legibly and indelibly printed; and
- (b) be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp), and dated; and
- (c) set out the following information in relation to the prescriber:
  - (i) the prescriber's full name; and
  - (ii) the full street address of the prescriber's place of work or, in the absence of the prescriber having a place of work, the postal address of the prescriber; and
  - (iii) the prescriber's telephone number; and
- (d) set out—
  - (i) the surname, each given name, and the address of the person for whose use the prescription is given; and
  - (ii) in the case of a child under the age of 13 years, the date of birth of the child; and
- (e) indicate by name the medicine and, where appropriate, the strength that is required to be dispensed; and
- (f) indicate the total amount of medicine that may be sold or dispensed, or the total period of supply; and

- (g) if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of dose; and
- (h) if the medicine is for application externally, indicate the method and frequency of use; and
- (i) *[Revoked]*
- (j) in the case of a prescription relating to the treatment of an animal,—
  - (i) set out the surname, each given name, and the address of the owner of the animal; and
  - (ii) contain the following statement, or words of similar meaning:  
“Not for human use”.

Regulation 41(c): substituted, on 1 December 2011, by regulation 18(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(d)(i): substituted, on 1 December 2011, by regulation 18(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(f): substituted, on 1 December 2011, by regulation 18(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(i): revoked, on 1 December 2011, by regulation 18(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(j)(i): substituted, on 1 December 2011, by regulation 18(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **42 Dispensing of prescription medicines**

- (1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinarian, pharmacist, pharmacy graduate, a pharmacy technician, a student, or dispensary technician may dispense a prescription medicine.
- (1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:
  - (a) dispensary technicians:
  - (b) pharmacy graduates:
  - (c) pharmacy technicians:
  - (d) students.
- (2) An agent or employee of a veterinarian may, in any particular case, dispense any prescription medicine at the direction of the veterinarian for use in the treatment of any animal under the care of the veterinarian.
- (3) Every person dispensing a prescription relating to a prescription medicine must comply with the following requirements:
  - (a) if the prescription has been communicated orally under regulation 40A(1), the prescription must not be dispensed on more than 1 occasion before the pharmacist has received the written confirmation of the prescription, as required by regulation 40A(2):

- (b) the following information must be recorded on the prescription:
    - (i) the name and address of the proprietor of the business at which the prescription is dispensed; and
    - (ii) the date on which the prescription is dispensed; and
    - (iii) the quantity of medicine dispensed; and
    - (iv) a unique identifying number or code for the prescription:
  - (c) a prescription for a medicine other than an oral contraceptive must not be dispensed on any occasion after 6 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:
  - (d) a prescription for a medicine that is an oral contraceptive must not be dispensed on any occasion after 9 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:
  - (e) every prescription must be retained for a period of 3 years by the pharmacist on the premises on which it was dispensed or at a place approved by the Medical Officer of Health and must be kept in an orderly and consecutive manner so as to be readily available for inspection.
- (4) If an authorised prescriber or a veterinarian refers in a prescription to a medicine by its trade mark or trade name, or by reference to the name of its manufacturer, a pharmacist may supply an alternative brand of medicine, provided that—
- (a) the authorised prescriber or veterinarian has not marked the prescription “No brand substitution permitted” or with words of similar meaning; and
  - (b) the substituted brand contains the same active ingredient or active ingredients, and no other active ingredients; and
  - (c) the substituted brand is in the same dose form and strength as the prescribed brand; and
  - (d) there is no clinical reason why the substituted brand should not be supplied; and
  - (e) the pharmacist records the brand substitution on the prescription; and
  - (f) the pharmacist signs and dates the prescription; and
  - (g) the pharmacist informs the patient of the brand substitution.
- (5) This regulation is subject to regulation 43.

Regulation 42(1): substituted, on 11 October 2001, by regulation 12(1) of the Medicines Amendment Regulations 2001 (SR 2001/232).

Regulation 42(1): amended, on 1 August 2011, by regulation 19(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 42(1): amended, on 1 October 2005, by regulation 11(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 42(1): amended, on 19 December 2002, by regulation 4(1) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

Regulation 42(1A): inserted, on 19 December 2002, by regulation 4(2) of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

Regulation 42(2): amended, on 1 August 2011, by regulation 19(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 42(3): substituted, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 42(4): substituted, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 42(5): added, on 1 August 2011, by regulation 19(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### **43 Director-General may waive certain requirements**

- (1) Despite the requirements in regulations 41 and 42, the Director-General may, at his or her discretion,—
  - (a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and
  - (b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.
- (2) A form of prescription that may be authorised under subclause (1)(a) includes, but is not limited to, an electronic form of prescription.

Regulation 43: substituted, on 1 August 2011, by regulation 20 of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### **44 Prescriptions for prescription medicines not required in certain cases**

A prescription medicine may be sold or dispensed otherwise than under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber if it is sold to or dispensed for—

- (a) a person licensed to sell the prescription medicine by wholesale; or
- (b) a person obtaining the prescription medicine for use in any process of manufacture or trade not involving the resale of the medicine; or
- (c) an analyst under the Act, or a person approved by the Director-General and in charge of a laboratory maintained for the purposes of research, study, or analysis; or
- (d) a hospital care operator within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or
- (e) a pharmacist in control of any pharmacy, or any dispensary in a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or

- (f) an authorised prescriber or veterinarian; or
- (fa) *[Revoked]*
- (fb) *[Revoked]*
- (g) a patient under his or her care by an authorised prescriber; or
- (ga) *[Revoked]*
- (gb) *[Revoked]*
- (h) a patient under the care of an authorised prescriber, provided that—
  - (i) the medicine is administered by a person who has been instructed by the authorised prescriber (either verbally or in writing) to do so; and
  - (ii) the person administering the medicine records the administration in the patient’s medical record; and
  - (iii) the authorised prescriber records the instruction under subparagraph (i) in the patient’s medical record; or
- (ha) *[Revoked]*
- (hb) *[Revoked]*
- (i) the master of a New Zealand ship within the meaning of the Maritime Transport Act 1994,—
  - (i) if the medicine is prescribed by rules under section 36(1)(e) of that Act; or
  - (ii) at a time before the commencement of the first rules made under section 36(1)(e) of that Act, if the medicine is authorised or required by scales issued under section 138 or section 239 of the Shipping and Seamen Act 1952; or
- (ia) the master of a foreign ship within the meaning of the Maritime Transport Act 1994, if the law of the State whose flag the ship is entitled to fly requires the master to carry the medicine; or
- (j) a person for inclusion in an emergency medical kit kept or to be kept for use in any vessel to which paragraph (i) does not apply, and is so sold or dispensed pursuant to an order signed by a Medical Officer of Health; or
- (k) the person in charge of an aircraft if the medicine is required to be carried on the aircraft as a condition of the issue of a certificate of airworthiness; or
- (l) a person for inclusion in an emergency medical kit pursuant to an order signed by a Medical Officer of Health for use in a place of a class approved by the Director-General; or
- (m) a person who has previously been supplied with the medicine on the prescription of an authorised prescriber for a particular condition, and is so sold or dispensed—

- (i) by a pharmacist who is satisfied that the person requires an emergency supply of the medicine for that condition; and
- (ii) in an amount not exceeding the quantity reasonably required by that person for a period of 72 hours, or a minimum pack of a special container from which it is not practicable to dispense a lesser amount; or
- (n) any person by a veterinarian for the treatment of an animal under the care of the veterinarian; or
- (o) a person or body authorised to distribute, or a person authorised to administer, the prescription medicine in an approved immunisation programme.

Regulation 44 heading: amended, on 11 October 2001, by regulation 13(1) of the Medicine Amendment Regulations 2001 (SR 2001/232).

Regulation 44: amended, on 30 November 2000, by regulation 10(1) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(d): substituted, on 1 October 2002, by section 58(3) of the Health and Disability Services (Safety) Act 2001 (2001 No 93).

Regulation 44(e): substituted, on 1 October 2002, by section 58(3) of the Health and Disability Services (Safety) Act 2001 (2001 No 93).

Regulation 44(f): substituted, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(f): amended, on 1 August 2011, by regulation 21(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 44(fa): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(fb): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(g): substituted, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(ga): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(gb): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(h): substituted, on 1 August 2011, by regulation 21(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 44(ha): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(hb): revoked, on 1 October 2005, by regulation 12(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(i): substituted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(ia): inserted, on 30 November 2000, by regulation 10(2) of the Medicines Amendment Regulations 2000 (SR 2000/220).

Regulation 44(m): amended, on 1 August 2011, by regulation 21(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 44(m): amended, on 1 October 2005, by regulation 12(2) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44(n): amended, on 1 August 2011, by regulation 21(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 44(n): amended, on 17 April 1992, by regulation 3(2) of the Medicines Regulations 1984, Amendment No 5 (SR 1992/43).

Regulation 44(o): added, on 17 April 1992, by regulation 3(1) of the Medicines Regulations 1984, Amendment No 5 (SR 1992/43).

#### **44A Administration of vaccines in approved immunisation programmes**

- (1) Any medical practitioner or other person who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.
- (2) The Director-General or a Medical Officer of Health may authorise any person to administer a vaccine for the purposes of an approved immunisation programme if that person, following written application, provides documentary evidence satisfying the Director-General or the Medical Officer of Health, as the case may be, that that person—
  - (a) can carry out basic emergency techniques including resuscitation and the treatment of anaphylaxis; and
  - (b) has knowledge of the safe and effective handling of immunisation products and equipment; and
  - (c) can demonstrate clinical interpersonal skills; and
  - (d) has knowledge of the relevant diseases and vaccines in order to be able to explain the vaccination to the patient, or to the parent or guardian of the patient who is to consent to the vaccination on behalf of the patient, to ensure that the patient or the parent or guardian of the patient can give informed consent to the vaccination.
- (3) Subject to subclause (4), any authorisation given by the Director-General or a Medical Officer of Health under subclause (2) shall be valid for a period of 2 years and shall be subject to such conditions as the Director-General or the Medical Officer of Health, as the case may be, thinks fit.
- (4) An authorisation given to any person under subclause (2) may be withdrawn at any time before its expiry if the Director-General or a Medical Officer of Health is satisfied that the authorised person has failed to comply with any condition specified by the Director-General or the Medical Officer of Health under subclause (3).

Regulation 44A: inserted, on 17 April 1992, by regulation 4 of the Medicines Regulations 1984, Amendment No 5 (SR 1992/43).

Regulation 44A(2)(a): amended, on 11 October 2001, by regulation 14 of the Medicines Amendment Regulations 2001 (SR 2001/232).



#### **44B Duty to supply information**

- (1) The Medical Officer of Health may require any authorised prescriber to supply information relating to the prescribing, administering, or supplying of any prescription medicines if the Medical Officer of Health has reason to suspect that prescription medicines may have been improperly prescribed, administered, or supplied by the authorised prescriber.
- (2) Every requirement to supply information must be in writing, stating the reasons for the Medical Officer of Health's suspicion.
- (3) The information that must be supplied is information justifying the prescription, administering, or supply of the prescription medicines as follows:
  - (a) the age of the patient:
  - (b) the diagnosis of the patient's condition:
  - (c) the prognosis of the patient's condition:
  - (d) details of any specialist referral:
  - (e) any alternative treatments considered or tried.
- (4) An authorised prescriber to whom any such notice is sent must supply the required information in writing to the Medical Officer of Health within 30 days.

Regulation 44B: inserted, on 18 September 1997, by regulation 2(1) of the Medicines Amendment Regulations 1997 (SR 1997/165).

Regulation 44B(1): amended, on 1 October 2005, by regulation 13(1) of the Medicines Amendment Regulations 2005 (SR 2005/255).

Regulation 44B(4): amended, on 1 October 2005, by regulation 13(2) of the Medicines Amendment Regulations 2005 (SR 2005/255).

### **Part 7A**

#### **Export of prescription medicines**

Part 7A: inserted, on 3 November 2000, by regulation 11 of the Medicines Amendment Regulations 2000 (SR 2000/220).

#### **44C No export of prescription medicines for retail sale without New Zealand prescription**

- (1) No person may export a prescription medicine in the course or for the purpose of retail sale, otherwise than under a prescription given by a practitioner, a registered midwife, or a designated prescriber.
- (2) The meaning of **retail sale** in subclause (1) must be determined by reference to section 5(2) of the Act.
- (3) Subclause (1) is intended to limit the sale and supply of prescription medicines pursuant to section 33(b) of the Act.

Regulation 44C: inserted, on 3 November 2000, by regulation 11 of the Medicines Amendment Regulations 2000 (SR 2000/220).

## Part 7B

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

Part 7B: inserted, on 18 September 2004, by regulation 3 of the Medicines Amendment Regulations 2004 (SR 2004/300).

#### 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.

Regulation 44D: inserted, on 18 September 2004, by regulation 3 of the Medicines Amendment Regulations 2004 (SR 2004/300).

## Part 8

### Licences

#### 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.

Regulation 45: substituted, on 18 September 2004, by regulation 4 of the Medicines Amendment Regulations 2004 (SR 2004/300).

#### **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 appropriate fee prescribed in Schedule 5A; 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.

Regulation 45A: inserted, on 18 September 2004, by regulation 4 of the Medicines Amendment Regulations 2004 (SR 2004/300).

Regulation 45A(1)(b)(i): substituted, on 21 August 2006, by regulation 4 of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

#### **45B Licences that relate to CBD products**

- (1) A licence to manufacture medicines, to sell medicines by wholesale, to pack medicines, or to operate a pharmacy that is issued under these regulations does not apply to a CBD product (as defined by section 2A of the Misuse of Drugs Act 1975) unless expressly authorised by the licence.
- (2) The licence must not be issued, or amended, to expressly authorise its application to a CBD product unless the product has been assessed as complying with the minimum quality standard under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.
- (3) A product is assessed as complying with the minimum quality standard under those regulations if—
  - (a) an application is made under those regulations to assess the CBD product, in which case those regulations (including the requirement to pay fees) apply for that purpose as if the product were being assessed as a medicinal cannabis product; and
  - (b) the Director-General assesses the evidence in the application and is satisfied that a representative sample of at least 10% of each of 3 batches of the product complied with the minimum quality standard.

Regulation 45B: inserted, on 1 April 2020, by regulation 85 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (LI 2019/321).

#### **46 Form and conditions of licence**

- (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.
- (2) On granting a licence under the Act, the licensing authority may impose such conditions as he thinks fit.

Regulation 46(1): substituted, on 18 September 2004, by regulation 5 of the Medicines Amendment Regulations 2004 (SR 2004/300).

#### **47 Licence to manufacture medicines**

- (1) Every application for a licence to manufacture any medicine shall specify which of the following descriptions or classes the medicine comes within or belongs to:
- (a) antibiotics and preparations of antibiotics:
  - (b) vaccines and sera:
  - (c) sterile preparations:
  - (d) hormones and steroid preparations:
  - (e) preparations, other than vitamins, that have a dose of 5 milligrams or less per unit dose:
  - (f) antineoplastic agents and immunosuppressant agents, other than steroid preparations:
  - (g) other medicines.
- (2) Where an application to manufacture medicines applies to 1 or more medicines or descriptions or classes of medicines, the licensing authority may grant a licence for all the medicines or descriptions or classes of medicines to which the application relates, or for such of the medicines or descriptions or classes of medicines to which the application relates as the licensing authority is satisfied the applicant is qualified to manufacture and capable of manufacturing.

#### **48 Licence to hawk certain medicines**

- (1) Subject to subclause (2), and without affecting the generality of regulation 46(2), every licence to hawk any prescription medicine, restricted medicine, or pharmacy-only medicine shall be granted subject to the following conditions:
- (a) the licence shall apply only to those medicines or descriptions or classes of medicine specified in the licence:
  - (b) the licensee shall keep the stocks of medicines in a place approved by the licensing authority:

- (c) where the licensing authority imposes a limit on the quantity of medicines that may be carried by the licensee when hawking, the licensee shall not carry medicines in excess of that quantity:
  - (d) the licensee shall hawk medicines only to those persons or classes of persons specified in the licence.
- (2) No person shall be granted a licence to hawk any prescription medicines, restricted medicines, or pharmacy-only medicines by retail.

#### **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).

Regulation 48A: inserted, on 18 September 2004, by regulation 6 of the Medicines Amendment Regulations 2004 (SR 2004/300).

#### **49 Surrender of licence**

- (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) The licensing authority, on receiving a licence pursuant to subclause (1A), shall retain the licence for the remainder of the current licence period.
- (3) Nothing in this regulation shall prevent a licensee who has surrendered his licence pursuant to subclause (1A) from applying to the licensing authority for restoration of the licence to the licensee at any time during the current licence period.
- (4) In any such case, but subject to subclause (5), the licensing authority, on being satisfied that the licensee complies with the requirements of the Act and these regulations relating to the granting of licences, shall restore the licence to the licensee.

- (5) Notwithstanding anything in these regulations, it shall not be necessary for any licensee who surrenders his licence to pay a further licence fee on application for restoration of that licence.

Regulation 49(1): substituted, on 18 September 2004, by regulation 7(1) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Regulation 49(1A): inserted, on 18 September 2004, by regulation 7(1) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Regulation 49(2): amended, on 18 September 2004, by regulation 7(2) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Regulation 49(3): amended, on 18 September 2004, by regulation 7(3) of the Medicines Amendment Regulations 2004 (SR 2004/300).

## **Part 9**

### **Withdrawal of medicines, etc**

#### **50 Withdrawal of medicines, etc**

- (1) The Director-General may issue to any importer, manufacturer, or seller of any medicine, related product, or medical device an order—
- (a) directing the withdrawal from sale of any medicine, related product, or medical device in respect of which there is in force a notice given by the Minister under section 35 or section 37 of the Act, or of any portion of the produced quantity of any such medicine, related product, or medical device, if the Director-General believes on reasonable grounds that such withdrawal is necessary to protect the public; or
  - (b) directing the withdrawal from sale of any medicine, related product, or medical device, or any portion of the produced quantity of any medicine, related product, or medical device, that does not conform to the specifications claimed for that medicine, related product, or medical device; or
  - (c) requiring the disposal of any medicine or related product, or any specific quantity of a medicine or related product, that has been directed to be withdrawn under paragraph (a) or paragraph (b); or
  - (d) requiring the disposal or destruction of any medical device, or any specific quantity of any medical device, that has been directed to be withdrawn under paragraph (a) or paragraph (b).
- (2) The importer, manufacturer, or seller shall, on receipt of an order made under subclause (1), advise the Director-General of the manner and time in which he proposes to comply with the order, and shall give written notice to the Director-General when the order has been complied with.
- (3) Notwithstanding anything in subclause (2), the Director-General may issue directions to the recipient of an order made under subclause (1) as to the manner and time in which the order is to be complied with.

## Part 10

### Data sheets

#### 51 Interpretation

In this Part, unless the context otherwise requires, **data sheet**, in relation to a medicine, means a document containing information relating to the safe and effective use of the medicine.

Regulation 51: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### 52 Approval of data sheets for new medicines

- (1) A person who applies under section 20 or 23 of the Act for the consent of the Minister to the distribution of a prescription medicine or restricted medicine (an **applicant**) must include with his or her application a proposed data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health.
- (2) On receipt of the proposed data sheet, the Minister may—
  - (a) approve the data sheet; or
  - (b) require the data sheet to be resubmitted for approval after such changes have been made to it as the Minister considers appropriate.
- (3) Within 10 days after the Minister's consent to the distribution of a prescription medicine or restricted medicine has been notified in the *Gazette*, the applicant must send to the Director-General for publication an electronic copy of the approved data sheet for that medicine.

Regulation 52: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### 53 Approval of data sheets for changed medicines

- (1) An importer or manufacturer who gives to the Director-General a notice under section 24(1) of the Act describing a material change to a prescription medicine or restricted medicine must include with the notice a proposed revised data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health if a revision of the data sheet is necessary or desirable because of the material change.
- (2) On receipt of the proposed revised data sheet, the Director-General may—
  - (a) approve the revised data sheet; or
  - (b) require the revised data sheet to be resubmitted for approval after such changes have been made to it as the Director-General considers appropriate.
- (3) After the Director-General has approved a revised data sheet, the Director-General must give written notice of the approval to the importer or manufacturer.



- (4) Within 10 days after receiving a notice of approval under subclause (3), the importer or manufacturer must send to the Director-General for publication an electronic copy of the approved revised data sheet.

Regulation 53: substituted, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

#### **54 Particulars in data sheets**

*[Revoked]*

Regulation 54: revoked, on 1 August 2011, by regulation 22 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## **Part 11 Records**

### **54A Sale of Medicines Registers**

- (1) This regulation applies to the sale of a medicine if it is—
- (a) a restricted medicine sold by retail otherwise than under a prescription; or
  - (b) a prescription medicine, restricted medicine, or pharmacy-only medicine, sold by wholesale.
- (2) A person who makes sales to which subclause (1) applies must—
- (a) maintain a Sale of Medicines Register for recording and keeping the information stated in subclause (4); and
  - (b) ensure that the information kept in it is arranged in such a way that the information about each particular sale can be conveniently inspected, or retrieved and inspected.
- (3) The register must be in 1 or more of the following forms:
- (a) a system for recording and keeping the information electronically;
  - (b) a book for recording and keeping the information in writing;
  - (c) some other system for recording and keeping the information, approved by the Director-General (either generally or in any particular case) for the purposes of this regulation.
- (4) The information to be recorded and kept in relation to each sale is—
- (a) the date of the sale;
  - (b) the buyer's name;
  - (c) the address of the buyer's place of business or residence;
  - (d) the name of the medicine sold;
  - (e) the quantity of the medicine sold;
  - (f) the name of the person making the sale.

Regulation 54A: inserted, on 30 November 2000, by regulation 12 of the Medicines Amendment Regulations 2000 (SR 2000/220).

### **55 Records of sales by retail or wholesale**

- (1) Before giving to the buyer a medicine to whose sale regulation 54A(1) applies, the person making the sale must record in the Sale of Medicines Register maintained under regulation 54A(2) the information stated in regulation 54A(4).
- (2) It is not necessary to comply with subclause (1) in relation to a sale by wholesale if the information stated in regulation 54A(4) can be discovered from the seller's books and records.

Regulation 55: substituted, on 30 November 2000, by regulation 12 of the Medicines Amendment Regulations 2000 (SR 2000/220).

### **56 Record of hawker's sales**

- (1) Every person who hawks any prescription medicine, restricted medicine, or pharmacy-only medicine shall keep and maintain a "Hawker's Medicines" book that records the medicines that he hawks or has in his possession.
- (2) Each page of the Hawker's Medicines book shall—
  - (a) be in the form set out in Schedule 4:
  - (b) relate to only 1 form and 1 strength of 1 medicine.
- (3) The particulars in the Hawker's Medicines book shall be legibly and indelibly entered not later than the ordinary business day next following the day on which the medicine concerned was sold.
- (4) Every person to whom subclause (1) applies shall—
  - (a) satisfy himself that the purchaser is entitled to the medicine; and
  - (b) before selling the medicine to the purchaser, obtain from the purchaser a printed request for the medicine, signed and dated by the purchaser, that contains the following particulars:
    - (i) the date of each transaction:
    - (ii) the name of the purchaser:
    - (iii) the address of the place of business or residence of the purchaser:
    - (iv) the name of the medicine sold:
    - (v) the quantity of the medicine sold.

### **57 Record of supplies pursuant to prescriptions**

- (1) Every person who dispenses or supplies any prescription medicine or restricted medicine pursuant to a prescription shall, not later than the ordinary business day next following the day on which the medicine was dispensed or supplied, record that dispensing or supply of the medicine in a "Prescriptions" register, or in such other form, or within such other period of time, as the Director-General may from time to time approve.

- (a) the date of each transaction:
- (b) the name of the patient or (as the case may require) the owner of the animal:
- (c) the address of the patient or (as the case may require) the owner of the animal:
- (d) the name of the medicine supplied:
- (e) the quantity of the medicine supplied:
- (f) the name of the prescriber:
- (g) in the case of a prescription medicine, the unique identifying number or code of the prescription.

### **58 Records to be kept**

- (1) The person responsible for a record to which this Part applies must keep it for at least 3 years after it was made (or, if it is kept together with other records, for at least 3 years after the most recent of them was made).
- (2) The person must keep the record—
  - (a) in a secure place at his or her place of business; or
  - (b) in some other place authorised by the licensing authority.

Regulation 58: substituted, on 30 November 2000, by regulation 13 of the Medicines Amendment Regulations 2000 (SR 2000/220).

## **Part 12 Miscellaneous**

### **58A Substances that are not medicines or related products for purposes of Act**

- (1) The following classes of substances are not medicines or related products for the purposes of the Act:
  - (a) dentifrice products, provided that—
    - (i) the dentifrice product does not contain a medicine specified in Schedule 1; and
    - (ii) the dentifrice product is not claimed to be for use in relation to any therapeutic purpose other than one or both of the following:
      - (A) preventing dental decay:
      - (B) improving oral hygiene:
  - (b) anti-dandruff hair products, provided that—
    - (i) the hair product does not contain a medicine specified in Schedule 1; and

- (ii) the hair product is not claimed to be for use in relation to any therapeutic purpose except controlling dandruff; and
    - (iii) the hair product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the scalp and not through any other process:
  - (c) anti-acne skin care products, provided that—
    - (i) the skin care product does not contain a medicine specified in Schedule 1; and
    - (ii) the skin care product is not claimed to be for use in relation to any therapeutic purpose except preventing acne; and
    - (iii) the skin care product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the skin and not through any other process:
  - (d) barrier cream products, provided that—
    - (i) the barrier cream product does not contain a medicine specified in Schedule 1; and
    - (ii) the barrier cream product is not claimed to be for use in relation to any therapeutic purpose except preventing nappy rash; and
    - (iii) the barrier cream product is claimed to be effective through providing a barrier to the transmission of moisture and not through any other process:
  - (e) anti-bacterial skin products, provided that—
    - (i) the product does not contain a medicine specified in Schedule 1; and
    - (ii) the product is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium); and
    - (iii) the product is not presented as being for use in connection with—
      - (A) any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
      - (B) either of the procedures specified in subclause (2); and
    - (iv) the product is not recommended for use in connection with the provision of health services (as defined in section 2 of the Health and Disability Commissioner Act 1994).
- (2) The procedures referred to in subclause (1)(e)(iii)(B) are—
- (a) piercing the skin or mucous membrane for any purpose; and
  - (b) venipuncture, or the delivery of an injection.

Regulation 58A: inserted, on 1 August 2011, by regulation 23 of the Medicines Amendment Regulations 2011 (SR 2011/245).

**58B Fluoridating agents and fluoridated water not medicines or related products**

- (1) This regulation applies in relation to drinking water in a drinking-water supply.
- (2) Fluoridating agents for use in fluoridating drinking water are not medicines or related products for the purposes of the Act.
- (3) The addition of 1 or more fluoridating agents to drinking water does not make the drinking water a medicine or related product for the purposes of the Act.
- (4) In this regulation,—

**drinking water** and **drinking-water supply** have the same meanings as in section 69G of the Health Act 1956

**fluoridating agent** means—

- (a) hydrofluorosilicic acid:
- (b) sodium fluoride:
- (c) sodium silicofluoride:
- (d) any other substance that releases fluoride when added to water.

Regulation 58B: inserted, on 30 January 2015, by regulation 4 of the Medicines Amendment Regulations 2015 (LI 2015/7).

**58C Substances used to terminate pregnancy are medicines**

Substances used to terminate a pregnancy are medicines for the purposes of the Act.

Regulation 58C: inserted, on 24 March 2020, by section 18(2) of the Abortion Legislation Act 2020 (2020 No 6).

**58D Non-oral products containing nicotine are medicines**

- (1) Products containing nicotine that are not for oral use are medicines for the purposes of the Act.
- (2) To avoid doubt, **oral use** includes (without limitation) inhalation.

Regulation 58D: inserted, on 11 November 2020, by section 30 of the Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020 (2020 No 62).

**59 General sale medicines may be sold by vending machine**

- (1) The Director-General may, by notice in the *Gazette*,—
  - (a) approve the sale of a general sale medicine by means of a vending machine:
  - (b) specify any conditions to which an approval under paragraph (a) is subject:
  - (c) withdraw an approval given under paragraph (a):
  - (d) vary or revoke any conditions specified under paragraph (b), or specify additional conditions, to which an approval under paragraph (a) is subject.

- (2) A notice given under subclause (1) takes effect on the day after the date of notification.

Regulation 59: substituted, on 1 August 2011, by regulation 24 of the Medicines Amendment Regulations 2011 (SR 2011/245).

## 60 Certificate of analyst

The certificate of an analyst given for the purposes of section 70 of the Act shall be in the form set out in Schedule 5.

## 61 Fees

- (1) The licence fees set out in Schedule 5A are payable for the licences to which they relate.
- (2) The amount to be deposited with the Medicines Review Committee pursuant to section 13(2) of the Act shall be \$9,000.
- (3) The fee to accompany an application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be \$122,625 where any active ingredient of the medicine that is the subject of the application is not generally available as at the date of that application.
- (4) The fee to accompany any other application made under section 21 of the Act for the Minister's consent under section 20 of the Act shall be \$43,875.
- (5) The fee to accompany an application made under section 21 of the Act (as applied by section 96(1) of the Act) for the Minister's consent under section 20 of the Act in relation to a related product shall be \$5,500.
- (6) The fee to accompany an application made under section 23 of the Act for the Minister's provisional consent shall be \$8,437.
- (7) The fee to accompany a notice deposited with the Director-General under section 24 of the Act shall be \$3,200.
- (8) The fee to accompany an application made under section 30 of the Act for the approval of a clinical trial, and of the persons (in that section called investigators) who will conduct that trial, shall be \$9,843.
- (9) For the purposes of section 70(4) of the Act, the fee for a copy of a certificate of an analyst, or (as the case may be) a copy of a report made by an analyst in respect of a sample, shall be \$60.
- (10) For the purposes of section 97(1) of the Act, the fee for procuring a sample of any medicine and submitting it for analysis shall be \$600.
- (11) For the purposes of subclause (3), **not generally available** means not legally available other than pursuant to an exemption granted under any or all of sections 25, 26, 27, 28, 29, 30, 31, 32, 32A, or 33 of the Act.

Regulation 61: substituted, on 29 August 1991, by regulation 2 of the Medicines Regulations 1984, Amendment No 4 (SR 1991/134).

Regulation 61(1): substituted, on 21 August 2006, by regulation 5(1) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Regulation 61(3): amended, on 21 August 2006, by regulation 5(2) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Regulation 61(4): amended, on 21 August 2006, by regulation 5(3) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Regulation 61(6): amended, on 21 August 2006, by regulation 5(4) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Regulation 61(7): amended, on 21 August 2006, by regulation 5(5) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

Regulation 61(8): amended, on 21 August 2006, by regulation 5(6) of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

#### **61A Waiver and refund of fees**

- (1) The Director-General may, in a particular case or class of cases, waive or refund, in whole or in part, any fee otherwise payable under regulation 61.
- (2) In exercising his or her powers under subclause (1), the Director-General shall have regard to—
  - (a) the time reasonably required to consider any application made or notice given under the Act:
  - (b) the degree of complexity involved in considering any such application or notice:
  - (c) the interests of public health in New Zealand.

Regulation 61A: inserted, on 29 August 1991, by regulation 2 of the Medicines Regulations 1984, Amendment No 4 (SR 1991/134).

#### **61B Fees inclusive of goods and services tax**

The fees fixed by these regulations are inclusive of goods and services tax under the Goods and Services Tax Act 1985.

Regulation 61B: inserted, on 29 August 1991, by regulation 2 of the Medicines Regulations 1984, Amendment No 4 (SR 1991/134).

#### **62 Medical devices**

No person shall sell any medical device that is claimed to operate by inducing, concentrating, directing, or producing, or counteracting, screening, or giving protection from, any magnetic, galvanic, electric, electronic, radiation, or vibratory forces or effects unless—

- (a) such properties are, before or at the time of sale, quantitatively described to the purchaser in writing in terms that can be measured by scientific physical means; and
- (b) the medical device demonstrably has the properties claimed and described.

#### **63 Restriction on, and supervision of, compounding medicine**

- (1) A dispensary technician must not undertake any process of compounding a medicine.

- (2) The following persons may compound a medicine, but only if under the direct personal supervision of a pharmacist:
- (a) pharmacy graduates:
  - (b) pharmacy technicians:
  - (c) students:
  - (d) despite subclause (1), dispensary technicians who have served an apprenticeship in pharmacy under the Pharmacy Act 1939.

Regulation 63: substituted, on 19 December 2002, by regulation 6 of the Medicines Amendment Regulations (No 2) 2002 (SR 2002/374).

#### **64 Offences**

- (1) Every person commits an offence against these regulations who—
- (a) contravenes or fails to comply with any of the provisions of regulations 26(1), 26(2), 27, 28(3), 29, 30, 31(5), 32(1), 32(2), 33(1), 33(2), 33(3), 34, 35(1), 35(3), 35(7), 35(9), 35(10), 36, 37(1), 39, 39A(1), 40(1), 40A(2), 42(1), 42(3), 42(4), 44B(4), and 49(1); or
  - (b) fails to comply with any order made by the Director-General under regulation 50(1); or
  - (c) contravenes or fails to comply with any of the provisions of regulations 50(2), 52(3), 53(4), 55(1), 56(1), 56(3), 56(4), 57(1), 58, 62, and 63.
- (2) Every person who commits an offence against these regulations is liable on conviction to a fine not exceeding \$500.

Regulation 64(1)(a): amended, on 1 August 2011, by regulation 25(1) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 64(1)(a): amended, on 11 October 2001, by regulation 16 of the Medicines Amendment Regulations 2001 (SR 2001/232).

Regulation 64(1)(a): amended, on 18 September 1997, by regulation 2(2) of the Medicines Amendment Regulations 1997 (SR 1997/165).

Regulation 64(1)(c): amended, on 1 August 2011, by regulation 25(2) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 64(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

#### **65 Appeals to District Court**

- (1) Any occupier of premises in respect of which any decision has been made under regulation 31 by a Medical Officer of Health, may appeal against that decision to a District Court within 14 days after being notified in writing of the decision.
- (2) An appeal under this regulation shall be made by way of originating application in accordance with the District Courts Rules 2014, and shall be filed in the office of the court nearest to the place of business or employment of the appellant.



- (3) On hearing an appeal brought under this regulation, the court may confirm, reverse, or modify the decision made by the Medical Officer of Health, and the decision of the court on the appeal shall be final.

Regulation 65(2): amended, on 1 July 2014, by regulation 4 of the Medicines Amendment Regulations 2014 (LI 2014/165).

**65A Transitional provision arising from enactment of Medicines Amendment Regulations 2011**

- (1) Until 1 February 2012, it is sufficient compliance with the advertising requirements of regulations 8 and 11 to comply with regulations 8 and 11 as in force immediately before 1 August 2011.
- (2) For medicines and related products manufactured or imported before 1 September 2012, it is sufficient compliance with the labelling requirements of regulations 13 to 16, 19, 22, 23, and 37 to comply with regulations 13 to 16, 19, 20, 22, 23, and 37 as in force immediately before 1 August 2011.

Regulation 65A: inserted, on 1 August 2011, by regulation 26 of the Medicines Amendment Regulations 2011 (SR 2011/245).

**66 Revocations**

- (1) The regulations specified in Schedule 6 are hereby revoked.
- (2) *Amendment(s) incorporated in the Drug Tariff 1981 (SR 1981/171).*

## Schedule 1

### Prescription, restricted, and pharmacy-only medicines

r 3

Schedule 1: replaced, on 25 October 2018, by regulation 4 of the Medicines Amendment Regulations 2018 (LI 2018/179).

Every reference to a medicine in this schedule applies whether the medicine is synthetic in origin or is from biological or mineral sources.

Unless specific reference is made otherwise, every reference applies also to medicines that are—

- preparations and admixtures containing any proportion of any substance listed in this schedule:
- salts and esters of any substance listed in this schedule:
- preparations or extracts of biological materials listed in this schedule:
- salts or oxides of elements listed in this schedule.

Unless specific reference is made otherwise, every reference to a medicine in this schedule applies,—

- if the medicine is an injection or eye preparation, to any concentration of that medicine; and
- if the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram.

Where any reference is modified by a statement of the strength of the medicine, the strength is calculated using the free acid, base, alcohol, or element unless specifically stated otherwise.

### Part 1

#### Prescription medicines

Amending or replacing this Part may affect designated prescriber regulations under section 105(1)(q) of the Act.

- 1 19-norandrostenedione
- 2 2,4-dinitrochlorobenzene
- 3 4-aminopyridine
- 4 4-chloromethandienone
- 5 4-chlorotestosterone
- 6 5-aminolevulinic acid
- 7 Abacavir
- 8 Abatacept
- 9 Abciximab

- 10 Abiraterone
- 11 Abrus precatorius; at all strengths
- 12 Acamprosate
- 13 Acarbose
- 14 Acebutolol
- 15 Acepromazine
- 16 Acetanilides
- 17 Acetarsol
- 18 Acetazolamide
- 19 Acetohexamide
- 20 Acetylcarbromal
- 21 Acetylcholine; except in medicines containing 1 milligram or less per litre or per kilogram
- 22 Acetylcysteine; for injection or inhalation
- 23 Acetyldigitoxin
- 24 Acetylmethyldimethyloximidophenylhydrazine
- 25 Acetylstrophanthidin
- 26 Aciclovir; except when specified elsewhere in this schedule
- 27 Acipimox
- 28 Acitretin
- 29 Aclidinium bromide
- 30 Acokanthera ouabaio
- 31 Acokanthera schimperi
- 32 Aconitum spp; except when specified elsewhere in this schedule
- 33 Acrivastine
- 34 Adalimumab
- 35 Adapalene; except in medicines containing 1 milligram or less per millilitre or gram and when supplied by a pharmacist in a pack containing not more than 30 grams for the treatment of comedo, popular, and pustular acne (acne vulgaris) of the face, chest, or back
- 36 Adefovir
- 37 Adenosine; for injection
- 38 Adinazolam
- 39 Adiphenine
- 40 Adonis vernalis

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- 41 Adrafinil
  - 42 Adrenal extract; except for dermal use in medicines containing 0.02% or less of ketosteroids
  - 43 Adrenaline; in medicines containing more than 1%
  - 44 Adrenocortical hormones; except adrenal extract for dermal use containing 0.02% or less of ketosteroids
  - 45 Afamelanotide
  - 46 Afatinib
  - 47 Aflibercept
  - 48 Agalsidase
  - 49 Agomelatine
  - 50 Alatrofloxacin
  - 51 Albendazole
  - 52 Albumin; except human albumin
  - 53 Alclofenac
  - 54 Alclometasone; except when specified elsewhere in this schedule
  - 55 Alcohol; for injection in medicines containing more than 20%
  - 56 Alcuronium
  - 57 Aldesleukin
  - 58 Aldosterone; except in medicines containing 10 micrograms or less per litre or per kilogram
  - 59 Alectinib
  - 60 Alefacept
  - 61 Alemtuzumab
  - 62 Alendronic acid
  - 63 Alfacalcidol
  - 64 Alfentanil
  - 65 Alfuzosin
  - 66 Alglucerase
  - 67 Alglucosidase
  - 68 Alirocumab
  - 69 Aliskiren
  - 70 Alkyl sulfonals
  - 71 Allergens
  - 72 Allopurinol

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- 73 Allylisopropylacetylurea; at all strengths
  - 74 Allyloestrenol
  - 75 Alogliptin
  - 76 Aloracetam
  - 77 Alosetron
  - 78 Alpha<sub>1</sub>-proteinase inhibitor
  - 79 Alphadolone
  - 80 Alphaxalone
  - 81 Alprazolam
  - 82 Alprenolol
  - 83 Alprostadil
  - 84 Alseroxylon
  - 85 Alteplase
  - 86 Altretamine
  - 87 Amantadine
  - 88 Ambenonium
  - 89 Ambrisentan
  - 90 Ambucetamide
  - 91 Ambutonium
  - 92 Amcinonide
  - 93 Amethocaine; except when specified elsewhere in this schedule; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
  - 94 Amfebutamone
  - 95 Amfepramone
  - 96 Amidopyrine
  - 97 Amifampridine
  - 98 Amifostine
  - 99 Amikacin
  - 100 Amiloride
  - 101 Aminocaproic acid
  - 102 Aminoglutethimide
  - 103 Aminometradine
  - 104 Aminophenazone; at all strengths
  - 105 Aminophylline; except when specified elsewhere in this schedule

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- 106 Aminopterin
  - 107 Aminorex
  - 108 Aminosalicyclic acid
  - 109 Amiodarone
  - 110 Amiphenazole
  - 111 Amisometradine
  - 112 Amisulpride
  - 113 Amitriptyline
  - 114 Amlodipine
  - 115 Ammi visnaga
  - 116 Ammonium bromide
  - 117 Amobarbital
  - 118 Amodiaquine
  - 119 Amorolfine; except when specified elsewhere in this schedule; except in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
  - 120 Amoxapine
  - 121 Amoxicillin
  - 122 Amphomycin
  - 123 Amphotericin
  - 124 Ampicillin
  - 125 Amprenavir
  - 126 Amrinone
  - 127 Amsacrine
  - 128 Amygdalin; at all strengths
  - 129 Amyl nitrite; except when sold to a person who is appropriately authorised under the Health and Safety at Work Act 2015
  - 130 Amylocaine
  - 131 Anabolic steroids
  - 132 Anagrelide
  - 133 Anakinra
  - 134 Anastrozole
  - 135 Ancestim
  - 136 Anchusa officinalis; at all strengths
  - 137 Ancrod and its immunoglobulin antidote

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- 138 Androgenic and anabolic steroidal agents
  - 139 Androgens
  - 140 Androisoxazole
  - 141 Androstanolone
  - 142 Androstenediol
  - 143 Androstenedione
  - 144 Anecortave
  - 145 Angiotensinamide
  - 146 Anidulafungin
  - 147 Aniracetam
  - 148 Anistreplase
  - 149 Antazoline; except for ophthalmic use
  - 150 Antibiotic substances; except when specified elsewhere in this schedule
  - 151 Antigens
  - 152 Antihistamines; except when specified elsewhere in this schedule
  - 153 Antimony; except in medicines containing 1 milligram or less per litre or per kilogram
  - 154 Antisera; for injection
  - 155 AOD-9604
  - 156 Apalutamide
  - 157 Apixaban
  - 158 Apocynum spp
  - 159 Apomorphine; except in medicines containing 1 milligram or less per litre or per kilogram
  - 160 Apraclonidine
  - 161 Apremilast
  - 162 Aprepitant
  - 163 Apronal
  - 164 Aprotinin
  - 165 Arecoline
  - 166 Aripiprazole
  - 167 Aristolochia spp; at all strengths
  - 168 Aristolochic acid; at all strengths
  - 169 Armodafinil

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- 170 Arsenic; except in medicines containing 1 milligram or less per litre or per kilogram
- 171 Artemether
- 172 Artesunate
- 173 Articaine; except when used as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council
- 174 Asenapine
- 175 Asfotase alfa
- 176 Asparaginase
- 177 Aspirin; except when specified elsewhere in this schedule; for injection; when combined with caffeine, paracetamol, or salicylamide
- 178 Astemizole
- 179 Asunaprevir
- 180 Atamestane
- 181 Atazanavir
- 182 Atenolol
- 183 Atezolizumab
- 184 Atomoxetine
- 185 Atorvastatin
- 186 Atosiban
- 187 Atovaquone
- 188 Atracurium
- 189 Atropa belladonna; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less of total solanaceous alkaloids per litre or per kilogram
- 190 Atropine; except when specified elsewhere in this schedule; except when used as an antidote in a device designed for self-injection; except in medicines containing 300 micrograms or less per litre or per kilogram
- 191 Atropine methonitrate
- 192 Auranofin
- 193 Aurothiomalate sodium
- 194 Avanafil
- 195 Aviptadil
- 196 Axitinib
- 197 Azacitidine
- 198 Azacyclonol



- 199 Azapropazone
- 200 Azaribine
- 201 Azatadine; except when specified elsewhere in this schedule
- 202 Azathioprine
- 203 Azelaic acid; except when specified elsewhere in this schedule
- 204 Azelastine; except when specified elsewhere in this schedule
- 205 Azithromycin
- 206 Azlocillin
- 207 Aztreonam
- 208 Bacampicillin
- 209 Bacitracin
- 210 Baclofen
- 211 Balsalazide
- 212 Bambuterol
- 213 Bamethan
- 214 Bamipine
- 215 Barbitol
- 216 Barbiturates
- 217 Basiliximab
- 218 Bazedoxifene
- 219 Becaplermin
- 220 Beclamide
- 221 Beclomethasone; except when specified elsewhere in this schedule
- 222 Bedaquiline
- 223 Belatacept
- 224 Belimumab
- 225 Bemegride
- 226 Benactyzine
- 227 Benazepril
- 228 Bendamustine
- 229 Bendrofluazide
- 230 Benethamine penicillin
- 231 Benorylate
- 232 Benoxaprofen
- 233 Benperidol

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- 234 Benserazide
  - 235 Benzathine penicillin
  - 236 Benzatropine
  - 237 Benzbromarone
  - 238 Benzhexol
  - 239 Benzilonium
  - 240 Benzocaine; except when specified elsewhere in this schedule
  - 241 Benzodiazepine derivatives; except when specified elsewhere in this schedule
  - 242 Benzodiazepines; except when specified elsewhere in this schedule
  - 243 Benzoyl metronidazole
  - 244 Benzoyl peroxide; except when specified elsewhere in this schedule
  - 245 Benzthiazide
  - 246 Benzydamine; except when specified elsewhere in this schedule
  - 247 Benzylpenicillin
  - 248 Bepridil
  - 249 Beractant
  - 250 Besifloxacin
  - 251 Beta carotene; in medicines containing more than 18 milligrams per recommended daily dose
  - 252 Betahistine
  - 253 Betaine; for the treatment of homocystinuria
  - 254 Betamethasone
  - 255 Betaxolol
  - 256 Bethanechol
  - 257 Bethanidine
  - 258 Bevacizumab
  - 259 Bevantolol
  - 260 Bexarotene
  - 261 Bezafibrate
  - 262 Bezlotoxumab
  - 263 Bicalutamide
  - 264 Bictegravir
  - 265 Bifonazole; except when specified elsewhere in this schedule
  - 266 Bilastine; except when specified elsewhere in this schedule
  - 267 Bimatoprost

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- 268 Binimetinib
  - 269 Biperiden
  - 270 Bismuth; except for external use in medicines containing 3% or less
  - 271 Bisoprolol
  - 272 Bithionol; at all strengths
  - 273 Bivalirudin
  - 274 Bleomycin
  - 275 Boceprevir
  - 276 Bolandiol
  - 277 Bolasterone
  - 278 Bolazine
  - 279 Boldenone
  - 280 Bolenol
  - 281 Bolmantalate
  - 282 Boron, including borax and boric acid; except in medicines for internal use containing 6 milligrams or less per recommended daily dose; except in medicines for dermal use other than paediatric use containing 0.35% or less; except when present as an excipient
  - 283 Bortezomib
  - 284 Bosentan
  - 285 Bosutinib
  - 286 Botulinum toxins
  - 287 Brentuximab vedotin
  - 288 Bretylium
  - 289 Brexpiprazole
  - 290 Brimonidine
  - 291 Brinzolamide
  - 292 Brivaracetam (and its stereoisomers)
  - 293 Bromazepam
  - 294 Bromocriptine
  - 295 Bromoform
  - 296 Brompheniramine; except when specified elsewhere in this schedule
  - 297 Bromvaletone
  - 298 Brotizolam
  - 299 Brugmansia spp

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- 300 Buclizine; except for oral use
  - 301 Budesonide; except when specified elsewhere in this schedule
  - 302 Bufexamac; except in suppositories; except for dermal use in medicines containing 5% or less
  - 303 Bumetanide
  - 304 Buniodyl sodium; at all strengths
  - 305 Buphenine
  - 306 Bupivacaine
  - 307 Buprenorphine
  - 308 Bupropion
  - 309 Buserelin
  - 310 Buspirone
  - 311 Busulphan
  - 312 Butacaine
  - 313 Butobarbital
  - 314 Butoconazole; except for vaginal use
  - 315 Butorphanol
  - 316 Butyl aminobenzoate; except in medicines for dermal use containing 2% or less
  - 317 Butyl nitrite
  - 318 Butylchloral hydrate
  - 319 Cabazitaxel
  - 320 Cabergoline
  - 321 Cabozantinib
  - 322 Cacalia spp; at all strengths
  - 323 Cadmium
  - 324 Calcipotriol; except in medicines containing not more than 50 micrograms per gram or per millilitre and when sold in a pack of not more than 30 grams or 30 millilitres by a pharmacist to an adult with mild to moderate psoriasis previously diagnosed by a doctor
  - 325 Calcitonin
  - 326 Calcitriol
  - 327 Calcium carbimide
  - 328 Calcium polystyrene sulphonate
  - 329 Calotropis gigantea
  - 330 Calotropis procera

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- 331 Calusterone
  - 332 Camazepam
  - 333 Camphorated oil
  - 334 Camphotamide
  - 335 Canagliflozin
  - 336 Canakinumab
  - 337 Candesartan
  - 338 Candicidin
  - 339 Cannabidiol
  - 340 Capecitabine
  - 341 Capreomycin
  - 342 Captodiame
  - 343 Captopril
  - 344 Capuride
  - 345 Caramiphen
  - 346 Carbachol
  - 347 Carbamazepine
  - 348 Carbaryl; except for external use in medicines containing 2% or less
  - 349 Carbazochrome
  - 350 Carbenicillin
  - 351 Carbenoxolone; except for external use
  - 352 Carbetocin
  - 353 Carbidopa
  - 354 Carbimazole
  - 355 Carbocromen
  - 356 Carboplatin
  - 357 Carboprost
  - 358 Carbromal
  - 359 Carbutamide
  - 360 Carbuterol
  - 361 Carfilzomib
  - 362 Carglumic acid
  - 363 Carindacillin
  - 364 Carisoprodol
  - 365 Carmustine

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- 366 Carprofen
  - 367 Carvedilol
  - 368 Caspofungin
  - 369 Catumaxomab
  - 370 Cebaracetam (and its stereoisomers)
  - 371 Cefacetrile
  - 372 Cefaclor
  - 373 Cefaloridine
  - 374 Cefamandole
  - 375 Cefapirin
  - 376 Cefazolin
  - 377 Cefepime
  - 378 Cefetamet
  - 379 Cefixime
  - 380 Cefodizime
  - 381 Cefonicid
  - 382 Cefoperazone
  - 383 Cefotaxime
  - 384 Cefotetan
  - 385 Cefotiam
  - 386 Cefoxitin
  - 387 Cefpirome
  - 388 Cefpodoxime
  - 389 Cefsulodin
  - 390 Ceftaroline fosamil
  - 391 Ceftazidime
  - 392 Ceftibuten
  - 393 Ceftolozane
  - 394 Ceftriaxone
  - 395 Cefuroxime
  - 396 Celecoxib
  - 397 Celiprolol
  - 398 Cephaelis acuminata; except in medicines containing less than 0.2% of emetine
  - 399 Cephaelis ipecacuanha; except in medicines containing less than 0.2% of emetine

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- 400 Cephalexin
  - 401 Cephalothin
  - 402 Cephradine
  - 403 Ceritinib
  - 404 Cerivastatin
  - 405 Certolizumab pegol
  - 406 Ceruletide
  - 407 Cetirizine; except when specified elsewhere in this schedule
  - 408 Cetrorelix
  - 409 Cetuximab
  - 410 Chenodeoxycholic acid
  - 411 Chloral hydrate; except for dermal use in medicines containing 2% or less
  - 412 Chloralformamide
  - 413 Chloralose
  - 414 Chlorambucil
  - 415 Chloramphenicol; except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except when specified elsewhere in this schedule
  - 416 Chlorandrostenolone
  - 417 Chlorazanil
  - 418 Chlorcyclizine
  - 419 Chlordiazepoxide
  - 420 Chlormerodrin
  - 421 Chlormethiazole
  - 422 Chlormezanone
  - 423 Chloroform; for anaesthesia; except when specified elsewhere in this schedule
  - 424 Chloroquine
  - 425 Chlorothiazide
  - 426 Chlorotrianisene
  - 427 Chloroxydienone
  - 428 Chloroxymesterone
  - 429 Chlorpheniramine; except when specified elsewhere in this schedule
  - 430 Chlorphentermine
  - 431 Chlorpromazine
  - 432 Chlorpropamide

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- 433 Chlorprothixene
  - 434 Chlorquinaldol
  - 435 Chlortetracycline
  - 436 Chlorthalidone
  - 437 Chlorzoxazone
  - 438 Cholera vaccine; except in the form of an oral liquid containing vibrio cholerae when sold in a pharmacy by a registered pharmacist
  - 439 Cholic acid
  - 440 Choline salicylate; except in medicines containing 10% or less and in pack sizes of 15 grams or less
  - 441 Chorionic gonadotrophin; except in pregnancy test kits
  - 442 Chymopapain
  - 443 Ciclacillin
  - 444 Ciclesonide
  - 445 Ciclopirox; except when specified elsewhere in this schedule
  - 446 Cidofovir
  - 447 Cilastatin
  - 448 Cilazapril
  - 449 Cilostazol
  - 450 Cimetidine; except when specified elsewhere in this schedule
  - 451 Cinacalcet
  - 452 Cinchocaine; for injection; for ophthalmic use; for external use in medicines containing more than 0.5%
  - 453 Cinchophen
  - 454 Cinnarizine
  - 455 Cinoxacin
  - 456 Ciprofloxacin
  - 457 Cisapride
  - 458 Cisatracurium
  - 459 Cisplatin
  - 460 Citalopram
  - 461 CJC-1295
  - 462 Cladribine
  - 463 Clarithromycin
  - 464 Clavulanic acid



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- 465 Clemastine; except for oral use
  - 466 Clemizole
  - 467 Clenbuterol
  - 468 Clevidipine
  - 469 Clidinium
  - 470 Clindamycin
  - 471 Clioquinol; at all strengths
  - 472 Clobazam
  - 473 Clobetasol
  - 474 Clobetasone; except when specified elsewhere in this schedule
  - 475 Clocortolone
  - 476 Clodronic acid
  - 477 Clofarabine
  - 478 Clofazimine
  - 479 Clofenamide
  - 480 Clofibrate
  - 481 Clomiphene
  - 482 Clomipramine
  - 483 Clomocycline
  - 484 Clonazepam
  - 485 Clonidine
  - 486 Clopamide
  - 487 Clopidogrel
  - 488 Clorazepic acid
  - 489 Clorexolone
  - 490 Clorprenaline
  - 491 Clostebol
  - 492 Clotiazepam
  - 493 Clotrimazole; except when specified elsewhere in this schedule
  - 494 Cloxacillin
  - 495 Cloxazolam
  - 496 Clozapine
  - 497 Cobalt
  - 498 Cobicistat
  - 499 Cobimetinib

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- 500 Cocaine; except when specified elsewhere in this schedule
- 501 Codeine; except when specified elsewhere in this schedule
- 502 Co-dergocrine
- 503 Colaspase
- 504 Colchicine
- 505 Colchicum
- 506 Colecalciferol; except in medicines containing 25 micrograms or less per recommended daily dose; except in parenteral nutrition replacement preparations
- 507 Colestipol
- 508 Colestyramine
- 509 Colfosceril
- 510 Colistin
- 511 Collagen; in injections or implants for tissue augmentation or cosmetic use
- 512 Collagenase clostridium histolyticum
- 513 Coluracetam
- 514 Conium maculatum; at all strengths
- 515 Convallaria keiski
- 516 Convallaria majalis
- 517 Corifollitropin alfa
- 518 Coronilla spp
- 519 Corticosterone
- 520 Corticotrophin
- 521 Cortisone and other steroidal hormones of the adrenal cortex; except when specified elsewhere in this schedule; except adrenal extract for dermal use in medicines containing 0.02% or less of ketosteroids
- 522 Cotarnine; at all strengths
- 523 Co-trimoxazole
- 524 Coumarin
- 525 Crizotinib
- 526 Crofelemer
- 527 Crotalaria spp; at all strengths
- 528 Croton tiglium; except in medicines containing 1 milligram or less per litre or per kilogram
- 529 Crystal violet
- 530 Curare

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- 531 Cyclandelate
  - 532 Cyclizine; except when specified elsewhere in this schedule
  - 533 Cyclobenzaprine
  - 534 Cyclofenil
  - 535 Cycloheximide
  - 536 Cyclopenthiazide
  - 537 Cyclopentolate; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
  - 538 Cyclophosphamide
  - 539 Cyclopropane
  - 540 Cycloserine
  - 541 Cyclosporin
  - 542 Cyclothiazide
  - 543 Cycrimine
  - 544 Cymarin
  - 545 Cynoglossum spp; at all strengths
  - 546 Cyproheptadine; except for oral use
  - 547 Cyproterone
  - 548 Cysteamine
  - 549 Cytarabine
  - 550 Dabigatran
  - 551 Dabrafenib mesilate
  - 552 Dacarbazine
  - 553 Daclatasvir
  - 554 Daclizumab
  - 555 Dactinomycin
  - 556 Dalfopristin
  - 557 Dalteparin
  - 558 Danaparoid
  - 559 Danazol
  - 560 Danthron
  - 561 Dantrolene
  - 562 Dapagliflozin
  - 563 Dapoxetine
  - 564 Dapsone

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- 565 Daptomycin  
566 Daratumumab  
567 Darbepoetin  
568 Darifenacin  
569 Darunavir  
570 Dasabuvir  
571 Dasatinib  
572 Datura spp; except for oral use when specified elsewhere in this schedule;  
except datura stramonium or datura tatula for smoking or burning  
573 Daunorubicin  
574 Deanol  
575 Debrisoquine  
576 Decamethonium  
577 Deferasirox  
578 Deferiprone  
579 Defibrotide  
580 Deflazacort  
581 Degarelix  
582 Dehydrochloromethyltestosterone  
583 Dehydrocorticosterone  
584 Delavirdine  
585 Delorazepam  
586 Demecarium  
587 Demeclocycline  
588 Denosumab  
589 Deoxycortone  
590 Deoxycholic acid; for injection; except for oral use  
591 Deoxyribonuclease; except for external use  
592 Dermatophagoides farina allergen extract  
593 Dermatophagoides pteronyssinus allergen extract  
594 Desferrioxamine  
595 Desflurane  
596 Desipramine  
597 Desirudin  
598 Deslanoside

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- 599 Desloratadine; except for oral use
- 600 Deslorelin
- 601 Desmopressin
- 602 Desogestrel; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand Incorporated approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme
- 603 Desonide
- 604 Desoximetasone
- 605 Desvenlafaxine
- 606 Dexamethasone
- 607 Dexamfetamine
- 608 Dexchlorpheniramine; except when specified elsewhere in this schedule
- 609 Dexfenfluramine
- 610 Dexmedetomidine
- 611 Dextromethorphan; except when specified elsewhere in this schedule
- 612 Dextromoramide
- 613 Dextropropoxyphene
- 614 Dextrorphan
- 615 Di-iodohydroxy quinoline; except when specified elsewhere in this schedule
- 616 Di-isopropylamine dichloroacetate
- 617 Diazepam
- 618 Diazoxide
- 619 Dibenzepin
- 620 Dibotermine
- 621 Dibrompropamide; except for ophthalmic use
- 622 Dichloralphenazone
- 623 Dichlorophen
- 624 Dichlorphenamide
- 625 Diclofenac; in preparations for the treatment of solar keratosis; except when specified elsewhere in this schedule; except in preparations for topical use other than for the treatment of solar keratosis
- 626 Dicloxacin

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- 627 Dicyclomine
  - 628 Didanosine
  - 629 Dienoestrol
  - 630 Dienogest
  - 631 Diethazine
  - 632 Diethylcarbamazine
  - 633 Diethylstilbestrol
  - 634 Diflorasone
  - 635 Diflucortolone
  - 636 Diflunisal
  - 637 Digitalis lanata
  - 638 Digitalis purpurea
  - 639 Digitoxin
  - 640 Digoxin
  - 641 Digoxin-specific antibody fragment
  - 642 Dihydralazine
  - 643 Dihydrocodeine
  - 644 Dihydroergotoxine
  - 645 Dihydrolone
  - 646 Dihydrotachysterol
  - 647 Diltiazem
  - 648 Dimenhydrinate; except when specified elsewhere in this schedule
  - 649 Dimercaprol
  - 650 Dimethandrostanolone
  - 651 Dimethazine
  - 652 Dimethindene; except for oral use
  - 653 Dimethothiazine
  - 654 Dimethoxanate
  - 655 Dimethyl fumarate
  - 656 Dimethyl sulphoxide
  - 657 Dimiracetam (and its stereoisomers)
  - 658 Dinitrocresols
  - 659 Dinitronaphthols
  - 660 Dinitrophenols
  - 661 Dinitrothymols

- 662 Dinoprost
- 663 Dinoprostone
- 664 Dipiperdon
- 665 Diphemanil; except for dermal use
- 666 Diphenhydramine; except when specified elsewhere in this schedule
- 667 Diphenidol
- 668 Diphenoxylate; except when specified elsewhere in this schedule
- 669 Diphenylpyraline
- 670 Diphtheria, tetanus and pertussis (acellular, component) vaccine; except when administered in a single dose to a person 18 years of age or over or to a pregnant woman aged 13 years or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health
- 671 Diphtheria toxoid
- 672 Diphtheria vaccine
- 673 Dipivefrin
- 674 Dipyridamole
- 675 Dirithromycin
- 676 Disopyramide
- 677 Distigmine
- 678 Disulfiram
- 679 Disulphamide
- 680 Ditiocarb
- 681 Dobutamine
- 682 Docetaxel
- 683 Dofetilide
- 684 Dolasetron
- 685 Doliracetam (and its stereoisomers)
- 686 Dolutegravir
- 687 Domperidone
- 688 Donepezil
- 689 Dopamine
- 690 Dopexamine
- 691 Doripenem
- 692 Dornase

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- 693 Dorzolamide  
694 Dothiepin  
695 Doxantrazole  
696 Doxapram  
697 Doxazosin  
698 Doxepin  
699 Doxorubicin  
700 Doxycycline  
701 Doxylamine; except when specified elsewhere in this schedule  
702 Dronedarone  
703 Droperidol  
704 Drospirenone  
705 Drostanolone  
706 Drotrecogin  
707 Duboisia leichhardtii; except when specified elsewhere in this schedule  
708 Duboisia myoporides; except when specified elsewhere in this schedule  
709 Dulcin; at all strengths  
710 Duloxetine  
711 Dupilumab  
712 Dupracetam  
713 Dutasteride  
714 Dydrogesterone  
715 Econazole; except when specified elsewhere in this schedule  
716 Ecothiopate  
717 Ectylurea  
718 Eculizumab  
719 Edetic acid; except in medicines containing 0.25% or less; except in contact lens preparations; except dicobalt edetate for the treatment of cyanide poisoning  
720 Edoxudine  
721 Edrophonium  
722 Efalizumab  
723 Efavirenz  
724 Eflornithine  
725 Elbasvir



- 726 Eletriptan
- 727 Elosulfase alfa
- 728 Elotuzumab
- 729 Eltrombopag olamine
- 730 Eluxadoline
- 731 Elvitegravir
- 732 Emepromium
- 733 Emetine; except in medicines containing 0.2% or less
- 734 Emicizumab
- 735 Empagliflozin
- 736 Emtricitabine
- 737 Enalapril
- 738 Encorafenib
- 739 Enestebol
- 740 Enflurane
- 741 Enfuvirtide
- 742 Enobosarm
- 743 Enoxacin
- 744 Enoxaparin
- 745 Enoximone
- 746 Enprostil
- 747 Entacapone
- 748 Entecavir
- 749 Enzalutamide
- 750 Ephedrine
- 751 Epicillin
- 752 Epinastine
- 753 Epirubicin
- 754 Epiteostanol
- 755 Eplerenone
- 756 Epoetins
- 757 Epoprostenol
- 758 Eprosartan
- 759 Eptifibatide
- 760 Erenumab

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- 761 Ergocalciferol; except in medicines containing 25 micrograms or less per recommended daily dose
- 762 Ergometrine
- 763 Ergot
- 764 Ergotamine
- 765 Ergotoxine
- 766 Eribulin
- 767 Erlotinib
- 768 Ertapenem
- 769 Ertugliflozin
- 770 Erysimum spp; except in medicines containing 1 milligram or less per litre or per kilogram
- 771 Erythromycin
- 772 Erythropoietin
- 773 Escitalopram
- 774 Esmolol
- 775 Esomeprazole; except when specified elsewhere in this schedule
- 776 Estazolam
- 777 Estramustine
- 778 Estropipate
- 779 Etanercept
- 780 Ethacrynic acid
- 781 Ethambutol
- 782 Ethamivan
- 783 Ethanolamine; for injection
- 784 Ethchlorvynol
- 785 Ether; for anaesthesia; except when specified elsewhere in this schedule
- 786 Ethinamate
- 787 Ethinyloestradiol; except when supplied at a strength of 35 micrograms or less in combination with either levonorgestrel or norethisterone for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand Incorporated approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

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- 788 Ethionamide
  - 789 Ethisterone
  - 790 Ethoglucid
  - 791 Ethoheptazine
  - 792 Ethopropazine
  - 793 Ethosuximide
  - 794 Ethotoin
  - 795 Ethoxzolamide
  - 796 Ethyl chloride; for inhalation
  - 797 Ethyl loflazepate
  - 798 Ethyldienolone
  - 799 Ethylhexanediol; at all strengths
  - 800 Ethyloestrenol
  - 801 Ethynodiol
  - 802 Etidocaine
  - 803 Etidronic acid; except in medicines for external use containing 1% or less
  - 804 Etilefrine
  - 805 Etiracetam
  - 806 Etodolac
  - 807 Etofenamate; except for external use
  - 808 Etomidate
  - 809 Etonogestrel
  - 810 Etoposide
  - 811 Etoricoxib
  - 812 Etravirine
  - 813 Etrexinate
  - 814 Everolimus
  - 815 Evolocumab
  - 816 Exemestane
  - 817 Exenatide
  - 818 Ezetimibe
  - 819 Factor VIII inhibitor bypassing fraction
  - 820 Famciclovir; except when specified elsewhere in this schedule
  - 821 Famotidine; except when specified elsewhere in this schedule
  - 822 Fampridine

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- 823 Farfugium japonicum; at all strengths
  - 824 Fasoracetam (and its stereoisomers)
  - 825 Febuxostat
  - 826 Felbamate
  - 827 Felbinac; except for external use
  - 828 Felodipine
  - 829 Felypressin; except when combined with a local anaesthetic and used in practice by a dental therapist or oral health therapist registered with the Dental Council
  - 830 Fenbufen
  - 831 Fenclofenac
  - 832 Fenfluramine
  - 833 Fenofibrate
  - 834 Fenoldopam
  - 835 Fenoprofen
  - 836 Fenoterol
  - 837 Fenpipramide
  - 838 Fenpiprane
  - 839 Fentanyl
  - 840 Ferric carboxymaltose
  - 841 Ferric derisomaltose
  - 842 Fexofenadine; except when specified elsewhere in this schedule
  - 843 Fibrin
  - 844 Fibrinolysin; except for external use
  - 845 Fibroblast growth factor
  - 846 Fidaxomicin
  - 847 Filgrastim
  - 848 Finasteride
  - 849 Fingolimod
  - 850 Flecainide
  - 851 Fleroxacin
  - 852 Floctafenine
  - 853 Fluanisone
  - 854 Flubromazolam
  - 855 Fluclorolone

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- 856 Flucloxacillin
  - 857 Fluconazole; except when specified elsewhere in this schedule
  - 858 Flucytosine
  - 859 Fludarabine
  - 860 Fludiazepam
  - 861 Fludrocortisone
  - 862 Flufenamic acid
  - 863 Flumazenil
  - 864 Flumethasone
  - 865 Flumethiazide
  - 866 Flunarizine
  - 867 Flunisolide
  - 868 Flunitrazepam
  - 869 Fluocinolone
  - 870 Fluocinonide
  - 871 Fluocortin
  - 872 Fluocortolone
  - 873 Fluorescein; for injection
  - 874 Fluorides; for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council
  - 875 Fluorometholone
  - 876 Fluorouracil
  - 877 Fluoxetine
  - 878 Fluoxymesterone
  - 879 Flupenthixol
  - 880 Fluphenazine
  - 881 Flurandrenolone
  - 882 Flurazepam
  - 883 Flurbiprofen; except when specified elsewhere in this schedule
  - 884 Fluoxetine
  - 885 Fluspirilene
  - 886 Flutamide

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- 887 Fluticasone; except when specified elsewhere in this schedule
- 888 Fluvastatin
- 889 Fluvoxamine
- 890 Folic acid; except when specified elsewhere in this schedule
- 891 Folinic acid; except when specified elsewhere in this schedule
- 892 Follicle-stimulating hormone; except in medicines containing 100 micrograms or less per litre or per kilogram
- 893 Follistatin
- 894 Follitropin
- 895 Follitropin delta
- 896 Fomepizole
- 897 Fomivirsen
- 898 Fondaparinux
- 899 Fonturacetam (and its stereoisomers)
- 900 Formebolone
- 901 Formestane
- 902 Formoterol
- 903 Fosamprenavir
- 904 Fosaprepitant
- 905 Foscarnet
- 906 Fosfestrol
- 907 Fosfomycin
- 908 Fosinopril
- 909 Fosphenytoin
- 910 Fotemustine
- 911 Framycetin
- 912 Fulvestrant
- 913 Furaltadone
- 914 Furazabol
- 915 Furazolidone
- 916 Furosemide
- 917 Fusidic acid
- 918 Gabapentin
- 919 Galantamine
- 920 Galanthus spp

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- 921 Gallamine
  - 922 Galsulfase
  - 923 Ganciclovir
  - 924 Ganirelix
  - 925 Gatifloxacin
  - 926 Gefitinib
  - 927 Gemcitabine
  - 928 Gemeprost
  - 929 Gemfibrozil
  - 930 Gemifloxacin
  - 931 Gemtuzumab ozogamicin
  - 932 Gentamicin
  - 933 Gestodene
  - 934 Gestonorone
  - 935 Gestrinone
  - 936 Ghrelin
  - 937 Gitalin
  - 938 Glatiramer acetate
  - 939 Glecaprevir
  - 940 Glibenclamide
  - 941 Glibornuride
  - 942 Gliclazide
  - 943 Glimepiride
  - 944 Glipizide
  - 945 Glisoxepide
  - 946 Glutathione; for injection
  - 947 Glyceryl trinitrate; for injection; for transdermal use; except in medicines containing 100 micrograms or less per litre or per kilogram
  - 948 Glycopyrronium
  - 949 Glymidine
  - 950 Golimumab
  - 951 Gonadorelin
  - 952 Gonadotrophic hormones; except when specified elsewhere in this schedule
  - 953 Goserelin
  - 954 Gramicidin

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- 955 Granisetron  
956 Grazoprevir  
957 Grepafloxacin  
958 Griseofulvin  
959 Growth hormone releasing hormones  
960 Growth hormone releasing peptide-6  
961 Growth hormone releasing peptides  
962 Guaifenesin; except when specified elsewhere in this schedule  
963 Guanabenz  
964 Guanethidine  
965 Guanfacine  
966 Guanidine  
967 Guselkumab  
968 Hachimycin  
969 Haematin  
970 Haemophilus influenzae vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds  
971 Halazepam  
972 Halcinonide  
973 Halofantrine  
974 Halofenate  
975 Haloperidol; except in medicines containing 1 milligram or less per litre or per kilogram  
976 Halothane  
977 Haloxazolam  
978 Halquinol; except for external use  
979 Heliotropium spp; at all strengths  
980 Hemerocallis  
981 Heparins; except when present as an excipient; except for external use  
982 Hepatitis A vaccine  
983 Hepatitis B vaccine  
984 Hetacillin  
985 Hexachlorophane; in medicines containing more than 3%; except when specified elsewhere in this schedule  
986 Hexamethonium



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- 987 Hexarelin
  - 988 Hexetidine; except for external use
  - 989 Hexobendine
  - 990 Hexocyclium
  - 991 Hexoprenaline
  - 992 Hexaminolevulinate
  - 993 Histamine; except in medicines containing 0.5% or less
  - 994 Homatropine
  - 995 Human chorionic gonadotrophin; except in pregnancy test kits
  - 996 Human growth hormone secretagogues
  - 997 Human papillomavirus vaccine
  - 998 Human protein C
  - 999 Hyaluronic acid; in injections or implants for tissue augmentation or cosmetic use
  - 1000 Hydralazine
  - 1001 Hydrargaphen
  - 1002 Hydrochlorothiazide
  - 1003 Hydrocortisone; except when specified elsewhere in this schedule
  - 1004 Hydrocyanic acid; except when specified elsewhere in this schedule
  - 1005 Hydroflumethiazide
  - 1006 Hydromorphone
  - 1007 Hydroquinone; except when specified elsewhere in this schedule
  - 1008 Hydroxychloroquine
  - 1009 Hydroxyephedrine
  - 1010 Hydroxyphenamate
  - 1011 Hydroxyprogesterone
  - 1012 Hydroxystenozol
  - 1013 Hydroxyurea
  - 1014 Hydroxyzine
  - 1015 Hylan polymer; in injections or implants for tissue augmentation or cosmetic use
  - 1016 Hyoscine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram
  - 1017 Hyoscine butylbromide; except when specified elsewhere in this schedule

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- 1018 Hyoscyamine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram
  - 1019 Hyoscyamus niger; except when specified elsewhere in this schedule
  - 1020 Hypothalamic releasing factors
  - 1021 Hypromellose; for injection; except in intraocular viscoelastic products
  - 1022 Ibandronic acid
  - 1023 Ibogaine
  - 1024 Ibritumomab tiuxetan
  - 1025 Ibrutinib
  - 1026 Ibufenac
  - 1027 Ibuprofen; except when specified elsewhere in this schedule
  - 1028 Ibuprofen
  - 1029 Ibutilide
  - 1030 Icatibant
  - 1031 Idarubicin
  - 1032 Idarucizumab
  - 1033 Idebenone
  - 1034 Idelalisib
  - 1035 Idoxuridine; except for dermal use in medicines containing 0.5% or less
  - 1036 Idursulfase
  - 1037 Ifosfamide
  - 1038 Iloprost
  - 1039 Imatinib
  - 1040 Imiglucerase
  - 1041 Imipenem
  - 1042 Imipramine
  - 1043 Imiquimod
  - 1044 Immunoglobulins
  - 1045 Imuracetam
  - 1046 Indacaterol
  - 1047 Indapamide
  - 1048 Indinavir
  - 1049 Indomethacin; except when specified elsewhere in this schedule
  - 1050 Indoprofen
  - 1051 Indoramin

- 1052 Infliximab
- 1053 Influenza and coryza vaccines; for injection; for nasal use
- 1054 Influenza vaccine; except when administered to a person 13 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health
- 1055 Ingenol mebutate
- 1056 Insulin degludec
- 1057 Insulin-like growth factors; except when specified elsewhere in this schedule
- 1058 Insulins
- 1059 Interferons
- 1060 Interleukins
- 1061 Iodothiouracil
- 1062 Ipamorelin
- 1063 Ipecacuanha; except when specified elsewhere in this schedule
- 1064 Ipilimumab
- 1065 Ipratropium; except for nasal use
- 1066 Ipriflavone
- 1067 Iprindole
- 1068 Iproniazid
- 1069 Irbesartan
- 1070 Irinotecan
- 1071 Iron; except when specified elsewhere in this schedule
- 1072 Isoaminile
- 1073 Isoamyl nitrite
- 1074 Isobutyl nitrite
- 1075 Isocarboxazid
- 1076 Isoconazole; except when specified elsewhere in this schedule
- 1077 Isoetarine
- 1078 Isoflurane
- 1079 Isometheptene
- 1080 Isoniazid
- 1081 Isoprenaline
- 1082 Isoprinosine
- 1083 Isopropamide; except when specified elsewhere in this schedule

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- 1084 Isosorbide dinitrate
  - 1085 Isosorbide mononitrate
  - 1086 Isotretinoin
  - 1087 Isoxicam
  - 1088 Isoxsuprine
  - 1089 Isradipine
  - 1090 Itraconazole
  - 1091 Ivabradine
  - 1092 Ivacaftor
  - 1093 Ivermectin
  - 1094 Ixabepilone
  - 1095 Ixazomib
  - 1096 Ixekizumab
  - 1097 Japanese encephalitis vaccine
  - 1098 Juniperus sabina; at all strengths
  - 1099 Kanamycin
  - 1100 Ketamine
  - 1101 Ketanserin
  - 1102 Ketazolam
  - 1103 Ketoconazole; except when specified elsewhere in this schedule
  - 1104 Ketoprofen; except when specified elsewhere in this schedule
  - 1105 Ketorolac
  - 1106 Ketotifen; except for ophthalmic use in medicines containing 0.025% or less
  - 1107 Khellin
  - 1108 Labetalol
  - 1109 Lacidipine
  - 1110 Lacosamide
  - 1111 Lamivudine
  - 1112 Lamotrigine
  - 1113 Lanatosides
  - 1114 Lanreotide
  - 1115 Lansoprazole; except when specified elsewhere in this schedule
  - 1116 Lanthanum
  - 1117 Lapatinib
  - 1118 Laronidase-rch

- 1119 Laropiprant
- 1120 Latamoxef
- 1121 Latanoprost
- 1122 Laudexium
- 1123 Lauromacrogols; for injection
- 1124 Lead
- 1125 Ledipasvir
- 1126 Lefetamine
- 1127 Leflunomide
- 1128 Lenalidomide
- 1129 Lenograstim
- 1130 Lenvatinib
- 1131 Lepirudin
- 1132 Leptazol
- 1133 Lercanidipine
- 1134 Lesinurad
- 1135 Letermovir
- 1136 Letrozole
- 1137 Leucovorin; for injection
- 1138 Leuprorelin
- 1139 Levallorphan
- 1140 Levamisole
- 1141 Levetiracetam
- 1142 Levobunolol
- 1143 Levobupivacaine
- 1144 Levocabastine; except for nasal or ophthalmic use
- 1145 Levocetirizine; except for oral use
- 1146 Levodopa
- 1147 Levomepromazine
- 1148 Levomilnacipran
- 1149 Levonorgestrel; except when specified elsewhere in this schedule; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health; except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health; except when supplied for oral contraception to women who meet the

clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand Incorporated approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

- 1150 Levosimendan
- 1151 Lidoflazine
- 1152 Lidocaine; for injection except when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatrists Board or by a dental therapist or an oral health therapist registered with the Dental Council; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use except in throat lozenges containing 30 milligrams or less per dose form; for external use in medicines containing more than 10%; except in throat sprays in medicines containing 2% or less; except when specified elsewhere in this schedule
- 1153 Ligularia dentata; at all strengths
- 1154 Linagliptin
- 1155 Lincomycin
- 1156 Lindane; except for external use in medicines containing 2% or less
- 1157 Linezolid
- 1158 Liothyronine
- 1159 Lipegfilgrastim
- 1160 Liraglutide
- 1161 Lisdexamfetamine
- 1162 Lisinopril
- 1163 Lisuride
- 1164 Lithium; except when specified elsewhere in this schedule; except when present as an excipient in dermal medicines containing 0.25% or less
- 1165 Lixisenatide
- 1166 Lodoxamide; except in medicines for ophthalmic use
- 1167 Lofexidine
- 1168 Lomefloxacin
- 1169 Lomustine
- 1170 Loperamide; except when specified elsewhere in this schedule
- 1171 Lopinavir
- 1172 Loprazolam

- 1173 Loracarbef
- 1174 Loratadine; except when specified elsewhere in this schedule
- 1175 Lorazepam
- 1176 Lormetazepam
- 1177 Losartan
- 1178 Loteprednol
- 1179 Lovastatin; except when present as an unmodified, naturally occurring substance in a food that has not been subject to a manufacturing process other than heating, freezing, drying, preserving, bottling, canning, or packaging in retort pouches
- 1180 Loxapine
- 1181 Lumacaftor
- 1182 Lumefantrine
- 1183 Lumiracoxib
- 1184 Lurasidone
- 1185 Luteinising hormone
- 1186 Lymecline
- 1187 Macitentan
- 1188 Mafenide
- 1189 Mannomustine
- 1190 Maprotiline
- 1191 Maraviroc
- 1192 Mazindol
- 1193 Measles vaccine
- 1194 Mebanazine
- 1195 Mebeverine
- 1196 Mebhydrolin
- 1197 Mebolazine
- 1198 Mebutamate
- 1199 Mecamylamine
- 1200 Mecasermin
- 1201 Mecillinam
- 1202 Meclocycline
- 1203 Meclofenamate
- 1204 Meclofenoxate

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- 1205 Meclozine; except when specified elsewhere in this schedule
  - 1206 Medazepam
  - 1207 Medigoxin
  - 1208 Medroxyprogesterone
  - 1209 Medrysone
  - 1210 Mefenamic acid; except when specified elsewhere in this schedule
  - 1211 Mefloquine
  - 1212 Mefruside
  - 1213 Megestrol
  - 1214 Melagatran
  - 1215 Melanocyte stimulating compounds
  - 1216 Melatonin
  - 1217 Melengestrol
  - 1218 Melia azedarach; at all strengths
  - 1219 Meloxicam
  - 1220 Melphalan
  - 1221 Memantine
  - 1222 Meningococcal vaccine; except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health
  - 1223 Menotrophin
  - 1224 Mepacrine
  - 1225 Mepenzolate
  - 1226 Mephenesin
  - 1227 Mephentermine
  - 1228 Mepindolol
  - 1229 Mepitiostane
  - 1230 Mepivacaine
  - 1231 Mepolizumab
  - 1232 Meprobamate
  - 1233 Meptazinol
  - 1234 Mepyramine; except when specified elsewhere in this schedule
  - 1235 Mequitazine
  - 1236 Mercaptomerin



- 1237 Mercaptopurine
- 1238 Mercurochrome; except when specified elsewhere in this schedule
- 1239 Mercury; except when specified elsewhere in this schedule
- 1240 Meropenem
- 1241 Mersalyl
- 1242 Mesabolone
- 1243 Mesalazine
- 1244 Mesna
- 1245 Mestanolone
- 1246 Mesterolone
- 1247 Mestranol
- 1248 Metamfetamine
- 1249 Metandienone
- 1250 Metaraminol
- 1251 Metenolone
- 1252 Metergoline
- 1253 Metformin
- 1254 Methacholine
- 1255 Methacycline
- 1256 Methadone
- 1257 Methallenoestril
- 1258 Methandriol
- 1259 Methanthelinium
- 1260 Methazolamide
- 1261 Methdilazine; except for oral use
- 1262 Methicillin
- 1263 Methimazole
- 1264 Methisazone
- 1265 Methixene
- 1266 Methocarbamol
- 1267 Methohexitone
- 1268 Methoin
- 1269 Methotrexate
- 1270 Methoxamine; except when specified elsewhere in this schedule
- 1271 Methoxsalen

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- 1272 Methoxyflurane
  - 1273 Methsuximide
  - 1274 Methyclothiazide
  - 1275 Methyl aminolevulinate
  - 1276 Methyl androstanolone
  - 1277 Methyl clostebol
  - 1278 Methyl mercury; except in medicines containing 300 micrograms or less per litre or per kilogram
  - 1279 Methyl salicylate; except for external use; except for internal use when present as an excipient in medicines containing 1.04% or less per dose form
  - 1280 Methyl trienolone
  - 1281 Methyldopa
  - 1282 Methylene blue; for injection
  - 1283 Methylergometrine
  - 1284 Methylhexanamine (1,3-dimethylamylamine (DMAA)); except when present as an unmodified, naturally occurring substance
  - 1285 Methylnaltrexone
  - 1286 Methylpentynol
  - 1287 Methylphenidate
  - 1288 Methylphenobarbital
  - 1289 Methylprednisolone
  - 1290 Methyltestosterone
  - 1291 Methylthiouracil
  - 1292 Methyprylon
  - 1293 Methysergide
  - 1294 Metoclopramide; except when specified elsewhere in this schedule
  - 1295 Metolazone
  - 1296 Metoprolol
  - 1297 Metribolone
  - 1298 Metrifonate
  - 1299 Metronidazole
  - 1300 Metyrapone
  - 1301 Mexiletine
  - 1302 Mezlocillin
  - 1303 Mianserin

- 1304 Mibefradil
- 1305 Mibolerone
- 1306 Micafungin
- 1307 Miconazole; except when specified elsewhere in this schedule
- 1308 Midazolam
- 1309 Midodrine
- 1310 Mifepristone
- 1311 Migalastat
- 1312 Miglitol
- 1313 Miglustat
- 1314 Milnacipran
- 1315 Milrinone
- 1316 Minocycline
- 1317 Minoxidil; except for dermal use in medicines containing 5% or less
- 1318 Mirabegron
- 1319 Mirtazapine
- 1320 Misoprostol
- 1321 Mitobronitol
- 1322 Mitomycin
- 1323 Mitoxantrone
- 1324 Mitragyna speciosa
- 1325 Mitragynine
- 1326 Mivacurium
- 1327 Moclobemide
- 1328 Modafinil
- 1329 Molgramostim
- 1330 Molindone
- 1331 Molracetam
- 1332 Mometasone; except when specified elsewhere in this schedule
- 1333 Monobenzene
- 1334 Monoclonal antibodies; except in pregnancy test kits
- 1335 Montelukast
- 1336 Moperone
- 1337 Morazone
- 1338 Moricizine

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- 1339 Morphine; except when specified elsewhere in this schedule
  - 1340 Motrazepam
  - 1341 Motretinide
  - 1342 Moxifloxacin
  - 1343 Mumps vaccine
  - 1344 Mupirocin
  - 1345 Muraglitazar
  - 1346 Muromonab
  - 1347 Mustine
  - 1348 Mycophenolic acid
  - 1349 Nabilone
  - 1350 Nabumetone
  - 1351 Nadolol
  - 1352 Nadroparin
  - 1353 Nafarelin
  - 1354 Naftidrofuryl
  - 1355 Nalbuphine
  - 1356 Nalidixic acid
  - 1357 Nalmefene
  - 1358 Nalorphine
  - 1359 Naloxegol
  - 1360 Naloxone; except when provided as part of an approved emergency kit for the treatment of opioid overdose
  - 1361 Naltrexone
  - 1362 Nandrolone
  - 1363 Naproxen; except when specified elsewhere in this schedule
  - 1364 Naratriptan
  - 1365 Natalizumab
  - 1366 Natamycin
  - 1367 Nateglinide
  - 1368 Nebacumab
  - 1369 Nebivolol
  - 1370 Nebracetam (and its stereoisomers)
  - 1371 Nedocromil
  - 1372 Nefazodone

- 1373 Nefiracetam
- 1374 Nefopam
- 1375 Nelfinavir
- 1376 Neomycin
- 1377 Neostigmine
- 1378 Nepafenac
- 1379 Nepidermin
- 1380 Nerium oleander
- 1381 Nesiritide
- 1382 Netilmicin
- 1383 Netupitant
- 1384 Nevirapine
- 1385 Nialamide
- 1386 Nicardipine
- 1387 Nicergoline
- 1388 Nicofuranose
- 1389 Nicoracetam
- 1390 Nicorandil
- 1391 Nicotine; except when specified elsewhere in the schedule; except in preparations for oromucosal or transdermal absorption; for nasal use except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner; in medicines other than for smoking cessation
- 1392 Nicotinic acid except nicotinamide; except when specified elsewhere in this schedule
- 1393 Nicoumalone
- 1394 Nifedipine
- 1395 Nifenazone
- 1396 Nikethamide
- 1397 Nilotinib
- 1398 Nilutamide
- 1399 Nimesulide
- 1400 Nimetazepam
- 1401 Nimodipine
- 1402 Nimorazole
- 1403 Nintedanib

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- 1404 Niridazole
  - 1405 Nisoldipine
  - 1406 Nitazoxanide
  - 1407 Nitisinone
  - 1408 Nitrazepam
  - 1409 Nitrendipine
  - 1410 Nitric oxide
  - 1411 Nitrofurantoin
  - 1412 Nitrofurazone
  - 1413 Nitrous oxide; when supplied for inhalation
  - 1414 Nitroxoline
  - 1415 Nivolumab
  - 1416 Nizatidine; except when specified elsewhere in this schedule
  - 1417 Nomegestrol
  - 1418 Nomifensine
  - 1419 Noopept (and its stereoisomers)
  - 1420 Noradrenaline
  - 1421 Norandrostenolone
  - 1422 Norbolethone
  - 1423 Norclostebol
  - 1424 Nordazepam
  - 1425 Norelgestromin
  - 1426 Norethandrolone
  - 1427 Norethisterone; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand Incorporated approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme
  - 1428 Norfloxacin
  - 1429 Norgestrel
  - 1430 Noribogaine
  - 1431 Normethandrone
  - 1432 Nortriptyline
  - 1433 Noxiptyline

- 1434 Nusinersen
- 1435 Nux vomica; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine
- 1436 Nystatin; except when specified elsewhere in this schedule
- 1437 Obinutuzumab
- 1438 Ocrelizumab
- 1439 Ocriplasmin
- 1440 Octamylamine
- 1441 Octatropine
- 1442 Octreotide
- 1443 Octyl nitrite
- 1444 Oestradiol; except in medicines containing 10 micrograms or less per litre or per kilogram
- 1445 Oestriol
- 1446 Oestrogens
- 1447 Oestrone; except in medicines containing 1 milligram or less per litre or per kilogram
- 1448 Ofatumumab
- 1449 Ofloxacin
- 1450 Olanzapine
- 1451 Olaparib
- 1452 Oleandomycin
- 1453 Oleandrin
- 1454 Olmesartan
- 1455 Olodaterol
- 1456 Olopatadine
- 1457 Olsalazine
- 1458 Omalizumab
- 1459 Ombitasvir
- 1460 Omeprazole; except when specified elsewhere in this schedule
- 1461 Ondansetron
- 1462 Opipramol
- 1463 Opium; except when specified elsewhere in this schedule
- 1464 Orciprenaline

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- 1465 Orlistat; except in medicines for weight control containing 120 milligrams or less per dose form
  - 1466 Ornidazole
  - 1467 Ornipressin
  - 1468 Orphenadrine
  - 1469 Orthopterin
  - 1470 Oseltamivir; except when specified elsewhere in this schedule
  - 1471 Osimertinib
  - 1472 Otilonium bromide
  - 1473 Ouabain
  - 1474 Ovandrotone
  - 1475 Oxabolone
  - 1476 Oxacillin
  - 1477 Oxaliplatin
  - 1478 Oxandrolone
  - 1479 Oxaprozin
  - 1480 Oxazepam
  - 1481 Oxazolam
  - 1482 Oxcarbazepine
  - 1483 Oxedrine; except in medicines containing 30 milligrams or less per recommended daily dose
  - 1484 Oxetacaine; except for internal use
  - 1485 Oxiconazole; except when specified elsewhere in this schedule
  - 1486 Oxiracetam (and its stereoisomers)
  - 1487 Oxitropium
  - 1488 Oxolamine
  - 1489 Oxolinic acid
  - 1490 Oxpentifylline
  - 1491 Oxprenolol
  - 1492 Oxybuprocaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
  - 1493 Oxybutynin
  - 1494 Oxycodone
  - 1495 Oxymesterone
  - 1496 Oxymetholone



- 1497 Oxyphenbutazone
- 1498 Oxyphencyclimine
- 1499 Oxyphenisatin; at all strengths
- 1500 Oxyphenonium
- 1501 Oxytetracycline
- 1502 Oxytocin; except in medicines containing 1 microgram or less per litre or per kilogram
- 1503 Paclitaxel
- 1504 Palbociclib
- 1505 Palifermin
- 1506 Paliperidone
- 1507 Palivizumab
- 1508 Palonosetron
- 1509 Pamaquin
- 1510 Pamidronic acid
- 1511 Pancreatic enzymes; except in medicines containing 20 000 BP units or less of lipase activity
- 1512 Pancuronium
- 1513 Panitumumab
- 1514 Panobinostat
- 1515 Pantoprazole; except when specified elsewhere in this schedule
- 1516 Papaveretum
- 1517 Papaverine; for injection
- 1518 Paracetamol; except when specified elsewhere in this schedule
- 1519 Paraldehyde
- 1520 Paramethadione
- 1521 Paramethasone
- 1522 Parecoxib
- 1523 Paricalcitol
- 1524 Paritabprevir
- 1525 Paromomycin
- 1526 Paroxetine
- 1527 Pasireotide
- 1528 Patent blue V; for injection when used in diagnostic procedures
- 1529 Patiromer sorbitex calcium

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- 1530 Pazopanib
  - 1531 Pecazine
  - 1532 Pefloxacin
  - 1533 Pegaptanib
  - 1534 Pegaspargase
  - 1535 Pegfilgrastim
  - 1536 Peginterferon
  - 1537 Peginterferon beta-1a
  - 1538 Pegvisomant
  - 1539 Pembrolizumab
  - 1540 Pemetrexed
  - 1541 Pemoline
  - 1542 Pempidine
  - 1543 Penbutolol
  - 1544 Penciclovir; except when specified elsewhere in this schedule
  - 1545 Penicillamine
  - 1546 Pentaerythrityl tetranitrate
  - 1547 Pentagastrin
  - 1548 Pentamethonium
  - 1549 Pentamidine
  - 1550 Pentazocine
  - 1551 Penthienate
  - 1552 Pentolinium
  - 1553 Pentosan polysulfate sodium
  - 1554 Pentostatin
  - 1555 Pentoxifylline
  - 1556 Peramivir
  - 1557 Perampanel
  - 1558 Pergolide
  - 1559 Perhexiline
  - 1560 Pericyazine
  - 1561 Perindopril
  - 1562 Permethrin; except in medicines containing 5% or less
  - 1563 Perphenazine
  - 1564 Pertussis antigen

- 1565 Pertussis (whooping cough) vaccine
- 1566 Pertuzumab
- 1567 Pethidine
- 1568 Phenacemide
- 1569 Phenacetin; except when present as an excipient
- 1570 Phenaglycodol
- 1571 Phenazone; except for external use
- 1572 Phenazopyridine
- 1573 Phenelzine
- 1574 Pheneticillin
- 1575 Phenformin
- 1576 Phenglutarimide
- 1577 Phenibut
- 1578 Phenindione
- 1579 Pheniramine; except when specified elsewhere in this schedule
- 1580 Phenisatin
- 1581 Phenobarbital
- 1582 Phenol; for injection
- 1583 Phenolphthalein
- 1584 Phenoperidine
- 1585 Phenoxybenzamine
- 1586 Phenoxyethylpenicillin
- 1587 Phensuximide
- 1588 Phentermine
- 1589 Phenthimentionium
- 1590 Phentolamine
- 1591 Phenylbutazone
- 1592 Phenylephrine; except when specified elsewhere in this schedule
- 1593 Phenylpropanolamine
- 1594 Phenyltoloxamine
- 1595 Phenytoin
- 1596 Phleum pratense extract
- 1597 Pholcodine; except when specified elsewhere in this schedule

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- 1598 Phosphodiesterase type 5 inhibitors; except when present as an unmodified, naturally occurring substance; except when specified elsewhere in this schedule
- 1599 Phthalylsulfathiazole
- 1600 Physostigmine
- 1601 Pibrentasvir
- 1602 Picibanil
- 1603 Picric acid
- 1604 Picrotoxin
- 1605 Pilocarpine; except in medicines containing 0.025% or less
- 1606 Pimecrolimus
- 1607 Pimozide
- 1608 Pinacidil
- 1609 Pinazepam
- 1610 Pindolol
- 1611 Pioglitazone
- 1612 Pipecuronium
- 1613 Pipemidic acid
- 1614 Pipenzolate
- 1615 Piperacetam
- 1616 Piperacillin
- 1617 Piperidine
- 1618 Piperidolate
- 1619 Pipobroman
- 1620 Pipothiazine
- 1621 Pipradrol
- 1622 Piracetam
- 1623 Pirbuterol
- 1624 Pirenoxine
- 1625 Pirenzepine
- 1626 Piretanide
- 1627 Pirfenidone
- 1628 Piroxicam; except for external use
- 1629 Pirprofen
- 1630 Pitavastatin

- 1631 Pituitary hormones
- 1632 Pivampicillin
- 1633 Pizotifen
- 1634 Plerixafor
- 1635 Plicamycin
- 1636 Pneumococcal vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
- 1637 Podophyllotoxin; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 1%; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 1638 Podophyllum emodi; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 20% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 1639 Podophyllum peltatum; for internal use; for external use for the treatment of anogenital warts; for other external use in medicines containing more than 20% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 1640 Polidexide
- 1641 Poliomyelitis vaccine
- 1642 Polyacrylamide; in injections or implants for tissue augmentation or cosmetic use
- 1643 Polyestradiol
- 1644 Polylactic acid; in injections or implants for tissue augmentation or cosmetic use
- 1645 Polymyxin
- 1646 Polysulfated glycosaminoglycans; for injection except in intraocular viscoelastic products
- 1647 Polythiazide
- 1648 Pomalidomide
- 1649 Ponatinib
- 1650 Poractant alfa
- 1651 Posaconazole
- 1652 Potassium bromide
- 1653 Potassium perchlorate
- 1654 Practolol
- 1655 Pradofloxacin

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- 1656 Pralatrexate
  - 1657 Pralidoxime
  - 1658 Pralmorelin
  - 1659 Pramipexole
  - 1660 Pramiracetam
  - 1661 Pramocaine
  - 1662 Prampine
  - 1663 Prasterone
  - 1664 Prasugrel
  - 1665 Pravastatin
  - 1666 Prazepam
  - 1667 Praziquantel
  - 1668 Prazosin
  - 1669 Prednisolone
  - 1670 Prednisone
  - 1671 Pregabalin
  - 1672 Pregnenolone
  - 1673 Prenalterol
  - 1674 Prenylamine
  - 1675 Prilocaine; for injection except when used as a local anaesthetic in practice by a dental therapist or an oral therapist registered with the Dental Council; except when specified elsewhere in this schedule
  - 1676 Primaquine
  - 1677 Primidone
  - 1678 Probenecid
  - 1679 Probucol
  - 1680 Procainamide
  - 1681 Procaine
  - 1682 Procaine penicillin
  - 1683 Procarbazine
  - 1684 Prochlorperazine; except when specified elsewhere in this schedule; except when sold for the treatment of nausea associated with emergency contraception by pharmacists or nurses accredited to sell levonorgestrel for emergency contraception
  - 1685 Procyclidine; except for dermal use in medicines containing 5% or less

- 1686 Progesterone; except in medicines containing 1 milligram or less per litre or per kilogram
- 1687 Progestogens
- 1688 Proglumide
- 1689 Proguanil
- 1690 Prolintane
- 1691 Promazine
- 1692 Promethazine; except when specified elsewhere in this schedule
- 1693 Promoxolane
- 1694 Propafenone
- 1695 Propamidine; except for ophthalmic use
- 1696 Propanidid
- 1697 Propantheline
- 1698 Propetandrol
- 1699 Propionibacterium acnes
- 1700 Propofol
- 1701 Propranolol; except in medicines containing 1 milligram or less per litre or per kilogram
- 1702 Propylthiouracil
- 1703 Propyphenazone
- 1704 Proquazone
- 1705 Proscillaridin
- 1706 Prostaglandins
- 1707 Protamine
- 1708 Prothionamide
- 1709 Prothipendyl
- 1710 Protirelin
- 1711 Protoveratrines
- 1712 Protriptyline
- 1713 Proxymetacaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 1714 Prucalopride
- 1715 Pseudoephedrine
- 1716 Pulmonaria spp; at all strengths
- 1717 Pyrazinamide

- 1718 Pyridinolcarbamate
- 1719 Pyridostigmine
- 1720 Pyridoxal; except in medicines containing 200 milligrams or less per recommended daily dose
- 1721 Pyridoxamine; except in medicines containing 200 milligrams or less per recommended daily dose
- 1722 Pyridoxine; except in medicines containing 200 milligrams or less per recommended daily dose
- 1723 Pyrimethamine
- 1724 Pyrvinium
- 1725 Quazepam
- 1726 Quetiapine
- 1727 Quinagolide
- 1728 Quinapril
- 1729 Quinbolone
- 1730 Quinethazone
- 1731 Quinidine
- 1732 Quinine; except in medicines containing 50 milligrams or less per recommended daily dose
- 1733 Quinisocaine
- 1734 Quinupristin
- 1735 Rabeprazole
- 1736 Rabies vaccine
- 1737 Raloxifene
- 1738 Raltegravir
- 1739 Raltitrexed
- 1740 Ramipril
- 1741 Ramucirumab
- 1742 Ranibizumab
- 1743 Ranitidine; except when specified elsewhere in this schedule
- 1744 Ranolazine
- 1745 Rapacuronium
- 1746 Rasagiline
- 1747 Rasburicase
- 1748 Rauwolfia serpentina



- 1749 Rauwolfia vomitoria
- 1750 Razoxane
- 1751 Reboxetine
- 1752 Recombinant human epidermal growth factor
- 1753 Recombinant varicella zoster virus glycoprotein E antigen
- 1754 Regorafenib
- 1755 Remestemcel-L
- 1756 Remifentanyl
- 1757 Remoxipride
- 1758 Repaglinide
- 1759 Reserpine
- 1760 Reslizumab
- 1761 Retapamulin
- 1762 Reteplase
- 1763 Retigabine
- 1764 Ribavirin
- 1765 Ribociclib
- 1766 Ridaforolimus
- 1767 Rifabutin
- 1768 Rifampicin
- 1769 Rifamycin
- 1770 Rifapentine
- 1771 Rifaximin
- 1772 Rilmazafone
- 1773 Rilpivirine
- 1774 Riluzole
- 1775 Rimexolone
- 1776 Rimiterol
- 1777 Rimonabant
- 1778 Riociguat
- 1779 Risedronic acid
- 1780 Risperidone
- 1781 Ritodrine
- 1782 Ritonavir
- 1783 Rituximab

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- 1784 Rivaroxaban
  - 1785 Rivastigmine
  - 1786 Rizatriptan; except when specified elsewhere in this schedule
  - 1787 Rocuronium
  - 1788 Rofecoxib
  - 1789 Roflumilast
  - 1790 Rolipram (and its stereoisomers)
  - 1791 Rolitetracycline
  - 1792 Rolziracetam
  - 1793 Romidepsin
  - 1794 Romiplostim
  - 1795 Ropinirole
  - 1796 Ropivacaine
  - 1797 Rosiglitazone
  - 1798 Rosoxacin
  - 1799 Rosuvastatin
  - 1800 Rotavirus vaccine
  - 1801 Rotigotine
  - 1802 Roxibolone
  - 1803 Roxithromycin
  - 1804 Rubella vaccine
  - 1805 Ruboxistaurin
  - 1806 Rufinamide
  - 1807 Rupatadine
  - 1808 Ruxolitinib
  - 1809 Sabadilla; except in preparations containing 10 milligrams or less of total alkaloids of *schoenocaulon officinale* per litre or per kilogram
  - 1810 Sacubitril
  - 1811 Safrole; for internal use except in medicines containing 0.1% or less
  - 1812 Salbutamol
  - 1813 Salcatonin
  - 1814 Salmeterol
  - 1815 Sapropterin
  - 1816 Saquinavir
  - 1817 Sargramostim

- 1818 Sarilumab
- 1819 Saxagliptin
- 1820 Schoenocaulon officinale; except in preparations containing 10 milligrams or less of total alkaloids of schoenocaulon officinale per litre or per kilogram
- 1821 Scopolia carniolica
- 1822 Sebelipase alfa
- 1823 Secbutabarbitol
- 1824 Secobarbital
- 1825 Secukinumab
- 1826 Selective androgen receptor modulators
- 1827 Seletacetam (and its stereoisomers)
- 1828 Selegiline
- 1829 Selenium; except when specified elsewhere in this schedule; except for oral use in medicines containing 150 micrograms or less per recommended daily dose
- 1830 Selexipag
- 1831 Serelaxin
- 1832 Sermorelin
- 1833 Sertindole
- 1834 Sertraline
- 1835 Serum, dried human
- 1836 Sevelamer
- 1837 Sevoflurane
- 1838 Sex hormones and all substances having sex hormone activity
- 1839 Sialoepoetin
- 1840 Sibutramine
- 1841 Silandrone
- 1842 Sildenafil and its structural analogues; except sildenafil in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35–70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand Incorporated
- 1843 Silicones; for injection
- 1844 Silodosin
- 1845 Siltuximab
- 1846 Silver sulfadiazine; except for external use in packs containing 50 grams or less

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- 1847 Simeprevir
  - 1848 Simvastatin
  - 1849 Sirolimus
  - 1850 Sisomicin
  - 1851 Sitagliptin
  - 1852 Sitaxentan
  - 1853 Sodium bromide
  - 1854 Sodium cellulose phosphate; for internal use
  - 1855 Sodium cromoglycate; except for nasal and ophthalmic use
  - 1856 Sodium morrhuate; for injection
  - 1857 Sodium nitroprusside
  - 1858 Sodium phenylbutyrate
  - 1859 Sodium phosphate; in oral laxative preparations
  - 1860 Sodium polystyrene sulphonate
  - 1861 Sodium tetradecyl sulphate; for injection
  - 1862 Sodium zirconium cyclosilicate
  - 1863 Sofosbuvir
  - 1864 Solasidine
  - 1865 Solifenacin
  - 1866 Somatostatin
  - 1867 Somatropin
  - 1868 Sonidegib
  - 1869 Sontoquine
  - 1870 Sorafenib
  - 1871 Sotalol
  - 1872 Sparfloxacin
  - 1873 Sparteine
  - 1874 Spectinomycin
  - 1875 Spiramycin
  - 1876 Spirapril
  - 1877 Spironolactone
  - 1878 Stanolone
  - 1879 Stanozolol
  - 1880 Staphylococcus aureus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds

- 1881 Stavudine
- 1882 Stenbolone
- 1883 Steroid hormones
- 1884 Stilboestrol
- 1885 Stiripentol
- 1886 Stramonium; except for oral use when specified elsewhere in this schedule; except datura stramonium or datura tatula for smoking or burning
- 1887 Streptococcus beta-haemolyticus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds
- 1888 Streptodornase
- 1889 Streptokinase
- 1890 Streptomycin
- 1891 Streptozocin
- 1892 Strontium ranelate
- 1893 Strophanthins
- 1894 Strophanthus spp
- 1895 Strychnos spp; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine
- 1896 Styramate
- 1897 Succimer
- 1898 Sufentanil
- 1899 Sugammadex
- 1900 Sulbactam
- 1901 Sulconazole; except for dermal use
- 1902 Sulfacetamide; except for ophthalmic use in medicines containing 10% or less
- 1903 Sulfadiazine; except silver sulfadiazine for external use in pack sizes of 50 grams or less
- 1904 Sulfadimethoxine
- 1905 Sulfadimidine
- 1906 Sulfadoxine
- 1907 Sulfafurazole
- 1908 Sulfaguanidine
- 1909 Sulfamerazine
- 1910 Sulfamethizole
- 1911 Sulfamethoxazole

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- 1912 Sulfamethoxydiazine
  - 1913 Sulfamethoxypyridazine
  - 1914 Sulfametrole
  - 1915 Sulfamonomethoxine
  - 1916 Sulfamoxole
  - 1917 Sulfaphenazole
  - 1918 Sulfapyridine
  - 1919 Sulfasalazine
  - 1920 Sulfathiazole
  - 1921 Sulfatroxazole
  - 1922 Sulfinpyrazone
  - 1923 Sulfomyxin
  - 1924 Sulfonmethane
  - 1925 Sulindac
  - 1926 Sultamicillin
  - 1927 Sulthiame
  - 1928 Sumatriptan; except when specified elsewhere in this schedule
  - 1929 Sunifiram
  - 1930 Sunitinib
  - 1931 Suprofen
  - 1932 Suvorexant
  - 1933 Sutilains
  - 1934 Suxamethonium
  - 1935 Suxethonium
  - 1936 T cell receptor antibody
  - 1937 Tacrine
  - 1938 Tacrolimus
  - 1939 Tadalafil and its structural analogues
  - 1940 Tafenoquine succinate
  - 1941 Tafluprost
  - 1942 Taliglucerase alfa
  - 1943 Talimogene laherparepvec
  - 1944 Tamoxifen
  - 1945 Tamsulosin
  - 1946 Tanacetum vulgare; except in medicines containing 0.8% or less of oil of tansy

- 1947 Tapentadol
- 1948 Tasonermin
- 1949 Tazarotene
- 1950 Tazobactam
- 1951 Teduglutide
- 1952 Tegafur
- 1953 Tegaserod
- 1954 Teicoplanin
- 1955 Telaprevir
- 1956 Telbivudine
- 1957 Telithromycin
- 1958 Telmisartan
- 1959 Telotristat ethyl
- 1960 Temazepam
- 1961 Temozolomide
- 1962 Temsirolimus
- 1963 Tenecteplase
- 1964 Teniposide
- 1965 Tenofovir
- 1966 Tenoxicam
- 1967 Terazosin
- 1968 Terbinafine; except when specified elsewhere in this schedule
- 1969 Terbutaline
- 1970 Terfenadine
- 1971 Teriflunomide
- 1972 Teriparatide
- 1973 Terlipressin
- 1974 Terodiline
- 1975 Teropterin
- 1976 Tesamorelin
- 1977 Testolactone
- 1978 Testosterone; except in medicines containing 1 milligram or less per litre or per kilogram
- 1979 Tetanus antitoxin
- 1980 Tetanus toxoid

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- 1981 Tetanus vaccine
  - 1982 Tetrabenazine
  - 1983 Tetracosactrin
  - 1984 Tetracycline
  - 1985 Tetraethylammonium
  - 1986 Tetrahydrocannabinol
  - 1987 Tetrazepam
  - 1988 Tetroxoprim
  - 1989 Thalidomide
  - 1990 Thenyldiamine
  - 1991 Theophylline; except when specified elsewhere in this schedule
  - 1992 Thevetia peruviana
  - 1993 Thevetin
  - 1994 Thiambutosine
  - 1995 Thiazosulfone
  - 1996 Thiethylperazine
  - 1997 Thioacetazone
  - 1998 Thiocarlide
  - 1999 Thioguanine
  - 2000 Thiomesterone
  - 2001 Thiopentone
  - 2002 Thiopropazate
  - 2003 Thioproperazine
  - 2004 Thioridazine
  - 2005 Thiotepa
  - 2006 Thiothixene
  - 2007 Thiouracil
  - 2008 Thiourea; except in medicines containing 0.1% or less
  - 2009 Thymosin beta-4
  - 2010 Thymoxamine
  - 2011 Thyroid
  - 2012 Thyrotrophin
  - 2013 Thyrotrophin-releasing factor
  - 2014 Thyroxine; except in medicines containing 10 micrograms or less per litre or per kilogram



- 2015 Tiagabine
- 2016 Tianeptine
- 2017 Tiaprofenic acid
- 2018 Tiaramide
- 2019 Tibolone
- 2020 Ticagrelor
- 2021 Ticarcillin
- 2022 Ticlopidine
- 2023 Tiemonium
- 2024 Tienilic acid
- 2025 Tigecycline
- 2026 Tigloidine
- 2027 Tiletamine
- 2028 Tilidine
- 2029 Tiludronic acid
- 2030 Timbetasin
- 2031 Timolol
- 2032 Tinidazole
- 2033 Tinzaparin
- 2034 Tioconazole; except when specified elsewhere in this schedule
- 2035 Tiotropium
- 2036 Tipepidine
- 2037 Tipiracil
- 2038 Tiprinavir
- 2039 Tirilazad
- 2040 Tirofiban
- 2041 Tizanidine
- 2042 Tobramycin
- 2043 Tocainide
- 2044 Tocilizumab
- 2045 Tofacitinib
- 2046 Tolazamide
- 2047 Tolazoline
- 2048 Tolbutamide
- 2049 Tolcapone

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- 2050 Tolfenamic acid
  - 2051 Tolmetin
  - 2052 Tolonium
  - 2053 Tolpropamine
  - 2054 Tolrestat
  - 2055 Tolterodine
  - 2056 Tolvaptan
  - 2057 Topiramate
  - 2058 Topotecan
  - 2059 Torasemide
  - 2060 Toremfene
  - 2061 Toxoids; for injection
  - 2062 Tramadol
  - 2063 Trametinib dimethyl sulfoxide
  - 2064 Trandolapril
  - 2065 Tranexamic acid
  - 2066 Tranylcypromine
  - 2067 Trastuzumab
  - 2068 Trastuzumab emtansine
  - 2069 Travoprost
  - 2070 Trazodone
  - 2071 Trenbolone
  - 2072 Treosulphan
  - 2073 Treprostinil
  - 2074 Trestolone
  - 2075 Tretamine
  - 2076 Tretinoin
  - 2077 Triacetyloleandomycin
  - 2078 Triamcinolone; except when specified elsewhere in this schedule
  - 2079 Triamterene
  - 2080 Triaziquone
  - 2081 Triazolam
  - 2082 Trichlormethiazide
  - 2083 Trichloroacetic acid; except for external use in medicines containing 12.5% or less for the treatment of warts other than anogenital warts

- 2084 Trichloroethylene
- 2085 Trichodesma africana; at all strengths
- 2086 Triclofos
- 2087 Tricyclamol
- 2088 Tridihexethyl
- 2089 Trientine
- 2090 Trifluoperazine
- 2091 Trifluperidol
- 2092 Triflupromazine
- 2093 Trifluridine
- 2094 Trimeprazine; except when specified elsewhere in this schedule
- 2095 Trimetaphan
- 2096 Trimethoprim; except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16–65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections
- 2097 Trimipramine
- 2098 Trimustine
- 2099 Trinitrophenol
- 2100 Trioxysalen
- 2101 Triparanol; at all strengths
- 2102 Triple antigen vaccine
- 2103 Triprolidine; except when specified elsewhere in this schedule
- 2104 Triptorelin
- 2105 Troglitazone
- 2106 Trometamol; for injection in medicines containing more than 3%
- 2107 Tropicamide; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 2108 Tropisetron
- 2109 Trovafloxacin
- 2110 Troxidone
- 2111 Tryptophan; except in medicines containing 100 milligrams or less per recommended daily dose; except in parenteral nutrition replacement preparations
- 2112 Tuberculin
- 2113 Tuberculosis vaccine

- 2114 Tubocurarine
- 2115 Tulobuterol
- 2116 Typhoid vaccine
- 2117 Ulipristal
- 2118 Umeclidinium bromide
- 2119 Unoprostone
- 2120 Uracil
- 2121 Urapidil
- 2122 Urethane
- 2123 Urofollitropin
- 2124 Urokinase
- 2125 Ursodeoxycholic acid
- 2126 Ustekinumab
- 2127 Vaccines; except when specified elsewhere in this schedule
- 2128 Vaccinia virus vaccine
- 2129 Valaciclovir
- 2130 Valdecoxib
- 2131 Valganciclovir
- 2132 Valnoctamide
- 2133 Valproic acid
- 2134 Valsartan
- 2135 Vancomycin
- 2136 Vandetanib
- 2137 Vardenafil and its structural analogues
- 2138 Varenicline
- 2139 Varicella vaccine; except when administered for the prevention of herpes zoster (shingles) to a person 50 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health
- 2140 Vasopressin
- 2141 Vecuronium
- 2142 Vedolizumab
- 2143 Velaglucerase alfa
- 2144 Velpatasvir

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- 2145 Vemurafenib
  - 2146 Venetoclax
  - 2147 Venlafaxine
  - 2148 Verapamil
  - 2149 Veratrum spp
  - 2150 Vernakalant
  - 2151 Verteporfin
  - 2152 Veruprevir
  - 2153 Vidarabine
  - 2154 Vigabatrin
  - 2155 Vilanterol
  - 2156 Vildagliptin
  - 2157 Viloxazine
  - 2158 Vinblastine
  - 2159 Vincamine
  - 2160 Vincristine
  - 2161 Vindesine
  - 2162 Vinflunine
  - 2163 Vinorelbine
  - 2164 Vinyl ether
  - 2165 Virginiamycin
  - 2166 Vismodegib
  - 2167 Visnadine
  - 2168 Vitamin A; except for internal use in medicines containing 3 milligrams or less of retinol equivalents per recommended daily dose; except in parenteral nutrition replacement preparations; except for external use in medicines containing 1% or less
  - 2169 Vitamin D; except for external use; except for internal use in medicines containing 25 micrograms or less per recommended daily dose; except in parenteral nutrition replacement preparations
  - 2170 Vorapaxar
  - 2171 Voriconazole
  - 2172 Vorinostat
  - 2173 Vortioxetine
  - 2174 Warfarin
  - 2175 Xamoterol

- 2176 Xanthinol nicotinate
- 2177 Ximelagatran
- 2178 Xipamide
- 2179 Yellow fever vaccine
- 2180 Yohimbine
- 2181 Zafirlukast
- 2182 Zalcitabine
- 2183 Zaleplon
- 2184 Zanamivir
- 2185 Zidovudine
- 2186 Zimeldine
- 2187 Zinc; except for internal use in medicines containing 25 milligrams or less per recommended daily dose; except for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines, when sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except for external use when in medicines containing 5% or less; except in parenteral nutrition replacement preparations
- 2188 Ziprasidone
- 2189 Zoledronic acid
- 2190 Zolmitriptan; except when specified elsewhere in this schedule
- 2191 Zolpidem
- 2192 Zonisamide
- 2193 Zopiclone
- 2194 Zoster immunoglobulin, human
- 2195 Zoxazolamine
- 2196 Zuclopenthixol

## **Part 2**

### **Restricted medicines**

- 1 Adrenaline; in medicines containing 1% or less except in medicines for injection containing 0.02% or less
- 2 Alclometasone; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the

- Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack
- 3 Aminophylline; for oral use in liquid form in medicines containing 2% or less
  - 4 Amorolfine; for external use in medicines containing more than 0.25%
  - 5 Aspirin; in slow-release forms; in enteric coated forms containing more than 300 milligrams per dose form
  - 6 Azatadine; for oral use in adults and children over 2 years of age
  - 7 Azelastine; in medicines for ophthalmic use containing 0.05% or less
  - 8 Brompheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
  - 9 Buclizine; for oral use
  - 10 Butoconazole; for vaginal use
  - 11 Chloramphenicol; for ophthalmic use; except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
  - 12 Chlorbutol; except when specified elsewhere in this schedule
  - 13 Chlorpheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
  - 14 Ciclopirox; for external use in medicines containing more than 2%; in preparations for application to the nails containing more than 8%
  - 15 Cimetidine; in medicines for the symptomatic relief of heartburn, dyspepsia, and hyperacidity or to be used on the recommendation of a registered medical practitioner, when sold in the manufacturer's original pack containing not more than 14 days' supply
  - 16 Clemastine; for oral use
  - 17 Clobetasone; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack
  - 18 Clotrimazole; for vaginal use
  - 19 Codeine; in medicines for oral use containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, for use as an analgesic and when sold in a pack of not more than 5 days' supply,

- approved by the Minister or the Director-General for distribution as a restricted medicine
- 20 Cyclizine; for oral use other than in medicines used for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 6 dosage units; for oral use in medicines used for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 21 Cyproheptadine; for oral use
- 22 Dexchlorpheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 23 Di-iodohydroxy quinoline; for vaginal use
- 24 Diclofenac; in solid dose form in medicines containing 25 milligrams or less and more than 12.5 milligrams per dose form in packs containing not more than 30 tablets or capsules
- 25 Dimenhydrinate; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule
- 26 Dimethindene; for oral use
- 27 Diphenhydramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 28 Dithranol
- 29 Doxylamine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 30 Econazole; for vaginal use
- 31 Erythrityl tetranitrate
- 32 Famciclovir; in divided solid dosage forms for oral use containing 500 milligrams or less for the treatment of recurrent herpes labialis when sold in the manufacturer's original pack containing up to 3 dosage units
- 33 Flavoxate
- 34 Fluconazole; for oral use in medicines that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack containing 150 milligrams or less as a single dose for the treatment of vaginal candidiasis
- 35 Fluorides; for external use in liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packs



- approved by the Minister or the Director-General for distribution as restricted medicines; for external use in non-liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram, except in medicines containing 1.5 grams or less and more than 1 gram per litre or per kilogram; except when supplied to a dental professional registered with the Dental Council
- 36 Glucagon; except in medicines containing 100 micrograms or less per litre or per kilogram
- 37 Glyceryl trinitrate; for oral or sublingual use; for rectal use
- 38 Guaifenesin; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing more than 10 days' supply but not more than 30 days' supply; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing not more than 10 days' supply; except for oral use in medicines containing 2% or less or 200 milligrams or less per dose form
- 39 Haemophilus influenzae vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds
- 40 Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; for dermal use in medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base with no other active ingredient except an anti-fungal and in a quantity of 30 grams or less or 30 millilitres or less per container; for dermal use in medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base with no other active ingredient except 5% or less by weight of aciclovir and in a quantity of 2 grams or less or 2 millilitres or less per container in adults and children 12 years of age and older; in rectal medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base and in combination with a local anaesthetic and in a quantity of 35 grams or less per container or up to 12 suppositories per pack
- 41 Hyoscine butylbromide; for oral use in medicines containing not more than 20 milligrams per dose form and in packs containing not more than 10 tablets or capsules for the relief of muscle spasm of the gastrointestinal tract
- 42 Ibuprofen; for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack labelled for use by adults or children over 12 years of age
- 43 Inositol nicotinate
- 44 Isoconazole; for vaginal use
- 45 Ketoprofen; in solid dose form containing 25 milligrams or less per dose form in packs of not more than 30 capsules or tablets

- 46 Lansoprazole; in divided solid dosage forms for oral use containing 15 milligrams or less with a maximum daily dose of 15 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over for the relief of heartburn when sold in the manufacturer's original pack containing not more than 14 dosage units
- 47 Levonorgestrel; in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams
- 48 Macrogols; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures
- 49 Malathion; except for external use in medicines containing 2% or less
- 50 Mannityl hexanitrate
- 51 Meclozine; in a pack size of up to 10 dosage units for the treatment of insomnia
- 52 Mepyramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 53 Methdilazine; for oral use
- 54 Metoclopramide; when compounded with paracetamol in packs of not more than 10 tablets or capsules for the treatment of nausea associated with migraine
- 55 Miconazole; for the treatment of oral candidiasis; for vaginal use
- 56 Nicotinic acid except nicotinamide; in medicines containing 250 milligrams or less but more than 100 milligrams per dose form; except in medicines containing 100 milligrams or less per dose form
- 57 Nicotiny alcohol; except in medicines containing 100 milligrams or less per dose form
- 58 Nystatin; for the treatment of oral candidiasis; for vaginal use
- 59 Orlistat; in medicines for weight control containing 120 milligrams or less per dose form
- 60 Oseltamivir; in solid dosage forms for oral use containing 75 milligrams in a pack size of up to 10 dosage units for the treatment or prophylaxis of influenza in adults and children aged 13 years and older who have been exposed to the influenza virus
- 61 Oxiconazole; for vaginal use
- 62 Pheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 63 Pneumococcal vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

- 64 Podophyllotoxin; for external use for the treatment of warts other than anogenital warts in medicines containing 1% or less and more than 0.5%; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 65 Podophyllum emodi; for external use for the treatment of warts other than anogenital warts in medicines containing 20% or less and more than 10% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 66 Podophyllum peltatum; for external use for the treatment of warts other than anogenital warts in medicines containing 20% or less and more than 10% of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 67 Prochlorperazine; in packs containing not more than 10 tablets or capsules for the treatment of nausea associated with migraine
- 68 Promethazine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 69 Rizatriptan; for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms, when in wafers containing 5 milligrams or less per wafer and when sold in a pack containing not more than 2 wafers approved by the Minister or the Director-General for distribution as a restricted medicine
- 70 Salicylic acid; except in medicines for dermal use containing 40% or less
- 71 Santonin
- 72 Sodium phosphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures
- 73 Sodium picosulphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures
- 74 Staphylococcus aureus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds
- 75 Stramonium; for oral use in liquid form; in solid dose form in medicines containing more than 0.3 milligrams per dose or more than 1.2 milligrams per recommended daily dose
- 76 Streptococcus beta-haemolyticus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds
- 77 Sulfacetamide; for ophthalmic use in medicines containing 10% or less
- 78 Sumatriptan; for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when

- sold in a pack containing not more than 2 tablets that has received the consent of the Minister or the Director-General to its sale as a restricted medicine
- 79 Theophylline; in liquid form for oral use in medicines containing 2% or less
- 80 Tioconazole; for vaginal use
- 81 Triamcinolone; for buccal use in medicines containing 0.1% or less of triamcinolone acetonide and in pack sizes of 5 grams or less
- 82 Trimeprazine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
- 83 Triprolidine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule
- 84 Zolmitriptan; in a pre-filled nasal spray device containing not more than 5 milligrams of zolmitriptan, for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms and when sold in a pack of not more than 2 devices approved by the Minister or the Director-General for distribution as a restricted medicine

### Part 3

#### Pharmacy-only medicines

- 1 8-hydroxyquinoline and its non-halogenated derivatives; in medicines containing more than 1% of such substances; except for hydroxyquinoline sulphate for external use
- 2 Acetic acid and preparations containing more than 80% of acetic acid (CH<sub>3</sub>COOH); excluding its salts and derivatives
- 3 Acetylcysteine; for oral use in medicines containing more than 1 gram per recommended daily dose
- 4 Aciclovir; for external use for the treatment of herpes labialis except in medicines containing 5% or less and in tubes containing 10 grams or less
- 5 Aconitum spp; for oral use in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids; for dermal use in concentrations of 0.02% or less and in packs containing 0.2 milligrams or less and more than 0.02 milligrams of total alkaloids
- 6 Aloes; for internal use; except when obtained solely from the mucilaginous gel of the leaf
- 7 Aloin
- 8 Aloxiprin
- 9 Amethocaine; for external use in medicines containing 10% or less and more than 2%; except in medicines for external use containing 2% or less

- 10 Amorolfine; in preparations for topical use; except in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 11 Antazoline; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 12 Atropa belladonna; for external use in medicines containing 0.03% or less of the alkaloids of belladonna; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of the alkaloids of belladonna
- 13 Atropine; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose; in medicines containing atropine sulphate for the treatment of organophosphorus poisoning either in packs of not more than 20 dose units containing 0.6 milligrams or less per dose unit or in injections in packs of not more than 5 vials containing 0.6 milligrams per millilitre; except when sold as an antidote in a device designed for self-injection from outlets licensed to sell organophosphorus poisons; except in medicines containing 300 micrograms or less per litre or per kilogram
- 14 Azelaic acid; for dermal use
- 15 Azelastine; in preparations for nasal use containing 0.15% azelastine hydrochloride or less; in topical eye preparations containing 0.05% or less
- 16 Beclomethasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril) in a pack containing 200 actuations or less
- 17 Benzocaine; in preparations for topical use, other than eye drops, containing 10% or less of total anaesthetic substances except in dermal preparations containing 2% or less of total anaesthetic substances; in divided preparations containing 200 milligrams or less of total anaesthetic substances per dosage unit except in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit
- 18 Benzoyl peroxide; for external use in medicines containing more than 5% and not more than 10%; except for medicines for external use containing 5% or less
- 19 Benzydamine; for external use except for oromucosal or topical use
- 20 Bephenium

- 21 Bifonazole; except when specified elsewhere in this schedule; except for dermal use in medicines for tinea pedis only or in shampoos containing 1% or less or when sold in practice by a podiatrist registered with the Podiatrists Board
- 22 Bilastine; in divided solid dosage forms for oral use containing 20 milligrams or less for the treatment of the symptoms of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria when sold in a pack containing not more than 30 dosage units
- 23 Bisacodyl
- 24 Bromhexine
- 25 Brompheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing brompheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 26 Budesonide; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation and when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril) in a pack containing 200 actuations or less
- 27 Carbetapentane; except in medicines containing 0.5% or less
- 28 Carbocisteine
- 29 Cetirizine; for oral use except in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply
- 30 Chlophedianol
- 31 Chlorbutol; in medicines containing 5% or less and more than 0.5%; except in medicines containing 0.5% or less
- 32 Chloroform; in medicines other than for anaesthesia containing more than 0.5%; except in medicines containing 0.5% or less
- 33 Chlorpheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing chlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 34 Ciclopirox; for external use in medicines containing 2% or less except when for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; in preparations for application to the nails containing 8% or less
- 35 Cinchocaine; for external use in medicines containing 0.5% or less

- 36 Cinnamedrine
- 37 Clotrimazole; for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 38 Cocaine; in medicines for oral use, containing not more than 0.1% of cocaine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, and when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine
- 39 Codeine; in medicines for oral use, containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, for the treatment of the symptoms of cough and cold and when sold in a pack of not more than 6 days' supply, approved by the Minister or the Director-General for distribution as a pharmacy-only medicine
- 40 Colocynth
- 41 Creosote; except in medicines containing 10% or less
- 42 Cresols; except in medicines containing 3% or less
- 43 Datura spp; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 44 Delphinium staphisagria; except in medicines containing 0.2% or less
- 45 Desloratadine; for oral use
- 46 Dexchlorpheniramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing dexchlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 47 Dextromethorphan; in liquid form containing more than 0.25% or in solid dose form containing more than 15 milligrams per dose form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams; in medicines for the treatment of the symptoms of cough and cold in children aged 6–12 years; except in liquid form containing 0.25% or less in solid dose form containing 15 milligrams or less per dose form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams
- 48 Dibrompropamide; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

- 49 Diclofenac; in solid dose form in medicines containing 12.5 milligrams or less per dose form in packs containing not more than 30 tablets or capsules and with a recommended daily dose of not more than 75 milligrams
- 50 Diphenoxylate; in liquid form containing in each millilitre not more than 0.5 milligrams of diphenoxylate calculated as base and not less than 5 micrograms of atropine sulphate; in solid dose form containing not more than 2.5 milligrams of diphenoxylate calculated as base and not less than 5 micrograms of atropine sulphate
- 51 Dimenhydrinate; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults or children over 2 years of age except when sold at a transport terminal or aboard a ship or an aircraft
- 52 Diphenhydramine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing diphenhydramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or an aircraft
- 53 Doxylamine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing doxylamine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 54 *Duboisia leichhardtii*; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 55 *Duboisia myoporides*; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 56 Econazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 57 Esomeprazole; in oral preparations containing 20 milligrams or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply



- 58 Etafedrine
- 59 Ether; in medicines containing more than 10%; except in medicines containing 10% or less
- 60 Etofenamate; for external use
- 61 Famotidine; for the symptomatic relief of heartburn, dyspepsia, and hyperacidity or to be used on the recommendation of a registered medical practitioner, when sold in the manufacturer's original pack containing not more than 14 days' supply
- 62 Felbinac; for external use
- 63 Fexofenadine; for oral use except for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply
- 64 Fluorides; for internal use in medicines containing 0.5 milligrams or less per dose unit; except in parenteral nutrition replacement preparations; for external use in liquid form in medicines containing 1 gram or less per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as pharmacy-only medicines except in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride; except when supplied to any dental professional registered with the Dental Council; except in medicines containing 15 milligrams or less per litre or per kilogram
- 65 Flurbiprofen; in locally acting oromucosal preparations containing 10 milligrams or less per dosage unit
- 66 Fluticasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation with a maximum recommended daily dose of 200 micrograms (as a single dose) in a pack containing 200 actuations or less
- 67 Folic acid; for oral use in medicines containing more than 500 micrograms per recommended daily dose; except for oral use in medicines containing 500 micrograms or less per recommended daily dose; except in parenteral nutrition replacement preparations
- 68 Folinic acid; for oral use in medicines containing more than 500 micrograms per recommended daily dose; except for oral use in medicines containing 500 micrograms or less per recommended daily dose
- 69 Formaldehyde; except in medicines containing 5% or less
- 70 Gelsemium sempervirens; except in medicines containing 1 milligram or less per litre or per kilogram
- 71 Glutaraldehyde

- 72 Hexachlorophane; in medicines containing 3% or less but more than 0.75%; except in medicines containing 0.75% or less
- 73 Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; for dermal use in medicines containing 0.5% or less by weight of hydrocortisone base with no other active ingredient except an antifungal and in a quantity of 30 grams or less or 30 millilitres or less per container; in rectal medicines containing 0.5% or less by weight of hydrocortisone base and in combination with a local anaesthetic and in a quantity of 35 grams or less per container or 12 suppositories or fewer per pack
- 74 Hydrocyanic acid; for oral use in packs containing 5 milligrams or less and more than 0.5 milligrams; except in medicines containing 1 microgram or less per litre or per kilogram; except for oral use in packs containing 0.5 milligrams or less
- 75 Hydroquinone; for external use in medicines containing 2% or less except in hair preparations containing 1% or less
- 76 Hyoscine; for transdermal use in medicines containing 2 milligrams or less of total solanaceous alkaloids per dose unit; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 77 Hyoscyamine; for external use in medicines containing 0.03% or less of total solanaceous alkaloids; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 78 Hyoscyamus niger; for oral use in liquid form in medicines containing 0.03% or less (300 micrograms or less of total solanaceous alkaloids per litre or per kilogram) and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose except in packs containing 30 micrograms or less of total solanaceous alkaloids
- 79 Ibuprofen; for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100

- dose units; except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units; except for external use
- 80 Indanazoline
- 81 Indomethacin; for external use in medicines containing 1% or less; except in medicines containing 1 milligram or less per litre or per kilogram
- 82 Iodine; except for external use in medicines containing 2.5% or less; for internal use in medicines containing less than 300 micrograms per recommended daily dose
- 83 Ipecacuanha; in medicines containing 0.2% or less of emetine and 40 micrograms or more of ipecacuanha alkaloids per recommended dose for the treatment of the symptoms of cough and cold in children aged 6–12 years; except in medicines containing less than 40 micrograms of ipecacuanha alkaloids per recommended dose for the treatment of the symptoms of cough and cold in children aged 6–12 years
- 84 Ipomoea spp; except ipomoea batatas
- 85 Ipratropium; for nasal use
- 86 Iron; for oral use either in medicines containing more than 24 milligrams per recommended daily dose or in medicines containing more than 5 milligrams per dose unit and more than 750 milligrams of iron per pack; except in parenteral nutrition replacement preparations; except for oral use in medicines containing 24 milligrams or less per recommended daily dose in medicines containing not more than 5 milligrams per dose unit; except for oral use in medicines containing 24 milligrams or less per recommended daily dose in medicines containing more than 5 milligrams per dose unit in packs containing not more than 750 milligrams of iron
- 87 Isoconazole; for dermal use except when sold in practice by a podiatrist registered with the Podiatrists Board
- 88 Isopropamide; for dermal use in preparations containing 2% or less
- 89 Jalap resin
- 90 Ketoconazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; except in medicines for treatment of the scalp containing 1% or less
- 91 Ketotifen; for ophthalmic use in medicines containing 0.025% or less except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 92 Leucovorin; in medicines containing more than 500 micrograms per recommended daily dose

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- 93 Levocabastine; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 94 Levocetirizine; for oral use
- 95 Lignocaine; for urethral use; for external use in medicines containing 10% or less and more than 2%
- 96 Lindane; for external use in medicines containing 2% or less
- 97 Lithium; for dermal use in medicines containing 1% or less but more than 0.01%; except for dermal use in medicines containing 0.01% or less
- 98 Lobelia inflata; except in medicines for smoking or burning
- 99 Lobeline; except when in medicines for smoking or burning
- 100 Lodoxamide; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 101 Loperamide; in packs containing not more than 20 tablets or capsules; except in divided solid dosage forms for oral use containing 2 milligrams or less of loperamide per dosage form when sold in a pack containing not more than 8 dosage forms approved by the Minister or the Director-General for distribution as a general sales medicine for the symptomatic treatment of acute non-specific diarrhoea
- 102 Loratadine; for oral use; except in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply
- 103 Macrogols; in preparations for oral use as a liquid concentrate for laxative use
- 104 Mebendazole
- 105 Meclozine; in a sealed container of not more than 12 tablets or capsules for the prevention or treatment of travel sickness except when sold at a transport terminal or aboard a ship or aircraft
- 106 Mefenamic acid; in solid dose form in packs containing not more than 30 tablets or capsules for the treatment of dysmenorrhoea
- 107 Mepyramine; for dermal use; except for external use in medicines containing 2% or less in packs not exceeding 25 grams
- 108 Mercuric oxide; for ophthalmic use
- 109 Mercurochrome; in preparations for external use containing 2% or less
- 110 Mercury; for external use in medicines containing 0.5% or less; except in medicines containing 1 milligram or less per litre or per kilogram
- 111 Methoxamine; for external use in medicines containing more than 1%; except for external use in medicines containing 1% or less
- 112 Methoxyphenamine

- 113 Methylephedrine
- 114 Miconazole; for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 115 Minoxidil; for dermal use in medicines containing 5% or less
- 116 Mometasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 200 micrograms (as a single dose) in a pack containing 200 actuations or less
- 117 Morphine; in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine
- 118 Naphazoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 119 Naproxen; in solid dose form containing 250 milligrams or less per dose form in packs of not more than 30 tablets or capsules
- 120 Niclosamide
- 121 Nicotine; for inhalation except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner, nurse, pharmacist, or psychologist
- 122 Nizatidine; in medicines for the symptomatic relief of heartburn, dyspepsia, and hyperacidity or to be used on the recommendation of a registered medical practitioner, when sold in the manufacturer's original pack containing not more than 14 days' supply
- 123 Noscapine
- 124 Nystatin; for dermal use except when sold in practice by a podiatrist registered with the Podiatrists Board; except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 125 Omeprazole; in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units
- 126 Opium; in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

- 127 Oxetacaine; for internal use
- 128 Oxiconazole; for dermal use except in medicines for tinea pedis only
- 129 Oxymetazoline; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less
- 130 Pantoprazole; in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units
- 131 Papaverine; except for injection
- 132 Paracetamol; in liquid form; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams and not more than 50 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack; except in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; except in powder form in sachets containing 1 gram or less and in packs of not more than 10 grams
- 133 Paraformaldehyde; except in medicines containing 5% or less
- 134 Penciclovir; for external use for the treatment of herpes labialis; except in medicines for external use containing 1% or less in a pack containing 10 grams or less for the treatment of herpes labialis
- 135 Phedrazine
- 136 Phenazone; for external use
- 137 Pheniramine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing pheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 138 Phenol; except in medicines other than for injection containing 3% or less
- 139 Phenylephrine; for nasal use in medicines containing more than 1%; for ophthalmic use in medicines containing 5% or less and more than 1%; for oral use in medicines containing more than 50 milligrams per recommended daily dose or in packs containing more than 250 milligrams of phenylephrine per pack; in medicines for the treatment of the symptoms of cough and cold in children aged 6–12 years; except for nasal or ophthalmic use in medicines containing

- 1% or less; except for oral use in medicines containing 50 milligrams or less per recommended daily dose and in packs containing 250 milligrams or less of phenylephrine per pack
- 140 Pholcodine; in medicines for oral use containing not more than 15 milligrams of pholcodine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of pholcodine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine
- 141 Piperazine
- 142 Podophyllotoxin; for external use for the treatment of warts other than anogenital warts in medicines containing 0.5% or less; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 143 Podophyllum emodi; for external use for the treatment of warts other than anogenital warts in medicines containing 10% or less of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 144 Podophyllum peltatum; for external use for the treatment of warts other than anogenital warts in medicines containing 10% or less of podophyllin; except in medicines containing 1 milligram or less of podophyllin per litre or per kilogram
- 145 Potassium; for internal use: in slow-release or enteric coated forms; except for internal use: in medicines containing 100 milligrams or less per recommended dose; in medicines containing more than 100 milligrams per recommended dose except in medicines for oral rehydration therapy, parenteral nutrition replacement, or dialysis; except in glucosamine sulphate complexed products containing 600 milligrams or less of potassium chloride per recommended dose; except for external use
- 146 Potassium chlorate; except in medicines containing 10% or less
- 147 Prilocaine; for dermal use in medicines containing 10% or less of local anaesthetic substances
- 148 Procyclidine; for dermal use in medicines containing 5% or less
- 149 Promethazine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing promethazine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft

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- 150 Propamidine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 151 Pyrantel
- 152 Pyrethrins; except in medicines containing 10% or less
- 153 Pyrithione zinc; except in medicines for treatment of the scalp containing 2% or less
- 154 Ranitidine; in medicines for the symptomatic relief of heartburn, dyspepsia, and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply; except in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply
- 155 Salicylamide
- 156 Selenium; for oral use in medicines containing 300 micrograms or less and more than 150 micrograms per recommended daily dose; for external use except in medicines containing 3.5% or less of selenium sulphide
- 157 Sennosides
- 158 Silver; except in oral solutions containing 0.3% or less or other medicines containing 1% or less
- 159 Silver sulfadiazine; for external use in pack sizes of 50 grams or less
- 160 Sodium cromoglycate; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 161 Sodium nitrite; except for use as an excipient
- 162 Sodium picosulphate; in oral laxative preparations
- 163 Squill; except in medicines containing 1% or less
- 164 Stramonium; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids
- 165 Sulconazole; for dermal use
- 166 Sulfadiazine, silver; for external use in pack sizes of 50 grams or less
- 167 Terbinafine; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 168 Tetrachloroethylene
- 169 Tetrahydrozoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 170 Thiabendazole



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- 171 Tioconazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board
- 172 Tramazoline
- 173 Triamcinolone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age and when in aqueous nasal sprays delivering up to 55 micrograms per actuation when the maximum recommended daily dose is no greater than 220 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine
- 174 Trimeprazine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing trimeprazine or when at least 1 of the other therapeutically active ingredients is a sympathomimetic decongestant
- 175 Triprolidine; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing triprolidine or when at least 1 of the other active ingredients is a sympathomimetic decongestant
- 176 Tuaminoheptane
- 177 Tymazoline
- 178 Xylenols; except in medicines containing 3% or less
- 179 Xylometazoline; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- 180 Zinc chloride; for dermal use in medicines containing more than 5%

## Schedule 2

### Form 1

Application for licence to manufacture, hawk, sell, or pack medicine

*[Before completing this form you should make yourself familiar with the provisions of the Medicines Act 1981 and the Medicines Regulations 1984, especially those parts that deal with licences.]*

*This form may be used to apply for licences to manufacture, pack, sell, or hawk medicines. It is divided into 7 parts. Every applicant must complete either Part 1 or Part 2, and must also complete at least one of Parts 3, 4, 5, 6, and 7.*

*Every application must be accompanied by the prescribed fee for each licence applied for (viz, regulation 61, Medicines Regulations 1984).]*

The form must be completed in type, or in block capitals.

#### **Part 1**

*[To be completed where the applicant is an individual applying for a licence on his own behalf.]*

Name of applicant: [surname] [first names]

I am a New Zealand resident: **Yes/No**

Date of birth: [day/month/year]

Address (home):

Name of business:

Street address of business premises:

Postal address:

General nature of business:

Position of applicant (for example, "owner", "manager" etc):

Have you previously held a licence to manufacture, pack, sell, or hawk medicines?  
**Yes/No**

If **yes** give details:

Have you ever been declined, or had revoked, a licence to manufacture, pack, sell, or hawk medicines? **Yes/No**

If **yes** give details:

**Part 2**

*[To be completed where the applicant is an officer of a body corporate applying for a licence on behalf of the body corporate.]*

Name of body corporate:

The body corporate is incorporated in New Zealand **Yes/No**

Street address of body corporate:

Postal address:

General nature of business of body corporate:

Name of person completing this form: [*surname*] [*first names*]

Position in body corporate of person completing form:

Details of persons nominated to be responsible persons under the Medicines Act 1981:

<b>Name</b>	<b>Date of birth</b>	<b>Position in body corporate</b>
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Have any of the above nominees ever been declined, or had revoked, a licence to manufacture, pack, sell, or hawk medicines? **Yes/No**

If **yes** give details:

Have any of the above nominees ever been a licensee or responsible person under the Restricted Drugs Act 1960 or the Medicines Act 1981? **Yes/No**

If **yes** give details:

### ***Part 3***

#### ***Application to manufacture medicines***

I hereby make application for a licence to manufacture the medicines listed below (attach extra list if insufficient space provided here). Indicate (by reference to one of the following paragraphs) which of the following classes the medicines come within:

- (a) antibiotics, or preparations of antibiotics:
- (b) vaccines and sera:
- (c) sterile preparations:
- (d) hormones and steroid preparations:
- (e) preparations, other than vitamins, having a dose of 5 milligrams or less per unit dose:
- (f) antineoplastic agents and immunosuppressant agents other than steroid preparations:
- (g) other medicines not included in paragraphs (a) to (f), above.

<b>Appropriate designation</b>	<b>Trade name of medicine</b>	<b>Class</b>
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Premises where manufacture (including packing and labelling) of the medicines will be carried out:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:

***Part 4***

***Application to pack medicines***

I hereby make application for a licence to pack the medicines listed below (attach extra list if insufficient space provided here). Indicate in the third column whether the medicine is a prescription medicine, restricted medicine, or pharmacy-only medicine.

<b>Appropriate designation</b>	<b>Trade name of medicine</b>	<b>Class</b>
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Premises where packing and labelling will be carried out:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:

***Part 5***

***Application to sell medicines by wholesale***

I hereby make application to sell by wholesale the following medicines (attach extra list if insufficient space provided here):

Premises from where medicines are to be sold:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:

### ***Part 6***

#### ***Application to sell medicines by retail***

I hereby make application to sell by retail the following medicines (attach extra list if insufficient space provided here):

Premises from where medicines are to be sold:

I declare the above premises are more than 10 kilometres by road from the nearest pharmacy.

The reasons for this application are:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:

### ***Part 7***

#### ***Application to hawk medicines***

I hereby make application for a licence to hawk medicines.

Premises where stock of medicines will be kept:

Place where records of sale of medicines will be kept:

Geographical area in which it is proposed to hawk medicines:

Persons or classes of persons to whom it is proposed to hawk medicines:

Name and maximum quantity of medicines intended to be transported when hawking:

I enclose the fee of:

Signature of applicant (or Common Seal where applicant is a body corporate):

Date:

Schedule 2 form 1 heading: substituted, on 18 September 2004, by regulation 9(1)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 1 Part 1: amended, on 18 September 2004, by regulation 9(1)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 1 Part 2: amended, on 18 September 2004, by regulation 9(1)(c) of the Medicines Amendment Regulations 2004 (SR 2004/300).

## Form 1A

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

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

**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*], [*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 [*date of incorporation*]; and
- (b) has the following board members:  
[*full names of all board members*].

The address of the company is [*address*].

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

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

**Street address and description of pharmacy**

The street address of the pharmacy to which this application relates is [*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: [*name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or “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)): [*name of the interest holder(s) and his or her relevant position (or “none” if applicable)*].

### Eligibility to hold licence

\*The share capital of the company is more than 50% owned by [*full name of pharmacist*† (*or* [*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
  - or*
  - (ii) subject to any conditions that the licensing authority proposes, the extended period or periods permitted by the licensing authority.

*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): [*name(s) and address(es) of pharmacy (or pharmacies) (or "none" if applicable)*].

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

### **\*Mortgagee in possession**

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

\*Delete if inapplicable.

<sup>†</sup>For the purposes of this application a **mortgagee in possession** has the same meaning as in section 4 of the Property Law Act 2007.

Signature of applicant:

### **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 [*place, date*] before me:

[*Signature*]

Justice of the Peace

(*or* other person authorised to take a statutory declaration)

Schedule 2 form 1A: inserted, on 18 September 2004, by regulation 10 of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 1A: amended, on 1 January 2008, by regulation 4 of the Medicines (Property Law Act 2007) Amendment Regulations 2007 (SR 2007/382).

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)

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

**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:

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

\*Delete if inapplicable.

My address (*or* The address of the body corporate) is [*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:

[*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 [*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: [*name(s) of person(s) or company (or companies), their address(es), and the particulars of the interest held (or "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)*): [*name of the interest holder(s) and his or her relevant position (or "none" if applicable)*].

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

[*Specify number, or “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 4 of the Property Law Act 2007.

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 [*place, date*] before me:

[*Signature*]

Justice of the Peace

(*or* other person authorised to take a statutory declaration)

Schedule 2 form 1B: inserted, on 18 September 2004, by regulation 10 of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 1B: amended, on 1 August 2011, by regulation 28 of the Medicines Amendment Regulations 2011 (SR 2011/245).

Form 2  
Licence to manufacture medicines  
(Issued pursuant to the Medicines Act 1981)

Licence No:

Name of licensee:

Address of licensee:

Name of responsible persons:

The \*licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to manufacture, pack, label, and sell by wholesale the following medicines or classes of medicines:

\*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

(1) The manufacture, packing, labelling, or sale of the medicines shall be carried out in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.

(2) [*Further conditions imposed by the licensing authority*]:

This licence shall expire on [*date*].

[*Signature*]

(Licensing authority)

Schedule 2 form 2: amended, on 18 September 2004, by regulation 9(2)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 2: amended, on 18 September 2004, by regulation 9(2)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Form 3  
Licence to hawk medicines  
*(Issued pursuant to the Medicines Act 1981)*

Licence No:

Name of licensee:

Address of licensee:

Names of responsible persons:

The \*licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to hawk the following medicines:

\*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

- (1) All sales shall be made in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
- (2) The stock of medicines held by the licensee or responsible person shall be stored only at the following place or places:
- (3) The records of sale shall be kept at the following premises:
- (4) Sales shall only be made within the following geographical area:
- (5) Sales shall only be made to the following persons or classes of persons:
- (6) *[Further conditions imposed by the licensing authority]:*

This licence shall expire on *[date]*.

*[Signature]*  
(Licensing authority)



Schedule 2 form 3: amended, on 18 September 2004, by regulation 9(3)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 3: amended, on 18 September 2004, by regulation 9(3)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Form 4  
Licence to sell medicines by wholesale  
(Issued pursuant to the Medicines Act 1981)

Licence No:

Name of licensee:

Address of licensee:

Name of responsible persons:

Address of business premises:

The \*licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to sell by wholesale the following medicines:

\*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

- (1) The sale of the above medicines shall not take place other than at the business premises set out above.
- (2) All sales shall be made in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
- (3) [*Further conditions imposed by the licensing authority*]:

This licence shall expire on [*date*].

[*Signature*]  
(Licensing authority)

Schedule 2 form 4: amended, on 18 September 2004, by regulation 9(3)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 4: amended, on 18 September 2004, by regulation 9(3)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Form 5  
Licence to sell medicines by retail  
(Issued pursuant to the Medicines Act 1981)

Licence No:

Name of licensee:

Address of licensee:

Name of responsible persons:

Address of business premises:

The \*licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to sell by retail, and supply in circumstances corresponding to retail sale, the following medicines:

\*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

- (1) The sale of the above medicines shall not take place other than at the business premises set out above.
- (2) All sales shall be made in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
- (3) [*Further conditions imposed by the licensing authority*]:

This licence shall expire on [*date*].

[*Signature*]  
(Licensing authority)

Schedule 2 form 5: amended, on 18 September 2004, by regulation 9(3)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 5: amended, on 18 September 2004, by regulation 9(3)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Form 6  
Licence to pack medicines  
*(Issued pursuant to the Medicines Act 1981)*

Licence No:

Name of licensee:

Address of licensee:

Names of responsible persons:

Address of business premises:

The \*licensee or every responsible person named above is hereby authorised pursuant to section 51 of the Medicines Act 1981 to pack or label for the purpose of sale, and sell by wholesale the following medicines:

\*Delete whichever does not apply.

The authority granted by this licence is subject to the following conditions:

- (1) The packing, labelling, or sale of the medicines shall be carried out in accordance with the Medicines Act 1981 and the Medicines Regulations 1984.
- (2) *[Further conditions imposed by the licensing authority]:*

This licence shall expire on *[date]*.

*[Signature]*  
(Licensing authority)

Schedule 2 form 6: amended, on 18 September 2004, by regulation 9(3)(a) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Schedule 2 form 6: amended, on 18 September 2004, by regulation 9(3)(b) of the Medicines Amendment Regulations 2004 (SR 2004/300).

Form 7  
Licence to operate pharmacy

r 46(1)(f)

*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 [*date*].

[*Signature*]

(Licensing authority)

Schedule 2 form 7: added, on 18 September 2004, by regulation 11 of the Medicines Amendment Regulations 2004 (SR 2004/300).



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**Schedule 3**  
**Loose sheet data sheet requirements**

*[Revoked]*

r 53(2)

Schedule 3: revoked, on 1 August 2011, by regulation 29 of the Medicines Amendment Regulations 2011 (SR 2011/245).

**Schedule 4**  
**Hawker's Medicines book**

r 56(2)(a)

Name of medicine	Form	Strength	Page	
<hr/> <b>Name and address of supplier of medicine</b> <i>or</i> <b>Name and address of person to whom medicine sold</b>				
Date	Order No	In	Out	Balance

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**Schedule 5**  
**Analyst's certificate under the Medicines Act 1981**

r 60

I, *[name]*, an analyst under the Medicines Act 1981, certify that on *[date]* there was submitted to me by *[name and address of the officer from whom the sample was received]* an officer within the meaning of that Act, a sample of *[name or description of sample]* for analysis in a *[nature of the package in which the sample was enclosed, and how it was labelled, marked, and sealed]* and that the same has been analysed and that the result of the analysis is as follows *[analysis and observations]*:

Date:

*[Signature]*  
Analyst

## Schedule 5A Licence fees

rr 45A(1)(b)(i), 61(1)

Schedule 5A: inserted, on 21 August 2006, by regulation 6 of the Medicines (Fees) Amendment Regulations 2006 (SR 2006/188).

		\$
1	An application for a licence to manufacture medicines	13,750
2	An application for a licence to pack medicines	845
3	An application for a licence to sell medicines by retail	845
4	An application for a licence to sell medicines by wholesale	1,054
5	An application for a licence to hawk medicines	845
6	An application for a combined licence to pack, and to sell by retail, medicines	300
7	An application for a licence to operate a pharmacy	1,030

## **Schedule 6**

### **Regulations revoked**

r 62

#### **Part A**

#### **Restricted drugs**

**Restricted Drugs Regulations 1964 (SR 1964/64)**

**Restricted Drugs Regulations 1964, Amendment No 1 (SR 1966/84)**

**Restricted Drugs Regulations 1964, Amendment No 2 (SR 1967/250)**

**Restricted Drugs Regulations 1964, Amendment No 3 (SR 1969/95)**

**Restricted Drugs Regulations 1964, Amendment No 4 (SR 1969/193)**

**Restricted Drugs Regulations 1964, Amendment No 5 (SR 1971/55)**

**Restricted Drugs Regulations 1964, Amendment No 6 (SR 1972/53)**

**Restricted Drugs Regulations 1964, Amendment No 7 (SR 1972/163)**

**Restricted Drugs Regulations 1964, Amendment No 8 (SR 1973/111)**

**Restricted Drugs Regulations 1964, Amendment No 9 (SR 1974/93)**

**Restricted Drugs Regulations 1964, Amendment No 10 (SR 1974/133)**

**Restricted Drugs Regulations 1964, Amendment No 11 (SR 1975/25)**

**Restricted Drugs Regulations 1964, Amendment No 12 (SR 1977/130)**

**Restricted Drugs Regulations 1964, Amendment No 13 (SR 1978/52)**

**Restricted Drugs Regulations 1964, Amendment No 14 (SR 1979/37)**

**Restricted Drugs Regulations 1964, Amendment No 15 (SR 1979/273)**

**Restricted Drugs Regulations 1964, Amendment No 16 (SR 1981/120)**

**Restricted Drugs Regulations 1964, Amendment No 17 (SR 1982/32)**

**Restricted Drugs Regulations 1964, Amendment No 18 (SR 1982/248)**

**Restricted Drugs Regulations 1964, Amendment No 19 (SR 1983/132)**

**Restricted Drugs Regulations 1964, Amendment No 20 (SR 1983/289)**

**Restricted Drugs Regulations 1964, Amendment No 21 (SR 1984/78)**

**Part B  
Restricted drugs licences**

**Restricted Drug Licences Regulations 1961 (SR 1961/39)**

**Restricted Drug Licences Regulations 1961, Amendment No 1 (SR 1963/123)**

**Restricted Drug Licences Regulations 1961, Amendment No 2 (SR 1983/133)**

**Part C  
Therapeutic drugs (permitted sales)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978 (SR 1978/34)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 1  
(SR 1978/230)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 2  
(SR 1979/168)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 3  
(SR 1980/114)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 4  
(SR 1980/264)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 5  
(SR 1981/119)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 6  
(SR 1981/324)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 7  
(SR 1982/189)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 8  
(SR 1983/20)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 9  
(SR 1983/73)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 10  
(SR 1983/147)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 11  
(SR 1983/205)**

**Therapeutic Drugs (Permitted Sales) Regulations 1978, Amendment No 12  
(SR 1984/41)**

P G Millen,  
Clerk of the Executive Council.

Issued under the authority of the Legislation Act 2012.  
Date of notification in *Gazette*: 7 June 1984.

## Reprints notes

### 1 *General*

This is a reprint of the Medicines Regulations 1984 that incorporates all the amendments to those regulations as at the date of the last amendment to them.

### 2 *Legal status*

Reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by any amendments to that enactment. Section 18 of the Legislation Act 2012 provides that this reprint, published in electronic form, has the status of an official version under section 17 of that Act. A printed version of the reprint produced directly from this official electronic version also has official status.

### 3 *Editorial and format changes*

Editorial and format changes to reprints are made using the powers under sections 24 to 26 of the Legislation Act 2012. See also <http://www.pco.parliament.govt.nz/editorial-conventions/>.

### 4 *Amendments incorporated in this reprint*

Medicines Amendment Regulations 2020 (LI 2020/262)

Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020 (2020 No 62): section 30

Abortion Legislation Act 2020 (2020 No 6): section 18(2)

Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (LI 2019/321): regulations 84, 85

Medicines Amendment Regulations 2018 (LI 2018/179)

Medicines Amendment Regulations 2015 (LI 2015/7)

Medicines Amendment Regulations 2014 (LI 2014/165)

Medicines Amendment Regulations 2012 (SR 2012/329)

Criminal Procedure Act 2011 (2011 No 81): section 413

Medicines Amendment Regulations 2011 (SR 2011/245)

Medicines (Property Law Act 2007) Amendment Regulations 2007 (SR 2007/382)

Medicines (Fees) Amendment Regulations 2006 (SR 2006/188)

Medicines Amendment Regulations 2006 (SR 2006/158)

Medicines (Designated Prescriber: Nurse Practitioners) Regulations 2005 (SR 2005/266): regulation 12(2)(a)

Medicines Amendment Regulations 2005 (SR 2005/255)

Medicines Amendment Regulations 2004 (SR 2004/300)

Health Practitioners Competence Assurance Act 2003 (2003 No 48): section 175(3)

Medicines Amendment Regulations (No 2) 2002 (SR 2002/374)

Health and Disability Services (Safety) Act 2001 (2001 No 93): section 58(3)

Medicines Amendment Regulations 2001 (SR 2001/232)

Medicines Amendment Regulations 2000 (SR 2000/220)

Medicines Amendment Regulations 1997 (SR 1997/165)  
Medicines Regulations 1984, Amendment No 6 (SR 1994/299)  
Medicines Regulations 1984, Amendment No 5 (SR 1992/43)  
Medicines Regulations 1984, Amendment No 4 (SR 1991/134)