Reprint
as at 25 October 2018

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 recommenda-

tion 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.

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, tinplate 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 personally (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).

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).

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

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

73 Allylisopropylacetylurea; at all strengths

74 Allyloestrenol

75 Alogliptin

76 Aloracetam

77 Alosetron

78 $Alpha_1$-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

106 Aminopterin

107 Aminorex

108 Aminosalicylic 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 Amoxycillin

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

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

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 Barbital
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

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

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

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

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

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

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

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

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

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

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

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

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 eligbility 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 Dibotermin

621 Dibrompropamidine; 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 Dicloxacillin

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 Diperodon

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

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 Emepronium
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 Epitiostanol
755 Eplerenone
756 Epoetins
757 Epoprostenol
758 Eprosartan
759 Eptifibatide
760 Erenumab

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

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 Etretinate
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

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

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 Fluroxene

885 Fluspirilene

886 Flutamide

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

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

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

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

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 Ibuterol

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

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 Lymecycline

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

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

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 Monobenzone
1334 Monoclonal antibodies; except in pregnancy test kits
1335 Montelukast
1336 Moperone
1337 Morazone
1338 Moricizine

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

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

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

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 Phenoxymethylpenicillin
1587 Phensuximide
1588 Phentermine
1589 Phenthimentonium
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

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

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 Remifentanil
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

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 Ruxolitnib
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 Secbutabarbital

1824 Secobarbital

1825 Secukinumab

1826 Selective androgen receptor modulators

1827 Seletracetam (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

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 Solasadine
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

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

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

2050 Tolfenamic acid
2051 Tolmetin
2052 Tolonium
2053 Tolpropamine
2054 Tolrestat
2055 Tolterodine
2056 Tolvaptan
2057 Topiramate
2058 Topotecan
2059 Torasemide
2060 Toremifene
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

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 antifungal 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 Nicotinyl 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 Staphyloccocus 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_3COOH); 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 Dibrompropamidine; 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

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

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

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:

Name	**Date of birth**	**Position in body corporate**

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.

Appropriate designation	Trade name of medicine	Class

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.

Appropriate designation	Trade name of medicine	Class

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 applicaton relates is a (*or* are) practioner(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*] who is a 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† 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 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 applicaton relates is a (*or* are) practioner(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).

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

Date	Name and address of supplier of medicine *or* Name and address of person to whom medicine sold	Order No	In	Out	Balance

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 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)

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