Version
as at 1 February 2026

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

The Parliamentary Counsel Office has made editorial and format changes to this version using the powers under subpart 2 of Part 3 of the Legislation Act 2019.

Note 4 at the end of this version provides a list of the amendments included in it.

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 publica-

tion, the term means the name or one of the synonyms used in that specified publication for that medicine, related product, or ingredient:

(b) where the medicine, related product, or ingredient—

(i) is not named or described in a monograph contained in the current edition of any specified publication but was named or described in a monograph contained in an earlier edition; and

(ii) is not sold under any name or description except the name or one of the synonyms used in that earlier edition for that medicine, related product, or ingredient,—

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

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

(i) the international non-proprietary name of the medicine, related product, or ingredient; or

(ii) if it has no international non-proprietary name, the name appearing in a list published in the United Kingdom on the recommendation of the Medicines Commission pursuant to section 100 of the Medicines Act 1968 (UK); or

(iii) if the medicine, related product, or ingredient has neither an international non-proprietary name nor a name appearing in a list referred to in subparagraph (ii), its accepted scientific name or some other name descriptive of the true nature of the medicine, related product, or ingredient

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

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

(b) in any other case, means the percentage of each of those ingredients contained in the medicine or related product, or the quantity of each of those ingredients contained in a stated quantity of the medicine or related product

approved immunisation programme means a vaccination programme—

(a) pursuant to the National Immunisation Schedule administered by Pharmac; or

(b) approved by the Director-General or a Medical Officer of Health

biochemical preparation includes—

(a) an antigen; and

(b) an antitoxin; and

(c) a toxin; and

(d) a blood fractionation preparation; and

(e) an insulin; and

(f) a preparation from a mammalian gland; and

(g) a serum; and

(h) a vaccine; and

(i) any other substance or preparation that is similar in nature to any of those specified in paragraphs (a) to (h),—

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

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

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

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

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

(a) classifies the holder as a dispensary assistant; or

(b) records that the person has completed the requirements of the Pharmacy Technicians Certificate

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

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

Pharmac means the Pharmaceutical Management Agency continued by section 67 of the Pae Ora (Healthy Futures) Act 2022

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) **Pharmac**: amended, on 1 July 2022, by section 104 of the Pae Ora (Healthy Futures) Act 2022 (2022 No 30).

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).

2A Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in Schedule 1AA have effect according to their terms.

Regulation 2A: inserted, on 16 June 2023, by regulation 4 of the Medicines Amendment Regulations 2023 (SL 2023/130).

Part 1
Classification of medicines

3 Classification of medicines

(1) All medicines and classes of medicines specified in Part 1 of Schedule 1 are hereby declared to be prescription medicines.

(1A) *[Revoked]*

(1B) *[Revoked]*

(2) All medicines and classes of medicines specified in Part 2 of Schedule 1 are hereby declared to be restricted medicines.

(3) Subject to subclause (4), all medicines and classes of medicines specified in Part 3 of Schedule 1 are hereby declared to be pharmacy-only medicines.

(4) Nothing in subclause (3) shall apply to a remedy that is, and is described as, homoeopathic.

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

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

Part 2
Standards

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

(1) Any medicine or related product, other than a medicine or related product for which a standard is otherwise prescribed in these regulations, shall, where it is described as conforming to a monograph in a specified publication, conform to the description and tests set out in that publication for that medicine or related product.

(2) Every medicine, related product, or cosmetic used or represented as suitable for application into the eye shall conform to the tests for sterility set out in a specified publication.

(3) Every medicine, related product, or cosmetic that is a dusting powder for use on the skin of a baby, or on any inflamed, abraded, or broken skin, shall be free of pathogenic organisms.

(4) No medicine, related product, cosmetic, or dentifrice intended for sale shall contain or have attached to it or enclosed with it any extraneous thing that is harmful, dangerous, or offensive.

(5) A surgical dressing that is described as conforming to a monograph in a specified publication shall conform to the description and tests set out in that publication for that surgical dressing.

(6) A medical device that is described as conforming to a particular description shall conform to that description.

4A Standard for CBD products

(1) The minimum quality standard imposed by Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 applies to a CBD product as if it were both a cannabis-based ingredient and a medicinal cannabis product under those regulations.

(2) However, the minimum quality standard does not apply to a CBD product that is imported by—

(a) a medical practitioner whose purpose is to prescribe, supply, or administer it for the treatment of a particular patient under their care; or

(b) a pharmacist for a prescription to which paragraph (a) applies.

(3) Subclause (4) applies to a CBD product of a type that, at the commencement of this regulation, has been imported into New Zealand by the holder of a licence issued under the Medicines Act 1981.

(4) The minimum quality standard does not apply to any of that product of the licence holder until 1 October 2021.

(4A) The minimum quality standard does not apply to a CBD product if—

(a) it is carried by a traveller when they enter or leave New Zealand; or

(b) it is supplied for a clinical trial under section 30 of the Medicines Act 1981; or

(c) it is used for veterinary medicine; or

(d) it is used for research, testing, analysis, or product development that is not for, or does not relate to, a therapeutic purpose; or

(e) its ingredients are not derived from a cannabis plant; or

(f) it has consent for distribution under the Medicines Act 1981.

(5) In this regulation, **CBD product** has the meaning given by section 2A of the Misuse of Drugs Act 1975.

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

Regulation 4A(4): amended, on 30 March 2021, by regulation 4 of the Medicines Amendment Regulations 2021 (LI 2021/44).

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

Regulation 4A(4A): inserted, on 5 July 2024, by regulation 49 of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (SL 2024/129).

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 4 of the Pae Ora (Healthy Futures) Act 2022); 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).

Regulation 11(3)(a)(ii): amended, on 1 July 2022, by section 104 of the Pae Ora (Healthy Futures) Act 2022 (2022 No 30).

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).

38A Prohibition relating to personal importation of CBD products

A person must not import into New Zealand any CBD product (regardless of whether the ingredients are made from cannabis) for their personal use by any method of import (such as overseas courier or post), except by physically carrying it on the person when entering New Zealand.

Regulation 38A: inserted, on 5 July 2024, by regulation 50 of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (SL 2024/129).

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 12 months' supply.

(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 12 months' supply:

(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 12 months' supply.

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

Regulation 39A(1): replaced, on 1 February 2026, by regulation 4(1) of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

Regulation 39A(2)(a): amended, on 1 February 2026, by regulation 4(2) of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

Regulation 39A(2)(b): amended, on 1 February 2026, by regulation 4(2) of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

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

(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 issue a prescription in paper or electronic form that confirms the oral communication and forward or transmit the prescription to the pharmacist.

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

Regulation 40A heading: amended, on 22 December 2022, by regulation 4(1) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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 22 December 2022, by regulation 4(2) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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

(1) A prescription issued or given under these regulations must be in paper or electronic form.

(2) Every prescription must—

(a) *[Revoked]*

(b) be dated with the date on which it was issued; 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".

(3) A paper prescription must—

(a) be legible and indelible; and

(b) be signed physically by the prescriber in their own handwriting.

(4) An electronic prescription must be completed using, and transmitted through, an approved system.

(5) Any reference in these regulations that relates to including or recording anything in or on a prescription means, for an electronic prescription, including or recording it in the electronic records for the electronic prescription.

(6) In this regulation, **approved system** means a system approved by the Director-General by notice in the *Gazette*.

Regulation 41(1): inserted, on 22 December 2022, by regulation 5(1) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(2): amended, on 22 December 2022, by regulation 5(2) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(2)(a): revoked, on 22 December 2022, by regulation 5(3) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(2)(b): replaced, on 22 December 2022, by regulation 5(3) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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

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

Regulation 41(2)(f): substituted, on 1 December 2011, by regulation 18(3) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(2)(i): revoked, on 1 December 2011, by regulation 18(4) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(2)(j)(i): substituted, on 1 December 2011, by regulation 18(5) of the Medicines Amendment Regulations 2011 (SR 2011/245).

Regulation 41(3): inserted, on 22 December 2022, by regulation 5(4) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(4): inserted, on 22 December 2022, by regulation 5(4) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(5): inserted, on 22 December 2022, by regulation 5(4) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 41(6): inserted, on 22 December 2022, by regulation 5(4) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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 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 must not be dispensed for the first time after 3 months have elapsed from the date on which the prescription was issued or, if given under regulation 40A(1), communicated orally:

(d) a prescription for a medicine must not be dispensed on any occasion after 12 months have elapsed from the date on which the prescription was issued or, if given under regulation 40A(1), communicated orally:

(da) a prescription for a medicine must not, unless requested in accordance with authorisation under regulation 43(1)(c), be dispensed on any occasion in a quantity that exceeds—

(i) 6 months' supply in the case of an oral contraceptive; or

(ii) 3 months' supply in any other case:

(e) every paper 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 dates the prescription; and

(fa) for a paper prescription, the pharmacist signs 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(3)(a): amended, on 22 December 2022, by regulation 6(1) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 42(3)(c): replaced, on 1 February 2026, by regulation 5 of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

Regulation 42(3)(d): replaced, on 1 February 2026, by regulation 5 of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

Regulation 42(3)(da): inserted, on 1 February 2026, by regulation 5 of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

Regulation 42(3)(e): amended, on 22 December 2022, by regulation 6(3) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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

Regulation 42(4)(f): amended, on 22 December 2022, by regulation 6(4) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

Regulation 42(4)(fa): inserted, on 22 December 2022, by regulation 6(5) of the Medicines Amendment Regulations (No 2) 2022 (SL 2022/304).

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; and

(c) authorise—

(i) an authorised prescriber to request dispensing for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in regulation 42(3)(da)(i) or (ii):

(ii) a class of authorised prescribers to request dispensing for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in regulation 42(3)(da)(i) or (ii).

(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).

Regulation 43(1)(c): inserted, on 1 February 2026, by regulation 6 of the Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203).

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 Medicines 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 and supply of vaccines and other medicines 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 or supply, for the purposes of an approved immunisation pro-

gramme, a vaccine or other prescription medicine may, in carrying out that immunisation programme, administer or supply that prescription medicine otherwise than pursuant to a prescription.

(1A) 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 or supply a restricted or pharmacy-only medicine for the purposes of an approved immunisation programme may supply or administer that medicine for those purposes without complying with section 18(1) of the Act.

(2) The Director-General or a Medical Officer of Health may authorise any person for the purposes of subclause (1) or (1A) 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 heading: replaced, on 19 December 2025, by regulation 4(1) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

Regulation 44A(1): amended, on 19 December 2025, by regulation 4(2) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

Regulation 44A(1): amended, on 19 December 2025, by regulation 4(3) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

Regulation 44A(1A): inserted, on 19 December 2025, by regulation 4(4) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

Regulation 44A(2): amended, on 19 December 2025, by regulation 4(5) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

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

44AA Alternative authorisation of vaccinators

(1) The Director-General or a Medical Officer of Health may authorise a person who meets the requirements of this regulation to—

(a) prepare a vaccine:

(b) administer a vaccine without a prescription.

(2) An authorised person must, at all times while performing the tasks authorised under these regulations, work under the clinical supervision and direction of a suitably qualified health practitioner.

Application for authorisation

(3) In applying for authorisation, a person must provide evidence to satisfy the Director-General or the Medical Officer of Health, as the case may be,—

(a) that the person has successfully completed training as approved by the Director-General for either or both of the following:

(i) preparing for administration the 1 or more vaccines for which the person has applied for authorisation:

(ii) administering those vaccines; and

(b) that the person also has the following competencies:

(i) the person can carry out basic emergency techniques, including resuscitation and the treatment of anaphylaxis; and

(ii) the person has knowledge of the safe and effective handling of immunisation products and equipment.

Conditions, etc, of authorisation

(4) The Director-General or the Medical Officer of Health, as the case may be,—

(a) must specify in the authorisation the 1 or more vaccines that the authorised person may prepare or administer (or both):

(b) may, on application by the authorised person, amend the authorisation by adding or removing any vaccine.

(5) An application to add a vaccine must be made in accordance with subclause (3)(a).

(6) The Director-General or the Medical Officer of Health, as the case may be, may—

(a) impose conditions on an authorisation as they think fit:

(b) amend or revoke any condition by written notice to the authorised person.

(7) An authorisation is valid for a period of 2 years, unless it is revoked earlier under subclause (8).

(8) The Director-General or the Medical Officer of Health, as the case may be, may revoke an authorisation by written notice to the authorised person if satisfied that the authorised person has failed to comply with any condition on their authorisation.

Regulation 44AA: inserted, on 19 May 2022, by regulation 4 of the Medicines Amendment Regulations 2022 (SL 2022/116).

44AB Authorisation of COVID-19 vaccinators

[Revoked]

Regulation 44AB: revoked, on 1 June 2023, by regulation 44AB(5).

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).

44BA Restriction on prescribing gonadotropin-releasing hormone analogues

(1) An authorised prescriber must not prescribe a prescription medicine that is a gonadotropin-releasing hormone analogue for the purpose of puberty suppression in a person who is a child or adolescent with—

(a) gender incongruence; or

(b) gender dysphoria.

(2) *See* Part 2 of Schedule 1AA for a transitional provision in respect of this regulation.

Regulation 44BA: inserted, on 19 December 2025, by regulation 4 of the Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025 (SL 2025/256).

Regulation 44BA(1): amended, on 19 December 2025, by regulation 4 of the Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations (No 2) 2025 (SL 2025/302).

Part 7A
Export of prescription medicines

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

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

(1) No person may export a prescription medicine in the course or for the purpose of retail sale, otherwise than under a prescription given by a practitioner, a registered midwife, or a designated prescriber.

(2) The meaning of **retail sale** in subclause (1) must be determined by reference to section 5(2) of the Act.

(3) Subclause (1) is intended to limit the sale and supply of prescription medicines pursuant to section 33(b) of the Act.

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

Part 7B
Supply of restricted medicine and pharmacy-only medicine

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

44D Supply of restricted medicine and pharmacy-only medicine

(1) A person may, in the course of any business carried on by that person, supply a restricted medicine or pharmacy-only medicine if he or she—

(a) is authorised to supply the medicine in accordance with a standing order; and

(b) supplies that medicine in accordance with that standing order.

(2) The circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under subclause (1) are in addition to the circumstances in which a person may supply a restricted medicine or pharmacy-only medicine under section 18(1)(b) or (c) of the Medicines Act 1981.

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

Part 8
Licences

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

(1) Every application for a licence to manufacture, hawk, sell, or pack medicine must—

(a) be made in form 1 of Schedule 2:

(b) be accompanied by the appropriate fee:

(c) specify—

(i) the premises the applicant intends to use for the activity to which the application relates; or

(ii) in the case of an application for a licence to hawk medicines, the area in which the applicant intends to operate:

(d) specify the medicines, or the descriptions or classes of medicines, that the applicant proposes to manufacture, hawk, sell, or pack:

(e) specify—

(i) the applicant's qualifications; or

(ii) if the applicant is a body corporate, the qualifications of every person who will, if the application is successful, be a responsible person for the purposes of the licence to which the application relates:

(f) in the case of an application for a licence to sell any medicine by retail or to hawk any medicine, be accompanied by a certificate of character that states that the applicant—

(i) is well known to the person giving the certificate; and

(ii) is of good character; and

(iii) is considered by the person giving the certificate to be a fit and proper person to be licensed to sell or hawk medicine.

(2) A licence to undertake an activity referred to in subclause (1) may only be granted in respect of 1 place of business.

(3) Despite subclause (2), the licensing authority may grant a licence that allows for the manufacture of medicine, or a description or class of medicines, at more than 1 place of business if—

(a) the application to which the licence relates is made by a body corporate; and

(b) the licensing authority is satisfied that the body corporate has taken steps to ensure appropriate supervision of the manufacture of the product at each of the places of business.

(4) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:

(a) further information:

(b) an opportunity to inspect the applicant's premises and equipment.

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

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

45A Application for licence to operate pharmacy

(1) Every application for a licence to operate a pharmacy must—

(a) be made,—

(i) in the case of a company, in form 1A of Schedule 2; and

(ii) in the case of a person (including a body corporate that is not a company), in form 1B of Schedule 2; and

(b) be accompanied by—

(i) the appropriate fee prescribed in Schedule 5A; and

(ii) a completed statutory declaration (as set out in the relevant form).

(2) A licence to operate a pharmacy may only be granted in respect of 1 place of business.

(3) Every applicant for a licence under this regulation must provide the licensing authority with the following things if required by the licensing authority under section 51 of the Act:

(a) further information:

(b) an opportunity to inspect the applicant's premises and equipment.

(4) The licensing authority may, in order to determine if a person to whom section 51(1)(d) of the Act applies has a sufficient knowledge of the obligations of a

licensee and of the hazards associated with the medicines to which a licence to operate a pharmacy relates, require that person to undertake and pass any oral, written, or practical tests that the licensing authority considers reasonably necessary in the particular case.

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

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

45B Licences that relate to CBD products

(1) A licence to manufacture medicines, to sell medicines by wholesale, to pack medicines, or to operate a pharmacy that is issued under these regulations does not apply to a CBD product (as defined by section 2A of the Misuse of Drugs Act 1975) unless expressly authorised by the licence.

(2) The licence must not be issued, or amended, to expressly authorise its application to the supply of a CBD product unless—

(a) the product has been assessed as complying with the minimum quality standard under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019; or

(b) the product is being manufactured and supplied for export only and the exporter provides evidence to the Director-General that the ingredients and products are accepted by the importing country; or

(c) the product has consent for distribution under the Medicines Act 1981; or

(d) the product is not intended for therapeutic use in a human; or

(e) the active ingredients and cannabinoids in the product are not made from cannabis; or

(f) the product is being imported and supplied by a pharmacist under regulation 4A(2); or

(g) the product is being supplied for a clinical trial under section 30 of the Medicines Act 1981.

(3) A product is assessed as complying with the minimum quality standard under those regulations if—

(a) an application is made under those regulations to assess the CBD product, in which case those regulations (including the requirement to pay fees) apply for that purpose as if the product were being assessed as a medicinal cannabis product; and

(b) the Director-General assesses the evidence in the application and is satisfied that a representative sample of at least 10% of each of 3 batches of the product complied with the minimum quality standard.

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

Regulation 45B(2): replaced, on 5 July 2024, by regulation 51 of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (SL 2024/129).

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 has the same meaning as in section 6 of the Water Services Act 2021

drinking water supply has the same meaning as in section 9 of the Water Services Act 2021

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).

Regulation 58B(1): amended, on 15 November 2021, by section 206(2) of the Water Services Act 2021 (2021 No 36).

Regulation 58B(4) **drinking water**: replaced, on 15 November 2021, by section 206(2) of the Water Services Act 2021 (2021 No 36).

Regulation 58B(4) **drinking water supply**: replaced, on 15 November 2021, by section 206(2) of the Water Services Act 2021 (2021 No 36).

58C Substances used to terminate pregnancy are medicines

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

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

58D Non-oral products containing nicotine are medicines

(1) Products containing nicotine that are not for oral use are medicines for the purposes of the Act.

(2) To avoid doubt, **oral use** includes (without limitation) inhalation.

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

58E Medications used for assisted dying are medicines

Medications, when used for assisted dying under the End of Life Choice Act 2019, are medicines for the purposes of the Act.

Regulation 58E: inserted, on 7 November 2021, by regulation 4 of the Medicines (Assisted Dying Medications) Amendment Regulations 2021 (LI 2021/266).

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 $79,877.

(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 $5,731.

(6) The fee to accompany an application made under section 23 of the Act for the Minister's provisional consent shall be $85,202.

(7) The fee to accompany a notice deposited with the Director-General under section 24 of the Act shall be $79,877.

(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 1 July 2022, by regulation 6(1) of the Medicines Amendment Regulations 2022 (SL 2022/116).

Regulation 61(5): amended, on 1 July 2022, by regulation 6(2) of the Medicines Amendment Regulations 2022 (SL 2022/116).

Regulation 61(6): amended, on 1 July 2022, by regulation 6(3) of the Medicines Amendment Regulations 2022 (SL 2022/116).

Regulation 61(7): amended, on 1 July 2022, by regulation 6(4) of the Medicines Amendment Regulations 2022 (SL 2022/116).

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), 44BA, 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 38A, 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 19 December 2025, by regulation 5 of the Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025 (SL 2025/256).

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 5 July 2024, by regulation 52 of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (SL 2024/129).

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

[Revoked]

Regulation 65A: revoked, on 16 June 2023, by regulation 5 of the Medicines Amendment Regulations 2023 (SL 2023/130).

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 1AA
Transitional, savings, and related provisions

r 2A

Schedule 1AA: inserted, on 16 June 2023, by regulation 6 of the Medicines Amendment Regulations 2023 (SL 2023/130).

Part 1
Provisions relating to Medicines Amendment Regulations 2023

Schedule 1AA Part 1: inserted, on 16 June 2023, by regulation 6 of the Medicines Amendment Regulations 2023 (SL 2023/130).

1 Exemption from requirement in regulation 13(1)(f) for zopiclone and zolpidem supplied before 1 July 2023

The requirement in regulation 13(1)(f) does not apply in respect of zopiclone or zolpidem supplied by a retailer, manufacturer, or wholesaler before 1 July 2023.

Schedule 1AA clause 1: inserted, on 16 June 2023, by regulation 6 of the Medicines Amendment Regulations 2023 (SL 2023/130).

2 Exemption from requirement in regulation 13(1)(f) for tramadol supplied before 1 October 2023

The requirement in regulation 13(1)(f) does not apply in respect of tramadol supplied by a retailer, manufacturer, or wholesaler before 1 October 2023.

Schedule 1AA clause 2: inserted, on 16 June 2023, by regulation 6 of the Medicines Amendment Regulations 2023 (SL 2023/130).

Part 2
Provision relating to Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025

Schedule 1AA Part 2: inserted, on 19 December 2025, by regulation 6(a) of the Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025 (SL 2025/256).

3 Application of restriction in regulation 44BA

The restriction in regulation 44BA does not apply in respect of a person who has been prescribed a prescription medicine that is a gonadotropin-releasing hormone analogue for a purpose described in regulation 44BA before 19 December 2025.

Schedule 1AA clause 3: inserted, on 19 December 2025, by regulation 6(a) of the Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025 (SL 2025/256).

Part 3
Provisions relating to Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025

Schedule 1AA Part 3: inserted, on 19 December 2025, by regulation 5(b) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

4 Interpretation

In this Part,—

commencement date means the date on which the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 come into force

existing authorisation means an authorisation given before the commencement date under regulation 44A to administer, for the purposes of an approved immunisation programme, a vaccine otherwise than pursuant to a prescription.

Schedule 1AA clause 4: inserted, on 19 December 2025, by regulation 5(b) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

5 Existing authorisations

A medical practitioner or other person who has an existing authorisation is treated as having been authorised to administer or supply, for the purposes of an approved immunisation programme,—

(a) a vaccine or other prescription medicine otherwise than pursuant to a prescription; and

(b) a restricted or pharmacy-only medicine without complying with section 18(1) of the Act.

Schedule 1AA clause 5: inserted, on 19 December 2025, by regulation 5(b) of the Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318).

Schedule 1
Prescription, restricted, and pharmacy-only medicines

r 3

Schedule 1: replaced, on 1 September 2021, by regulation 4 of the Medicines Amendment Regulations (No 2) 2021 (LI 2021/228).

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 Abemaciclib

11 Abiraterone

12 Abrus precatorius; at all strengths

13 Acamprosate

14 Acarbose

15 Acebutolol

16 Acepromazine

17 Acetanilides

18 Acetarsol

19 Acetazolamide

20 Acetohexamide

21 Acetylcarbromal

22 Acetylcholine; except in medicines containing 1 milligram or less per litre or per kilogram

23 Acetylcysteine; for injection or inhalation

24 Acetyldigitoxin

25 Acetylmethyldimethyloximidophenylhydrazine

26 Acetylstrophanthidin

27 Aciclovir; except when specified elsewhere in this schedule

28 Acipimox

29 Acitretin

30 Aclidinium bromide

31 Acokanthera ouabaio

32 Acokanthera schimperi

33 Aconitum spp; except when specified elsewhere in this schedule

34 Acrivastine

35 Adalimumab

36 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

37 Adefovir

38 Adenosine; for injection

39 Adinazolam

40 Adiphenine

41 Adonis vernalis

42 Adrafinil

43 Adrenal extract; except for dermal use in medicines containing 0.02% or less of ketosteroids

44 Adrenaline; in medicines containing more than 1%

45 Adrenocortical hormones; except adrenal extract for dermal use containing 0.02% or less of ketosteroids

46 Afamelanotide

47 Afatinib

48 Aflibercept

49 Agalsidase

50 Agomelatine

51 Alatrofloxacin

52 Albendazole

53 Albumin; except human albumin

54 Alclofenac

55 Alclometasone; except when specified elsewhere in this schedule

56 Alcohol; for injection in medicines containing more than 20%

57 Alcuronium

58 Aldesleukin

59 Aldosterone; except in medicines containing 10 micrograms or less per litre or per kilogram

60 Alectinib

61 Alefacept

62 Alemtuzumab

63 Alendronic acid

64 Alfacalcidol

65 Alfentanil

66 Alfuzosin

67 Alglucerase

68 Alglucosidase

69 Alirocumab

70 Aliskiren

71 Alitretinoin

72 Alkyl nitrites

73 Alkyl sulfonals

74 Allergens

75 Allopurinol

76 Allylisopropylacetylurea; at all strengths

77 Allyloestrenol

78 Alogliptin

79 Aloracetam

80 Alosetron

81 Alpelisib

82 $Alpha_1$-proteinase inhibitor

83 Alphadolone

84 Alphaxalone

85 Alprazolam

86 Alprenolol

87 Alprostadil

88 Alseroxylon

89 Alteplase

90 Altretamine

91 Amantadine

92 Ambenonium

93 Ambrisentan

94 Ambucetamide

95 Ambutonium

96 Amcinonide

97 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

98 Amfebutamone

99 Amfepramone

100 Amidopyrine

101 Amifampridine

102 Amifostine

103 Amikacin

104 Amiloride

105 Aminocaproic acid

106 Aminoglutethimide

107 Aminometradine

108 Aminophenazone; at all strengths

109 Aminophylline; except when specified elsewhere in this schedule

110 Aminopterin

111 Aminorex

112 Aminosalicylic acid

113 Amiodarone

114 Amiphenazole

115 Amisometradine

116 Amisulpride

117 Amitriptyline

118 Amlodipine

119 Ammi visnaga

120 Ammonium bromide

121 Amobarbital

122 Amodiaquine

123 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

124 Amoxapine

125 Amoxycillin

126 Amphomycin

127 Amphotericin

128 Ampicillin

129 Amprenavir

130 Amrinone

131 Amsacrine

132 Amygdalin; at all strengths

133 Amyl nitrite; except when sold to a person who is appropriately authorised under the Health and Safety at Work Act 2015

134 Amylocaine

135 Anabolic steroids

136 Anagrelide

137 Anakinra

138 Anastrozole

139 Ancestim

140 Anchusa officinalis; at all strengths

141 Ancrod and its immunoglobulin antidote

142 Androgenic and anabolic steroidal agents

143 Androgens

144 Androisoxazole

145 Androstanolone

146 Androstenediol

147 Androstenedione

148 Anecortave

149 Angiotensinamide

150 Anidulafungin

151 Aniracetam

152 Anistreplase

153 Antazoline; except for ophthalmic use

154 Antibiotic substances; except when specified elsewhere in this schedule

155 Antigens

156 Antihistamines; except when specified elsewhere in this schedule

157 Antimony; except in medicines containing 1 milligram or less per litre or per kilogram

158 Antisera; for injection

159 AOD-9604

160 Apalutamide

161 Apixaban

162 Apocynum spp

163 Apomorphine; except in medicines containing 1 milligram or less per litre or per kilogram

164 Apraclonidine

165 Apremilast

166 Aprepitant

167 Apronal

168 Aprotinin

169 Arecoline

170 Aripiprazole

171 Aristolochia spp; at all strengths

172 Aristolochic acid; at all strengths

173 Armodafinil

174 Arsenic; except in medicines containing 1 milligram or less per litre or per kilogram

175 Artemether

176 Artemisia annua extract

177 Artesunate

178 Articaine; except when used as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council

179 Asenapine

180 Asfotase alfa

181 Asparaginase

182 Aspirin; except when specified elsewhere in this schedule; for injection; when combined with caffeine, paracetamol, or salicylamide

183 Astemizole

184 Asunaprevir

185 Atamestane

186 Atazanavir

187 Atenolol

188 Atezolizumab

189 Atomoxetine

190 Atorvastatin

191 Atosiban

192 Atovaquone

193 Atracurium

194 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

195 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

196 Atropine methonitrate

197 Auranofin

198 Aurothiomalate sodium

199 Avanafil

200 Avelumab
201 Avibactam
202 Aviptadil
203 Axitinib
204 Azacitidine
205 Azacyclonol
206 Azapropazone
207 Azaribine
208 Azatadine; except when specified elsewhere in this schedule
209 Azathioprine
210 Azelaic acid; except when specified elsewhere in this schedule
211 Azelastine; except when specified elsewhere in this schedule
212 Azithromycin
213 Azlocillin
214 Aztreonam
215 Bacampicillin
216 Bacitracin
217 Baclofen
218 Baloxavir marboxil
219 Balsalazide
220 Bambuterol
221 Bamethan
222 Bamipine
223 Bamlanivimab
224 Barbital
225 Barbiturates
226 Baricitinib
227 Basiliximab
228 Bazedoxifene
229 Becaplermin
230 Beclamide
231 Beclomethasone; except when specified elsewhere in this schedule
232 Bedaquiline
233 Belatacept
234 Belimumab

235 Bemegride
236 Benactyzine
237 Benazepril
238 Bendamustine
239 Bendrofluazide
240 Benethamine penicillin
241 Benorylate
242 Benoxaprofen
243 Benperidol
244 Benralizumab
245 Benserazide
246 Benzathine penicillin
247 Benzatropine
248 Benzbromarone
249 Benzhexol
250 Benzilonium
251 Benzocaine; except when specified elsewhere in this schedule
252 Benzodiazepine derivatives; except when specified elsewhere in this schedule
253 Benzodiazepines; except when specified elsewhere in this schedule
254 Benzoyl metronidazole
255 Benzoyl peroxide; except when specified elsewhere in this schedule
256 Benzthiazide
257 Benzydamine; except when specified elsewhere in this schedule
258 Benzylpenicillin
259 Bepridil
260 Beractant
261 Besifloxacin
262 Beta carotene; in medicines containing more than 18 milligrams per recommended daily dose
263 Betahistine
264 Betaine; for the treatment of homocystinuria
265 Betamethasone
266 Betaxolol
267 Bethanechol
268 Bethanidine

269 Bevacizumab

270 Bevantolol

271 Bexarotene

272 Bezafibrate

273 Bezlotoxumab

274 Bicalutamide

275 Bictegravir

276 Bifonazole; except when specified elsewhere in this schedule

277 Bilastine; except when specified elsewhere in this schedule

278 Bimatoprost

279 Binimetinib

280 Biperiden

281 Bismuth; except for external use in medicines containing 3% or less

282 Bisoprolol

283 Bithionol; at all strengths

284 Bivalirudin

285 Bleomycin

286 Blinatumomab

287 Boceprevir

288 Bolandiol

289 Bolasterone

290 Bolazine

291 Boldenone

292 Bolenol

293 Bolmantalate

294 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

295 Bortezomib

296 Bosentan

297 Bosutinib

298 Botulinum toxins

299 Brentuximab vedotin

300 Bretylium

301 Brexpiprazole
302 Brigatinib
303 Brimonidine
304 Brinzolamide
305 Brivaracetam (and its stereoisomers)
306 Brolucizumab
307 Bromazepam
308 Bromocriptine
309 Bromoform
310 Brompheniramine; except when specified elsewhere in this schedule
311 Bromvaletone
312 Brotizolam
313 Brugmansia spp
314 Buclizine; except for oral use
315 Budesonide; except when specified elsewhere in this schedule
316 Bufexamac; except in suppositories; except for dermal use in medicines containing 5% or less
317 Bumetanide
318 Buniodyl sodium; at all strengths
319 Buphenine
320 Bupivacaine
321 Buprenorphine
322 Bupropion
323 Buserelin
324 Buspirone
325 Busulphan
326 Butacaine
327 Butobarbital
328 Butoconazole; except for vaginal use
329 Butorphanol
330 Butyl aminobenzoate; except in medicines for dermal use containing 2% or less
331 Butyl nitrite
332 Butylchloral hydrate
333 Cabazitaxel

334 Cabergoline

335 Cabotegravir

336 Cabozantinib

337 Cacalia spp; at all strengths

338 Cadmium

339 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

340 Calcitonin

341 Calcitriol

342 Calcium carbimide

343 Calcium polystyrene sulphonate

344 Calotropis gigantea

345 Calotropis procera

346 Calusterone

347 Camazepam

348 Camphorated oil

349 Camphotamide

350 Canagliflozin

351 Canakinumab

352 Candesartan

353 Candicidin

354 Cannabidiol

355 Capecitabine

356 Capreomycin

357 Captodiame

358 Captopril

359 Capuride

360 Caramiphen

361 Carbachol

362 Carbamazepine

363 Carbaryl; except for external use in medicines containing 2% or less

364 Carbazochrome

365 Carbenicillin

366 Carbenoxolone; except for external use
367 Carbetocin
368 Carbidopa
369 Carbimazole
370 Carbocromen
371 Carboplatin
372 Carboprost
373 Carbromal
374 Carbutamide
375 Carbuterol
376 Carfilzomib
377 Carglumic acid
378 Carindacillin
379 Carisoprodol
380 Carmustine
381 Carprofen
382 Carvedilol
383 Caspofungin
384 Catumaxomab
385 Cebaracetam (and its stereoisomers)
386 Cedazuridine
387 Cefacetrile
388 Cefaclor
389 Cefaloridine
390 Cefamandole
391 Cefapirin
392 Cefazolin
393 Cefepime
394 Cefetamet
395 Cefixime
396 Cefodizime
397 Cefonicid
398 Cefoperazone
399 Cefotaxime
400 Cefotetan

401 Cefotiam
402 Cefoxitin
403 Cefpirome
404 Cefpodoxime
405 Cefsulodin
406 Ceftaroline fosamil
407 Ceftazidime
408 Ceftibuten
409 Ceftolozane
410 Ceftriaxone
411 Cefuroxime
412 Celecoxib
413 Celiprolol
414 Cenegermin
415 Cephaelis acuminata; except in medicines containing less than 0.2% of emetine
416 Cephaelis ipecacuanha; except in medicines containing less than 0.2% of emetine
417 Cephalexin
418 Cephalothin
419 Cephradine
420 Ceritinib
421 Cerivastatin
422 Cerliponase alfa
423 Certolizumab pegol
424 Ceruletide
425 Cetirizine; except when specified elsewhere in this schedule
426 Cetrorelix
427 Cetuximab
428 Chenodeoxycholic acid
429 Chloral hydrate; except for dermal use in medicines containing 2% or less
430 Chloralformamide
431 Chloralose
432 Chlorambucil

433 Chloramphenicol; except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except when specified elsewhere in this schedule

434 Chlorandrostenolone

435 Chlorazanil

436 Chlorcyclizine

437 Chlordiazepoxide

438 Chlormerodrin

439 Chlormethiazole

440 Chlormezanone

441 Chloroform; for anaesthesia; except when specified elsewhere in this schedule

442 Chloroquine

443 Chlorothiazide

444 Chlorotrianisene

445 Chloroxydienone

446 Chloroxymesterone

447 Chlorpheniramine; except when specified elsewhere in this schedule

448 Chlorphentermine

449 Chlorpromazine

450 Chlorpropamide

451 Chlorprothixene

452 Chlorquinaldol

453 Chlortetracycline

454 Chlorthalidone

455 Chlorzoxazone

456 Cholera vaccine; except in the form of an oral liquid containing vibrio cholerae when sold in a pharmacy by a registered pharmacist

457 Cholic acid

458 Choline salicylate; except in medicines containing 10% or less and in pack sizes of 15 grams or less

459 Chorionic gonadotrophin; except in pregnancy test kits

460 Chymopapain

461 Ciclacillin

462 Ciclesonide

463 Ciclopirox; except when specified elsewhere in this schedule

464 Cidofovir

465 Cilastatin

466 Cilazapril

467 Cilnidipine

468 Cilostazol

469 Cimetidine; except when specified elsewhere in this schedule

470 Cinacalcet

471 Cinchocaine; for injection; for ophthalmic use; for external use in medicines containing more than 0.5%

472 Cinchophen

473 Cinnarizine

474 Cinoxacin

475 Ciprofloxacin

476 Cisapride

477 Cisatracurium

478 Cisplatin

479 Citalopram

480 CJC-1295

481 Cladribine

482 Clarithromycin

483 Clavulanic acid

484 Clemastine; except for oral use

485 Clemizole

486 Clenbuterol

487 Clevidipine

488 Clidinium

489 Clindamycin

490 Clioquinol; at all strengths

491 Clobazam

492 Clobetasol

493 Clobetasone; except when specified elsewhere in this schedule

494 Clocortolone

495 Clodronic acid

496 Clofarabine

497 Clofazimine

498 Clofenamide
499 Clofibrate
500 Clomiphene
501 Clomipramine
502 Clomocycline
503 Clonazepam
504 Clonidine
505 Clopamide
506 Clopidogrel
507 Clorazepic acid
508 Clorexolone
509 Clorprenaline
510 Clostebol
511 Clotiazepam
512 Clotrimazole; except when specified elsewhere in this schedule
513 Cloxacillin
514 Cloxazolam
515 Clozapine
516 Cobalt
517 Cobicistat
518 Cobimetinib
519 Cocaine; except when specified elsewhere in this schedule
520 Codeine
521 Co-dergocrine
522 Colaspase
523 Colchicine
524 Colchicum
525 Colecalciferol; except in medicines containing 25 micrograms or less per recommended daily dose; except in parenteral nutrition replacement preparations
526 Colestipol
527 Colestyramine
528 Colfosceril
529 Colistin
530 Collagen; in injections or implants for tissue augmentation or cosmetic use
531 Collagenase clostridium histolyticum

532 Coluracetam

533 Conium maculatum; at all strengths

534 Convallaria keiski

535 Convallaria majalis

536 Corifollitropin alfa

537 Coronilla spp

538 Corticosterone

539 Corticotrophin

540 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

541 Cotarnine; at all strengths

542 Co-trimoxazole

543 Coumarin

544 COVID-19 vaccines; except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the COVID-19 Vaccinator Education Course (or any equivalent training course on COVID-19 vaccination approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course or the COVID-19 Vaccinator - Working under Supervision Course)

545 Crisaborole

546 Crizotinib

547 Crofelemer

548 Crotalaria spp; at all strengths

549 Croton tiglium; except in medicines containing 1 milligram or less per litre or per kilogram

550 Crystal violet

551 Curare

552 Cyclandelate

553 Cyclizine; except when specified elsewhere in this schedule

554 Cyclobenzaprine

555 Cyclofenil

556 Cycloheximide

557 Cyclopenthiazide

558 Cyclopentolate; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

559 Cyclophosphamide
560 Cyclopropane
561 Cycloserine
562 Cyclosporin
563 Cyclothiazide
564 Cycrimine
565 Cymarin
566 Cynoglossum spp; at all strengths
567 Cyproheptadine; except for oral use
568 Cyproterone
569 Cysteamine
570 Cytarabine
571 Dabigatran
572 Dabrafenib mesilate
573 Dacarbazine
574 Daclatasvir
575 Daclizumab
576 Dactinomycin
577 Dalfopristin
578 Dalteparin
579 Danaparoid
580 Danazol
581 Danthron
582 Dantrolene
583 Dapagliflozin
584 Dapoxetine
585 Dapsone
586 Daptomycin
587 Daratumumab
588 Darbepoetin
589 Darifenacin
590 Darolutamide
591 Darunavir
592 Dasabuvir
593 Dasatinib

594 Datura spp; except for oral use when specified elsewhere in this schedule; except datura stramonium or datura tatula for smoking or burning

595 Daunorubicin

596 Deanol

597 Debrisoquine

598 Decamethonium

599 Decitabine

600 Deferasirox

601 Deferiprone

602 Defibrotide

603 Deflazacort

604 Degarelix

605 Dehydrochloromethyltestosterone

606 Dehydrocorticosterone

607 Delavirdine

608 Delorazepam

609 Demecarium

610 Demeclocycline

611 Denosumab

612 Deoxycortone

613 Deoxycholic acid; for injection; except for oral use

614 Deoxyribonuclease; except for external use

615 Dermatophagoides farina allergen extract

616 Dermatophagoides pteronyssinus allergen extract

617 Desferrioxamine

618 Desflurane

619 Desipramine

620 Desirudin

621 Deslanoside

622 Desloratadine; except for oral use

623 Deslorelin

624 Desmopressin

625 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

626 Desonide

627 Desoximetasone

628 Desvenlafaxine

629 Dexamethasone

630 Dexamfetamine

631 Dexchlorpheniramine; except when specified elsewhere in this schedule

632 Dexfenfluramine

633 Dexmedetomidine

634 Dextromethorphan; except when specified elsewhere in this schedule

635 Dextromoramide

636 Dextropropoxyphene

637 Dextrorphan

638 Di-iodohydroxy quinoline; except when specified elsewhere in this schedule

639 Di-isopropylamine dichloroacetate

640 Diazepam

641 Diazoxide

642 Dibenzepin

643 Dibotermin

644 Dibrompropamidine; except for ophthalmic use

645 Dichloralphenazone

646 Dichlorophen

647 Dichlorphenamide

648 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

649 Dicloxacillin

650 Dicyclomine

651 Didanosine

652 Dienoestrol

653 Dienogest

654 Diethazine

655 Diethylcarbamazine

656 Diethylstilbestrol
657 Diflorasone
658 Diflucortolone
659 Diflunisal
660 Digitalis lanata
661 Digitalis purpurea
662 Digitoxin
663 Digoxin
664 Digoxin-specific antibody fragment
665 Dihydralazine
666 Dihydrocodeine
667 Dihydroergotoxine
668 Dihydrolone
669 Dihydrotachysterol
670 Diltiazem
671 Dimenhydrinate; except when specified elsewhere in this schedule
672 Dimercaprol
673 Dimethandrostanolone
674 Dimethazine
675 Dimethindene; except for oral use
676 Dimethothiazine
677 Dimethoxanate
678 Dimethyl fumarate
679 Dimethyl sulphoxide
680 Dimiracetam (and its stereoisomers)
681 Dinitrocresols
682 Dinitronaphthols
683 Dinitrophenols
684 Dinitrothymols
685 Dinoprost
686 Dinoprostone
687 Diperodon
688 Diphemanil; except for dermal use
689 Diphenhydramine; except when specified elsewhere in this schedule
690 Diphenidol

691 Diphenoxylate; except when specified elsewhere in this schedule

692 Diphenylpyraline

693 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 the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

694 Diphtheria toxoid

695 Diphtheria vaccine

696 Dipivefrin

697 Dipyridamole

698 Dirithromycin

699 Disopyramide

700 Distigmine

701 Disulfiram

702 Disulphamide

703 Ditiocarb

704 DMHA, including the isomers 2-amino-6-methylheptane (also known as 1,5-dimethylhexylamine, and octodrine) and 2-amino-5-methylheptane (also known as 1,4-dimethylhexylamine)

705 Dobutamine

706 Docetaxel

707 Dofetilide

708 Dolasetron

709 Doliracetam (and its stereoisomers)

710 Dolutegravir

711 Domperidone

712 Donepezil

713 Dopamine

714 Dopexamine

715 Doravirine

716 Doripenem

717 Dornase

718 Dorzolamide

719 Dothiepin
720 Doxantrazole
721 Doxapram
722 Doxazosin
723 Doxepin
724 Doxorubicin
725 Doxycycline
726 Doxylamine; except when specified elsewhere in this schedule
727 Dronedarone
728 Droperidol
729 Drospirenone
730 Drostanolone
731 Drotrecogin
732 Duboisia leichhardtii; except when specified elsewhere in this schedule
733 Duboisia myoporides; except when specified elsewhere in this schedule
734 Dulaglutide
735 Dulcin; at all strengths
736 Duloxetine
737 Dupilumab
738 Dupracetam
739 Durvalumab
740 Dutasteride
741 Dydrogesterone
742 Econazole; except when specified elsewhere in this schedule
743 Ecothiopate
744 Ectylurea
745 Eculizumab
746 Edetic acid; except in medicines containing 0.25% or less; except in contact lens preparations; except dicobalt edetate for the treatment of cyanide poisoning
747 Edoxudine
748 Edrophonium
749 Efalizumab
750 Efavirenz
751 Eflornithine

752 Elbasvir
753 Eletriptan
754 Elosulfase alfa
755 Elotuzumab
756 Eltrombopag olamine
757 Eluxadoline
758 Elvitegravir
759 Emepronium
760 Emetine; except in medicines containing 0.2% or less
761 Emicizumab
762 Empagliflozin
763 Emtricitabine
764 Enalapril
765 Enasidenib
766 Encorafenib
767 Enestebol
768 Enflurane
769 Enfuvirtide
770 Enobosarm
771 Enoxacin
772 Enoxaparin
773 Enoximone
774 Enprostil
775 Entacapone
776 Entecavir
777 Entrectinib
778 Enzalutamide
779 Ephedrine
780 Epicillin
781 Epinastine
782 Epirubicin
783 Epitiostanol
784 Eplerenone
785 Epoetins
786 Epoprostenol

787 Eprosartan

788 Eptifibatide

789 Erenumab

790 Ergocalciferol; except in medicines containing 25 micrograms or less per recommended daily dose

791 Ergometrine

792 Ergot

793 Ergotamine

794 Ergotoxine

795 Eribulin

796 Erlotinib

797 Ertapenem

798 Ertugliflozin

799 Erysimum spp; except in medicines containing 1 milligram or less per litre or per kilogram

800 Erythromycin

801 Erythropoietin

802 Escitalopram

803 Esketamine

804 Esmolol

805 Esomeprazole; except when specified elsewhere in this schedule

806 Estazolam

807 Estramustine

808 Estropipate

809 Etanercept

810 Ethacrynic acid

811 Ethambutol

812 Ethamivan

813 Ethanolamine; for injection

814 Ethchlorvynol

815 Ether; for anaesthesia; except when specified elsewhere in this schedule

816 Ethinamate

817 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 Incorpor-

ated 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

818 Ethionamide

819 Ethisterone

820 Ethoglucid

821 Ethoheptazine

822 Ethopropazine

823 Ethosuximide

824 Ethotoin

825 Ethoxzolamide

826 Ethyl chloride; for inhalation

827 Ethyl loflazepate

828 Ethyldienolone

829 Ethylhexanediol; at all strengths

830 Ethyloestrenol

831 Ethynodiol

832 Etidocaine

833 Etidronic acid; except in medicines for external use containing 1% or less

834 Etilefrine

835 Etiracetam

836 Etodolac

837 Etofenamate; except for external use

838 Etomidate

839 Etonogestrel

840 Etoposide

841 Etoricoxib

842 Etravirine

843 Etretinate

844 Everolimus

845 Evolocumab

846 Exemestane

847 Exenatide

848 Ezetimibe

849 Factor VIII inhibitor bypassing fraction

850 Famciclovir; except when specified elsewhere in this schedule

851 Famotidine; except when specified elsewhere in this schedule

852 Fampridine

853 Farfugium japonicum; at all strengths

854 Fasoracetam (and its stereoisomers)

855 Febuxostat

856 Felbamate

857 Felbinac; except for external use

858 Felodipine

859 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

860 Fenbufen

861 Fenclofenac

862 Fenfluramine

863 Fenofibrate

864 Fenoldopam

865 Fenoprofen

866 Fenoterol

867 Fenpipramide

868 Fenpiprane

869 Fentanyl

870 Ferric carboxymaltose

871 Ferric derisomaltose

872 Fexofenadine; except when specified elsewhere in this schedule

873 Fibrin

874 Fibrinolysin; except for external use

875 Fibroblast growth factor

876 Fidaxomicin

877 Filgrastim

878 Finasteride

879 Fingolimod

880 Flecainide

881 Fleroxacin

882 Floctafenine

883 Fluanisone

884 Flubromazolam

885 Fluclorolone

886 Flucloxacillin

887 Fluconazole; except when specified elsewhere in this schedule

888 Flucytosine

889 Fludarabine

890 Fludiazepam

891 Fludrocortisone

892 Flufenamic acid

893 Flumazenil

894 Flumethasone

895 Flumethiazide

896 Flunarizine

897 Flunisolide

898 Flunitrazepam

899 Fluocinolone

900 Fluocinonide

901 Fluocortin

902 Fluocortolone

903 Fluorescein; for injection

904 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

905 Fluorometholone

906 Fluorouracil

907 Fluoxetine

908 Fluoxymesterone

909 Flupenthixol

910 Fluphenazine

911 Flurandrenolone

912 Flurazepam
913 Flurbiprofen; except when specified elsewhere in this schedule
914 Fluroxene
915 Fluspirilene
916 Flutamide
917 Fluticasone; except when specified elsewhere in this schedule
918 Fluvastatin
919 Fluvoxamine
920 Folic acid; except when specified elsewhere in this schedule
921 Folinic acid; except when specified elsewhere in this schedule
922 Follicle-stimulating hormone; except in medicines containing 100 micrograms or less per litre or per kilogram
923 Follistatin
924 Follitropin
925 Follitropin delta
926 Fomepizole
927 Fomivirsen
928 Fondaparinux
929 Fonturacetam (and its stereoisomers)
930 Formebolone
931 Formestane
932 Formoterol
933 Fosamprenavir
934 Fosaprepitant
935 Foscarnet
936 Fosfestrol
937 Fosfomycin
938 Fosinopril
939 Fosnetupitant
940 Fosphenytoin
941 Fotemustine
942 Framycetin
943 Fremanezumab
944 Fulvestrant
945 Furaltadone

946 Furazabol
947 Furazolidone
948 Furosemide
949 Fusidic acid
950 Gabapentin
951 Galantamine
952 Galanthus spp
953 Galcanezumab
954 Gallamine
955 Galsulfase
956 Ganciclovir
957 Ganirelix
958 Gatifloxacin
959 Gefitinib
960 Gemcitabine
961 Gemeprost
962 Gemfibrozil
963 Gemifloxacin
964 Gemtuzumab ozogamicin
965 Gentamicin
966 Gestodene
967 Gestonorone
968 Gestrinone
969 Ghrelin
970 Gilteritinib
971 Gitalin
972 Glatiramer acetate
973 Glecaprevir
974 Glibenclamide
975 Glibornuride
976 Gliclazide
977 Glimepiride
978 Glipizide
979 Glisoxepide
980 Glutathione; for injection

981 Glyceryl trinitrate; for injection; for transdermal use; except in medicines containing 100 micrograms or less per litre or per kilogram

982 Glycopyrronium

983 Glymidine

984 Golimumab

985 Gonadorelin

986 Gonadotrophic hormones; except when specified elsewhere in this schedule

987 Goserelin

988 Gramicidin

989 Granisetron

990 Grazoprevir

991 Grepafloxacin

992 Griseofulvin

993 Growth hormone releasing hormones

994 Growth hormone releasing peptide-6

995 Growth hormone releasing peptides

996 Guaifenesin; except when specified elsewhere in this schedule

997 Guanabenz

998 Guanethidine

999 Guanfacine

1000 Guanidine

1001 Guselkumab

1002 Hachimycin

1003 Haematin

1004 Haemophilus influenzae vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds

1005 Halazepam

1006 Halcinonide

1007 Halofantrine

1008 Halofenate

1009 Haloperidol; except in medicines containing 1 milligram or less per litre or per kilogram

1010 Halothane

1011 Haloxazolam

1012 Halquinol; except for external use

1013 Heliotropium spp; at all strengths

1014 Hemerocallis

1015 Heparins; except when present as an excipient; except for external use

1016 Hepatitis A vaccine

1017 Hepatitis B vaccine

1018 Hetacillin

1019 Hexachlorophane; in medicines containing more than 3%; except when specified elsewhere in this schedule

1020 Hexamethonium

1021 Hexarelin

1022 Hexetidine; except for external use

1023 Hexobendine

1024 Hexocyclium

1025 Hexoprenaline

1026 Hexaminolevulinate

1027 Histamine; except in medicines containing 0.5% or less

1028 Homatropine

1029 Human chorionic gonadotrophin; except in pregnancy test kits

1030 Human growth hormone secretagogues

1031 Human papillomavirus vaccine; except when administered by a registered pharmacist or registered intern pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

1032 Human protein C

1033 Hyaluronic acid; in injections or implants for tissue augmentation or cosmetic use

1034 Hydralazine

1035 Hydrargaphen

1036 Hydrochlorothiazide

1037 Hydrocortisone; except when specified elsewhere in this schedule

1038 Hydrocyanic acid; except when specified elsewhere in this schedule

1039 Hydroflumethiazide

1040 Hydromorphone

1041 Hydroquinone; except when specified elsewhere in this schedule

1042 Hydroxychloroquine

1043 Hydroxyephedrine

1044 Hydroxyphenamate

1045 Hydroxyprogesterone

1046 Hydroxystenozol

1047 Hydroxyurea

1048 Hydroxyzine

1049 Hylan polymer; in injections or implants for tissue augmentation or cosmetic use

1050 Hyoscine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram

1051 Hyoscine butylbromide; except when specified elsewhere in this schedule

1052 Hyoscyamine; except when specified elsewhere in this schedule; except in medicines containing 300 micrograms or less per litre or per kilogram

1053 Hyoscyamus niger; except when specified elsewhere in this schedule

1054 Hypothalamic releasing factors

1055 Hypromellose; for injection; except in intraocular viscoelastic products

1056 Ibandronic acid

1057 Ibogaine

1058 Ibritumomab tiuxetan

1059 Ibrutinib

1060 Ibufenac

1061 Ibuprofen; except when specified elsewhere in this schedule

1062 Ibutamoren

1063 Ibuterol

1064 Ibutilide

1065 Icatibant

1066 Idarubicin

1067 Idarucizumab

1068 Idebenone

1069 Idelalisib

1070 Idoxuridine; except for dermal use in medicines containing 0.5% or less

1071 Idursulfase

1072 Ifosfamide

1073 Iloprost

1074 Imatinib

1075 Imiglucerase

1076 Imipenem

1077 Imipramine

1078 Imiquimod

1079 Immunoglobulins

1080 Imuracetam

1081 Indacaterol

1082 Indapamide

1083 Indinavir

1084 Indocyanine green

1085 Indomethacin; except when specified elsewhere in this schedule

1086 Indoprofen

1087 Indoramin

1088 Infliximab

1089 Influenza and coryza vaccines; for injection; for nasal use

1090 Influenza vaccine; except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

1091 Ingenol mebutate

1092 Inotuzumab ozogamicin

1093 Insulin degludec

1094 Insulin-like growth factors; except when specified elsewhere in this schedule

1095 Insulins

1096 Interferons

1097 Interleukins

1098 Iodothiouracil

1099 Ipamorelin

1100 Ipecacuanha; except when specified elsewhere in this schedule

1101 Ipilimumab

1102 Ipratropium; except for nasal use

1103 Ipriflavone

1104 Iprindole

1105 Iproniazid
1106 Irbesartan
1107 Irinotecan
1108 Iron; except when specified elsewhere in this schedule
1109 Isatuximab
1110 Isavuconazole
1111 Isoaminile
1112 Isoamyl nitrite
1113 Isobutyl nitrite
1114 Isocarboxazid
1115 Isoconazole; except when specified elsewhere in this schedule
1116 Isoetarine
1117 Isoflurane
1118 Isometheptene
1119 Isoniazid
1120 Isoprenaline
1121 Isoprinosine
1122 Isopropamide; except when specified elsewhere in this schedule
1123 Isosorbide dinitrate
1124 Isosorbide mononitrate
1125 Isotretinoin
1126 Isoxicam
1127 Isoxsuprine
1128 Isradipine
1129 Itraconazole
1130 Ivabradine
1131 Ivacaftor
1132 Ivermectin
1133 Ixabepilone
1134 Ixazomib
1135 Ixekizumab
1136 Japanese encephalitis vaccine
1137 Juniperus sabina; at all strengths
1138 Kanamycin
1139 Ketamine

1140 Ketanserin
1141 Ketazolam
1142 Ketoconazole; except when specified elsewhere in this schedule
1143 Ketoprofen; except when specified elsewhere in this schedule
1144 Ketorolac
1145 Ketotifen; except for ophthalmic use in medicines containing 0.025% or less
1146 Khellin
1147 Labetalol
1148 Lacidipine
1149 Lacosamide
1150 Lamivudine
1151 Lamotrigine
1152 Lanadelumab
1153 Lanatosides
1154 Lanreotide
1155 Lansoprazole; except when specified elsewhere in this schedule
1156 Lanthanum
1157 Lapatinib
1158 Laronidase-rch
1159 Laropiprant
1160 Larotrectinib
1161 Latamoxef
1162 Latanoprost
1163 Laudexium
1164 Lauromacrogols; for injection
1165 Lead
1166 Ledipasvir
1167 Lefetamine
1168 Leflunomide
1169 Lenalidomide
1170 Lenograstim
1171 Lenvatinib
1172 Lepirudin
1173 Leptazol
1174 Lercanidipine

1175 Lesinurad

1176 Letermovir

1177 Letrozole

1178 Leucovorin; for injection

1179 Leuprorelin

1180 Levallorphan

1181 Levamisole

1182 Levetiracetam

1183 Levobunolol

1184 Levobupivacaine

1185 Levocabastine; except for nasal or ophthalmic use

1186 Levocetirizine; except for oral use

1187 Levodopa

1188 Levomepromazine

1189 Levomilnacipran

1190 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

1191 Levosimendan

1192 Lidoflazine

1193 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

1194 Lifitegrast

1195 Ligularia dentata; at all strengths

1196 Linaclotide

1197 Linagliptin

1198 Lincomycin

1199 Lindane; except for external use in medicines containing 2% or less

1200 Linezolid

1201 Liothyronine

1202 Lipegfilgrastim

1203 Liraglutide

1204 Lisdexamfetamine

1205 Lisinopril

1206 Lisuride

1207 Lithium; except when specified elsewhere in this schedule; except when present as an excipient in dermal medicines containing 0.25% or less

1208 Lixisenatide

1209 Lodoxamide; except in medicines for ophthalmic use

1210 Lofexidine

1211 Lomefloxacin

1212 Lomustine

1213 Loperamide; except when specified elsewhere in this schedule

1214 Lopinavir

1215 Loprazolam

1216 Loracarbef

1217 Loratadine; except when specified elsewhere in this schedule

1218 Lorazepam

1219 Lorlatinib

1220 Lormetazepam

1221 Losartan

1222 Loteprednol

1223 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

1224 Loxapine

1225 Lumacaftor

1226 Lumefantrine

1227 Lumiracoxib

1228 Lurasidone

1229 Luteinising hormone

1230 Lymecycline

1231 Macitentan

1232 Mafenide

1233 Mannomustine

1234 Maprotiline

1235 Maraviroc

1236 Mazindol

1237 Measles vaccine; except when administered, in combination with mumps and rubella vaccines in a combination product the supply of which the Minister of Health has consented to, by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

1238 Mebanazine

1239 Mebeverine

1240 Mebhydrolin

1241 Mebolazine

1242 Mebutamate

1243 Mecamylamine

1244 Mecasermin

1245 Mecillinam

1246 Meclocycline

1247 Meclofenamate

1248 Meclofenoxate

1249 Meclozine; except when specified elsewhere in this schedule

1250 Medazepam

1251 Medigoxin

1252 Medroxyprogesterone

1253 Medrysone

1254 Mefenamic acid; except when specified elsewhere in this schedule

1255 Mefloquine

1256 Mefruside

1257 Megestrol

1258 Melagatran

1259 Melanocyte stimulating compounds

1260 Melatonin; except when supplied in medicines for oral use containing 3 milligrams or less per immediate release dose unit, or 2 milligrams or less per modified release dose unit, when sold in the manufacturer's original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks by a registered pharmacist

1261 Meldonium

1262 Melengestrol

1263 Melia azedarach; at all strengths

1264 Meloxicam

1265 Melphalan

1266 Memantine

1267 Meningococcal vaccine; except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

1268 Menotrophin

1269 Mepacrine

1270 Mepenzolate

1271 Mephenesin

1272 Mephentermine

1273 Mepindolol

1274 Mepitiostane

1275 Mepivacaine

1276 Mepolizumab

1277 Meprobamate

1278 Meptazinol

1279 Mepyramine; except when specified elsewhere in this schedule

1280 Mequitazine

1281 Mercaptomerin

1282 Mercaptopurine
1283 Mercurochrome; except when specified elsewhere in this schedule
1284 Mercury; except when specified elsewhere in this schedule
1285 Meropenem
1286 Mersalyl
1287 Mesabolone
1288 Mesalazine
1289 Mesna
1290 Mestanolone
1291 Mesterolone
1292 Mestranol
1293 Metamfetamine
1294 Metamizole
1295 Metandienone
1296 Metaraminol
1297 Metenolone
1298 Metergoline
1299 Metformin
1300 Methacholine
1301 Methacycline
1302 Methadone
1303 Methallenoestril
1304 Methandriol
1305 Methanthelinium
1306 Methazolamide
1307 Methdilazine; except for oral use
1308 Methicillin
1309 Methimazole
1310 Methisazone
1311 Methixene
1312 Methocarbamol
1313 Methohexitone
1314 Methoin
1315 Methotrexate
1316 Methoxamine; except when specified elsewhere in this schedule

1317 Methoxsalen

1318 Methoxyflurane

1319 Methsuximide

1320 Methyclothiazide

1321 Methyl aminolevulinate

1322 Methyl androstanolone

1323 Methyl clostebol

1324 Methyl mercury; except in medicines containing 300 micrograms or less per litre or per kilogram

1325 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

1326 Methyl trienolone

1327 Methyldopa

1328 Methylene blue; for injection

1329 Methylergometrine

1330 Methylhexanamine (1,3-dimethylamylamine (DMAA)); except when present as an unmodified, naturally occurring substance

1331 Methylnaltrexone

1332 Methylpentynol

1333 Methylphenidate

1334 Methylphenobarbital

1335 Methylphenylpiracetam

1336 Methylprednisolone

1337 Methyltestosterone

1338 Methylthiouracil

1339 Methyprylon

1340 Methysergide

1341 Metoclopramide; except when specified elsewhere in this schedule

1342 Metolazone

1343 Metoprolol

1344 Metribolone

1345 Metrifonate

1346 Metronidazole

1347 Metyrapone

1348 Mexiletine

1349 Mezlocillin
1350 Mianserin
1351 Mibefradil
1352 Mibolerone
1353 Micafungin
1354 Miconazole; except when specified elsewhere in this schedule
1355 Midazolam
1356 Midodrine
1357 Midostaurin
1358 Mifepristone
1359 Migalastat
1360 Miglitol
1361 Miglustat
1362 Milnacipran
1363 Milrinone
1364 Minocycline
1365 Minoxidil; except for dermal use in medicines containing 5% or less
1366 Mirabegron
1367 Mirtazapine
1368 Misoprostol
1369 Mitobronitol
1370 Mitomycin
1371 Mitoxantrone
1372 Mitragyna speciosa
1373 Mitragynine
1374 Mivacurium
1375 Moclobemide
1376 Modafinil
1377 Molgramostim
1378 Molindone
1379 Molracetam
1380 Mometasone; except when specified elsewhere in this schedule
1381 Monobenzone
1382 Monoclonal antibodies; except in pregnancy test kits
1383 Montelukast

1384 Moperone

1385 Morazone

1386 Moricizine

1387 Morphine; except when specified elsewhere in this schedule

1388 Motrazepam

1389 Motretinide

1390 Moxifloxacin

1391 Mumps vaccine; except when administered, in combination with measles and rubella vaccines in a combination product the supply of which the Minister of Health has consented to, by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

1392 Mupirocin

1393 Muraglitazar

1394 Muromonab

1395 Mustine

1396 Mycophenolic acid

1397 Nabilone

1398 Nabumetone

1399 Nadolol

1400 Nadroparin

1401 Nafarelin

1402 Naftidrofuryl

1403 Nalbuphine

1404 Nalidixic acid

1405 Nalmefene

1406 Nalorphine

1407 Naloxegol

1408 Naloxone; except when provided as part of an approved emergency kit for the treatment of opioid overdose

1409 Naltrexone

1410 Nandrolone

1411 Naproxen; except when specified elsewhere in this schedule

1412 Naratriptan

1413 Natalizumab

1414 Natamycin

1415 Nateglinide

1416 Nebacumab

1417 Nebivolol

1418 Nebracetam (and its stereoisomers)

1419 Nedocromil

1420 Nefazodone

1421 Nefiracetam

1422 Nefopam

1423 Nelfinavir

1424 Neomycin

1425 Neostigmine

1426 Nepafenac

1427 Nepidermin

1428 Neratinib

1429 Nerium oleander

1430 Nesiritide

1431 Netilmicin

1432 Netupitant

1433 Nevirapine

1434 Nialamide

1435 Nicardipine

1436 Nicergoline

1437 Nicofuranose

1438 Nicoracetam

1439 Nicorandil

1440 Nicotine; except when specified elsewhere in this 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

1441 Nicotinic acid except nicotinamide; except when specified elsewhere in this schedule

1442 Nicoumalone

1443 Nifedipine
1444 Nifenazone
1445 Nikethamide
1446 Nilotinib
1447 Nilutamide
1448 Nimesulide
1449 Nimetazepam
1450 Nimodipine
1451 Nimorazole
1452 Nintedanib
1453 Niraparib
1454 Niridazole
1455 Nisoldipine
1456 Nitazoxanide
1457 Nitisinone
1458 Nitrazepam
1459 Nitrendipine
1460 Nitric oxide
1461 Nitrofurantoin
1462 Nitrofurazone
1463 Nitrous oxide; when supplied for inhalation
1464 Nitroxoline
1465 Nivolumab
1466 Nizatidine; except when specified elsewhere in this schedule
1467 Nomegestrol
1468 Nomifensine
1469 Noopept (and its stereoisomers)
1470 Noradrenaline
1471 Norandrostenolone
1472 Norbolethone
1473 Norclostebol
1474 Nordazepam
1475 Norelgestromin
1476 Norethandrolone

1477 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

1478 Norfloxacin

1479 Norgestrel

1480 Noribogaine

1481 Normethandrone

1482 Nortriptyline

1483 Noxiptyline

1484 Nusinersen

1485 Nux vomica; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine

1486 Nystatin; except when specified elsewhere in this schedule

1487 Obeticholic acid

1488 Obinutuzumab

1489 Ocrelizumab

1490 Ocriplasmin

1491 Octamylamine

1492 Octatropine

1493 Octreotide

1494 Octyl nitrite

1495 Oestradiol; except in medicines containing 10 micrograms or less per litre or per kilogram

1496 Oestriol

1497 Oestrogens

1498 Oestrone; except in medicines containing 1 milligram or less per litre or per kilogram

1499 Ofatumumab

1500 Ofloxacin

1501 Olanzapine

1502 Olaparib

1503 Olaratumab

1504 Oleandomycin

1505 Oleandrin

1506 Olmesartan

1507 Olodaterol

1508 Olopatadine

1509 Olsalazine

1510 Omalizumab

1511 Omberacetam

1512 Ombitasvir

1513 Omeprazole; except when specified elsewhere in this schedule

1514 Ondansetron

1515 Opipramol

1516 Opium

1517 Orciprenaline

1518 Orlistat; except in medicines for weight control containing 120 milligrams or less per dose form

1519 Ornidazole

1520 Ornipressin

1521 Orphenadrine

1522 Orthopterin

1523 Oseltamivir; except when specified elsewhere in this schedule

1524 Osimertinib

1525 Otilonium bromide

1526 Ouabain

1527 Ovandrotone

1528 Oxabolone

1529 Oxacillin

1530 Oxaliplatin

1531 Oxandrolone

1532 Oxaprozin

1533 Oxazepam

1534 Oxazolam

1535 Oxcarbazepine

1536 Oxedrine; except in medicines containing 30 milligrams or less per recommended daily dose

1537 Oxetacaine; except for internal use

1538 Oxiconazole; except when specified elsewhere in this schedule

1539 Oxiracetam (and its stereoisomers)

1540 Oxitropium

1541 Oxolamine

1542 Oxolinic acid

1543 Oxpentifylline

1544 Oxprenolol

1545 Oxybuprocaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

1546 Oxybutynin

1547 Oxycodone

1548 Oxymesterone

1549 Oxymetholone

1550 Oxyphenbutazone

1551 Oxyphencyclimine

1552 Oxyphenisatin; at all strengths

1553 Oxyphenonium

1554 Oxytetracycline

1555 Oxytocin; except in medicines containing 1 microgram or less per litre or per kilogram

1556 Ozanimod

1557 Paclitaxel

1558 Palbociclib

1559 Palifermin

1560 Paliperidone

1561 Palivizumab

1562 Palonosetron

1563 Pamaquin

1564 Pamidronic acid

1565 Pancreatic enzymes; except in medicines containing 20 000 BP units or less of lipase activity

1566 Pancuronium

1567 Panitumumab

1568 Panobinostat

1569 Pantoprazole; except when specified elsewhere in this schedule

1570 Papaveretum
1571 Papaverine; for injection
1572 Paracetamol; except when specified elsewhere in this schedule
1573 Paraldehyde
1574 Paramethadione
1575 Paramethasone
1576 Parecoxib
1577 Paricalcitol
1578 Paritabprevir
1579 Paromomycin
1580 Paroxetine
1581 Pasireotide
1582 Patent blue V; for injection when used in diagnostic procedures
1583 Patiromer sorbitex calcium
1584 Pazopanib
1585 Pecazine
1586 Pefloxacin
1587 Pegaptanib
1588 Pegaspargase
1589 Pegfilgrastim
1590 Peginterferon
1591 Peginterferon beta-1a
1592 Pegvisomant
1593 Pembrolizumab
1594 Pemetrexed
1595 Pemoline
1596 Pempidine
1597 Penbutolol
1598 Penciclovir; except when specified elsewhere in this schedule
1599 Penicillamine
1600 Pentaerythrityl tetranitrate
1601 Pentagastrin
1602 Pentamethonium
1603 Pentamidine
1604 Pentazocine

1605 Penthienate
1606 Pentolinium
1607 Pentosan polysulfate sodium
1608 Pentostatin
1609 Pentoxifylline
1610 Peramivir
1611 Perampanel
1612 Pergolide
1613 Perhexiline
1614 Pericyazine
1615 Perindopril
1616 Permethrin; except in medicines containing 5% or less
1617 Perphenazine
1618 Pertussis antigen
1619 Pertussis (whooping cough) vaccine
1620 Pertuzumab
1621 Pethidine
1622 Phenacemide
1623 Phenacetin; except when present as an excipient
1624 Phenaglycodol
1625 Phenazone; except for external use
1626 Phenazopyridine
1627 Phenelzine
1628 Pheneticillin
1629 Phenformin
1630 Phenglutarimide
1631 Phenibut
1632 Phenindione
1633 Pheniramine; except when specified elsewhere in this schedule
1634 Phenisatin
1635 Phenobarbital
1636 Phenol; for injection
1637 Phenolphthalein
1638 Phenoperidine
1639 Phenoxybenzamine

1640 Phenoxymethylpenicillin

1641 Phensuximide

1642 Phentermine

1643 Phenthimentonium

1644 Phentolamine

1645 Phenylbutazone

1646 Phenylephrine; except when specified elsewhere in this schedule

1647 Phenylpiracetam

1648 Phenylpropanolamine

1649 Phenyltoloxamine

1650 Phenytoin

1651 Phleum pratense extract

1652 Pholcodine; except when specified elsewhere in this schedule

1653 Phosphodiesterase type 5 inhibitors; except when present as an unmodified, naturally occurring substance; except when specified elsewhere in this schedule

1654 Phthalylsulfathiazole

1655 Physostigmine

1656 Pibrentasvir

1657 Picibanil

1658 Picric acid

1659 Picrotoxin

1660 Pilocarpine; except in medicines containing 0.025% or less

1661 Pimecrolimus

1662 Pimozide

1663 Pinacidil

1664 Pinazepam

1665 Pindolol

1666 Pioglitazone

1667 Pipecuronium

1668 Pipemidic acid

1669 Pipenzolate

1670 Piperacetam

1671 Piperacillin

1672 Piperidine

1673 Piperidolate

1674 Pipobroman

1675 Pipothiazine

1676 Pipradrol

1677 Piracetam

1678 Pirbuterol

1679 Pirenoxine

1680 Pirenzepine

1681 Piretanide

1682 Pirfenidone

1683 Piroxicam; except for external use

1684 Pirprofen

1685 Pitavastatin

1686 Pituitary hormones

1687 Pivampicillin

1688 Pizotifen

1689 Plerixafor

1690 Plicamycin

1691 Plitidepsin

1692 Pneumococcal vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds

1693 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

1694 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

1695 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

1696 Polatuzumab vedotin

1697 Polidexide

1698 Poliomyelitis vaccine

1699 Polyacrylamide; in injections or implants for tissue augmentation or cosmetic use

1700 Polyestradiol

1701 Polylactic acid; in injections or implants for tissue augmentation or cosmetic use

1702 Polymyxin

1703 Polysulfated glycosaminoglycans; for injection except in intraocular viscoelastic products

1704 Polythiazide

1705 Pomalidomide

1706 Ponatinib

1707 Poractant alfa

1708 Posaconazole

1709 Potassium bromide

1710 Potassium perchlorate

1711 Practolol

1712 Pradofloxacin

1713 Pralatrexate

1714 Pralidoxime

1715 Pralmorelin

1716 Pramipexole

1717 Pramiracetam

1718 Pramocaine

1719 Prampine

1720 Prasterone

1721 Prasugrel

1722 Pravastatin

1723 Prazepam

1724 Praziquantel

1725 Prazosin

1726 Prednisolone

1727 Prednisone

1728 Pregabalin

1729 Pregnenolone

1730 Prenalterol

1731 Prenylamine

1732 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

1733 Primaquine

1734 Primidone

1735 Probenecid

1736 Probucol

1737 Procainamide

1738 Procaine

1739 Procaine penicillin

1740 Procarbazine

1741 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

1742 Procyclidine; except for dermal use in medicines containing 5% or less

1743 Progesterone; except in medicines containing 1 milligram or less per litre or per kilogram

1744 Progestogens

1745 Proglumide

1746 Proguanil

1747 Prolintane

1748 Promazine

1749 Promethazine; except when specified elsewhere in this schedule

1750 Promoxolane

1751 Propafenone

1752 Propamidine; except for ophthalmic use

1753 Propanidid

1754 Propantheline

1755 Propetandrol

1756 Propionibacterium acnes

1757 Propofol

1758 Propranolol; except in medicines containing 1 milligram or less per litre or per kilogram

1759 Propylthiouracil

1760 Propyphenazone

1761 Proquazone

1762 Proscillaridin

1763 Prostaglandins

1764 Protamine

1765 Prothionamide

1766 Prothipendyl

1767 Protirelin

1768 Protoveratrines

1760 Protriptyline

1770 Proxymetacaine; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

1771 Prucalopride

1772 Pseudoephedrine; except when specified elsewhere in this schedule

1773 Pulmonaria spp; at all strengths

1774 Pyrazinamide

1775 Pyridinolcarbamate

1776 Pyridostigmine

1777 Pyridoxal; except in medicines containing 200 milligrams or less per recommended daily dose

1778 Pyridoxamine; except in medicines containing 200 milligrams or less per recommended daily dose

1779 Pyridoxine; except in medicines containing 200 milligrams or less per recommended daily dose

1780 Pyrimethamine

1781 Pyrvinium

1782 Quazepam

1783 Quetiapine

1784 Quinagolide

1785 Quinapril

1786 Quinbolone

1787 Quinethazone

1788 Quinidine

1789 Quinine; except in medicines containing 50 milligrams or less per recommended daily dose

1790 Quinisocaine

1791 Quinupristin
1792 Rabeprazole
1793 Rabies vaccine
1794 Racetams; except when specified elsewhere in this schedule
1795 Raloxifene
1796 Raltegravir
1797 Raltitrexed
1798 Ramipril
1799 Ramucirumab
1800 Ranibizumab
1801 Ranitidine; except when specified elsewhere in this schedule
1802 Ranolazine
1803 Rapacuronium
1804 Rasagiline
1805 Rasburicase
1806 Rauwolfia serpentina
1807 Rauwolfia vomitoria
1808 Razoxane
1809 Reboxetine
1810 Recombinant human epidermal growth factor
1811 Recombinant varicella zoster virus glycoprotein E antigen
1812 Regorafenib
1813 Remdesivir
1814 Remestemcel-L
1815 Remifentanil
1816 Remoxipride
1817 Repaglinide
1818 Reserpine
1819 Reslizumab
1820 Retapamulin
1821 Reteplase
1822 Retigabine
1823 Ribavirin
1824 Ribociclib
1825 Ridaforolimus

1826 Rifabutin
1827 Rifampicin
1828 Rifamycin
1829 Rifapentine
1830 Rifaximin
1831 Rilmazafone
1832 Rilpivirine
1833 Riluzole
1834 Rimexolone
1835 Rimiterol
1836 Rimonabant
1837 Riociguat
1838 Ripretinib
1839 Risankizumab
1840 Risedronic acid
1841 Risperidone
1842 Ritodrine
1843 Ritonavir
1844 Rituximab
1845 Rivaroxaban
1846 Rivastigmine
1847 Rizatriptan; except when specified elsewhere in this schedule
1848 Rocuronium
1849 Rofecoxib
1850 Roflumilast
1851 Rolipram (and its stereoisomers)
1852 Rolitetracycline
1853 Rolziracetam
1854 Romidepsin
1855 Romiplostim
1856 Romosozumab
1857 Ropinirole
1858 Ropivacaine
1859 Rosiglitazone
1860 Rosoxacin

1861 Rosuvastatin

1862 Rotavirus vaccine

1863 Rotigotine

1864 Roxibolone

1865 Roxithromycin

1866 Rubella vaccine; except when administered, in combination with measles and mumps vaccines in a combination product the supply of which the Minister of Health has consented to, by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course)

1867 Ruboxistaurin

1868 Rufinamide

1869 Rupatadine

1870 Ruxolitnib

1871 Sabadilla; except in preparations containing 10 milligrams or less of total alkaloids of schoenocaulon officinale per litre or per kilogram

1872 Sacubitril

1873 Safinamide

1874 Safrole; for internal use except in medicines containing 0.1% or less

1875 Salbutamol

1876 Salcatonin

1877 Salmeterol

1878 Sapropterin

1879 Saquinavir

1880 Sargramostim

1881 Sarilumab

1882 Saxagliptin

1883 Schoenocaulon officinale; except in preparations containing 10 milligrams or less of total alkaloids of schoenocaulon officinale per litre or per kilogram

1884 Scopolia carniolica

1885 Sebelipase alfa

1886 Secbutabarbital

1887 Secobarbital

1888 Secukinumab

1889 Selective androgen receptor modulators

1890 Seletracetam (and its stereoisomers)

1891 Selegiline

1892 Selenium; except when specified elsewhere in this schedule; except for oral use in medicines containing 150 micrograms or less per recommended daily dose

1893 Selexipag

1894 Semaglutide

1895 Serelaxin

1896 Sermorelin

1897 Sertindole

1898 Sertraline

1899 Serum, dried human

1900 Sevelamer

1901 Sevoflurane

1902 Sex hormones and all substances having sex hormone activity

1903 Sialoepoetin

1904 Sibutramine

1905 Silandrone

1906 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

1907 Silicones; for injection

1908 Silodosin

1909 Siltuximab

1910 Silver sulfadiazine; except for external use in packs containing 50 grams or less

1911 Simeprevir

1912 Simvastatin

1913 Siponimod

1914 Sirolimus

1915 Sisomicin

1916 Sitagliptin

1917 Sitaxentan

1918 Sodium bromide

1919 Sodium cellulose phosphate; for internal use

1920 Sodium cromoglycate; except for nasal and ophthalmic use

1921 Sodium morrhuate; for injection

1922 Sodium nitroprusside

1923 Sodium phenylbutyrate

1924 Sodium phosphate; in oral laxative preparations

1925 Sodium polystyrene sulphonate

1926 Sodium tetradecyl sulphate; for injection

1927 Sodium zirconium cyclosilicate

1928 Sofosbuvir

1929 Solasadine

1930 Solifenacin

1931 Somatostatin

1932 Somatropin

1933 Sonidegib

1934 Sontoquine

1935 Sorafenib

1936 Sotalol

1937 Sparfloxacin

1938 Sparteine

1939 Spectinomycin

1940 Spiramycin

1941 Spirapril

1942 Spironolactone

1943 Squill

1944 Stanolone

1945 Stanozolol

1946 Staphylococcus aureus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds

1947 Stavudine

1948 Stenabolic (SR9009) and other synthetic REV-ERB agonists

1949 Stenbolone

1950 Steroid hormones

1951 Stilboestrol

1952 Stiripentol

1953 Stramonium; except for oral use when specified elsewhere in this schedule; except datura stramonium or datura tatula for smoking or burning

1954 Streptococcus beta-haemolyticus vaccine; except in oral vaccines for the prophylaxis of bacterial complications of colds

1955 Streptodornase

1956 Streptokinase

1957 Streptomycin

1958 Streptozocin

1959 Strontium ranelate

1960 Strophanthins

1961 Strophanthus spp

1962 Strychnos spp; except in medicines containing 1 milligram or less per litre or per kilogram of strychnine

1963 Styramate

1964 Succimer

1965 Sufentanil

1966 Sugammadex

1967 Sulbactam

1968 Sulconazole; except for dermal use

1969 Sulfacetamide; except for ophthalmic use in medicines containing 10% or less

1970 Sulfadiazine; except silver sulfadiazine for external use in pack sizes of 50 grams or less

1971 Sulfadimethoxine

1972 Sulfadimidine

1973 Sulfadoxine

1974 Sulfafurazole

1975 Sulfaguanidine

1976 Sulfamerazine

1977 Sulfamethizole

1978 Sulfamethoxazole

1979 Sulfamethoxydiazine

1980 Sulfamethoxypyridazine

1981 Sulfametrole

1982 Sulfamonomethoxine

1983 Sulfamoxole

1984 Sulfaphenazole
1985 Sulfapyridine
1986 Sulfasalazine
1987 Sulfathiazole
1988 Sulfatroxazole
1989 Sulfinpyrazone
1990 Sulfomyxin
1991 Sulfonmethane
1992 Sulindac
1993 Sultamicillin
1994 Sulthiame
1995 Sumatriptan; except when specified elsewhere in this schedule
1996 Sunifiram
1997 Sunitinib
1998 Suprofen
1999 Suvorexant
2000 Sutilains
2001 Suxamethonium
2002 Suxethonium
2003 T cell receptor antibody
2004 Tacrine
2005 Tacrolimus
2006 Tadalafil and its structural analogues
2007 Tafamidis
2008 Tafenoquine succinate
2009 Tafluprost
2010 Talazoparib
2011 Taliglucerase alfa
2012 Talimogene laherparepvec
2013 Tamoxifen
2014 Tamsulosin
2015 Tanacetum vulgare; except in medicines containing 0.8% or less of oil of tansy
2016 Tapentadol
2017 Tasonermin
2018 Tazarotene

2019 Tazobactam
2020 Teduglutide
2021 Tegafur
2022 Tegaserod
2023 Teicoplanin
2024 Telaprevir
2025 Telbivudine
2026 Telithromycin
2027 Telmisartan
2028 Telotristat ethyl
2029 Temazepam
2030 Temozolomide
2031 Temsirolimus
2032 Tenecteplase
2033 Teniposide
2034 Tenofovir
2035 Tenoxicam
2036 Terazosin
2037 Terbinafine; except when specified elsewhere in this schedule
2038 Terbutaline
2039 Terfenadine
2040 Teriflunomide
2041 Teriparatide
2042 Terlipressin
2043 Terodiline
2044 Teropterin
2045 Tesamorelin
2046 Testolactone
2047 Testosterone; except in medicines containing 1 milligram or less per litre or per kilogram
2048 Tetanus antitoxin
2049 Tetanus toxoid
2050 Tetanus vaccine
2051 Tetrabenazine
2052 Tetracosactrin

2053 Tetracycline
2054 Tetraethylammonium
2055 Tetrahydrocannabinol
2056 Tetrazepam
2057 Tetroxoprim
2058 Thalidomide
2059 Thenyldiamine
2060 Theophylline; except when specified elsewhere in this schedule
2061 Thevetia peruviana
2062 Thevetin
2063 Thiambutosine
2064 Thiazosulfone
2065 Thiethylperazine
2066 Thioacetazone
2067 Thiocarlide
2068 Thioguanine
2069 Thiomesterone
2070 Thiopentone
2071 Thiopropazate
2072 Thioproperazine
2073 Thioridazine
2074 Thiotepa
2075 Thiothixene
2076 Thiouracil
2077 Thiourea; except in medicines containing 0.1% or less
2078 Thymosin beta-4
2079 Thymoxamine
2080 Thyroid
2081 Thyrotrophin
2082 Thyrotrophin-releasing factor
2083 Thyroxine; except in medicines containing 10 micrograms or less per litre or per kilogram
2084 Tiagabine
2085 Tianeptine
2086 Tiaprofenic acid

2087 Tiaramide
2088 Tibolone
2089 Ticagrelor
2090 Ticarcillin
2091 Ticlopidine
2092 Tiemonium
2093 Tienilic acid
2094 Tigecycline
2095 Tigloidine
2096 Tiletamine
2097 Tilidine
2098 Tilmanocept
2099 Tiludronic acid
2100 Timbetasin
2101 Timolol
2102 Tinidazole
2103 Tinzaparin
2104 Tioconazole; except when specified elsewhere in this schedule
2105 Tiotropium
2106 Tipepidine
2107 Tipiracil
2108 Tiprinavir
2109 Tirilazad
2110 Tirofiban
2111 Tivozanib
2112 Tizanidine
2113 Tobramycin
2114 Tocainide
2115 Tocilizumab
2116 Tofacitinib
2117 Tolazamide
2118 Tolazoline
2119 Tolbutamide
2120 Tolcapone
2121 Tolfenamic acid

2122 Tolmetin
2123 Tolonium
2124 Tolpropamine
2125 Tolrestat
2126 Tolterodine
2127 Tolvaptan
2128 Topiramate
2129 Topotecan
2130 Torasemide
2131 Toremifene
2132 Toxoids; for injection
2133 Tramadol
2134 Trametinib dimethyl sulfoxide
2135 Trandolapril
2136 Tranexamic acid
2137 Tranylcypromine
2138 Trastuzumab
2139 Trastuzumab emtansine
2140 Travoprost
2141 Trazodone
2142 Trenbolone
2143 Treosulphan
2144 Treprostinil
2145 Trestolone
2146 Tretamine
2147 Tretinoin
2148 Triacetyloleandomycin
2149 Triamcinolone; except when specified elsewhere in this schedule
2150 Triamterene
2151 Triaziquone
2152 Triazolam
2153 Trichlormethiazide
2154 Trichloroacetic acid; except for external use in medicines containing 12.5% or less for the treatment of warts other than anogenital warts
2155 Trichloroethylene

2156 Trichodesma africana; at all strengths

2157 Triclofos

2158 Tricyclamol

2159 Tridihexethyl

2160 Trientine

2161 Trifluoperazine

2162 Trifluperidol

2163 Triflupromazine

2164 Trifluridine

2165 Trimeprazine; except when specified elsewhere in this schedule

2166 Trimetaphan

2167 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

2168 Trimipramine

2169 Trimustine

2170 Trinitrophenol

2171 Trioxysalen

2172 Triparanol; at all strengths

2173 Triple antigen vaccine

2174 Triprolidine; except when specified elsewhere in this schedule

2175 Triptorelin

2176 Troglitazone

2177 Trometamol; for injection in medicines containing more than 3%

2178 Tropicamide; except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

2179 Tropisetron

2180 Trovafloxacin

2181 Troxidone

2182 Tryptophan; except in medicines containing 100 milligrams or less per recommended daily dose; except in parenteral nutrition replacement preparations

2183 Tuberculin

2184 Tuberculosis vaccine

2185 Tubocurarine

2186 Tucatinib

2187 Tulobuterol

2188 Typhoid vaccine

2189 Ulipristal

2190 Umeclidinium bromide

2191 Unifiram

2192 Unoprostone

2193 Upadacitinib

2194 Uracil

2195 Urapidil

2196 Urethane

2197 Urofollitropin

2198 Urokinase

2199 Ursodeoxycholic acid

2200 Ustekinumab

2201 Vaccines; except when specified elsewhere in this schedule

2202 Vaccinia virus vaccine

2203 Valaciclovir

2204 Valdecoxib

2205 Valganciclovir

2206 Valnoctamide

2207 Valproic acid

2208 Valsartan

2209 Vancomycin

2210 Vandetanib

2211 Vardenafil and its structural analogues

2212 Varenicline

2213 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 the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

2214 Vasopressin

2215 Vecuronium

2216 Vedolizumab

2217 Velaglucerase alfa

2218 Velpatasvir

2219 Vemurafenib

2220 Venetoclax

2221 Venlafaxine

2222 Verapamil

2223 Veratrum spp

2224 Vernakalant

2225 Verteporfin

2226 Veruprevir

2227 Vidarabine

2228 Vigabatrin

2229 Vilanterol

2230 Vildagliptin

2231 Viloxazine

2232 Vinblastine

2233 Vincamine

2234 Vincristine

2235 Vindesine

2236 Vinflunine

2237 Vinorelbine

2238 Vinyl ether

2239 Virginiamycin

2240 Vismodegib

2241 Visnadine

2242 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

2243 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

2244 Voglibose

2245 Vorapaxar

2246 Voretigene neparvovec

2247 Voriconazole

2248 Vorinostat

2249 Vortioxetine

2250 Voxilaprevir

2251 Warfarin

2252 Xamoterol

2253 Xanthinol nicotinate

2254 Ximelagatran

2255 Xipamide

2256 Yellow fever vaccine

2257 Yohimbine

2258 Zafirlukast

2259 Zalcitabine

2260 Zaleplon

2261 Zanamivir

2262 Zidovudine

2263 Zimeldine

2264 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

2265 Ziprasidone

2266 Zoledronic acid

2267 Zolmitriptan; except when specified elsewhere in this schedule

2268 Zolpidem

2269 Zonisamide

2270 Zopiclone

2271 Zoster immunoglobulin, human

2272 Zoxazolamine

2273 Zuclopenthixol

Schedule 1 Part 1 item 1090: amended, on 19 May 2022, by regulation 7 of the Medicines Amendment Regulations 2022 (SL 2022/116).

Schedule 1 Part 1 item 1772: amended, on 21 March 2024, by regulation 4(1) of the Medicines (Pseudoephedrine) Amendment Regulations 2024 (SL 2024/4).

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 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

20 Cyproheptadine; for oral use

21 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

22 Dextromethorphan; in liquid 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 symptoms of cough and cold in adults and children aged six years and over

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 Paracetamol; in modified-release forms containing 665 milligrams or less

63 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

64 Pneumococcal vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

65 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

66 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

67 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

68 Prochlorperazine; in packs containing not more than 10 tablets or capsules for the treatment of nausea associated with migraine

69 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

69A Pseudoephedrine; in solid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 720 milligrams or less; in liquid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 800 milligrams or less

70 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

71 Salicylic acid; except in medicines for dermal use containing 40% or less

72 Santonin

73 Sodium phosphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures

74 Sodium picosulphate; in oral preparations for bowel cleansing prior to diagnostic, medical, or surgical procedures

75 Staphyloccocus aureus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

76 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

77 Streptococcus beta-haemolyticus vaccine; in oral vaccines for the prophylaxis of bacterial complications of colds

78 Sulfacetamide; for ophthalmic use in medicines containing 10% or less

79 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

80 Theophylline; in liquid form for oral use in medicines containing 2% or less

81 Tioconazole; for vaginal use

82 Triamcinolone; for buccal use in medicines containing 0.1% or less of triamcinolone acetonide and in pack sizes of 5 grams or less

83 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

84 Triprolidine; for oral use in medicines for adults and children over 2 years of age; except when specified elsewhere in this schedule

85 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

Schedule 1 Part 2 item 69A: inserted, on 21 March 2024, by regulation 4(2) of the Medicines (Pseudoephedrine) Amendment Regulations 2024 (SL 2024/4).

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)

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 64 micrograms per actuation and when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril)

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 Colocynth

40 Creosote; except in medicines containing 10% or less

41 Cresols; except in medicines containing 3% or less

42 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

43 Delphinium staphisagria; except in medicines containing 0.2% or less

44 Desloratadine; for oral use

45 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

46 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

47 Dibrompropamidine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

48 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

49 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

50 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

51 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

52 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

53 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

54 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

55 Econazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

56 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

57 Etafedrine

58 Ether; in medicines containing more than 10%; except in medicines containing 10% or less

59 Etofenamate; for external use

60 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

61 Felbinac; for external use

62 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 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 180 milligrams when sold in the manufacturer's original pack containing 5 dosage units or less and not more than 5 days' supply

63 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

64 Flurbiprofen; in locally acting oromucosal preparations containing 10 milligrams or less per dosage unit

65 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)

66 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

67 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

68 Formaldehyde; except in medicines containing 5% or less

69 Gelsemium sempervirens; except in medicines containing 1 milligram or less per litre or per kilogram

70 Glutaraldehyde

71 Hexachlorophane; in medicines containing 3% or less but more than 0.75%; except in medicines containing 0.75% or less

72 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

73 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

74 Hydroquinone; for external use in medicines containing 2% or less except in hair preparations containing 1% or less

75 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

76 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

77 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

78 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

79 Indanazoline

80 Indomethacin; for external use in medicines containing 1% or less; except in medicines containing 1 milligram or less per litre or per kilogram

81 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

82 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

83 Ipomoea spp; except ipomoea batatas

84 Ipratropium; for nasal use

85 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

86 Isoconazole; for dermal use except when sold in practice by a podiatrist registered with the Podiatrists Board

87 Isopropamide; for dermal use in preparations containing 2% or less

88 Jalap resin

89 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

90 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

91 Leucovorin; in medicines containing more than 500 micrograms per recommended daily dose

92 Levocabastine; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

93 Levocetirizine; for oral use

94 Lignocaine; for urethral use; for external use in medicines containing 10% or less and more than 2%

95 Lindane; for external use in medicines containing 2% or less

96 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

97 Lobelia inflata; except in medicines for smoking or burning

98 Lobeline; except when in medicines for smoking or burning

99 Lodoxamide; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

100 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

101 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

102 Macrogols; in preparations for oral use as a liquid concentrate for laxative use

103 Mebendazole

104 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

105 Mefenamic acid; in solid dose form in packs containing not more than 30 tablets or capsules for the treatment of dysmenorrhoea

106 Mepyramine; for dermal use; except for external use in medicines containing 2% or less in packs not exceeding 25 grams

107 Mercuric oxide; for ophthalmic use

108 Mercurochrome; in preparations for external use containing 2% or less

109 Mercury; for external use in medicines containing 0.5% or less; except in medicines containing 1 milligram or less per litre or per kilogram

110 Methoxamine; for external use in medicines containing more than 1%; except for external use in medicines containing 1% or less

111 Methoxyphenamine

112 Methylephedrine

113 Miconazole; for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

114 Minoxidil; for dermal use in medicines containing 5% or less

115 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

116 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

117 Naphazoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

118 Naproxen; in solid dose form containing 250 milligrams or less per dose form in packs of not more than 30 tablets or capsules

119 Niclosamide

120 Nicotine; for inhalation except when sold from a smoking cessation clinic run under the auspices of a registered medical practitioner, nurse, pharmacist, or psychologist

121 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

122 Noscapine

123 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

124 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

125 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

126 Oxetacaine; for internal use

127 Oxiconazole; for dermal use except in medicines for tinea pedis only

128 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

129 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

130 Papaverine; except for injection

131 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 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

132 Paraformaldehyde; except in medicines containing 5% or less

133 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

134 Phedrazine

135 Phenazone; for external use

136 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

137 Phenol; except in medicines other than for injection containing 3% or less

138 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

139 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

140 Piperazine

141 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

142 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

143 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

144 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

145 Potassium chlorate; except in medicines containing 10% or less

146 Prilocaine; for dermal use in medicines containing 10% or less of local anaesthetic substances

147 Procyclidine; for dermal use in medicines containing 5% or less

148 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

149 Propamidine; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

150 Pyrantel

151 Pyrethrins; except in medicines containing 10% or less

152 Pyrithione zinc; except in medicines for treatment of the scalp containing 2% or less

153 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

154 Salicylamide

155 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

156 Sennosides

157 Silver; except in oral solutions containing 0.3% or less or other medicines containing 1% or less

158 Silver sulfadiazine; for external use in pack sizes of 50 grams or less

159 Sodium cromoglycate; for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

160 Sodium nitrite; except for use as an excipient

161 Sodium picosulphate; in oral laxative preparations

162 Squill; except in medicines containing 1% or less

163 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

164 Sulconazole; for dermal use

165 Sulfadiazine, silver; for external use in pack sizes of 50 grams or less

166 Terbinafine; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

167 Tetrachloroethylene

168 Tetrahydrozoline; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board

169 Thiabendazole

170 Tioconazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

171 Tramazoline

172 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

173 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

174 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

175 Tuaminoheptane

176 Tymazoline

177 Xylenols; except in medicines containing 3% or less

178 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

179 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	14,328
2	An application for a licence to pack medicines	880
3	An application for a licence to sell medicines by retail	880
4	An application for a licence to sell medicines by wholesale	1,123
5	An application for a licence to hawk medicines	880
6	An application for a combined licence to pack, and to sell by retail, medicines	313
7	An application for a licence to operate a pharmacy	1,097

Schedule 5A: amended, on 1 July 2022, by regulation 8 of the Medicines Amendment Regulations 2022 (SL 2022/116).

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 2019.
Date of notification in *Gazette*: 7 June 1984.

Notes

1 General

This is a consolidation of the Medicines Regulations 1984 that incorporates the amendments made to the legislation so that it shows the law as at its stated date.

2 Legal status

A consolidation is taken to correctly state, as at its stated date, the law enacted or made by the legislation consolidated and by the amendments. This presumption applies unless the contrary is shown.

Section 78 of the Legislation Act 2019 provides that this consolidation, published as an electronic version, is an official version. A printed version of legislation that is produced directly from this official electronic version is also an official version.

3 Editorial and format changes

The Parliamentary Counsel Office makes editorial and format changes to consolidations using the powers under subpart 2 of Part 3 of the Legislation Act 2019. See also PCO editorial conventions for consolidations.

4 Amendments incorporated in this consolidation

Medicines (Administration and Supply of Medicines in Approved Immunisation Programmes) Amendment Regulations 2025 (SL 2025/318)

Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations (No 2) 2025 (SL 2025/302)

Medicines (Restriction on Prescribing Gonadotropin-releasing Hormone Analogues) Amendment Regulations 2025 (SL 2025/256)

Medicines (Increasing the Period of Supply) Amendment Regulations 2025 (SL 2025/203)

Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (SL 2024/129): regulations 49–52

Medicines (Pseudoephedrine) Amendment Regulations 2024 (SL 2024/4)

Medicines Amendment Regulations 2023 (SL 2023/130)

Medicines Amendment Regulations (No 2) 2022 (SL 2022/304)

Pae Ora (Healthy Futures) Act 2022 (2022 No 30): section 104

Medicines Amendment Regulations 2022 (SL 2022/116)

Water Services Act 2021 (2021 No 36): section 206(2)

Medicines (Assisted Dying Medications) Amendment Regulations 2021 (LI 2021/266)

Medicines Amendment Regulations (No 2) 2021 (LI 2021/228)

Medicines Amendment Regulations 2021 (LI 2021/44)

Medicines Amendment Regulations 2020 (LI 2020/262)

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

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

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

Medicines Amendment Regulations 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)

Medicines Regulations 1984 (SR 1984/143): regulation 44AB(5)

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