Version
as at 1 July 2022

Medicines Act 1981

Public Act	1981 No 118
Date of assent	23 October 1981
Commencement	see section 1(2)

Contents

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.

This Act is administered by the Ministry of Health.

Part 1
Application and administration of Act

Application

Administration

Part 2
Dealings with medicines and medical devices

Qualifying new medicines

Approval of medicines required for use in special emergency

Part 8
Miscellaneous provisions

An Act to consolidate and amend the law relating to the manufacture, sale, and supply of medicines, medical devices, and related products

1 Short Title and commencement

(1) This Act may be cited as the Medicines Act 1981.

(2) This Act shall come into force on a date to be appointed by the Governor-General by Order in Council, and different dates may be so appointed in respect of different provisions of this Act.

(3) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 1(2): this Act (except section 21(1)(a)) brought into force, on 1 August 1984, by the Medicines Act Commencement Order 1984 (SR 1984/142).

Section 1(3): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

2 Interpretation

(1) In this Act, unless the context otherwise requires,—

administer means administer to a human being, either—

(a) orally or by injection or by introduction into the body in any other way; or

(b) by external application, whether by direct contact with the body or not;—

and every reference in this Act to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered

advertisement has the meaning assigned to that term by section 56

advertising material means material used or intended to be used as an advertisement

analyst means—

(a) any person who is designated by the Minister by notice as the analyst in charge of an approved laboratory; or

(b) any person who works in an approved laboratory and who is authorised, by the analyst in charge of that laboratory, to act as an analyst for the purposes of this Act, either generally or in any particular case

animal includes a bird, a fish, and a reptile; but does not include a human being

animal food means any substance or article that—

(a) is manufactured or imported only as food for animals; and

(b) if sold or supplied in New Zealand, is so sold or supplied only as food for animals

animal remedy or **remedy** means any drug, remedy, or therapeutic preparation, or any biochemical substance, which is manufactured, imported, or advertised for sale or is sold for any of the following purposes:

(a) curing, diagnosing, treating, controlling, or preventing any disease in animals; or

(b) destroying or preventing parasites on or in animals; or

(c) maintaining or improving the health, condition, productivity, or appearance of any animal; or

(d) capturing or immobilising any animal;—

but does not include any preparation, substance, or product which is used primarily as a food for animals

appropriate committee means a committee appointed under section 8(1)

approved laboratory means a laboratory approved by the Minister by notice for the purposes of this Act

authorised prescriber means—

(a) a nurse practitioner; or

(b) an optometrist; or

(c) a practitioner; or

(d) a registered midwife; or

(e) a designated prescriber

bulk cargo container means an article of transport equipment, being a lift van, movable tank, or other similar structure,—

(a) of a permanent character and accordingly strong enough to be suitable for repeated use; and

(b) specially designed to facilitate the carriage of goods by 1 or more modes of transport, without immediate repacking; and

(c) fitted with devices permitting its ready handling and its transfer from one mode of transport to another; and

(d) so designed as to be easy to fill and empty; and

(e) having an internal volume of 1 cubic metre or more;—

and includes the normal accessories and equipment of the container, when imported with the container and used exclusively with it; but does not include any vehicle, or any ordinary packing case, crate, box, or other similar article used for packing

business includes—

(a) a professional practice; and

(b) any activity carried on for reward by any person

carrier includes every person engaged in carrying goods for hire or reward by any mode of transport, whether by land, water, or air

container, in relation to a medicine or medical device, means the bottle, jar, box, packet, or other receptacle that contains or is to contain it, not being a capsule, cachet, or other article in which the medicine or device is or is to be administered; and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle

controlled drug has the same meaning as in section 2(1) of the Misuse of Drugs Act 1975

cosmetic means any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering, or cleansing the hair, skin, or complexion of human beings; and includes—

(a) any perfume:

(b) any deodorant:

(c) any insect repellant:

(d) any dusting powder

Customs or **the Customs** has the meaning given to Customs in section 5(1) of the Customs and Excise Act 2018

decision includes requirement

delegated prescriber means a health practitioner to whom a delegated prescribing order has been issued

delegated prescribing order means a written instruction, issued in accordance with regulations by an authorised prescriber, authorising a health practitioner to prescribe prescription medicines

delegated prescribing rights means prescribing rights granted by regulations made under section 105(1)(qaa)

dentifrice means any substance or mixture of substances used or represented for use for the purpose of cleansing the mouths or teeth (natural or artificial) of human beings; and includes any denture fixative

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

designated prescriber means a person, other than a practitioner, nurse practitioner, optometrist, or a registered midwife, who—

(a) belongs to a class of registered health professionals authorised by regulations made under this Act to prescribe any specified prescription medicines, or any specified class or description of prescription medicines subject to the satisfaction of requirements specified in or imposed under those regulations; and

(b) satisfies any applicable requirement relating to competency, qualifications, or training specified in or imposed under regulations made under this Act

Director-General means the Director-General of Health; and, except in section 98, includes any other officer of the Ministry of Health exercising, with the authority of the Director-General, any functions conferred on the Director-General by this Act

disease includes any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind

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

(a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and

(b) the packaging, labelling, recording, and delivery of that medicine

EPA means the Environmental Protection Authority established by section 7 of the Environmental Protection Authority Act 2011

examine includes weigh, count, and measure

health services has the same meaning as it has in section 2 of the Health and Disability Commissioner Act 1994

herbal remedy means a medicine (not being or containing a prescription medicine, or a restricted medicine, or a pharmacy-only medicine) consisting of—

(a) any substance produced by subjecting a plant to drying, crushing, or any other similar process; or

(b) a mixture comprising 2 or more such substances only; or

(c) a mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance

hospital includes a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001

importer means any person by or for whom any goods are imported; and includes the consignee of any goods; and also includes any person who is or becomes—

(a) the owner of any goods; or

(b) entitled to the possession of any goods; or

(c) beneficially interested in any goods—

on or at any time after the importation of those goods and before they have ceased to be subject to the control of Customs in accordance with the Customs and Excise Act 2018

label, in relation to a container of a medicine, means any written, pictorial, or other descriptive matter marked on or affixed to the container; and **to label**, **labelled**, and **labelling** have corresponding meanings

labelling material means material used or intended to be used as a label

licence means a licence issued under this Act; and **licensed** and **licensee** have corresponding meanings

licensee corporation means a corporation holding a licence under this Act

licensing authority—

(a) means the Director-General; and

(b) to avoid doubt, includes any person or persons acting as the Director-General's delegate as a consequence of a delegation under clauses 2 and 3 of Schedule 6 of the Public Service Act 2020

manufacture, in relation to a medicine, includes any process carried out in the course of making the medicine; but does not include—

(a) dissolving or dispersing the medicine in, or diluting or mixing it with, some other substance used as a medium for the purpose of administering the medicine to a particular person:

(b) incorporating the medicine in any animal food

medical device has the meaning given to it by section 3A

Medical Officer of Health means the Medical Officer of Health appointed under the Health Act 1956 for a health district; and includes any Deputy Medical Officer of Health; and also includes the Director-General of Health and other officers upon whom the functions of a Medical Officer of Health are conferred by section 22 of that Act

medical practitioner means a health practitioner who is, or is deemed to be, registered with the Medical Council of New Zealand continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of medicine

medicine, **new medicine**, **pharmacy-only medicine**, **prescription medicine**, and **restricted medicine** have the meanings assigned to those terms by section 3

Medicines Review Committee means the committee established under section 10

Minister means the Minister of Health

new organism has the same meaning as in section 2A of the Hazardous Substances and New Organisms Act 1996

nurse practitioner means a health practitioner who—

(a) is, or is deemed to be, registered with the Nursing Council of New Zealand continued by section 114(1)(a) of the Health Practitioners Competence Assurance Act 2003 as a practitioner of the profession of nursing and whose scope of practice permits the performance of nurse practitioner functions; and

(b) holds a current practising certificate

Nursing Council means the Nursing Council of New Zealand continued by section 114(1)(a) of the Health Practitioners Competence Assurance Act 2003

officer means—

(a) any officer of the Ministry of Health:

(b) any person appointed under section 15 to be an officer

optometrist means a person—

(a) who is, or is deemed to be, registered with the Optometrists and Dispensing Opticians Board as a practitioner of optometry; and

(b) for whom the Optometrists and Dispensing Opticians Board has authorised a scope of practice that includes prescribing medicines

Optometrists and Dispensing Opticians Board means the Optometrists and Dispensing Opticians Board continued by section 114(1)(a) of the Health Practitioners Competence Assurance Act 2003

pack means to enclose in a container for the purpose of sale or supply

package, in relation to any medicine or medical device, means any box, packet, or other receptacle in which 1 or more containers of the medicine or device are or are to be enclosed; and, where any such box, packet, or other receptacle is or is to be itself enclosed in 1 or more other boxes, packets, or other receptacles, includes every such box, packet, or other receptacle

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

pharmacy means a place where pharmacy practice is carried on

pharmacy practice includes, without limitation, the following:

(a) the compounding and dispensing of prescription medicines, restricted medicines, or pharmacy-only medicines:

(b) the supply of a medicine by a pharmacist to suit the needs of a particular person:

(c) the sale of prescription medicines, restricted medicines, or pharmacy-only medicines

plant includes any part of a plant

practitioner means a medical practitioner or a dentist

qualifying new medicine means a new medicine that—

(a) is or contains a new organism; and

(b) meets the criteria set out in section 38I(3) of the Hazardous Substances and New Organisms Act 1996

qualifying organism means a new organism that is or is contained in a qualifying new medicine

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

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

regulations means regulations made under this Act

related product and **new related product** have the meanings assigned to those terms by section 94

responsible authority has the meaning given to it in section 5(1) of the Health Practitioners Competence Assurance Act 2003

responsible person, in relation to a licensee corporation, means an agent or employee of that corporation who is a pharmacist or a person approved by the licensing authority as a responsible person for the purposes of the licence

sell includes—

(a) barter; and

(b) offering or attempting to sell, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or allowing to be sold, or offered or exposed for sale; and

(c) supplying by way of gift or sample for the purpose of promoting a sale;—

and **sale** has a corresponding meaning

selling by wholesale, **selling by retail**, and **selling in circumstances corresponding to retail sale** have the meanings assigned to those terms by section 5

standing order means—

(a) a written instruction issued by a practitioner, registered midwife, nurse practitioner, or optometrist, in accordance with any applicable regulations, authorising any specified class of persons engaged in the delivery of health services to supply and administer any specified class or description of prescription medicines or controlled drugs to any specified class of persons, in circumstances specified in the instruction, without a prescription:

(b) a written instruction issued by a veterinarian, in accordance with any applicable regulations, authorising any specified class of persons to supply and administer any specified class or description of prescription medicines or controlled drugs to any specified class of animals, in circumstances specified in the instruction, without a prescription:

(c) a written instruction issued by a practitioner, registered midwife, nurse practitioner, or optometrist, in accordance with any applicable regulations, authorising any specified class of persons engaged in the delivery of health services to supply and administer any specified class or description of pharmacy-only medicines or restricted medicines to any specified class of persons, in circumstances specified in the instruction:

(d) a written instruction issued by a veterinarian in accordance with any applicable regulations, authorising any specified class of persons to supply and administer any specified class or description of pharmacy-only medicines or restricted medicines to any specified class of animals, in circumstances specified in the instruction

substance means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour

therapeutic purpose has the meaning assigned to that term by section 4

vehicle includes an aircraft, a hovercraft, and a ship

veterinarian means a person who is registered as a veterinarian or specialist within the meaning of section 4 of the Veterinarians Act 2005.

(2) Any approval by the Minister of a laboratory as an approved laboratory for the purposes of this Act may be given on such terms and conditions as the Minister thinks fit and as are specified in the notice approving that laboratory.

(3) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1960 No 97 s 2(1); 1969 No 7 s 2(1); 1975 No 116 s 31(1); 1979 No 27 s 2(1); SR 1964/64 r 2(1); SR 1969/193 r 2(1); SR 1973/79 r 2(1); Medicines Act 1968 ss 130(9), 132(1) (UK)

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 2(1) **analyst**: substituted, on 1 July 1992, by section 2(1) of the Medicines Amendment Act 1992 (1992 No 50).

Section 2(1) **analyst**: amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 2(1) **animal**: amended, on 28 May 2002, by section 5 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 2(1) **animal remedy**: substituted, on 2 July 2001, by section 85 of the Agricultural Compounds and Veterinary Medicines Act 1997 (1997 No 87).

Section 2(1) **approved laboratory**: inserted, on 1 July 1992, by section 2(2) of the Medicines Amendment Act 1992 (1992 No 50).

Section 2(1) **approved laboratory**: amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 2(1) **authorised prescriber**: replaced, on 1 July 2014, by section 4(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **controlled drug**: inserted, on 22 October 2003, by section 3(1) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 2(1) **Customs** or **the Customs**: inserted, on 1 October 1996, by section 289(1) of the Customs and Excise Act 1996 (1996 No 27).

Section 2(1) **Customs** or **the Customs**: amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

Section 2(1) **delegated prescriber**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **delegated prescribing order**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **delegated prescribing rights**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **dentist**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **designated prescriber**: inserted, on 15 October 1999, by section 2(3) of the Medicines Amendment Act 1999 (1999 No 117).

Section 2(1) **designated prescriber**: amended, on 1 July 2014, by section 4(2)(a) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **designated prescriber** paragraph (a): amended, on 1 July 2014, by section 4(2)(b) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **Director-General**: substituted, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 2(1) **dispensing**: inserted, on 18 September 2004, by section 3(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **EPA**: inserted, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Section 2(1) **ERMA**: repealed, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Section 2(1) **health services**: inserted, on 15 October 1999, by section 2(3) of the Medicines Amendment Act 1999 (1999 No 117).

Section 2(1) **hospital**: substituted, on 1 October 2002, by section 58(1) of the Health and Disability Services (Safety) Act 2001 (2001 No 93).

Section 2(1) **importer**: amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

Section 2(1) **licensing authority**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **licensing authority** paragraph (b): amended, on 7 August 2020, by section 135 of the Public Service Act 2020 (2020 No 40).

Section 2(1) **medical device**: replaced, on 1 July 2014, by section 4(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **Medical Officer of Health**: amended, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 2(1) **medical practitioner**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **new organism**: inserted, on 30 October 2003, by section 3 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Section 2(1) **nurse practitioner**: replaced, on 31 January 2018, by section 4 of the Medicines Amendment Act 2016 (2016 No 78).

Section 2(1) **Nursing Council**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **officer**: substituted, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 2(1) **optician**: repealed, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **optometrist**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **Optometrists and Dispensing Opticians Board**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **pharmacist**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **pharmacy**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **pharmacy practice**: inserted, on 18 September 2004, by section 3(4) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **qualifying new medicine**: inserted, on 30 October 2003, by section 3 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Section 2(1) **qualifying organism**: inserted, on 30 October 2003, by section 3 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Section 2(1) **registered health professional**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **registered midwife**: substituted, on 18 September 2004, by section 3(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 2(1) **regulations**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **responsible authority**: inserted, on 1 July 2014, by section 4(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **standing order**: inserted, on 15 October 1999, by section 2(3) of the Medicines Amendment Act 1999 (1999 No 117).

Section 2(1) **standing order** paragraph (a): amended, on 1 July 2014, by section 4(4) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **standing order** paragraph (a): amended, on 22 October 2003, by section 3(2) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 2(1) **standing order** paragraph (b): amended, on 22 October 2003, by section 3(2) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 2(1) **standing order** paragraph (c): added, on 22 October 2003, by section 3(3) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 2(1) **standing order** paragraph (c): amended, on 1 July 2014, by section 4(5) of the Medicines Amendment Act 2013 (2013 No 141).

Section 2(1) **standing order** paragraph (d): added, on 22 October 2003, by section 3(3) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 2(1) **veterinarian**: added, on 15 October 1999, by section 2(2) of the Medicines Amendment Act 1999 (1999 No 117).

Section 2(1) **veterinarian**: amended, on 22 December 2005, by section 105 of the Veterinarians Act 2005 (2005 No 126).

Section 2(1) **veterinary surgeon**: repealed, on 15 October 1999, by section 2(2) of the Medicines Amendment Act 1999 (1999 No 117).

Section 2(2): added, on 1 July 1992, by section 2(3) of the Medicines Amendment Act 1992 (1992 No 50).

Section 2(3): replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

3 Meaning of medicine, new medicine, prescription medicine, and restricted medicine

(1) In this Act, unless the context otherwise requires, **medicine**—

(a) means any substance or article that—

(i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

(ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and

(b) includes any substance or article—

(i) that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or

(ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but

(c) does not include—

(i) a medical device; or

(ii) any food within the meaning of section 2 of the Food Act 1981; or

(iii) any radioactive material within the meaning of section 5(1) of the Radiation Safety Act 2016; or

(iv) any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or

(v) any animal remedy; or

(vi) any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act.

(2) *[Repealed]*

(3) In this Act, unless the context otherwise requires,—

new medicine means—

(a) any medicine that has not been generally available in New Zealand—

(i) before the commencement of this Act; or

(ii) at any time during the period of 5 years immediately preceding the date on which it is proposed to become so available:

(b) any medicine that, immediately before the commencement of Part 2, was a therapeutic drug to which section 12 of the Food and Drug Act 1969 applied, and in respect of the sale or distribution of which the Minister had not given his consent under that section:

(c) any medicine that becomes a medicine within the meaning of this Act for the first time after the commencement of this Act:

(d) any medicine that is referred to the Minister under section 24(5)

pharmacy-only medicine means a medicine that is declared by regulations made under this Act or by a notice given under section 106 to be one that, except as may be permitted by the regulations, may be—

(a) sold by retail only—

(i) in a pharmacy or hospital; or

(ii) in any shop described in section 51(2) and in accordance with a licence issued under Part 3; or

(b) supplied in circumstances corresponding to retail sale only—

(i) in a pharmacy or hospital; or

(ii) in any shop described in section 51(2) and in accordance with a licence issued under Part 3; or

(iii) in accordance with a standing order

prescription medicine means a medicine that is declared by regulations or by a notice given under section 106 to be one that, except as may be permitted by regulations, may be—

(a) sold by retail only under a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; and

(b) supplied in circumstances corresponding to retail sale only—

(i) under a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; or

(ii) in accordance with a standing order; and

(c) administered only in accordance with—

(i) a prescription given by an authorised prescriber, veterinarian, or delegated prescriber; or

(ii) a standing order

restricted medicine means a medicine that is declared by regulations made under this Act or by a notice given under section 106 to be one that, except as may be permitted by the regulations, may be—

(a) sold by retail only by a pharmacist in a pharmacy or hospital; or

(b) supplied in circumstances corresponding to retail sale only—

(i) by a pharmacist in a pharmacy or hospital; or

(ii) in accordance with a standing order.

Compare: Medicines Act 1968 s 130(1), (3), (5), (7) (UK)

Section 3(1): replaced, on 1 July 2014, by section 5(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 3(1)(c)(iii): amended, on 7 March 2017, by section 99 of the Radiation Safety Act 2016 (2016 No 6).

Section 3(2): repealed, on 1 July 2014, by section 5(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 3(3) **pharmacy-only medicine**: substituted, on 22 October 2003, by section 4(1) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 3(3) **prescription medicine**: replaced, on 1 July 2014, by section 5(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 3(3) **restricted medicine**: substituted, on 22 October 2003, by section 4(2) of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

3A Meaning of medical device

In this Act, unless the context otherwise requires, **medical device**—

(a) means any device, instrument, apparatus, appliance, or other article that—

(i) is intended to be used in, on, or for human beings for a therapeutic purpose; and

(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

(b) includes a material that—

(i) is intended to be used in or on human beings for a therapeutic purpose; and

(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

(c) also includes—

(i) anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and

(ii) any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of this Act; but

(d) does not include a device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations not to be a medical device for the purposes of this Act.

Section 3A: inserted, on 1 July 2014, by section 6 of the Medicines Amendment Act 2013 (2013 No 141).

4 Meaning of therapeutic purpose

In this Act, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or

(b) influencing, inhibiting, or modifying a physiological process; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling, or preventing conception; or

(e) testing for pregnancy; or

(f) investigating, replacing, or modifying parts of the human anatomy.

Section 4: replaced, on 1 July 2014, by section 7 of the Medicines Amendment Act 2013 (2013 No 141).

5 Meaning of selling by wholesale, selling by retail, and selling in circumstances corresponding to retail sale

(1) In this Act, unless the context otherwise requires, every reference to selling anything by wholesale is a reference to selling it to a person whom the vendor believes to be buying it—

(a) for the purpose of—

(i) selling or supplying it; or

(ii) administering it or causing it to be administered to 1 or more human beings—

in the course of a business carried on by that person; or

(b) for the purpose of—

(i) using it in any scientific, educational, or commercial laboratory; or

(ii) using it in any process of manufacture or trade not involving the resale of that thing.

(2) In this Act every reference to selling anything by retail is a reference to selling it to a person whom the vendor believes to be buying it for a purpose other than one specified in subsection (1).

(3) In this Act every reference to supplying anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person whom the supplier believes to be receiving it for a purpose other than one specified in subsection (1).

Compare: Medicines Act 1968 s 131 (UK)

5A Relationship with Hazardous Substances and New Organisms Act 1996

In relation to medicines that are or contain hazardous substances or new organisms, the requirements of this Act are additional to the requirements of the Hazardous Substances and New Organisms Act 1996.

First section 5A: inserted, on 30 October 2003, by section 4 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

5A Meaning of holding an interest in a pharmacy

(1) For the purposes of this Act, a person holds an interest in a pharmacy if the person has, or acquires, any direct or indirect estate or interest in the pharmacy (whether by way of shares in a company or by way of charge, loan, guarantee, indemnity, or otherwise) that affects the ownership, management, or control of the pharmacy practice carried on in the pharmacy.

(2) For the purposes of subsection (1), a person acquires a direct or indirect estate or interest in a pharmacy if the acquisition is made in the person's name, or in the name of a nominee, or the acquisition is made by the person by means of any device or arrangement.

(3) Despite subsections (1) and (2),—

(a) a person does not hold an interest in a pharmacy merely by—

(i) making, in good faith and in the ordinary course of business to facilitate the carrying on of the pharmacy, any loan of money; or

(ii) holding any security for repayment of that loan:

(b) a person does not hold an interest in a pharmacy that is being carried on by an administrator of the estate of a deceased pharmacist, or by an administrator of the estate of a deceased operator of a pharmacy, merely by holding an interest in that estate.

(4) Despite subsection (3), any covenant, condition, or stipulation, expressed or implied in any contract or agreement restricting the operator of a pharmacy in the purchase of pharmaceutical requirements or other stock in trade is to be treated, for the purposes of this Act, as a device or arrangement affecting the management and control of the pharmacy practice carried on in that pharmacy.

Compare: 1970 No 143 s 2(2)–(4)

Second section 5A: inserted, on 18 September 2004, by section 4 of the Medicines Amendment Act 2003 (2003 No 50).

5B Meaning of operating a pharmacy

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

(a) establishes, or carries on business in, a pharmacy; or

(b) establishes, owns, or is responsible for the management or control of a hospital in which there is a pharmacy; or

(c) establishes, or is responsible for the management or control of a pharmacy carried on, on a not for profit basis.

Section 5B: inserted, on 18 September 2004, by section 4 of the Medicines Amendment Act 2003 (2003 No 50).

5C Transitional, savings, and related provisions

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

Section 5C: inserted, on 25 May 2021, by section 5 of the Medicines Amendment Act 2021 (2021 No 16).

Part 1
Application and administration of Act

Application

6 Act to bind Crown

This Act shall bind the Crown.

Compare: 1960 No 97 s 55; 1969 No 7 s 5; 1979 No 27 s 3

7 Principals and agents

(1) For the purposes of this Act, but subject to subsection (2), every person shall be deemed to manufacture, sell, supply, pack, or label any medicine whether he does so on his own account or as the agent or employee of any other person; and references to things done by a person in the course of a business shall be deemed to include references to things done by an agent or employee of that person in the course of that business.

(2) For the purposes of this Act, if a person who is authorised by or under this Act to manufacture, sell, supply, pack, or label a medicine does so, in accordance with that authority, as the agent or employee of another person who is not so authorised, that other person shall not be held to have manufactured, sold, supplied, packed, or labelled that medicine.

(3) For the purposes of this Act, while a person who is authorised by or under this Act to manufacture, sell, supply, pack, or label a medicine has that medicine in his custody or under his control as the agent or employee of another person who is not so authorised, that other person shall not be held to be in possession of that medicine.

(4) For the purposes of this Act, any natural person who manufactures, sells, supplies, packs, or labels a medicine while working under the supervision and control of a responsible person or of another natural person authorised by or under this Act, otherwise than by section 32, to manufacture, sell, supply, pack, or label that medicine, shall be deemed to be the agent or employee of the responsible person or the person so authorised, and in any such case the responsible person or person so authorised shall be deemed to be the principal or employer of the first-mentioned person, without prejudice to the liability of any other person under section 79.

Compare: 1960 No 97 s 2(2)–(5); 1979 No 27 s 6

Administration

8 Advisory and technical committees

(1) The Minister may from time to time appoint such advisory or technical committees as he thinks fit to advise him for any of the purposes of this Act, and may from time to time determine the functions of any such committee.

(2) There may be paid out of money appropriated by Parliament for the purpose to the members of any committee appointed under this section remuneration by way of fees, salary, or allowances and travelling allowances and expenses in accordance with the Fees and Travelling Allowances Act 1951, and the provisions of that Act shall apply accordingly as if the committee were a statutory board within the meaning of that Act.

(3) Subject to the provisions of this Act and of any regulations made under this Act, every such committee may determine its own procedure.

Compare: 1960 No 97 s 5; 1969 No 7 s 20; 1979 No 27 s 8

9 Medicines Classification Committee

(1) The Minister shall appoint under section 8 an advisory committee to be called the Medicines Classification Committee, whose duty it shall be to make recommendations to the Minister in respect of the classification of any medicines as prescription medicines or restricted medicines or pharmacy-only medicines under this Act.

(2) The Committee shall also consider and report to the Minister on such other matters in relation to any of the purposes of this Act as may from time to time be referred to it by the Minister.

(3) The Committee shall consist of—

(a) 2 persons, to be nominated by the New Zealand Medical Association:

(b) 2 persons, to be nominated by the Pharmaceutical Society of New Zealand:

(c) 2 persons, being officers of the Ministry of Health, one of whom shall be appointed as chairman.

(4) The members of the Committee shall hold office—

(a) in the case of any member appointed under subsection (3)(c), during the pleasure of the Minister:

(b) in the case of any other member, for a term of 3 years, subject to subsection (5), but any such member may be reappointed for 1 further term.

(5) Any member of the Committee may at any time be removed from office by the Minister for disability, neglect of duty, or misconduct proved to the satisfaction of the Minister, or may at any time resign his office by writing addressed to the Minister.

(6) If any member of the Committee dies, resigns, or is removed from office, the vacancy so created shall be filled in the manner in which the appointment to the vacant office was originally made, and in the case of a vacancy in the office of a nominated member, every person so appointed shall be appointed for the residue of the term for which his predecessor was appointed.

(7) Unless he sooner vacates his office under subsection (6), every nominated member of the Committee shall continue in office until his successor comes into office, notwithstanding that the term for which he was appointed may have expired.

(8) The powers of the Committee shall not be affected by any vacancy in its membership.

(9) At any meeting of the Committee, 4 members shall form a quorum.

Compare: 1960 No 97 s 6; 1967 No 108 s 2; 1979 No 28 s 5(1)

Section 9(3)(c): amended, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

10 Medicines Review Committee established

(1) Without limiting section 8, for the purposes of this Act there shall be a committee, to be called the Medicines Review Committee.

(2) The Committee shall consist of 6 members appointed by the Minister, of whom 1 shall be appointed by the Minister as chairman, and shall include at least—

(a) 1 person with wide experience in the practice of medicine:

(b) 1 person with wide experience in the practice of pharmacy:

(c) 1 person with wide experience in the pharmaceutical manufacturing industry:

(d) 1 person with wide experience in a form of chemistry other than pharmaceutical chemistry.

(3) The Minister shall also appoint 1 person with wide experience in the practice of natural therapy to act as a member of the Committee whenever any matter relating to the practice of natural therapy is before the Committee.

(4) There may be paid out of money appropriated by Parliament for the purpose to the members of the Committee remuneration by way of fees, salary, or allowances and travelling allowances and expenses in accordance with the Fees and Travelling Allowances Act 1951, and the provisions of that Act shall apply accordingly as if the Committee were a statutory board within the meaning of that Act.

Compare: 1960 No 97 s 6; 1967 No 51 s 6(3); 1967 No 108 s 2; 1979 No 28 s 5(1)

11 Deputies of members

(1) In any case where the Minister is satisfied that any member of the Medicines Review Committee is incapacitated by illness or absence or other sufficient cause from performing the duties of his office, the Minister may appoint a deputy to act for that member during his incapacity.

(2) No person shall be appointed a deputy under subsection (1) unless he is eligible for membership of the Committee under the same provision of section 10 as the member in whose place he is to act.

(3) Every deputy appointed under this section shall, while he acts as such, be deemed to be a member of the Committee, and any deputy acting for the chairman shall have all the powers of the chairman.

(4) No appointment of a deputy and no acts done by him as such, and no acts done by the Committee while any deputy is acting as such, shall be questioned in any proceedings on the ground that the occasion for his appointment had not arisen or had ceased.

Compare: 1979 No 27 s 14

12 Committee may appoint subcommittees

(1) The Medicines Review Committee may from time to time appoint such subcommittees comprising 2 or more members of the Committee as it thinks fit to hear and determine such matters as the Committee may from time to time delegate to them.

(2) Notwithstanding subsection (1), where the Committee delegates to any subcommittee any matter relating to the practice of natural therapy, the person appointed under section 10(3) shall act as a member of the subcommittee.

(3) Every subcommittee appointed under this section shall be subject in all things to the control of the Committee, and may at any time be discharged, altered, or reconstituted by the Committee.

(4) Any delegation under this section may at any time be revoked by the Committee.

Compare: 1979 No 27 s 17

13 Functions, powers, and procedures of Medicines Review Committee

(1) The functions of the Medicines Review Committee shall be as follows:

(a) to inquire into any objection to the terms of a recommendation of the appropriate committee made under section 22(2), and to report its findings to the Minister:

(b) to hear appeals under section 88.

(2) On receipt of an objection made in accordance with section 22(4), and of a deposit by the objector of the prescribed amount, the Committee shall inquire into the objection and report its findings to the Minister as soon as practicable.

(3) On receipt of an appeal made in accordance with section 88, the Committee shall inquire into and determine the appeal as soon as practicable.

(4) In carrying out its inquiries under subsection (2) or subsection (3), the Committee shall not be bound to follow any formal procedure, but shall observe the rules of natural justice, and shall consider all submissions made by or on behalf of the objector or appellant.

(5) Every report by the Committee to the Minister on an objection shall include a recommendation as to the decision the Minister should make in respect of the matter to which the objection relates.

(6) The Committee may make such order as to costs as it thinks fit.

(7) Subject to any order made under subsection (6), the Committee shall, on completing its deliberations on any objection, refund to the objector the deposit paid by him under subsection (2).

(8) Subject to the provisions of this section and of any regulations made under this Act, the Committee may determine its own procedure.

14 Servicing of committees

The Minister shall provide every committee appointed under section 8, and the Medicines Review Committee, with such staff, accommodation, services, and other facilities as appear to him to be necessary or expedient for the proper performance of its functions by that committee.

15 Appointment of officers

(1) There may from time to time be appointed under the Public Service Act 2020 such officers as are required for the purposes of this Act.

(2) The Director-General may from time to time appoint any person, not being an officer of the public service, as an officer, either in a part- or full-time capacity, for the purposes of this Act.

(3) Any appointment under subsection (2) may be made either generally for the purposes of this Act or for any specified purpose, or for the exercise of any specified power or function of an officer under this Act, or for any specified period; and may be made in respect of New Zealand generally or in respect of any specified area or areas.

(4) There may be paid out of money appropriated by Parliament for the purpose to any person appointed under subsection (2) such remuneration as may be fixed by the Director-General.

(5) No person appointed under subsection (2) shall be deemed by reason of that appointment to be employed in the service of Her Majesty the Queen for the purposes of the Public Service Act 2020 or the Government Superannuation Fund Act 1956.

Compare: 1960 No 97 s 7; 1969 No 7 s 19; 1979 No 27 s 9

Section 15(1): amended, on 7 August 2020, by section 135 of the Public Service Act 2020 (2020 No 40).

Section 15(1): amended, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 15(2): substituted, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 15(2): amended, on 7 August 2020, by section 135 of the Public Service Act 2020 (2020 No 40).

Section 15(4): amended, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 15(5): amended, on 7 August 2020, by section 135 of the Public Service Act 2020 (2020 No 40).

16 Exercise of powers of Director-General and other officers

(1) The Director-General, every Medical Officer of Health, and every other officer, shall exercise the powers and functions conferred on him by this Act subject to the direction and control of the Minister.

(2) Subject to subsection (1), each Medical Officer of Health employed in the Ministry of Health, and every other officer of the Ministry of Health, shall exercise

the powers and functions conferred on him by this Act subject to the direction and control of the Director-General of Health and of every other officer of the Ministry of Health to whom he is subordinate.

(1A) *[Repealed]*

(3) Where, by virtue of any provision of this Act, a reasonable belief in any particular state of affairs is a prerequisite for the exercise of any power by an officer, it shall be sufficient if the officer exercises that power at the direction of any other officer who is superior to him and who, at the time of giving the direction, held such a belief in that state of affairs.

Compare: 1979 No 27 s 10

Section 16(2): amended, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 16(2): amended, on 1 April 1984, by section 98 of the Area Health Boards 1983 (1983 No 134).

Section 16(1A): repealed, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Part 2
Dealings with medicines and medical devices

17 Manufacturers, wholesalers, packers of medicines, and operators of pharmacies to be licensed

(1) Except as provided in sections 25 to 34, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person,—

(a) manufacture any medicine; or

(b) sell any medicine by wholesale; or

(c) pack or label any medicine; or

(d) operate any pharmacy,—

otherwise than in accordance with a licence issued under Part 3.

(2) Every person who contravenes subsection (1) commits an offence and is liable on conviction to a fine not exceeding $40,000.

Compare: 1960 No 97 ss 8, 12(1), 14(1); 1969 No 44 s 3; 1979 No 27 ss 19, 20; 1979 No 28 s 6(1)

Section 17 heading: amended, on 18 September 2004, by section 5(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 17(1)(c): substituted, on 18 September 2004, by section 5(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 17(1)(d): added, on 18 September 2004, by section 5(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 17(2): substituted, on 18 September 2004, by section 5(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 17(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

18 Sale of medicines by retail

(1) Except as provided in sections 25, 27, and 30 to 33, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person, sell by retail, or supply in circumstances corresponding to retail sale, or distribute by way of gift or loan or sample or in any other way,—

(a) any prescription medicine unless—

(i) the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(ii) the medicine is supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order; or

(aa) *[Repealed]*

(b) any restricted medicine unless the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(c) any pharmacy-only medicine unless the medicine is sold, supplied, or distributed by—

(i) a person under the supervision of a pharmacist in a pharmacy or a hospital; or

(ii) a person who sells, supplies, or distributes the medicine in any shop described in section 51(2) and in accordance with a licence issued under Part 3.

(2) No person may sell by retail any prescription medicine otherwise than under a prescription given by an authorised prescriber, a veterinarian, or a delegated prescriber.

(2A) No person may supply, in circumstances corresponding to retail sale, any prescription medicine otherwise than—

(a) under a prescription given by an authorised prescriber, a veterinarian, or a delegated prescriber; or

(b) in accordance with a standing order.

(2B) Despite subsections (2) and (2A), a person may sell by retail, or supply, in circumstances corresponding to retail sale, any prescription medicine, where permitted by section 25 or section 30 or section 31 or section 69 or by regulations made under this Act.

(3) Except as may be permitted by regulations made under this Act, no person shall hawk any prescription medicine or restricted medicine or pharmacy-only medicine—

(a) from house to house; or

(b) in any public place within the meaning of section 2 of the Summary Offences Act 1981,—

otherwise than pursuant to any authority to do so expressly conferred by a licence held by him under Part 3, and in accordance with any conditions or restrictions specified in the licence.

(4) Except as may be permitted by regulations made under this Act, no person shall sell any medicine by means of an automatic vending machine or by auctioning the medicine.

(5) Every person who sells or supplies or distributes a prescription medicine in contravention of subsection (1) commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $40,000.

(6) Every person commits an offence against this Act who contravenes any of the provisions of this section (otherwise than in circumstances that constitute an offence against subsection (5)).

Compare: 1960 No 97 ss 8(1), (4), 9, 13(1); 1969 No 7 ss 18, 39(6); 1969 No 44 s 3; SR 1964/64 rr 12, 65; Medicines Act 1968 ss 52–54 (UK)

Section 18(1)(a): substituted, on 18 September 2004, by section 6(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 18(1)(aa): repealed, on 18 September 2004, by section 6(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 18(1)(b): substituted, on 18 September 2004, by section 6(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 18(1)(c): substituted, on 18 September 2004, by section 6(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 18(2): substituted, on 15 October 1999, by section 4(2) of the Medicines Amendment Act 1999 (1999 No 117).

Section 18(2): amended, on 1 July 2014, by section 9 of the Medicines Amendment Act 2013 (2013 No 141).

Section 18(2A): inserted, on 15 October 1999, by section 4(2) of the Medicines Amendment Act 1999 (1999 No 117).

Section 18(2A)(a): amended, on 1 July 2014, by section 9 of the Medicines Amendment Act 2013 (2013 No 141).

Section 18(2B): inserted, on 15 October 1999, by section 4(2) of the Medicines Amendment Act 1999 (1999 No 117).

Section 18(3)(b): substituted, on 15 October 1999, by section 4(3) of the Medicines Amendment Act 1999 (1999 No 117).

Section 18(5): amended, on 18 September 2004, by section 6(2) of the Medicines Amendment Act 2003 (2003 No 50).

19 Administering prescription medicines

(1) A prescription medicine may be administered to any person only in accordance with—

(a) the directions of the authorised prescriber or delegated prescriber who prescribed the medicine; or

(b) a standing order.

(2) Despite subsection (1), a prescription medicine may be administered where permitted by section 25 or by regulations made under this Act.

(3) Every person commits an offence against this Act who contravenes subsection (1).

(4) *[Repealed]*

Section 19: substituted, on 15 October 1999, by section 5 of the Medicines Amendment Act 1999 (1999 No 117).

Section 19(1)(a): amended, on 1 July 2014, by section 10 of the Medicines Amendment Act 2013 (2013 No 141).

Section 19(4): repealed, on 18 September 2004, by section 7 of the Medicines Amendment Act 2003 (2003 No 50).

20 Restrictions on sale or supply of new medicines

(1) Except as provided in sections 25, 26(4), 28, 30, 31, and 32, this section applies to new medicines.

(2) No person shall—

(a) sell; or

(b) distribute by way of gift or loan or sample or in any other way; or

(c) advertise the availability of—

any medicine to which this section applies before the consent or provisional consent oft he Minister to the distribution of the medicine has been given by notice, or otherwise than in accordance with such conditions as may be imposed by the Minister on giving his or her consent or provisional consent and set out in the notice.

(3) No consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates.

(4) A person who contravenes subsection (2) commits an offence, and is liable on conviction—

(a) in the case of an individual, to imprisonment for a term not exceeding 6 months or a fine not exceeding $20,000:

(b) in the case of a body corporate, to a fine not exceeding $100,000.

(5) In any proceedings for an offence against subsection (4) in which it is alleged that this section applies to a medicine by reason of subsection (1), it shall be presumed that the medicine is a medicine to which this section applies until the contrary is proved.

(6) The provisions of this section are in addition to, and not in substitution for, the provisions of any other enactment prohibiting, regulating, or restricting the sale or distribution of medicines, and nothing in any such other enactment shall authorise any person to act in contravention of the provisions of this section; but in the event of any conflict, the provisions of this section shall prevail.

(6A) The Minister, after having given consent or provisional consent to the distribution of any medicine in accordance with this Act, shall give written notification to the EPA of the consent or provisional consent and any condition attached to that consent.

(7) Any consent that was given in respect of any medicine by the Minister under section 12(2) of the Food and Drug Act 1969 and in force immediately before the commencement of this Act shall be deemed for the purposes of this section and section 35 to have been given under this section.

(8) A notice under subsection (2) is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1969 No 7 s 12

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14
	The Ministry of Foreign Affairs and Trade considers that the secondary legislation may have international transparency obligations under the CPTPP. As a result the maker may also have to comply with s 75 of the Legislation Act 2019	LA19 ss 74(2), 75
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 20(2): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 20(4): substituted, on 19 May 1998, by section 11 of the Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 (1998 No 20).

Section 20(6A): inserted, on 2 July 2001, by section 149 of the Hazardous Substances and New Organisms Act 1996 (1996 No 30).

Section 20(6A): amended, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Section 20(8): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

21 Applications for Minister's consent

(1) Every application for the Minister's consent under section 20 shall—

(a) *[Repealed]*

(b) be made in the true name of the manufacturer or importer or proprietor, or the proposed manufacturer or importer or proprietor, in New Zealand of the medicine, by that person or by his duly authorised agent:

(c) be addressed to the Director-General:

(ca) be accompanied by the prescribed fee:

(d) state, or be accompanied by a statement of, the particulars specified in subsection (2).

(2) The particulars required by subsection (1)(d) are the following:

(a) the business address of the person in whose name the application is made, and, where that person is not the manufacturer of the medicine and of each of the principal ingredients of the medicine, the true name and business address of each such manufacturer:

(b) the name under which the medicine will be distributed:

(c) details of the method of manufacture of the medicine:

(d) a full statement of the ingredients named by the descriptive or non-proprietary names of the medicine, including details of the quantities in which they are present:

(e) a description of the quality of the raw materials used in the manufacture of the medicine:

(f) a description of the form or forms of the medicine:

(g) the proposed or recommended dosage and frequency of dose, and the manner in which the medicine will be recommended to be administered, applied, or otherwise used:

(h) the purposes for which the medicine will be recommended to be used, and the claims or representations to be made in respect of its usefulness:

(i) reports of any tests made to establish the safety of the medicine for the purposes for which and in the manner in which it is intended to be used:

(j) reports of any tests made to control the strength, quality, purity, or safety of the medicine and of the method of testing:

(k) any reports relating to the efficacy of the medicine:

(l) a translation into English, authenticated in such manner as the Director-General may require, of any report referred to in paragraph (i) or paragraph (j) or paragraph (k) that is not in English:

(m) any evidence to show that the distribution in any country other than New Zealand of the medicine in the form and for the purposes that it is proposed to be distributed in New Zealand has been approved or consented to by the appropriate authorities in that country:

(n) the intended method of distribution of the medicine in New Zealand:

(o) a coloured specimen of every label and other descriptive matter proposed to be used on or included in, or to accompany, packages or containers containing the medicine:

(p) the name and address of the place or places where the manufacture, preparation, or packing is intended to be carried out.

(3) Notwithstanding anything in subsection (1), in the case of a medicine to which section 20 applies by virtue of subsection (1) of that section, the notice deposited with the Director-General under section 24 shall, subject to subsections (4)

and (5), be a sufficient application for the consent of the Minister under the said section 20.

(4) At any time before the publication of a notice signifying the consent of the Minister to the distribution of a medicine in respect of which an application under section 20 has been made, the Director-General may, by notice in writing given to the person in whose name the application was made, require that person to supply—

(a) such samples of the medicine; and

(b) such further information or particulars concerning the medicine, or the manufacture, intended sale, distribution, or advertising of the medicine,—

as the Director-General may specify in his notice.

(5) The Director-General may, if he thinks fit, require any person to verify by statutory declaration any statement in an application made, or in any further information or particulars supplied, under this section and signed by that person.

Compare: 1969 No 7 s 13

Section 21(1)(a): repealed (without coming into force), on 8 March 1985, by section 2 of the Medicines Amendment Act 1985 (1985 No 29).

Section 21(1)(ca): inserted, on 8 August 1990, by section 2 of the Medicines Amendment Act (No 2) 1990 (1990 No 97).

Section 21(4): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

22 Procedure in respect of applications for Minister's consent

(1) On receipt of an application for his consent to the distribution of a medicine for the purposes of section 20(2), the Minister shall—

(a) consider all the particulars and information relating to the medicine submitted under section 21, and such other matters as appear to him to be relevant; and

(b) as far as practicable, weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person.

(2) If, after complying with subsection (1), the Minister is not satisfied that he should give his consent to the distribution of the medicine, he shall refer the matter to the appropriate committee, which shall consider the matter, and shall report on it to the Minister with a recommendation as to the decision that the Minister should make.

(3) On receipt of the recommendation of the appropriate committee under subsection (2), the Minister shall, before making his decision, if the recommendation is to refuse consent to the distribution of the medicine, notify the applicant for consent of the terms of the recommendation, and of the reasons for it.

(4) The applicant for consent may, within 28 days after being notified under subsection (3) of the recommendation of the appropriate committee, object to the recommendation in writing to the Minister.

(5) On receipt of an objection under subsection (4), the Minister shall, before making his decision, refer the matter to the Medicines Review Committee, which shall convene such meeting or meetings as may be necessary for it to consider the matter, and shall report on it to the Minister with a recommendation as to the decision that the Minister should make.

Compare: Medicines Act 1968 ss 20(3), 21 (UK)

23 Minister may give provisional consent

(1) Notwithstanding sections 20 to 22, the Minister may, by notice, in accordance with this section, give provisional consent to the sale or supply or use of a new medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied, or used.

(2) An application for the Minister's provisional consent under this section shall—

(a) be made in accordance with paragraphs (b) and (ca) of section 21(1):

(b) be addressed to the Director-General:

(c) state, or be accompanied by a statement of, the particulars specified in paragraphs (a) to (h) of section 21(2):

(d) be determined by the Minister in accordance with section 22.

(3) On giving his provisional consent under this section, the Minister may impose—

(a) such conditions relating to the persons to whom the medicine may be sold or supplied; or

(b) such conditions relating to the area in which the medicine may be distributed; or

(c) such other conditions, not being inconsistent with the purposes of this section,—

as he thinks fit.

(4) Subject to subsections (4A) and (5), every provisional consent given under this section shall have effect for 2 years or such shorter period as the Minister may determine, and shall then expire.

(4A) The Minister may, by notice, from time to time renew any provisional consent given under this section for a period not exceeding 2 years on any one occasion.

(4B) Subsections (3) and (5) shall apply to any renewal of a provisional consent given under subsection (4A) as if it were a provisional consent given under subsection (1).

(5) If, during the currency of a provisional consent given in respect of any medicine, the Minister grants a consent under section 20 in respect of the same medicine, the provisional consent shall be deemed to be revoked.

(6) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14
	The Ministry of Foreign Affairs and Trade considers that the secondary legislation may have international transparency obligations under the CPTPP. As a result the maker may also have to comply with s 75 of the Legislation Act 2019	LA19 ss 74(2), 75
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 23(1): replaced, on 25 May 2021, by section 4 of the Medicines Amendment Act 2021 (2021 No 16).

Section 23(1): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 23(2)(a): amended, on 8 August 1990, by section 3 of the Medicines Amendment Act (No 2) 1990 (1990 No 97).

Section 23(4): amended, on 23 February 1987, by section 2(1) of the Medicines Amendment Act 1987 (1987 No 9).

Section 23(4A): inserted, on 23 February 1987, by section 2(2) of the Medicines Amendment Act 1987 (1987 No 9).

Section 23(4A): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 23(4B): inserted, on 23 February 1987, by section 2(2) of the Medicines Amendment Act 1987 (1987 No 9).

Section 23(6): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

23A Interpretation

In this section, and in sections 23B and 23C, unless the context otherwise requires,—

applicant means—

(a) a person who makes or has made, as the case may be, an application; and

(b) a person on whose behalf an application is, or has been, made, as the case may be

application means an application for the consent of the Minister under section 20, or for the provisional consent of the Minister under section 23, in relation to a medicine

commencement date means the date this section and sections 23B and 23C come into force

confidential information includes—

(a) trade secrets; and

(b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information

confidential supporting information means confidential information given—

(a) in, or in relation to, an innovative medicine application; and

(b) about the medicine that is or was, as the case may be, the subject of that application

ingredient includes a chemical or biological entity

innovative medicine application means,—

(a) in relation to an application made after the commencement date, an application that refers to an active ingredient—

(i) that is an active ingredient of the medicine to which the application relates; and

(ii) that has not, before that application is received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine; and

(b) in relation to an application made before the commencement date, an application that referred to an active ingredient—

(i) that is or was, as the case may be, an active ingredient of the medicine to which the application related; and

(ii) that had not, before that application was received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine

protected period means—

(a) in relation to confidential supporting information, relating to an innovative medicine application, received by the Minister after the commencement date, a period commencing on the date that information is received by the Minister and ending,—

(i) where—

(A) the Minister has given notice of consent, not being provisional consent, under section 20, or refused to give consent, in relation to the medicine that is the subject of the innovative medicine application; and

(B) the date of publication of the notice of consent or the date of the refusal is not more than 5 years after the Minister received an application in relation to that medicine,—

on the date 5 years after the date of that notification or refusal; or

(ii) in any other case, on the date 5 years after the innovative medicine application to which that information relates is or was, as the case may be, received by the Minister:

(b) in relation to confidential supporting information, relating to an innovative medicine application, received by the Minister not more than 5 years before the commencement date, a period commencing on the commencement date and ending,—

(i) where—

(A) the Minister has given or gives notice of consent, not being provisional consent, under section 20, or refused or refuses to give consent, in relation to the medicine that was the subject of the innovative medicine application; and

(B) the date of publication of the notice of consent or the date of the refusal is or was, as the case may be, not more than 5 years after the Minister received an application in relation to that medicine,—

on the date 5 years after the date of that notification or refusal; or

(ii) in any other case, on the date 5 years after the innovative medicine application to which that information related was received by the Minister

WTO country means a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on 15 April 1994.

Section 23A: inserted, on 1 January 1995, by section 2 of the Medicines Amendment Act 1994 (1994 No 128).

Section 23A **confidential information**: replaced, on 8 November 2016, by section 11 of the Agricultural Compounds and Veterinary Medicines Amendment Act 2016 (2016 No 82).

Section 23A(a)(i)(A) **protected period**: replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 23A(a)(i)(B) **protected period**: amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 23A(b)(i)(A) **protected period**: replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 23A(b)(i)(B) **protected period**: amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

23B Protection of confidential supporting information about innovative medicines

Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential support-

ing information, the Minister, during the protected period in relation to that confidential supporting information,—

(a) shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and

(b) shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

Section 23B: inserted, on 1 January 1995, by section 2 of the Medicines Amendment Act 1994 (1994 No 128).

23C Circumstances where protection under section 23B does not apply

(1) Notwithstanding section 23B, the Minister may, during the protected period in relation to confidential supporting information,—

(a) disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

(i) with the consent of the applicant who made the application to which the confidential supporting information relates or related; or

(ii) if that disclosure or use is, in the opinion of the Minister, necessary to protect the health or safety of members of the public; or

(b) if, in the opinion of the Minister, the relevant committee, adviser, government department, statutory body, or person will take reasonable steps to ensure the confidential supporting information is kept confidential, disclose that confidential supporting information to—

(i) an advisory or technical committee appointed under section 8; or

(ii) the Medicines Classification Committee appointed under section 9; or

(iii) the Medicines Review Committee established under section 10; or

(iv) any adviser for the purpose of obtaining advice about the medicine to which the confidential supporting information relates; or

(v) a government department or statutory body for the purposes of the government department or statutory body; or

(c) disclose that confidential supporting information to any 1 or more of the following—

(i) the World Health Organisation:

(ii) the Food and Agriculture Organisation:

(iii) any regulatory agency of a WTO country:

(iv) any person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

(2) The power to grant consent under subsection (1)(a)(i) may be exercised by a person other than the applicant referred to in that subsection if—

(a) that applicant—

(i) has notified the Minister in writing that that other person may grant that consent; and

(ii) has not notified the Minister in writing that that person's authority to grant that consent has been withdrawn; or

(b) that applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that other person has notified the Minister in writing of the transfer.

Section 23C: inserted, on 1 January 1995, by section 2 of the Medicines Amendment Act 1994 (1994 No 128).

24 Distribution of changed medicines restricted

(1) If at any time a material change of a kind specified in subsection (2) is made by the manufacturer of a medicine, whether in New Zealand or elsewhere, and whether or not he was the manufacturer of the medicine before that change, the importer or manufacturer in New Zealand of the medicine shall, unless he is of the opinion that section 20 applies to the medicine by virtue of paragraph (a) or paragraph (b) or paragraph (c) of the definition of the term new medicine in section 3(3), deposit with the Director-General a notice in writing in English describing the change and giving particulars, so far as they are known, of any effect that the change might have on the safety and efficacy of the medicine.

(1A) Every notice deposited with the Director-General under subsection (1) shall be accompanied by the prescribed fee.

(2) Subsection (1) applies to every material change in any of the following matters:

(a) the purpose for which the medicine is represented to be used, or the recommended dosage, or the recommended manner of administration:

(b) the labelling of the medicine, or of any container or package in which the medicine is packed, or any descriptive matter accompanying or enclosed in any such medicine, container, or package:

(c) the strength, quality, or purity of the medicine:

(d) the methods of manufacture of the medicine, or the facilities for testing its strength, quality, purity, or safety:

(e) the location of the premises in which the medicine is manufactured.

(3) Except as provided in sections 25, 27, 28, 29, and 30, or with the prior written consent of the Director-General, no person shall—

(a) sell any medicine in respect of which there has been made a material change of which notice is required to be deposited with the Director-General under subsection (1); or

(b) supply any such medicine by way of gift or loan or sample, or in any other way—

until after the expiry of at least 90 days after the date on which such notice is deposited with the Director-General.

(4) Within 45 days after the receipt of any notice in accordance with subsection (1), the Director-General may, by written notice to the importer or manufacturer, require the importer or manufacturer to supply such further information or particulars, or such samples, as the Director-General may require with respect to any matter set out in the importer's or manufacturer's notice.

(5) If the Director-General, after considering the particulars, information, or samples required by or under subsection (1) or subsection (4), is of the opinion, at any time within the period specified in subsection (3),—

(a) that the change is of such a character or degree that the medicine ought not, without the consent of the Minister,—

(i) to be distributed in New Zealand; or

(ii) to be represented, recommended, advertised, or labelled in the terms set out in the notice; or

(b) that he is insufficiently informed, for the purposes of paragraph (a), in respect of—

(i) the strength, quality, purity, safety, or efficacy of the medicine; or

(ii) the methods of manufacture of, or the facilities for testing, the medicine,—

he shall refer the medicine to the Minister, and forthwith inform the importer or manufacturer by notice in writing that he has done so.

(6) Every person commits an offence against this Act who—

(a) fails to comply with subsection (1) or subsection (4); or

(b) contravenes subsection (3).

(7) A person who commits an offence under subsection (6) is liable on conviction—

(a) in the case of an individual, to imprisonment for a term not exceeding 3 months or a fine not exceeding $20,000:

(b) in the case of a body corporate, to a fine not exceeding $100,000.

Compare: 1969 No 7 ss 14, 39(5)

Section 24(1A): inserted, on 8 August 1990, by section 4 of the Medicines Amendment Act (No 2) 1990 (1990 No 97).

Section 24(7): added, on 19 May 1998, by section 12 of the Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 (1998 No 20).

Qualifying new medicines

Heading: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24A Assessment of qualifying new medicines

The Director-General may grant an approval under section 38I of the Hazardous Substances and New Organisms Act 1996 for the release of a qualifying new medicine if he or she—

(a) has the consent of the Minister to do so; and

(b) is acting under a delegation from the EPA given under section 19 of that Act.

Section 24A: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Section 24A(b): amended, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

24B Procedure if Director-General declines to grant approval

If the Director-General declines to grant an approval because the new organism is not a qualifying new medicine, then—

(a) the Director-General must—

(i) inform the EPA that the new medicine is not a qualifying new medicine; and

(ii) provide the EPA with a copy of all information (from assessing the safety, quality, and efficacy of the new medicine) that the Director-General considers may assist the EPA in deciding whether to approve or decline the application under the Hazardous Substances and New Organisms Act 1996; and

(b) the Minister must not consent under section 20 or give provisional consent under section 23 to the distribution, sale, or advertising of the medicine unless the Minister receives written advice from the EPA that the medicine has been approved for release under the Hazardous Substances and New Organisms Act 1996.

Section 24B: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Section 24B(a)(i): amended, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Section 24B(a)(ii): amended, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Section 24B(b): amended, on 1 July 2011, by section 53(1) of the Environmental Protection Authority Act 2011 (2011 No 14).

Approval of medicines required for use in special emergency

Heading: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24C Interpretation

In sections 24D to 24G, unless the context otherwise requires,—

hazardous substance has the same meaning as in section 2(1) of the Hazardous Substances and New Organisms Act 1996

responsible Minister has the same meaning as in section 49A of the Hazardous Substances and New Organisms Act 1996

special emergency has the same meaning as in section 49A of the Hazardous Substances and New Organisms Act 1996.

Section 24C: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24D Approval of medicines required for use in special emergency

(1) An application may be made to the Minister for approval to distribute, sell, or advertise in a special emergency a medicine that is or contains a hazardous substance or new organism.

(2) The Minister may approve an application under subsection (1) with or without conditions, as long as the Minister is satisfied that—

(a) the special emergency has been declared and has not come to an end; and

(b) the medicine is required for the special emergency; and

(c) the application complies with subsection (3).

(3) An application under subsection (1) must—

(a) be accompanied by the prescribed application fee (if any); and

(b) be in a form approved by the Director-General; and

(c) be accompanied by any information that the Minister considers is necessary for determining whether or not to approve the application.

Section 24D: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24E Notification or publication of approval

The approval of an application under section 24D must be notified in the *Gazette*.

Section 24E: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24F Duration of approval

An approval of an application under section 24D takes effect on the day specified in the approval, and expires on the earlier of—

(a) the date of expiry (if any) of the special emergency specified by the responsible Minister in—

(i) the declaration declaring the special emergency; or

(ii) a later declaration declaring that the special emergency has ceased; or

(b) the date of expiry (if any) specified by the responsible Minister in the approval, which must not be later than the date of expiry of the special emergency; or

(c) if paragraph (a) or paragraph (b) does not apply, 2 years after the date on which the approval is granted.

Section 24F: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

24G Consequences of expiry of approval

On the expiry of an approval of an application under section 24D, the medicine to which the approval applies must not be distributed or used unless authorised by or under any other provision of this Act.

Section 24G: inserted, on 30 October 2003, by section 5 of the Medicines Amendment Act (No 2) 2003 (2003 No 56).

Exemptions

25 Exemptions for practitioners and others

(1) An authorised prescriber may—

(a) manufacture, pack, and label a medicine that is specially prepared for, or intended for administration to, a particular patient of that authorised prescriber:

(b) sell or supply, or procure the sale or supply of, any medicine to any such patient or to a person who has the care of the patient:

(c) administer, or procure the administration of, any medicine to any such patient:

(d) at the request of another authorised prescriber, pack, and label a medicine that is specially prepared for, or intended for administration to, a particular patient of that other authorised prescriber:

(e) at the request of another authorised prescriber, sell or supply a medicine to that other authorised prescriber, or to a person who has the care of the patient:

(f) at the request of another authorised prescriber, administer a medicine to a particular patient of that other authorised prescriber.

(2) Despite subsection (1), in relation to any new medicine the distribution of which is prohibited under section 20,—

(a) paragraphs (a) and (d) of subsection (1) do not apply:

(b) paragraphs (b), (c), (e), and (f) of that subsection apply only for the purpose of enabling the medicine to be administered to a particular patient who is known and identifiable at the time when the medicine is sold or supplied to the authorised prescriber.

(3) Subsection (1) applies despite sections 17 to 24, but is subject to the other provisions of this Act and any regulations made under this Act.

(4) *[Repealed]*

Section 25: substituted, on 15 October 1999, by section 6 of the Medicines Amendment Act 1999 (1999 No 117).

Section 25(4): repealed, on 18 September 2004, by section 8 of the Medicines Amendment Act 2003 (2003 No 50).

26 Exemptions for pharmacists

(1) Notwithstanding section 17, but subject to subsections (2) and (3) and to the other provisions of this Act and to any regulations made under this Act, a pharmacist may manufacture, pack, label, sell, and supply any medicine.

(2) The authority conferred by subsection (1) shall extend only to the manufacture, packing, labelling, selling, or supplying of medicines,—

(a) in the case of a pharmacist employed in a hospital, in the course of that pharmacist's employment as a pharmacist in that hospital:

(b) in any other case, by a pharmacist in a pharmacy.

(3) Subsection (1) shall not authorise—

(a) the sale or supply of any medicine, except—

(i) pursuant to an order given or a request made by the person to whom the medicine is sold or supplied; or

(ii) in the ordinary course of business with reference to the needs expressed by that person; or

(b) the sale or supply of a prescription medicine otherwise than pursuant to a prescription.

(4) Subject to subsection (2), nothing in section 20 or section 24 shall apply in respect of the sale or supply by a pharmacist of a medicine compounded by that pharmacist to suit the needs of a particular person.

Compare: 1960 No 97 ss 11(1), (2)(c), 13(1)(a), (2), 14(1)(a)

27 Exemptions for veterinarians and certain registered health practitioners

Notwithstanding anything in section 17 or section 18, but subject to the other provisions of this Act and to any regulations made under this Act,—

(a) any veterinarian may manufacture, sell, supply, or administer a medicine for the treatment of an animal under the care of that veterinarian or

under the care of another veterinarian, and may pack or label the medicine for the purposes of any such sale or supply:

(b) *[Repealed]*

(c) any person may sell or supply—

(i) to a veterinarian, or, if so required by that veterinarian, to any other person, any medicine for administration to an animal under the care of that veterinarian.

(ii) *[Repealed]*

Compare: 1969 No 7 s 18(3)(g)(i), (ii)

Section 27 heading: amended, on 18 September 2004, by section 9(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 27 heading: amended, on 15 October 1999, by section 7 of the Medicines Amendment Act 1999 (1999 No 117).

Section 27(a): amended, on 15 October 1999, by section 7 of the Medicines Amendment Act 1999 (1999 No 117).

Section 27(b): repealed, on 1 July 2014, by section 16(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 27(c)(i): amended, on 15 October 1999, by section 7 of the Medicines Amendment Act 1999 (1999 No 117).

Section 27(c)(ii): repealed, on 1 July 2014, by section 16(2) of the Medicines Amendment Act 2013 (2013 No 141).

28 Exemptions in respect of herbal remedies

(1) Notwithstanding section 17, but subject to the other provisions of this Act and to any regulations made under this Act, any person may, in the course of a business carried on by that person, manufacture, pack, and label, or sell or supply, any herbal remedy for administration to a particular person after being requested by or on behalf of that person to use his own judgment as to the treatment required.

(2) Notwithstanding anything in sections 17 and 20 to 24, but subject to the other provisions of this Act and to any regulations made under this Act, any person may manufacture, pack, and label any herbal remedy, and sell or supply any herbal remedy, if the remedy is or is to be sold or supplied—

(a) under a designation that specifies only the plant from which it is made and the process to which the plant has been subjected during the production of the remedy, and does not apply any other name to the remedy; and

(b) without any written recommendation (whether by means of a labelled container or package or a leaflet or in any other way) as to the use of the remedy.

Compare: Medicines Act 1968 ss 12, 56 (UK)

29 Exemption for medicine required by medical practitioner

(1) Neither section 20 nor section 24 shall prevent—

(a) the supply by any person to any medical practitioner, on the medical practitioner's request, of any medicine required by that medical practitioner for the treatment of a particular patient currently under that medical practitioner's care; or

(b) the administration by any medical practitioner of any such medicine to any such patient.

(2) Every person who, for the purposes of subsection (1), sells or supplies to any practitioner any medicine that is a new medicine by virtue of paragraph (a) of the definition of the term new medicine in section 3(3) before the consent of the Minister to the distribution of that medicine has been published under the Legislation Act 2019 shall, as soon as practicable after the end of every month in which he has so sold or supplied any such medicine, report that sale or supply to the Director-General in writing, naming the practitioner and patient, describing the medicine, and identifying the occasion when and the place where the medicine was so sold or supplied.

(3) Without limiting section 48, if any person fails to comply with subsection (2), the Minister may, in the manner prescribed in that section but without complying with subsection (2) of that section, prohibit that person from selling and supplying any new medicine to which subsection (2) applies before the consent of the Minister to the distribution of that medicine has been published under the Legislation Act 2019.

Compare: 1969 No 7 s 16

Section 29(2): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 29(3): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

30 Exemption for clinical trial

(1) Notwithstanding section 20 or section 24, but subject to the succeeding provisions of this section, the importer or manufacturer in New Zealand of any medicine may distribute it for the sole purpose of obtaining clinical and scientific information with respect to its safety and efficacy, if the clinical trial, and the persons (in this section called the **investigators**) who will conduct the trial, have been approved by the Director-General on the recommendation of the Health Research Council of New Zealand.

(2) An application for the approval of the Director-General in respect of this section shall be made by the importer, manufacturer, or packer, or the intending manufacturer, packer, seller, or supplier, in New Zealand of the medicine, and shall—

(a) be made in the prescribed manner (if any); and

(b) be addressed to the Director-General; and

(c) set out the true name of the applicant; and

(ca) be accompanied by the prescribed fee; and

(d) state, or be accompanied by a statement of, the particulars set out in subsection (3).

(3) The particulars required by subsection (2)(d) are the following:

(a) the nature of the medicine, its identifying name or mark, and its chemical formula:

(b) the purpose of the trial:

(c) the names and qualifications of the investigators who will conduct the trial, and their curricula vitae:

(d) a written consent to nomination from each of the investigators:

(e) a copy of the information supplied to the investigators, particularly in relation to the safe use of the medicine:

(f) a protocol of the trial, setting out—

(i) the number of patients to be involved; and

(ii) the form that the trial is to take, and the nature of the records to be kept; and

(iii) the persons or classes of persons (if any) who are to be specially excluded from the trial; and

(iv) any special measures proposed to be taken to ensure the safety of the patients:

(g) the names and addresses of the institutions or laboratories where the medicines will be used by approved persons, and a description of the facilities that will be available to those persons.

(4) The Director-General shall determine every application for his approval under this section within 45 days after the receipt of the application, and shall notify the applicant of his decision and (where he declines the application) the reasons for his decision.

(5) At any time after a clinical trial has been approved by the Director-General, the applicant may apply to the Director-General for the approval of an investigator, notwithstanding that the name of that person did not appear in the application for approval of the clinical trial; and paragraphs (a) to (c) of subsection (2), and paragraphs (c), (d), and (g) of subsection (3), shall apply in respect of every such application.

(6) The Director-General may at any time, by notice in writing given to an applicant, require the applicant to supply such further information and particulars as he thinks fit relating to a clinical trial or to the identity and qualifications of an investigator.

(7) The distribution of any medicine under this section shall be subject to the following conditions:

(a) the Director-General shall be informed, before the medicine is so distributed, of the identifying name or mark by which it may be recognised:

(b) every label on every package or container of the medicine shall bear the words "To be used by qualified investigators only":

(c) the importer or manufacturer shall, before so distributing the medicine, take all reasonable steps to ensure that every person to whom it is supplied is approved under this section as a person qualified to carry out, and has available the necessary facilities for, the trial to be conducted by him, and the medicine shall be used solely by that person or under his direction for the purposes of the trial:

(d) the importer or manufacturer shall—

(i) keep complete and accurate records of all quantities of the medicine supplied under this section:

(ii) keep the Director-General informed of the progress of the trial by 6-monthly reports:

(iii) supply to the Director-General a copy of the results of the trial on its completion.

(8) The Director-General may at any time, by notice in writing to the applicant, revoke or suspend his approval of a clinical trial.

Compare: 1969 No 7 s 15

Section 30(1): amended, on 1 October 1990, by section 57 of the Health Research Council Act 1990 (1990 No 68).

Section 30(2)(ca): inserted, on 8 August 1990, by section 5 of the Medicines Amendment Act (No 2) 1990 (1990 No 97).

31 Exemptions for agents and employees

(1) Notwithstanding sections 17 to 24, but subject to subsections (2) and (3) and to the other provisions of this Act and to any regulations made under this Act,—

(a) any authority conferred by a licence to manufacture, sell, supply, pack, or label any medicine other than a restricted medicine; and

(b) any authority conferred by section 26 or section 27 to sell, supply, pack, or label any medicine other than a restricted medicine; and

(c) any authority conferred by section 28(2) to sell or supply a herbal remedy; and

(d) any authority conferred by section 30 to manufacture, sell, supply, pack, or label a medicine—

shall extend and apply to any agent or employee of a person so authorised acting in the course of that person's agency or employment.

(2) Except as provided in regulations made under this Act, any authority conferred by subsection (1) to sell, supply, pack, or label a medicine shall,—

(a) in the case of a sale by retail, or supply in circumstances corresponding to retail sale, of prescription medicines, extend and apply only to the sale and supply of those medicines by, or under the supervision of, a pharmacist, responsible person, or other person licensed to sell those medicines:

(b) in the case of the packing or labelling of medicines, extend and apply only to the packing and labelling of the medicines by, or under the supervision of, a pharmacist, responsible person, or other person licensed to sell medicines.

(3) Subsection (1) shall not authorise a person to manufacture, sell, supply, pack, or label a medicine—

(a) at any place, if that person's principal or employer is not authorised by or under this Act to manufacture, sell, supply, pack, or label (as the case may require) medicines at that place; or

(b) otherwise than in accordance with any conditions, imposed by or under this Act, to which that person's principal or employer is subject.

(4) Subsection (3)(a) does not apply in respect of any authority conferred by section 26 on a pharmacist or on a pharmacist employed or engaged by a person who is not a pharmacist but who holds a licence to operate a pharmacy.

Compare: 1960 No 97 ss 13(1)(a), (f), (6), 14(1)

Section 31(4): added, on 18 September 2004, by section 10 of the Medicines Amendment Act 2003 (2003 No 50).

32 Exemptions for natural therapists and others

Notwithstanding sections 17 and 20 to 24 or anything in any licence, but subject to the other provisions of this Act and to any regulations made under this Act, any natural therapist or other person may manufacture, pack, label, sell by retail, or supply in circumstances corresponding to retail sale, any medicine that neither is nor contains—

(a) a prescription medicine; or

(b) a restricted medicine; or

(c) a pharmacy-only medicine,—

for administration to a particular person after being requested by or on behalf of that person to use his own judgment as to the treatment required.

32A Exemptions in respect of importation by the Crown

(1) Notwithstanding anything in this Act, but subject to subsection (2), the Crown may, in respect of any medicine approved by the Director-General for the purposes of this section,—

(a) import the medicine into New Zealand; and

(b) sell the medicine, or distribute it by way of gift or loan or sample or in any other way, or advertise it for sale, or advertise the availability of it—

and, subject to subsection (2), in doing any of those things, it shall not be necessary for the Crown to comply with any of the provisions of this Act.

(2) Nothing in subsection (1) limits or affects the application to the Crown of sections 20, 44, and 45.

(3) Section 50(2), to the extent that it relates to the payment of a fee on the application for a licence to sell a medicine by wholesale, applies to the Crown in the same way as it applies to other persons in any case where the Crown would, but for subsection (1), be required to obtain a licence to sell a medicine imported by the Crown under subsection (1) by wholesale.

(4) Nothing in section 24 prevents a person who holds a licence to sell a medicine imported by the Crown under subsection (1) by wholesale from selling the medicine, or supplying it by way of gift or loan or sample or in any other way.

(5) Nothing in section 24 prevents—

(a) a pharmacist employed in a hospital in the course of that pharmacist's employment as a pharmacist in that hospital, selling a medicine imported by the Crown under subsection (1) or supplying it by way of gift or loan or sample or in any other way:

(b) any other pharmacist, in any pharmacy, selling a medicine imported by the Crown under subsection (1), or supplying it by way of gift or loan or sample or in any other way.

(6) *[Repealed]*

(7) The powers conferred by this section to do anything in respect of a medicine include the power to do likewise in respect of any advertising material, container, label, labelling material, or package (as those terms are defined in section 2), or a data sheet or other written or printed material, relating to that medicine.

(8) In this section the term **sell** includes the matters specified in paragraphs (a) to (c) of the definition of that term in section 2.

Section 32A: substituted, on 1 August 1990, by section 2(1) of the Medicines Amendment Act 1990 (1990 No 69).

Section 32A(6): repealed, on 26 November 2018, by section 459 of the Social Security Act 2018 (2018 No 32).

33 Exemptions in respect of procuring and exporting medicines

Notwithstanding sections 17 to 24 or anything in any licence, but subject to the other provisions of this Act and to any regulations made under this Act,—

(a) any person may procure a medicine if the person from whom he procures that medicine is authorised by or under this Act to sell or supply the medicine to him:

(b) any person may export, in the course or for the purpose of sale, any medicine that, at the time when it is exported, might lawfully be sold by a pharmacist to a person in New Zealand, whether pursuant to a prescription or otherwise.

34 Exemption for sale by wholesale of medicines that are not prescription, restricted, or pharmacy-only medicines

Section 17 does not apply in respect of the sale by wholesale of a medicine that is not a prescription medicine or a restricted medicine or a pharmacy-only medicine.

Section 34: substituted, on 23 February 1987, by section 3 of the Medicines Amendment Act 1987 (1987 No 9).

COVID-19 vaccines

Heading: inserted, on 23 June 2022, by section 4 of the Medicines Amendment Act 2022 (2022 No 31).

34A Director-General may authorise off-label administration of COVID-19 vaccines

(1) This section applies if—

(a) the Minister has given consent or provisional consent to a COVID-19 vaccine; and

(b) a data sheet is approved for the vaccine under the regulations.

Notice

(2) The Director-General may, by notice, authorise the administration of the vaccine other than in accordance with the data sheet.

(3) The notice may specify any 1 or more of the following matters in relation to the administration of the vaccine:

(a) who it may be administered to:

(b) the recommended number and frequency of doses:

(c) the recommended manner of administration:

(d) any circumstances in which it may be administered.

(4) Before issuing a notice under this section, the Director-General must—

(a) have regard to the likely therapeutic value of the proposed administration of the vaccine and the risk (if any) that the proposed administration of the vaccine may injuriously affect the health of any person; and

(b) be satisfied that the proposed administration of the vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

Effect of notice

(5) A COVID-19 vaccine is not a new medicine for the purpose of section 20 by reason only of—

(a) a notice made under this section in relation to the vaccine; or

(b) administration of the vaccine in accordance with the notice.

(6) Any person or class of persons permitted by the Act or by regulations to administer the vaccine may administer the vaccine in accordance with the notice.

(7) Nothing in this section limits section 24.

Status of notice

(8) A notice made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	The maker must publish it in accordance with the Legislation (Publication) Regulations 2021	LA19 s 74(1)(aa)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 34A: inserted, on 23 June 2022, by section 4 of the Medicines Amendment Act 2022 (2022 No 31).

Quality and standards

35 Revocation and suspension of consents

(1) The Minister may at any time, by notice, revoke, or suspend for such period as he may determine, any consent given under section 20 or section 23, if he is of the opinion that—

(a) the medicine can no longer be regarded as a medicine that can be administered or used safely for the purposes indicated in the application for consent, or in a notice deposited under section 24; or

(b) the specifications and standards with respect to the manufacture of the medicine that were included in the terms of a consent can no longer be regarded as satisfactory; or

(c) the efficacy of the medicine can no longer be regarded as satisfactory.

(2) Where a consent is suspended under this section, it shall be deemed for the purposes of subsections (2) and (4) of section 20 not to have been granted.

(3) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: Medicines Act 1968 s 28, Schedule 2 (UK)

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14
	The Ministry of Foreign Affairs and Trade considers that the secondary legislation may have international transparency obligations under the CPTPP. As a result the maker may also have to comply with s 75 of the Legislation Act 2019	LA19 ss 74(2), 75
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 35(1): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 35(3): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

36 Control of established medicines

(1) Without limiting subsection (5) of section 24, if the Director-General has reason to believe that any medicine, not being a new medicine, may be unsafe or ineffective for the therapeutic purpose for which it is sold, he may, by notice in writing to an importer or manufacturer in New Zealand, state the reasons for his belief and require the importer or manufacturer to satisfy him of the safety or efficacy of that medicine.

(2) If the Director-General is not satisfied, by evidence supplied to him pursuant to a notice under subsection (1) or otherwise, of the safety and efficacy of a medicine to which that notice relates, he may at any time after the expiration of 60 days from the date of that notice refer a description of the medicine to the appropriate committee, and shall forthwith by notice in writing inform the importer or manufacturer that he has done so.

(3) In any case to which this section applies, the Minister may, by notice in writing to the importer or manufacturer,—

(a) prohibit the importer or manufacturer, either indefinitely or for such period as may be specified in the notice, from selling or supplying the medicine; or

(b) impose such conditions as may be specified in the notice on the sale or supply of the medicine by the importer or manufacturer.

(4) The Minister may at any time, by a like notice, revoke any notice given under subsection (3), or vary, revoke, or add to any conditions imposed in any such notice.

(5) Every person commits an offence and is liable on conviction to imprisonment for a term not exceeding 6 months or a fine not exceeding $5,000 who sells or supplies any medicine in contravention of a notice given under subsection (3),

or of a condition imposed in any such notice or in a notice given under subsection (4).

Section 36(5): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

37 Powers of Minister to prohibit import, etc, of medicines

(1) The Minister may from time to time, by notice, prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines of any specified description or medical devices of any specified kind, either absolutely or subject to such conditions as he thinks fit, for any specified period not exceeding 1 year; but he shall not exercise this power more than once in respect of medicines or medical devices so specified.

(2) Where the Minister gives a notice under subsection (1), he shall, on the written request of any person, state his reasons for doing so.

(3) Every person commits an offence against this Act who contravenes any notice given under subsection (1).

(4) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1960 No 97 s 28; 1967 No 108 s 3

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14
	The Ministry of Foreign Affairs and Trade considers that the secondary legislation may have international transparency obligations under the CPTPP. As a result the maker may also have to comply with s 75 of the Legislation Act 2019	LA19 ss 74(2), 75
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 37(1): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 37(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

38 Restrictions on sale of medical devices

(1) For the purposes of this section,—

(a) the term **medical device** includes an irradiating apparatus within the meaning of section 5(1) of the Radiation Safety Act 2016:

(b) a medical device is unsafe if the use of that device may be injurious to the health of the person using it or the person in respect of whom it is used:

(c) 2 or more medical devices shall be deemed to be of the same kind, notwithstanding any minor differences or any difference in any name, if they are—

(i) substantially similar to one another; and

(ii) designed to be used in the same way; and

(iii) sold for the same therapeutic purpose.

(2) If the Director-General has reason to believe that any medical device may be unsafe, he may, by notice in writing to the importer or manufacturer in New Zealand, state the reasons for his belief, and require the importer or manufacturer to satisfy him of the safety of that medical device.

(3) The importer or manufacturer shall supply to the Director-General, within 45 days after receiving the notice under subsection (2), or such further time as the Director-General may allow, evidence of the safety of the medical device.

(4) If the Director-General is not satisfied, by evidence supplied to him pursuant to a notice under subsection (3) or otherwise of the safety of the medical device, he may at any time, within the period of 45 days following the receipt of that evidence, by a further notice under subsection (2) require the manufacturer or importer to supply him with further evidence of the safety of the medical device.

(5) The fact that the Director-General does not exercise the powers conferred on him by this section in respect of a medical device shall not be deemed to warrant the safety of the medical device.

(6) The Director-General may exercise the powers conferred on him by this section from time to time with respect to different importers or manufacturers of the same kind of medical devices, and the fact that he has not exercised any of those powers in respect of a particular kind of medical device, or that he has informed any person that he is satisfied of the safety of a particular kind of medical device, shall not prevent him from exercising any such power in respect of that kind of medical device where new information comes to his attention.

(7) In any proceedings for an offence against this section in which it is alleged that 2 or more medical devices are of the same kind, it shall be presumed that those medical devices are of the same kind until the contrary is proved.

(8) Every person commits an offence and is liable on conviction to imprisonment for a term not exceeding 6 months or a fine not exceeding $5,000 who,—

(a) having received a notice under subsection (2) and failed to comply with subsection (3), sells the medical device; or

(b) having received a notice under subsection (4), sells the medical device before he has been notified by the Director-General that he is satisfied of the safety of the medical device.

Section 38(1)(a): amended, on 7 March 2017, by section 99 of the Radiation Safety Act 2016 (2016 No 6).

Section 38(8): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

39 Adulteration of medicines

(1) No person shall—

(a) add any substance to, or abstract any substance from, a medicine so as to affect injuriously the composition of the medicine, with intent that the medicine shall be sold or supplied in that state:

(b) sell or supply any medicine the composition of which has been injuriously affected by the addition or abstraction of any substance.

(2) Every person commits an offence against this Act who contravenes subsection (1).

Compare: Medicines Act 1968 s 63 (UK)

40 Compliance with standards

(1) If a standard is prescribed in respect of a medicine, or a medical device, or the ingredient of a medicine, no person shall, in the course of any business, sell or supply any substance or article under a name that is likely to cause the person to whom the substance or article is sold or supplied to believe that that person is purchasing or otherwise acquiring that medicine, or that medical device, or a substance containing that ingredient, unless the substance or article, or the ingredient of the substance or article, complies with the standard.

(2) If a person sells an article to a purchaser in response to a request for a medicine or a medical device of a kind for which a standard is prescribed, he shall be deemed to sell a medicine or medical device of that kind and under such a description as is specified in subsection (1) unless he clearly notifies the purchaser at the time of sale that the article is not of that kind.

(3) Notwithstanding that a medicine, or a medical device, or an ingredient of a medicine, otherwise conforms with the standard prescribed for that medicine, medical device, or ingredient, it shall be deemed not to conform with that standard if anything has been added to it—

(a) the addition of which is not expressly required or permitted by regulations made under this Act; or

(b) in a quantity or proportion greater or lesser than that so required or permitted; or

(c) that does not comply with the standard (if any) prescribed for that kind of thing.

(4) Every person commits an offence against this Act who contravenes subsection (1).

Compare: 1969 No 7 ss 6, 39(1); Medicines Act 1968 s 65 (UK)

41 Duty of importer or manufacturer to report untoward effects of medicines

(1) If at any time the importer or manufacturer in New Zealand of any medicine has reason to believe that any substantial untoward effects have arisen from the use of the medicine whether in New Zealand or elsewhere, the importer or manufacturer shall forthwith notify the Director-General of the nature of those effects and the circumstances in which they have arisen, so far as they are known to him.

(2) Every person commits an offence against this Act and is liable on conviction to a fine not exceeding $1,000 who fails to comply with subsection (1).

Compare: 1969 No 7 ss 17, 39(5)

Section 41(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

42 Duty of importer and manufacturer to have and produce specifications of medicines

(1) No importer or manufacturer shall sell, or distribute by way of gift or loan or sample or in any other way, or advertise for sale, or advertise the availability of, any medicine other than a herbal remedy unless he is in possession of—

(a) details of the specifications for testing the quality of that medicine; and

(b) a certificate of the results of testing in respect of every batch of that medicine distributed or to be distributed in New Zealand.

(2) Every importer or manufacturer in New Zealand shall, on demand, supply to an officer the details and certificates referred to in subsection (1).

(3) A person who contravenes this section commits an offence, and is liable on conviction—

(a) in the case of an individual, to imprisonment for a term not exceeding 3 months or a fine not exceeding $10,000:

(b) in the case of a body corporate, to a fine not exceeding $100,000.

Section 42(3): substituted, on 19 May 1998, by section 13 of the Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 (1998 No 20).

Restrictions on operation of pharmacies

Heading: inserted, on 18 September 2004, by section 11 of the Medicines Amendment Act 2003 (2003 No 50).

42A Every pharmacy must be under supervision of pharmacist

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

Compare: 1970 No 143 s 41

Section 42A: inserted, on 18 September 2004, by section 11 of the Medicines Amendment Act 2003 (2003 No 50).

42B Security of pharmacies

(1) Every person who operates a pharmacy must ensure that every prescription medicine or restricted medicine in the pharmacy is at all times secured in a way that prevents the public gaining ready access to the medicine.

(2) Every person who operates a pharmacy must ensure that all medicines held in storage for the purposes of the pharmacy are secured in a way that prevents the public gaining access to the medicines.

(3) Subsections (1) and (2) do not prevent a pharmacist engaged at the pharmacy or another person authorised by a pharmacist engaged at the pharmacy, from supplying any medicine to a member of the public.

(4) The requirements imposed by subsections (1) and (2) are in addition to the requirements imposed by section 47 or any regulations made under this Act.

Section 42B: inserted, on 18 September 2004, by section 11 of the Medicines Amendment Act 2003 (2003 No 50).

42C Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies

(1) No authorised prescriber or delegated prescriber may hold an interest in a pharmacy other than a pharmacy for which the person holds a licence to operate, except with the consent of the licensing authority and in accordance with any conditions or restrictions imposed by that authority.

(2) No person who has an interest in a pharmacy may permit or enable any authorised prescriber or delegated prescriber to hold or acquire that or any other interest in the pharmacy contrary to subsection (1).

(3) The licensing authority may not give its consent under subsection (1) unless it is satisfied that there are sufficient safeguards to prevent the issue of prescriptions, the manner in which prescriptions are issued, or the other provision of health care by the authorised prescriber or delegated prescriber from being influenced by the commercial or financial interests of the authorised prescriber, or delegated prescriber, or any other person holding an interest in the pharmacy.

Section 42C: inserted, on 18 September 2004, by section 11 of the Medicines Amendment Act 2003 (2003 No 50).

Section 42C heading: amended, on 1 July 2014, by section 22(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 42C(1): amended, on 1 July 2014, by section 22(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 42C(2): amended, on 1 July 2014, by section 22(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 42C(3): amended, on 1 July 2014, by section 22(4)(a) of the Medicines Amendment Act 2013 (2013 No 141).

Section 42C(3): amended, on 1 July 2014, by section 22(4)(b) of the Medicines Amendment Act 2013 (2013 No 141).

Miscellaneous provisions

43 Restrictions on possession of prescription medicines

(1) No person shall, without reasonable excuse, import, procure, receive, store, use, or otherwise have in his possession, any prescription medicine.

(2) Without limiting the meaning of the expression reasonable excuse in subsection (1), a person has a **reasonable excuse** for the purpose of that subsection if—

(a) the possession or act that might otherwise be a contravention of that subsection—

(i) is that of a person, licensed or otherwise authorised under this Act or any regulations made under this Act, to manufacture, sell, supply, pack, or administer the medicine or to be in possession of it; and

(ii) is necessary as incidental to the business, calling, or purpose for which the person is so licensed or otherwise authorised; or

(b) the possession or act that might otherwise be a contravention of that subsection—

(i) is that of a carrier, or an employee of a carrier; and

(ii) is necessary or incidental to the business of that carrier; or

(c) the possession or act that might otherwise be a contravention of that subsection—

(i) is that of a person to whom the medicine has been lawfully supplied for his or her use, or for use by any other person, as a patient under the care of an authorised prescriber or a delegated prescriber or in accordance with a standing order, and who does not have in his or her possession any other supplies of a prescription medicine prescribed or supplied for the same purpose by another authorised prescriber or delegated prescriber or in accordance with a standing order; and

(ii) is necessary or incidental to such use; or

(d) the possession or act that might otherwise be a contravention of that subsection—

(i) is that of a person who has possession of the medicine only for the purpose of administering it to the person for whom it has been prescribed; and

(ii) is necessary or incidental to that purpose; or

(e) the possession or act that might otherwise be a contravention of that subsection—

(i) is that of a person in the service of the Crown; and

(ii) is necessary or incidental to the performance of that person's duties.

(3) In any proceedings under this section against any person in which it is proved that that person procured, received, stored, used, or otherwise had in his possession any prescription medicine, the onus of proving that he had a reasonable excuse (whether by reason of the fact that 1 or more of the provisions of paragraphs (a) to (e) of subsection (2) apply to his case or otherwise) shall lie on the defendant.

(4) In any proceedings under this section, the fact that the defendant did not know that the medicine that is the subject of the prosecution was a prescription medicine is not by itself a reasonable excuse.

(5) Every person commits an offence against this Act who contravenes subsection (1).

(6) *[Repealed]*

Compare: 1960 No 97 s 26; 1969 No 44 s 7

Section 43(2): substituted, on 15 October 1999, by section 8(1) of the Medicines Amendment Act 1999 (1999 No 117).

Section 43(2)(c)(i): amended, on 1 July 2014, by section 23(1)(a) of the Medicines Amendment Act 2013 (2013 No 141).

Section 43(2)(c)(i): amended, on 1 July 2014, by section 23(1)(b) of the Medicines Amendment Act 2013 (2013 No 141).

Section 43(6): repealed, on 1 July 2014, by section 23(2) of the Medicines Amendment Act 2013 (2013 No 141).

44 Containers and packages of medicines

(1) Except as may be permitted by regulations made under this Act, no person shall, in the course of any business, pack, store, sell, supply, or cause to be transported any medicine, unless—

(a) the medicine is in a container that—

(i) is impervious to the medicine; and

(ii) is so constructed that it can be readily and effectively resealed after any portion of the contents has been used; and

(iii) is of the prescribed character or type; and

(iv) is labelled in the prescribed manner; and

(b) if the container is enclosed in a package that is required to be of a prescribed character or type, or to be labelled in a prescribed manner, the package is of that character or type, or is labelled in that manner.

(2) Notwithstanding subsection (1)(a)(ii), where—

(a) the container bears a label with directions to the effect that the whole of the contents must be used immediately on opening; and

(b) the quantity and nature of the contents are such that it is unlikely that less than the whole of the contents will be used on any one occasion—

the container need not be of a type that can be readily and effectively resealed.

(3) Every person commits an offence against this Act who contravenes subsection (1).

Compare: 1960 No 97 s 22

45 Records

(1) Every person who, in the course of any business, manufactures, packs, or sells, or supplies in circumstances corresponding to retail sale, any medicine shall keep, in some place of security at his place of business, such records as may be prescribed and shall retain them for such period as may be prescribed.

(2) Every person who, in the course of any business, manufactures, packs, or sells, or supplies in circumstances corresponding to retail sale, any medicine shall at all times permit any officer, or any constable, to inspect and make copies of any such record, and shall at all times on demand afford to any officer or to any constable all further information in his possession with respect to any dealings by that person relating to medicines.

(3) Every person commits an offence against this Act who—

(a) contravenes or fails to comply in any respect with any of the provisions of this section; or

(b) obstructs or hinders any inspection under subsection (2).

Compare: 1960 No 97 s 23

Section 45(2): amended, on 1 October 2008, pursuant to section 116(a)(ii) of the Policing Act 2008 (2008 No 72).

46 Custody of medicines

(1) Every person commits an offence against this Act who has any medicine in his charge or possession (whether for the purposes of sale or for any other purpose) otherwise than in a container conforming to the relevant requirements (if any) of this Act and of any regulations made under this Act, except in the course of manufacturing or packing that medicine.

(2) It is a defence to a charge brought under subsection (1) if the defendant proves that, at the material time,—

(a) the medicine was in the container in which he acquired it, and the container bore the label that it bore when he acquired the container:

(b) the medicine had been necessarily removed from its container for the effective and lawful use of that medicine.

Compare: 1960 No 97 s 24

47 Storage and delivery of medicines

(1) No person who is in possession or charge of any prescription medicine or restricted medicine shall put it—

(a) in any cupboard, box, shelf, or other place of storage in which articles of food or drink are stored or kept for ready use; or

(b) in any place to which young children or unauthorised persons have ready access.

(2) No person shall pack any medicine, or prepare it for use, in any room, or on any table or bench, that is used for the purpose of packing, preparing, or consuming any food or drink.

(3) Except as otherwise provided in any regulations made under this Act, no person who is in possession, for the purposes of any business, of a prescription medicine or a restricted medicine that is kept for the time being within any building or vehicle shall leave that building or vehicle unattended, unless he has taken all reasonable steps to secure that building or vehicle, or the part of it in which the medicine is kept, against unlawful entry.

(4) No person shall deliver on retail sale, or in circumstances corresponding to retail sale, any medicine otherwise than through the post or by handing it or causing it to be handed to the person, or another person reasonably believed to be acting on that person's behalf, to whom it is addressed or for whose use it is intended.

(5) Every person commits an offence against this Act who, without reasonable excuse, contravenes any of the provisions of this section.

Compare: 1960 No 97 s 25; 1969 No 44 s 6

47A Effect of grant of delegated prescribing rights

If regulations made under sections 105(1)(qaa) and 105D grant delegated prescribing rights to a class of registered health professional,—

(a) an authorised prescriber who is not a designated prescriber may, in accordance with the regulations, issue a delegated prescribing order to a specified person belonging to that class of registered health professional; and

(b) the person to whom the delegated prescribing order is issued (the delegated prescriber) may prescribe specified prescription medicines, or a specified class or description of prescription medicines, in accordance with the terms of his or her delegated prescribing order.

Section 47A: inserted, on 1 July 2014, by section 24 of the Medicines Amendment Act 2013 (2013 No 141).

48 Powers of Minister to prohibit prescribing, etc

(1) The Minister may at any time, by notice in the *Gazette*,—

(a) prohibit any specified authorised prescriber, veterinarian, or delegated prescriber from prescribing prescription medicines or any particular class or description of prescription medicines:

(b) prohibit, either generally or in relation to any particular class or description of medicines, any specified person from exercising all or any of the rights conferred by this Act, whether those rights are so conferred on persons generally or on a particular class to which that person belongs.

(2) The Minister may not exercise any power conferred on him or her by subsection (1),—

(a) in the case of a medical practitioner, except on the recommendation of the Medical Council of New Zealand; or

(b) in the case of a dentist, except on the recommendation of the Dental Council of New Zealand; or

(c) in the case of a pharmacist, except on the recommendation of the Pharmacy Council; or

(d) in the case of a registered midwife or a nurse, except on the recommendation of the Midwifery Council or the Nursing Council of New Zealand; or

(e) in the case of a veterinarian, except on the recommendation of the Veterinary Council of New Zealand; or

(ea) in the case of an optometrist, except on the recommendation of the Optometrists and Dispensing Opticians Board; or

(f) in the case of any other designated prescriber or delegated prescriber, except on the recommendation of the responsible authority for the health profession to which the designated prescriber or delegated prescriber belongs.

(3) The Minister may at any time, by notice in the *Gazette*, revoke any notice given under subsection (1).

Section 48: substituted, on 15 October 1999, by section 9 of the Medicines Amendment Act 1999 (1999 No 117).

Section 48(1)(a): amended, on 1 July 2014, by section 25(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 48(2)(c): amended, on 18 September 2004, by section 12(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 48(2)(d): amended, on 18 September 2004, by section 12(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 48(2)(ea): inserted, on 1 July 2014, by section 25(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 48(2)(f): replaced, on 1 July 2014, by section 25(3) of the Medicines Amendment Act 2013 (2013 No 141).

48A Powers of councils and boards

(1) Despite anything in any other Act, each council or board referred to in section 48 has jurisdiction to inquire into any prescribing of or dealing in medicines by a member of the profession with which it is concerned, and any other incidental matter, for the purpose of considering and determining whether or not to make a recommendation to the Minister under that section, when such prescribing or dealing has been brought or otherwise comes to its attention.

(2) For the purposes of subsection (1), each such council or board has and may exercise any powers with respect to summoning witnesses, administering oaths, hearing evidence and other matters of procedure, and with respect to the payment and receiving of costs and expenses, conferred on it or any disciplinary committee or disciplinary tribunal, in relation to disciplinary proceedings, by the enactment under which the council or board is constituted.

(3) Despite subsection (2), it is not necessary, unless the council or board so requires, for any other body to conduct an investigation or inquiry or to be represented at the inquiry conducted by the council or board.

(4) Without prejudice to the liability of any person under any other provision of this Act, a person who contravenes any notice given under section 48(1) commits an offence against this Act.

Section 48A: inserted, on 15 October 1999, by section 9 of the Medicines Amendment Act 1999 (1999 No 117).

49 Restrictions on supply to particular persons

(1) In this section the term **restricted person** means a person who is the subject of a notice given under subsection (2) and for the time being in force.

(2) Where a Medical Officer of Health is satisfied that any person—

(a) is addicted or habituated to the use of any prescription medicine or restricted medicine or has been obtaining any prescription medicine or restricted medicine from several different sources; and

(b) is likely to seek further supplies of that prescription medicine or restricted medicine, or prescriptions for the supply of that prescription medicine or restricted medicine,—

he may from time to time, by notice in such form as he thinks fit, prohibit, subject to such conditions and exceptions as he may prescribe in the notice, any authorised prescriber or delegated prescriber from issuing prescriptions for the supply of, and any person from supplying, that or any similar prescription medicine or that or any similar restricted medicine, to the restricted person.

(3) The Medical Officer of Health may at any time, by a like notice, revoke, or vary, or modify any prohibition, condition, or exception contained in a notice given by him under this section.

(4) The Medical Officer of Health shall cause a copy of every notice under subsection (2) or subsection (3) to be served on the restricted person, but a failure to comply with this requirement shall not invalidate the notice.

(5) Any person who is aggrieved by the issue of a notice under this section, or by the refusal of the Medical Officer of Health to revoke, vary, or modify any prohibition, condition, or exception contained in any such notice, may appeal in writing to the Minister whose decision shall be final.

(6) Every person commits an offence against this Act who—

(a) prescribes for or supplies to any person whom he knows to be a restricted person any prescription medicine or restricted medicine in contravention of a notice given under subsection (2) or subsection (3); or

(b) being a restricted person, procures or attempts to procure a prescription or a prescription medicine or a restricted medicine from any person whom he knows is prohibited by a notice under subsection (2) or subsection (3) from issuing the prescription or supplying the medicine to the restricted person.

Compare: SR 1964/64 r 20A; SR 1969/45 r 6

Section 49(2): amended, on 1 July 2014, by section 26 of the Medicines Amendment Act 2013 (2013 No 141).

49A Statements regarding persons dependent on prescription medicines or restricted medicines

(1) If a Medical Officer of Health has reason to believe that any person is or is likely to become dependent on any prescription medicine or restricted medicine, the Medical Officer of Health may, for the purpose of preventing or restricting the supply of prescription medicines or restricted medicines to that person, or of assisting in the cure or mitigation or avoidance of the dependence of that person, publish statements relating to that person to all or any of the members of all or any of the classes of persons set out in subsection (3).

(2) Every statement made under subsection (1) shall be privileged unless the publication is proved to be made with malice.

(3) The classes of persons referred to in subsection (1) are as follows:

(a) officers:

(b) officers and employees of Health New Zealand established by section 11 of the Pae Ora (Healthy Futures) Act 2022:

(c) people providing, or employed in providing, hospital care (within the meaning of the Health and Disability Services (Safety) Act 2001):

(d) managers of prisons within the meaning of the Corrections Act 2004:

(e) managers of treatment centres within the meaning of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017:

(f) authorised prescribers:

(g) delegated prescribers:

(ga) *[Repealed]*

(gb) *[Repealed]*

(h) Police employees:

(i) persons who deal in prescription medicines or restricted medicines in the course of business.

(4) Nothing in subsection (1) or subsection (2) shall limit or affect any right or duty that a Medical Officer of Health may otherwise possess to publish a statement to any person.

(5) Every person commits an offence against this Act who, except in the course of duty as a member of a class set out in subsection (3) or as an officer or servant of the Crown, publishes any information obtained, whether by that person or any other person, from a statement made pursuant to subsection (1), or any comment on any such statement.

Section 49A: inserted, on 23 February 1987, by section 4 of the Medicines Amendment Act 1987 (1987 No 9).

Section 49A(3)(a): substituted, on 1 July 1993, by section 32 of the Health Sector (Transfers) Act 1993 (1993 No 23).

Section 49A(3)(b): replaced, on 1 July 2022, by section 104 of the Pae Ora (Healthy Futures) Act 2022 (2022 No 30).

Section 49A(3)(c): substituted, on 1 October 2002, by section 58(1) of the Health and Disability Services (Safety) Act 2001 (2001 No 93).

Section 49A(3)(d): substituted, on 1 June 2005, by section 206 of the Corrections Act 2004 (2004 No 50).

Section 49A(3)(e): replaced, on 21 February 2018, by section 122(1) of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (2017 No 4).

Section 49A(3)(f): replaced, on 1 July 2014, by section 27 of the Medicines Amendment Act 2013 (2013 No 141).

Section 49A(3)(g): replaced, on 1 July 2014, by section 27 of the Medicines Amendment Act 2013 (2013 No 141).

Section 49A(3)(ga): repealed, on 1 July 2014, by section 27 of the Medicines Amendment Act 2013 (2013 No 141).

Section 49A(3)(gb): repealed, on 1 July 2014, by section 27 of the Medicines Amendment Act 2013 (2013 No 141).

Section 49A(3)(h): amended, on 1 October 2008, by section 130(1) of the Policing Act 2008 (2008 No 72).

Part 3
Provisions relating to licences

50 Applications for licences

(1) Every application for a licence must be made in the prescribed form to the Director-General or to any person designated for the purpose by the Director-General by notice in the *Gazette*.

(2) Every such application shall contain or be accompanied by such particulars, information, documents, samples, and other material as may be prescribed, and shall be accompanied by the prescribed fee.

(3) The application shall indicate the descriptions of the medicines in respect of which the licence is sought, either by specifying those descriptions, or by reference to an appropriate general classification.

(4) An application may be made either by an individual who is a New Zealand resident on the person's own behalf or by an appropriate officer of a body corporate that is incorporated in New Zealand on behalf of that body corporate.

(5) If a person authorised to receive an application under subsection (1) is satisfied that an application complies with the requirements of this section and of any regulations made under this Act that are applicable to the application, the person must refer the application to the licensing authority.

Compare: 1960 No 97 s 15; 1979 No 27 s 35; Medicines Act 1968 s 18 (UK)

Section 50(1): substituted, on 18 September 2004, by section 13(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 50(4): substituted, on 18 September 2004, by section 13(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 50(5): substituted, on 18 September 2004, by section 13(2) of the Medicines Amendment Act 2003 (2003 No 50).

51 Grant of licences

(1) Subject to subsection (2) and to sections 52, 55A, and 55B, on receiving an application, the licensing authority shall issue a licence, in accordance with regulations made under this Act, to the applicant if he is satisfied in respect of all the following matters:

(a) that the requirements of section 50 have been complied with:

(b) that, in the case of an application made by a natural person on his own behalf, the applicant is a fit and proper person to hold the licence applied for, or, in the case of an application made on behalf of a body corporate, the applicant (body corporate) is of good repute:

(c) that the applicant is not subject to any disqualification under section 83:

(d) that, in the case of an application made by a natural person on his own behalf, the applicant, or, in the case of an application made on behalf of a body corporate, every person proposed to be a responsible person for the purposes of the licence applied for, has a sufficient knowledge of the obligations of a licensee and of the hazards associated with the medicines in which it is proposed to deal:

(e) that the premises and equipment that the applicant proposes to use are suitable and adequate for the purposes for which the licence is sought:

(f) that adequate arrangements have been made or are to be made for the making, maintaining, and safekeeping of adequate records in respect of

medicines that are manufactured, stored, packed, labelled, or sold in pursuance of the licence or, in the case of an application for a licence to operate a pharmacy, in respect of medicines that are manufactured, stored, packed, labelled, or sold on the premises or in any other place for which the licence to operate is sought.

(1A) In determining, under subsection (1)(b), whether an applicant is a fit and proper person or of good repute (as the case requires), the licensing authority may take into account, among other things,—

(a) any conviction of the applicant for—

(i) an offence under this Act, or regulations made under it; or

(ii) an offence under the Misuse of Drugs Act 1975, or regulations made under it; or

(iii) a crime involving dishonesty (within the meaning of section 2(1) of the Crimes Act 1961); and

(b) any determination of a professional conduct committee.

(2) Except as may be permitted by regulations made under this Act, the licensing authority shall not issue a licence to sell medicines by retail in respect of any premises other than a shop that is open to the public and is situated at least 10 kilometres by the most practicable route from a pharmacy in respect of which a licence to operate has been, or is deemed to have been, issued.

(3) The licensing authority shall not decline an application for a licence under this section without first giving the applicant a reasonable opportunity to be heard.

(4) A licence—

(a) must be in the prescribed form; and

(b) is subject to—

(i) any conditions that the licensing authority thinks fit; and

(ii) any conditions specified in regulations.

(4A) The licensing authority may, by written notice to the holder of a licence, revoke or amend any condition imposed under subsection (4)(b)(i) or add any new condition.

(5) A licence to sell a medicine may be combined with a licence to pack that medicine.

(6) If in any case the licensing authority is satisfied that the holder of a licence has failed or is failing to comply with any conditions attached to the licence, the licensing authority may cancel the licence.

(6AA) The licensing authority may not cancel a licence under subsection (6) unless the holder has been given a reasonable opportunity to be heard, or to make written submissions, in relation to the matter.

(6AAB) The licensing authority may suspend a licence for a reasonable period to enable the licensing authority to consider whether to cancel the licence under subsection (6).

(6A) If the licensing authority is satisfied that the holder of a licence to operate a pharmacy has failed to comply with any conditions affecting the licence, the licensing authority may, instead of or as well as exercising the powers conferred by subsection (4A) or (6),—

(a) impose on the holder of the licence a penalty not exceeding $40,000:

(b) forbid the licence holder or any person with an interest in the pharmacy from holding any interest in or operating a pharmacy for a period, not exceeding 5 years, specified by the licensing authority.

(6B) A penalty imposed under subsection (6A) may be recovered in a court of competent jurisdiction as a debt due to the licensing authority.

(7) If the licensing authority refuses to issue a licence, or attaches conditions to a licence, or cancels a licence under this section or under section 55A, and the applicant for the licence or the licensee requests him to give his reasons for such refusal, or for the attachment of such conditions, or for the cancellation of the licence, the licensing authority shall state his reasons in writing to that person accordingly.

(8) In this section, **professional conduct committee** means a committee appointed under section 71 of the Health Practitioners Competence Assurance Act 2003.

Compare: 1960 No 97 s 16; 1979 No 27 s 36

Section 51(1): amended, on 18 September 2004, by section 14(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(1)(f): amended, on 18 September 2004, by section 14(2) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(1A): inserted, on 1 July 2014, by section 28(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(2): amended, on 18 September 2004, by section 14(3) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(4): replaced, on 1 July 2014, by section 28(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(4A): inserted, on 1 July 2014, by section 28(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(6): replaced, on 1 July 2014, by section 28(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(6AA): inserted, on 1 July 2014, by section 28(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(6AAB): inserted, on 1 July 2014, by section 28(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(6A): inserted, on 18 September 2004, by section 14(4) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(6A): amended, on 1 July 2014, by section 28(4) of the Medicines Amendment Act 2013 (2013 No 141).

Section 51(6B): inserted, on 18 September 2004, by section 14(4) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(7): amended, on 18 September 2004, by section 14(5) of the Medicines Amendment Act 2003 (2003 No 50).

Section 51(8): inserted, on 1 July 2014, by section 28(5) of the Medicines Amendment Act 2013 (2013 No 141).

52 Effect of licences

(1) Subject to sections 20, 24, and 25 to 34,—

(a) a licence to manufacture medicines shall authorise the manufacture, packing and labelling, and sale by wholesale, of the medicines described in the licence:

(b) a licence to pack medicines shall authorise the packing and labelling, and the sale by wholesale of the medicines described in the licence:

(c) a licence to sell medicines by wholesale shall authorise the sale by wholesale of the medicines described in the licence:

(d) a licence to sell medicines by retail shall authorise the sale by retail, and the supply in circumstances corresponding to retail sale, of the medicines described in the licence:

(e) a licence to operate a pharmacy authorises the establishment of the pharmacy and the carrying on of pharmacy practice in the pharmacy.

(2) A licence to sell medicines by retail shall not authorise the sale by retail, or the supply in circumstances corresponding to retail sale, of any prescription medicine or any restricted medicine.

(3) A licence is subject to—

(a) any conditions imposed by the licensing authority under section 51(4)(b)(i) or (4A); and

(b) any conditions specified in regulations.

(4) Except as may be permitted by the terms of the licence, or by any regulations made under this Act, a licence shall not authorise the manufacture, packing and labelling, or sale of a medicine elsewhere than in the premises specified or described in the licence.

Compare: 1960 No 97 s 17; 1979 No 27 s 37

Section 52(1)(e): added, on 18 September 2004, by section 15(1) of the Medicines Amendment Act 2003 (2003 No 50).

Section 52(3): replaced, on 1 July 2014, by section 29(2) of the Medicines Amendment Act 2013 (2013 No 141).

53 Duration of licences

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

(2) Any licence issued within the period of 2 months preceding the date of expiration of an existing licence that it is intended to supersede shall continue in force for a period of 1 year beginning on that date.

(3) If a licensee applies for a new licence not more than 3 months and not less than 1 month before the date of expiration of an existing licence that the new licence is intended to supersede, and the application is not disposed of before that date, the existing licence shall continue in force until the application is disposed of.

Compare: 1960 No 97 s 18; 1979 No 27 s 38

Section 53(1): substituted, on 18 September 2004, by section 16 of the Medicines Amendment Act 2003 (2003 No 50).

54 Display of licences

(1) Every licensee shall cause his current licence to be permanently exhibited in some conspicuous place where it can be readily seen by all persons having access to the premises to which the licence relates.

(2) Every licensee who is authorised by his licence to sell medicines elsewhere than in his regular business premises shall produce his licence for inspection whenever required by an officer to do so, or, if he is unable to do so, shall produce it at the office of the licensing authority within 24 hours thereafter.

(3) Every person commits an offence against this Act who contravenes subsection (1), or fails to produce his licence as required by subsection (2).

Compare: 1960 No 97 s 19; 1979 No 27 s 39

55 Register of licences

(1) Every licensing authority shall keep at his office a register of the licences issued by the authority under this Act, and such other registers and records as may be prescribed.

(2) Any person may have access to the register of licences for the purpose of inspection during the hours and upon the days appointed by regulations made under this Act or, if no such times are so appointed, at all reasonable times.

Compare: 1960 No 97 s 20

55A Additional criteria to be satisfied by pharmacy operators

(1) The licensing authority must not grant an application for a licence to operate a pharmacy unless the authority is satisfied that, in addition to satisfying the criteria set out in section 51(1),—

(a) the applicant is a person who is qualified under any of sections 55D, 55E, or 55G, to be granted a licence to operate a pharmacy; and

(b) the applicant is a person who is able to satisfy the condition set out in section 55C.

(2) If the licensing authority has reasonable grounds to believe that the holder of a licence to operate a pharmacy has ceased to be a person who satisfies each of

the criteria set out in subsection (1), the licensing authority may suspend the licence for a reasonable period to enable the authority to consider the case.

(3) If, after giving the holder of a licence to operate a pharmacy whose licence is suspended under subsection (2) a reasonable opportunity to be heard and after considering any evidence adduced or submissions made by the licensee, the licensing authority is not satisfied that the holder satisfies all of the criteria set out in subsection (1), the licensing authority may cancel the licence.

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

Section 55A: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

55B Licensing authority may require further information

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

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

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

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

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

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

Section 55B: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

55C Mandatory condition of licence to operate pharmacy

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

Section 55C: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

Restrictions on persons allowed to operate pharmacies

Heading: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

55D Restriction on companies operating pharmacies

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

(2) A company may be granted a licence to operate a pharmacy if—

(a) at all times more than 50% of the share capital of the company is owned by a pharmacist or pharmacists, and effective control of the company is vested in that pharmacist or those pharmacists; or

(b) it is exempt from the requirements set out in paragraph (a) under an Order in Council made under section 105C or complies with any modification of those requirements authorised by an Order in Council made under that section; or

(c) it is deemed to have been issued with a licence under section 114A(2); or

(d) the pharmacy is in a hospital owned or operated by the company; or

(e) it is a company that, at the commencement of this section, was lawfully operating a pharmacy.

(3) Subsection (2)(e) ceases to apply to a company if there is or are a change or changes in the ownership of shares representing 25% of the share capital of the company after the commencement of this section.

(4) For the purposes of subsection (2), **pharmacist** includes an administrator of the estate of a deceased pharmacist, and an assignee within the meaning of the Insolvency Act 2006 of the estate of a pharmacist, until—

(a) the expiry of the period of 1 year after the date of the death of the deceased pharmacist, or the date on which the pharmacist was adjudicated bankrupt, has expired; or

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

Compare: 1970 No 143 s 42

Section 55D: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

Section 55D(4): amended, on 3 December 2007, by section 445 of the Insolvency Act 2006 (2006 No 55).

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

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

(a) the person is a pharmacist; or

(b) the person is exempt from the requirements set out in paragraph (a) under an Order in Council made under section 105C or complies with any modification of those requirements authorised by that Order in Council; or

(c) the person is deemed to have been issued with a licence under section 114A(2); or

(d) the pharmacy is in a hospital owned or operated by the person; or

(e) the person, at the commencement of this section, was lawfully operating a pharmacy.

(2) For the purposes of subsection (1), a person does not hold an interest in a pharmacy merely by reason of the person's membership of a company, or of any other body of persons (whether corporate or unincorporate) other than a partnership, that is lawfully carrying on business in a pharmacy.

(3) For the purposes of subsection (1),—

person does not include a company

pharmacist includes the following persons:

(a) an administrator of the estate of a deceased pharmacist:

(b) an assignee, within the meaning of the Insolvency Act 2006, carrying on a pharmacy in his or her capacity as assignee of the estate of a pharmacist:

(c) a liquidator carrying on a pharmacy under the authority of section 260 and Schedule 6 of the Companies Act 1993:

(d) a receiver or manager of the property of a company carrying on, subject to the Receiverships Act 1993, a pharmacy comprised in that property.

(4) Subsection (3) does not entitle any person to carry on business in a pharmacy after—

(a) the expiry of 1 year after the date of the death of the deceased pharmacist, or the date on which the pharmacist was adjudicated bankrupt, or the date of the first appointment of a liquidator, receiver, or manager, in respect of a company that has carried on a pharmacy; or

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

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

Compare: 1970 No 143 s 43

Section 55E: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

Section 55E(3) **pharmacist** paragraph (b): amended, on 3 December 2007, by section 445 of the Insolvency Act 2006 (2006 No 55).

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

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

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

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

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

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

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

(5) Subsection (1) does not apply to Health New Zealand established by section 11 of the Pae Ora (Healthy Futures) Act 2022.

Compare: 1970 No 143 s 45

Section 55F: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

Section 55F(5): inserted, on 1 July 2022, by section 104 of the Pae Ora (Healthy Futures) Act 2022 (2022 No 30).

55G Exemption for mortgagees in possession

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

(2) In this section, **mortgagee in possession** has the same meaning as in section 4 of the Property Law Act 2007.

Compare: 1970 No 143 s 47

Section 55G: inserted, on 18 September 2004, by section 17 of the Medicines Amendment Act 2003 (2003 No 50).

Section 55G(2): amended, on 1 January 2008, by section 364(1) of the Property Law Act 2007 (2007 No 91).

Part 4
Medical advertisements

56 Interpretation

In this Part, unless the context otherwise requires,—

advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and **advertising** and **advertised** have corresponding meanings

medical advertisement means an advertisement relating, or likely to cause any person to believe that it relates, to any medicine or medical device or any ingredient or component thereof, or to any method of treatment

method of treatment means any method of treatment for reward undertaken, or represented to be undertaken, for a therapeutic purpose

publish means—

(a) insert in any newspaper or other periodical publication printed or published in New Zealand; or

(b) send to any person through the Post Office or otherwise; or

(c) deliver to any person or leave upon premises in the occupation of any person; or

(d) broadcast within the meaning of the Broadcasting Act 1989; or

(e) bring to the notice of the public in New Zealand in any other manner.

Compare: 1969 No 7 s 2; 1979 No 27 s 2

Section 56 **publish** paragraph (d): amended, on 1 July 1989, pursuant to section 89(1) of the Broadcasting Act 1989 (1989 No 25).

57 Restrictions on advertisements

(1) No person shall publish or cause to be published, either on that person's own account or as the agent or employee of the person seeking to promote the sale, any medical advertisement that—

(a) directly or by implication qualifies or is contrary to any statement or other particulars required by regulations made under this Act to be marked on or attached to medicines or medical devices of the description, kind, or class, to which the medicines or medical devices advertised, or appearing to be advertised, belong or appear to belong, or on or to packages or containers enclosing medicines or medical devices of that description, kind, or class; or

(b) is prohibited by any such regulations from being marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(c) omits from the name or description of the medicines or medical devices advertised any word or words required by any such regulations to be included in the name or description marked on or attached to, or on or to packages or containers enclosing, medicines or medical devices of that description, kind, or class; or

(d) fails to make any statement required by any such regulations to be made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(e) makes any statement prohibited by any such regulations from being made in an advertisement relating to medicines or medical devices of that description, kind, or class; or

(f) is false, or is likely to mislead any other person, with regard to the nature, quality, strength, purity, composition, origin, age, uses, or effects of medicines or medical devices of that description, kind, or class or of any ingredient or component thereof; or

(g) directly or by implication states or suggests that medicines or medical devices of that description, kind, or class, cannot harm any person, or any person belonging to a particular class of persons, or is not habit-forming.

(2) For the purposes of subsection (1), any words that must be included in an advertisement in order to avoid a contravention of that subsection shall, where they appear in an advertisement published by television or otherwise in a transitory manner on a screen, be disregarded unless they are exposed in clearly legible lettering for a length of time sufficient to enable them to be read by the ordinary viewer.

(3) For the purposes of subsection (1)(f), a medical advertisement shall be deemed to be likely to mislead any person with regard to the uses or effects of medicines or medical devices of a particular description, kind, or class, or of any ingredient or component thereof, if it is likely to mislead with regard to—

(a) any purposes for which medicines or medical devices of that description, kind, or class, or any ingredient or component thereof, can be used with reasonable safety; or

(b) any purposes for which such medicines or medical devices, or any such ingredient or component, cannot be so used; or

(c) any effects that such medicines or medical devices, or any such ingredient or component, when used, or when used in any particular way referred to in the advertisement, produce or are intended to produce.

(4) Without prejudice to any liability in respect of any offence against any regulations made under this Act, every person commits an offence against this Act who contravenes any of the provisions of subsection (1).

Compare: 1960 No 97 s 29; 1969 No 7 s 8; SR 1964/64 r 21

58 Further restrictions on advertisements

(1) Subject to section 60, no person shall publish, or cause or permit to be published, any medical advertisement that—

(a) directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent, alleviate, or cure any disease, or prevent, reduce, or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part 1 of Schedule 1; or

(b) directly or by implication claims, indicates, or suggests that medicines of the description, or medical devices of the kind, or the method of treatment, advertised will prevent or cure any disease, or prevent or terminate any physiological condition specified, or belonging to a class of disease or physiological condition specified, in Part 2 of Schedule 1; or

(c) directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised—

(i) is a panacea or infallible; or

(ii) is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed therein; or

(iii) has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement; or

(d) invites correspondence or the sending of hair, blood, urine, or other bodily specimens or photographs for the purposes of diagnosis or treatment concerning any disease or physiological condition.

(2) Every person commits an offence against this Act who contravenes any of the provisions of subsection (1).

(3) It shall be a good defence in a prosecution for an offence against paragraph (a) or paragraph (b) of subsection (1) if the defendant proves that the matter claimed, indicated, or suggested in the advertisement is true.

Compare: 1969 No 7 ss 10, 39(3)

59 Advertisements to contain true name of advertiser

(1) Subject to subsection (2), no person shall publish, or cause or permit to be published, any medical advertisement that does not contain a statement of the true

name of the person for whom or on whose behalf the advertisement is published, and the address of that person's place of residence or business.

(2) In the case of a body corporate, it shall be sufficient compliance with subsection (1) if, instead of the address of the body corporate's place of business, the advertisement states the name of the place where the body corporate has its registered office, or, if it is not a registered company, other headquarters.

(3) Any statement that is contained in any medical advertisement and purports to set forth the name of the person for whom or on whose behalf the advertisement is published, shall, until the contrary is proved, be sufficient evidence of the name of the person for whom or on whose behalf the advertisement has been published.

(4) Nothing in this section applies to—

(a) any medical advertisement that complies with any regulations made under this Act relating to the disclosure or otherwise of the name and address of the place of residence or business of the manufacturer or seller of the medicines of the description or medical devices of the kind advertised, or the agent of either of them; or

(b) any medical advertisement relating to any description of medicines or any kind of medical devices in respect of which an exemption granted under or by virtue of this Act from the material provisions of any such regulations is for the time being in force.

(5) Every person commits an offence and is liable on conviction to a fine not exceeding $1,000 who contravenes subsection (1).

Compare: 1969 No 7 s 9

Section 59(5): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

60 Exemption for certain advertisements

Without limiting any power to make regulations under this Act, nothing in section 57(1)(g) or section 58 or section 59 shall apply to any medical advertisement that—

(a) is distributed only to persons referred to in section 58(1)(c)(ii); or

(b) is contained in a publication that in the ordinary course circulates solely or principally, or is distributed solely or principally, to those persons; or

(c) not being an advertisement relating to a prescription medicine, or a restricted medicine, or a pharmacy-only medicine, is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes and to persons privately consulting them.

Compare: 1969 No 7 s 11

61 Misleading branding

(1) No person shall sell any medicine or medical device—

(a) that bears or has attached to it, or is enclosed in a package or container that bears or has attached to it, any false or misleading statement, word, brand, picture, label, 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 of the medicine or medical device enclosed in the package or container, or of any ingredient thereof; or

(b) that has been packed, processed, or treated in a manner that is false or misleading in relation to any of the matters mentioned in paragraph (a).

(2) Every person commits an offence against this Act who contravenes subsection (1).

Compare: 1969 No 7 s 7

62 Regulations relating to advertisements

(1) Without limiting section 105 but subject to subsection (2), the Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:

(a) requiring and regulating the insertion in any medical advertisement, or any particular class of medical advertisement, of such information or warning, or kind of information or warning, concerning any unwanted, incidental, or untoward effects of medicines of the description, or of medical devices of the kind, or of the method of treatment, advertised, and such statement or kind of statement of the precautions to be taken by any user of medicines of that description, or of medical devices of that kind, or of that method of treatment, as may be prescribed:

(b) prohibiting the advertising of any specified description of medicine, or kind of medical device, or method of treatment, or of any specified class of medicine, medical device, or method of treatment, in any medical advertisement, or a particular class of medical advertisement, and prohibiting, or requiring and regulating, the mention in any medical advertisement of such matters relating to the composition, properties, nomenclature, origin, and use of medicines of the description or medical devices of the kind or the method of treatment advertised, as may be prescribed:

(c) enabling the Minister to require, after consultation with such organisations as appear to him to represent any class or classes of persons whose interests might be affected by the requirement, the insertion of particular words specified by the Minister in, or the omission of particular words or other matter so specified from, any particular medical advertisement or class of medical advertisement, and to give directions with respect to the location, size, and appearance of any such insertion and with respect to other matters incidental thereto, and providing a right of appeal in respect of any such requirement or direction:

(d) generally regulating medical advertisements or any particular class of medical advertisements, or medical advertisements relating to medicines of a particular description, or to medical devices of a particular kind, or to a particular method of treatment, or relating to particular classes of medicines, medical devices, or methods of treatment.

(2) Any regulations made under subsection (1)(a)—

(a) shall be made only on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations; and

(b) shall be designed to achieve a fair and balanced indication of the potential effects of the medicine or medical device or method of treatment advertised; and

(c) shall not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published, or the inclusion of which in the advertisement is otherwise impracticable.

(3) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

(4) If the regulations enable the Minister to make requirements or directions under subsection (1)(c),—

(a) those requirements or directions are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements); and

(b) the regulations must contain a statement to that effect.

Compare: 1969 No 7 s 46(1)(r), (s), (2)

Legislation Act 2019 requirements for secondary legislation referred to in subsection (3)		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Legislation Act 2019 requirements for secondary legislation referred to in subsection (4)(a)		
Publication	See the relevant publication, presentation, and disallowance table in the secondary legislation referred to in subsection (3)	LA19 ss 73, 74, Sch 1 cl 14
Presentation	The Minister must present it to the House of Representatives, unless a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 62(3): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 62(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Part 5
Enforcement

63 Powers of officers

(1) In this section the expression **article to which this section applies** means—

(a) any medicine; and

(b) any medical device; and

(c) any cosmetic; and

(d) any equipment used or intended to be used in connection with the manufacture, packing, or labelling of anything referred to in any of paragraphs (a) to (c); and

(e) any package or container, and any advertising material or labelling material, used or intended to be used in any such connection.

(2) An officer, and any other person assisting him and acting under his direct supervision, may at any reasonable time—

(a) enter and inspect any premises (not being a dwellinghouse) or vehicle (including any fixtures, fittings, or appliances in the premises or vehicle) where the officer reasonably believes that any article to which this section applies is manufactured, packed, stored, or kept for sale:

(b) enter any premises (not being a dwellinghouse) or vehicle where the officer reasonably believes that any books, documents, or other records are kept relating to any such manufacture, packing, storage, or keeping for sale:

(c) open and examine any package or container that the officer reasonably believes contains any article to which this section applies:

(d) examine any article to which this section applies:

(e) examine any process of manufacture or packing of any article to which this section applies, and the means employed at any stage in the processes of manufacture or packing for testing the materials after they have been subjected to those processes:

(f) subject to section 69, purchase or take samples of any medicine or medical device or cosmetic that the officer reasonably believes to be intended for sale or to have been sold:

(g) purchase or take—

(i) any package or container in which the officer reasonably believes any medicine or medical device is intended to be packed for sale; or

(ii) any advertising material or labelling material that the officer reasonably believes is intended for use in connection with the sale of any medicine or medical device, or to have been used for such purpose:

(h) examine any books, documents, or other records that the officer reasonably believes contain information relevant to the enforcement of this Act or any regulations made under this Act, and make copies of or take extracts from any such records:

(i) seize and detain any article to which this section applies, not being equipment, by means of or in relation to which the officer reasonably believes an offence against this Act or against any regulations made under this Act has been committed:

(j) seize and detain any advertising material or labelling material that contravenes or does not comply with the requirements of this Act or any regulations made under this Act:

(k) take photographs of any premises or vehicle, or any article to which this section applies, or any other thing, where or by means of or in relation to which the officer reasonably believes an offence against this Act or against any regulations made under this Act has been committed.

(3) On demand by any person in any premises or vehicle, or claiming any interest in any article, in or in respect of which any power is exercised under this section, the officer exercising the power shall identify himself and produce evidence that he is an officer.

(4) *[Repealed]*

Compare: 1969 No 7 s 21(1), (2), (4); 1979 No 27 s 47(1)–(6)

Section 63(4): repealed, on 1 April 1987, by section 25(1) of the Official Information Amendment Act 1987 (1987 No 8).

64 Further provisions relating to seizure and detention of articles

(1) If any officer seizes any article under section 63 in any premises or vehicle that is not in the occupation or use of the owner of the article, he shall forthwith give notice in writing of the seizure to the owner, or to the consignor or consignee, or to the agent of the owner, of the article, if his name and address are on or attached to the article or are otherwise known to the officer, and the address is that of a place in New Zealand.

(2) Subject to subsection (3), where any article is seized under paragraph (i) or paragraph (j) of section 63(2), it may, at the option of the officer concerned, be detained in the premises or vehicle where it was ordered to be seized, or

removed to another place and detained there, at the expense of the owner at the time of the seizure.

(3) An officer shall release any article seized by him under section 63 when he is satisfied—

(a) that all the provisions of this Act and of any regulations made under this Act, to the extent that they are material, have been complied with in respect of the article; and

(b) that the article is fit for the purpose for which it is intended to be sold or used.

(4) If, within the time limited by section 65(1), the seized article has not been released and no application for disallowance of that seizure has been made under that section or any such application has been dismissed, the article shall become the property of the Crown; and the owner of the article at the time of the seizure shall be liable for any costs or expenses incurred in the disposition of that article.

(5) Without prejudice to the owner's liability under subsections (2) and (4), where the article was, at the time of the seizure, in the possession of a person who was not the owner and the identity of the owner is not known to the officer, the person in whose possession the article was at that time shall be liable for any costs and expenses incurred in the detention, removal, or disposition of that article.

(6) If any article seized under section 63 is not destroyed or otherwise disposed of under this section, it shall be returned to the person from whom it was seized when the officer concerned is satisfied of the matters referred to in subsection (3).

Compare: 1969 No 7 s 21(5)–(8)

65 District Court may order return of property or compensation

(1) Any person claiming an interest in any substance or article seized under section 63(2)(i), may, within 7 days thereafter, apply to the District Court for an order—

(a) that the seizure be disallowed and that the article be returned or otherwise made available to him:

(b) that the Crown shall pay to him such sum by way of compensation for any depreciation in the value of the substance or article resulting from its seizure, detention, or removal as the court thinks fit.

(2) On any such application, the court may dismiss it, or, subject to subsections (3) and (4), order—

(a) that the seizure be disallowed in whole or in part; or

(b) that the detention of the substance or article be terminated in whole or in part; or

(c) that compensation be paid by the Crown for any depreciation in the value of the substance or article resulting from its seizure, detention, or removal, and any transport and storage costs,—

and any such order may be made upon and subject to such terms and conditions as the court thinks fit.

(3) No order that the seizure of the substance or article be disallowed or that the detention of the substance or article be terminated in whole or in part shall be made if the court is of the opinion that the purpose to which that substance or article or that part is intended to be put will probably involve the commission of an offence against this Act, or any regulation made under this Act, or that the continued detention of that substance or article or that part is expedient for the purpose of its production in any pending proceedings under this Act.

(4) No order for the payment of compensation shall be made except in respect of a substance or article or part that, in the opinion of the court, ought not to have been seized or continued to be detained, as the case may be, and except to the extent that the court disallows the seizure or terminates the detention.

(5) Where the court makes an order for the payment of any sum by way of compensation to any person under this section, the sum so awarded shall be recoverable by that person as a debt due from the Crown.

(6) Every application to the court under this section shall be made and dealt with by way of originating application filed in the office of the court nearest to the place where the substance or article in dispute was seized or ordered to be detained.

(7) The applicant shall serve notice of his application on the respondent on or before the date on which he files it in the court.

(8) Except as modified by subsections (6) and (7), the rules of procedure for the time being in force under the District Court Act 2016 shall apply with respect to every application to the court under this section.

(9) Every order made by the court under this section shall be final and binding on all parties.

(10) Nothing in this section shall limit or affect the Customs and Excise Act 2018 or any other enactment.

Compare: 1969 No 7 s 22; 1979 No 27 s 49; SR 1964/64 r 20(f)

Section 65(1): amended, on 1 March 2017, by section 261 of the District Court Act 2016 (2016 No 49).

Section 65(8): amended, on 1 March 2017, by section 261 of the District Court Act 2016 (2016 No 49).

Section 65(10): amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

66 Powers to require information

(1) Without limiting section 63, where the Director-General or a Medical Officer of Health reasonably suspects that any person is in possession—

(a) of any medicine or medical device for the purpose of sale; or

(b) of any substance or article for the purpose of the manufacture, packing, sale, or supply of any medicine or medical device; or

(c) of any advertising material or labelling material for use as an advertisement or label,—

in breach of this Act or of any regulations made under this Act, he may require that person to produce for his inspection, or to produce to any officer specially authorised by him for the purpose, any books, documents, or other records dealing with the importation, purchase, reception, manufacture, packing, storage, carriage, delivery, sale, or supply of any such medicine, medical device, substance, article, or material.

(2) The Director-General or the Medical Officer of Health may make or cause to be made copies of or extracts from any such books, documents, or other records, and the copies of extracts, certified as such by him or by any specially authorised officer, shall be deemed to be true and correct copies or extracts, unless the contrary is proved.

(3) Every person commits an offence against this Act who refuses or fails to comply with any requisition made pursuant to this section.

(4) *[Repealed]*

(5) For the purposes of this section, any goods that have been seized or ordered to be detained, whether pursuant to this Act or any other enactment, shall be deemed to be still in the possession of the person who had them in his possession when they were seized or ordered to be detained.

Compare: 1960 No 97 s 40; 1969 No 7 s 27; 1979 No 27 s 50

Section 66(4): repealed, on 1 April 1987, section 25(1) of the Official Information Amendment Act 1987 (1987 No 8).

67 Power to require name and address of seller

(1) Any officer acting in the exercise of any of his powers under this Act may require any person who is in possession of any substance or article appearing to the officer to be a medicine or medical device for sale, or for delivery upon sale, to state correctly his name and address and, so far as he is aware of them, the name and address of the person from whom he obtained the substance or article.

(2) Every person commits an offence against this Act who fails, without reasonable excuse, to comply with any requirement of an officer under subsection (1).

Compare: 1969 No 7 s 28; 1979 No 27 s 51

68 Source of information or reports need not be disclosed

No prosecutor or witness in any prosecution under this Act shall be compelled to disclose the fact that the prosecutor or witness received any information, or the nature of such information, or the name of any person who gave such information; and no officer appearing as a prosecutor or witness shall be compelled to produce any confidential reports or documents made or received by that officer in his official capacity, or to make any statement in relation thereto.

Compare: 1969 No 7 s 37; 1979 No 27 s 52

69 Procuring samples for analysis

(1) When an officer intends to procure a sample of a substance or article for the purposes of analysis, he shall—

(a) pay or tender the current market value of the sample to the owner thereof or the person from whom the sample is to be obtained:

(b) before or forthwith after obtaining the sample, inform the owner of the sample or the person from whom the sample is obtained of his intention to submit the sample to an analyst.

(2) For the purposes of subsection (1), an officer may require the person in possession of a substance or an article that the officer reasonably believes to be a medicine, or his employee or agent, to show and permit the inspection of any package or container enclosing the substance or article and to take therefrom the sample demanded.

(3) Where any such substance or article is kept for retail sale in an unopened container, no person shall be required by any officer to sell less than the whole of the contents of the container.

(4) Nothing in this section shall—

(a) apply to the procuring of a sample of a substance or article from a vending machine if the officer obtains the sample by properly making payment for it and no person present admits to being in charge of the machine:

(b) prevent an officer from taking or purchasing samples of substances or articles for examination otherwise than by way of analysis, but in any such case the officer shall pay or tender the current market value of the sample to the owner thereof or the person from whom the sample is to be obtained.

(5) Notwithstanding anything in this section,—

(a) an officer shall not be obliged to submit to an analyst any sample that he has obtained:

(b) an officer may inspect, select, and take or purchase any sample for the purposes of analysis without complying with those sections, but in that event no regard shall be had to the result of any such analysis in any pro-

ceedings before any court in respect of an offence against this Act or against any regulations made under this Act.

(6) The procuring of a prescription medicine by an officer under this section shall not, for the purposes of section 18(2), be a sale or supply of that medicine.

(7) Every person commits an offence against this Act who refuses or fails to comply with any demand or requisition made by an officer pursuant to this section.

(8) For the purposes of this section, every person who is in possession of any substance or article that, in the opinion of the officer, is intended for sale shall, until the contrary is proved, be deemed to be the seller of the substance or, as the case may be, the agent or employee of the seller.

Compare: 1960 No 97 s 33(1)–(5); 1969 No 7 s 23; 1979 No 27 s 53

70 Analysis of sample and certificate of analyst

(1) The certificate of the analyst shall be in the prescribed form.

(2) Where any method of analysis of any substance or article is prescribed, an analyst shall use that method and shall declare in his certificate of analysis that he has done so.

(3) Any certificate of the result of an analysis given by an analyst in pursuance of this section shall be signed by the analyst, but the analysis may be made by any person acting under the direction of the analyst.

(4) When any sample is procured by an officer under this Act and submitted for analysis, the person from whom the sample was procured, or the manufacturer or importer of the substance or article, may, on payment of the prescribed fee, obtain a copy of the analyst's certificate or, if there is no such certificate, a copy of the report made by the analyst in respect of the sample.

(5) *[Repealed]*

(6) Every person commits an offence against this Act who publishes or causes to be published any advertisement relating to any medicine or medical device which states that the medicine or medical device has been analysed by an analyst under this Act, or quotes or purports to quote the findings of any analyst under this Act in relation to the medicine or medical device, whether or not those findings are given in any certificate or report prepared for the purposes of this Act.

Compare: 1969 No 7 s 25; 1979 No 27 s 55

Section 70(5): repealed, on 1 April 1987, by section 25(1) of the Official Information Amendment Act 1987 (1987 No 8).

71 Evidence of analysis

(1) Subject to subsections (2) and (3), in any proceedings for an offence against this Act, a certificate purporting to be signed by an analyst in the prescribed form shall, in the absence of evidence to the contrary, be sufficient evidence of

the authority of the person who signed the certificate and of the facts stated in the certificate.

(2) A certificate referred to in subsection (1) shall be admissible in evidence only if—

(a) at least 14 clear days before the hearing at which the certificate is tendered, a copy of that certificate (in addition to the copy required by section 77(4) to be served with the summons) is served, by or on behalf of the prosecutor, on the defendant, and the defendant is, at the same time, informed in writing that the prosecutor does not propose to call the analyst as a witness at the hearing; and

(b) the defendant does not, by notice in writing given to the prosecutor at least 7 clear days before the hearing, require the analyst to be called by the prosecutor as a witness at the hearing.

(3) No certificate referred to in subsection (1) shall be admissible in evidence if the court, of its own motion, directs that the result of the analysis shall be disregarded unless that result is proved by the oral evidence of the analyst.

(4) No certificate of an analyst and no other evidence of an analysis under this Act shall be ruled inadmissible or disregarded by reason only of the fact that any of the provisions of this Act or of any regulations made under this Act relating to the taking or analysing of samples have not been strictly complied with, if there has been reasonable compliance with those provisions.

Compare: 1969 No 7 s 36; 1979 No 27 s 56

72 Special provisions relating to imported consignments

(1) Where, in any port any officer takes any sample under section 69 from any imported consignment of any substance reasonably believed by him to be a medicine, the following provisions shall apply:

(a) the officer shall forthwith notify the importer that he has taken the sample:

(b) subject to paragraphs (c) and (d), an officer shall direct the Customs to detain the remainder of the consignment in the port under the control of the Customs until the analysis or examination has been completed:

(c) any such consignment may, with the approval of an officer, be removed at the expense of the importer from the port to a specified place if the importer undertakes in writing, in a form approved by the officer, that he will detain the consignment for such time as may be necessary to obtain results of analysis or to complete an examination:

(d) where any such consignment is in a bulk cargo container, the officer may, in accordance with paragraph (c), approve the removal of that container to a specified place at which a sample can be taken:

(e) where any consignment is to be removed to a specified place under paragraph (c) or paragraph (d), an officer shall mark it:

(f) if, as a result of the analysis or examination, an officer reasonably believes that the consignment does not comply with any of the provisions of this Act or any regulations made under this Act, he may—

(i) seize and detain the goods; or

(ii) order the goods returned by the importer to their place of origin, or some other place outside New Zealand, at the expense of the importer; or

(iii) permit the goods to be released subject to such conditions as he may specify, including a condition that a new label be substituted for any label on each or any package comprising part of the consignment:

(g) nothing in paragraph (c) or paragraph (d) or paragraph (f)(iii) shall limit or affect the Customs and Excise Act 2018.

(2) Where an officer seizes any goods under this section, he shall serve notice of his action on the importer of the goods; and, if the goods are still under the control of the Customs, he shall also serve a copy of the notice on the Customs who shall ensure that the goods are not delivered from the control of the Customs without the written consent of the officer.

(3) Where any goods are seized under this section, section 65 shall apply with all necessary modifications.

(4) It shall be the duty of all officers of the Customs to assist in carrying out the provisions of this section, and to prevent the introduction into New Zealand of anything contrary to this Act; and for that purpose they may, in respect of anything so introduced or attempted to be introduced, exercise all the powers conferred by the Customs and Excise Act 2018 in the case of uncustomed or prohibited goods.

Compare: 1979 No 27 s 57

Section 72(1)(b): amended, on 1 October 1996, by section 289(1) of the Customs and Excise Act 1996 (1996 No 27).

Section 72(1)(g): amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

Section 72(2): amended, on 1 October 1996, by section 289(1) of the Customs and Excise Act 1996 (1996 No 27).

Section 72(4): amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

73 Certain matters presumed

(1) In any prosecution for an offence against this Act or against any regulations made under this Act, it shall be presumed, until the contrary is proved, that the contents of a container conform with any purported description of the contents shown on any label attached to the container.

(2) In any prosecution for an offence against this Act or against any regulations made under this Act involving any medicine that is a new medicine by virtue of section 3(3)(c), it shall be presumed that the medicine is a new medicine until the contrary is proved.

Compare: 1960 No 97 s 50A; 1979 No 27 s 58

74 Certificates of Director-General or Medical Officer of Health

(1) In any proceedings under this Act, a copy of a record or an extract therefrom made by an officer pursuant to this Act and certified to be a true copy by the officer who made it pursuant to section 63(2)(h) or the person who was caused by the Director-General or the Medical Officer of Health to make it pursuant to section 66(2) shall be deemed to be a true and correct copy until the contrary is proved.

(2) In any proceedings under this Act, a certificate purporting to be signed by a licensing authority—

(a) relating to any contents of the register kept under section 55; or

(b) stating that on a date specified in the certificate the name of any person did not appear in the said register as a licensee, or any particulars specified in the certificate did not appear in the said register—

shall, without proof of the signature of the licensing authority, be sufficient evidence until the contrary is proved of the facts set out in the certificate.

Compare: 1960 No 97 s 33(b); 1969 No 7 s 36

75 Obstruction of officers

(1) Every person commits an offence against this Act who wilfully obstructs, hinders, resists, or deceives any officer in the execution of any powers conferred on that officer by or under this Act.

(2) Without limiting subsection (1), every person shall be deemed to have obstructed an officer if—

(a) except with the authority of an officer or under an order of a court, he removes, alters, or interferes in any way with any article seized or detained under this Act; or

(b) except with the authority of an officer or of an analyst or under an order of a court, he erases, alters, opens, breaks, or removes any mark, seal, or fastening placed by an officer under this Act on any sample or part of a sample procured under this Act, other than a part of a sample or bottle or container left with the owner of the medicine from which the sample was taken or the person from whom the sample was procured; or

(c) he refuses to sell to an officer, or to allow an officer to take, in the quantity that the officer reasonably requires as a sample, any medicine that appears to the officer to be intended for sale or to have been sold, or any advertising material or labelling material, that appears to the officer to be

intended for use in connection with the sale of any article to which section 63 applies or to have been so used; or

(d) he refuses or fails to give an officer any assistance that that officer may reasonably require him to give, or to give to an officer any information, or to produce or permit an officer to examine and make copies of and extracts from any books, documents, or other records, that that officer is expressly authorised by this Act to require to be given or produced or to examine or make, or may reasonably require to be given or produced or to examine or make, or when required to give any such information or to produce any such books, documents, or other records, knowingly makes any false statement in respect thereof.

Compare: 1969 No 7 s 29; 1979 No 27 s 59

76 Penalty for false statement

(1) Every person commits an offence against this Act who, for the purpose of obtaining, whether for himself or for any other person, the grant of any licence under this Act, or for any other purposes in relation to this Act,—

(a) make any declaration or statement that he knows is false in any particular; or

(b) utters, produces, or makes use of any such declaration or statement, or any document containing the same; or

(c) utters, produces, or makes use of any document that he knows is not genuine.

(2) Every person who commits an offence against this section is liable on conviction to imprisonment for a term not exceeding 6 months or a fine not exceeding $1,000.

Compare: 1960 No 97 s 47; 1969 No 44 s 10; 1979 No 27 s 60

Section 76(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

76A Offences in relation to authorised prescribers and delegated prescribers

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

Compare: 1970 No 143 s 49(1)(a)

Section 76A: inserted, on 18 September 2004, by section 18 of the Medicines Amendment Act 2003 (2003 No 50).

Section 76A heading: amended, on 1 July 2014, by section 30(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 76A: amended, on 1 July 2014, by section 30(2) of the Medicines Amendment Act 2013 (2013 No 141).

77 Jurisdiction of District Court

(1) *[Repealed]*

(2) Despite anything to the contrary in section 25 of the Criminal Procedure Act 2011, the limitation period in respect of an offence against this Act or any regulations made under it ends on the date that is 12 months after the date on which the offence was committed.

(3) The summons in any such proceedings shall not be made returnable in less than 14 days from the day on which it is served.

(4) There shall be served with the summons in any such proceedings a copy of the analyst's certificate or report (if any) relating to the prosecution.

Compare: 1969 No 7 s 38; 1979 No 27 s 61

Section 77 heading: amended, on 1 March 2017, by section 261 of the District Court Act 2016 (2016 No 49).

Section 77(1): repealed, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

Section 77(2): replaced, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

78 General penalty

Every person who commits any offence against this Act for which no penalty is provided elsewhere than in this section is liable on conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding $500, and, if the offence is a continuing one, to a further fine not exceeding $50 for every day or part of a day during which the offence has continued.

Compare: 1969 No 7 s 39; 1979 No 27 s 62

Section 78: amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

79 Liability of principal for acts of agents, etc

(1) Where an offence is committed against this Act or against any regulations made under this Act by any person acting as the agent or employee of another person, that other person shall, without prejudice to the liability of the first-mentioned person, be liable under this Act in the same manner and to the same extent as if he had personally committed the offence.

(2) Notwithstanding anything in subsection (1), where any proceedings are brought by virtue of that subsection it shall be a good defence to the charge if the defendant proves that the offence was committed without his knowledge and that he took all reasonable steps to prevent the commission of the offence.

(3) Where any body corporate is convicted of an offence against this Act or against any regulations made under this Act, every director and every person concerned in the management of the body corporate shall be guilty of a like offence if it is proved that the act that constituted the offence took place with his authority, permission, or consent, or that he knew the offence was to be or

was being committed and failed to take all reasonable steps to prevent or stop it.

Compare: 1969 No 7 s 30; 1979 No 27 s 63

80 Strict liability

(1) In any prosecution for selling a medicine or medical device contrary to any provision of this Act or of any regulation made under this Act, it shall not be necessary for the prosecution to prove that the defendant intended to commit an offence.

(2) Subject to subsection (3), it shall be a good defence in any such prosecution if the defendant proves—

(a) that he did not intend to commit an offence against this Act or any regulations made under this Act; and

(b) that he took all reasonable steps to ensure that the sale of the article would not constitute any such offence.

(3) Except as provided in subsection (4), subsection (2) shall not apply unless, within 7 days after the service of the summons, or within such further time as the court may allow, the defendant has delivered to the prosecutor a written notice—

(a) stating that he intends to rely on subsection (2); and

(b) specifying the reasonable steps that he will claim to have taken.

(4) In any such prosecution, evidence that the defendant took a step not specified in the written notice required by subsection (3) shall not, except with the leave of the court, be admissible for the purpose of supporting a defence under subsection (2).

Compare: 1969 No 7 s 31

81 Further defences

(1) Subject to subsections (2) and (4), it shall be a good defence in a prosecution for selling or supplying any medicine or medical device contrary to any provision of this Act or any regulations made under this Act if the defendant proves—

(a) that he purchased the article sold or supplied by him in reliance on a written warranty or other written statement as to the nature of the article purchased, signed by or on behalf of the person from whom the defendant purchased the article; and

(b) that if the article had truly conformed to the warranty or statement, the sale or supply of the article by the defendant would not have constituted the offence charged against him; and

(c) that he had no reason to believe or suspect that the article sold or supplied by him did not conform to the warranty or statement; and

(d) that at the time of the commission of the alleged offence, the article was in the same state as it was when he purchased it.

(2) No warranty or statement shall be any defence under this section unless—

(a) it was given or made by or on behalf of a person resident in New Zealand or a company having a registered office in New Zealand or a firm having a place of business in New Zealand; and

(b) the signature to the warranty or statement is written by hand; and

(c) the defendant proves that at the time he received the warranty or statement he took reasonable steps to ascertain, and did in fact believe, that the signature was that of the person from whom he purchased the article, or, as the case may be, of some person purporting to sign on behalf of the person from whom the defendant purchased the article.

(3) Subject to subsection (4), it shall be a good defence in a prosecution for selling or supplying any medicine or medical device contrary to any provision of this Act or of any regulations made under this Act if the defendant proves—

(a) that he purchased the article sold or supplied by him in a container and sold or supplied in the same container and in the same condition as the article was in at the time when he purchased it; and

(b) that he could not with reasonable diligence have ascertained that the sale or supply of the article would constitute the offence charged against him.

(4) Neither subsection (1) nor subsection (3) shall apply unless, within 7 days after the service of the summons, or within such further time as the court may allow, the defendant has delivered to the prosecutor a copy of the warranty or statement, if any, and a written notice to the effect that he intends to rely on it or on subsection (3), as the case may require, and specifying the name and address of the person from whom he received the warranty or statement or container, and has also, within the same time, sent by post a like notice of his intention to that person.

(5) Where the defendant is an agent or employee of the person who purchased the article under such a warranty or statement or in such a container, he shall be entitled to the benefit of this section in the same manner and to the same extent as his principal or employer would have been if he had been the defendant.

Compare: 1969 No 7 s 32

82 Liability of persons named on labels

(1) If any medicine or medical device is sold or supplied in the container in which it was enclosed when purchased by the person who sells or supplies the substance or article, and which has not since that purchase been opened by that person or any agent or employee of that person, every person who appears from any statement or label on or attached to the container to be—

(a) the person who has manufactured, imported, or packed the medicine or medical device; or

(b) the person who is the owner of the rights of manufacture of the medicine or medical device, or who has packed it; or

(c) the agent of any such person,—

shall, unless he proves the contrary, be deemed to have so manufactured, imported, or packed the medicine or medical device, or, as the case may require, to be the agent of such a person, and shall be liable in the same manner and to the same extent as if he had actually sold or supplied the medicine or medical device at the time and place at which the sale or supply was made, and, if that sale or supply involved the commission of an offence against this Act, he shall be deemed to be a party to that offence.

(2) Subject to subsection (3), it shall be a defence in a prosecution under subsection (1) if the defendant proves—

(a) in the case of a prosecution relating to the condition of a medicine or medical device, that when the container left his possession, the medicine or medical device was in such a condition that its sale or supply then would not have involved the commission of the offence with which he is charged; or

(b) in the case of a prosecution relating to manufacture, packing, or labelling, that the offence with which he is charged arises from an alteration made to the container or labelling since the container left his possession.

(3) Subsection (2) shall not apply unless, within 7 days after the service of the summons, or within such further time as the court may allow, the defendant has delivered to the prosecutor a written notice—

(a) stating that he intends to rely on subsection (2); and

(b) identifying the person to whom the defendant consigned or delivered the medicine or medical device or explaining why the defendant is unable to identify that person.

(4) Nothing in subsection (1) shall apply in respect of any offence against section 17 or section 18.

Compare: 1969 No 7 s 33

83 Cancellation of licence

(1) In any case where a licensee is convicted of an offence against this Act, or against any regulations made under this Act, the court may, in addition to or instead of imposing any other penalty,—

(a) cancel the licence, either forthwith or with effect from such future date as may be specified by the court:

(b) disqualify the licensee from obtaining any new licence for such period as the court may specify:

(c) cause particulars of the conviction, and of any order made under paragraph (a) or paragraph (b) to be endorsed on the licence.

(2) When a court cancels a licence pursuant to subsection (1), the licence shall cease to have effect either forthwith or on the date specified by the court, as the case may require.

(3) When a court, pursuant to subsection (1), disqualifies a person from obtaining a new licence, no licence shall be issued to that person during the period specified by the court.

(4) Any licence cancelled or required by the court for endorsement under this section shall be produced by the licensee in such manner and within such time as the court directs.

(5) Every person commits an offence against this Act who, without reasonable excuse, fails to produce any licence in accordance with subsection (4).

(6) For the purposes of Part 6 of the Criminal Procedure Act 2011, the cancellation or endorsement of a licence, or a disqualification, under this section shall be deemed to be a sentence or part of a sentence, as the case may be.

(7) The particulars of any cancellation, disqualification, or endorsement under this section, and the particulars of the conviction relating thereto, shall be notified in writing to the Director-General by the Registrar of the court.

Compare: 1960 No 97 s 21; 1979 No 27 s 64

Section 83(6): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

84 Payment of expenses of analysis on conviction

(1) Where any person is convicted of an offence against this Act or any regulations made under this Act, the court may order that all fees and other expenses incidental to the analysis of any medicine in respect of which the conviction is obtained shall be paid by the defendant.

(2) All such fees and expenses shall be deemed to be part of the costs attending the conviction, and shall be recoverable accordingly.

Compare: 1969 No 7 s 41; 1979 No 27 s 65

85 Forfeiture on conviction

(1) Where any person is convicted of an offence against this Act or any regulations made under this Act, the court may order that any medicine or medical device, or any advertising material or labelling material, to which the conviction relates, and any similar medicine, medical device, or material found on the premises of the defendant or in the defendant's possession at the time of the offence, together with all packages or containers containing the medicine, medical device, or material, shall be forfeited to the Crown.

(2) Everything so forfeited to the Crown shall be disposed of as the Minister directs.

Compare: 1969 No 7 s 40; 1979 No 27 s 66

86 Courts may order withdrawal of goods from circulation

(1) If any person who manufactures, packs, or imports medicines of any description, or medical devices of any kind, is convicted of an offence against section 61 in respect of medicines of that description, or medical devices of that kind, the court may in its discretion order that person to withdraw from sale all medicines of that description, or medical devices of that kind, until the matter in relation to which the offence was committed has been remedied.

(2) If the court makes an order under subsection (1), the Director-General shall cause particulars of the order and of the offence in relation to which the order was made to be published in the *Gazette*; and thereupon every distributor, wholesaler, or retailer who has possession of any medicines of the same description, or medical devices of the same kind, that are packed and labelled in the same way as the medicines or medical devices in relation to which the offence was committed shall withdraw them from sale, and may—

(a) return them to the person who supplied them; or

(b) remedy the matter in relation to which the offence was committed.

(3) Every distributor, wholesaler, or retailer who takes action in accordance with paragraph (a) or paragraph (b) of subsection (2) may recover all the costs and expenses incurred in so acting (including, if action is taken under the said paragraph (a), the purchase price of the medicines or medical devices) from the person who supplied them as a debt due by that person to the distributor, wholesaler, or retailer.

(4) Without limiting subsection (1), if any person referred to in that subsection is convicted of an offence against any of the provisions of sections 57, 58, and 61 in respect of any container, or of any advertising material or labelling material, the court may in its discretion order that person to withdraw from use all containers or material of the same description until the matter in relation to which the offence was committed has been remedied; and in any such case subsections (2) and (3) shall apply with any necessary modifications.

(5) Where any person referred to in subsection (1) is convicted of an offence against any of sections 57, 58, and 61, the Director-General may cause particulars of the offence and a description of the substances or articles in relation to which the offence was committed to be published in the *Gazette*.

Compare: 1969 No 7 s 35

87 Notification of conviction of practitioners, etc

If a person who is a veterinarian, practitioner, pharmacist, nurse, optometrist, designated prescriber, or delegated prescriber is convicted of an offence against

this Act or regulations made under it, the court must send particulars of the conviction to—

(a) the Registrar of the Veterinary Council of New Zealand, if the person is a veterinarian; or

(b) the responsible authority for the health profession to which the person belongs, in any other case.

Section 87: replaced, on 1 July 2014, by section 31 of the Medicines Amendment Act 2013 (2013 No 141).

Part 6
Appeals

88 Refusal of licensing authority to grant licence

(1) Any person who is aggrieved by a decision—

(a) of the Director-General made under section 30 or section 38; or

(b) of the licensing authority made under section 51—

may appeal against that decision to the Medicines Review Committee.

(2) Every appeal under subsection (1) shall be commenced within 28 days after the date on which the decision that is the subject of the appeal has been given to the person seeking to bring the appeal, or within such extended time as the Medicines Review Committee may allow.

(3) On any such appeal, the Medicines Review Committee may confirm or reverse or modify the decision that is the subject of the appeal, as it thinks fit.

89 Right of appeal to High Court

(1) Subject to subsections (2) and (3), any person who is aggrieved by—

(a) a decision of the Minister refusing, revoking, or suspending any consent or approval, or imposing, varying, or adding to any conditions, under any of sections 20, 23, 24, and 35; or

(b) a decision to issue a notice under section 36(3) or section 37(1), or the imposition, variation, or addition of conditions under that section; or

(c) a decision of the Medicines Review Committee made under section 88,—

may appeal to the High Court.

(2) The grounds on which an appeal may be brought under subsection (1) are—

(a) that any relevant requirement of this Act or of any regulations made under this Act has not been complied with:

(b) that the decision that is the subject of the appeal is unreasonable.

(3) Every appeal under subsection (1) shall be commenced within 28 days after the date on which notice of the decision that is the subject of the appeal has been

given to the person seeking to bring the appeal, or within such extended time as the court may allow.

(4) *[Repealed]*

(5) Subject to subsection (6), on any appeal under subsection (1), the court may—

(a) by interim order, suspend the operation of the decision to which the appeal relates until the final determination of the proceedings:

(b) dismiss the appeal, or make such modifications in the decision to which the appeal relates as it thinks fit, or quash the decision with or without substituting a new decision in its place.

(6) The court shall not quash or modify the decision to which the appeal relates on any ground other than a ground specified in subsection (2).

Compare: 1960 No 97 s 42; 1979 No 27 s 67

Section 89(4): repealed, on 15 August 1991, by section 3(4) of the Judicature Amendment Act 1991 (1991 No 60).

90 Proceedings before court

(1) At the hearing of an appeal under section 89, the court shall hear all evidence tendered and representations made by or on behalf of the parties that the court considers relevant to the subject matter of the appeal.

(2) The court may, at any such hearing, receive as evidence any statement, document, information, or matter that may, in its opinion, assist it to deal effectually with the matters before it, whether or not it would be otherwise admissible in a court of law.

(3) For the purpose of modifying any decision of the Medicines Review Committee, or substituting a new decision, the court shall have all the powers and discretions that the Medicines Review Committee had in respect of the same matter.

(4) The court in its discretion may, having regard to the interests of all parties concerned and to the public interest, order that the hearing or any part of it shall be held in private.

(5) Subject to the provision of this Act, the procedure in respect of any appeal under section 89 shall be in accordance with rules of court.

Compare: 1979 No 27 s 68

91 Further provisions relating to appeals

(1) Subject to any order made by the court pursuant to paragraph (a) of subsection (5) of section 89, every decision referred to in subsection (1) of that section shall take effect according to its terms, notwithstanding that the time for appealing has not expired or that an appeal has not been determined.

(2) No person shall be deprived of the right of appeal conferred by section 89 merely because he has accepted a licence or complied with any requirement or condition imposed under this Act.

(3) Where the High Court or the Court of Appeal modifies a decision of the Medicines Review Committee, or substitutes a new decision, the Minister, or the Director-General, or the licensing authority, as the case may require, shall take all necessary measures to implement the decision of the court.

Compare: 1979 No 27 s 69

92 Court may state case for Court of Appeal

The Judge of the High Court may, on the application of any party to an appeal under section 89, or of his own motion, state a case for the opinion of the Court of Appeal on any question of law arising in the proceedings.

Compare: 1979 No 27 s 70

93 Appeal to Court of Appeal in certain cases

(1) Any party to any appeal before the High Court under section 89 who is dissatisfied with any determination of the court may, with the leave of the court or of the Court of Appeal, appeal to the Court of Appeal.

(2) In determining whether to grant leave to appeal under this section, the court to which the application for leave is made shall have regard to the following matters:

(a) whether any question of law or general principle is involved:

(b) the importance of the issues to the parties:

(c) such other matters as in the particular circumstances the court thinks fit.

(3) The court granting leave under this section may in its discretion impose such conditions as it thinks fit, whether as to costs or otherwise.

(4) For the purpose of determining any appeal under this Act, the Court of Appeal shall have the same powers and discretions as are conferred on the High Court by sections 89 and 90.

(5) The decision of the Court of Appeal on any appeal under this section shall be final.

(6) Notwithstanding the preceding provisions of this section, the decision of the High Court shall have effect according to its terms, pending the determination of any appeal under this section, unless—

(a) leave to appeal is given by the court whose decision is the subject of the appeal; and

(b) that court, when giving such leave, directs that that decision shall not take effect pending the determination of the appeal.

(7) Where the court gives any direction under paragraph (b) of subsection (6), the court may make such order with regard to the application of the decision to which the appeal under section 89 related, pending the determination of an

appeal under this section, as seems to it to be just, and subsection (3) of section 91 shall apply accordingly.

Compare: 1979 No 27 s 71

Part 7
Related products

94 Interpretation

(1) In this Part, unless the context otherwise requires, the term **related product** means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose; but does not include—

(a) any medicine:

(aa) any medical device:

(b) any substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a related product for the purposes of this Act.

(2) In this Part, unless the context otherwise requires, the term **new related product** means a related product that—

(a) is not identical with any related product that could have been sold lawfully immediately before the commencement of this Part for the same therapeutic purpose as that claimed in respect of the new product; or

(b) is of a kind that has been referred to the Minister under section 24(5) (as applied to related products by section 96(3)).

Section 94(1)(aa): inserted, on 1 July 2014, by section 33(1) of the Medicines Amendment Act 2013 (2013 No 141).

95 Application of Act to related products

Except as provided in section 96, this Act shall not apply to related products.

96 Certain provisions to apply to related products as if medicines

(1) Sections 20 to 22, and 35, with all necessary modifications, shall apply to new related products in the same manner and to the same extent as they apply to new medicines.

(2) Subsections (1) and (2) of section 24 shall apply to every material change made in respect of a related product in the same manner and to the same extent as they apply to material changes in respect of medicines, subject to the following modifications:

(a) the reference in subsection (1) to the efficacy of the medicine shall be read as a reference only to the efficacy of the related product for a therapeutic purpose:

(b) subsection (2)(a) shall be read as applying only to the recommended dosage or the recommended manner of administration or use for a therapeutic purpose:

(c) subsection (2)(b) shall be read as applying only to any labelling or descriptive matter relating to a therapeutic purpose:

(d) subsection (2)(c) and subsection (2)(d) shall be read as applying only to a material change that is relevant to a therapeutic purpose.

(3) Subsections (3) to (6) of section 24, and sections 37, 40, and 44, Parts 4 and 5 (except section 83), Part 6, and sections 98 and 107, with all necessary modifications, shall apply to related products in the same manner and to the same extent as they apply to medicines.

(4) All or any of the powers conferred by paragraphs (f), (g), (h), (i), (k), (l), and (y) of subsection (1) of section 105 may be exercised in respect of related products, and the powers conferred by paragraph (k) of that subsection may be exercised in respect of any ingredient of any related product, as they may be exercised in respect of medicines; and for this purpose subsections (2) to (4) of that section shall, so far as they are applicable, apply in respect of related products and ingredients of related products and kinds of related products as they apply in respect of medicines and descriptions of medicines.

Part 7A
Restrictions on specified biotechnical procedures

Part 7A: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96A Interpretation

In this Part, unless the context otherwise requires,—

biological material means—

(a) the whole or part of any organ, bone, tissue, or cell; or

(b) blood or body fluids

specified biotechnical procedure means any xenotransplantation

xenotransplantation—

(a) means a medical procedure that involves the insertion or injection into a human being of any matter that consists of, or includes, living biological material of an animal, whether or not that biological material also includes biological material of a human being; and

(b) includes the transfusion into a human being of any human blood or any human body fluid if the blood or the fluid has, as part of a biotechnical procedure, been in contact with living biological material of an animal.

Section 96A: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 96A **cloned human organism**: repealed, on 21 August 2005, by section 86(1) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

Section 96A **cloning procedure**: repealed, on 21 August 2005, by section 86(1) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

Section 96A **genetically modified embryo**: repealed, on 21 August 2005, by section 86(1) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

Section 96A **genetically modified gamete**: repealed, on 21 August 2005, by section 86(1) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

Section 96A **germ-cell genetic procedure**: repealed, on 21 August 2005, by section 86(1) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

Section 96A **specified biotechnical procedure**: substituted, on 21 August 2005, by section 86(2) of the Human Assisted Reproductive Technology Act 2004 (2004 No 92).

96B Restrictions on specified biotechnical procedures

(1) No person may conduct a specified biotechnical procedure otherwise than in accordance with an authorisation under section 96C or section 96D.

(2) Subsection (1) applies to a person who continues, after the commencement of this section, to conduct a specified biotechnical procedure that was begun before that commencement.

(3) Every person commits an offence and is liable on conviction to imprisonment for a term not exceeding 6 months or to a fine not exceeding $200,000 who contravenes subsection (1).

Section 96B: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 96B(3): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

96C Authorisation of particular procedures

(1) The Minister may, by notice in writing, authorise a person or a body of persons to conduct a particular specified biotechnical procedure.

(2) The Minister may issue a notice under subsection (1) only if satisfied that the conduct of the procedure concerned meets each of the criteria specified in section 96E(1).

(3) An authorisation granted by a notice under subsection (1) may be granted unconditionally or subject to any conditions that are specified in the notice.

(4) The Minister may, at any time, by written notice, do any 1 or more of the following in relation to an authorisation granted under subsection (1):

(a) vary the authorisation:

(b) vary or revoke any condition subject to which the authorisation was granted:

(c) make the authorisation subject to new conditions:

(d) revoke the authorisation.

(5) As soon as practicable after giving a notice under subsection (1) or subsection (4), the Minister must publish the notice in the *Gazette* and present a copy of the notice to the House of Representatives.

Section 96C: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96D Authorisation of class of procedure

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, authorise the conduct of 1 or more classes of specified biotechnical procedure.

(2) The Minister may make a recommendation under subsection (1) only if satisfied that the conduct of every class of procedure concerned meets each of the criteria specified in section 96E(1).

(3) An authorisation granted by an Order in Council under this section may be granted unconditionally or subject to any conditions specified in the order.

(4) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 96D: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 96D(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

96E Criteria for authorisations

(1) The Minister may grant or recommend an authorisation sought by an application under section 96G only if satisfied that the application relates to the conduct of a specified biotechnical procedure or class of specified biotechnical procedure that meets each of the following criteria:

(a) the conduct of the procedure or class of procedure does not pose an unacceptable risk to the health or safety of the public:

(b) any risks posed by the conduct of the procedure or class of procedure will be appropriately managed:

(c) any ethical issues have been adequately addressed:

(d) any cultural issues have been adequately addressed:

(e) any spiritual issues have been adequately addressed.

(2) A reference in any of paragraphs (c) to (e) of subsection (1) to issues is a reference to issues raised—

(a) by the conduct of the procedure or class of procedure to which the application relates; and

(b) by any technology involved in that conduct.

(3) If the Minister is not satisfied that the conduct of the procedure or class of procedure to which the application relates meets any 1 or more of the criteria specified in subsection (1), the Minister—

(a) may direct that advice on the question whether or not the conduct of the procedure or class of procedure meets that criterion (or, as the case may be, those criteria) be obtained from persons who, in the Minister's opinion, are appropriately qualified, or have the appropriate expertise, to advise on the question; and

(b) after obtaining that advice, may resume his or her consideration of the application on the basis of that advice.

Section 96E: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96F Advice on applicability of criteria

(1) For the purpose of obtaining advice of the kind referred to in section 96E(3)(a) in relation to an application, the Minister may do any 1 or more of the following:

(a) establish a committee to advise on the criteria in question:

(b) request a body or a committee or an association of persons formed or recognised by or under an enactment to advise on the criteria in question:

(c) request the person who made the application under section 96G (in this section referred to as the **applicant**) to obtain advice on the criteria in question from a committee consisting of persons nominated by the Minister.

(2) A committee or body or an association of persons that is to provide advice for the purposes of section 96E(3)(a) may provide that advice only after it has—

(a) given interested parties and members of the public a reasonable opportunity to make submissions in writing or orally, or both; and

(b) taken any such submissions into account.

(3) Parts 2 and 3 of the Inquiries Act 2013 apply, with all necessary modifications, to the establishment and procedures of a committee that is to be, or has been, established under subsection (1) as if it were an inquiry established that Act.

(4) The Minister may agree with an applicant whose application relates to the work of a committee, body, or association established or requested under subsection (1)(a) or (b) that the applicant will pay, or contribute towards the payment of,

any costs incurred or to be incurred by the committee or body or association in the examination of aspects of the applicant's application that, in the Minister's opinion, could have significant commercial benefits (whether or not that examination also benefits the public).

(5) The Minister may agree with an applicant whose application relates to the work of a committee of persons nominated by the Minister under subsection (1)(c) that the Minister will pay, or contribute towards the payment of, any costs incurred or to be incurred by the committee in the examination of aspects of the applicant's application that, in the Minister's opinion, are likely to benefit the public (whether or not that examination also has commercial benefits).

(6) If the Minister is, under subsection (4), attempting to reach an agreement with the applicant, the Minister may direct the committee, body, or association concerned not to consider any matters relating to the applicant's application until agreement under subsection (4) has been reached; and the committee or body or association must give effect to that direction.

Section 96F: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 96F(3): replaced, on 1 July 2022, by section 104 of the Pae Ora (Healthy Futures) Act 2022 (2022 No 30).

96G Applications

(1) A person may, by application to the Minister, request the Minister to grant an authorisation under section 96C or to recommend an authorisation under section 96D(1).

(2) An application under subsection (1) must be in a form approved by the Director-General and must be accompanied by the prescribed fee.

(3) If the Minister has, under section 96F(1)(c), requested a person who applies under subsection (1) to obtain any advice, the Minister may defer consideration of the person's application until the person has obtained that advice.

Section 96G: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96H No compensation

No compensation is payable by the Crown to any person for any loss or damage arising from the restrictions imposed by section 96B.

Section 96H: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96I Enforcement powers

(1) Sections 63(1), 63(2)(a) to (d), (h), (k), and (3), 66, 68, 74(1), and 85 apply to any investigation or, as the case requires, any prosecution of an offence against section 96B as if—

(a) **medical device** included any substance or thing used as part of, or in connection with, a specified biotechnical procedure (within the meaning of this Part):

(b) there were inserted in section 63(2)(a), after the word "manufactured", the word "used,":

(c) there were inserted in section 63(2)(b), after the word "manufacture", the word "use,":

(d) there were inserted in section 66(1)(a), after the word "sale", the words "or for use in a specified biotechnical procedure (within the meaning of Part 7A)":

(e) there were inserted in section 66(1), after the words "dealing with the importation", the word "use,".

(2) To avoid any doubt, subsection (1) does not limit the application of any of sections 75, 76, 79, and 84 to any matter concerning, or arising out of, the commission, investigation, or prosecution of an offence against section 96B.

Section 96I: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

96J Expiry of Part

(1) This Part expires on the close of 30 September 2025.

(2) The Governor-General may, by Order in Council, before the date specified in subsection (1), on the recommendation of the Minister, specify a later date in substitution for that date.

(3) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 96J: inserted, on 28 May 2002, by section 6 of the Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14).

Section 96J(1): amended, on 29 September 2020, by clause 3 of the Medicines (Deferral of Expiry of Part 7A) Order 2020 (LI 2020/243).

Section 96J(2): amended, on 24 May 2005, by section 3(2) of the Medicines (Specified Biotechnical Procedures) Amendment Act 2005 (2005 No 73).

Section 96J(3): replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Part 8
Miscellaneous provisions

97 Duty of officer to procure samples for analysis on request

(1) Where any person, other than the manufacturer of the medicine or any agent or employee of the manufacturer, requests any officer in writing to procure a sample of any medicine and submit it for analysis for any purpose specified by that person, the officer, on payment by that person of the prescribed fee together with the cost of the sample, shall procure or arrange for another officer to procure a sample of the medicine and submit it for analysis for the specified purpose, unless he reasonably believes that the request is frivolous or vexatious.

(2) Sections 69 and 70 shall, so far as they are applicable and with the necessary modifications, apply with respect to the procuring and analysis of the sample.

Compare: 1969 No 7 s 26

98 Statement by Director-General

(1) The Director-General may, for the purpose of protecting the public, publish statements relating to medicines of any description or medical devices of any kind or to any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisements, relating to medicines of any description or medical devices of any kind.

(2) Every statement published under this section shall be protected by qualified privilege.

Compare: 1960 No 97 s 41; 1969 No 7 s 42; 1979 No 27 s 77

99 Director-General to publish lists of general sale medicines

(1) The Director-General shall from time to time, in such manner as he thinks fit, publish a list or lists of general sale medicines.

(2) In this section **general sale medicines** means medicines that may be lawfully sold in New Zealand, other than prescription medicines, restricted medicines, and pharmacy-only medicines.

100 Power of court to restrict publication of name of medicine

(1) Where, in the course of proceedings in any court or before a Coroner, reference is made to any medicine, the court or Coroner may in its or his discretion order that the name of that medicine shall not be published in relation to those proceedings at any time before the expiration of a period of 5 years from the date of the final disposal of those proceedings.

(2) Notwithstanding anything in subsection (1), no order made under that subsection shall apply to the publication of that name to scientists or to members of the legal, medical, dental, veterinary, nursing, or pharmaceutical professions, or to persons studying to become scientists or members of those professions, or to designated prescribers, or in any publication of a scientific or technical charac-

ter intended solely or principally for circulation among scientists or members of those professions or persons so studying.

(3) Where the publication of the name of a medicine is prohibited under this section in relation to any proceedings, no person shall, within the said period of 5 years, publish the name of that medicine or any name or particulars likely to lead to the identification of the description or class of medicine as the description or class of medicine to which the medicine referred to in those proceedings belonged.

(4) Nothing in this section shall limit the provisions of any other enactment relating to the prohibition or regulation of the publication of reports or particulars relating to any judicial proceedings.

(5) Every person commits an offence against this Act who contravenes subsection (3).

Compare: 1960 No 97 s 43; 1964 No 31 s 2; 1979 No 27 s 78

Section 100(2): amended, on 15 October 1999, by section 13 of the Medicines Amendment Act 1999 (1999 No 117).

101 Examination of Customs entries

For the purposes of this Act, every officer shall have the right at all times, subject to the convenience of the Customs, to inspect any Customs entry relating to any goods imported or proposed to be imported into New Zealand, or to inspect any certificate or invoice relating to those goods, if and so long as any such document is in the possession or control of the Customs.

Compare: 1969 No 7 s 43; 1979 No 27 s 79

Section 101: amended, on 1 October 1996, by section 289(1) of the Customs and Excise Act 1996 (1996 No 27).

102 Protection of persons acting under authority of Act

No person who does any act in pursuance or intended pursuance of any of the functions conferred on him by or under this Act shall be under any civil or criminal liability in respect of the act, whether on the ground of want of jurisdiction, or mistake of law or fact, or on any other ground, unless he has acted in bad faith or without reasonable care.

Compare: 1969 No 7 s 44; 1979 No 27 s 80

103 Service of documents

(1) Any document required or authorised under this Act, or under any regulations made under this Act, to be served on or given to any person may be served or given by delivering it to that person, or by leaving it at his usual or last known place of residence or business, or by posting it by registered letter addressed to him at his usual or last known place of residence or business.

(2) Every such notice posted in accordance with subsection (1) shall be deemed, in the absence of proof to the contrary, to have been served or given at the time when the registered letter would be delivered in the ordinary course of post.

(3) If the person is absent from New Zealand, the document may be served or given, in any manner referred to in subsection (1), on or to his agent in New Zealand.

(4) If the person is deceased, the document may be served or given, in any manner referred to in subsection (1), on or to his personal representative.

(5) If the person, or his place of residence or business, is not known, or if he is absent from New Zealand and has no known agent in New Zealand, or is deceased and has no personal representative, the document may be served or given in such manner as may be directed by a District Court Judge.

(6) Notwithstanding anything in the foregoing provisions of this section, a District Court Judge may in any case make an order directing the manner in which any document is to be served or given or dispensing with the service or giving of any such document.

Compare: 1979 No 27 s 81

104 Amendment of Schedule 1

(1) The Governor-General may from time to time, by Order in Council, add to or omit from Part 1 or Part 2 of Schedule 1 any disease or physiological condition or class of disease or physiological condition, or otherwise amend that schedule, and every such Order in Council shall have effect according to its terms.

(2) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1969 No 7 s 45

Legislation Act 2019 requirements for secondary legislation made under this section		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 104(2): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

105 Regulations

(1) The Governor-General may from time to time, by Order in Council made on the advice of the Minister tendered after consultation with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations, make regulations for all or any of the following purposes:

(a) prescribing forms, fees, registers, particulars, notifications, and records for the purposes of this Act, the method of keeping such registers and records; and prescribing the persons or classes of persons by or to whom any such records shall be kept or notifications given:

(aaa) prescribing, in relation to any application or class of application under this Act, any of the following:

(i) the manner in which the application must be made; and

(ii) the information that must accompany or be contained in the application; and

(iii) the manner in which the application must be determined by the decision-maker; and

(iv) any matters that the decision-maker must take into account when determining the application:

(aa) approving persons or organisations, or classes of persons or organisations, for the purposes of section 23C(1)(c)(iv):

(b) prescribing qualifications for and conditions of licences under this Act; and providing for or regulating the custody, production, suspension, or revocation of licences:

(c) permitting the manufacture, packing, labelling, administration, sale, or supply of medicines otherwise than pursuant to a licence under this Act and otherwise than in accordance with an authority conferred by this Act, subject to such conditions or restrictions (if any) as may be prescribed by or imposed under the regulations:

(d) prohibiting, limiting, restricting, or imposing conditions on, either generally or in relation to particular cases or classes of case, or particular descriptions or classes of medicines, or particular classes of person, the prescribing, manufacture, packing, labelling, administration, sale, or supply of medicines pursuant to any provision of this Act:

(e) prohibiting, limiting, restricting, or imposing conditions on the import, export, manufacture, packing, labelling, storage, sale, or supply of medicines of any description or medical devices of any kind:

(f) withdrawing medicines and medical devices from sale:

(g) regulating the situation, construction, sanitation, and use of premises in which medicines or medical devices are manufactured, packed, labelled, stored, sold, or supplied; prescribing the accommodation (including the amount of space) to be provided for any such purpose; prescribing standards of sanitation, cleanliness, temperature, and humidity, or other factors relating to the risks of deterioration or contamination, to be observed in connection with any such purpose; and prohibiting, or providing for the prohibition of, the use of particular premises or particular classes of premises for any such purpose:

(h) regulating the manufacture, packing, labelling, storage, safe-keeping, and destruction of medicines and medical devices:

(i) specifying, by name or description, substances or articles, or kinds or classes of substances or articles, that are, or are not, medicines or medical devices for the purposes of this Act:

(j) specifying descriptions of medicines that are prescription medicines or restricted medicines or pharmacy-only medicines:

(k) prescribing standards of composition, including standards of strength, weight, quality, purity, or quantity for any description or class of medicine or any kind or class of medical device or for anything contained in or added to or intended to be contained in or added to any medicine or medical device; prescribing standards of accuracy of performance for any kind or class of medical device; permitting the addition of a specified thing, or specified class of thing, in a specified quantity or proportion to medicines or medical devices, or to medicines of any specified description or class, or to medical devices of any specified kind or class, for which a standard is prescribed; and prohibiting the sale or supply of any medicine or medical device, not belonging to a description or class of medicine, or kind or class of medical device, for which a standard is prescribed, to which a specified thing or specified class of thing has been added or has been added in a quantity or proportion in excess of or less than a specified quantity or proportion:

(l) prescribing and regulating the mode of labelling of packages and containers of medicines or medical devices or substances or articles used or intended for use in the manufacture, or as ingredients or parts, of any medicine or medical device; prescribing the matter to be contained or not to be contained in any such label and the nature and appearance of any package or container enclosing a particular description or class of medicine or particular kind or class of medical device; and permitting the sale or supply of medicines or medical devices otherwise than in packages and containers labelled in accordance, and otherwise conforming with, any such regulations:

(m) prescribing methods to be used in the colouring of medicines of any description or class; requiring that any specified description or class of medicines shall be artificially coloured by the addition thereto of such colouring substance or substances as may be prescribed, in such proportion or proportions as may be prescribed; and prohibiting the sale or supply of any such medicine not so coloured:

(n) prohibiting the use of any package or container of a kind specified or described in the regulations for any purpose other than the storage of medicines for internal use:

(o) providing for the ascertainment, assessment, notification, and correction of damage to or leakage from packages or containers of medicines or medical devices, and the notification of any suspected contamination of medicines or medical devices sustained, in the course of storage or transportation by any means:

(p) requiring persons who are engaged in the manufacture, import, packing, labelling, sale, or supply of any medicines, or who utilise any medicine in the course of or in connection with their profession, trade, or calling, or any occupation whether paid or unpaid, or who otherwise undertake the supply or administration of any medicine, to furnish information with respect to such matters and in such form as may be prescribed:

(q) regulating the issue by authorised prescribers, veterinarians, and delegated prescribers of prescriptions for the supply of any medicine, including the transmission and storage of prescriptions, and requiring persons issuing or dispensing prescriptions in respect of any medicine to furnish such information relating to those prescriptions as may be prescribed:

(qa) authorising any class of registered health professional to prescribe specified prescription medicines, or a specified class or description of prescription medicines, in accordance with any conditions, limitations, requirements, or restrictions specified in or imposed under the regulations:

(qaa) granting and regulating delegated prescribing rights:

(qb) regulating the issue of standing orders, imposing conditions, limitations, requirements, or restrictions in relation to the contents of standing orders and their use, and providing for such other matters as are necessary or desirable for the administration of standing orders:

(r) requiring any medical practitioner who attends a person whom he considers, or has reasonable grounds to suspect, is dependent (within the meaning of the regulations) on medicines of any description or class to furnish such particulars with respect to that person as may be prescribed:

(s) prohibiting, regulating, or restricting the sale or supply of medicines to any person so dependent, and the issue of prescriptions for such sale or supply:

(t) regulating the dispensing and compounding of medicines:

(u) regulating the procedure of any committee established under this Act:

(v) regulating and controlling the exercise of powers by officers:

(w) applying any provision of this Act, subject to any exceptions and modifications that may be prescribed, that refers to things done in the course of a business carried on by a person, to things done by him or by his agent or employee in the course of any other activity specified or described in the regulations:

(x) providing for the waiver of fees in whole or in part in particular cases or classes of cases and for the total or partial refund of fees:

(y) prescribing offences in respect of the contravention of or non-compliance with any regulations made under this Act, and the amounts of fines that may be imposed in respect of any such offences, which fines shall be an amount not exceeding $500 and, where the offence is a continuing one, a further amount not exceeding $50 for every day or part of a day during which the offence has continued:

(z) exempting, or providing for the exemption of, any persons or classes of persons, or excepting any description or class of medicines, or any description or classes of medical devices, from any provision of any regulation made under this Act that imposes conditions or obligations:

(za) providing for such other matters as are contemplated by or necessary for giving full effect to the provisions of this Act and for its due administration.

(2) Any regulations made under subsection (1) may—

(a) apply to medicines or medical devices generally or to particular descriptions or classes of medicines, or particular kinds or classes of medical devices, specified or described in the regulations, and may make different provision for different descriptions or classes of medicines, or different kinds or classes of medical devices, so specified or described:

(b) relate to any description or kind of substances or articles specified by their name or trade names, or to any class of substances or articles identified in such manner as may be appropriate:

(c) identify any substances or articles or class of substances or articles by reference to their registration under any enactments, or to their pharmacological action, or to their use for the purpose for which they are used or intended to be used:

(d) specify the circumstances in which any description or kind of substances or articles are or are not to be medicines, prescription medicines, restricted medicines, or medical devices, or any 2 or more of those things for the purposes of this Act:

(e) provide for depriving particular persons of any rights, privileges, or exemptions conferred on any class of person to which those persons belong by this Act or any such regulations.

(3) Any regulations made under subsection (1) may prescribe a standard by reference to the name or description of a medicine, and the standard applicable thereto, appearing in a monograph contained in a specified publication within the meaning of section 108(1), or otherwise incorporate the whole or any part of any such monograph in the regulations by reference to any such specified publication.

(4) Any reference included in any regulations pursuant to subsection (3) may be expressed to be to a particular edition of a specified publication or to a specified publication without mentioning a particular edition, and to medicines generally or to any particular description or descriptions or class or classes of medicines, and to monographs generally, or to any particular monograph or monographs or class or classes of monographs, and the following provisions shall apply in relation to any such reference:

(a) if the regulations refer to a particular edition of a specified publication, the reference shall be construed as including all amendments, additions, and deletions made to that edition and published before the date on which the regulations are made:

(b) if the regulations do not refer to a particular edition of a specified publication, the reference shall be construed as applying to the edition of the specified publication in force when the regulations are made, so long as that edition remains in force, and thereafter to every subsequent edition of that publication for the time being in force, and as extending to all amendments, additions, and deletions made to any such edition and published whether before, on, or after the date on which the regulations are made.

(5) All or any of the powers conferred by paragraphs (g), (h), (k), and (l) of subsection (1) may be exercised in respect of any cosmetic or dentifrice (whether or not it is a related product within the meaning of Part 7).

(5A) For the purposes of subsection (1)(qa),—

(a) **specified prescription medicines** means prescription medicines specified by the Director-General by notice; and

(b) **specified class or description of prescription medicines** means a class or description of prescription medicines specified by the Director-General by notice.

(5B) Before issuing a notice under subsection (5A), the Director-General must consult with those organisations or bodies that appear to the Director-General to be representative of persons likely to be substantially affected by the notice.

(6) Notwithstanding anything contained in any regulation made under this section, any person may, at any time within 12 months after the date of the commencement of the regulation, sell any medicine or medical device of which the sale is otherwise lawful, if he proves that at that date the medicine or medical device was part of the existing stock-in-trade in New Zealand of any person carrying on business there, and that since that date no act has been done whereby the medicine or medical device fails to conform to the regulation.

(7) For the purposes of subsection (6) any goods purchased before the said date for importation into New Zealand shall be deemed to be part of the purchaser's stock-in-trade in New Zealand.

(8) The following are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements):

(a) regulations under this section:

(b) a notice under subsection (5A).

Compare: 1960 No 97 ss 4, 53; 1969 No 7 s 46; 1969 No 44 s 13; 1979 No 27 s 82

Legislation Act 2019 requirements for secondary legislation referred to in subsection (8)(a)		
Publication	PCO must publish it on the legislation website and notify it in the *Gazette*	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Legislation Act 2019 requirements for secondary legislation referred to in subsection (8)(b)		
Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 105(1)(a): amended, on 1 July 2014, by section 35(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(aaa): inserted, on 1 July 2014, by section 35(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(aa): inserted, on 1 January 1995, by section 3 of the Medicines Amendment Act 1994 (1994 No 128).

Section 105(1)(i): replaced, on 1 July 2014, by section 35(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(q): substituted, on 15 October 1999, by section 14 of the Medicines Amendment Act 1999 (1999 No 117).

Section 105(1)(q): amended, on 1 July 2014, by section 35(4) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(qa): replaced, on 1 July 2014, by section 35(5) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(qaa): inserted, on 1 July 2014, by section 35(5) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(1)(qb): inserted, on 15 October 1999, by section 14 of the Medicines Amendment Act 1999 (1999 No 117).

Section 105(2)(c): amended, on 22 October 2003, by section 5 of the Medicines Amendment Act (No 3) 2003 (2003 No 84).

Section 105(5A): inserted, on 1 July 2014, by section 35(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(5A)(a): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 105(5A)(b): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 105(5B): inserted, on 1 July 2014, by section 35(6) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105(8): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

105A Regulations relating to veterinarians and authorised prescribers who are not designated prescribers

(1) Without limiting the generality of section 105(1)(d), regulations may be made under that provision—

(a) requiring any veterinarian, or authorised prescriber who is not a designated prescriber, or a specified class of such persons, before commencing for the first time to prescribe prescription medicines or prescription medicines of a specified class or description, to satisfy 1 or more of the following requirements:

(i) to obtain any specified qualification or any qualification specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation:

(ii) to undertake specified training or any training specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation:

(iii) to demonstrate, to the satisfaction of the relevant professional organisation, that the person is sufficiently knowledgeable to safely prescribe prescription medicines or prescription medicines of a specified class or description:

(b) requiring any veterinarian, or authorised prescriber who is not a designated prescriber, or any class of such persons, to undergo specified training or to undergo training specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation (including training of an ongoing nature):

(c) requiring any veterinarian, or authorised prescriber who is not a designated prescriber, or any class of such persons, to undergo an assessment of competence to prescribe prescription medicines of a specified class or description (including an assessment at regular intervals):

(d) requiring any veterinarian, or authorised prescriber who is not a designated prescriber, or any class of such persons who prescribes prescription medicines of any specified class or description to undertake those duties under the supervision of a practitioner or a specified class of practitioner:

(e) prohibiting any veterinarian, or authorised prescriber who is not a designated prescriber who fails to comply with any requirement imposed by or under regulations referred to in paragraphs (a) to (d) from prescribing prescription medicines or prescription medicines of any specified class or description.

(2) In this section, **relevant professional organisation** means,—

(a) in the case of a veterinarian or any class of veterinarian, the Veterinary Council of New Zealand:

(b) in any other case, the responsible authority for the health profession to which the person belongs.

Section 105A: inserted, on 15 October 1999, by section 15 of the Medicines Amendment Act 1999 (1999 No 117).

Section 105A heading: replaced, on 1 July 2014, by section 36(1) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(1)(a): amended, on 1 July 2014, by section 36(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(1)(b): amended, on 1 July 2014, by section 36(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(1)(c): amended, on 1 July 2014, by section 36(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(1)(c): amended, on 17 May 2005, by section 3 of the Medicines Amendment Act 2005 (2005 No 60).

Section 105A(1)(d): amended, on 1 July 2014, by section 36(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(1)(e): amended, on 1 July 2014, by section 36(2) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(2)(a): replaced, on 1 July 2014, by section 36(3) of the Medicines Amendment Act 2013 (2013 No 141).

Section 105A(2)(b): replaced, on 1 July 2014, by section 36(3) of the Medicines Amendment Act 2013 (2013 No 141).

105B Regulations relating to designated prescribers

(1) Without limiting the generality of section 105(1)(d) or (qa), regulations may be made under section 105(1)(qa)—

(a) requiring any person who belongs to any class of registered health professional authorised to prescribe prescription medicines of any specified class or description by regulations made under section 105(1)(qa), or a specified class of such persons, before commencing for the first time to prescribe prescription medicines or prescription medicines of a specified class or description, to satisfy 1 or more of the following requirements:

(i) to obtain any specified qualification or any qualification specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation:

(ii) to undertake specified training or any training specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation:

(iii) to demonstrate, to the satisfaction of the relevant professional organisation, that the person is sufficiently knowledgeable to

safely prescribe prescription medicines or prescription medicines of a specified class or description:

(b) requiring any designated prescriber or any class of designated prescriber to undergo specified training or to undergo training specified from time to time by notice in the *Gazette* by the Minister, or by the relevant professional organisation (including training of an ongoing nature):

(c) requiring any designated prescriber or any class of designated prescriber to undergo an assessment of competence to prescribe prescription medicines of a specified class or description (including an assessment at regular intervals):

(d) requiring any designated prescriber or any class of designated prescriber who prescribes prescription medicines of any specified class or description to undertake those duties under the supervision of—

(i) a practitioner, or any specified class of practitioner; or

(ii) a nurse practitioner:

(e) prohibiting any person who fails to comply with any requirement imposed by or under regulations referred to in paragraphs (a) to (d) from prescribing prescription medicines or prescription medicines of any specified class or description.

(2) In this section, **relevant professional organisation** means the authority under the Health Practitioners Competence Assurance Act 2003 that has jurisdiction in respect of the class of registered health professional to which a designated prescriber, or a class of designated prescriber, belongs.

Section 105B: inserted, on 15 October 1999, by section 15 of the Medicines Amendment Act 1999 (1999 No 117).

Section 105B(1)(c): amended, on 17 May 2005, by section 4 of the Medicines Amendment Act 2005 (2005 No 60).

Section 105B(1)(d): replaced, on 31 January 2018, by section 5 of the Medicines Amendment Act 2016 (2016 No 78).

Section 105B(2): amended, on 18 September 2004, by section 20 of the Medicines Amendment Act 2003 (2003 No 50).

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

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

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

(b) modify the application of the provisions of section 55D(2)(a) or section 55E(1)(a) in respect of any person or class of person.

(2) The Minister must not recommend the making of any Order in Council under subsection (1) unless in the opinion of the Minister—

(a) health services or access to those services will be improved by the making of that Order in Council; and

(b) the making of that Order in Council is necessary to meet the needs of the community in the particular location of the pharmacy or proposed pharmacy.

(3) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless it relates exclusively to an individual.

(4) An order under this section that is not secondary legislation must be published on an Internet site maintained by or on behalf of the department.

(5) The Minister's reasons for recommending the making of the order must be published with the order.

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	PCO must publish it on the legislation website and notify it in the *Gazette*. Subsection (5) must also be complied with	LA19 s 69(1)(c)
Presentation	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 105C: inserted, on 18 September 2004, by section 21 of the Medicines Amendment Act 2003 (2003 No 50).

Section 105C(3): replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 105C(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 105C(5): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

105D Regulations relating to delegated prescribers

Without limiting the generality of section 105(1)(d) or (qaa), regulations may be made under section 105(1)(qaa)—

(a) granting delegated prescribing rights to any class of registered health professional:

(b) regulating the issue of delegated prescribing orders by authorised prescribers:

(c) specifying the responsibilities of authorised prescribers who issue delegated prescribing orders:

(d) imposing conditions, limitations, requirements, or restrictions in relation to the contents of delegated prescribing orders and their use:

(e) requiring any person who belongs to any class of registered health professional with delegated prescribing rights, or a specified class of those persons, before commencing to prescribe prescription medicines or pre-

scription medicines of a specified class or description under a delegated prescribing order, to satisfy 1 or more of the following requirements:

(i) to obtain any specified qualification or any qualification specified from time to time by notice in the *Gazette* by the Minister, or by the responsible authority:

(ii) to undertake specified training or any training specified from time to time by notice in the *Gazette* by the Minister, or by the responsible authority:

(iii) to demonstrate, to the satisfaction of the responsible authority, that the person is sufficiently knowledgeable to safely prescribe prescription medicines or prescription medicines of a specified class or description:

(f) requiring any delegated prescriber or any class of delegated prescriber to undergo specified training or to undergo training specified from time to time by notice in the *Gazette* by the Minister, or by the responsible authority (including training of an ongoing nature):

(g) requiring any delegated prescriber or any class of delegated prescriber to undergo an assessment of competence to prescribe prescription medicines of a specified class or description (including an assessment at regular intervals):

(h) prohibiting any person who fails to comply with any requirement imposed by or under regulations referred to in paragraphs (e) to (g) from prescribing prescription medicines or prescription medicines of any specified class or description.

Section 105D: inserted, on 1 July 2014, by section 37 of the Medicines Amendment Act 2013 (2013 No 141).

105E Power of Director-General to specify prescription medicines for delegated prescribers

(1) The Director-General may, by notice, specify the prescription medicines, or the class or description of prescription medicines, that may be prescribed under delegated prescribing orders (and different prescription medicines, or different classes or descriptions of prescription medicines, may be specified for different classes of health professional).

(2) Before issuing a notice under subsection (1), the Director-General must consult with those organisations or bodies that appear to the Director-General to be representative of persons likely to be substantially affected by the notice.

(3) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14

Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 105E: inserted, on 1 July 2014, by section 37 of the Medicines Amendment Act 2013 (2013 No 141).

Section 105E(1): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 105E(3): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

105F Incorporation by reference

(1) Regulations made under section 105 may incorporate the following written material by reference:

(a) a standard, framework, code of practice, recommended practice, or requirement of an international or national organisation:

(b) a standard, framework, code of practice, recommended practice, or requirement prescribed in any country or jurisdiction, or by any group of countries:

(c) any other written material that deals with technical matters and that can reasonably be regarded as being too large or impractical to include in, or publish as part of, the regulations.

(2) The provisions of Schedule 3 apply to material incorporated by reference in regulations made in reliance on this section.

Section 105F: inserted, on 1 July 2014, by section 37 of the Medicines Amendment Act 2013 (2013 No 141).

106 Minister may classify medicines by notice in the *Gazette*

(1) The Minister may, by notice, declare any medicine to be a prescription medicine or a restricted medicine or a pharmacy-only medicine.

(2) To the extent that any such notice is inconsistent with any provisions of any regulations made under section 105(1)(j), those provisions shall cease to have effect while the notice remains in force.

(3) Every notice given under this section shall, unless sooner revoked by the Minister, remain in force for a period of 6 months commencing with the date on which it comes into force, and shall then cease to have effect.

(4) A notice under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this section

Publication	The maker must publish it in the *Gazette*	LA19 ss 73, 74(1)(a), Sch 1 cl 14

Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the Act.

Section 106(1): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 106(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

107 Power to obtain information for purposes of regulations

(1) In this section the term **manufacturer**, in relation to a medicine, includes a person who, as owner, packs or causes to be packed medicines of that description for sale or supply.

(2) For the purpose of enabling the making of regulations under this Act, or the giving of any notice under section 106, the Director-General may from time to time, by notice in writing to any manufacturer or importer in New Zealand of medicines of any description, or medical devices of any kind, require the manufacturer or importer to state correctly in writing to the Director-General the nature of the ingredients or components of such medicines or devices, and the proportions or manner in which those ingredients or components are contained in them.

(3) The disclosure of any information pursuant to subsection (2) shall not prejudice any application subsequently made for a patent.

(4) Every person commits an offence against this Act and is liable on conviction to a fine not exceeding $1,000 who fails to comply with any requirement under subsection (2).

Compare: 1969 No 7 ss 39(5), 47

Section 107(4): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

108 Specified publications

(1) In this section, and for the purposes of any regulations made under this Act, **specified publication** means—

(a) the European Pharmacopoeia:

(b) the British Pharmacopoeia:

(c) the British Pharmaceutical Codex:

(d) the United States Pharmacopoeia:

(e) the United States National Formulary:

(f) the Therapeutic Goods Standards of Australia.

(2) Where any licence or consent or approval under this Act refers to a specified publication, but not to a particular edition of that publication, then, for the pur-

pose of determining whether anything done, at a time when the licence, consent, or approval is in force, is done in accordance with the licence, consent, or approval, the reference shall, unless the licence, consent, or approval otherwise expressly provides, be construed as a reference to the current edition of that publication as in force at that time.

(3) In this section any reference to the current edition of a specified publication as in force at a particular time is a reference to the edition of that publication in force at that time together with any amendments, additions, and deletions made to it up to that time.

Compare: Medicines Act 1968 s 103(1), (2), (5) (UK)

109 Relationship with Misuse of Drugs Act 1975

(1) Subject to subsection (3), in the case of a medicine that is a controlled drug within the meaning of the Misuse of Drugs Act 1975, the prohibitions, conditions, and requirements contained in or imposed under this Act shall be in addition to the prohibitions, conditions, and requirements contained in or imposed under that Act to the extent that they are not inconsistent therewith.

(2) Nothing in section 8 of the Misuse of Drugs Act 1975 shall authorise any person to prescribe, manufacture, pack, label, sell by wholesale or retail, administer, procure, receive, store, use, or otherwise have in that person's possession any medicine contrary to the provisions of this Act.

(3) So long as a person is authorised by a licence under the Misuse of Drugs Act 1975 to manufacture, pack, or sell by wholesale or retail, any controlled drug that is a medicine, that person shall be deemed to be licensed under this Act to manufacture, pack, or sell by wholesale or retail, as the case may require, that medicine, and, if that person is so authorised to procure, receive, store, use or otherwise have in his possession any such controlled drug, that person shall, for the purposes of section 43, be deemed to have a reasonable excuse for such procurement, receipt, storage, use, or other possession, as the case may require.

(3A) A drug and substance checking service provider under the Misuse of Drugs Act 1975 does not commit an offence against this Act or its regulations if the service provider breaches this Act or the regulations in the course of performing the service provider's functions.

(3B) Subsection (3A) is subject to the conditions of the service provider's licence.

(4) Except as provided in subsections (1) and (2), this Act shall be read subject to the Misuse of Drugs Act 1975 and, in the event of any inconsistency between the provisions of that Act and the provisions of this Act, or between the provisions of any regulations made under that Act and the provisions of any regulations made under this Act, the provisions of that Act and of the regulations made under that Act shall prevail.

Section 109(3A): inserted, on 7 December 2021, by section 19 of the Drug and Substance Checking Legislation Act 2021 (2021 No 50).

Section 109(3B): inserted, on 7 December 2021, by section 19 of the Drug and Substance Checking Legislation Act 2021 (2021 No 50).

110 Relationship with Hazardous Substances and New Organisms Act 1996

(1) Subject to subsection (2), nothing in this Act shall affect or derogate from the Hazardous Substances and New Organisms Act 1996.

(2) In the event of any inconsistency between the provisions of the Hazardous Substances and New Organisms Act 1996 and the provisions of this Act, or between the provisions of any regulations made or EPA notices issued under that Act and the provisions of any regulations made under this Act, in the case of a medicine that is also a hazardous substance within the meaning of that Act, the provisions of this Act and of the regulations made under this Act shall prevail.

Section 110: substituted, on 2 July 2001, by section 149 of the Hazardous Substances and New Organisms Act 1996 (1996 No 30).

Section 110(2): amended, on 1 December 2017, by section 55 of the Hazardous Substances and New Organisms Amendment Act 2015 (2015 No 72).

111 Amendment of and effect on Animal Remedies Act 1967

[Repealed]

Section 111: repealed, on 2 July 2001, by section 86(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 (1997 No 87).

112 Amendment of Consumer Information Act 1969

[Repealed]

Section 112: repealed, on 1 May 1987, by section 49(2) of the Fair Trading Act 1986 (1986 No 121).

113 Amendment of Ombudsmen Act 1975

Amendment(s) incorporated in the Act(s).

114 Transitional

(1) Without limiting section 20 of the Acts Interpretation Act 1924, but subject to subsection (2),—

(a) every person who, immediately before the commencement of Part 2, held a wholesaler's restricted drugs licence under the Restricted Drugs Act 1960 that authorised him to sell prescription drugs by wholesale shall be deemed to be licensed to sell prescription medicines, restricted medicines, and pharmacy-only medicines by wholesale until the date on which his licence would have expired if that Act had not been repealed:

(b) every person who, immediately before the commencement of Part 2, held a packer's restricted drugs licence under the Restricted Drugs Act 1960 that authorised him to pack prescription drugs shall be deemed to

be licensed to pack and label prescription medicines, restricted medicines, and pharmacy-only medicines, and to sell such medicines by wholesale, until the date on which his licence would have expired if that Act had not been repealed.

(2) Subject to section 34, if a licence referred to in subsection (1) is limited with respect to the substances that may be sold or packed, as the case may require, the authority conferred by that subsection shall not extend to the selling or packing of any other substance or article.

(3) Notwithstanding the repeal by section 115 of this Act of sections 12, 13, and 14 of the Food and Drug Act 1969, those sections shall continue to apply—

(a) in respect of any application for the consent of the Minister under the said section 12 that is awaiting determination at the commencement of Part 2:

(b) in respect of any notice that was deposited with the Director-General under the said section 14 within 90 days before the commencement of Part 2.

114A Certain persons deemed to have licence to operate pharmacy

[Expired]

Section 114A: expired, on 18 September 2005, by section 114B.

114B Expiry of section 114A

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

Section 114B: inserted, on 18 September 2004, by section 22 of the Medicines Amendment Act 2003 (2003 No 50).

115 Repeals

The enactments specified in Schedule 2 are hereby repealed.

Schedule 1AA
Transitional, savings, and related provisions

s 5C

Schedule 1AA: inserted, on 25 May 2021, by section 6 of the Medicines Amendment Act 2021 (2021 No 16).

Part 1
Provisions relating to Medicines Amendment Act 2021

Schedule 1AA Part 1: inserted, on 25 May 2021, by section 6 of the Medicines Amendment Act 2021 (2021 No 16).

1 Validation of certain provisional consents

(1) The following provisional consents must be treated as having been given under section 23 as amended by the Medicines Amendment Act 2021:

(a) the provisional consent for Comirnaty (COVID-19 mRNA vaccine) (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2021-go338)):

(b) the provisional consent for Necon 0.5/35 (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go2377)):

(c) the provisional consent for 0.9% Sodium Chloride Injection (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2020-go3009)):

(d) the provisional consent for the Panvax vaccine (as notified in Provisional Consent to the Distribution of a New Medicine (*Gazette* 2018-go6374)):

(e) the provisional consent for Brevinor 28 Day (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2020-go1987)):

(f) the provisional consent for H5N1 Influenza Vaccine (as notified in Provisional Consent to the Distribution of New Medicines (*Gazette* 2018-go576)).

(2) For the purposes of subclause (1),—

(a) the Medicines Amendment Act 2021 must be treated as having been in force when the provisional consents were given; and

(b) a reference to a provisional consent includes any renewal of the provisional consent or subsequent provisional consent for the same product; and

(c) a reference to a notice in the *Gazette* includes any notice that amends or replaces that notice.

Schedule 1AA clause 1: inserted, on 25 May 2021, by section 6 of the Medicines Amendment Act 2021 (2021 No 16).

Schedule 1

s 58(1)(a), (b)

Part 1

Alcoholism
Appendicitis
Arteriosclerosis
Arthritis
Baldness
Blood pressure, disorders of
Bust, underdevelopment of
Cancer
Cataract
Central nervous system, disorders of
Diabetes
Diphtheria
Dropsy
Epilepsy
Gallstones, kidney stones, bladder stones
Gangrene
Glaucoma
Goitre
Heart disease
Infertility
Leukemia
Menopause, disorders of
Menstrual flow, disorders of
Mental disorders
Nephritis
Pernicious anaemia
Pleurisy
Pneumonia
Poliomyelitis
Prostate gland, disorders of
Septicaemia

Sexual impotence
Smallpox
Tetanus
Thrombosis
Trachoma
Tuberculosis
Tumours
Typhoid Fever
Ulcers of the gastro-intestinal tract
Venereal diseases

Part 2

Asthma
Blindness
Common cold
Dental decay
Disorders arising from the ingestion of alcohol
Gout
Haemorrhoids
Hernias
Impaired hearing
Impetigo
Influenza
Obesity
Psoriasis
Pyorrhoea
Rheumatism
Varicose ulcers
Varicose veins

Schedule 2
Enactments repealed

s 115

Food and Drug Act 1969 (1969 No 7)

Food and Drug Amendment Act 1977 (1977 No 114)

Restricted Drugs Act 1960 (1960 No 97)

Restricted Drugs Amendment Act 1962 (1962 No 93)

Restricted Drugs Amendment Act 1964 (1964 No 31)

Restricted Drugs Amendment Act 1967 (1967 No 108)

Restricted Drugs Amendment Act 1969 (1969 No 44)

Restricted Drugs Amendment Act 1979 (1979 No 28)

Schedule 3
Incorporation by reference

s 105F(2)

Schedule 3: inserted, on 1 July 2014, by section 38 of the Medicines Amendment Act 2013 (2013 No 141).

1 Requirement to consult on proposal to incorporate material by reference

(1) Before regulations incorporating material by reference in reliance on section 105F are made, the Director-General must—

(a) make copies of the material proposed to be incorporated by reference (the **proposed material**) available for inspection during working hours for a reasonable period, free of charge, at the head office of the Ministry of Health and any other places that the Director-General may, at his or her discretion, determine are appropriate; and

(b) state where copies of the proposed material are available for purchase; and

(c) make copies of the proposed material available, free of charge, on an Internet site maintained by or on behalf of the Ministry of Health, unless doing so would infringe copyright; and

(d) give notice in the *Gazette* stating—

(i) that the proposed material is available for inspection during working hours, free of charge, and stating the places at which it can be inspected and the period during which it can be inspected; and

(ii) that copies of the proposed material can be purchased and stating the places at which they can be purchased; and

(iii) if applicable, that the proposed material is available on the Internet, free of charge, and stating the Internet site address; and

(e) allow a reasonable opportunity for persons to comment on the proposal to incorporate the proposed material by reference; and

(f) consider any comments made.

(2) The Director-General—

(a) may make copies of the proposed material available in any other way that he or she considers appropriate in the circumstances; and

(b) must, if paragraph (a) applies, give notice in the *Gazette* stating that the proposed material is available in other ways and giving details of where or how it can be accessed or obtained.

(3) The Director-General may comply with subclause (1)(c) (if applicable) by providing a hypertext link from an Internet site maintained by or on behalf of the Ministry of Health to a copy of the proposed material that is available, free of charge, on an Internet site that is maintained by or on behalf of someone else.

(4) The references in this clause to material include, if the material is not in an official New Zealand language, as well as the material itself, an accurate translation of the material in an official New Zealand language.

(5) A failure to comply with this clause does not invalidate regulations that incorporate material by reference in reliance on section 105F.

(6) For the purposes of subclause (1)(c), the Director-General may not rely on section 66 of the Copyright Act 1994 as authority to make the proposed material available on an Internet site.

2 Access to material incorporated by reference

(1) This clause applies if regulations incorporating material by reference in reliance on section 105F are made.

(2) The Director-General must—

(a) make the material (the **incorporated material**) available for inspection during working hours, free of charge, at the head office of the Ministry of Health and any other places that the Director-General may, at his or her discretion, determine are appropriate; and

(b) state where copies of the incorporated material are available for purchase; and

(c) make copies of the incorporated material available, free of charge, on an Internet site maintained by or on behalf of the Ministry of Health, unless doing so would infringe copyright; and

(d) give notice in the *Gazette* stating—

(i) that the incorporated material is incorporated in the regulations and stating the date on which the regulations were made; and

(ii) that the incorporated material is available for inspection during working hours, free of charge, and stating the places at which it can be inspected; and

(iii) that copies of the incorporated material can be purchased and stating the places at which they can be purchased; and

(iv) if applicable, that the incorporated material is available on the Internet, free of charge, and stating the Internet site address.

(3) The Director-General—

(a) may make copies of the incorporated material available in any other way that he or she considers appropriate in the circumstances; and

(b) must, if paragraph (a) applies, give notice in the *Gazette* stating that the incorporated material is available in other ways and giving details of where or how it can be accessed or obtained.

(4) The Director-General may comply with subclause (2)(c) (if applicable) by providing a hypertext link from an Internet site maintained by or on behalf of the

Ministry of Health to a copy of the incorporated material that is available, free of charge, on an Internet site that is maintained by or on behalf of someone else.

(5) The references in this clause to material are to—

(a) material incorporated by reference in the regulations; and

(b) if the material is not in an official New Zealand language, the material itself together with an accurate translation of the material in an official New Zealand language.

(6) A failure to comply with this clause does not invalidate regulations that incorporate material by reference.

(7) For the purposes of subclause (2)(c), the Director-General may not rely on section 66 of the Copyright Act 1994 as authority to make the incorporated material available on an Internet site.

3 Effect of material incorporated by reference

(1) This clause applies to material incorporated by reference in regulations in reliance on section 105F.

(2) Material to which this clause applies has legal effect as part of the regulations in which it is incorporated.

4 Effect of amendments to material incorporated by reference

(1) This clause applies if the material incorporated by reference in reliance on section 105F is amended by the originator of the material after the regulations are made.

(2) If this clause applies, any amendments made by the originator of the material have no legal effect as part of the regulations unless they are specifically incorporated by later regulations made under this Act.

(3) For the purposes of this section, material is **amended** if the material or any part of it—

(a) is amended or replaced; or

(b) expires or is revoked; or

(c) otherwise ceases to have effect.

5 Proof of material incorporated by reference

(1) A copy of material incorporated by reference in regulations in reliance on section 105F must be—

(a) certified as a correct copy of the material by the Director-General; and

(b) retained by the Director-General.

(2) The production in proceedings of a certified copy of the material is, in the absence of evidence to the contrary, sufficient evidence of the material incorporated by reference in the regulations.

6 Application of Legislation Act 2019 to material incorporated by reference

Subpart 1 of Part 3 and section 114 of the Legislation Act 2019 do not apply to material that is incorporated by reference in regulations in reliance on section 105F of this Act merely because it is incorporated.

Schedule 3 clause 6: replaced, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

7 Application of Regulations (Disallowance) Act 1989 to material incorporated by reference

[Repealed]

Schedule 3 clause 7: repealed, on 1 July 2014, by section 39 of the Medicines Amendment Act 2013 (2013 No 141).

8 Application of Standards and Accreditation Act 2015, other enactments, and rules of law not affected

Nothing in this schedule affects the application of sections 29 to 32 of the Standards and Accreditation Act 2015, any other enactment, or any rule of law.

Schedule 3 clause 8 heading: amended, on 1 March 2016, by section 45(1) of the Standards and Accreditation Act 2015 (2015 No 91).

Schedule 3 clause 8: amended, on 1 March 2016, by section 45(1) of the Standards and Accreditation Act 2015 (2015 No 91).

Notes

1 General

This is a consolidation of the Medicines Act 1981 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 Amendment Act 2022 (2022 No 31)

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

Drug and Substance Checking Legislation Act 2021 (2021 No 50): section 19

Secondary Legislation Act 2021 (2021 No 7): section 3

Medicines Amendment Act 2021 (2021 No 16)

Medicines (Deferral of Expiry of Part 7A) Order 2020 (LI 2020/243): clause 3

Public Service Act 2020 (2020 No 40): section 135

Social Security Act 2018 (2018 No 32): section 459

Customs and Excise Act 2018 (2018 No 4): section 443(3)

Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (2017 No 4): section 122(1)

Agricultural Compounds and Veterinary Medicines Amendment Act 2016 (2016 No 82): section 11

Medicines Amendment Act 2016 (2016 No 78)

District Court Act 2016 (2016 No 49): section 261

Radiation Safety Act 2016 (2016 No 6): section 99

Standards and Accreditation Act 2015 (2015 No 91): section 45(1)

Hazardous Substances and New Organisms Amendment Act 2015 (2015 No 72): section 55

Medicines Amendment Act 2013 (2013 No 141)

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

Environmental Protection Authority Act 2011 (2011 No 14): section 53(1)

Policing Act 2008 (2008 No 72): sections 116(a)(ii), 130(1)

Property Law Act 2007 (2007 No 91): section 364(1)

Insolvency Act 2006 (2006 No 55): section 445

Veterinarians Act 2005 (2005 No 126): section 105

Medicines (Specified Biotechnical Procedures) Amendment Act 2005 (2005 No 73)

Medicines Amendment Act 2005 (2005 No 60)

Human Assisted Reproductive Technology Act 2004 (2004 No 92): section 86(1), (2)

Corrections Act 2004 (2004 No 50): section 206

Medicines Amendment Act (No 3) 2003 (2003 No 84)

Medicines Amendment Act (No 2) 2003 (2003 No 56)

Medicines Amendment Act 2003 (2003 No 50)

Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 (2002 No 14)

Health and Disability Services (Safety) Act 2001 (2001 No 93): section 58(1)

Medicines Amendment Act 1999 (1999 No 117)

Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 (1998 No 20): sections 11–13

Agricultural Compounds and Veterinary Medicines Act 1997 (1997 No 87): sections 85, 86(1)

Hazardous Substances and New Organisms Act 1996 (1996 No 30): section 149

Customs and Excise Act 1996 (1996 No 27): section 289(1)

Medicines Amendment Act 1994 (1994 No 128)

Health Sector (Transfers) Act 1993 (1993 No 23): section 32

Medicines Amendment Act 1992 (1992 No 50)

Judicature Amendment Act 1991 (1991 No 60): section 3(4)

Medicines Amendment Act (No 2) 1990 (1990 No 97)

Medicines Amendment Act 1990 (1990 No 69)

Health Research Council Act 1990 (1990 No 68): section 57

Broadcasting Act 1989 (1989 No 25): section 89(1)

Medicines Amendment Act 1987 (1987 No 9)

Official Information Amendment Act 1987 (1987 No 8): section 25(1)

Fair Trading Act 1986 (1986 No 121): section 49(2)

Medicines Amendment Act 1985 (1985 No 29)

Medicines Act Commencement Order 1984 (SR 1984/142)

Area Health Boards Act 1983 (1983 No 134): section 98

Medicines Act 1981 (1981 No 118): section 114B

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