Medicines Amendment Bill

Government Bill

Explanatory note

General policy statement

In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 and its associated regulations. The Medicines Amendment Bill will address some problematic provisions of the Medicines Act 1981 to—

- modernise the definitions of medicine, medical device, and therapeutic purpose to align the boundary between medicines and medical devices with international norms:
- amend the approval process for new medicines:
- align the prescribing framework for nurse practitioners and optometrists with medical practitioners, dentists, and midwives:
- establish a new category of delegated prescriber, whose members will be allowed to prescribe under an authorisation (a delegated prescribing order) issued by an authorised prescriber:
- establish a mechanism to allow time-limited demonstration sites of extended prescribing rights to new groups of health practitioners:
- make minor and technical amendments to update and clarify the provisions for granting licences to manufacture, pack, and sell medicines and to operate a pharmacy:

- expand the regulation-making powers in the Act to provide for new standards and innovative practice, such as electronic prescribing.

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 2 December 2010 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact statement can be found at—

- http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements
- http://www.treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 provides for the commencement of the Act.

Clause 3 provides that the Bill amends the Medicines Act 1981.

Part 1
Amendments to principal Act

Clause 4 amends section 2 by inserting a new definition of authorised prescriber, which includes nurse practitioners and optometrists. Nurse practitioners and optometrists currently have prescribing rights conferred on them by regulations rather than the Act. *Clause 4* also inserts definitions relating to delegated prescribers, definitions of nurse practitioner and optometrist, and a definition of responsible authority.

Clause 5 amends the definitions of medicine and prescription medicine in section 3.

Clause 6 inserts *new section 3A*, which contains a new definition of medical device.

Clause 7 substitutes *new section 4* with an amended definition of therapeutic purpose.

Clause 8 amends section 13, which describes the functions, powers, and procedures of the Medicines Review Committee. The amend-

ments ensure that the committee has the power to investigate objections to decisions of the Minister to refuse to give consent, or provisional consent, to the distribution of a medicine.

Clause 9 makes amendments to section 18 to replace references to individual categories of authorised prescriber with a general reference to authorised prescribers and also to insert a reference to delegated prescribers.

Clause 10 amends section 19 so that a prescription medicine may be administered in accordance with the directions of a delegated prescriber as well as an authorised prescriber.

Clause 11 makes amendments to section 20 that are consequential on the substitution of *new sections 20A to 23AAB*.

Clause 12 repeals sections 21 to 23 and substitutes new provisions. Those provisions set out the criteria to be applied when the Minister determines whether to give consent, or provisional consent, to the distribution of a new medicine. They also make provision about applications for the Minister's consent, and the procedure to be followed when those applications are determined. The details of that procedure will be set out in regulations. *New sections 22A and 23AAB* contain a process for objecting to a decision of the Minister. *New section 23* sets out the process for applying for provisional consent to the distribution of a medicine. *New section 23AAB* deals with the duration and effect of provisional consents.

Clause 13 makes consequential amendments to section 23A.

Clause 14 repeals section 24, which makes provision for applications to distribute changed medicines, and inserts *new sections 23D to 24AA*. The changes broadly mirror those made in relation to the process for applying for the Minister's consent under section 20.

Clause 15 makes an amendment to section 26 that is consequential on the replacement of section 24.

Clause 16 amends section 27 to reflect the change to the definition of therapeutic purpose.

Clauses 17 to 20 make amendments that are consequential on the changes made by *clause 14*.

Clause 21 amends section 42C. This section restricts authorised prescribers from holding an interest in pharmacies. The amendments extend that restriction to delegated prescribers.

Clause 22 amends section 43. That section contains restrictions on the possession of prescription medicines. *Clause 22* updates the section to refer to delegated prescribers and delegated prescribing orders. The definition of authorised prescriber in section 43(6) is repealed because the expression is already defined in section 2(1).

Clause 23 inserts *new sections 47A to 47C*. *New sections 47A and 47B* enable the Minister to approve a class of registered health professionals to have delegated prescribing rights. Applications for delegated prescribing rights will be made by the authority with responsibility for the registration and oversight of that class of health professionals under the Health Practitioners Competence Assurance Act 2003. An authorised prescriber (other than a designated precriber) may then issue a delegated prescribing order to a member of such a class of registered health professionals, and that person will then be authorised to prescribe prescription medicines in accordance with the delegated prescribing order. *New section 47C* makes provision for temporary prescribing rights. These will be authorised by the Minister in favour of a class of registered health professionals and will be limited to a specified place and for a limited period of up to 1 year.

Clause 24 amends section 48 to replace references to individual categories of authorised prescriber with a general reference to authorised prescribers, to insert references to delegated prescribers, and to update the list of authorities in section 48(2).

Clause 25 makes an amendment to section 49 to replace references to individual categories of authorised prescriber with a general reference to authorised prescribers and to insert a reference to delegated prescribers.

Clause 26 amends section 49A to replace references to individual categories of authorised prescriber with a general reference to authorised prescribers and to insert a reference to delegated prescribers.

Clause 27 makes changes to section 51, which makes provision for the grant of licences. A *new subsection (1A)* enables a licensing authority to take into account previous convictions when considering the applicant's fitness to hold a licence. *New subsection (4)* provides that licence conditions may be imposed by the licensing authority as well as by regulations made under the Act. *New subsections (6) to (6AAB)* set out the process for dealing with a licence holder who has failed or is failing to comply with licence conditions.

Clause 28 makes consequential amendments to section 52.

Clause 29 amends section 76A to insert a reference to delegated prescribers.

Clause 30 substitutes *new section 87*, which includes a reference to delegated prescribers.

Clauses 31 and 32 make further amendments that are consequential on the changes made by *clause 14*.

Clause 33 updates section 96, which applies certain provisions of the Act to related products in the same way as they apply to medicines.

Clause 34 makes changes to the regulation-making powers in section 105 to enable regulations to be made declaring substances or articles to be medicines and medical devices, and to broaden the existing power to make regulations about the issue of prescriptions so that regulations about the storage and transmission of prescriptions (including electronic prescriptions) may be made. The changes also update references to authorised prescribers and allow regulations to be made about delegated prescribing orders.

Clause 35 replaces references in section 105A to individual categories of authorised prescriber with a general reference to authorised prescribers.

Clause 36 inserts *new section 105D*, which contains a new power to make regulations about qualifications for delegated prescribers, and *new section 105E*, which makes provision for material to be incorporated by reference into regulations made under section 105.

Clause 37 adds *new Schedule 3*, which contains further provision for incorporation by reference.

Part 2
Consequential amendments to other enactments, transitional provisions, and related matters

Clauses 38 to 44 amend the Misuse of Drugs Act 1975, amend and revoke certain regulations, and make a transitional provision.

Hon Tony Ryall

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Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Medicines Amendment Act **2011**.

2 Commencement

(1) This Act comes into force on a date appointed by the Governor-General by Order in Council, and 1 or more orders may be made bringing different provisions into force on different dates.

(2) Any provision that has not earlier been brought into force comes into force on **1 July 2013**.

3 Principal Act amended

This Act amends the Medicines Act 1981.

Part 1
Amendments to principal Act

4 Interpretation

(1) Section 2(1) is amended by repealing the definition of **authorised prescriber** and substituting the following definition:

"**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".

(2) Section 2(1) is amended by repealing the definition of **designated prescriber** and substituting the following definition:

"**designated prescriber** means a person who—

"(a) belongs to a class of registered health professionals authorised by regulations to prescribe prescription medicines; and

"(b) satisfies any applicable requirement relating to competency, qualifications, or training specified in or imposed under regulations".

(3) Section 2(1) is amended by repealing the definition of **medical device** and substituting the following definition:

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

(4) Paragraph (a) of the definition of **standing order** in section 2(1) is amended by omitting "a practitioner or registered midwife" and substituting "a practitioner, registered midwife, nurse practitioner, or optometrist".

(5) Paragraph (c) of the definition of **standing order** in section 2(1) is amended by omitting "a practitioner, or midwife" and substituting "a practitioner, registered midwife, nurse practitioner, or optometrist".

(6) Section 2(1) is amended by inserting the following definitions in their appropriate alphabetical order:

"**delegated prescriber** means a health practitioner to whom a delegated prescribing order has been issued under **section 47A(2)**

"**delegated prescribing order** means a written instruction, issued in accordance with regulations by an authorised prescriber under **section 47A(2)**, authorising a health practitioner to prescribe prescription medicines

"**delegated prescribing rights** means rights granted under **section 47A**

"**nurse practitioner** means a health practitioner—

"(a) who is, or is deemed to be, registered with the Nursing Council as a practitioner of the profession of nursing; and

"(b) for whom the Nursing Council has authorised a scope of practice that includes prescribing medicines

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

"**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

"**regulations** means regulations made under this Act

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

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

(1) Section 3 is amended by repealing subsections (1) and (2) and substituting the following subsection:

"(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 2(1) of the Radiation Protection Act 1965; 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) Paragraph (d) of the definition of **new medicine** in section 3(3) is amended by omitting "24(5)" and substituting "**24AA(2)**".

(3) Section 3(3) is amended by repealing the definition of **prescription medicine** and substituting the following definition:

"**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".

6 New section 3A inserted

The following section is inserted after section 3:

"**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."

7 New section 4 substituted

Section 4 is repealed and the following section substituted:

"**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."

8 Functions, powers, and procedures of Medicines Review Committee

(1) Section 13(1) is amended by repealing paragraph (a) and substituting the following paragraph:

"(a) to inquire into any objection to the decision of the Minister to refuse to give consent, or provisional consent, to the distribution of a medicine:".

(2) Section 13(2) is amended by omitting "22(4)" and substituting "**22A(1) or 23AA(1)**".

9 Sale of medicines by retail

Section 18 is amended by omitting "a practitioner, registered midwife, veterinarian, or designated prescriber" in each place where it appears and substituting in each case "an authorised prescriber, a veterinarian, or a delegated prescriber".

10 Administering prescription medicines

Section 19(1)(a) is amended by inserting "or delegated prescriber" after "authorised prescriber".

11 Restrictions on sale or supply of new medicines

(1) Section 20(1) is amended by omitting "applies" and substituting "and **sections 20A to 23AAB** apply".

(2) Section 20(2) is amended by inserting ", given in accordance with **sections 20A to 23AAB**," after "the medicine".

12 New sections 20A to 23AB substituted

Sections 21 to 23 are repealed and the following sections substituted:

"**20A Criteria for consenting to distribution of new medicine**

"(1) The Minister must not give consent, or provisional consent, to the distribution of a medicine under section 20 unless he or she is satisfied that the likely therapeutic value of the medicine outweighs the risk (if any) of the use of the medicine injuriously affecting the health of any person.

"(2) The Minister may give provisional consent to the distribution of a medicine under section 20 or **23** if he or she is of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

"**21 Applications for Minister's consent**

"(1) An application for the Minister's consent to the distribution of a medicine under section 20 must be made by one of the following (the **applicant**):

"(a) the manufacturer, importer, or proprietor of the medicine; or

"(b) the proposed manufacturer, importer, or proprietor of the medicine; or

"(c) any authorised agent of a person referred to in **paragraph (a) or (b)**.

"(2) The application must—

"(a) be made in the prescribed manner; and

"(b) contain, or be accompanied by, the information required by regulations; and

"(c) be accompanied by the prescribed fee.

"**22 Procedure for determining applications for Minister's consent**

"(1) Every application for the Minister's consent to the distribution of a medicine under section 20 must be determined in accordance with regulations.

"(2) In determining an application, the Minister may—

"(a) give consent to the distribution of the medicine; or

"(b) give provisional consent to the distribution of the medicine; or

"(c) refuse to give consent to the distribution of the medicine.

"(3) On giving consent, or provisional consent, to the distribution of a medicine, the Minister may impose any conditions that he or she thinks fit, including conditions relating to—

"(a) the persons to whom the medicine may be sold or supplied; or

"(b) the area in which the medicine may be distributed.

"(4) The Minister must, as soon as is reasonably practicable after determining the application,—

"(a) notify the applicant of his or her decision; and

"(b) if applicable, publish, by notice in the *Gazette*, his or her consent, or provisional consent, to the distribution of the medicine.

"**22A Objection to decision**

"(1) If the Minister refuses to give consent to the distribution of a medicine, the applicant may object in writing to the Minister within 28 days after being notified under **section 22(4)(a)**.

"(2) As soon as is reasonably practicable after receipt of an objection under **subsection (1)**, the Minister must refer the matter to the Medicines Review Committee.

"**23 Procedure for applications for Minister's provisional consent**

"(1) An application for the Minister's provisional consent to the distribution of a medicine must be made by one of the following (the **applicant**):

"(a) the manufacturer, importer, or proprietor of the medicine; or

"(b) the proposed manufacturer, importer, or proprietor of the medicine; or

"(c) any authorised agent of a person referred to in **paragraph (a) or (b)**.

"(2) The application must—

"(a) be made in the prescribed manner; and

"(b) contain, or be accompanied by, the information required by regulations; and

"(c) be accompanied by the prescribed fee.

"(3) The Minister must determine the application in accordance with regulations.

"(4) In determining the application, the Minister may—

"(a) give provisional consent to the distribution of the medicine; or

"(b) refuse to give provisional consent to the distribution of the medicine.

"(5) On giving provisional consent, the Minister may impose any conditions that he or she thinks fit, including conditions relating to—

"(a) the persons to whom the medicine may be sold or supplied; or

"(b) the area in which the medicine may be distributed.

"(6) The Minister must, as soon as is reasonably practicable after determining the application,—

"(a) notify the applicant of his or her decision; and

"(b) if applicable, publish by notice in the *Gazette*, his or her provisional consent to the distribution of the medicine.

"**23AA Objection to decision**

"(1) If the Minister refuses to give provisional consent to the distribution of a medicine, the applicant may object in writing to the Minister within 28 days after being notified under **section 23(6)(a)**.

"(2) As soon as is reasonably practicable after receipt of an objection under **subsection (1)**, the Minister must refer the matter to the Medicines Review Committee.

"**23AAB Duration and effect of provisional consent**

"(1) A provisional consent has effect for any period, not exceeding 2 years beginning with the date of the publication of the notice under **section 22(4)(b) or 23(6)(b)**, that the Minister specifies in that notice.

"(2) The Minister may, by notice in the *Gazette*, on 1 occasion only, renew a provisional consent for a period not exceeding 2 years beginning with the date of the publication of the notice.

"(3) **Section 23(5) and (6)(a)**, with any necessary modifications, apply to a renewal of a provisional consent under **subsection (2)**.

"(4) If, during the currency of a provisional consent, the Minister consents to the distribution of the same medicine under section 20, the provisional consent is treated as being revoked."

13 Interpretation

(1) Paragraph (a)(i)(A) of the definition of **protected period** in section 23A is amended by omitting "section 20" and substituting "**section 22(4)(b)**".

(2) Paragraph (b)(i)(A) of the definition of **protected period** in section 23A is amended by omitting "section 20" and substituting "**section 22(4)(b)**".

14 New sections 23D to 24AA substituted

Section 24 is repealed and the following sections are substituted:

"**23D Restrictions on sale or supply of changed medicines**

"(1) Except as provided in sections 25, 27, 28, 29, and 30, no person may do either of the following without the written consent of the Director-General:

"(a) sell a medicine in respect of which there has been a material change; or

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

"(2) Every person commits an offence who—

"(a) fails to comply with **subsection (1)**; or

"(b) fails to comply with **section 24(1)**.

"(3) A person who commits an offence against **subsection (2)** is liable on conviction,—

"(a) in the case of an individual,—

"(i) to imprisonment for a term not exceeding 3 months; or

"(ii) to a fine not exceeding $20,000:

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

"(4) In this section and **section 24**, **material change** means, in relation to a medicine, any change to—

"(a) the purpose for which the medicine is represented to be used:

"(b) the recommended dosage:

"(c) the recommended manner of administration:

"(d) the labelling of the medicine, or of any container or package in which the medicine is packed:

"(e) any descriptive matter accompanying any medicine, or any container or package in which the medicine is packed:

"(f) the strength, quality, or purity of the medicine:

"(g) the methods of manufacture of the medicine:

"(h) the facilities for testing the medicine's strength, quality, purity, or safety:

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

"**24 Applications for consent to distribution of changed medicines**

"(1) If a manufacturer or importer of a medicine makes a material change to the medicine, the applicant must—

"(a) apply to the Director-General for consent to the distribution of the changed medicine; or

"(b) apply to the Minister for consent to distribute the medicine under section 20, if the manufacturer or importer is of the opinion that the change to the medicine is such that the medicine is now a new medicine within the meaning of paragraph (a), (b), or (c) of the definition of new medicine in section 3(3).

"(2) An application under **subsection (1)(a)** must—

"(a) be made in the prescribed manner; and

"(b) contain, or be accompanied by, the information required by regulations; and

"(c) be accompanied by the prescribed fee.

"(3) In this section and **section 24AA**, **applicant** means—

"(a) the manufacturer or importer of the medicine; or

"(b) any authorised agent of that manufacturer or importer.

"**24AA Procedure for determining applications for Director-General's consent**

"(1) Every application to the Director-General for consent to the distribution of a changed medicine must be determined in accordance with regulations.

"(2) If, after considering the application, the Director-General is of the opinion that the change to the medicine is such that the medicine should be treated as a new medicine, he or she must refer it to the Minister for consideration as an application under **section 21**.

"(3) The Director-General may, by written notice to the applicant, within 45 working days of the date that the application was received, require the applicant to supply any further information or samples that the Director-General may require for the purposes of determining the application.

"(4) In any case where the Director-General has not required the applicant to supply further information or samples, the Dir-

ector-General must determine the application, or, if the case requires, refer the application to the Minister, within 45 working days of the date that the application was received.

"(5) In determining the application, the Director-General may—

"(a) give consent to the distribution of the changed medicine; or

"(b) refuse to give consent to the distribution of the changed medicine.

"(6) The Director-General must, as soon as is reasonably practicable after determining the application, or referring the application to the Minister, notify the applicant of his or her decision.

"(7) An application that is referred to the Minister must be treated as if it had been made under **section 21**, and **sections 22 and 22A** apply accordingly."

15 Exemption for pharmacists

Section 26(4) is amended by omitting "24" and substituting "**23D**".

16 Exemption for veterinarians and certain registered health practitioners

(1) Section 27(b) is repealed.

(2) Section 27(c)(ii) is repealed.

17 Exemption for medicine required by medical practitioner

Section 29(1) is amended by omitting "24" and substituting "**23D**".

18 Exemption for clinical trial

Section 30(1) is amended by omitting "24" and substituting "**23D**".

19 Exemptions in respect of importation by the Crown

(1) Section 32A(4) is amended by omitting "24" and substituting "**23D**".

(2) Section 32A(5) is amended by omitting "24" and substituting "**23D**".

20 Control of established medicines

Section 36(1) is amended by omitting "subsection (5) of section 24" and substituting "**section 24AA(2)**".

21 Restriction on authorised prescribers holding interest in pharmacies

(1) The heading to section 42C is amended by inserting "**and delegated prescribers**" after "**authorised prescribers**".

(2) Section 42C(1) is amended by inserting "or delegated prescriber" after "authorised prescriber".

(3) Section 42C(2) is amended by inserting "or delegated prescriber" after "authorised prescriber".

(4) Section 42C(3) is amended by—

(a) inserting "or delegated prescriber" after "the authorised prescriber"; and

(b) inserting ", or delegated prescriber," after "of the authorised prescriber".

22 Restrictions on possession of prescription medicines

(1) Section 43(2)(c)(i) is amended by—

(a) inserting "or a delegated prescriber" after "an authorised prescriber"; and

(b) inserting "or delegated prescriber" after "another authorised prescriber"; and

(c) inserting "or a delegated prescribing order" after "standing order" in each place where it appears.

(2) Section 43(6) is repealed.

23 New sections 47A to 47C inserted

The following sections are inserted after section 47:

"**47A Delegated prescribing rights**

"(1) The Minister may, on an application under **section 47B**, approve the grant of delegated prescribing rights to a class of registered health professionals.

"(2) The effect of the approval is that an authorised prescriber who is not a designated prescriber may issue a delegated prescribing order in accordance with regulations to a specified per-

son belonging to a class of registered health professionals with delegated prescribing rights.

"(3) A delegated prescriber may prescribe prescription medicines in accordance with the terms of his or her delegated prescribing order.

"**47B Procedure for applications for delegated prescribing rights**

"(1) An application for the Minister's approval under **section 47A** must be made by the responsible authority (the **applicant**) in the prescribed manner.

"(2) The Minister must determine the application in accordance with regulations.

"(3) The Minister must, as soon as is reasonably practicable after making a decision under this section, notify the applicant of the decision.

"(4) If the Minister approves the application, the applicant must, as soon as is reasonably practicable after the approval has been granted, arrange for the approval to be notified in the *Gazette*.

"**47C Temporary prescribing rights**

"(1) The Minister may, by notice in the *Gazette* and after consulting with any organisations or bodies that appear to the Minister to be representative of persons likely to be substantially affected, authorise a class of registered health professionals to prescribe prescription medicines of a specified class or description for a period not exceeding 1 year at a specified place or at specified places.

"(2) An authority under **subsection (1)** must—

"(a) identify the class of registered health professional authorised by the notice; and

"(b) identify the prescription medicines that may be prescribed under the notice; and

"(c) specify the place or places at which the prescribing is authorised; and

"(d) specify any conditions, limitations, requirements, or restrictions that apply to the prescribing; and

"(e) specify the period during which the notice applies.

"(3) The Minister may, by notice in the *Gazette*, renew an authority given under **subsection (1)** on 1 occasion only, and for a period not exceeding 1 year beginning with the date of publication of the notice."

24 Powers of Minister to prohibit prescribing, etc

(1) Section 48(1)(a) is amended by omitting "specified practitioner, veterinarian, registered midwife, or designated prescriber" and substituting "specified authorised prescriber, veterinarian, or delegated prescriber".

(2) Section 48(2) is amended by inserting the following paragraph after paragraph (e):

"(ea) in the case of an optometrist, except on the recommendation of the Optometrists and Dispensing Opticians Board; or".

(3) Section 48(2) is amended by repealing paragraph (f) and substituting the following paragraph:

"(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."

25 Restrictions on supply to particular persons

Section 49(2) is amended by omitting "practitioner, registered midwife, or designated prescriber" and substituting "authorised prescriber or delegated prescriber".

26 Statements regarding persons dependent on prescription medicines or restricted medicines

Section 49A(3) is amended by repealing paragraphs (f) to (gb) and substituting the following paragraphs:

"(f) authorised prescribers:

"(g) delegated prescribers:".

27 Grant of licences

(1) Section 51 is amended by inserting the following subsection after subsection (1):

"(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, any conviction of the applicant for—

"(a) an offence under this Act, or regulations made under it; or

"(b) an offence under the Misuse of Drugs Act 1975 or regulations made under it; or

"(c) a crime involving dishonesty (within the meaning of section 2(1) of the Crimes Act 1961)."

(2) Section 51 is amended by repealing subsection (4) and substituting the following subsections:

"(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."

(3) Section 51 is amended by repealing subsection (6) and substituting the following subsection:

"(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)**."

(4) Section 51(6A) is amended by inserting "**(4A)** or " after "subsection".

28 Effect of licences

(1) Section 52(1) is amended by omitting "24" and substituting "**23D**".

(2) Section 52 is amended by repealing subsection (3) and substituting the following subsection:

"(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."

29 Offences in relation to authorised prescribers

(1) The heading to section 76A is amended by adding "**and delegated prescribers**".

(2) Section 76A is amended by inserting "or to any delegated prescriber" after "authorised prescriber".

30 New section 87 substituted

Section 87 is repealed and the following section substituted:

"**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."

31 Right of appeal to High Court

Section 89(1)(a) is amended by omitting "20, 23, 24, and 35" and substituting "20, **22, 23, 23AAB, 24AA,** and 35".

32 Interpretation

Section 94(2)(b) is amended by omitting "24(5)" and substituting "**24AA(2)**".

33 Certain provisions to apply to related products as if medicines

(1) Section 96 is amended by repealing subsection (2) and substituting the following subsection:

"(2) **Section 23D** applies to related products in the same manner and to the same extent as it applies to medicines, subject to the following modifications:

"(a) **subsection (4)(b)** must be read as applying only to the recommended dosage for a therapeutic purpose:

"(b) **subsection (4)(c)** must be read as applying only to the recommended manner of administration for a therapeutic purpose:

"(c) **subsection (4)(d)** must be read as applying only to any labelling relating to a therapeutic purpose:

"(d) **subsection (4)(e)** must be read as applying only to any descriptive matter relating to a therapeutic purpose:

"(e) **subsection (4)(f) and (g)** must be read as applying only to a material change that is relevant to a therapeutic purpose."

(2) Section 96(3) is amended by omitting "Subsections (3) to (6) of section 24, and sections 37, 40" and substituting "**Sections 24, 24AA**, 37, 40".

34 Regulations

(1) Section 105(1)(a) is amended by omitting ", and the manner of making applications under this Act".

(2) Section 105(1) is amended by inserting the following paragraph after paragraph (a):

"(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:".

(3) Section 105(1) is amended by repealing paragraph (i) and substituting the following paragraph:

"(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:".

(4) Section 105(1)(q) is amended by omitting "practitioners, veterinarians, registered midwives, and designated prescribers of prescriptions for the supply of any medicine" and substituting "authorised prescribers, veterinarians, and delegated prescribers of prescriptions for the supply of any medicine, including the transmission and storage of prescriptions".

(5) Section 105(1) is amended by repealing paragraph (qa) and substituting the following paragraphs:

"(qa) authorising any class of registered health professional to prescribe a specified class of prescription medicines in accordance with any conditions, limitations, requirements, or restrictions specified in or imposed under the regulations:

"(qaa) regulating the grant of delegated prescribing rights and the issue of delegated prescribing orders, and imposing conditions, limitations, requirements, or restrictions in relation to the contents of delegated prescribing orders and their use:".

(6) Section 105 is amended by inserting the following subsection after subsection (5):

"(5A) For the purposes of **subsection (1)(qa)**, **specified class of prescription medicines** means a class specified by the Director-General by notice in the *Gazette*."

35 Regulations relating to practitioners, veterinarians, and registered midwives

(1) Section 105A is amended by omitting the heading and substituting the following heading: "**Regulations relating to veterinarians and authorised prescribers who are not designated prescribers**".

(2) Section 105A is amended by omitting "practitioner, veterinarian, or registered midwife" in each place where it appears

and substituting in each case "veterinarian, or authorised prescriber who is not a designated prescriber".

(3) Section 105A(2) is amended by repealing paragraphs (a) and (b) and substituting the following paragraphs:

"(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."

36 New sections 105D and 105E inserted

The following sections are inserted after section 105C:

"**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) requiring any person who belongs to any class of registered health professional with delegated prescribing rights under **section 47A**, or a specified class of those persons, before commencing to prescribe prescription medicines or prescription 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:

"(b) 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):

"(c) 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):

"(d) prohibiting any person who fails to comply with any requirement imposed by or under regulations referred to in **paragraphs (a) to (c)** from prescribing prescription medicines or prescription medicines of any specified class or description.

"**105E 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."

37 New Schedule 3 added

The Schedule 3 set out in the Schedule of this Act is added.

Part 2
Consequential amendments to other enactments, transitional provisions, and related matters

Subpart 1—Amendment to Misuse of Drugs Act 1975

38 Amendment to Misuse of Drugs Act 1975

Section 39 amends the Misuse of Drugs Act 1975.

39 Section 33 substituted

Section 33 is repealed and the following section substituted:

"**33 Notification of conviction of medical practitioners, etc**

"(1) If a person who is a veterinarian, medical practitioner, pharmacist, dentist, midwife, or designated prescriber is convicted of any 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.

"(2) In this section, **responsible authority** has the meaning given to it in **section 5(1)** of the Health Practitioners Competence Assurance Act 2003."

Subpart 2—Amendments to, and revocation of, regulations

40 Amendment to Electricity (Safety) Regulations 2010

(1) This section amends the Electricity (Safety) Regulations 2010.

(2) The definition of **electrical medical device** in regulation 4(1) is amended by omitting "section 2(1)" and substituting "**section 3A**".

41 Amendment to Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001

(1) This section amends the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.

(2) Regulation 5(2)(a) is amended by omitting "section 3(1)(b)" and substituting "**section 3(1)(b)(i)**".

42 Amendment to Medicines (Database of Medical Devices) Regulations 2003

(1) This section amends the Medicines (Database of Medical Devices) Regulations 2003.

(2) The definition of **medical device** in regulation 3 is amended by omitting "section 2(1)" and substituting "**section 3A**".

43 Regulations revoked

The following regulations are revoked:

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

(b) Medicines (Designated Prescriber: Optometrists) Regulations 2005 (SR 2005/256).

Subpart 3—Transitional provision

44 Transitional provision regarding medicines

(1) This section applies to any substance or article that—

(a) was a medicine within the meaning of section 3 of the principal Act immediately before the commencement date; and

(b) on the commencement date became a medical device by virtue of section 3A of the principal Act (as inserted by this Act); and

(c) on the commencement date is part of the existing stock-intrade in New Zealand of any person carrying on a business in New Zealand.

(2) A substance or an article to which this section applies may be sold or supplied after the commencement date as long as—

(a) the substance or article continues to comply with the former law; and

(b) any requirements in the former law that relate to or affect the continued sale or supply of the substance or article continue to be complied with.

(3) In this section,—

commencement date means the date on which this section comes into force; and

former law means the principal Act, regulations, and any other instruments made under it as in force immediately before the commencement date.

Schedule

s 37

New Schedule 3 added

Schedule 3

s 105E(2)

Incorporation by reference

1 Requirement to consult on proposal to incorporate material by reference

(1) Before regulations incorporating material by reference in reliance on **section 105E** 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—

Schedule 3—*continued*

(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 **subsection (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 105E**.

(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 105E** 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

Schedule 3—*continued*

(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

Schedule 3—*continued*

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 105E**.

(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 105E** 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 105E** must be—

(a) certified as a correct copy of the material by the Director-General; and

(b) retained by the Director-General.

Schedule 3—*continued*

(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 Acts and Regulations Publication Act 1989 to material incorporated by reference

The Acts and Regulations Publication Act 1989 does not apply to material that is for the time being incorporated by reference in regulations in reliance on **section 105E**.

7 Application of Regulations (Disallowance) Act 1989 to material incorporated by reference

(1) Nothing in section 4 of the Regulations (Disallowance) Act 1989 requires material that is incorporated by reference in regulations in reliance on **section 105E** to be laid before the House of Representatives.

(2) The Regulations (Disallowance) Act 1989, apart from the modification to the application of section 4 of that Act made by **subclause (1)**, applies to regulations that incorporate material by reference.

8 Application of Standards Act 1988, other enactments, and rules of law not affected

Nothing in this Schedule affects the application of sections 22 to 25 of the Standards Act 1988, any other enactment, or any rule of law.

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