# Medicines Amendment Bill

Government Bill

As reported from the Health Committee

## Commentary

### Recommendation

The Health Committee has examined the Medicines Amendment Bill, and recommends that it be passed with the amendments shown.

### Introduction

This bill seeks to amend the Medicines Act 1981 in order to modernise the definitions of medicine, medical device, and therapeutic purpose; to amend the medicine approval process to make it less prescriptive and to make some changes to the prescribing framework, and some minor or technical changes.

The bill is an interim measure intended to address some problematic provisions of the Medicines Act, in advance of a comprehensive overhaul of the medicines legislation. The comprehensive overhaul will be undertaken via the Therapeutic Products and Medicines Bill which is intended to be progressed in 2013 and is a key part of the legislative infrastructure required to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA).

ANZTPA will replace Australia's Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). It will create a single market for therapeutic products

by administering a single regulatory scheme across both countries. It will regulate the full range of therapeutic products including prescription medicines, over-the-counter medicines, medical devices, and biological medicines.

This commentary covers the main amendments we recommend to the bill.

## Commencement clause

We recommend that the default commencement date for the provisions in the bill that would come into force by Order in Council be amended. Any provision relating to the medicines approvals process that had not come into force earlier would come into force on 1 July 2017, and any other provision in the bill that had not come into force earlier would come into force on 1 July 2014.

The bill seeks to remove the provisions in the Act that deal with the process for medicines approvals and replace them with a regulation-making power. The new regulations would be expected to include a new approval process for medicines. Setting an earlier commencement date for these provisions would require the development of a New Zealand-only medicines approval process, concurrently with the development of a medicines approval process for the joint ANZTPA regulatory scheme. Any New Zealand-only scheme would be in force for a short time before being replaced by the ANZTPA regulatory scheme before 1 July 2017. The extended commencement date means that legislative change and prolonged consultation can be avoided.

Setting the commencement date at 1 July 2017 recognises that if negotiations on ANZTPA progress according to schedule, the medicines approvals provisions in the bill will be superseded. If negotiations are prolonged, however, the bill provides an alternative avenue for making the desired amendments to the medicines approvals process.

## Definitions

There was general support for updating the definitions of medicine, medical device, and therapeutic purpose to align them with international norms. We do not consider full alignment with the regulatory definitions used in Australia appropriate. The definitions in the

bill have been developed to reflect New Zealand's current regulatory framework, and will be reviewed and updated by the Therapeutic Products and Medicines Bill, which is required to establish the Australia New Zealand Therapeutic Products Agency.

## Delegated prescriber

The delegated prescriber category would enable a registered health professional to prescribe within limited parameters, under the sanction of an authorised prescriber. The intention of delegated prescribing is to give patients more convenient, efficient access to medicines by broadening the range of practitioners who may prescribe, while ensuring patients' safety. A delegated prescribing order is the mechanism by which specific conditions and restrictions on prescribing would be imposed for an individual delegated prescriber. The limits on prescribing by delegated prescribers would reflect their required level of qualifications, training, and competency. Delegated prescribing would be monitored by the authorised prescriber who issued the order.

An application for delegated prescribing rights would require the support of the relevant responsible authority and the approval of the Minister of Health. We recommend that the implementation of delegated prescribing rights be via regulation. Requiring a regulatory mechanism enables scrutiny by the Regulation Review Committee and reflects the significant responsibilities that accompany any form of prescribing.

To ensure clarity about the controls on delegated prescribing, we recommend adding more detail to section 105D, which sets out the kinds of regulations that could be made relating to delegated prescribers. Regulations could then be made granting delegated prescribing rights, regulating how delegated prescribing orders are issued, setting out the supervisory responsibilities of authorised prescribers, and imposing other requirements on delegated prescribers.

We recommended inserting new section 105DA to ensure that the prescription medicines that may be prescribed under a delegated prescribing order be specified by the Director-General of Health by notice in the *Gazette* rather than specified in delegated prescriber regulations. Specifying the list via *Gazette* notice would enable the list to be updated more efficiently in response to changes in best practice

and to changes in product funding within a therapeutic group. This would also require the Director-General of Health to consult with the relevant organisations or bodies that are considered representative of persons likely to be substantially affected before specifying the prescription medicines by notice in the *Gazette*.

## Temporary prescribing

As introduced the bill contains provisions for temporary prescribing rights. However, it has since been determined that designated and delegated prescribing regulations can specify a time limit, as well as other conditions that would enable the authorisation of temporary prescribing rights. Accordingly a separate provision for temporary prescribing is superfluous. We therefore recommend the deletion of new section 47C.

## Regulations relating to designated prescribing

Clause 34 makes changes to the regulation-making powers in section 105 of the Act. This section of the Act allows regulations to be made authorising designated prescribing and specifying the prescription medicines that can be prescribed. We recommend amending the bill to reinsert a deleted reference to description of medicines in section 105(1)(qa) to ensure flexibility in drawing up the list of medicines. We further recommend that the medicines that designated prescribers can prescribe be specified by the Director-General by notice in the *Gazette*. As noted previously, specifying the medicines via *Gazette* notice would enable the list to be updated more efficiently.

## Functions, powers and procedures of the Medicines Review Committee

Clause 8 seeks to amend section 13, to give the Medicines Review Committee the power to investigate any objections to the Minister's decisions on the distribution of medicines. We consider the wording of new section 13(1)(a) too narrow, and believe it should also allow appeals against the imposition of conditions on approvals. Accordingly we recommend amending section 13(1)(a) to ensure that the committee provides an avenue for appeal in this respect.

## Applications for Minister's consent

Sections 21 and 23 (inserted by clause 12) 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. We believe that the term "applicant" in section 21(1) and 23(1) needs to be defined more clearly, as the provision as introduced implies that an overseas manufacturer could submit an application, which is not the intention. Therefore, we recommend amending new sections 21(1) and 23(1) to include a requirement that the applicant for consent be a person or company in New Zealand. We recommend an equivalent amendment to new section 24(3) (inserted by clause 14), regarding consent for distribution of changed medicines.

## Grant of licenses

We recommend amending clause 27 to allow the licensing authority to take determinations of professional conduct committees into account when assessing an applicant's fitness to hold a license. We note that new section 51(1A) does not preclude other considerations than those specified being taken into account for this purpose.

## Amendments to Misuse of Drugs Act 1975

We recommend the insertion of new clauses 38A to 38E and 39A which make consequential amendments to the Misuse of Drugs Act 1975.

These amendments would ensure nurse practitioners retain their current controlled drug prescribing rights once the Medicines Amendment Bill is enacted and nurse practitioners are named as authorised prescribers.

This section would also ensure that the current mechanism allowing prescribing authorisation via regulation is retained for optometrists once the Medicines Amendment Bill is enacted and optometrists are named as authorised prescribers.

We were concerned about the reference to midwives prescribing pethidine as it is no longer the preferred pain medication during childbirth. We recommend removing the reference to midwives prescribing pethidine. Midwives' prescribing rights regarding controlled drugs would be set out in regulations.

# Appendix

## Committee process

The Medicines Amendment Bill was referred to the committee on 28 February 2012. The closing date for submissions was 13 April 2012. We received and considered 43 submissions from interested groups and individuals. We heard 19 submissions in Wellington.

We received advice from the Ministry of Health.

## Committee membership

Dr Paul Hutchison (Chairperson)
Shane Ardern
Dr Jackie Blue
Dr Cam Calder
Kevin Hague
Iain Lees-Galloway
Andrew Little
Barbara Stewart
Hon Maryan Street
Dr Jian Yang

# Key to symbols used in reprinted bill

## As reported from a select committee

text inserted unanimously

~~text deleted unanimously~~

*Hon Peter Dunne*

# Medicines Amendment Bill

Government Bill

## Contents

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## 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** .~~

**2 Commencement**

(1) Sections 5(2), 8, 11 to 15, 17 to 20, 28(1), 31, 32(1), and 33 come into force on the earlier of the following:

(a) a date appointed by the Governor-General by Order in Council (and 1 or more Orders in Council may be made bringing different provisions into force on different dates):

(b) **1 July 2017**.

(2) The rest of this Act comes into force on the earlier of the following:

(a) a date appointed by the Governor-General by Order in Council (and 1 or more Orders in Council may be made bringing different provisions into force on different dates):

(b) **1 July 2014.**

**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".~~

(2) The definition of **designated prescriber** in section 2(1) is amended by—

(a) inserting ", nurse practitioner, optometrist," after "practitioner"; and

(b) inserting in paragraph (a) "specified prescription medicines, or any" after "any".

(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 prescribing rights ~~granted~~ granted by regulations made under **section 105(1)(qaa)** ~~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~~ 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)~~ **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:"~~

"(a) to inquire into any objection to the decision of the Minister—

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

"(ii) to impose any conditions under **section 22(3) or 23(5)**:".

(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~~ 23AAB 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, in New Zealand of the medicine; or

"(b) the proposed manufacturer, importer, or proprietor, in New Zealand 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, or imposes any conditions under **section 22(3)**, 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, in New Zealand of the medicine; or

"(b) the proposed manufacturer, importer, or proprietor, in New Zealand 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~~ 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, or imposes any conditions under **section 23(5)**, 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 accompanying any container or package in which the medicine is packed for sale:

"(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~~, importer, or proprietor, in New Zealand of the medicine; or

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

"**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 Director-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~~ Exemptions for pharmacists**

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

**16 ~~Exemption~~ Exemptions 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**".

**19A Revocation and suspension of consents**

(1) Section 35(1) is amended by omitting "section 20 or section 23" and substituting "section 20, **23, or 24AA**".

(2) Section 35(1)(a) is amended by omitting ", or in a notice deposited under section 24".

**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~~ section 47A inserted**

The following ~~sections are~~ section is 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 person 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.~~

"**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.

"~~**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).~~

"(1A) In determining, under subsection (1)(b), whether an applicant is a fit and proper person or of good repute (as the case re-

quires), 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) 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~~ subsections:

"(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".~~

(4) Section 51(6A) is amended by omitting "(6)" and substituting "**(4A) or (6)**".

(5) Section 51 is amended by adding the following subsection:

"(8) In this section, **professional conduct committee** means a committee appointed under section 71 of the Health Practitioners Competence Assurance Act 2003."

**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**

(1AA) Section 94(1) is amended by inserting the following paragraph after paragraph (a):

"(aa) any medical device:".

(1) 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~~ 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) 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:~~

"(qaa) granting and regulating delegated prescribing rights:".

(6) Section 105 is amended by inserting the following ~~subsection~~ subsections 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*.~~

"(5A) For the purposes of **subsection (1)(qa)**,—

"(a) **specified prescription medicines** means prescription medicines specified by the Director-General by notice in the *Gazette*; and

"(b) **specified class or description of prescription medicines** means a class or description of prescription medicines specified by the Director-General by notice in the *Gazette*.

"(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."

### 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~~ to 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)**—

"(aa) granting delegated prescribing rights to any class of registered health professional:

"(aab) regulating the issue of delegated prescribing orders by authorised prescribers:

"(aac) specifying the responsibilities of authorised prescribers who issue delegated prescribing orders:

"(aad) imposing conditions, limitations, requirements, or restrictions in relation to the contents of delegated prescribing orders and their use:

"(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 compe-

tence 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.

"**105DA Power of Director-General to specify prescription medicines for delegated prescribers**

"(1) The Director-General may, by notice in the *Gazette*, 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.

"**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.~~
The principal Act is amended by adding the **Schedule 3** set out in the **Schedule** of this Act.

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

### Subpart 1—~~Amendment~~ Amendments to Misuse of Drugs Act 1975

**38 ~~Amendment~~ Amendments to Misuse of Drugs Act 1975**

~~Section 39 amends~~ **Sections 38A to 39A** amend the Misuse of Drugs Act 1975.

**38A Interpretation**

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

"**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".

**38B Exemptions from sections 6 and 7**

(1) Section 8(1) is amended by inserting "nurse practitioner, optometrist," after "midwife," in each place where it appears.

(2) Section 8(2) is amended by repealing paragraph (aa).

(3) Section 8(2)(b)(iii) is amended by inserting "nurse practitioner, optometrist, midwife," after "dentist,".

(4) Section 8(2) is amended by repealing paragraph (ba).

(5) Section 8(2) is amended by repealing paragraph (da).

(6) Section 8(2)(l) is amended by inserting "nurse practitioner, optometrist, midwife," after "medical practitioner," in each place where it appears.

(7) Section 8(2A)(a) is amended by omitting "designated prescriber or any midwife" and substituting "designated prescriber, nurse practitioner, optometrist, or midwife".

**38C Statements regarding drug dependent persons**

Section 20(3) is amended by inserting the following paragraphs after paragraph (fb):

"(fc) nurse practitioners:

"(fd) optometrists:".

**38D Powers of Minister to prohibit prescribing, etc**

(1) Section 23(1)(a) is amended by inserting "nurse practitioner, optometrist," after "midwife,".

(2) Section 23(1) is amended by repealing paragraph (aa).

(3) Section 23(2) is amended by inserting the following paragraphs after paragraph (d):

"(da) in the case of a nurse practitioner, except on the recommendation of the Nursing Council; or

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

(4) Section 23(6) is amended by inserting "nurse practitioner, optometrist," after "midwife,".

(5) Section 23(7) is repealed.

**38E Treatment of people dependent on controlled drugs**

Section 24(1A) is amended by inserting ", nurse practitioner, optometrist," after "midwife".

**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, nurse practitioner, optometrist, 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)**~~ section 5(1) of the Health Practitioners Competence Assurance Act 2003."

**39A Regulations**

Section 37(1)(g) is amended by inserting "nurse practitioners, optometrists," after "midwives,".

## 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~~ **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)**~~ **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 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~~ schedule affects the application of sections 22 to 25 of the Standards Act 1988, any other enactment, or any rule of law.

## Legislative history

| | |
|---|---|
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